

Clinical trial results: Medically III Patient Assessment of Rivaroxaban Versus Placebo in Reducing Post-Discharge Venous Thrombo-Embolism Risk Summary

E draCT n mber	2014-000305-13	
Trial pro ocol	DK HU CZ IT ES NL LT BG GR LV AT DE GB PT SK HR	
Global end of rial da e	03 Ma 2018	
Results information		
Re I er ion n mber	1 (c rren)	
Thi er ion p blica ion da e	05 Ma 2019	
Fir er ion p blica ion da e	05 Ma 2019	

Trial information

Trial identification		
Spon or pro ocol code	RIVAROXDVT3002	
Additional study identifiers		
ISRCTN n mber	-	
ClinicalTrial .go id (NCT n mber)	NCT02111564	
WHO ni er al rial n mber (UTN)	-	

No e :

Sponsors	
Spon or organi a ion name	Jan en Re earch & De elopmen LLC
Spon or organi a ion addre	920 US High a 202, Rari an, Uni ed S a e , NJ 08869
P blic con ac	Clinical Regi r gro p, Jan en Re earch & De elopmen LLC, ClinicalTrial EU@i .jnj.com
Scien ific con ac	Clinical Regi r gro p, Jan en Re earch & De elopmen LLC, ClinicalTrial EU@i .jnj.com

No e:

Paediatric regulatory details	
I rial par of an agreed paedia ric in e iga ion plan (PIP)	No
Doe ar icle 45 of REGULATION (EC) No 1901/2006 appl o hi rial?	No
Doe ar icle 46 of REGULATION (EC) No 1901/2006 appl o hi rial?	No

No e:

Results analysis stage		
Anal i age	Final	
Da e of in erim/final anal i	03 Ma 2018	
I hi he anal i of he primar comple ion da a?	No	
Global end of rial reached?	Ye	
Global end of rial da e	03 Ma 2018	
Wa he rial ended prema rel ?	No	

No e:

General information about the trial

Main objec i e of he rial:

The primar objec i e of hi d a o a e he efficac and afe of ri aro⊡aban, compared i h placebo in he pre en ion of mp oma ic eno hromboemboli m e en (lo er e□remi deep ein hrombo i [DVT] and non-fa al p Imonar emboli m [PE]) and eno hromboemboli m e en rela ed dea h (dea h d e o PE or dea h in hich PE co ld no be r led o a he ca e) po ho pi al di charge in high-ri k, medicall ill bjec .

Pro ec ion of rial bjec :

Thi d a cond c ed in accordance i h he e hical principle ha ha e heir origin in he Declara ion of Hel inki and ha are con i en i h Good Clinical Prac ice (GCP) and applicable reg la or req iremen . Safe a e men incl ded ad er e e en and In erna ional Socie on Thrombo i and Haemo a i (ISTH) major bleeding, non-major clinicall rele an bleeding, o her bleeding and clinical labora or e.

Backgro nd herap: -

E idence for compara or: -	
Ac al ar da e of recr i men	10 J ne 2014
Long erm follo - p planned	No
Independen da a moni oring commi ee (IDMC) in ol emen ?	Ye

No e:

Population of trial subjects

Subjects enrolled per country			
Co nr: N mber of	bjec	enrolled	Argen ina: 242
Co nr:N mber of	bjec	enrolled	A ralia: 88
Co nr:N mber of	bjec	enrolled	A ria: 14
Co nr:N mber of	bjec	enrolled	B Igaria: 1428
Co nr:N mber of	bjec	enrolled	Bo nia and Her ego ina: 597
Co nr:N mber of	bjec	enrolled	Belar : 133
Co nr:N mber of	bjec	enrolled	Bra il: 92
Co nr:N mber of	bjec	enrolled	Canada: 43
Co nr:N mber of	bjec	enrolled	Colombia: 140
Co nr:N mber of	bjec	enrolled	C ech Rep blic: 231
Co nr:N mber of	bjec	enrolled	German : 17
Co nr:N mber of	bjec	enrolled	Denmark: 7
Co nr:N mber of	bjec	enrolled	Spain: 383
Co nr:N mber of	bjec	enrolled	E onia: 11
Co nr:N mber of	bjec	enrolled	Uni ed Kingdom: 8
Co nr:N mber of	bjec	enrolled	Georgia: 1762
Co nr:N mber of	bjec	enrolled	Greece: 131

Co nr:N mber of	bjec enrolled	Croa ia: 270
Co nr:N mber of	bjec enrolled	H ngar : 549
Co nr:N mber of	bjec enrolled	I rael: 111
Co nr:N mber of	bjec enrolled	I al : 147
Co nr:N mber of	bjec enrolled	Li h ania: 164
Co nr:N mber of	bjec enrolled	La ia: 308
Co nr:N mber of	bjec enrolled	Me□co: 32
Co nr:N mber of	bjec enrolled	Macedonia, he former Y go la Rep blic of: 902
Co nr:N mber of	bjec enrolled	Ne herland: 17
Co nr:N mber of	bjec enrolled	Per : 65
Co nr:N mber of	bjec enrolled	Poland: 619
Co nr:N mber of	bjec enrolled	P er o Rico: 1
Co nr:N mber of	bjec enrolled	Por gal: 13
Co nr:N mber of	bjec enrolled	Romania: 324
Co nr:N mber of	bjec enrolled	R ian Federa ion: 1142
Co nr:N mber of	bjec enrolled	Serbia: 609
Co nr: N mber of	bjec enrolled	T rke: 70
Co nr: N mber of	bjec enrolled	Ukraine: 854
Co nr: N mber of	bjec enrolled	Uni ed S a e : 290
Co nr: N mber of	bjec enrolled	So h Africa: 205
World ide oaln mb	er of bjec	12019
EEA o al n mber of	bjec	4641

No e:

Subjects enrolled per age group		
In ero	0	
Pre erm ne born - ge a ional age < 37 k	0	
Ne born (0-27 da)	0	
Infan and oddler (28 da -23 mon h)	0	
Children (2-11 ear)	0	
Adole cen (12-17 ear)	0	
Ad I (18-64 ear)	3655	
From 65 o 84 ear	7626	
85 ear and o er	738	

Subject disposition

Recruitment

Recr i men de ail:

Thi d a cond c ed from 10-J ne-2014 o 03-Ma -2018.

Pre-assignment

Screening de ail:

13708 bjec ere creened for eligibili . Of he e 12024 bjec ere randomi ed (Ri aro⊡aban-6007 and Placebo- 6017). 5 bjec in placebo ere e⊡cl ded from ITT pop la ion (2-in alid con en , 3 randomi ed prior o Heal h A hori appro al).

Period 1	
Period 1 i le	O erall S d (o erall period)
I hi he ba eline period?	Ye
Alloca ion me hod	Randomi ed - con rolled
Blinding ed	Do ble blind
Role blinded	In e iga or, S bjec
Arms	
Are arm m all e□cl i e?	Ye
Arm title	Ri aro⊡aban 10 mg or 7.5 mg

Arm de crip ion:

S bjec i h a crea inine clearance (CrCl) a creening grea er han or eq al o (>=) 50 millili er per min e (mL/min) a creening recei ed 10 milligram (mg) ri aro⊡aban able once dail orall and bjec i h a crea inine clearance a creening from >=30 o le han (<) 50 mL/min a creening recei ed 7.5 mg ri aro⊡aban able once dail for 45 da .

Arm pe	E⊑perimen al
In e iga ional medicinal prod c name	Ri aro⊡aban
In e iga ional medicinal prod c code	
O her name	JNJ-39039039, BAY 59-7939
Pharmace ical form	Table
Ro e of admini ra ion	Oral e

Do age and admini ra ion de ail:

S bjec ere randomi ed o recei e 10 mg or 7.5 mg ri aro□aban able once dail for 45 da .

