

ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt  
Release Date: 07/09/2014

ClinicalTrials.gov ID: NCT01107886

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### Study Identification

Unique Protocol ID: D1680C00003

Brief Title: Does Saxagliptin Reduce the Risk of Cardiovascular Events When Used Alone or Added to Other Diabetes Medications  
( SAVOR- TIMI 53 )

Official Title: A Multicentre, Randomised, Double-Blind, Placebo-Controlled Phase IV Trial to Evaluate the Effect of Saxagliptin on the  
Incidence of Cardiovascular Death, Myocardial Infarction or Ischaemic Stroke in Patients With Type 2 Diabetes

Secondary IDs: EudraCT No 2009-017358-10

### Study Status

Record Verification: July 2014

Overall Status: Completed

Study Start: May 2010

Primary Completion: May 2013 [Actual]

Study Completion: May 2013 [Actual]

### Sponsor/Collaborators

Sponsor: AstraZeneca

Responsible Party: Sponsor

Collaborators: Bristol-Myers Squibb

### 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: 63634  
Serial Number:  
Has Expanded Access? No

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

Data Monitoring?: Yes

Plan to Share Data?:

Oversight Authorities: Argentina: Ministry of Health  
Argentina: Ministry of Health  
Australia: Department of Health and Ageing Therapeutic Goods Administration  
Brazil: Ministry of Health  
Canada: Health Canada  
Chile: Instituto de Salud Pública de Chile  
China: Food and Drug Administration  
Czech Republic: State Institute for Drug Control  
France: Ministry of Health  
Germany: Ethics Commission  
Hungary: National Institute of Pharmacy  
India: Drugs Controller General of India  
Israel: Ministry of Health  
Italy: National Monitoring Centre for Clinical Trials - Ministry of Health  
Mexico: Federal Commission for Protection Against Health Risks  
Netherlands: The Central Committee on Research Involving Human Subjects (CCMO)  
Peru: Instituto Nacional de Salud  
Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products  
Russia: Ministry of Health of the Russian Federation  
South Africa: Medicines Control Council  
Spain: Agencia Española de Medicamentos y Productos Sanitarios  
Sweden: Medical Products Agency  
Taiwan: Department of Health  
Thailand: Food and Drug Administration  
United Kingdom: Medicines and Healthcare Products Regulatory Agency  
United States: Food and Drug Administration

## Study Description

**Brief Summary:** The purpose of this study is to determine whether saxagliptin can reduce the risk of cardiovascular events when used alone or added to other diabetes medications

**Detailed Description:** A Multicentre, Randomised, Double-Blind, Placebo-Controlled Phase IV Trial to Evaluate the Effect of Saxagliptin on the Incidence of Cardiovascular Death, Myocardial Infarction or Ischaemic Stroke in Patients with Type 2 Diabetes

## Conditions

**Conditions:** Type 2 Diabetes Mellitus

**Keywords:** Risk of cardiovascular disease and death in patients with type 2 diabetes mellitus

## Study Design

**Study Type:** Interventional

**Primary Purpose:** Treatment

**Study Phase:** Phase 4

**Intervention Model:** Parallel Assignment

**Number of Arms:** 2

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

**Allocation:** Randomized

**Endpoint Classification:** Efficacy Study

**Enrollment:** 18206 [Actual]

## Arms and Interventions

Arms	Assigned Interventions
Experimental: Saxagliptin	Drug: Saxagliptin 5 mg or 2.5 mg once daily  Other Names: <ul style="list-style-type: none"><li>• Onglyza</li></ul>
Placebo Comparator: Placebo Placebo	Drug: Placebo

## Outcome Measures

[See Results Section.]

## Eligibility

Minimum Age: 40 Years

Maximum Age: 150 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Patients with type 2 diabetes mellitus
- HbA1c  $\geq 6.5\%$ . (based on the last measured and documented laboratory measurement within 6 months)
- High risk for CV events -Established cardiovascular disease and/or multiple risk factors

Exclusion Criteria:

- Current or previous (within 6 months) treatment with DPP4 inhibitors and/or GLP-1 mimetics
- Acute vascular event <2months prior to randomisation

## Contacts/Locations

Study Officials: Eugene Braunwald  
Study Chair  
TIMI

Itamar Raz  
Study Principal Investigator  
Hadassah Medical Organisation

Deepak Bhatt  
Study Principal Investigator  
TIMI

Locations: China  
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Argentina  
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Philadelphia, Pennsylvania, United States

United States, Florida  
Research Site  
St. Petersburg, Florida, United States

United States, Nebraska  
Research Site  
Omaha, Nebraska, United States

United States, Ohio  
Research Site  
Toledo, Ohio, United States

United States, Puerto Rico  
Research Site  
Jardines de Loiza, Loiza, Puerto Rico, United States

United States, Pennsylvania  
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Johnstown, Pennsylvania, United States

United States, Puerto Rico  
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Ponce, Puerto Rico, United States

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Denver, Colorado, United States

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Dallas, Texas, United States

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## References

### Citations:

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Description D1680C00003\_CSR\_Synopsis

Study Data/Documents:

## Study Results

### Participant Flow

Recruitment Details	The first participant was enrolled on 10 May 2010 and the last participant completed the study on 16 May 2013. A total of 18206 subjects were enrolled in the study of which 16492 were randomised. Study participants were randomized from 790 centers in 26 countries.
Pre-Assignment Details	Subjects meeting all inclusion criteria and with no exclusion criteria were randomised in a 1:1 ratio to receive either saxagliptin or matching placebo (Day 0).

#### Reporting Groups

	Description
Saxagliptin	5 mg once daily in subjects with normal renal function or mild impaired renal function (eGFR >50 mL/min); 2.5 mg once daily in subjects with moderate to severe renal impairment (eGFR ≤50 mL/min).
Placebo	Matching Placebo

#### Overall Study

	Saxagliptin	Placebo
Started	8280 <sup>[1]</sup>	8212 <sup>[1]</sup>
Completed	8078 <sup>[2]</sup>	7998 <sup>[2]</sup>
Not Completed	202	214
Lost to Follow-up	15	13
Withdrawal by Subject	180	196
Administrative withdrawal of consent	7	5

[1] Randomized subjects

[2] Completed subjects

## Baseline Characteristics

### Reporting Groups

	Description
Saxagliptin	5 mg once daily in subjects with normal renal function or mild impaired renal function (eGFR >50 mL/min); 2.5 mg once daily in subjects with moderate to severe renal impairment (eGFR ≤50 mL/min).
Placebo	Matching Placebo

### Baseline Measures

	Saxagliptin	Placebo	Total
Number of Participants	8280	8212	16492
Age, Continuous [units: Years] Mean (Standard Deviation)	65.1 (8.52)	65.0 (8.58)	65.0 (8.55)
Gender, Male/Female [units: Participants]			
Female	2768	2687	5455
Male	5512	5525	11037
Ethnicity (NIH/OMB) [units: Participants]			
Hispanic or Latino	1778	1763	3541
Not Hispanic or Latino	6502	6449	12951
Unknown or Not Reported	0	0	0
Race (NIH/OMB) [units: Participants]			
American Indian or Alaska Native	18	33	51
Asian	896	884	1780
Native Hawaiian or Other Pacific Islander	11	11	22
Black or African American	278	290	568
White	6241	6166	12407



	Saxagliptin	Placebo	Total
More than one race	768	758	1526
Unknown or Not Reported	68	70	138
Cardiovascular Risk Category: Cardiovascular disease/ Multiple risk factors (CVD/ MRF) <sup>[1]</sup> [units: Participants]			
CVD	6494	6465	12959
MRF	1786	1747	3533
Renal Functione Categor: Normal or Mild impairment/ Moderate impairment/Severe impairment <sup>[2]</sup> [units: Participants]			
Normal or Mild impairment	6986	6930	13916
Moderate impairment	1122	1118	2240
Severe impairment	172	164	336

[1] CVD subjects were defined as subjects with history of established CV disease. MRF subjects were defined as subjects with MRF for vascular disease without established CV disease.

[2] Renal function categories Normal function – Mild impairment defined as: eGFR >50 mL/min; Moderate impairment defined as: eGFR 30 to 50 mL/min; Severe impairment defined as: eGFR eGFR <30 mL/min.

## Outcome Measures

### 1. Primary Outcome Measure:

Measure Title	Participants With Any Event From the Composite of Cardiovascular Death (CV Death), Non-fatal Myocardial Infarction (MI), or Non-fatal Ischaemic Stroke
Measure Description	Participants with CV death, non-fatal MI or non-fatal ischaemic stroke. If no event, censoring occurs at the patient withdrawal of consent, last contact, or death (when applicable)—whichever was later.
Time Frame	Randomization (day 0) up to 2.9 years
Safety Issue?	No

#### Analysis Population Description

Intention To Treat (ITT) analysis of randomized population. Events were adjudicated by the Clinical Event Adjudication Committee.

#### Reporting Groups

	Description
Saxagliptin	5 mg once daily in subjects with normal renal function or mild impaired renal function (eGFR >50 mL/min); 2.5 mg once daily in subjects with moderate to severe renal impairment (eGFR ≤50 mL/min).
Placebo	Matching Placebo

#### Measured Values

	Saxagliptin	Placebo
Number of Participants Analyzed	8280	8212
Participants With Any Event From the Composite of Cardiovascular Death (CV Death), Non-fatal Myocardial Infarction (MI), or Non-fatal Ischaemic Stroke [units: participants]	613	609

#### 2. Secondary Outcome Measure:

Measure Title	Participants With Any Event From the Composite of CV Death, Non-fatal MI, Non-fatal Ischaemic Stroke, Hospitalisation for Heart Failure, Hospitalisation for Unstable Angina Pectoris, or Hospitalisation for Coronary Revascularisation
Measure Description	Participants with CV death, non-fatal MI, non-fatal ischaemic stroke, hospitalisation for heart failure, hospitalisation for unstable angina pectoris, or hospitalisation for coronary revascularisation. If no event, censoring occurs at the patient withdrawal of consent, last contact, or death (when applicable)—whichever was later.
Time Frame	Randomization (day 0) up to 2.9 years
Safety Issue?	No

#### Analysis Population Description

Intention To Treat (ITT) analysis of randomized population. Events were adjudicated by the Clinical Event Adjudication Committee.

