

**Clinical trial results:**

A 24 month, multicenter, randomized, open-label safety and efficacy study of concentration-controlled everolimus with reduced calcineurin inhibitor vs mycophenolate with standard calcineurin inhibitor in de novo renal transplantation Advancing renal TRANSplant eFFicacy and safety Outcomes with an eveRolimus-based regiMen (TRANSFORM)

Summary

EudraCT number	2013-000322-66
Trial protocol	DE IT SK ES PT AT NL BE GR CZ SI BG PL HR NO SE FR
Global end of trial date	17 January 2018

Results information

Result version number	v1 (current)
This version publication date	19 October 2018
First version publication date	19 October 2018

Trial information**Trial identification**

Sponsor protocol code	CRAD001A2433
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01950819
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Novartis Pharma AG, Clinical Disclosure Office, 41 613241111, Novartis.email@novartis.com
Scientific contact	Study Director, Novartis Pharma, 41 613241111, Novartis.email@novartis.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 January 2018
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	17 January 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective for this trial was to evaluate the effect of everolimus with reduced exposure CNI versus MPA with standard exposure CNI on the binary composite of treated biopsy-proven acute rejection (tBPAR) or eGFR <50 mL/min/1.73m² (estimated glomerular filtration rate by MDRD4 formula) at Month 12 post-transplantation.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 December 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 77
Country: Number of subjects enrolled	Australia: 98
Country: Number of subjects enrolled	Austria: 34
Country: Number of subjects enrolled	Belgium: 56
Country: Number of subjects enrolled	Brazil: 86
Country: Number of subjects enrolled	Bulgaria: 12
Country: Number of subjects enrolled	Chile: 8
Country: Number of subjects enrolled	Colombia: 22
Country: Number of subjects enrolled	Croatia: 35
Country: Number of subjects enrolled	Czech Republic: 30
Country: Number of subjects enrolled	Egypt: 25
Country: Number of subjects enrolled	France: 85
Country: Number of subjects enrolled	Germany: 168
Country: Number of subjects enrolled	Greece: 24
Country: Number of subjects enrolled	India: 38
Country: Number of subjects enrolled	Israel: 20
Country: Number of subjects enrolled	Italy: 94
Country: Number of subjects enrolled	Japan: 34

Country: Number of subjects enrolled	Korea, Republic of: 53
Country: Number of subjects enrolled	Kuwait: 6
Country: Number of subjects enrolled	Lebanon: 17
Country: Number of subjects enrolled	Malaysia: 5
Country: Number of subjects enrolled	Mexico: 2
Country: Number of subjects enrolled	Netherlands: 143
Country: Number of subjects enrolled	Norway: 15
Country: Number of subjects enrolled	Philippines: 29
Country: Number of subjects enrolled	Poland: 25
Country: Number of subjects enrolled	Portugal: 19
Country: Number of subjects enrolled	Russian Federation: 47
Country: Number of subjects enrolled	Saudi Arabia: 21
Country: Number of subjects enrolled	Serbia: 14
Country: Number of subjects enrolled	Singapore: 5
Country: Number of subjects enrolled	Slovakia: 35
Country: Number of subjects enrolled	Slovenia: 9
Country: Number of subjects enrolled	South Africa: 1
Country: Number of subjects enrolled	Spain: 159
Country: Number of subjects enrolled	Sweden: 38
Country: Number of subjects enrolled	Switzerland: 22
Country: Number of subjects enrolled	Taiwan: 23
Country: Number of subjects enrolled	Thailand: 27
Country: Number of subjects enrolled	Turkey: 24
Country: Number of subjects enrolled	United States: 352
Worldwide total number of subjects	2037
EEA total number of subjects	981

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1731
From 65 to 84 years	306
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The full analysis set consisted of all randomized and transplanted patients. The safety set consisted of all patients who received at least one dose of study drug

Pre-assignment

Screening details:

2226 patients screened; 2037 patients transplanted and randomized to treatment.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	EVR+rCNI

Arm description:

Everolimus with reduced calcineurin inhibitor- everolimus (target trough level of 3-8 ng/mL) in combination with reduced exposure to CNI (cyclosporine or tacrolimus)

Arm type	Experimental
Investigational medicinal product name	Everolimus
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Everolimus was provided as 0.25, 0.5 and 0.75 and 1.0 mg tablets depending on locally approved dosage forms.

Arm title	MPA+sCNI
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Arm description:

Mycophenolate (mycophenolic acid sodium or mycophenolate mofetil) in combination with standard exposure to calcineurin inhibitor (cyclosporine or tacrolimus).

Arm type	Active comparator
Investigational medicinal product name	mycophenolate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

MPA as either mycophenolic acid (sodium) 180 or 360mg enteric-coated tablets or mycophenolate mofetil 250 or 500 mg film coated tablets or 250mg capsules, depending on locally approved dosage forms.

Number of subjects in period 1	EVR+rCNI	MPA+sCNI
Started	1022	1015
Completed	893	881
Not completed	129	134
Adverse event, serious fatal	29	34
technical problems	2	-
Graft Loss	35	30
Pregnancy	-	2
Subject / Gardian decision	54	51
Lost to follow-up	9	17

Baseline characteristics

Reporting groups

Reporting group title	EVR+rCNI
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Reporting group description:

Everolimus with reduced calcineurin inhibitor- everolimus (target trough level of 3-8 ng/mL) in combination with reduced exposure to CNI (cyclosporine or tacrolimus)

Reporting group title	MPA+sCNI
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Reporting group description:

Mycophenolate (mycophenolic acid sodium or mycophenolate mofetil) in combination with standard exposure to calcineurin inhibitor (cyclosporine or tacrolimus).

Reporting group values	EVR+rCNI	MPA+sCNI	Total
Number of subjects	1022	1015	2037
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	873	858	1731
From 65-84 years	149	157	306
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	48.79	48.75	-
standard deviation	± 14.123	± 14.515	-
Sex: Female, Male			
Units: Subjects			
Female	312	308	620
Male	710	707	1417
Race/Ethnicity, Customized			
Ethnicity			
Units: Subjects			
Hispany or Latino	157	132	289
not Hispanic or Latino	646	661	1307
Unknown or not reported	102	105	207
Other	117	117	234
Race/Ethnicity, Customized			
Race			
Units: Subjects			
Caucasian	743	735	1478
Asian	136	157	293
Black	43	35	78
Other	100	88	188

End points

End points reporting groups

Reporting group title	EVR+rCNI
Reporting group description:	Everolimus with reduced calcineurin inhibitor- everolimus (target trough level of 3-8 ng/mL) in combination with reduced exposure to CNI (cyclosporine or tacrolimus)
Reporting group title	MPA+sCNI
Reporting group description:	Mycophenolate (mycophenolic acid sodium or mycophenolate mofetil) in combination with standard exposure to calcineurin inhibitor (cyclosporine or tacrolimus).

Primary: Incidence of failure on the composite of treated biopsy-proven acute rejection (tBPAR) or estimated glomerular filtration rate (eGFR) < 50 mL/min/1.73m².