Arm title	Placebo

Arm de crip ion:

S bjec recei ed ma ching placebo able once dail for 45 da .

Arm pe	Placebo compara or
In e iga ional medicinal prod c name	Placebo
In e iga ional medicinal prod c code	
O her name	
Pharmace ical form	Table
Ro e of admini ra ion	Oral e

Do age and admini ra ion de ail :

S bjec recei ed ma ching placebo able once dail for 45 da .

Number of subjects in period 1	Ri aro⊡aban 10 mg or 7.5 mg	Placebo
S ar ed	6007	6012
Safe	5982	5980
Comple ed	5876	5869
No comple ed	131	143
Ad er e e en , erio fa al	92	99
Con en i hdra n b bjec	20	20
Ad er e e en , non erio	11	13
Ad er e e en , erio non-fa al	6	8
Lo o follo - p	2	3

Baseline characteristics

Reporting groups

Repor ing gro p i le	Ri aro⊡aban 10 mg or 7.5 mg	

Repor ing gro p de crip ion:

S bjec i h a crea inine clearance (CrCl) a creening grea er han or eq al o (>=) 50 millili er per min e (mL/min) a creening recei ed 10 milligram (mg) ri aro□aban able once dail orall and bjec i h a crea inine clearance a creening from >=30 o le han (<) 50 mL/min a creening recei ed 7.5 mg ri aro□aban able once dail for 45 da .

Repor ing gro p i le Placebo

Repor ing gro p de crip ion:

S bjec recei ed ma ching placebo able once dail for 45 da .

Reporting group values	Ri aro⊡aban 10 mg or 7.5 mg	Placebo	To al
N mber of bjec	6007	6012	12019
Ti le for AgeCa egorical			
Uni : bjec			
Children (2-11 ear)	0	0	0
Adole cen (12-17 ear)	0	0	0
Ad I (18-64 ear)	1809	1846	3655
From 65 o 84 ear	3866	3760	7626
85 ear and o er	332	406	738
Ti le for AgeCon in o			
Uni : ear			
ari hme ic mean	69.7	69.7	
andard de ia ion	10.6	10.22	-
Ti le for Gender			
Uni : bjec			
Male	3130	3154	6284
Female	2877	2858	5735

N mber of bjec incl ded in anal i	12019
Anal i pecifica ion	Pre- pecified
Anal i pe	periori
P- al e	= 0.136
Me hod	Co□propor ional ha ard model
Parame er e ima e	Ha ard ra io (HR)
Poin e ima e	0.76
Confidence in er al	
le el	95 %
ide	2- ided
lo er limi	0.52
pper limi	1.09

Primary: Event Rate based on Time from Randomization to the First occurrence of Major Bleeding Adjudicated by CEC

End poin i le	E en Ra e ba ed on Time from Randomi a ion o he Fir
	occ rrence of Major Bleeding Adj dica ed b CEC

End poin de crip ion:

A major bleeding e en a defined ing alida ed In erna ional Socie on Thrombo i and Haemo a i (ISTH) bleeding cri eria. E en ra e i defined a n mber of e en per 100 bjec in 45 da of follo p. S bjec ho did no ha e e en are cen ored on he minim m of la i i before or on dea h, or la do e+2 da . The Safe anal i e incl ded all enrolled bjec in he ITT anal i e ho recei ed a lea 1 do e of d dr g.

End poin p	ре	Primar
	•	

End poin imeframe:

Up o 45 Da

End point values	Ri aro⊡aban 10 mg or 7.5 mg	Placebo	
S bjec gro p pe	Repor ing gro p	Repor ing gro p	
N mber of bjec anal ed	5982	5980	
Uni : E en per 100 pa ien in 45 da			
n mber (no applicable)	0.28	0.15	

Statistical analyses

Statistical analysis title	Sai ical Anal i 1
Compari on gro p	Ri aro⊡aban 10 mg or 7.5 mg Placebo
N mber of bjec incl ded in anal i	11962
Anal i pecifica ion	Pre- pecified
Anal i pe	periori
P- al e	= 0.124
Me hod	Co□propor ional ha ard model
Parame er e ima e	Ha ard ra io (HR)
Poin e ima e	1.88

Confidence in er al	
le el	95 %
ide	2- ided
lo er limi	0.84
pper limi	4.23

Secondary: Event Rate Based on Time from Randomization to an Occurrence of VTE-**Related Death Adjudicated by CEC**

End poin i le	E en Ra e Ba ed on Time from Randomi a ion o an
	Occ rrence of VTE-Rela ed Dea h Adj dica ed b CEC

End poin de crip ion:

Time from randomi a ion o an occ rrence of VTE-rela ed dea h $\,$ a $\,$ a $\,$ e $\,$ ed. E en ra e i $\,$ defined a n $\,$ mber of e en $\,$ per $\,$ 100 $\,$ bjec $\,$ in 45 da $\,$ of follo $\,$ p. S $\,$ bjec $\,$ ho did no ha e e en $\,$ are cen ored on he minim $\,$ m of la $\,$ i $\,$ i $\,$ before or on dea h, or Da $\,$ 45. ITT anal $\,$ i $\,$ e $\,$ compri ed all randomi ed bjec ho igned a alid informed con en , regardle of ac al rea men recei ed.

End poin	pe	Secondar
End poin	imeframe:	

Up o Da 45

End point values	Ri aro⊡aban 10 mg or 7.5 mg	Placebo	
S bjec gro p pe	Repor ing gro p	Repor ing gro p	
N mber of bjec anal ed	6007	6012	
Uni : E en per 100 pa ien in 45 da			
n mber (no applicable)	0.72	0.77	

Statistical analyses

Statistical analysis title	Sai ical Anal i 1		
Compari on gro p	Ri aro⊡aban 10 mg or 7.5 mg Placebo		
N mber of bjec incl ded in anal i	12019		
Anal i pecifica ion	Pre- pecified		
Anal i pe	periori		
P- al e	= 0.751		
Me hod	Co□propor ional ha ard model		
Parame er e ima e	Ha ard ra io (HR)		
Poin e ima e	0.93		
Confidence in er al			
le el	95 %		
ide	2- ided		
lo er limi	0.62		
pper limi	1.42		

Secondary: Event Rate Based on Time from Randomization to the First Occurrence of a Symptomatic Venous Thromboembolism Event (VTE) Adjudicated by CEC

End poin i le	E en Ra e Ba ed on Time from Rand	lomi a ion o he Fir
	Occ rrence of a S mp oma ic Veno	Thromboemboli m E en
	(VTE) Adj dica ed b CEC	

End poin de crip ion:

Time from randomi a ion o he fir occ rrence of a mp oma ic VTE a a e ed. S mp oma ic VTE incl ded lo er e□remi DVT and non-fa al PE. E en ra e i defined a n mber of e en per 100 bjec in 45 da of follo p. S bjec ho did no ha e e en are cen ored on he minim m of la i i before or on dea h, or Da 45. ITT anal i e compri ed all randomi ed bjec ho igned a alid informed con en , regardle of ac al rea men recei ed.