#### Reporting Groups

	Description
Saxagliptin	5 mg once daily in subjects with normal renal function or mild impaired renal function (eGFR >50 mL/min); 2.5 mg once daily in subjects with moderate to severe renal impairment (eGFR ≤50 mL/min).

	Description
Placebo	Matching Placebo

#### Measured Values

	Saxagliptin	Placebo
Number of Participants Analyzed	8280	8212
Participants With Any Event From the Composite of CV Death, Non-fatal MI, Non-fatal Ischaemic Stroke, Hospitalisation for Heart Failure, Hospitalisation for Unstable Angina Pectoris, or Hospitalisation for Coronary Revascularisation [units: participants]	1059	1034

#### 3. Secondary Outcome Measure:

Measure Title	Participants With Event of Death
Measure Description	Participants with event of death. If no event, censoring occurs at the patient withdrawal of consent, or last contact — whichever was later.
Time Frame	Randomization (day 0) up to 2.9 years
Safety Issue?	No

#### Analysis Population Description

Intention To Treat (ITT) analysis of randomized population. Events were adjudicated by the Clinical Event Adjudication Committee.

#### Reporting Groups

	Description
Saxagliptin	5 mg once daily in subjects with normal renal function or mild impaired renal function (eGFR >50 mL/min); 2.5 mg once daily in subjects with moderate to severe renal impairment (eGFR ≤50 mL/min).
Placebo	Matching Placebo

#### Measured Values

	Saxagliptin	Placebo
Number of Participants Analyzed	8280	8212
Participants With Event of Death [units: participants]	420	378

## Reported Adverse Events

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

### Reporting Groups

	Description
Placebo	Matching Placebo
Saxagliptin	5 mg once daily in subjects with normal renal function or mild impaired renal function (eGFR >50 mL/min); 2.5 mg once daily in subjects with moderate to severe renal impairment (eGFR ≤50 mL/min).

### Serious Adverse Events

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	2075/8212 (25.27%)		2114/8280 (25.53%)	
Blood and lymphatic system disorders				
Anaemia <sup>A</sup> †	26/8212 (0.32%)	27	17/8280 (0.21%)	19
Anaemia megaloblastic <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Anaemia of chronic disease <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Coagulopathy <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Disseminated intravascular coagulation <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Febrile neutropenia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Haemorrhagic anaemia <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Haemorrhagic diathesis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Hypereosinophilic syndrome <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Hypochromic anaemia <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Iron deficiency anaemia <sup>A</sup> †	7/8212 (0.09%)	7	5/8280 (0.06%)	5
Leukocytosis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Leukopenia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Lymphopenia <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Microcytic anaemia <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Nephrogenic anaemia <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Neutropenia <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Normochromic normocytic anaemia <sup>A</sup> †	0/8212 (0%)	0	4/8280 (0.05%)	4
Pancytopenia <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Pernicious anaemia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Thrombocytopenia <sup>A</sup> †	3/8212 (0.04%)	3	5/8280 (0.06%)	5
Cardiac disorders				
Acute coronary syndrome <sup>A</sup> †	7/8212 (0.09%)	7	5/8280 (0.06%)	5
Acute left ventricular failure <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Acute myocardial infarction <sup>A</sup> †	2/8212 (0.02%)	2	6/8280 (0.07%)	6
Adams-Stokes syndrome <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Angina pectoris <sup>A</sup> †	106/8212 (1.29%)	116	89/8280 (1.07%)	98
Angina unstable <sup>A</sup> †	63/8212 (0.77%)	79	44/8280 (0.53%)	48
Aortic valve stenosis <sup>A</sup> †	5/8212 (0.06%)	5	6/8280 (0.07%)	6
Arrhythmia <sup>A</sup> †	4/8212 (0.05%)	4	3/8280 (0.04%)	3
Arteriosclerosis coronary artery <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Arteriospasm coronary <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Atrial fibrillation <sup>A</sup> †	76/8212 (0.93%)	90	78/8280 (0.94%)	85
Atrial flutter <sup>A</sup> †	11/8212 (0.13%)	13	22/8280 (0.27%)	25
Atrial septal defect acquired <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Atrial tachycardia <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Atrial thrombosis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Atrioventricular block <sup>A</sup> †	3/8212 (0.04%)	3	3/8280 (0.04%)	3
Atrioventricular block complete <sup>A</sup> †	13/8212 (0.16%)	13	6/8280 (0.07%)	6
Atrioventricular block first degree <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Atrioventricular block second degree <sup>A</sup> †	5/8212 (0.06%)	6	2/8280 (0.02%)	2
Bifascicular block <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Bradyarrhythmia <sup>A</sup> †	4/8212 (0.05%)	4	0/8280 (0%)	0
Bradycardia <sup>A</sup> †	11/8212 (0.13%)	11	14/8280 (0.17%)	15
Bundle branch block <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Bundle branch block left <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Cardiac aneurysm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cardiac arrest <sup>A</sup> †	4/8212 (0.05%)	4	5/8280 (0.06%)	5
Cardiac failure <sup>A</sup> †	24/8212 (0.29%)	24	21/8280 (0.25%)	22
Cardiac failure acute <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	3
Cardiac failure chronic <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Cardiac failure congestive <sup>A</sup> †	21/8212 (0.26%)	22	30/8280 (0.36%)	30
Cardiac fibrillation <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Cardiac tamponade <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Cardiac valve disease <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Cardio-respiratory arrest <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Cardiogenic shock <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Cardiomyopathy <sup>A</sup> †	3/8212 (0.04%)	3	2/8280 (0.02%)	2
Cardiopulmonary failure <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Cardiovascular disorder <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cardiovascular insufficiency <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Congestive cardiomyopathy <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Cor pulmonale <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Coronary artery disease <sup>A</sup> †	18/8212 (0.22%)	19	17/8280 (0.21%)	17
Coronary artery insufficiency <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Coronary artery occlusion <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Diastolic dysfunction <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hypertensive heart disease <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Hypertrophic cardiomyopathy <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Intracardiac thrombus <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Ischaemic cardiomyopathy <sup>A</sup> †	6/8212 (0.07%)	7	3/8280 (0.04%)	3
Left ventricular dysfunction <sup>A</sup> †	3/8212 (0.04%)	3	1/8280 (0.01%)	1
Left ventricular failure <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	3
Mitral valve incompetence <sup>A</sup> †	3/8212 (0.04%)	3	3/8280 (0.04%)	3
Myocardial infarction <sup>A</sup> †	5/8212 (0.06%)	5	3/8280 (0.04%)	3
Myocardial ischaemia <sup>A</sup> †	11/8212 (0.13%)	11	7/8280 (0.08%)	7

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Nodal arrhythmia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Palpitations <sup>A</sup> †	4/8212 (0.05%)	4	3/8280 (0.04%)	3
Pericardial effusion <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Pericarditis <sup>A</sup> †	3/8212 (0.04%)	4	0/8280 (0%)	0
Pulseless electrical activity <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Right ventricular dysfunction <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Sick sinus syndrome <sup>A</sup> †	14/8212 (0.17%)	14	10/8280 (0.12%)	10
Sinoatrial block <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Sinus arrhythmia <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Sinus bradycardia <sup>A</sup> †	6/8212 (0.07%)	6	3/8280 (0.04%)	3
Sinus tachycardia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Supraventricular tachycardia <sup>A</sup> †	4/8212 (0.05%)	4	9/8280 (0.11%)	10
Systolic dysfunction <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Tachyarrhythmia <sup>A</sup> †	1/8212 (0.01%)	2	1/8280 (0.01%)	1
Tachycardia <sup>A</sup> †	2/8212 (0.02%)	3	8/8280 (0.1%)	8
Torsade de pointes <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Tricuspid valve incompetence <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Trifascicular block <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Ventricular arrhythmia <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Ventricular extrasystoles <sup>A</sup> †	4/8212 (0.05%)	4	1/8280 (0.01%)	1
Ventricular fibrillation <sup>A</sup> †	5/8212 (0.06%)	5	3/8280 (0.04%)	3
Ventricular hypokinesia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0



	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Ventricular tachyarrhythmia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Ventricular tachycardia <sup>A</sup> †	11/8212 (0.13%)	16	16/8280 (0.19%)	17
Ear and labyrinth disorders				
Deafness <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Meniere's disease <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Sudden hearing loss <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Tinnitus <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	2
Tympanic membrane perforation <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	2
Vertigo <sup>A</sup> †	10/8212 (0.12%)	10	16/8280 (0.19%)	16
Vertigo positional <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Vestibular disorder <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Endocrine disorders				
Adrenal insufficiency <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Goitre <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Hypercorticism <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Hyperparathyroidism primary <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hyperthyroidism <sup>A</sup> †	2/8212 (0.02%)	2	6/8280 (0.07%)	6
Hypothyroidism <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Toxic nodular goitre <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Eye disorders				
Angle closure glaucoma <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Cataract <sup>A</sup> †	13/8212 (0.16%)	15	7/8280 (0.08%)	9

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Cataract cortical <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Diabetic retinopathy <sup>A</sup> †	1/8212 (0.01%)	1	6/8280 (0.07%)	7
Diplopia <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Eye haemorrhage <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Glaucoma <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Macular oedema <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Optic ischaemic neuropathy <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Retinal artery occlusion <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Retinal detachment <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Retinal haemorrhage <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Retinal ischaemia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Ulcerative keratitis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Vision blurred <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Vitreous haemorrhage <sup>A</sup> †	3/8212 (0.04%)	3	2/8280 (0.02%)	2
Gastrointestinal disorders				
Abdominal adhesions <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Abdominal discomfort <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Abdominal hernia <sup>A</sup> †	5/8212 (0.06%)	5	3/8280 (0.04%)	3
Abdominal hernia obstructive <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Abdominal pain <sup>A</sup> †	13/8212 (0.16%)	14	17/8280 (0.21%)	17
Abdominal pain lower <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Abdominal pain upper <sup>A</sup> †	2/8212 (0.02%)	2	4/8280 (0.05%)	4

