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

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 safet 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

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
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).	

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/1.73m2.
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.	
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

End point description:

Incidence of failure on the composite of (treated biopsy proven acute rejection (tBPAR), 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|	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/1.73m2

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

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/1.73m2
End point description: Incidence of eGFR < 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|	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)
End point description:	
Renal allograft function (mean estimated glomerular filtration rate, eGFR)	
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: mL/min/1.73m2				
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.
End point description:	
Rate of change of renal function, as eGFR, over time by slope 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: mL/min/1.73m2				
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/1.73m2				
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/1.73m2)|	21.38 (± 14.296)	20.10 (± 12.408)		
eGFR (Hoek) month 12 (mL/min/1.73m2)|	50.08 (± 14.430)	52.00 (± 14.533)		
eGFR (Hoek) month 24 (mL/min/1.73m2)|	49.86 (± 14.604)	52.75 (± 15.406)		
eGFR (MDRD4) baseline (mL/min/1.73m2)|	11.79 (± 8.697)	11.56 (± 8.853)		
eGFR (MDRD4) month 12 (mL/min/1.73m2)|	57.59 (± 19.685)	57.58 (± 18.768)		

eGFR (MDRD4) month 24 (mL/min/1.73m2)|	58.07 (± 20.168)	58.68 (± 19.541)		
eGFR-CKDEPI baseline (mL/min/1.73m2)|	11.29 (± 9.094)	11.05 (± 9.195)		
eGFR-CKDEPI month 12(mL/min/1.73m2)|	58.83 (± 20.686)	58.75 (± 19.757)		
eGFR-CKDEPI month 24 (mL/min/1.73m2)|	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.

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

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/1.73m2 among compliant subjects.

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

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

End point description:

Incidence tBPAR by severity and time to event

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				
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 eGRF<50 mL/min/1.73m2 by subgroup

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

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

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

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.1

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

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

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