End poin pe	Secondar
End poin imeframe:	
Up o Da 45	

End point values	Ri aro⊡aban 10 mg or 7.5 mg	Placebo	
S bjec gro p pe	Repor ing gro p	Repor ing gro p	
N mber of bjec anal ed	6007	6012	
Uni : E en per 100 pa ien in 45 da			
n mber (no applicable)	0.19	0.42	

Statistical analyses

Statistical analysis title	Sai ical Anal i 1		
Compari on gro p	Ri aro⊡aban 10 mg or 7.5 mg Placebo		
N mber of bjec incl ded in anal i	12019		
Anal i pecifica ion	Pre- pecified		
Anal i pe	periori		
P- al e	= 0.023		
Me hod	Co□propor ional ha ard model		
Parame er e ima e	Ha ard ra io (HR)		
Poin e ima e	0.44		
Confidence in er al			
le el	95 %		
ide	2- ided		
lo er limi	0.22		
pper limi	0.89		

Secondary: Event Rate Based on Time from Randomization to the First Occurrence of a Composite of Symptomatic VTE and All-Cause Mortality (ACM) Adjudicated by CEC

E en Ra e Ba ed on Time from Randomi a ion o he Fir
Occ rrence of a Compo i e of S mp oma ic VTE and All-Ca e Mor ali (ACM) Adj dica ed b CEC
(compared to the control of the con

End poin de crip ion:

Time from randomi a ion o he fir occ rrence of a compo i e of mp oma ic VTE and ACM a a e ed. E en ra e i defined a n mber of e en per 100 bjec in 45 da of follo p. S bjec ho did no ha e e en are cen ored on he minim m of la i i before or on dea h, or Da 45. ITT anal i e compri ed all randomi ed bjec ho igned a alid informed con en , regardle of ac al rea men recei ed.

End poin pe	Secondar
End poin imeframe:	
Up o Da 45	

End point values	Ri aro⊡aban 10 mg or 7.5 mg	Placebo	
S bjec gro p pe	Repor ing gro p	Repor ing gro p	
N mber of bjec anal ed	6007	6012	
Uni : E en per 100 pa ien in 45 da			
n mber (no applicable)	1.31	1.80	

Statistical analyses

Statistical analysis title	Sai ical Anal i 1		
Compari on gro p	Ri aro⊡aban 10 mg or 7.5 mg Placebo		
N mber of bjec incl ded in anal i	12019		
Anal i pecifica ion	Pre- pecified		
Anal i pe	periori		
P- al e	= 0.033		
Me hod	Co□propor ional ha ard model		
Parame er e ima e	Ha ard ra io (HR)		
Poin e ima e	0.73		
Confidence in er al			
le el	95 %		
ide	2- ided		
lo er limi	0.54		
pper limi	0.97		

Secondary: Event Rate Based on Time from Randomization to the First Occurrence of a Composite of Symptomatic VTE, Myocardial Infarction (MI), Non-Hemorrhagic Stroke, and Cardiovascular (CV) Death Adjudicated by CEC

End poin i le	E en Ra e Ba ed on Time from Randomi a ion o he Fir
	Occ rrence of a Compo i e of S mp oma ic VTE, M ocardial
	Infarc ion (MI), Non-Hemorrhagic S roke, and Cardio a c lar
	(CV) Dea h Adj dica ed b CEC

End poin de crip ion:

Time from randomi a ion o he fir occ rrence of a compo i e of mp oma ic VTE (lo er e□remi DVT and non-fa al PE), MI, non-hemorrhagic roke, and CV dea h (dea h d e o a kno n CV ca e and dea h in hich a CV ca e canno be r led o ; b hi defini ion, a VTE-rela ed dea h a con idered a CV dea h) a repor ed. E en ra e i defined a n mber of e en per 100 bjec in 45 da of follo p. S bjec ho did no ha e e en are cen ored on he minim m of la i i before or on dea h, or

Da 45. ITT anal i e compri ed all randomi ed bjec ho igned a alid informed con en , regardle of ac al rea men recei ed.

End poin	pe	Secondar
End poin	imeframe:	
Up o Da	45	

End point values	Ri aro⊡aban 10 mg or 7.5 mg	Placebo	
S bjec gro p pe	Repor ing gro p	Repor ing gro p	
N mber of bjec anal ed	6007	6012	
Uni : E en per 100 pa ien in 45 da			
n mber (no applicable)	1.58	2.03	

Statistical analyses

Statistical analysis title	S a i ical Anal i 1		
Compari on gro p	Ri aro⊡aban 10 mg or 7.5 mg Placebo		
N mber of bjec incl ded in anal i	12019		
Anal i pecifica ion	Pre- pecified		
Anal i pe	periori		
P- al e	= 0.073		
Me hod	Co□propor ional ha ard model		
Parame er e ima e	Ha ard ra io (HR)		
Poin e ima e	0.78		
Confidence in er al			
le el	95 %		
ide	2- ided		
lo er limi	0.6		
pper limi	1.02		

Secondary: Event Rate Based on Time from Randomization to an Occurrence of ACM Adjudicated by CEC

End poin i le	E en Ra e Ba ed on Time from Randomi a ion o an Occ rrence of ACM Adj dica ed b CEC		
End poin de crip ion:			
Time from randomi a ion o an occ rrence of all-ca e mor ali (ACM) a a e ed. E en ra e i defined a n mber of e en per 100 bjec in 45 da of follo p. S bjec ho did no ha e e en are cen ored on he minim m of la i i before or on dea h, or Da 45. ITT anal i e compri ed al randomi ed bjec ho igned a alid informed con en , regardle of ac al rea men recei ed.			
End poin pe	Secondar		

End poin imeframe:

Up o Da 45

End point values	Ri aro⊡aban 10 mg or 7.5 mg	Placebo	
S bjec gro p pe	Repor ing gro p	Repor ing gro p	
N mber of bjec anal ed	6007	6012	
Uni : E en per 100 pa ien in 45 da			
n mber (no applicable)	1.19	1.49	

Statistical analyses

Statistical analysis title	S a i ical Anal i 1		
Compari on gro p	Ri aro⊡aban 10 mg or 7.5 mg Placebo		
N mber of bjec incl ded in anal i	12019		
Anal i pecifica ion	Pre- pecified		
Anal i pe	periori		
P- al e	= 0.156		
Me hod	Co□propor ional ha ard model		
Parame er e ima e	Ha ard ra io (HR)		
Poin e ima e	0.8		
Confidence in er al			
le el	95 %		
ide	2- ided		
lo er limi	0.58		
pper limi	1.09		
P- al e Me hod Parame er e ima e Poin e ima e Confidence in er al le el ide lo er limi	= 0.156 Co□propor ional ha ard model Ha ard ra io (HR) 0.8 95 % 2- ided 0.58		

Adverse events

Adverse events information

Timeframe for repor ing ad er e e en :

Appro□ma el 80 da

Ad er e e en repor ing addi ional de crip ion:

In en ion- o- rea (ITT) anal i e compri ed all randomi ed bjec ho igned a alid informed con en , regardle of ac al rea men recei ed.

A e men pe Non- ema ic

Dictionary used

Dic ionar name	MedDRA
Dic ionar er ion	20.1

Reporting groups

-	4
Repor ing gro p i le	Ri aro□aban 10 mg or 7.5 mg

Repor ing gro p de crip ion:

S bjec i h a crea inine clearance (CrCl) a creening grea er han or eq al o (>=) 50 millili er per min e (mL/min) a creening recei ed 10 milligram (mg) ri aro□aban able once dail orall and bjec i h a crea inine clearance a creening from >=30 o le han (<) 50 mL/min a creening recei ed 7.5 mg ri aro□aban able once dail for 45 da .