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Abdominal strangulated hernia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Abdominal wall haematoma <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Anal fistula <sup>A</sup> †	2/8212 (0.02%)	3	0/8280 (0%)	0
Anal polyp <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Ascites <sup>A</sup> †	4/8212 (0.05%)	4	3/8280 (0.04%)	3
Colitis <sup>A</sup> †	5/8212 (0.06%)	5	4/8280 (0.05%)	4
Colitis ischaemic <sup>A</sup> †	1/8212 (0.01%)	1	6/8280 (0.07%)	6
Colitis ulcerative <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Colonic polyp <sup>A</sup> †	4/8212 (0.05%)	4	6/8280 (0.07%)	6
Colonic pseudo-obstruction <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Constipation <sup>A</sup> †	5/8212 (0.06%)	5	4/8280 (0.05%)	4
Crohn's disease <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Diabetic gastroparesis <sup>A</sup> †	2/8212 (0.02%)	5	1/8280 (0.01%)	1
Diaphragmatic hernia <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Diarrhoea <sup>A</sup> †	15/8212 (0.18%)	15	12/8280 (0.14%)	13
Diverticular perforation <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Diverticulitis intestinal haemorrhagic <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Diverticulum <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Diverticulum intestinal <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Diverticulum oesophageal <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Duodenal perforation <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Duodenal ulcer <sup>A</sup> †	7/8212 (0.09%)	7	4/8280 (0.05%)	4

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Duodenal ulcer haemorrhage <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Duodenal ulcer perforation <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Dyskinesia oesophageal <sup>A</sup> †	1/8212 (0.01%)	3	0/8280 (0%)	0
Dyspepsia <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Dysphagia <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Enteritis <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	3
Enterovesical fistula <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Epigastric discomfort <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Faecaloma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Femoral hernia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Food poisoning <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Gastric antral vascular ectasia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Gastric haemorrhage <sup>A</sup> †	4/8212 (0.05%)	4	0/8280 (0%)	0
Gastric ulcer <sup>A</sup> †	7/8212 (0.09%)	7	3/8280 (0.04%)	3
Gastric ulcer haemorrhage <sup>A</sup> †	4/8212 (0.05%)	4	3/8280 (0.04%)	3
Gastritis <sup>A</sup> †	11/8212 (0.13%)	12	15/8280 (0.18%)	15
Gastritis atrophic <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Gastritis erosive <sup>A</sup> †	3/8212 (0.04%)	3	1/8280 (0.01%)	1
Gastritis haemorrhagic <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Gastrointestinal angiodysplasia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Gastrointestinal haemorrhage <sup>A</sup> †	18/8212 (0.22%)	25	15/8280 (0.18%)	15
Gastrointestinal hypomotility <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Gastrointestinal inflammation <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Gastrointestinal telangiectasia <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Gastrointestinal ulcer haemorrhage <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Gastrointestinal vascular malformation <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Gastrooesophageal reflux disease <sup>A</sup> †	8/8212 (0.1%)	8	7/8280 (0.08%)	7
Gingival bleeding <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Haematemesis <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Haematochezia <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Haemorrhagic erosive gastritis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Haemorrhoidal haemorrhage <sup>A</sup> †	4/8212 (0.05%)	4	0/8280 (0%)	0
Haemorrhoids <sup>A</sup> †	3/8212 (0.04%)	3	5/8280 (0.06%)	5
Hiatus hernia <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Ileus <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Impaired gastric emptying <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Inflammatory bowel disease <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Inguinal hernia <sup>A</sup> †	4/8212 (0.05%)	4	6/8280 (0.07%)	6
Inguinal hernia, obstructive <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Intestinal ischaemia <sup>A</sup> †	2/8212 (0.02%)	3	1/8280 (0.01%)	1
Intestinal obstruction <sup>A</sup> †	3/8212 (0.04%)	3	5/8280 (0.06%)	5
Intestinal perforation <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Intestinal polyp haemorrhage <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Irritable bowel syndrome <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Large intestinal haemorrhage <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Large intestine perforation <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Lower gastrointestinal haemorrhage <sup>A</sup> †	4/8212 (0.05%)	4	0/8280 (0%)	0
Mallory-Weiss syndrome <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Megacolon <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Mesenteric artery stenosis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Mesenteric artery thrombosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Mesenteric vascular insufficiency <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Nausea <sup>A</sup> †	0/8212 (0%)	0	4/8280 (0.05%)	4
Oesophageal fibrosis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Oesophageal obstruction <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Oesophageal spasm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Oesophageal stenosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Oesophageal varices haemorrhage <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Oesophagitis <sup>A</sup> †	0/8212 (0%)	0	4/8280 (0.05%)	4
Oesophagitis ulcerative <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Omental infarction <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Pancreatic duct dilatation <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Pancreatic mass <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Pancreatitis <sup>A</sup> †	12/8212 (0.15%)	14	18/8280 (0.22%)	19
Pancreatitis acute <sup>A</sup> †	6/8212 (0.07%)	6	4/8280 (0.05%)	5
Pancreatitis chronic <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Pancreatolithiasis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Peptic ulcer <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Rectal haemorrhage <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Rectal polyp <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Rectal prolapse <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	3
Reflux gastritis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Retroperitoneal fibrosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Small intestinal haemorrhage <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Small intestinal obstruction <sup>A</sup> †	4/8212 (0.05%)	6	4/8280 (0.05%)	4
Small intestinal perforation <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	3
Tongue disorder <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Umbilical hernia <sup>A</sup> †	4/8212 (0.05%)	4	5/8280 (0.06%)	5
Umbilical hernia, obstructive <sup>A</sup> †	2/8212 (0.02%)	2	3/8280 (0.04%)	3
Upper gastrointestinal haemorrhage <sup>A</sup> †	9/8212 (0.11%)	10	5/8280 (0.06%)	5
Varices oesophageal <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Vomiting <sup>A</sup> †	1/8212 (0.01%)	1	6/8280 (0.07%)	6
General disorders				
Adverse drug reaction <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Application site pain <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Asthenia <sup>A</sup> †	1/8212 (0.01%)	1	4/8280 (0.05%)	4
Catheter site haemorrhage <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Chest discomfort <sup>A</sup> †	2/8212 (0.02%)	3	0/8280 (0%)	0

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Chest pain <sup>A</sup> †	10/8212 (0.12%)	10	14/8280 (0.17%)	14
Cyst <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Death <sup>A</sup> †	1/8212 (0.01%)	1	5/8280 (0.06%)	5
Device battery issue <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Device breakage <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	3
Device damage <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Device dislocation <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Device failure <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Device lead damage <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Device malfunction <sup>A</sup> †	0/8212 (0%)	0	4/8280 (0.05%)	4
Exercise tolerance decreased <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Fatigue <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Feeling cold <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Foaming at mouth <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Gait disturbance <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
General physical health deterioration <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
General symptom <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Generalised oedema <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Hernia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hernia obstructive <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hypothermia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Impaired healing <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3



	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Implant site haematoma <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Inflammation <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Ischaemic ulcer <sup>A</sup> †	1/8212 (0.01%)	2	0/8280 (0%)	0
Lipogranuloma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Malaise <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Medical device complication <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Multi-organ disorder <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Multi-organ failure <sup>A</sup> †	5/8212 (0.06%)	5	7/8280 (0.08%)	7
Necrobiosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Necrosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	2
Non-cardiac chest pain <sup>A</sup> †	109/8212 (1.33%)	131	108/8280 (1.3%)	125
Oedema peripheral <sup>A</sup> †	1/8212 (0.01%)	1	4/8280 (0.05%)	4
Organ failure <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Pain <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Polyp <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Pyrexia <sup>A</sup> †	7/8212 (0.09%)	7	7/8280 (0.08%)	7
Spinal pain <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Systemic inflammatory response syndrome <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Hepatobiliary disorders				
Bile duct obstruction <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Bile duct stone <sup>A</sup> †	5/8212 (0.06%)	5	3/8280 (0.04%)	3

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Biliary colic <sup>A</sup> †	4/8212 (0.05%)	4	0/8280 (0%)	0
Biliary dyskinesia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Biliary polyp <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cholangitis <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Cholangitis acute <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Cholecystitis <sup>A</sup> †	10/8212 (0.12%)	12	13/8280 (0.16%)	13
Cholecystitis acute <sup>A</sup> †	14/8212 (0.17%)	14	22/8280 (0.27%)	22
Cholecystitis chronic <sup>A</sup> †	4/8212 (0.05%)	4	1/8280 (0.01%)	1
Cholelithiasis <sup>A</sup> †	27/8212 (0.33%)	28	26/8280 (0.31%)	27
Drug-induced liver injury <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Gallbladder disorder <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Gallbladder perforation <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Hepatic cirrhosis <sup>A</sup> †	6/8212 (0.07%)	6	2/8280 (0.02%)	2
Hepatic failure <sup>A</sup> †	2/8212 (0.02%)	2	3/8280 (0.04%)	3
Hepatic function abnormal <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Hepatic ischaemia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hepatic lesion <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Hepatitis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Hydrocholecystis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Ischaemic hepatitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Jaundice <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Liver disorder <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Portal vein thrombosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Immune system disorders				
Allergy to venom <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Anaphylactic reaction <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Anaphylactic shock <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Autoimmune disorder <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cryoglobulinaemia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Drug hypersensitivity <sup>A</sup> †	4/8212 (0.05%)	4	4/8280 (0.05%)	4
Hypersensitivity <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	3
Sarcoidosis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Infections and infestations				
Abdominal abscess <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Abdominal wall abscess <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Abscess <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Abscess limb <sup>A</sup> †	4/8212 (0.05%)	4	5/8280 (0.06%)	5
Abscess soft tissue <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Acarodermatitis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Acinetobacter bacteraemia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Acute sinusitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Adenovirus infection <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Anal abscess <sup>A</sup> †	1/8212 (0.01%)	2	0/8280 (0%)	0
Appendicitis <sup>A</sup> †	9/8212 (0.11%)	9	7/8280 (0.08%)	7