End point title	Incidence of failure on the composite of treated biopsy-proven acute rejection (tBPAR) or estimated glomerular filtration rate (eGFR) < 50 mL/min/1.73m ² .
End point description:	Incidence of failure on the composite of treated biopsy-proven acute rejection (tBPAR) or estimated glomerular filtration rate (eGFR) < 50 mL/min/1.73m ² .
End point type	Primary
End point timeframe:	Month 12 is Primary, Month 24 secondary

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: participants				
month 12	489	456		
month 24	489	443		

Statistical analyses

Statistical analysis title	Difference between treatments
Statistical analysis description:	calculated at month 12
Comparison groups	EVR+rCNI v MPA+sCNI
Number of subjects included in analysis	2037
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.001
Method	Logistic Regression Model
Parameter estimate	Odds ratio (OR)
Point estimate	3

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	7.3

Secondary: Incidence of failure on the composite of (treated biopsy proven acute rejection (tBPAR), graft loss or death

End point title	Incidence of failure on the composite of (treated biopsy proven acute rejection (tBPAR), graft loss or death
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End point description:

Incidence of failure on the composite of (treated biopsy proven acute rejection (tBPAR), graft loss or death

End point type	Secondary
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End point timeframe:

Month 12 and 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: participants				
month 12	146	131		
month 24	169	147		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of failure on the composite endpoint of tBPAR, graft loss, death or eGFR < 50 mL/min/1.73m²

End point title	Incidence of failure on the composite endpoint of tBPAR, graft loss, death or eGFR < 50 mL/min/1.73m ²
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End point description:

Incidence of failure on the composite endpoint of tBPAR, graft loss, death or eGFR < 50 mL/min/1.73m²

End point type	Secondary
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End point timeframe:

Month 12 and 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: participants				
month 12	497	466		
month 24	497	457		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of failure on the composite endpoint of graft loss or death.

End point title	Incidence of failure on the composite endpoint of graft loss or death.
End point description:	Incidence of failure on the composite endpoint of graft loss or death.
End point type	Secondary
End point timeframe:	Month 12 and 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: participants				
month 12	51	54		
month 24	67	65		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of death, graft loss, tBPAR, BPAR, tAR, AR and humoral rejection

End point title	Incidence of death, graft loss, tBPAR, BPAR, tAR, AR and humoral rejection
End point description:	Incidence of death, graft loss, tBPAR (treated biopsy proven acute rejection), BPAR (biopsy proven acute rejection), tAR (treated acute rejection), AR (acute rejection) and humoral rejection (aAMR : active antibody mediated rejection and cAMR: chronic antibody mediated rejection)
End point type	Secondary
End point timeframe:	Month 12 and 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: participants				
deaths month 12	20	28		
deaths month 24	32	36		
graft loss month 12	33	28		
graft loss month 24	37	32		
tBPAR month 12	107	91		
tBPAR month 24	118	98		
BPAR month 12	114	95		
BPAR month 24	127	104		
tAR month 12	129	117		
tAR month 24	145	126		
AR month 12	147	133		
AR month 24	167	144		
aAMR month 12	73	61		
aAMR month 24	84	69		
cAMR month 12	9	14		
cAMR month 24	13	18		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of eGFR < 50 mL/min/1.73m²

End point title	Incidence of eGFR < 50 mL/min/1.73m ²
End point description:	Incidence of eGFR < 50 mL/min/1.73m ²
End point type	Secondary
End point timeframe:	Month 12 and 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: participants				
month 12	456	424		
month 24	474	423		

Statistical analyses

No statistical analyses for this end point

Secondary: Renal allograft function (mean estimated glomerular filtration rate, eGFR)

End point title	Renal allograft function (mean estimated glomerular filtration rate, eGFR)
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End point description:

Renal allograft function (mean estimated glomerular filtration rate, eGFR)

End point type	Secondary
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End point timeframe:

Month 12 and 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: mL/min/1.73m ²				
arithmetic mean (standard error)				
baseline (week 4)	53.13 (± 0.765)	52.25 (± 0.684)		
month 12	53.29 (± 0.698)	54.49 (± 0.667)		
month 24	52.63 (± 0.744)	54.91 (± 0.719)		

Statistical analyses

No statistical analyses for this end point

Secondary: Evolution of renal function, as eGFR, over time by slope analysis.

End point title	Evolution of renal function, as eGFR, over time by slope analysis.
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End point description:

Rate of change of renal function, as eGFR, over time by slope analysis.

End point type	Secondary
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End point timeframe:

Month 12 and 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: mL/min/1.73m ²				
arithmetic mean (standard error)				
slope of eGFR	0.0001 (± 0.0008)	0.0047 (± 0.0008)		
eGFR at month 12	55.32 (± 0.68)	57.44 (± 0.67)		
eGFR at month 24	55.43 (± 0.60)	57.28 (± 0.60)		

Statistical analyses

No statistical analyses for this end point

Secondary: Renal function by Cystatin C-based and other alternate formulae (e.g. CKD-EPI).

End point title	Renal function by Cystatin C-based and other alternate formulae (e.g. CKD-EPI).
End point description:	Mean Renal function by eGFR or ceatinine clearance Cystatin C-based and other alternate formulae (e.g. CKD-EPI). Analysis is done without considering missing values for analysis.
End point type	Secondary
End point timeframe:	Month 12 and 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: micromol/L; mL/min/1.73m ²				
arithmetic mean (standard deviation)				
screening baseline (creatinine, micromol/L)	590.1 (± 262.78)	601.8 (± 265.08)		
month 12 (creatinine, micromol/L)	129.8 (± 49.12)	128.6 (± 50.80)		
month 24 (creatinine, micromol/L)	130.1 (± 53.54)	127.6 (± 52.50)		
eGFR (Hoek) baseline (mL/min/1.73m ²)	21.38 (± 14.296)	20.10 (± 12.408)		
eGFR (Hoek) month 12 (mL/min/1.73m ²)	50.08 (± 14.430)	52.00 (± 14.533)		
eGFR (Hoek) month 24 (mL/min/1.73m ²)	49.86 (± 14.604)	52.75 (± 15.406)		
eGFR (MDRD4) baseline (mL/min/1.73m ²)	11.79 (± 8.697)	11.56 (± 8.853)		
eGFR (MDRD4) month 12 (mL/min/1.73m ²)	57.59 (± 19.685)	57.58 (± 18.768)		

eGFR (MDRD4) month 24 (mL/min/1.73m ²)	58.07 (± 20.168)	58.68 (± 19.541)		
eGFR-CKDEPI baseline (mL/min/1.73m ²)	11.29 (± 9.094)	11.05 (± 9.195)		
eGFR-CKDEPI month 12(mL/min/1.73m ²)	58.83 (± 20.686)	58.75 (± 19.757)		
eGFR-CKDEPI month 24 (mL/min/1.73m ²)	59.39 (± 21.077)	59.95 (± 20.652)		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of adverse events, serious adverse events and adverse events leading to study regimen discontinuation.