Repor ing gro p i le Placebo

Repor ing gro p de crip ion:

S bjec recei ed ma ching placebo able once dail for 45 da

Serious adverse events	Ri aro⊡aban 10 mg or 7.5 mg	Placebo	
To al bjec affec ed b erio ad er e e en			
bjec affec ed / e□po ed	475 / 6007 (7.91%)	493 / 6012 (8.20%)	
n mber of dea h (all ca e)	115	126	
n mber of dea h re ling from ad er e e en			
Neopla m benign, malignan and n pecified (incl c and pol p)			
Ac e Le kaemia			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Adenocarcinoma			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 1	0 / 0	
Adenocarcinoma of Colon			

bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Bladder Cancer Rec rren			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Bladder Neopla m			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Brea Cancer			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Brea Neopla m			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Colon Cancer Me a a ic			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 1	0 / 0	
Ga ric Cancer			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 1	0 / 0	
Hepa ic Cancer Me a a ic			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 1	0 / 0	
In a i e D c al Brea Carcinoma			

	_	_
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
L ng Cancer Me a a ic		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	2 / 6012 (0.03%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 2
dea h ca all rela ed o rea men / all	0 / 0	0 / 2
L ng Infil ra ion Malignan		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
L ng Neopla m		
bjec affec ed / e□po ed	2 / 6007 (0.03%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 1
dea h ca all rela ed o rea men / all	0 / 1	0 / 0
L ng Neopla m Malignan		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	5 / 6012 (0.08%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 5
dea h ca all rela ed o rea men / all	0 / 0	0 / 2
Malignan Neopla m of Unkno n Primar Si e		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 1
Malignan Ple ral Eff ion		
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Media in m Neopla m		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Meningioma		

bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Me a a ic Neopla m			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 1	
Non-Hodgkin' L mphoma			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Non-Small Cell L ng Cancer			
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
O arian Cancer			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Pla ma Cell M eloma			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Rec al Cancer			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Rec al Neopla m	I	[
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Rec o igmoid Cancer			

bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Renal Neopla m		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Sq amo Cell Carcinoma of L ng		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Va c lar di order		
Aor ic Di ec ion bjec affec ed / e⊏po ed	0 / 6007 (0 000/)	1 / 6012 /0 020/ \
occ rrence ca all rela ed o	0 / 6007 (0.00%)	1 / 6012 (0.02%)
rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Aor ic S eno i		
bjec affec ed / e□po ed	2 / 6007 (0.03%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Ar erial S eno i		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Di rib i e Shock	ĺ	ĺ
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
H per en ion		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	2 / 6012 (0.03%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 2
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
H per en i e Cri i		

bjec affec ed / e□po ed	0 / 6007 (0.00%)	3 / 6012 (0.05%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0/3	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
H po en ion			
bjec affec ed / e□po ed	5 / 6007 (0.08%)	3 / 6012 (0.05%)	
occ rrence ca all rela ed o rea men / all	0 / 5	0/3	
dea h ca all rela ed o rea men / all	0 / 0	0 / 1	
Peripheral Ar erial Occl i e Di ea e			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Peripheral Ar er Occl ion			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Peripheral Ar er Thrombo i			
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0/3	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	

A henia		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Che Pain		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Dea h		
bjec affec ed / e□po ed	25 / 6007 (0.42%)	30 / 6012 (0.50%)
occ rrence ca all rela ed o rea men / all	1 / 25	0 / 30
dea h ca all rela ed o rea men / all	1 / 25	0 / 30
Fa ig e		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	2 / 6012 (0.03%)
occ rrence ca all rela ed o rea men / all	0 / 1	1 / 2
dea h ca all rela ed o rea men / all	0 / 0	0 / 1
M I iple Organ D f nc ion S ndrome		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	2 / 6012 (0.03%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 2
dea h ca all rela ed o rea men / all	0 / 1	0 / 1
Oedema Peripheral		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Peripheral S elling		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
P re□a		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	3 / 6012 (0.05%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 3
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
S dden Cardiac Dea h		ĺ

1	1	ı	1 1
bjec affec ed / e□po ed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 2	
dea h ca all rela ed o rea men / all	0 / 1	0 / 2	
S emic Inflamma or Re pon e S ndrome			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Imm ne em di order			
Anaph lac ic Reac ion			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Social circ m ance			
Berea emen			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Immobile			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Re pira or , horacic and media inal di order			
Ac e P Imonar Oedema			
bjec affec ed / e□po ed	4 / 6007 (0.07%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 4	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 1	
Ac e Re pira or Fail re			ĺ
bjec affec ed / e⊏po ed	7 / 6007 (0.12%)	9 / 6012 (0.15%)	
occ rrence ca all rela ed o rea men / all	0 / 8	0 / 9	
dea h ca all rela ed o rea men / all	0 / 1	0 / 1	
A hma			

bjec affec ed / e□po ed	8 / 6007 (0.13%)	3 / 6012 (0.05%)
occ rrence ca all rela ed o rea men / all	0 / 10	0 / 3
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Bronchiec a i		
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	2 / 6012 (0.03%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 2
dea h ca all rela ed o rea men / all	0 / 0	0 / 1
Bronchi i Chronic		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Broncho pa m		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	3 / 6012 (0.05%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 3
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Chronic Obrcie Plmonar Dieae		
bjec affec ed / e⊏po ed	81 / 6007 (1.35%)	77 / 6012 (1.28%)
occ rrence ca all rela ed o rea men / all	0 / 88	0 / 87
dea h ca all rela ed o rea men / all	0 / 5	0 / 3
Chronic Re pira or Fail re		
bjec affec ed / e□po ed	4 / 6007 (0.07%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 4	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
D pnoea		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	5 / 6012 (0.08%)
occ rrence ca all rela ed o rea men / all	0 / 3	0 / 5
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
H dro hora□		İ
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
In er i ial L ng Di ea e		ĺ
·	•	•

bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
L p Ple ri			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Pick ickian S ndrome			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 1	0 / 0	
Ple ral Eff ion			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	3 / 6012 (0.05%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 3	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Pne monia A pira ion			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Pne mo hora□	1		
bjec affec ed / e□po ed	3 / 6007 (0.05%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 3	0 / 0	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Pne mo hora□Spon aneo		 	
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
P Imonar Ar erial H per en ion	İ	· 	
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
P Imonar Conge ion		· 	
•	•	•	1

	bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
	occ rrence ca all relaed o	0 / 1	0 / 0
	rea men / all	0 / 1	0 / 0
	dea h ca all rela ed o rea men / all	0 / 0	0 / 0
	P lmonar Fibro i		
	bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
	occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
	dea h ca all rela ed o rea men / all	0 / 0	0 / 0
	P Imonar Ma		
	bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
	occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
	dea h ca all rela ed o rea men / all	0 / 0	0 / 0
	P Imonar Oedema		
	bjec affec ed / e□po ed	1 / 6007 (0.02%)	4 / 6012 (0.07%)
	occ rrence ca all rela ed o rea men / all	0 / 1	0 / 4
	dea h ca all rela ed o rea men / all	0 / 0	0 / 1
	P Imonar Pne ma ocele		
	bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
	occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
	dea h ca all rela ed o rea men / all	0 / 0	0 / 0
	Re pira or Di re		
	bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)
	occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1
	dea h ca all rela ed o rea men / all	0 / 0	0 / 0
	Re pira or Fail re		
	bjec affec ed / e□po ed	9 / 6007 (0.15%)	8 / 6012 (0.13%)
	occ rrence ca all rela ed o rea men / all	0 / 10	0 / 8
	dea h ca all rela ed o rea men / all	0 / 4	0 / 5
Р	chia ric di order An⊡e		
	bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
	occ rrence ca all rela ed o rea men / all	0/0	0/1
	dea h ca all rela ed o rea men / all	0 / 0	0 / 0
	Con er ion Di order		İ
•	,	,	

bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Panic A ack			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Prod c i e			
De ice Di loca ion bjec affec ed / e□po ed	0 / 6007 (0 000/)	1 / 6012 /0 020/)	
	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 2	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
De ice Fail re			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
De ice Occl ion			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
In e iga ion			
A pira ion Bronchial bjec affec ed / e□po ed			
	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Bod Tempera re Increa ed			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Cardiac O p Decrea ed			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
M ocardial Necro i Marker	ĺ		İ