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Appendicitis perforated <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Arthritis bacterial <sup>A</sup> †	2/8212 (0.02%)	2	3/8280 (0.04%)	3
Arthritis infective <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Bacteraemia <sup>A</sup> †	2/8212 (0.02%)	2	3/8280 (0.04%)	3
Bacterial infection <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Bacterial sepsis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Bone abscess <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Breast cellulitis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Breast infection <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Bronchiolitis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Bronchitis <sup>A</sup> †	35/8212 (0.43%)	35	23/8280 (0.28%)	23
Bronchitis viral <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Bronchopneumonia <sup>A</sup> †	8/8212 (0.1%)	9	10/8280 (0.12%)	10
Bursitis infective <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Campylobacter infection <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Carbuncle <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Cellulitis <sup>A</sup> †	65/8212 (0.79%)	70	58/8280 (0.7%)	70
Cellulitis gangrenous <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cellulitis of male external genital organ <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Cellulitis staphylococcal <sup>A</sup> †	3/8212 (0.04%)	3	1/8280 (0.01%)	1
Cervicitis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Chest wall abscess <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Cholangitis suppurative <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cholecystitis infective <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Chronic sinusitis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Clostridial infection <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Clostridium difficile colitis <sup>A</sup> †	6/8212 (0.07%)	6	2/8280 (0.02%)	2
Clostridium difficile sepsis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Creutzfeldt-Jakob disease <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cystitis <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	4
Dengue fever <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Device related infection <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Diabetic foot infection <sup>A</sup> †	3/8212 (0.04%)	3	10/8280 (0.12%)	11
Diabetic gangrene <sup>A</sup> †	4/8212 (0.05%)	4	9/8280 (0.11%)	9
Diarrhoea infectious <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Diverticulitis <sup>A</sup> †	10/8212 (0.12%)	13	10/8280 (0.12%)	11
Ear infection <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Emphysematous cystitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Empyema <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Endocarditis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Endocarditis enterococcal <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Endophthalmitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Enterobacter bacteraemia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Enterobacter infection <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Enterobacter pneumonia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Enterococcal bacteraemia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Enterococcal sepsis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Enterocolitis infectious <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Erysipelas <sup>A</sup> †	6/8212 (0.07%)	6	6/8280 (0.07%)	6
Escherichia bacteraemia <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Escherichia infection <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Escherichia sepsis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Escherichia urinary tract infection <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Febrile infection <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Furuncle <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Gallbladder abscess <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Gangrene <sup>A</sup> †	16/8212 (0.19%)	17	22/8280 (0.27%)	23
Gastric ulcer helicobacter <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Gastroenteritis <sup>A</sup> †	17/8212 (0.21%)	17	28/8280 (0.34%)	29
Gastroenteritis clostridial <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Gastroenteritis norovirus <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Gastroenteritis shigella <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Gastroenteritis viral <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Graft infection <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Groin abscess <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Groin infection <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
H1N1 influenza <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
HIV infection <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Helicobacter infection <sup>A</sup> †	3/8212 (0.04%)	3	1/8280 (0.01%)	1
Hepatitis B <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Herpes zoster <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Herpes zoster ophthalmic <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Implant site cellulitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Incision site infection <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Infected dermal cyst <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Infected fistula <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Infected skin ulcer <sup>A</sup> †	8/8212 (0.1%)	9	4/8280 (0.05%)	4
Infection <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Infectious peritonitis <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Infectious thyroiditis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Infective exacerbation of chronic obstructive airways disease <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Influenza <sup>A</sup> †	2/8212 (0.02%)	2	6/8280 (0.07%)	6
Intestinal gangrene <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Klebsiella infection <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Labyrinthitis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Liver abscess <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Lobar pneumonia <sup>A</sup> †	8/8212 (0.1%)	8	16/8280 (0.19%)	16

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Localised infection <sup>A</sup> †	11/8212 (0.13%)	11	8/8280 (0.1%)	8
Lower respiratory tract infection <sup>A</sup> †	2/8212 (0.02%)	2	4/8280 (0.05%)	6
Ludwig angina <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Lung infection pseudomonal <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Lyme disease <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Mastoiditis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Mediastinitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Meningitis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Necrotising fasciitis <sup>A</sup> †	4/8212 (0.05%)	4	0/8280 (0%)	0
Oesophageal candidiasis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Orchitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Osteomyelitis <sup>A</sup> †	24/8212 (0.29%)	25	18/8280 (0.22%)	23
Osteomyelitis chronic <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Otitis externa <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Parametritis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Pelvic abscess <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Peridiverticular abscess <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Perihepatic abscess <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Perineal abscess <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Perinephric abscess <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Periorbital cellulitis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Perirectal abscess <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0



	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Peritoneal abscess <sup>A †</sup>	0/8212 (0%)	0	1/8280 (0.01%)	1
Peritonitis <sup>A †</sup>	4/8212 (0.05%)	4	5/8280 (0.06%)	5
Peritonitis bacterial <sup>A †</sup>	0/8212 (0%)	0	1/8280 (0.01%)	1
Pilonidal cyst <sup>A †</sup>	2/8212 (0.02%)	2	0/8280 (0%)	0
Pneumococcal bacteraemia <sup>A †</sup>	0/8212 (0%)	0	1/8280 (0.01%)	1
Pneumococcal sepsis <sup>A †</sup>	0/8212 (0%)	0	1/8280 (0.01%)	1
Pneumocystis jiroveci infection <sup>A †</sup>	0/8212 (0%)	0	1/8280 (0.01%)	1
Pneumonia <sup>A †</sup>	118/8212 (1.44%)	127	151/8280 (1.82%)	168
Pneumonia bacterial <sup>A †</sup>	2/8212 (0.02%)	2	0/8280 (0%)	0
Pneumonia chlamydial <sup>A †</sup>	0/8212 (0%)	0	1/8280 (0.01%)	1
Pneumonia fungal <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0
Pneumonia legionella <sup>A †</sup>	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Pneumonia mycoplasmal <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0
Pneumonia pneumococcal <sup>A †</sup>	0/8212 (0%)	0	1/8280 (0.01%)	1
Pneumonia staphylococcal <sup>A †</sup>	2/8212 (0.02%)	2	0/8280 (0%)	0
Pneumonia viral <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0
Post procedural infection <sup>A †</sup>	2/8212 (0.02%)	2	3/8280 (0.04%)	3
Post procedural sepsis <sup>A †</sup>	0/8212 (0%)	0	1/8280 (0.01%)	1
Postoperative abscess <sup>A †</sup>	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Postoperative wound infection <sup>A †</sup>	9/8212 (0.11%)	10	8/8280 (0.1%)	9
Prostatic abscess <sup>A †</sup>	0/8212 (0%)	0	1/8280 (0.01%)	1
Pseudomonal sepsis <sup>A †</sup>	0/8212 (0%)	0	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Pulmonary sepsis <sup>A</sup> †	4/8212 (0.05%)	4	6/8280 (0.07%)	6
Pyelonephritis <sup>A</sup> †	7/8212 (0.09%)	7	11/8280 (0.13%)	11
Pyelonephritis acute <sup>A</sup> †	1/8212 (0.01%)	1	5/8280 (0.06%)	6
Rectal abscess <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Renal abscess <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	3
Respiratory tract infection <sup>A</sup> †	3/8212 (0.04%)	3	2/8280 (0.02%)	2
Respiratory tract infection viral <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Retroperitoneal abscess <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Rhinitis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Sepsis <sup>A</sup> †	20/8212 (0.24%)	22	21/8280 (0.25%)	21
Sepsis syndrome <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Septic shock <sup>A</sup> †	9/8212 (0.11%)	9	11/8280 (0.13%)	11
Sinusitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Skin bacterial infection <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Skin infection <sup>A</sup> †	1/8212 (0.01%)	2	1/8280 (0.01%)	1
Staphylococcal bacteraemia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Staphylococcal infection <sup>A</sup> †	4/8212 (0.05%)	4	3/8280 (0.04%)	5
Staphylococcal sepsis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Staphylococcal skin infection <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Streptococcal bacteraemia <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Streptococcal urinary tract infection <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Subcutaneous abscess <sup>A</sup> †	3/8212 (0.04%)	3	4/8280 (0.05%)	4

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Subdiaphragmatic abscess <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Syphilis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Testicular abscess <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Thrombophlebitis septic <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Tracheobronchitis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Typhoid fever <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Upper respiratory tract infection <sup>A</sup> †	7/8212 (0.09%)	7	7/8280 (0.08%)	8
Urinary tract infection <sup>A</sup> †	49/8212 (0.6%)	50	40/8280 (0.48%)	42
Urinary tract infection bacterial <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Urinary tract infection staphylococcal <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Urosepsis <sup>A</sup> †	8/8212 (0.1%)	8	10/8280 (0.12%)	10
Vaginal abscess <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Viral infection <sup>A</sup> †	4/8212 (0.05%)	4	1/8280 (0.01%)	1
Viral upper respiratory tract infection <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Vulval abscess <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Wound infection <sup>A</sup> †	7/8212 (0.09%)	7	7/8280 (0.08%)	7
Wound infection staphylococcal <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Wound sepsis <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Injury, poisoning and procedural complications				
Accident <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Acetabulum fracture <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Allergic transfusion reaction <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Anaemia postoperative <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Anastomotic ulcer haemorrhage <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Ankle fracture <sup>A</sup> †	8/8212 (0.1%)	8	3/8280 (0.04%)	3
Arteriovenous fistula site complication <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Arteriovenous graft site haematoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Bone fissure <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Brachial plexus injury <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Burns second degree <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Burns third degree <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Carbon monoxide poisoning <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Cartilage injury <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cervical vertebral fracture <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Chest injury <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Clavicle fracture <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Concussion <sup>A</sup> †	2/8212 (0.02%)	2	5/8280 (0.06%)	5
Contrast media reaction <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Contusion <sup>A</sup> †	1/8212 (0.01%)	1	4/8280 (0.05%)	4
Craniocerebral injury <sup>A</sup> †	2/8212 (0.02%)	2	3/8280 (0.04%)	3
Cystitis radiation <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Face injury <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Facial bones fracture <sup>A</sup> †	2/8212 (0.02%)	2	3/8280 (0.04%)	3
Fall <sup>A</sup> †	8/8212 (0.1%)	8	6/8280 (0.07%)	6