End point title	Incidence of adverse events, serious adverse events and adverse events leading to study regimen discontinuation.
End point description:	Incidence of adverse events, serious adverse events and adverse events leading to study regimen discontinuation.
End point type	Secondary
End point timeframe:	Month 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1014	1012		
Units: participants	276	152		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of cytomegalovirus and BK virus, new onset diabetes mellitus, chronic kidney disease with associated proteinuria and calcineurin inhibitor associated adverse events.

End point title	Incidence of cytomegalovirus and BK virus, new onset diabetes mellitus, chronic kidney disease with associated proteinuria and calcineurin inhibitor associated adverse events.
End point description:	Incidence of cytomegalovirus and BK virus, new onset diabetes mellitus, chronic kidney disease with associated proteinuria and calcineurin inhibitor associated adverse events.
End point type	Secondary
End point timeframe:	Month 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1014	1012		
Units: participants				
clinical signs of CMV infection	53	132		
any BKV infection	103	154		
new onset of diabetes mellitus	144	138		
at least one event of interest	871	764		

Statistical analyses

No statistical analyses for this end point

Secondary: Urinary protein and albumin excretion by treatment estimated by urinary protein/creatinine and urinary albumin/creatinine ratios.

End point title	Urinary protein and albumin excretion by treatment estimated by urinary protein/creatinine and urinary albumin/creatinine ratios.
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End point description:

Mean urinary protein and albumin excretion by treatment estimated by mean urinary protein/creatinine and urinary albumin/creatinine ratios.

End point type	Secondary
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End point timeframe:

Month 12 and 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1014	1012		
Units: mg/g				
arithmetic mean (standard deviation)				
albumine /creatinine ratio baseline	1019.75 (± 2737.96)	646.111 (± 799.234)		
albumine /creatinine ratio month 12	150.061 (± 482.394)	111.322 (± 444.631)		
albumine /creatinine ratio month 24	149.049 (± 464.470)	116.618 (± 433.392)		
protein /creatinine ratio baseline	1648.10 (± 3768.22)	1142.59 (± 1003.69)		
protein /creatinine ratio month 12	298.557 (± 642.103)	234.698 (± 583.632)		
protein /creatinine ratio month 24	290.242 (± 588.119)	233.009 (± 524.383)		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of major cardiovascular events.

End point title	Incidence of major cardiovascular events.
End point description:	Incidence of major cardiovascular events by Preferred Term
End point type	Secondary
End point timeframe:	Month 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1014	1012		
Units: participants	66	86		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of malignancies.

End point title	Incidence of malignancies.
End point description:	Incidence of malignancies.
End point type	Secondary
End point timeframe:	Month 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1014	1012		
Units: participants	41	39		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of failure on the composite of treated biopsy-proven acute rejection (tBPAR) or estimated glomerular filtration rate (eGFR) < 50 mL/min/1.73m² among compliant subjects.

End point title	Incidence of failure on the composite of treated biopsy-proven acute rejection (tBPAR) or estimated glomerular filtration rate (eGFR) < 50 mL/min/1.73m ² among compliant subjects.
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End point description:

Incidence of failure on the composite of treated biopsy-proven acute rejection (tBPAR) or estimated glomerular filtration rate (eGFR) < 50 mL/min/1.73m² among compliant subjects.

End point type	Secondary
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End point timeframe:

Month 12 and 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	187	277		
Units: participants				
month 12	60	106		
month 24	62	102		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence tBPAR by severity and time to event

End point title	Incidence tBPAR by severity and time to event
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End point description:

Incidence tBPAR by severity and time to event

End point type	Secondary
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End point timeframe:

Month 12 and 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: participants				
no grade (missing)	25	18		
Patient's maximum tBPAR grade IA	34	36		
Patient's maximum tBPAR grade IB	23	17		
Patient's maximum tBPAR grade IIA	21	24		

Patient's maximum tBPAR grade IIB	9	3		
Patient's maximum tBPAR grade III	6	0		
overall number of tBPAR regardless of grade	146	116		
number of tBPAR regardless of grade days 1-90	72	63		
number of tBPAR regardless of grade days 91-180	24	14		
number of tBPAR regardless of grade days 181-360	25	20		
number of tBPAR regardless of grade days 361-540	12	15		
number of tBPAR regardless of grade days 541-720	11	2		
number of tBPAR regardless of grade days 721-810	2	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of tBPAR excluding grade IA rejections

End point title	Incidence of tBPAR excluding grade IA rejections
End point description:	Incidence of tBPAR excluding grade IA rejections
End point type	Secondary
End point timeframe:	Month 12 and 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: participants				
month 12	66	53		
month 24	74	55		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of composite of tBPAR or eGFR<50 mL/min/1.73m2 by subgroup

End point title	Incidence of composite of tBPAR or eGFR<50 mL/min/1.73m2 by subgroup
End point description:	Incidence of composite of tBPAR or eGFR<50 mL/min/1.73m2 by subgroup

End point type	Secondary
End point timeframe:	
Month 12 and 24	

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: participants				
month 12	489	456		
month 24	489	443		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of tBPAR (excluding grade IA rejections) or GFR<50 mL/min/1.73m2

End point title	Incidence of tBPAR (excluding grade IA rejections) or GFR<50 mL/min/1.73m2
End point description:	Incidence of tBPAR (excluding grade IA rejections) or GFR<50 mL/min/1.73m2
End point type	Secondary
End point timeframe:	
Month 12 and 24	

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: participants				
month 12	475	441		
month 24	475	426		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of failure on the composite of (treated biopsy proven acute rejection (tBPAR), graft loss or death or loss to follow-up

End point title	Incidence of failure on the composite of (treated biopsy proven acute rejection (tBPAR), graft loss or death or loss to follow-up
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End point description:

Incidence of failure on the composite of (treated biopsy proven acute rejection (tBPAR), graft loss or death or loss to follow-up

End point type	Secondary
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End point timeframe:

Month 12 and 24

End point values	EVR+rCNI	MPA+sCNI		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1022	1015		
Units: participants				
month 12	181	170		
month 24	218	201		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Timeframe for AE

Adverse event reporting additional description:

AE additional description

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.1
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Reporting groups

Reporting group title	MPA plus standard@CNI
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Reporting group description:

MPA plus standard@CNI

Reporting group title	Everolimus plus@reduced CNI
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Reporting group description:

Everolimus plus@reduced CNI

Serious adverse events	MPA plus standard@CNI	Everolimus plus@reduced CNI	
Total subjects affected by serious adverse events			
subjects affected / exposed	613 / 1012 (60.57%)	593 / 1014 (58.48%)	
number of deaths (all causes)	29	20	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	4 / 1012 (0.40%)	10 / 1014 (0.99%)	
occurrences causally related to treatment / all	4 / 5	8 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign gastrointestinal neoplasm			