Increa ed			
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Inj r , poi oning and proced ral complica ion			
Acciden al O erdo e			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Cer ical Ver ebral Frac re			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Fall			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Femoral Neck Frac re			
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Fem r Frac re			
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	3 / 6012 (0.05%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 3	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Head Inj r			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 2	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Hip Frac re	Į į	ĺ	İ
bjec affec ed / e□po ed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	

H mer Frac re		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0/0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
In e inal Ana omo i Complica ion		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Lacera ion		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Ligamen R p re		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Lo er Limb Frac re		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
L mbar Ver ebral Frac re		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
M liple Inj rie		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 1
Ner e Inj r		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Proced ral Pne mo hora□		

1	 	
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Rib Frac re		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Sof Ti e Inj r		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Tendon Inj r		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
To□ci o Vario Agen		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Tra maic L ng Inj r		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
T iddler' S ndrome	·	, , , , , , , , , , , , , , , , , , ,
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o		
rea men / all	0/0	0 / 0
Cardiac di order		
Ac e Lef Ven ric lar Fail re		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Angina Pec ori		

bjec affec ed / e□po ed	3 / 6007 (0.05%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 3	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Aor ic Val e Incompe ence bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0/1	0/0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
A rial Fibrilla ion			
bjec affec ed / e□po ed	13 / 6007 (0.22%)	10 / 6012 (0.17%)	
occ rrence ca all rela ed o rea men / all	0 / 13	0 / 10	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
A rial Fl er			
bjec affec ed / e□po ed	3 / 6007 (0.05%)	6 / 6012 (0.10%)	
occ rrence ca all rela ed o rea men / all	0 / 3	0 / 6	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
A rio en ric lar Block Comple e			
bjec affec ed / e□po ed	4 / 6007 (0.07%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 4	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
A rio en ric lar Block Second Degree			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Brad arrh hmia			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Brad cardia			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Cardiac Arre			

bjec affec ed / e□po ed	5 / 6007 (0.08%)	5 / 6012 (0.08%)	
occ rrence ca all rela ed o rea men / all	0 / 5	0 / 5	
dea h ca all rela ed o rea men / all	0 / 5	0 / 4	
Cardiac A hma			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Cardiac Fail re			
bjec affec ed / e□po ed	51 / 6007 (0.85%)	62 / 6012 (1.03%)	
occ rrence ca all rela ed o rea men / all	0 / 53	0 / 69	
dea h ca all rela ed o rea men / all	0 / 5	0 / 8	
Cardiac Fail re Ac e			
bjec affec ed / e⊏po ed	14 / 6007 (0.23%)	14 / 6012 (0.23%)	
occ rrence ca all rela ed o rea men / all	0 / 14	0 / 15	
dea h ca all rela ed o rea men / all	0 / 3	0 / 1	
Cardiac Fail re Chronic			
bjec affec ed / e⊏po ed	13 / 6007 (0.22%)	8 / 6012 (0.13%)	
occ rrence ca all rela ed o rea men / all	0 / 13	0 / 8	
dea h ca all rela ed o rea men / all	0 / 4	0 / 1	
Cardiac Fail re Conge i e			
bjec affec ed / e⊏po ed	24 / 6007 (0.40%)	25 / 6012 (0.42%)	
occ rrence ca all rela ed o rea men / all	0 / 27	0 / 26	
dea h ca all rela ed o rea men / all	0 / 5	0 / 5	
Cardiac Val e Di ea e			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Cardiac Ven ric lar Thrombo i			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Cardio-Re pira or Arre			

bjec affec ed / e□po ed	5 / 6007 (0.08%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 5	0 / 2	
dea h ca all rela ed o rea men / all	0 / 5	0 / 2	
Cardiogenic Shock			
bjec affec ed / e□po ed	4 / 6007 (0.07%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 4	0 / 2	
dea h ca all rela ed o rea men / all	0/3	0 / 2	
Cardiom opa h			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 1	
dea h ca all rela ed o rea men / all	0 / 1	0 / 1	
Cardiom opa h Ac e			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 1	
Cardiop Imonar Fail re			
bjec affec ed / e□po ed	4 / 6007 (0.07%)	4 / 6012 (0.07%)	
occ rrence ca all rela ed o rea men / all	0 / 4	0 / 4	
dea h ca all rela ed o rea men / all	0 / 4	0 / 4	
Conge i e Cardiom opa h			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Cor P Imonale			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Coronar Ar er Di ea e			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Coronar Ar er S eno i			

bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Dia olic D f nc ion			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
H per en i e Hear Di ea e			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 1	
In er en ric lar Sep mR p re			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
I chaemic Cardiom opa h			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Lef Ven ric lar Fail re			
bjec affec ed / e□po ed	4 / 6007 (0.07%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 4	0 / 2	
dea h ca all rela ed o rea men / all	0 / 2	0 / 0	
Mi ral Val e Incompe ence			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
M ocardial Fibro i			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
M ocardial I chaemia			

bjec affec ed / e□po ed occ rrence ca all rela ed orea men / all dea h ca all rela ed orea men / al				
rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Nodal Rh hm bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o	bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
rea men / all		0 / 1	0 / 1	
bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Nodal Rh hm bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Sin Brad cardia bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all Sin Node D f nc ion bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all Sin Node D f nc ion bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Spra en ric lar Tach cardia bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all		0 / 1	0 / 1	
occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all 0 / 0 0 / 1 0 / 1 0 / 0 0 / 1 0 / 0 0 / 1 0 / 0 0 / 1 0 / 0 0 /	M ocardi i			
rea men / all dea h ca all rela ed o rea men / all Nodal Rh hm bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all	bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
rea men / all		0 / 0	0 / 1	
bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all		0 / 0	0 / 1	
occ rrence ca all rela ed o rea men / all dea h	Nodal Rh hm			
rea men / all dea h ca all rela ed o rea men / all Dericardi i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all	bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
Pericardi i D/O D/O D/O D/O		0 / 1	0 / 0	
bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all lea h ca all rela ed o rea men / all		0 / 0	0 / 0	
occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all rela ed o rea men / all occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o occ rrence ca all rela ed o occ rea men / all occ rence ca all rela ed occ rea men / all occ rence ca all rela ed occ rea men / all occ rence ca all rela ed occ rea men / all occ rence ca all rela ed occ rea men / all occ rence ca all rela ed occ rea men / all occ rence ca all rela ed occ rea m	Pericardi i			
rea men / all dea h ca all rela ed o rea men / all Righ Ven ric lar Fail re bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Sin Brad cardia bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Sin Node D f nc ion bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all S pra en ric lar Tach cardia bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all	bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
Righ Ven ric lar Fail re bjec affec ed / e□po ed 1 / 6007 (0.02%) 0 / 6012 (0.00%) Occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / a		0 / 1	0 / 2	
bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all		0 / 0	0 / 0	
occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all	Righ Ven ric lar Fail re			
rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Sin Brad cardia bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all S pra en ric lar Tach cardia bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all	bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
Sin Brad cardia bjec affec ed / e□po ed 1 / 6007 (0.02%) 1 / 6012 (0.02%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea		0 / 1	0 / 0	
bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Sin Node D f nc ion bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all		0 / 0	0 / 0	
occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all	Sin Brad cardia			
rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Sin Node D f nc ion bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all S pra en ric lar Tach cardia bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all	bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
rea men / all 0 / 0 0 / 0 Sin Node D f nc ion bjec affec ed / e□po ed 2 / 6007 (0.03%) 1 / 6012 (0.02%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed 0 0 / 0 S pra en ric lar Tach cardia bjec affec ed / e□po ed 0 0 / 1 occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all		0 / 1	0 / 1	
bjec affec ed / e□po ed 2 / 6007 (0.03%) 1 / 6012 (0.02%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all S pra en ric lar Tach cardia bjec affec ed / e□po ed 1 / 6007 (0.02%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all		0 / 0	0 / 0	
bjec affec ed / e□po ed 2 / 6007 (0.03%) 1 / 6012 (0.02%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all S pra en ric lar Tach cardia bjec affec ed / e□po ed 1 / 6007 (0.02%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all	Sin Node D f nc ion			
rea men / all dea h ca all rela ed o rea men / all S pra en ric lar Tach cardia bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all o / 0 0 / 0 3 / 6012 (0.05%) 0 / 4 0 / 4		2 / 6007 (0.03%)	1 / 6012 (0.02%)	
dea h ca all rela ed o rea men / all 0 / 0 0 / 0 S pra en ric lar Tach cardia bjec affec ed / e□po ed 1 / 6007 (0.02%) 3 / 6012 (0.05%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all 0 / 0 0 / 0		0 / 2	0 / 1	
bjec affec ed / e□po ed	dea h ca all rela ed o	0 / 0	0 / 0	
bjec affec ed / e□po ed	S pra en ric lar Tach cardia			
rea men / all dea h ca all rela ed o rea men / all 0 / 0 0 / 0	·	1 / 6007 (0.02%)	3 / 6012 (0.05%)	
rea men / all 0 / 0 0 / 0		0 / 1	0 / 4	
Tach cardia		0 / 0	0 / 0	
	Tach cardia		- 	