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Feeding tube complication <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Femoral neck fracture <sup>A</sup> †	5/8212 (0.06%)	5	10/8280 (0.12%)	10
Femur fracture <sup>A</sup> †	10/8212 (0.12%)	10	13/8280 (0.16%)	15
Fibula fracture <sup>A</sup> †	4/8212 (0.05%)	4	1/8280 (0.01%)	1
Foot fracture <sup>A</sup> †	2/8212 (0.02%)	2	3/8280 (0.04%)	3
Forearm fracture <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Foreign body <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Fracture <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Fractured coccyx <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Graft complication <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Graft dysfunction <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Graft thrombosis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	2
Hand fracture <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Head injury <sup>A</sup> †	4/8212 (0.05%)	4	5/8280 (0.06%)	5
Heart injury <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hip fracture <sup>A</sup> †	10/8212 (0.12%)	10	8/8280 (0.1%)	9
Humerus fracture <sup>A</sup> †	5/8212 (0.06%)	5	9/8280 (0.11%)	9
Incisional hernia <sup>A</sup> †	5/8212 (0.06%)	5	6/8280 (0.07%)	6
Joint dislocation <sup>A</sup> †	1/8212 (0.01%)	1	4/8280 (0.05%)	4
Laceration <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Ligament rupture <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Ligament sprain <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Limb injury <sup>A</sup> †	1/8212 (0.01%)	1	4/8280 (0.05%)	4
Limb traumatic amputation <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Lower limb fracture <sup>A</sup> †	2/8212 (0.02%)	2	7/8280 (0.08%)	7
Lumbar vertebral fracture <sup>A</sup> †	3/8212 (0.04%)	3	1/8280 (0.01%)	1
Meniscus lesion <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Multiple drug overdose intentional <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Multiple fractures <sup>A</sup> †	4/8212 (0.05%)	4	3/8280 (0.04%)	3
Muscle strain <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Near drowning <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Overdose <sup>A</sup> †	3/8212 (0.04%)	3	2/8280 (0.02%)	2
Patella fracture <sup>A</sup> †	1/8212 (0.01%)	1	5/8280 (0.06%)	5
Pelvic fracture <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Peripheral artery restenosis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Periprosthetic fracture <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Pneumothorax traumatic <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Post concussion syndrome <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Post embolisation syndrome <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Post procedural bile leak <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Post procedural complication <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Post procedural discharge <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Post procedural haematoma <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Post procedural haematuria <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Post procedural haemorrhage <sup>A</sup> †	5/8212 (0.06%)	6	1/8280 (0.01%)	1
Postoperative fever <sup>A</sup> †	1/8212 (0.01%)	2	0/8280 (0%)	0
Postoperative hernia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Postoperative renal failure <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Postoperative thoracic procedure complication <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Postoperative wound complication <sup>A</sup> †	1/8212 (0.01%)	1	5/8280 (0.06%)	5
Procedural pain <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Pubis fracture <sup>A</sup> †	3/8212 (0.04%)	3	2/8280 (0.02%)	2
Radius fracture <sup>A</sup> †	5/8212 (0.06%)	5	5/8280 (0.06%)	5
Rib fracture <sup>A</sup> †	4/8212 (0.05%)	4	3/8280 (0.04%)	3
Road traffic accident <sup>A</sup> †	7/8212 (0.09%)	7	4/8280 (0.05%)	4
Scapula fracture <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Seroma <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Skeletal injury <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Skull fracture <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Skull fractured base <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Spinal compression fracture <sup>A</sup> †	7/8212 (0.09%)	7	2/8280 (0.02%)	2
Spinal fracture <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Splenic haematoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Splenic rupture <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Sternal fracture <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Subdural haematoma <sup>A</sup> †	8/8212 (0.1%)	8	9/8280 (0.11%)	9
Subdural haemorrhage <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Suture related complication <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Tendon injury <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Tendon rupture <sup>A</sup> †	3/8212 (0.04%)	3	3/8280 (0.04%)	3
Thermal burn <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Tibia fracture <sup>A</sup> †	3/8212 (0.04%)	3	1/8280 (0.01%)	1
Tooth fracture <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Toxicity to various agents <sup>A</sup> †	5/8212 (0.06%)	5	5/8280 (0.06%)	5
Tracheal injury <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Traumatic haematoma <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Traumatic intracranial haemorrhage <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Traumatic ulcer <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Ulna fracture <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Upper limb fracture <sup>A</sup> †	2/8212 (0.02%)	2	4/8280 (0.05%)	4
Vascular graft complication <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Vascular graft occlusion <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Vascular graft thrombosis <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Vascular pseudoaneurysm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Wound <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	3
Wound dehiscence <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Wound haemorrhage <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1



	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Wound necrosis <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	3
Wound secretion <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Wrist fracture <sup>A</sup> †	3/8212 (0.04%)	3	6/8280 (0.07%)	6
Investigations				
Alanine aminotransferase increased <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Arteriogram coronary <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Aspartate aminotransferase increased <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Blood bilirubin increased <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Blood creatine phosphokinase increased <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Blood creatinine increased <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Blood glucose increased <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Blood potassium increased <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Blood pressure abnormal <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Blood pressure increased <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
C-reactive protein increased <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cardiac stress test abnormal <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Chest X-ray abnormal <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Clostridium test positive <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Coagulation factor VIII level increased <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Coagulation test abnormal <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Ejection fraction decreased <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Electrocardiogram abnormal <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Haemoglobin decreased <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Heart rate increased <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hepatic enzyme increased <sup>A</sup> †	6/8212 (0.07%)	6	5/8280 (0.06%)	5
International normalised ratio increased <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Liver function test abnormal <sup>A</sup> †	3/8212 (0.04%)	3	2/8280 (0.02%)	2
Prostatic specific antigen increased <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Transaminases increased <sup>A</sup> †	0/8212 (0%)	0	4/8280 (0.05%)	4
Troponin increased <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Urine albumin/creatinine ratio increased <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Weight decreased <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Metabolism and nutrition disorders				
Decreased appetite <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Dehydration <sup>A</sup> †	17/8212 (0.21%)	18	13/8280 (0.16%)	13
Diabetes mellitus <sup>A</sup> †	13/8212 (0.16%)	14	12/8280 (0.14%)	14
Diabetes mellitus inadequate control <sup>A</sup> †	11/8212 (0.13%)	13	10/8280 (0.12%)	12
Diabetic complication <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Diabetic ketoacidosis <sup>A</sup> †	5/8212 (0.06%)	6	8/8280 (0.1%)	10
Electrolyte imbalance <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Failure to thrive <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Fluid overload <sup>A</sup> †	5/8212 (0.06%)	5	1/8280 (0.01%)	1
Fluid retention <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Gout <sup>A</sup> †	2/8212 (0.02%)	2	8/8280 (0.1%)	8

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Hypercalcaemia <sup>A</sup> †	3/8212 (0.04%)	3	1/8280 (0.01%)	1
Hyperglycaemia <sup>A</sup> †	58/8212 (0.71%)	62	51/8280 (0.62%)	55
Hyperglycaemic hyperosmolar nonketotic syndrome <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Hyperkalaemia <sup>A</sup> †	13/8212 (0.16%)	15	17/8280 (0.21%)	17
Hyperosmolar state <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Hypokalaemia <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Hyponatraemia <sup>A</sup> †	7/8212 (0.09%)	8	3/8280 (0.04%)	3
Hypovolaemia <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Ketoacidosis <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Lactic acidosis <sup>A</sup> †	3/8212 (0.04%)	3	1/8280 (0.01%)	1
Malnutrition <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Metabolic acidosis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Obesity <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Musculoskeletal and connective tissue disorders				
Arthralgia <sup>A</sup> †	4/8212 (0.05%)	4	8/8280 (0.1%)	8
Arthritis <sup>A</sup> †	5/8212 (0.06%)	5	3/8280 (0.04%)	3
Arthropathy <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Articular calcification <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Back pain <sup>A</sup> †	10/8212 (0.12%)	10	9/8280 (0.11%)	9
Bursitis <sup>A</sup> †	1/8212 (0.01%)	1	5/8280 (0.06%)	5
Carpal collapse <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Cervical spinal stenosis <sup>A †</sup>	2/8212 (0.02%)	2	0/8280 (0%)	0
Diabetic amyotrophy <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0
Dupuytren's contracture <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0
Exostosis <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0
Extraskeletal ossification <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0
Fasciitis <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0
Foot deformity <sup>A †</sup>	3/8212 (0.04%)	3	1/8280 (0.01%)	1
Fracture nonunion <sup>A †</sup>	0/8212 (0%)	0	1/8280 (0.01%)	1
Gouty arthritis <sup>A †</sup>	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Haemarthrosis <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0
Hip deformity <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0
Inguinal mass <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0
Intervertebral disc degeneration <sup>A †</sup>	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Intervertebral disc disorder <sup>A †</sup>	3/8212 (0.04%)	3	4/8280 (0.05%)	5
Intervertebral disc displacement <sup>A †</sup>	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Intervertebral disc protrusion <sup>A †</sup>	13/8212 (0.16%)	14	9/8280 (0.11%)	10
Joint ankylosis <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0
Joint stiffness <sup>A †</sup>	0/8212 (0%)	0	1/8280 (0.01%)	1
Lumbar spinal stenosis <sup>A †</sup>	3/8212 (0.04%)	3	6/8280 (0.07%)	6
Mobility decreased <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0
Monarthritits <sup>A †</sup>	0/8212 (0%)	0	1/8280 (0.01%)	1
Muscle spasms <sup>A †</sup>	1/8212 (0.01%)	1	0/8280 (0%)	0