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of thyroid gland		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign pancreatic neoplasm		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bowen's disease		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Breast cancer		
subjects affected / exposed	3 / 1012 (0.30%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchioloalveolar carcinoma		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cerebral haemangioma		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epstein-Barr virus associated lymphoma		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastric cancer		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Leydig cell tumour of the testis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoproliferative disorder		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		

subjects affected / exposed	1 / 1012 (0.10%)	4 / 1014 (0.39%)	
occurrences causally related to treatment / all	1 / 1	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of pleura metastatic			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to bone			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to lymph nodes			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to peritoneum			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to spine			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoclonal gammopathy			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary tumour of renal pelvis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Plasmacytoma		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polycythaemia vera		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post transplant lymphoproliferative disorder		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Prostate cancer		
subjects affected / exposed	0 / 1012 (0.00%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		

subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Renal cell carcinoma		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland cancer		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		
subjects affected / exposed	4 / 1012 (0.40%)	8 / 1014 (0.79%)
occurrences causally related to treatment / all	5 / 5	5 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of skin		
subjects affected / exposed	5 / 1012 (0.49%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	4 / 5	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Testicular neoplasm		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tumour of ampulla of Vater		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine leiomyoma		

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic perforation			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial stenosis			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial thrombosis			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula			
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Artery dissection			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			

subjects affected / exposed	12 / 1012 (1.19%)	20 / 1014 (1.97%)
occurrences causally related to treatment / all	2 / 14	9 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism venous		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		
subjects affected / exposed	3 / 1012 (0.30%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	6 / 1012 (0.59%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	5 / 1012 (0.49%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	8 / 1012 (0.79%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	1 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphocele		

subjects affected / exposed	21 / 1012 (2.08%)	34 / 1014 (3.35%)
occurrences causally related to treatment / all	4 / 22	18 / 36
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphorrhoea		
subjects affected / exposed	0 / 1012 (0.00%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant hypertension		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic venous thrombosis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		

subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shock haemorrhagic		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis superficial		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis		
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose ulceration		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Venous stenosis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Venous thrombosis		
subjects affected / exposed	3 / 1012 (0.30%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Venous thrombosis limb		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Arteriovenous fistula operation			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchidectomy			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Cephalhaematoma			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site haemorrhage			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			

subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chills		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Death		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Fatigue		
subjects affected / exposed	2 / 1012 (0.20%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gait inability		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
General physical health deterioration		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised oedema		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperthermia		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypothermia		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ill-defined disorder		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired healing		
subjects affected / exposed	1 / 1012 (0.10%)	10 / 1014 (0.99%)
occurrences causally related to treatment / all	1 / 1	10 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site discomfort		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site inflammation		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microlithiasis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-cardiac chest pain		

subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		
subjects affected / exposed	4 / 1012 (0.40%)	7 / 1014 (0.69%)
occurrences causally related to treatment / all	0 / 4	5 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Pain		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral swelling		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	36 / 1012 (3.56%)	35 / 1014 (3.45%)
occurrences causally related to treatment / all	13 / 40	16 / 45
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden death		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Suprapubic pain		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Swelling		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic inflammatory response syndrome		

subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic allograft nephropathy			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immunosuppression			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney transplant rejection			
subjects affected / exposed	17 / 1012 (1.68%)	18 / 1014 (1.78%)	
occurrences causally related to treatment / all	9 / 19	8 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal transplant failure			
subjects affected / exposed	5 / 1012 (0.49%)	4 / 1014 (0.39%)	
occurrences causally related to treatment / all	0 / 5	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transplant rejection			
subjects affected / exposed	25 / 1012 (2.47%)	45 / 1014 (4.44%)	
occurrences causally related to treatment / all	7 / 27	16 / 49	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			

Loss of personal independence in daily activities			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Walking disability			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired hydrocele			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	3 / 1012 (0.30%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometriosis			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erectile dysfunction			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Menorrhagia			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Ovarian cyst ruptured			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	4 / 1012 (0.40%)	3 / 1014 (0.30%)	
occurrences causally related to treatment / all	3 / 4	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal oedema			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular oedema			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	2 / 1012 (0.20%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	1 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	4 / 1012 (0.40%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	1 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthmatic crisis			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Bronchospasm			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	7 / 1012 (0.69%)	8 / 1014 (0.79%)	
occurrences causally related to treatment / all	1 / 8	3 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	2 / 1012 (0.20%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperventilation			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung disorder		
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infiltration		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuritic pain		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonitis		
subjects affected / exposed	0 / 1012 (0.00%)	4 / 1014 (0.39%)
occurrences causally related to treatment / all	0 / 0	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Productive cough		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary artery thrombosis			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	6 / 1012 (0.59%)	17 / 1014 (1.68%)	
occurrences causally related to treatment / all	1 / 6	6 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary hypertension			
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	2 / 1012 (0.20%)	3 / 1014 (0.30%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	4 / 1012 (0.40%)	3 / 1014 (0.30%)	
occurrences causally related to treatment / all	0 / 4	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute psychosis			

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aggression			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination, visual			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental disorder			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic stress disorder			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device leakage			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dilatation			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	3 / 1012 (0.30%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular injury			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perforation bile duct			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level above therapeutic			

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aspartate aminotransferase increased		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Biopsy kidney		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood creatine increased		
subjects affected / exposed	3 / 1012 (0.30%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Blood creatinine abnormal		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood creatinine increased		
subjects affected / exposed	36 / 1012 (3.56%)	50 / 1014 (4.93%)
occurrences causally related to treatment / all	6 / 44	18 / 63
deaths causally related to treatment / all	0 / 0	0 / 0
Blood glucose increased		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood phosphorus decreased		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood urea increased		

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
C-reactive protein increased			
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheterisation cardiac			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction abnormal			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram T wave inversion			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haptoglobin decreased			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immunosuppressant drug level increased			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory marker increased			

subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver function test increased		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Norovirus test positive		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Occult blood positive		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyomavirus test positive		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transaminases increased		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Troponin increased		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urine output decreased		
subjects affected / exposed	0 / 1012 (0.00%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Weight decreased		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaesthetic complication			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic haemorrhage			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aponeurosis contusion			
subjects affected / exposed	3 / 1012 (0.30%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial injury			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula aneurysm			

subjects affected / exposed	3 / 1012 (0.30%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula site complication		
subjects affected / exposed	4 / 1012 (0.40%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula thrombosis		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Avulsion fracture		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Complications of transplant surgery		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Complications of transplanted kidney		
subjects affected / exposed	28 / 1012 (2.77%)	34 / 1014 (3.35%)
occurrences causally related to treatment / all	3 / 32	9 / 41
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary bypass stenosis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Delayed graft function		

subjects affected / exposed	2 / 1012 (0.20%)	7 / 1014 (0.69%)
occurrences causally related to treatment / all	0 / 2	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Graft complication		
subjects affected / exposed	3 / 1012 (0.30%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Graft haemorrhage		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Graft loss		
subjects affected / exposed	12 / 1012 (1.19%)	16 / 1014 (1.58%)
occurrences causally related to treatment / all	2 / 12	3 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Graft thrombosis		

subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site complication		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	1 / 1012 (0.10%)	8 / 1014 (0.79%)
occurrences causally related to treatment / all	0 / 1	2 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Injury		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laceration		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle strain			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal injury			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	3 / 1012 (0.30%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial reocclusion			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perirenal haematoma			
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			