	_	_	
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Epilep			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Facial Paral i			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Headache			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
H pogl caemic Coma			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 1	0 / 0	
H pogl caemic Encephalopa h			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
I chaemic S roke			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
L mbar Radic lopa h			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Or ho a ic In olerance			
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bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Pre ncope			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Scia ica			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Sei re			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
S ncope			
bjec affec ed / e□po ed	6 / 6007 (0.10%)	5 / 6012 (0.08%)	
occ rrence ca all rela ed o rea men / all	0 / 7	0 / 5	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Va c lar Encephalopa h			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Ver ebral Ar er S eno i			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Ver igo CNS Origin			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Blood and I mpha ic em di order Anaemia			

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bjec affec ed / e□po ed	3 / 6007 (0.05%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	1 / 3	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
A oimm ne Haemol ic Anaemia		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Haemorrhagic Anaemia		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	1 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Iron Deficienc Anaemia		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Thromboc openia		
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Ear and lab rin h di order		
Mo ion Sickne bjec affec ed / e□po ed	0 / 600= /0	
	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Ver igo		
bjec affec ed / e□po ed	2 / 6007 (0.03%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Ver igo Po i ional	ĺ	ĺ
bjec affec ed / e⊑po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
E e di order		
	•	•

Conj nc i al Oedema	1		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0/0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
E⊡oph halmo			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Re inal Ar er Occl ion			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Ga roin e inal di order			
Abdominal Incarcera ed Hernia			
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Abdominal Pain			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Ac e Abdomen			
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
A ci e			
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Chronic Ga ri i			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Coli i I chaemic			

bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Diarrhoea			
bjec affec ed / e□po ed	3 / 6007 (0.05%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 3	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
D odenal Ulcer			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
D pep ia			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
D phagia			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
En erocoli i			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 3	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
En erocoli i Haemorrhagic			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
En ero e ical Fi la			ĺ
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0/0	
Ga ric Pol p			

bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Ga ric Ulcer			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Gari i			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Ga rooe ophageal Refl □Di ea e			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Haemorrhoid			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Ile			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 1	
Ing inal Hernia			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
In e inal I chaemia]		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Pancrea ic Di order			

bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Pancrea i i			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Pancrea i i Ac e			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Pep ic Ulcer			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Pep ic Ulcer Haemorrhage			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Pep ic Ulcer Perfora ion			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Rec al Pol p]		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Small In e inal Obrcion			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
S bile	· 	- 	-
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1	1	,	1
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Vomi ing			
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Hepa obiliar di order			
Bile D c Ob r c ion			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Bile D c S one			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Cholec i i			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	3 / 6012 (0.05%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 3	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Cholec i i Ac e			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Cholec i i Chronic			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Choleli hia i			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Hepa ic Le ion		· 	-
1 '	1	1	I

occ rrence ca all rela ed o rea men / all 0 / 0 0 / 1 dea h ca all rela ed o rea men / all 0 / 0 0 / 0 Skin and bc aneo i e di order Angioedema	
dea h ca all rela ed o rea men / all 0 / 0 0 / 0 Skin and bc aneo i e di order Angioedema bjec affec ed / e□po ed 2 / 6007 (0.03%) 0 / 6012 (0.00%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all 0 / 0 0 / 0 Derma i i Allergic bjec affec ed / e□po ed 0 / 6007 (0.00%) 1 / 6012 (0.02%)	
Angioedema bjec affec ed / e□po ed 0 / 6007 (0.03%) 0 / 6012 (0.00%) 0 / 0 0 / 0 0 / 0 0 / 0 Derma i i Allergic bjec affec ed / e□po ed 0 / 6007 (0.00%) 1 / 6012 (0.00%) 1 / 6012 (0.00%)	
bjec affec ed / e□po ed 2 / 6007 (0.03%) 0 / 6012 (0.00%) occ rrence ca all rela ed o	
occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all	
rea men / all dea h ca all rela ed o rea men / all Derma i i Allergic bjec affec ed / e□po ed 0 / 6007 (0.00%) 1 / 6012 (0.02%)	
rea men / all 0 / 0 0 / 0 Derma i i Allergic bjec affec ed / e□po ed 0 / 6007 (0.00%) 1 / 6012 (0.02%)	
bjec affec ed / e□po ed 0 / 6007 (0.00%) 1 / 6012 (0.02%)	
0, 000, (0,00,0)	
occ rrence ca all rela ed o 0 / 0 rea men / all	
dea h ca all rela ed o rea men / all 0 / 0 0 / 0	
Diabe ic Foo	
bjec affec ed / e□po ed 2 / 6007 (0.03%) 1 / 6012 (0.02%)	
occ rrence ca all rela ed o 0 / 2 0 / 1 rea men / all	
dea h ca all rela ed o rea men / all 0 / 0 0 / 0	
Ra h	
bjec affec ed / e□po ed 0 / 6007 (0.00%) 1 / 6012 (0.02%)	
occ rrence ca all rela ed o 0 / 0 1 / 1 rea men / all	
dea h ca all rela ed o rea men / all 0 / 0 0 / 0	
Skin Necro i	
bjec affec ed / e□po ed 0 / 6007 (0.00%) 1 / 6012 (0.02%)	
occ rrence ca all rela ed o 0 / 0 0 / 1 rea men / all	
dea h ca all rela ed o rea men / all 0 / 0 0 / 0	
Skin Ulcer	
bjec affec ed / e□po ed 1 / 6007 (0.02%) 2 / 6012 (0.03%)	
occ rrence ca all rela ed o 0 / 1 0 / 2 rea men / all	
dea h ca all rela ed o rea men / all 0 / 0 0 / 0	
Va c li ic Ulcer	i
bjec affec ed / e□po ed 0 / 6007 (0.00%) 1 / 6012 (0.02%)	
occ rrence ca all rela ed o 0 / 0 0 / 1 rea men / all	
dea h ca all rela ed o rea men / all 0 / 0 0 / 0	
Renal and rinar di order	

Ac e Kidne Inj r		
bjec affec ed / e□po ed	7 / 6007 (0.12%)	8 / 6012 (0.13%)
occ rrence ca all rela ed o rea men / all	0 / 8	0 / 8
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Chronic Kidne Di ea e		
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	2 / 6012 (0.03%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 2
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Ke on ria		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0/0	0 / 0
Nephri i		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Nephroli hia i		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Nephro ic S ndrome		
bjec affec ed / e□po ed	2 / 6007 (0.03%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 3	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Renal Fail re		
bjec affec ed / e□po ed	3 / 6007 (0.05%)	3 / 6012 (0.05%)
occ rrence ca all rela ed o rea men / all	0 / 3	0/3
dea h ca all rela ed o rea men / all	0 / 0	0 / 1
Renal Impairmen	ļ	
bjec affec ed / e□po ed	1 / 6007 (0.02%)	2 / 6012 (0.03%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 2
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Urinar Re en ion		

bjec affec ed / e⊏po ed	3 / 6007 (0.05%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 3	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
M c lo kele al and connec i e i e di order			
Ar hri i			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Back Pain			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Brii			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Compar men S ndrome			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
M c lo kele al Che Pain			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
O eoar hri i			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Rhe ma oid Ar hri i			-
bjec affec ed / e□po ed	1 / 6007 (0.02%)	3 / 6012 (0.05%)	
occ rrence ca all rela ed o rea men / all	0/1	0/3	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Ver ebral Le ion			

occ rrence ca all rela ed o rea men / all dea h ca all rela ed o all rela ed o all rela ed o all rela ed o all rela ed o all rela ed o all rela ed o all rela	bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Infec ion and infe a ion Abdominal Ab ce bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all				
Trea men / all		0,0	0,1	
Abdominal Ab ce bjec affec ed / elpo ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Ab ce Limb bjec affec ed / elpo ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all		0 / 0	0 / 0	
bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela	Infec ion and infe a ion			
occ rrence ca all rela ed o rea men / all dea h				
rea men / all dea h ca all rela ed o rea men / all Ab ce Limb bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men	bjec affec ed / e⊑po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
Ab ce Limb bjec affeced / e□po ed 0 / 6007 (0.00%) 1 / 6012 (0.02%) 0 / 6007 (0.00%) 1 / 6012 (0.02%) 0 / 6007 (0.00%) 0 / 1		0 / 0	0 / 1	
bjec affec ed / e□po ed 0 / 6007 (0.00%) 1 / 6012 (0.02%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o o o o o o o o o		0 / 0	0 / 0	
occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Anal Ab ce bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all Brea Cell li i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Bronchi i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Cell li i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all Cell li i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all	Ab ce Limb			
rea men / all dea h ca all rela ed o rea men / all Anal Ab ce bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Brea Cell li i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Bronchi i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Bronchop Imonar A pergillo i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Cell li i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all Cell li i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all	bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
Rane All O O O O		0 / 0	0 / 1	
bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all Brea Cell li i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Bronchop Imonar A pergillo i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all		0 / 0	0 / 0	
occ rrence ca all rela ed o rea men / all dea h ca all rela ed o	Anal Ab ce			
rea men / all dea h ca all rela ed o rea men / all Brea Cell li i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Bronchi i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Bronchop Imonar A pergillo i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all ldea h ca all rela ed o rea men / all ldea h ca all rela ed o rea men / all ldea h ca all rela ed o rea men / all ldea h ca all rela ed o rea men / all ldea h ca all rela ed o rea men / all ldea h ca all rela ed o rea men / all ldea h ca all rela ed o rea men / all ldea h ca all rela ed o rea men / all ldea h ca all rela ed o rea men / all ldea h ca all rela ed o rea men / all ldea h ca all rela ed o rea men / all	bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
Prea men / all 0 / 0 0 / 0				
bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all		0 / 0	0 / 0	
occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all	Brea Cell li i			
rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o	bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
rea men / all 0 / 0 0 / 0 Bronchi i bjec affec ed / e□po ed 5 / 6007 (0.08%) 3 / 6012 (0.05%) occ rrence ca all rela ed o rea men / all 0 / 5 0 / 3 dea h ca all rela ed o rea men / all 0 / 0 0 / 0 Bronchop Imonar A pergillo i bjec affec ed / e□po ed 0 / 6007 (0.00%) 1 / 6012 (0.02%) occ rrence ca all rela ed o rea men / all 0 / 0 0 / 1 dea h ca all rela ed o rea men / all 0 / 0 0 / 0 Cell li i bjec affec ed / e□po ed rea men / all 11 / 6007 (0.18%) 10 / 6012 (0.17%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o 0 / 12 0 / 12		0 / 0	0 / 1	
bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all dea h ca all rela ed o orea men / all occ rrence ca all rela ed o orea men / all dea h ca all rela ed o		0 / 0	0 / 0	
occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o orea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all bjec affec ed / e□po ed occ rrence ca all rela ed o orea men / all occ rrence ca all rela ed orea men / all occ rrence ca all rela ed orea men / all occ rrence ca all rela ed orea men / all dea h ca all rela ed orea men / all occ rrence ca all rela ed orea men / all occ rrence ca all rela ed orea men / all occ rrence ca all rela ed orea men / all occ rrence ca all rela ed orea men / all	Bronchi i			
rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / epo ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all dea h ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all bjec affec ed / epo ed of 0 0 0 0 1 / 6012 (0.02%) occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all dea h ca all rela ed o	bjec affec ed / e⊏po ed	5 / 6007 (0.08%)	3 / 6012 (0.05%)	
rea men / all 0 / 0 0 / 0 Bronchop Imonar A pergillo i bjec affec ed / e□po ed 0 / 6007 (0.00%) 1 / 6012 (0.02%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed 0 / 0 0 / 0 Cell li i bjec affec ed / e□po ed 11 / 6007 (0.18%) 10 / 6012 (0.17%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o		0 / 5	0/3	
bjec affec ed / e□po ed 0 / 6007 (0.00%) 1 / 6012 (0.02%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all bjec affec ed / e□po ed 0 / 1 / 6007 (0.00%) 0 / 1 Cell li i bjec affec ed / e□po ed 11 / 6007 (0.18%) 10 / 6012 (0.17%) occ rrence ca all rela ed o rea men / all dea h ca all rela ed o		0 / 0	0 / 0	
occ rrence ca all rela ed o rea men / all dea h ca all rela ed o rea men / all Cell li i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all occ rrence ca all rela ed o rea men / all dea h ca all rela ed o	Bronchop Imonar A pergillo i			
rea men / all dea h ca all rela ed o rea men / all Cell li i bjec affec ed / e□po ed occ rrence ca all rela ed o rea men / all dea h ca all rela ed o	bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
dea h ca all rela ed o rea men / all $0/0$ $0/0$ Cell li i bjec affec ed / e \Box po ed $11/6007 (0.18\%)$ $10/6012 (0.17\%)$ occ rrence ca all rela ed o rea men / all dea h ca all rela ed o				
bjec affec ed / e \square po ed $11 / 6007 (0.18\%)$ $10 / 6012 (0.17\%)$ occ rrence ca all rela ed o rea men / all dea h ca all rela ed o	dea h ca all rela ed o	0 / 0	0/0	
bjec affec ed / e \square po ed $11 / 6007 (0.18\%)$ $10 / 6012 (0.17\%)$ occ rrence ca all rela ed o rea men / all dea h ca all rela ed o	Cell li i		İ	
occ rrence ca all rela ed o 0 / 12 0 / 12 rea men / all dea h ca all rela ed o		11 / 6007 (0.18%)	10 / 6012 (0.17%)	
dea h ca all rela ed o		-		
		0 / 0	0 / 0	
Clo ridi m Difficile Coli i	! !		i	