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Muscular weakness <sup>A</sup> †	0/8212 (0%)	0	4/8280 (0.05%)	4
Musculoskeletal chest pain <sup>A</sup> †	32/8212 (0.39%)	35	23/8280 (0.28%)	23
Musculoskeletal pain <sup>A</sup> †	4/8212 (0.05%)	4	3/8280 (0.04%)	3
Myalgia <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Myopathy <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Myositis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Neck pain <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Neuropathic arthropathy <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Osteitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Osteoarthritis <sup>A</sup> †	40/8212 (0.49%)	42	49/8280 (0.59%)	51
Osteochondritis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Osteochondrosis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Osteolysis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Osteonecrosis <sup>A</sup> †	3/8212 (0.04%)	3	2/8280 (0.02%)	2
Osteoporotic fracture <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Pain in extremity <sup>A</sup> †	5/8212 (0.06%)	5	8/8280 (0.1%)	8
Pathological fracture <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Polymyalgia rheumatica <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Polymyositis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Rhabdomyolysis <sup>A</sup> †	4/8212 (0.05%)	4	2/8280 (0.02%)	2
Rheumatoid arthritis <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Rotator cuff syndrome <sup>A</sup> †	2/8212 (0.02%)	2	3/8280 (0.04%)	3

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Scoliosis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Spinal column stenosis <sup>A</sup> †	3/8212 (0.04%)	3	2/8280 (0.02%)	2
Spinal disorder <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Spinal osteoarthritis <sup>A</sup> †	6/8212 (0.07%)	6	7/8280 (0.08%)	7
Spondylitis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Synovial cyst <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Synovitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Tendonitis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Tenosynovitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Vertebral column mass <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Vertebral foraminal stenosis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Abdominal neoplasm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Acute myeloid leukaemia <sup>A</sup> †	2/8212 (0.02%)	4	0/8280 (0%)	0
Adenocarcinoma of the cervix <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Adenocarcinoma pancreas <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Adenoma benign <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Adrenal adenoma <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Angiocentric lymphoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	2
B-cell lymphoma <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Basal cell carcinoma <sup>A</sup> †	42/8212 (0.51%)	57	52/8280 (0.63%)	58
Basosquamous carcinoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Benign neoplasm of bladder <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Benign neoplasm of choroid <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Benign neoplasm of thyroid gland <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Benign ovarian tumour <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Benign renal neoplasm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Benign salivary gland neoplasm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Bile duct cancer <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Bladder cancer <sup>A</sup> †	9/8212 (0.11%)	9	12/8280 (0.14%)	13
Bladder cancer recurrent <sup>A</sup> †	5/8212 (0.06%)	5	2/8280 (0.02%)	2
Bladder cancer stage II <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Bladder neoplasm <sup>A</sup> †	4/8212 (0.05%)	4	2/8280 (0.02%)	2
Bladder transitional cell carcinoma <sup>A</sup> †	3/8212 (0.04%)	3	2/8280 (0.02%)	2
Bladder transitional cell carcinoma stage II <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Blast crisis in myelogenous leukaemia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Bone neoplasm malignant <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Bowen's disease <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Brain cancer metastatic <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Breast cancer <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Breast cancer female <sup>A</sup> †	12/8212 (0.15%)	12	10/8280 (0.12%)	10
Breast cancer metastatic <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Breast neoplasm <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Bronchial carcinoma <sup>A</sup> †	1/8212 (0.01%)	1	4/8280 (0.05%)	4
Burkitt's lymphoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Carcinoid tumour of the gastrointestinal tract <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Central nervous system lymphoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cervix carcinoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Choroid melanoma <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Chronic lymphocytic leukaemia <sup>A</sup> †	1/8212 (0.01%)	1	4/8280 (0.05%)	4
Chronic myeloid leukaemia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Colon adenoma <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	3
Colon cancer <sup>A</sup> †	18/8212 (0.22%)	18	13/8280 (0.16%)	13
Colon cancer metastatic <sup>A</sup> †	2/8212 (0.02%)	2	3/8280 (0.04%)	4
Colon neoplasm <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Colorectal cancer <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Diffuse large B-cell lymphoma <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Endometrial cancer <sup>A</sup> †	4/8212 (0.05%)	4	2/8280 (0.02%)	2
Endometrial cancer stage IV <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Gallbladder cancer metastatic <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Gastric cancer <sup>A</sup> †	9/8212 (0.11%)	11	6/8280 (0.07%)	6
Gastric cancer recurrent <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Gastric neoplasm <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Gastrointestinal cancer metastatic <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0



	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Gastrointestinal carcinoma <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Gastrointestinal neoplasm <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Gastrointestinal tract adenoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Glioblastoma <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Haemangioma <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Head and neck cancer <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hepatic cancer metastatic <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Hepatic neoplasm <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Hepatic neoplasm malignant <sup>A</sup> †	4/8212 (0.05%)	4	7/8280 (0.08%)	7
Hepatic neoplasm malignant recurrent <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Hodgkin's disease <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Hodgkin's disease nodular sclerosis stage unspecified <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Keratoacanthoma <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Laryngeal cancer <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Laryngeal cancer stage I <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Leiomyosarcoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Lentigo maligna <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Leukaemia <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Lip neoplasm malignant stage unspecified <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Lipoma <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Liposarcoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1

	Placebo		Saxaglipitin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Lung adenocarcinoma <sup>A</sup> †	5/8212 (0.06%)	5	2/8280 (0.02%)	2
Lung adenocarcinoma metastatic <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Lung adenocarcinoma stage III <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Lung cancer metastatic <sup>A</sup> †	4/8212 (0.05%)	4	6/8280 (0.07%)	6
Lung carcinoma cell type unspecified recurrent <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Lung carcinoma cell type unspecified stage 0 <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Lung carcinoma cell type unspecified stage III <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Lung neoplasm <sup>A</sup> †	1/8212 (0.01%)	1	6/8280 (0.07%)	6
Lung neoplasm malignant <sup>A</sup> †	15/8212 (0.18%)	16	19/8280 (0.23%)	20
Lung squamous cell carcinoma stage II <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Lung squamous cell carcinoma stage unspecified <sup>A</sup> †	2/8212 (0.02%)	2	4/8280 (0.05%)	4
Lymphoma <sup>A</sup> †	3/8212 (0.04%)	3	5/8280 (0.06%)	5
Malignant melanoma <sup>A</sup> †	9/8212 (0.11%)	9	11/8280 (0.13%)	11
Malignant melanoma in situ <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Malignant palate neoplasm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Malignant peritoneal neoplasm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Malignant urinary tract neoplasm <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Melanocytic naevus <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Meningioma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Mesothelioma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Mesothelioma malignant <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Metastases to bone <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Metastases to liver <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Metastases to lung <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Metastases to peritoneum <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Metastatic bronchial carcinoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Metastatic gastric cancer <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Metastatic neoplasm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Monoclonal gammopathy <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Multiple myeloma <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Myelodysplastic syndrome <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Myeloproliferative disorder <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Neoplasm malignant <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Neuroendocrine carcinoma <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Non-Hodgkin's lymphoma <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Non-small cell lung cancer <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Non-small cell lung cancer metastatic <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Ocular neoplasm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Oesophageal cancer metastatic <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Oesophageal carcinoma <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Ovarian adenoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Ovarian cancer metastatic <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Ovarian fibroma <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Ovarian neoplasm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Pancreatic carcinoma <sup>A</sup> †	8/8212 (0.1%)	8	2/8280 (0.02%)	2
Pancreatic carcinoma metastatic <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Pancreatic neoplasm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Pancreatic neuroendocrine tumour metastatic <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Plasmacytoma <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Polycythaemia vera <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Prostate cancer <sup>A</sup> †	34/8212 (0.41%)	34	41/8280 (0.5%)	43
Prostate cancer metastatic <sup>A</sup> †	4/8212 (0.05%)	4	1/8280 (0.01%)	1
Prostate cancer recurrent <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Prostate cancer stage II <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Prostate cancer stage IV <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Prostatic adenoma <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Rectal cancer <sup>A</sup> †	6/8212 (0.07%)	6	0/8280 (0%)	0
Rectal cancer metastatic <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Rectal neoplasm <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Renal cancer <sup>A</sup> †	4/8212 (0.05%)	4	4/8280 (0.05%)	4
Renal cancer metastatic <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Renal cell carcinoma <sup>A</sup> †	8/8212 (0.1%)	8	4/8280 (0.05%)	4
Renal cell carcinoma stage IV <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Renal neoplasm <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Retroperitoneal neoplasm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Rhabdomyosarcoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Sarcoma metastatic <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Sinonasal papilloma <sup>A</sup> †	1/8212 (0.01%)	2	0/8280 (0%)	0
Skin cancer <sup>A</sup> †	2/8212 (0.02%)	2	5/8280 (0.06%)	5
Small cell lung cancer metastatic <sup>A</sup> †	3/8212 (0.04%)	4	2/8280 (0.02%)	2
Small cell lung cancer stage unspecified <sup>A</sup> †	4/8212 (0.05%)	4	1/8280 (0.01%)	1
Small intestine carcinoma metastatic <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Squamous cell carcinoma <sup>A</sup> †	30/8212 (0.37%)	32	18/8280 (0.22%)	19
Squamous cell carcinoma of skin <sup>A</sup> †	6/8212 (0.07%)	6	7/8280 (0.08%)	7
Superficial spreading melanoma stage unspecified <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Testis cancer <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Thyroid adenoma <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Thyroid cancer <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Thyroid neoplasm <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Transitional cell carcinoma <sup>A</sup> †	6/8212 (0.07%)	7	1/8280 (0.01%)	1
Uterine cancer <sup>A</sup> †	1/8212 (0.01%)	1	4/8280 (0.05%)	4
Uterine leiomyoma <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Vascular neoplasm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Nervous system disorders				