subjects affected / exposed	1 / 1012 (0.10%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural discharge		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		
subjects affected / exposed	1 / 1012 (0.10%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematuria		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	4 / 1012 (0.40%)	4 / 1014 (0.39%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural persistent drain fluid		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural urine leak		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative fever		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative hernia		

subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal lymphocele			
subjects affected / exposed	1 / 1012 (0.10%)	3 / 1014 (0.30%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal transplant torsion			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scar			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal haematoma			
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seroma			

subjects affected / exposed	2 / 1012 (0.20%)	5 / 1014 (0.49%)
occurrences causally related to treatment / all	0 / 2	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Shunt aneurysm		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Shunt stenosis		
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress fracture		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Subcutaneous haematoma		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	3 / 1012 (0.30%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		

subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	4 / 1012 (0.40%)	5 / 1014 (0.49%)
occurrences causally related to treatment / all	3 / 4	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Transplant dysfunction		
subjects affected / exposed	7 / 1012 (0.69%)	7 / 1014 (0.69%)
occurrences causally related to treatment / all	2 / 8	2 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Transplant failure		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transplantation complication		
subjects affected / exposed	1 / 1012 (0.10%)	5 / 1014 (0.49%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic fracture		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna fracture		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric anastomosis complication		

subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary anastomotic leak		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vaccination complication		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft complication		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft stenosis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft thrombosis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound decomposition		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound dehiscence		

subjects affected / exposed	3 / 1012 (0.30%)	10 / 1014 (0.99%)	
occurrences causally related to treatment / all	0 / 3	7 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound secretion			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Arteriovenous malformation			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital cystic kidney disease			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital megaureter			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheo-oesophageal fistula			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			

Acute coronary syndrome			
subjects affected / exposed	2 / 1012 (0.20%)	4 / 1014 (0.39%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	6 / 1012 (0.59%)	6 / 1014 (0.59%)	
occurrences causally related to treatment / all	1 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	5 / 1012 (0.49%)	6 / 1014 (0.59%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia supraventricular			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			

subjects affected / exposed	12 / 1012 (1.19%)	12 / 1014 (1.18%)
occurrences causally related to treatment / all	2 / 15	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial flutter		
subjects affected / exposed	1 / 1012 (0.10%)	4 / 1014 (0.39%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	1 / 1012 (0.10%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	4 / 1012 (0.40%)	4 / 1014 (0.39%)
occurrences causally related to treatment / all	0 / 5	1 / 4
deaths causally related to treatment / all	0 / 3	0 / 3
Cardiac asthma		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac dysfunction		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure		
subjects affected / exposed	7 / 1012 (0.69%)	9 / 1014 (0.89%)
occurrences causally related to treatment / all	0 / 11	1 / 14
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac failure acute		
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac failure chronic		

subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac failure congestive			
subjects affected / exposed	3 / 1012 (0.30%)	6 / 1014 (0.59%)	
occurrences causally related to treatment / all	0 / 4	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiorenal syndrome			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	6 / 1012 (0.59%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 9	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery insufficiency			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive heart disease			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Left ventricular failure		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular hypertrophy		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial infarction		
subjects affected / exposed	6 / 1012 (0.59%)	5 / 1014 (0.49%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 2
Myocardial ischaemia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis constrictive		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulseless electrical activity		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		

subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachyarrhythmia			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ventricular tachycardia			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Ataxia			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune encephalopathy			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Brain stem infarction			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central nervous system lesion			

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar stroke		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral infarction		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ischaemia		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Coma		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	3 / 1012 (0.30%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Headache		
subjects affected / exposed	7 / 1012 (0.69%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	3 / 7	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemic seizure		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotonia		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelitis transverse		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neurotoxicity		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord compression		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		
subjects affected / exposed	3 / 1012 (0.30%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transverse sinus thrombosis			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual field defect			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	6 / 1012 (0.59%)	14 / 1014 (1.38%)	
occurrences causally related to treatment / all	2 / 9	6 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical haemolytic uraemic syndrome			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone marrow failure			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			

subjects affected / exposed	5 / 1012 (0.49%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	3 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Granulocytopenia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemolysis		
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemolytic uraemic syndrome		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytosis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leukopenia		
subjects affected / exposed	12 / 1012 (1.19%)	4 / 1014 (0.39%)
occurrences causally related to treatment / all	10 / 14	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphatic obstruction		

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphopenia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrogenic anaemia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenia		
subjects affected / exposed	6 / 1012 (0.59%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	4 / 6	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancytopenia		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Polycythaemia		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sickle cell anaemia with crisis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenomegaly		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombocytopenia		

subjects affected / exposed	1 / 1012 (0.10%)	3 / 1014 (0.30%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic microangiopathy			
subjects affected / exposed	3 / 1012 (0.30%)	8 / 1014 (0.79%)	
occurrences causally related to treatment / all	2 / 3	6 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Mastoid effusion			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	3 / 1012 (0.30%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual acuity reduced			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	2 / 1012 (0.20%)	4 / 1014 (0.39%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	14 / 1012 (1.38%)	9 / 1014 (0.89%)	
occurrences causally related to treatment / all	5 / 18	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	3 / 1012 (0.30%)	4 / 1014 (0.39%)	
occurrences causally related to treatment / all	3 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma			

subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Acute abdomen		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal polyp		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anogenital dysplasia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Barrett's oesophagus		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic gastritis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Colitis ulcerative		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	3 / 1012 (0.30%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	2 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Crohn's disease		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gastroparesis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	55 / 1012 (5.43%)	27 / 1014 (2.66%)
occurrences causally related to treatment / all	32 / 60	9 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal perforation		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Duodenal ulcer		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Encapsulating peritoneal sclerosis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal fistula		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	4 / 1012 (0.40%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	1 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hernial eventration		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	2 / 1012 (0.20%)	5 / 1014 (0.49%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired gastric emptying		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	5 / 1012 (0.49%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	2 / 1012 (0.20%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal perforation		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Intra-abdominal fluid collection		

subjects affected / exposed	1 / 1012 (0.10%)	5 / 1014 (0.49%)
occurrences causally related to treatment / all	0 / 1	3 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal haematoma		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal haemorrhage		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar hernia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mallory-Weiss syndrome		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mouth ulceration		

subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	9 / 1012 (0.89%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	3 / 11	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal achalasia		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal spasm		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis chronic		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		

subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retching		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haematoma		
subjects affected / exposed	5 / 1012 (0.49%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haemorrhage		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland enlargement		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal obstruction		
subjects affected / exposed	4 / 1012 (0.40%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	1 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Stomatitis		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia		
subjects affected / exposed	0 / 1012 (0.00%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Volvulus		

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus of small bowel			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	13 / 1012 (1.28%)	6 / 1014 (0.59%)	
occurrences causally related to treatment / all	5 / 18	3 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Capillaritis			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperhidrosis			