bjec affec ed / e□po ed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Clo ridi m Difficile Infec ion			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 1	
Diabe ic Foo Infec ion			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Di eric li i			
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Emp ema			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Endocardi i			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 2	
dea h ca all rela ed o rea men / all	0/0	0 / 1	
Endocardi i Bac erial			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0/0	0 / 0	
Endoph halmi i			
bjec affec ed / e⊏þo ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Endo o□c Shock			
·	-	-	•

bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Er ipela			
bjec affec ed / e⊡po ed	3 / 6007 (0.05%)	4 / 6012 (0.07%)	
occ rrence ca all rela ed o rea men / all	0 / 3	0 / 4	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
F ngal Oe ophagi i			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
F ngal Skin Infec ion			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Ga roen eri i			
bjec affec ed / e⊏po ed	2 / 6007 (0.03%)	3 / 6012 (0.05%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 4	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Ga roen eri i Salmonella			
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Ga roen eri i Viral			
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Haema oma Infec ion			
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 1	
Helicobac er Infec ion			

bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0/0	
In er er ebral Di ci i			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Lo er Re pira or Trac Infec ion			
bjec affec ed / e□po ed 	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 1	
dea h ca all rela ed o rea men / all	0 / 1	0 / 0	
L ng Ab ce			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
L ng Infec ion			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Media ini i			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
O eom eli i			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Paro i i			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o	0.40	0 / 1	
rea men / all	0 / 0	, -	
rea men / all dea h ca all rela ed o rea men / all	0 / 0	0/0	

bjec affec ed / e□po ed	58 / 6007 (0.97%)	48 / 6012 (0.80%)	
occ rrence ca all rela ed o rea men / all	0 / 59	0 / 49	
dea h ca all rela ed o rea men / all	0 / 7	0 / 5	
Pne monia Bac erial			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	4 / 6012 (0.07%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 4	
dea h ca all rela ed o rea men / all	0 / 0	0 / 1	
Pne monia P e domonal			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Pne monia S aph lococcal			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Po opera i e Wo nd Infec ion			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
P Imonar Sep i			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
P Imonar T berc lo i			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
P elonephri i	İ		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0/0	0/2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
P elonephri i Chronic		· '	
•	I .	1	

bjec affec ed / e□po ed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 1	
dea h ca all rela ed o rea men / all	0 / 1	0 / 0	
P oderma			
bjec affec ed / e⊏po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Re pira or Trac Infec ion			
bjec affec ed / e□po ed	3 / 6007 (0.05%)	3 / 6012 (0.05%)	
occ rrence ca all rela ed o rea men / all	0 / 3	0 / 3	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Sep i			
bjec affec ed / e⊏po ed	4 / 6007 (0.07%)	3 / 6012 (0.05%)	
occ rrence ca all rela ed o rea men / all	0 / 5	0 / 3	
dea h ca all rela ed o rea men / all	0 / 3	0 / 2	
Sep ic Shock			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	4 / 6012 (0.07%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 4	
dea h ca all rela ed o rea men / all	0 / 0	0 / 4	
Sin i i			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Sof Ti e Infec ion]	
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0/0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Splenic Ab ce			!
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
S aph lococcal Bac eraemia	İ		

bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
S aph lococcal Sep i			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
S emic Infec ion			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 1	0 / 0	
Tracheobronchi i			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
T berc lo Ple ri			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Upper Re pira or Trac Infec ion			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Urinar Trac Infec ion			
bjec affec ed / e□po ed	11 / 6007 (0.18%)	11 / 6012 (0.18%)	
occ rrence ca all rela ed o rea men / all	0 / 11	0 / 11	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Urinar Trac Infec ion Bac erial			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Uro ep i			
I '	I .	1	•

bjec affec ed / e□po ed	0 / 6007 (0.00%)	4 / 6012 (0.07%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 4
dea h ca all rela ed o rea men / all	0 / 0	0 / 2
Viral Infec ion		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Wo nd Infec ion		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Wo nd Infec ion S aph lococcal		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Me aboli m and n ri ion di order		
Deh dra ion		
bjec affec ed / e□po ed	2 / 6007 (0.03%)	3 / 6012 (0.05%)
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 4
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Diabe e Melli		
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Diabe e Melli Inadeq a e Con rol		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Diabe ic Me abolic Decompen a ion		
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Fail re o Thri e		

bjec affec ed / e□po ed	1 / (007 /0 029/)	0 / 6013 /0 000/	
	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0/0	
Fl id O erload			
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
Go			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 2	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
H pergl caemia			
bjec affec ed / e□po ed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
H perkalaemia			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
H poalb minaemia			
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occ rrence ca all rela ed o rea men / all	0 / 2	0 / 0	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
H pocalcaemia		ĺ	
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occ rrence ca all rela ed o rea men / all	0/0	0/1	
dea h ca all rela ed o rea men / all	0 / 0	0/0	
H pogl caemia	j		
bjec affec ed / e□po ed	3 / 6007 (0.05%)	5 / 6012 (0.08%)	
occ rrence ca all rela ed o rea men / all	0/3	0 / 5	
dea h ca all rela ed o rea men / all	0 / 0	0 / 0	
rea men / an	0,0		

bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
H pona raemia		
bjec affec ed / e⊏po ed	1 / 6007 (0.02%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
O er eigh		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
T pe 2 Diabe e Melli		
bjec affec ed / e□po ed	0 / 6007 (0.00%)	1 / 6012 (0.02%)
occ rrence ca all rela ed o rea men / all	0 / 0	0 / 1
dea h ca all rela ed o rea men / all	0 / 0	0 / 0
Vi amin B12 Deficienc		
bjec affec ed / e□po ed	1 / 6007 (0.02%)	0 / 6012 (0.00%)
occ rrence ca all rela ed o rea men / all	0 / 1	0 / 0
dea h ca all rela ed o rea men / all	0 / 0	0 / 0

Freq enc hre hold for repor ing non-erio ad er e e en : 1 %

Non-serious adverse events	Ri aro□aban 10 mg or 7.5 mg	Placebo	
To al bjec affec ed b non- erio ad er e e en			
bjec affec ed / e□po ed	250 / 6007 (4.16%)	280 / 6012 (4.66%)	
Va c lar di order			
H per en ion			
bjec affec ed / e□po ed	75 / 6007 (1.25%)	93 / 6012 (1.55%)	
occ rrence (all)	81	101	
Ner o em di order			
Headache			
bjec affec ed / e□po ed	114 / 6007 (1.90%)	147 / 6012 (2.45%)	
occ rrence (all)	137	174	
Ga roin e inal di order			

Diarrhoea			
bjec affec ed / e□po ed	69 / 6007 (1.15%)	52 / 6012 (0.86%)	
occ rrence (all)	80	53	

More information

Substantial protocol amendments (globally)

Were here an global b an ial amendmen o he pro ocol? Ye

Date	Amendment
15 J ne 2015	The o erall rea on for amendmen INT-5 a o modif d proced re , clarif eligibili cri eria (incl ding he ri k core cri erion), and o add bjec raining ma erial .
19 J ne 2015	The o erall rea on for amendmen INT-6 a o clarif pre cribed ma\(\sim m\) m dail do e of hromboproph lac ic agen d ring inde\(\sim ho\) pi ali a ion and o clarif capping of bgro p i h cer ain ba eline charac eri ic or b geographic region or co n r d ring enrollmen .
31 March 2017	The o erall rea on for amendmen INT-7 a o increa e he ma□m m n mber of bjec allo ed o be enrolled d e o a lo er han e□pec ed blinded pooled e en ra e in hi e en dri en d .

No e:

Interruptions (globally)

Were here an global in err p ion o he rial? No

Limitations and caveats

None repor ed