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Amnesia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Amyotrophic lateral sclerosis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Aphasia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Arachnoid cyst <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Ataxia <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Balance disorder <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Basal ganglia haemorrhage <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Brain injury <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Brain mass <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Brain stem haemorrhage <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Carotid arteriosclerosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Carotid artery aneurysm <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Carotid artery disease <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	4
Carotid artery occlusion <sup>A</sup> †	1/8212 (0.01%)	2	3/8280 (0.04%)	3
Carotid artery stenosis <sup>A</sup> †	11/8212 (0.13%)	11	29/8280 (0.35%)	29
Carotid sinus syndrome <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Carpal tunnel syndrome <sup>A</sup> †	3/8212 (0.04%)	3	1/8280 (0.01%)	2
Cerebral arteriosclerosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cerebral circulatory failure <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cerebral haemorrhage <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Cerebral infarction <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Cerebral ischaemia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Cerebral microangiopathy <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cerebrovascular accident <sup>A</sup> †	14/8212 (0.17%)	14	12/8280 (0.14%)	12
Cerebrovascular disorder <sup>A</sup> †	2/8212 (0.02%)	2	3/8280 (0.04%)	3
Cerebrovascular insufficiency <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Cervical myelopathy <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Cervical root pain <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cervicobrachial syndrome <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Cognitive disorder <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Coma <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Complex partial seizures <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Convulsion <sup>A</sup> †	4/8212 (0.05%)	4	3/8280 (0.04%)	3
Dementia <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	3
Dementia Alzheimer's type <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Demyelinating polyneuropathy <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Diabetic encephalopathy <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Diabetic neuropathy <sup>A</sup> †	6/8212 (0.07%)	6	7/8280 (0.08%)	7
Dizziness <sup>A</sup> †	10/8212 (0.12%)	11	16/8280 (0.19%)	16
Dysarthria <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Encephalitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Encephalomalacia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Encephalopathy <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Epilepsy <sup>A</sup> †	7/8212 (0.09%)	8	2/8280 (0.02%)	2

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Fahr's disease <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Guillain-Barre syndrome <sup>A</sup> †	1/8212 (0.01%)	2	0/8280 (0%)	0
Haemorrhage intracranial <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Haemorrhagic stroke <sup>A</sup> †	1/8212 (0.01%)	1	4/8280 (0.05%)	4
Headache <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Hemiparesis <sup>A</sup> †	2/8212 (0.02%)	2	4/8280 (0.05%)	4
Hemiplegia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hemisensory neglect <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hepatic encephalopathy <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Hydrocephalus <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hypertensive encephalopathy <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Hypoxic-ischaemic encephalopathy <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
IIIrd nerve paresis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
IVth nerve paralysis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Intracranial aneurysm <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Intraventricular haemorrhage <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Ischaemic neuropathy <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Ischaemic stroke <sup>A</sup> †	1/8212 (0.01%)	1	4/8280 (0.05%)	4
Lacunar infarction <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Lumbar radiculopathy <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Mental impairment <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Metabolic encephalopathy <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1



	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Migraine <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Monoplegia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Movement disorder <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Myasthenia gravis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Nerve root compression <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Neuralgia <sup>A</sup> †	1/8212 (0.01%)	2	0/8280 (0%)	0
Neurological symptom <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Neuropathy peripheral <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Occipital neuralgia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Optic neuritis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Orthostatic intolerance <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Paraesthesia <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Parkinson's disease <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Parkinsonism <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Polyneuropathy <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Presyncope <sup>A</sup> †	4/8212 (0.05%)	4	5/8280 (0.06%)	5
Radicular pain <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Radicular syndrome <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Sciatica <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Sensory disturbance <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Speech disorder <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Spinal cord infarction <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Subarachnoid haemorrhage <sup>A</sup> †	2/8212 (0.02%)	2	4/8280 (0.05%)	4
Syncope <sup>A</sup> †	32/8212 (0.39%)	33	37/8280 (0.45%)	39
Tension headache <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Thalamus haemorrhage <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Toxic encephalopathy <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Transient ischaemic attack <sup>A</sup> †	60/8212 (0.73%)	64	48/8280 (0.58%)	49
Ulnar nerve palsy <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Uraemic encephalopathy <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
VIIIth nerve paralysis <sup>A</sup> †	4/8212 (0.05%)	4	8/8280 (0.1%)	8
Vascular dementia <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Vascular encephalopathy <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Vertebral artery stenosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Vertebrobasilar insufficiency <sup>A</sup> †	3/8212 (0.04%)	3	3/8280 (0.04%)	3
Vocal cord paralysis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
White matter lesion <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Psychiatric disorders				
Adjustment disorder <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Adjustment disorder with depressed mood <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Agitation <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Alcoholism <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Anxiety <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	3

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Bipolar disorder <sup>A</sup> †	1/8212 (0.01%)	2	2/8280 (0.02%)	2
Completed suicide <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Confusional state <sup>A</sup> †	2/8212 (0.02%)	2	7/8280 (0.08%)	8
Delirium <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Depression <sup>A</sup> †	6/8212 (0.07%)	8	5/8280 (0.06%)	5
Drug abuse <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Hallucination <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Insomnia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Major depression <sup>A</sup> †	1/8212 (0.01%)	2	0/8280 (0%)	0
Mental status changes <sup>A</sup> †	5/8212 (0.06%)	5	7/8280 (0.08%)	8
Psychosomatic disease <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Psychotic disorder <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Stress <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Suicidal ideation <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Suicide attempt <sup>A</sup> †	4/8212 (0.05%)	4	3/8280 (0.04%)	3
Renal and urinary disorders				
Acute prerenal failure <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Azotaemia <sup>A</sup> †	2/8212 (0.02%)	2	3/8280 (0.04%)	3
Bladder outlet obstruction <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Calculus bladder <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Calculus ureteric <sup>A</sup> †	7/8212 (0.09%)	8	5/8280 (0.06%)	7
Calculus urinary <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Cystitis haemorrhagic <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Cystitis noninfective <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Diabetic nephropathy <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	3
Glomerulonephritis membranoproliferative <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Glomerulonephritis membranous <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Haematuria <sup>A</sup> †	7/8212 (0.09%)	7	5/8280 (0.06%)	6
Hydronephrosis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Lupus nephritis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Nephrolithiasis <sup>A</sup> †	11/8212 (0.13%)	11	13/8280 (0.16%)	16
Nephropathy <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Nephropathy toxic <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Nephrotic syndrome <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Renal artery stenosis <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Renal colic <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Renal cyst <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Renal failure <sup>A</sup> †	20/8212 (0.24%)	20	23/8280 (0.28%)	23
Renal failure acute <sup>A</sup> †	65/8212 (0.79%)	71	80/8280 (0.97%)	89
Renal failure chronic <sup>A</sup> †	17/8212 (0.21%)	18	18/8280 (0.22%)	19
Renal impairment <sup>A</sup> †	24/8212 (0.29%)	25	22/8280 (0.27%)	25
Renal infarct <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Renal mass <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Renal tubular necrosis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Stress urinary incontinence <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Tubulointerstitial nephritis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Ureteric stenosis <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Urethral stenosis <sup>A</sup> †	2/8212 (0.02%)	2	5/8280 (0.06%)	6
Urinary bladder polyp <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Urinary incontinence <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Urinary retention <sup>A</sup> †	4/8212 (0.05%)	4	8/8280 (0.1%)	8
Urinary tract obstruction <sup>A</sup> †	4/8212 (0.05%)	4	0/8280 (0%)	0
Reproductive system and breast disorders				
Acquired hydrocele <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Acquired phimosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Balanitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Benign prostatic hyperplasia <sup>A</sup> †	13/8212 (0.16%)	13	13/8280 (0.16%)	13
Breast mass <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Cervical polyp <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Colpocele <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Dysfunctional uterine bleeding <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Endometrial hyperplasia <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Epididymitis <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Metrorrhagia <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Ovarian cyst <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Postmenopausal haemorrhage <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Prostatic obstruction <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Prostatitis <sup>A</sup> †	4/8212 (0.05%)	4	1/8280 (0.01%)	1
Prostatomegaly <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Rectocele <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Testicular cyst <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Uterine haemorrhage <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Uterine polyp <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Uterine prolapse <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	2
Uterovaginal prolapse <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Respiratory, thoracic and mediastinal disorders				
Acute lung injury <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Acute pulmonary oedema <sup>A</sup> †	1/8212 (0.01%)	1	4/8280 (0.05%)	4
Acute respiratory distress syndrome <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Acute respiratory failure <sup>A</sup> †	3/8212 (0.04%)	3	12/8280 (0.14%)	12
Apnoea <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Aspiration <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Asthma <sup>A</sup> †	6/8212 (0.07%)	7	15/8280 (0.18%)	20
Atelectasis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Bronchitis chronic <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Bullous lung disease <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Chronic obstructive pulmonary disease <sup>A</sup> †	53/8212 (0.65%)	79	71/8280 (0.86%)	88

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Cough <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Dyspnoea <sup>A</sup> †	24/8212 (0.29%)	24	18/8280 (0.22%)	19
Dyspnoea exertional <sup>A</sup> †	4/8212 (0.05%)	4	2/8280 (0.02%)	2
Emphysema <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Epistaxis <sup>A</sup> †	3/8212 (0.04%)	3	8/8280 (0.1%)	9
Haemoptysis <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Haemothorax <sup>A</sup> †	3/8212 (0.04%)	3	0/8280 (0%)	0
Hydrothorax <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Hypercapnia <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hypoxia <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Interstitial lung disease <sup>A</sup> †	4/8212 (0.05%)	5	0/8280 (0%)	0
Laryngeal stenosis <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Lung consolidation <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Lung disorder <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Lung infiltration <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Nasal congestion <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Nasal obstruction <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Nasal polyps <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Nasal septum deviation <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Nocturnal dyspnoea <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Obstructive airways disorder <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	3
Pharyngeal hypertrophy <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1