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic ulcer			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peau d'orange			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin necrosis			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin oedema			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	37 / 1012 (3.66%)	46 / 1014 (4.54%)	
occurrences causally related to treatment / all	12 / 47	10 / 50	
deaths causally related to treatment / all	0 / 1	0 / 0	
Anuria			

subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck obstruction			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder obstruction			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder perforation			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis haemorrhagic			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic nephropathy			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dysuria			

subjects affected / exposed	5 / 1012 (0.49%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
End stage renal disease		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Focal segmental glomerulosclerosis		
subjects affected / exposed	3 / 1012 (0.30%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis chronic		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis membranoproliferative		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis membranous		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glycosuria		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		

subjects affected / exposed	14 / 1012 (1.38%)	9 / 1014 (0.89%)
occurrences causally related to treatment / all	0 / 15	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage urinary tract		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	6 / 1012 (0.59%)	9 / 1014 (0.89%)
occurrences causally related to treatment / all	0 / 6	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Hydroureter		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertonic bladder		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
IgM nephropathy		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic nephropathy		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocyturia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mesangioproliferative glomerulonephritis		

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephritis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy toxic		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive nephropathy		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oliguria		
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvi-ureteric obstruction		

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perinephric collection		
subjects affected / exposed	5 / 1012 (0.49%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 5	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pollakiuria		
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prerenal failure		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Proteinuria		
subjects affected / exposed	3 / 1012 (0.30%)	15 / 1014 (1.48%)
occurrences causally related to treatment / all	0 / 4	10 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelocaliectasis		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery dissection		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery occlusion		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		

subjects affected / exposed	7 / 1012 (0.69%)	4 / 1014 (0.39%)
occurrences causally related to treatment / all	0 / 7	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery thrombosis		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cortical necrosis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst haemorrhage		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst ruptured		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	3 / 1012 (0.30%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal haematoma		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		

subjects affected / exposed	25 / 1012 (2.47%)	23 / 1014 (2.27%)
occurrences causally related to treatment / all	7 / 26	11 / 30
deaths causally related to treatment / all	0 / 0	0 / 0
Renal ischaemia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal necrosis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tubular atrophy		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tubular necrosis		
subjects affected / exposed	5 / 1012 (0.49%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 5	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal vein thrombosis		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tubulointerstitial nephritis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric dilatation		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric obstruction		

subjects affected / exposed	1 / 1012 (0.10%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric stenosis		
subjects affected / exposed	6 / 1012 (0.59%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral obstruction		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral stenosis		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urge incontinence		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary bladder haemorrhage		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary bladder polyp		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary fistula		
subjects affected / exposed	2 / 1012 (0.20%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary incontinence		

subjects affected / exposed	1 / 1012 (0.10%)	9 / 1014 (0.89%)	
occurrences causally related to treatment / all	0 / 1	3 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	8 / 1012 (0.79%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 11	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	4 / 1012 (0.40%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinoma			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vesicoureteric reflux			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism tertiary			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	2 / 1012 (0.20%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	1 / 1012 (0.10%)	3 / 1014 (0.30%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin pain			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc space narrowing			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			

subjects affected / exposed	2 / 1012 (0.20%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia intercostal		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteitis		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	2 / 1012 (0.20%)	4 / 1014 (0.39%)
occurrences causally related to treatment / all	1 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		
subjects affected / exposed	1 / 1012 (0.10%)	9 / 1014 (0.89%)
occurrences causally related to treatment / all	1 / 1	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pubic pain		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sacroiliitis		

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal infection			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Actinomycosis			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenoviral haemorrhagic cystitis			

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenovirus infection		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	2 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	3 / 1012 (0.30%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula site infection		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis infective		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Asymptomatic bacteriuria		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atypical pneumonia		

subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
BK virus infection		
subjects affected / exposed	5 / 1012 (0.49%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	3 / 5	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	0 / 1012 (0.00%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 0	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial diarrhoea		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial infection		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial prostatitis		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial pyelonephritis		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	1 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial sepsis		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteriuria		

subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blister infected		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	3 / 1012 (0.30%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	1 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchopulmonary aspergillosis		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Campylobacter gastroenteritis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Candida infection		
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Candiduria		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	6 / 1012 (0.59%)	5 / 1014 (0.49%)
occurrences causally related to treatment / all	1 / 6	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Chest wall abscess		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic sinusitis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic tonsillitis		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	3 / 1012 (0.30%)	4 / 1014 (0.39%)
occurrences causally related to treatment / all	1 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Corona virus infection		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cryptococcosis		
subjects affected / exposed	3 / 1012 (0.30%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis viral		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cytomegalovirus colitis		

subjects affected / exposed	9 / 1012 (0.89%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	5 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cytomegalovirus enteritis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cytomegalovirus gastroenteritis		
subjects affected / exposed	3 / 1012 (0.30%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cytomegalovirus gastrointestinal infection		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cytomegalovirus hepatitis		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cytomegalovirus infection		
subjects affected / exposed	48 / 1012 (4.74%)	6 / 1014 (0.59%)
occurrences causally related to treatment / all	40 / 55	6 / 8
deaths causally related to treatment / all	0 / 1	0 / 0
Dengue fever		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatophytosis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		

subjects affected / exposed	3 / 1012 (0.30%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related sepsis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea infectious		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated tuberculosis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	3 / 1012 (0.30%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ear infection		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalitis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Endocarditis		

subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis infectious		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal infection		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal sepsis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis viral		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	0 / 1012 (0.00%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia bacteraemia		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia infection		

subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia pyelonephritis		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia sepsis		
subjects affected / exposed	1 / 1012 (0.10%)	5 / 1014 (0.49%)
occurrences causally related to treatment / all	1 / 1	2 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	7 / 1012 (0.69%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	4 / 9	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile infection		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fungal infection		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fungal sepsis		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gangrene		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		

subjects affected / exposed	23 / 1012 (2.27%)	18 / 1014 (1.78%)
occurrences causally related to treatment / all	8 / 25	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis clostridial		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis cryptosporidial		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis norovirus		
subjects affected / exposed	6 / 1012 (0.59%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	2 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	3 / 1012 (0.30%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	2 / 1012 (0.20%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	1 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
HIV infection		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma infection		

subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cyst infection		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis C		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis E		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis viral		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes simplex		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes simplex pneumonia		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	4 / 1012 (0.40%)	5 / 1014 (0.49%)
occurrences causally related to treatment / all	1 / 4	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster disseminated		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileal gangrene		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected lymphocele		
subjects affected / exposed	1 / 1012 (0.10%)	4 / 1014 (0.39%)
occurrences causally related to treatment / all	0 / 1	5 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Infected seroma		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	2 / 1012 (0.20%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	2 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious colitis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Infectious pleural effusion		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		

subjects affected / exposed	5 / 1012 (0.49%)	6 / 1014 (0.59%)
occurrences causally related to treatment / all	1 / 5	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal sepsis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney infection		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella bacteraemia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella sepsis		
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	3 / 1012 (0.30%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 4	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infection		
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site cellulitis		

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site infection		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis bacterial		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis cryptococcal		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasopharyngitis		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenic sepsis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nocardiosis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oral candidiasis		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oral herpes		

subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			
subjects affected / exposed	3 / 1012 (0.30%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	5 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	2 / 1012 (0.20%)	5 / 1014 (0.49%)	
occurrences causally related to treatment / all	1 / 2	4 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis chronic			
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parvovirus B19 infection			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perinephric abscess			
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillar abscess			
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngotonsillitis			

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumococcal sepsis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia		
subjects affected / exposed	3 / 1012 (0.30%)	6 / 1014 (0.59%)
occurrences causally related to treatment / all	2 / 3	6 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Pneumonia		
subjects affected / exposed	36 / 1012 (3.56%)	55 / 1014 (5.42%)
occurrences causally related to treatment / all	18 / 41	31 / 63
deaths causally related to treatment / all	0 / 2	0 / 0
Pneumonia bacterial		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia cryptococcal		
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia cytomegaloviral		
subjects affected / exposed	4 / 1012 (0.40%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Pneumonia fungal		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia haemophilus		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia influenzal		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia legionella		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyomavirus-associated nephropathy		
subjects affected / exposed	10 / 1012 (0.99%)	4 / 1014 (0.39%)
occurrences causally related to treatment / all	10 / 10	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	3 / 1012 (0.30%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 3	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous colitis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pseudomonal bacteraemia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonal sepsis		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	33 / 1012 (3.26%)	24 / 1014 (2.37%)
occurrences causally related to treatment / all	15 / 40	15 / 30
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	13 / 1012 (1.28%)	6 / 1014 (0.59%)
occurrences causally related to treatment / all	8 / 19	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis chronic		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyuria		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst infection		
subjects affected / exposed	3 / 1012 (0.30%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal graft infection		
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		

subjects affected / exposed	5 / 1012 (0.49%)	5 / 1014 (0.49%)
occurrences causally related to treatment / all	2 / 5	2 / 5
deaths causally related to treatment / all	0 / 2	0 / 0
Respiratory tract infection fungal		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Respiratory tract infection viral		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rhinitis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rhinovirus infection		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salmonellosis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		
subjects affected / exposed	7 / 1012 (0.69%)	20 / 1014 (1.97%)
occurrences causally related to treatment / all	4 / 7	9 / 23
deaths causally related to treatment / all	0 / 0	0 / 3
Septic shock		
subjects affected / exposed	8 / 1012 (0.79%)	6 / 1014 (0.59%)
occurrences causally related to treatment / all	3 / 9	2 / 6
deaths causally related to treatment / all	0 / 4	0 / 1
Sinusitis		

subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinusitis fungal		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal sepsis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous abscess		
subjects affected / exposed	0 / 1012 (0.00%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic candida		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis bacterial		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth abscess		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		

subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transplant abscess		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis gastrointestinal		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	4 / 1012 (0.40%)	5 / 1014 (0.49%)
occurrences causally related to treatment / all	3 / 5	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	93 / 1012 (9.19%)	78 / 1014 (7.69%)
occurrences causally related to treatment / all	49 / 124	37 / 110
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		
subjects affected / exposed	1 / 1012 (0.10%)	4 / 1014 (0.39%)
occurrences causally related to treatment / all	1 / 1	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection enterococcal		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection fungal		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	23 / 1012 (2.27%)	23 / 1014 (2.27%)
occurrences causally related to treatment / all	14 / 28	9 / 28
deaths causally related to treatment / all	0 / 1	0 / 0
Varicella		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Viral diarrhoea		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral infection		
subjects affected / exposed	2 / 1012 (0.20%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Viral myocarditis		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Viral upper respiratory tract infection		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vulvovaginal mycotic infection		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound abscess		

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	4 / 1012 (0.40%)	5 / 1014 (0.49%)	
occurrences causally related to treatment / all	1 / 4	3 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	2 / 1012 (0.20%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calciphylaxis			
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	2 / 1012 (0.20%)	2 / 1014 (0.20%)	
occurrences causally related to treatment / all	1 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	11 / 1012 (1.09%)	6 / 1014 (0.59%)	
occurrences causally related to treatment / all	2 / 11	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	10 / 1012 (0.99%)	9 / 1014 (0.89%)	
occurrences causally related to treatment / all	5 / 10	6 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	2 / 1012 (0.20%)	1 / 1014 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			

subjects affected / exposed	2 / 1012 (0.20%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	1 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid overload		
subjects affected / exposed	3 / 1012 (0.30%)	5 / 1014 (0.49%)
occurrences causally related to treatment / all	0 / 3	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid retention		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	1 / 1012 (0.10%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	6 / 1012 (0.59%)	5 / 1014 (0.49%)
occurrences causally related to treatment / all	4 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	10 / 1012 (0.99%)	11 / 1014 (1.08%)
occurrences causally related to treatment / all	2 / 11	2 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperlipidaemia		

subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertriglyceridaemia		
subjects affected / exposed	0 / 1012 (0.00%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypervolaemia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	1 / 1012 (0.10%)	2 / 1014 (0.20%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	5 / 1012 (0.49%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	0 / 1012 (0.00%)	3 / 1014 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	5 / 1012 (0.49%)	1 / 1014 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypophosphataemia		

subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	4 / 1012 (0.40%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 1014 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	MPA plus standard@CNI	Everolimus plus@reduced CNI	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	942 / 1012 (93.08%)	951 / 1014 (93.79%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	230 / 1012 (22.73%)	240 / 1014 (23.67%)	
occurrences (all)	264	275	

Hypotension subjects affected / exposed occurrences (all)	78 / 1012 (7.71%) 83	62 / 1014 (6.11%) 67	
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	64 / 1012 (6.32%) 77	59 / 1014 (5.82%) 63	
Oedema peripheral subjects affected / exposed occurrences (all)	244 / 1012 (24.11%) 339	347 / 1014 (34.22%) 512	
Pyrexia subjects affected / exposed occurrences (all)	132 / 1012 (13.04%) 162	112 / 1014 (11.05%) 130	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	102 / 1012 (10.08%) 110	86 / 1014 (8.48%) 100	
Dyspnoea subjects affected / exposed occurrences (all)	70 / 1012 (6.92%) 85	73 / 1014 (7.20%) 84	
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	59 / 1012 (5.83%) 66	51 / 1014 (5.03%) 57	
Insomnia subjects affected / exposed occurrences (all)	138 / 1012 (13.64%) 155	100 / 1014 (9.86%) 113	
Investigations Blood creatinine increased subjects affected / exposed occurrences (all)	133 / 1012 (13.14%) 160	141 / 1014 (13.91%) 167	
Weight increased subjects affected / exposed occurrences (all)	66 / 1012 (6.52%) 67	38 / 1014 (3.75%) 39	
Injury, poisoning and procedural complications			