	Placebo		Saxaglipatin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Pharyngeal inflammation <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Pleural effusion <sup>A</sup> †	8/8212 (0.1%)	9	5/8280 (0.06%)	5
Pleuritic pain <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Pneumonia aspiration <sup>A</sup> †	1/8212 (0.01%)	1	10/8280 (0.12%)	10
Pneumonitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Pneumothorax <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Pulmonary congestion <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Pulmonary embolism <sup>A</sup> †	10/8212 (0.12%)	10	11/8280 (0.13%)	11
Pulmonary fibrosis <sup>A</sup> †	2/8212 (0.02%)	2	3/8280 (0.04%)	5
Pulmonary haemorrhage <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Pulmonary hypertension <sup>A</sup> †	5/8212 (0.06%)	5	4/8280 (0.05%)	4
Pulmonary oedema <sup>A</sup> †	7/8212 (0.09%)	8	8/8280 (0.1%)	8
Pulmonary sarcoidosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Pulmonary toxicity <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Reflux laryngitis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Respiratory arrest <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Respiratory disorder <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Respiratory distress <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Respiratory failure <sup>A</sup> †	11/8212 (0.13%)	13	9/8280 (0.11%)	10
Sleep apnoea syndrome <sup>A</sup> †	6/8212 (0.07%)	6	2/8280 (0.02%)	2
Snoring <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Status asthmaticus <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0



	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Vocal cord polyp <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Skin and subcutaneous tissue disorders				
Actinic keratosis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Angioedema <sup>A</sup> †	1/8212 (0.01%)	1	5/8280 (0.06%)	5
Decubitus ulcer <sup>A</sup> †	0/8212 (0%)	0	4/8280 (0.05%)	4
Dermatitis contact <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Diabetic foot <sup>A</sup> †	23/8212 (0.28%)	25	22/8280 (0.27%)	24
Diabetic ulcer <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Drug eruption <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Dry gangrene <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Dyshidrosis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Ecchymosis <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Erythema <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hyperhidrosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Keloid scar <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Leukocytoclastic vasculitis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Neurodermatitis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Neuropathic ulcer <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Night sweats <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Panniculitis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Pemphigoid <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Pruritus <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Psoriasis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Purpura <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Rash <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Scar pain <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Skin fibrosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Skin necrosis <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Skin reaction <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Skin ulcer <sup>A</sup> †	22/8212 (0.27%)	24	21/8280 (0.25%)	22
Stasis dermatitis <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Stevens-Johnson syndrome <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Subcutaneous emphysema <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Toxic epidermal necrolysis <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Urticaria <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Surgical and medical procedures				
Coronary revascularisation <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Percutaneous coronary intervention <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Vascular disorders				
Accelerated hypertension <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Aortic aneurysm <sup>A</sup> †	8/8212 (0.1%)	8	4/8280 (0.05%)	4
Aortic calcification <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Aortic occlusion <sup>A</sup> †	0/8212 (0%)	0	2/8280 (0.02%)	2
Aortic stenosis <sup>A</sup> †	7/8212 (0.09%)	7	4/8280 (0.05%)	4

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Arterial insufficiency <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Arterial occlusive disease <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Arteriosclerosis <sup>A</sup> †	5/8212 (0.06%)	5	2/8280 (0.02%)	2
Arteriovenous fistula <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Blood pressure inadequately controlled <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Circulatory collapse <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Deep vein thrombosis <sup>A</sup> †	9/8212 (0.11%)	9	8/8280 (0.1%)	8
Diabetic macroangiopathy <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Embolism venous <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Extremity necrosis <sup>A</sup> †	3/8212 (0.04%)	3	6/8280 (0.07%)	6
Femoral artery embolism <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Femoral artery occlusion <sup>A</sup> †	7/8212 (0.09%)	8	2/8280 (0.02%)	2
Granulomatosis with polyangiitis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Haematoma <sup>A</sup> †	3/8212 (0.04%)	3	5/8280 (0.06%)	5
Haemorrhage <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	3
Haemorrhagic infarction <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Hypertension <sup>A</sup> †	30/8212 (0.37%)	33	29/8280 (0.35%)	32
Hypertensive crisis <sup>A</sup> †	16/8212 (0.19%)	17	17/8280 (0.21%)	18
Hypertensive emergency <sup>A</sup> †	3/8212 (0.04%)	3	2/8280 (0.02%)	2
Hypoperfusion <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Hypotension <sup>A</sup> †	17/8212 (0.21%)	18	19/8280 (0.23%)	22
Hypovolaemic shock <sup>A</sup> †	0/8212 (0%)	0	3/8280 (0.04%)	3

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Iliac artery occlusion <sup>A</sup> †	2/8212 (0.02%)	2	1/8280 (0.01%)	1
Intermittent claudication <sup>A</sup> †	10/8212 (0.12%)	11	10/8280 (0.12%)	11
Necrosis ischaemic <sup>A</sup> †	1/8212 (0.01%)	2	0/8280 (0%)	0
Orthostatic hypotension <sup>A</sup> †	5/8212 (0.06%)	6	6/8280 (0.07%)	6
Peripheral arterial occlusive disease <sup>A</sup> †	43/8212 (0.52%)	49	24/8280 (0.29%)	25
Peripheral artery aneurysm <sup>A</sup> †	3/8212 (0.04%)	3	1/8280 (0.01%)	1
Peripheral artery dissection <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Peripheral artery stenosis <sup>A</sup> †	8/8212 (0.1%)	9	18/8280 (0.22%)	20
Peripheral artery thrombosis <sup>A</sup> †	2/8212 (0.02%)	2	2/8280 (0.02%)	2
Peripheral embolism <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Peripheral ischaemia <sup>A</sup> †	39/8212 (0.47%)	46	24/8280 (0.29%)	35
Peripheral vascular disorder <sup>A</sup> †	20/8212 (0.24%)	22	21/8280 (0.25%)	24
Shock <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Shock haemorrhagic <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Subclavian artery occlusion <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Subclavian artery stenosis <sup>A</sup> †	2/8212 (0.02%)	2	0/8280 (0%)	0
Thrombophlebitis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Thrombosis <sup>A</sup> †	1/8212 (0.01%)	1	3/8280 (0.04%)	3
Varicose vein <sup>A</sup> †	1/8212 (0.01%)	1	2/8280 (0.02%)	2
Vascular occlusion <sup>A</sup> †	1/8212 (0.01%)	1	0/8280 (0%)	0
Vascular stenosis <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Vasculitis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Venous insufficiency <sup>A</sup> †	1/8212 (0.01%)	1	1/8280 (0.01%)	1
Venous thrombosis <sup>A</sup> †	0/8212 (0%)	0	1/8280 (0.01%)	1
Venous thrombosis limb <sup>A</sup> †	1/8212 (0.01%)	2	0/8280 (0%)	0

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 15.1

#### Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 2%

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	3641/8212 (44.34%)		3504/8280 (42.32%)	
Blood and lymphatic system disorders				
Anaemia <sup>A</sup> †	198/8212 (2.41%)	208	197/8280 (2.38%)	204
Cardiac disorders				
Angina pectoris <sup>A</sup> †	197/8212 (2.4%)	217	171/8280 (2.07%)	188
Gastrointestinal disorders				
Constipation <sup>A</sup> †	164/8212 (2%)	175	170/8280 (2.05%)	183
Diarrhoea <sup>A</sup> †	314/8212 (3.82%)	369	321/8280 (3.88%)	379
Nausea <sup>A</sup> †	182/8212 (2.22%)	215	200/8280 (2.42%)	218
General disorders				
Fatigue <sup>A</sup> †	192/8212 (2.34%)	215	167/8280 (2.02%)	179
Oedema peripheral <sup>A</sup> †	352/8212 (4.29%)	375	343/8280 (4.14%)	380
Infections and infestations				
Bronchitis <sup>A</sup> †	375/8212 (4.57%)	453	331/8280 (4%)	414
Influenza <sup>A</sup> †	195/8212 (2.37%)	232	199/8280 (2.4%)	230

	Placebo		Saxagliptin	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Nasopharyngitis <sup>A</sup> †	280/8212 (3.41%)	334	293/8280 (3.54%)	341
Upper respiratory tract infection <sup>A</sup> †	324/8212 (3.95%)	398	330/8280 (3.99%)	408
Urinary tract infection <sup>A</sup> †	323/8212 (3.93%)	431	307/8280 (3.71%)	389
Metabolism and nutrition disorders				
Diabetes mellitus <sup>A</sup> †	666/8212 (8.11%)	834	538/8280 (6.5%)	666
Hyperglycaemia <sup>A</sup> †	278/8212 (3.39%)	327	215/8280 (2.6%)	271
Musculoskeletal and connective tissue disorders				
Arthralgia <sup>A</sup> †	306/8212 (3.73%)	332	313/8280 (3.78%)	354
Back pain <sup>A</sup> †	319/8212 (3.88%)	350	330/8280 (3.99%)	358
Musculoskeletal pain <sup>A</sup> †	165/8212 (2.01%)	179	168/8280 (2.03%)	185
Pain in extremity <sup>A</sup> †	321/8212 (3.91%)	342	264/8280 (3.19%)	298
Nervous system disorders				
Dizziness <sup>A</sup> †	344/8212 (4.19%)	393	374/8280 (4.52%)	485
Headache <sup>A</sup> †	241/8212 (2.93%)	255	208/8280 (2.51%)	240
Respiratory, thoracic and mediastinal disorders				
Cough <sup>A</sup> †	302/8212 (3.68%)	337	258/8280 (3.12%)	282
Dyspnoea <sup>A</sup> †	199/8212 (2.42%)	217	182/8280 (2.2%)	196
Vascular disorders				
Hypertension <sup>A</sup> †	321/8212 (3.91%)	352	349/8280 (4.21%)	379

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 15.1

## 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.

AstraZeneca's Publication Policy, data disclosure and transparency are available at the website: <http://www.astrazeneca.com/responsibility/code-and-policies/policies?itemId=4861823&nav=yes>. All papers or abstracts must be submitted to the Steering Committee and the SPONSOR, through BRIGHAM, for review of its appropriateness and scientific merit at least six weeks prior to submission to any publication.

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