Complications of transplanted kidney subjects affected / exposed occurrences (all)	54 / 1012 (5.34%) 65	63 / 1014 (6.21%) 67	
Incision site pain subjects affected / exposed occurrences (all)	61 / 1012 (6.03%) 65	51 / 1014 (5.03%) 55	
Procedural pain subjects affected / exposed occurrences (all)	99 / 1012 (9.78%) 117	90 / 1014 (8.88%) 100	
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	52 / 1012 (5.14%) 59	53 / 1014 (5.23%) 62	
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	54 / 1012 (5.34%) 62	51 / 1014 (5.03%) 58	
Headache subjects affected / exposed occurrences (all)	113 / 1012 (11.17%) 144	133 / 1014 (13.12%) 172	
Tremor subjects affected / exposed occurrences (all)	145 / 1012 (14.33%) 161	100 / 1014 (9.86%) 103	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	238 / 1012 (23.52%) 267	227 / 1014 (22.39%) 260	
Leukocytosis subjects affected / exposed occurrences (all)	58 / 1012 (5.73%) 59	24 / 1014 (2.37%) 26	
Leukopenia subjects affected / exposed occurrences (all)	194 / 1012 (19.17%) 234	94 / 1014 (9.27%) 108	
Polycythaemia subjects affected / exposed occurrences (all)	42 / 1012 (4.15%) 44	52 / 1014 (5.13%) 58	

Thrombocytopenia subjects affected / exposed occurrences (all)	41 / 1012 (4.05%) 45	74 / 1014 (7.30%) 85	
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	104 / 1012 (10.28%) 126	94 / 1014 (9.27%) 107	
Abdominal pain upper subjects affected / exposed occurrences (all)	62 / 1012 (6.13%) 69	39 / 1014 (3.85%) 45	
Constipation subjects affected / exposed occurrences (all)	242 / 1012 (23.91%) 286	245 / 1014 (24.16%) 282	
Diarrhoea subjects affected / exposed occurrences (all)	318 / 1012 (31.42%) 437	242 / 1014 (23.87%) 315	
Nausea subjects affected / exposed occurrences (all)	225 / 1012 (22.23%) 271	191 / 1014 (18.84%) 238	
Vomiting subjects affected / exposed occurrences (all)	140 / 1012 (13.83%) 172	120 / 1014 (11.83%) 144	
Skin and subcutaneous tissue disorders			
Acne subjects affected / exposed occurrences (all)	37 / 1012 (3.66%) 39	56 / 1014 (5.52%) 58	
Alopecia subjects affected / exposed occurrences (all)	59 / 1012 (5.83%) 59	27 / 1014 (2.66%) 28	
Renal and urinary disorders			
Dysuria subjects affected / exposed occurrences (all)	74 / 1012 (7.31%) 78	60 / 1014 (5.92%) 66	
Haematuria			

subjects affected / exposed	101 / 1012 (9.98%)	102 / 1014 (10.06%)	
occurrences (all)	110	117	
Proteinuria			
subjects affected / exposed	69 / 1012 (6.82%)	131 / 1014 (12.92%)	
occurrences (all)	80	145	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	65 / 1012 (6.42%)	63 / 1014 (6.21%)	
occurrences (all)	74	72	
Back pain			
subjects affected / exposed	98 / 1012 (9.68%)	93 / 1014 (9.17%)	
occurrences (all)	106	103	
Pain in extremity			
subjects affected / exposed	61 / 1012 (6.03%)	66 / 1014 (6.51%)	
occurrences (all)	68	77	
Infections and infestations			
BK virus infection			
subjects affected / exposed	101 / 1012 (9.98%)	56 / 1014 (5.52%)	
occurrences (all)	118	68	
Cytomegalovirus infection			
subjects affected / exposed	93 / 1012 (9.19%)	24 / 1014 (2.37%)	
occurrences (all)	107	26	
Nasopharyngitis			
subjects affected / exposed	117 / 1012 (11.56%)	110 / 1014 (10.85%)	
occurrences (all)	152	135	
Upper respiratory tract infection			
subjects affected / exposed	102 / 1012 (10.08%)	81 / 1014 (7.99%)	
occurrences (all)	125	95	
Urinary tract infection			
subjects affected / exposed	249 / 1012 (24.60%)	219 / 1014 (21.60%)	
occurrences (all)	471	373	
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	120 / 1012 (11.86%)	133 / 1014 (13.12%)	
occurrences (all)	126	136	

Dyslipidaemia		
subjects affected / exposed	57 / 1012 (5.63%)	98 / 1014 (9.66%)
occurrences (all)	59	104
Hypercalcaemia		
subjects affected / exposed	67 / 1012 (6.62%)	39 / 1014 (3.85%)
occurrences (all)	74	42
Hypercholesterolaemia		
subjects affected / exposed	61 / 1012 (6.03%)	103 / 1014 (10.16%)
occurrences (all)	63	110
Hyperglycaemia		
subjects affected / exposed	144 / 1012 (14.23%)	140 / 1014 (13.81%)
occurrences (all)	162	155
Hyperkalaemia		
subjects affected / exposed	184 / 1012 (18.18%)	164 / 1014 (16.17%)
occurrences (all)	230	192
Hyperlipidaemia		
subjects affected / exposed	75 / 1012 (7.41%)	135 / 1014 (13.31%)
occurrences (all)	77	140
Hypertriglyceridaemia		
subjects affected / exposed	24 / 1012 (2.37%)	58 / 1014 (5.72%)
occurrences (all)	25	63
Hyperuricaemia		
subjects affected / exposed	64 / 1012 (6.32%)	49 / 1014 (4.83%)
occurrences (all)	69	55
Hypocalcaemia		
subjects affected / exposed	98 / 1012 (9.68%)	109 / 1014 (10.75%)
occurrences (all)	106	118
Hypokalaemia		
subjects affected / exposed	87 / 1012 (8.60%)	148 / 1014 (14.60%)
occurrences (all)	108	180
Hypomagnesaemia		
subjects affected / exposed	168 / 1012 (16.60%)	134 / 1014 (13.21%)
occurrences (all)	190	153
Hypophosphataemia		

subjects affected / exposed	167 / 1012 (16.50%)	190 / 1014 (18.74%)	
occurrences (all)	178	210	
Metabolic acidosis			
subjects affected / exposed	98 / 1012 (9.68%)	77 / 1014 (7.59%)	
occurrences (all)	109	93	
Vitamin D deficiency			
subjects affected / exposed	57 / 1012 (5.63%)	53 / 1014 (5.23%)	
occurrences (all)	58	54	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 July 2016	In response to the French Health Authorities (HA) request, the protocol was updated with the recent notifications for use of mycophenolate based on European Medicines Agency's (EMA) recommendation published on 23-Oct-2015, and the Dear Health Care Professional Letter (DHCPL) for CellCept that was distributed by Roche by 10-Nov-2015. Mycophenolate (mycophenolate mofetil or mycophenolic acid) is a confirmed teratogen associated with an increased rate of spontaneous abortion and congenital malformation compared with other immunosuppressants. Therefore, investigators should ensure that female and male patients taking mycophenolate understand the risk of harm to the baby, the need for effective contraception, and the need to immediately consult responsible investigator if there is a possibility of pregnancy or a suspected gap of contraception.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

NA

Notes: