Clinical trial results:
HORIZON: A Phase II, open-label, outcomes-assessor masked, multicentre,
randomized, controlled study to evaluate the safety and efficacy of two doses of GT005
administered as a single subretinal injection in subjects with geographic atrophy secondary to
dry age-related macular degeneration.

Summary

EudraCT number	2020-002431-30
Trial protocol	GB DE FR IE
Global end of trial date	10 June 2024

Results information

Result version number	v1 (current)
This version publication date	28 March 2025
First version publication date	28 March 2025

Trial information

Trial identification

Sponsor protocol code	GT005-03

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04566445
WHO universal trial number (UTN)	-
Other trial identifiers	Sponsor ID II: CPPY988A12201

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Novartis Campus, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 June 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 June 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the effect of GT005 vs untreated control on the progression of GA in subjects with GA due to AMD

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.nov for complete trial results.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 September 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 12
Country: Number of subjects enrolled	France: 7
Country: Number of subjects enrolled	Germany: 21
Country: Number of subjects enrolled	United Kingdom: 21
Country: Number of subjects enrolled	Poland: 5
Country: Number of subjects enrolled	Spain: 12
Country: Number of subjects enrolled	United States: 177
Worldwide total number of subjects	255
EEA total number of subjects	45

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	10
From 65 to 84 years	201
85 years and over	44

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects were enrolled at 53 centers in 7 countries: 37 centers in the United States, 2 centers in France, 4 centers in Germany, 1 center in Poland, 3 centers in Spain, 4 centers in the United Kingdom, and 2 centers in Australia. A total of 255 subjects were enrolled into the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	GT005 Medium dose [5E10 vg]

Arm description:

GT005 Medium dose [5E10 vg]

Arm type	Experimental
Investigational medicinal product name	GT005
Investigational medicinal product code	PPY988
Other name	PPY988
Pharmaceutical forms	Solution for injection
Routes of administration	Ophthalmic use

Dosage and administration details:

single time subretinal injection of GT005 [5E10 vg]

Arm title	GT005 High dose [2E11 vg]

Arm description:

GT005 High dose [2E11 vg]

Arm type	Experimental
Investigational medicinal product name	GT005
Investigational medicinal product code	PPY988
Other name	PPY988
Pharmaceutical forms	Solution for injection
Routes of administration	Ophthalmic use

Dosage and administration details:

single time subretinal injection of GT005 [2E11 vg]

Arm title	Untreated control

Arm description:

Untreated control

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	GT005 Medium dose [5E10 vg]	GT005 High dose [2E11 vg]	Untreated control
Started	87	86	82
Completed	54	51	35
Not completed	33	35	47
Adverse event, serious fatal	4	1	1
Consent withdrawn by subject	12	14	13
Adverse event, non-fatal	1	1	-
Randomized but not treated due to AE	2	1	-
Study terminated by sponsor	11	17	32
Lost to follow-up	3	1	1

Baseline characteristics

Reporting groups	
Reporting group title	GT005 Medium dose [5E10 vg]
Reporting group description: GT005 Medium dose [5E10 vg]	
Reporting group title	GT005 High dose [2E11 vg]
Reporting group description: GT005 High dose [2E11 vg]	
Reporting group title	Untreated control
Reporting group description: Untreated control	

Reporting group values	GT005 Medium dose [5E10 vg]	GT005 High dose [2E11 vg]	Untreated control
Number of subjects	87	86	82
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	6	3	1
From 65-84 years	69	66	66
85 years and over	12	17	15
Age Continuous Units: Years			
arithmetic mean	77.6	77.6	77.8
standard deviation	± 7.33	± 7.60	± 6.83
Sex: Female, Male Units: Participants			
Female	52	61	53
Male	35	25	29
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	87	80	80
More than one race	0	0	0
Unknown or Not Reported	0	5	2

Reporting group values	Total		
Number of subjects	255		

Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	10		
From 65-84 years	201		
85 years and over	44		
Age Continuous Units: Years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: Participants			
Female	166		
Male	89		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	1		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	0		
White	247		
More than one race	0		
Unknown or Not Reported	7		

End points

End points reporting groups	
Reporting group title	GT005 Medium dose [5E10 vg]
Reporting group description: GT005 Medium dose [5E10 vg]	
Reporting group title	GT005 High dose [2E11 vg]
Reporting group description: GT005 High dose [2E11 vg]	
Reporting group title	Untreated control
Reporting group description: Untreated control	

Primary: The change from baseline to Week 72 in geographic atrophy (GA)	
End point title	The change from baseline to Week 72 in geographic atrophy (GA)
End point description: GA area as measured by fundus autofluorescence (FAF)	
End point type	Primary
End point timeframe: Baseline, Weeks 12, 24, 36, 48 and 72	

End point values	GT005 Medium dose [5E10 vg]	GT005 High dose [2E11 vg]	Untreated control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	75	75	72	
Units: mm2				
least squares mean (standard error)				
Week 12 (n=75,71,72)	0.730 (± 0.0625)	0.752 (± 0.0634)	0.667 (± 0.0647)	
Week 24 (72,75,71)	1.151 (± 0.0833)	1.260 (± 0.0831)	1.054 (± 0.0860)	
Week 36 (n=66,66,71)	1.728 (± 0.1488)	1.955 (± 0.1503)	1.531 (± 0.1528)	
Week 48 (n=64,68,65)	2.098 (± 0.1841)	2.535 (± 0.1853)	2.047 (± 0.1896)	
Week 72 n=56,51,54)	3.225 (± 0.2337)	3.421 (± 0.2369)	2.919 (± 0.2412)	

Statistical analyses

Statistical analysis title	GT005 Medium dose [5E10 vg] v Untreated control
Statistical analysis description: Week 12	
Comparison groups	GT005 Medium dose [5E10 vg] v Untreated control

Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.062
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.087
upper limit	0.211
Variability estimate	Standard error of the mean
Dispersion value	0.0901

Statistical analysis title	GT005 High dose [2E11 vg] v Untreated control
Statistical analysis description:	
Week 12	
Comparison groups	GT005 High dose [2E11 vg] v Untreated control
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.084
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.066
upper limit	0.234
Variability estimate	Standard error of the mean
Dispersion value	0.091

Statistical analysis title	GT005 Medium dose [5E10 vg] v Untreated control
Statistical analysis description:	
Week 24	
Comparison groups	GT005 Medium dose [5E10 vg] v Untreated control
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.096

Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.102
upper limit	0.294
Variability estimate	Standard error of the mean
Dispersion value	0.1198

Statistical analysis title	GT005 High dose [2E11 vg] v Untreated control
Statistical analysis description: Week 24	
Comparison groups	GT005 High dose [2E11 vg] v Untreated control
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.205
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.007
upper limit	0.404
Variability estimate	Standard error of the mean
Dispersion value	0.12

Statistical analysis title	GT005 Medium dose [5E10 vg] v Untreated control
Statistical analysis description: Week 36	
Comparison groups	GT005 Medium dose [5E10 vg] v Untreated control
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.197
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.155
upper limit	0.55
Variability estimate	Standard error of the mean
Dispersion value	0.2135

Statistical analysis title	GT005 High dose [2E11 vg] v Untreated control
Statistical analysis description: Week 36	
Comparison groups	GT005 High dose [2E11 vg] v Untreated control
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.423
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.068
upper limit	0.779
Variability estimate	Standard error of the mean
Dispersion value	0.2152

Statistical analysis title	GT005 Medium dose [5E10 vg] v Untreated control
Statistical analysis description: Week 48	
Comparison groups	GT005 Medium dose [5E10 vg] v Untreated control
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.052
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.385
upper limit	0.489
Variability estimate	Standard error of the mean
Dispersion value	0.2644

Statistical analysis title	GT005 High dose [2E11 vg] v Untreated control
Statistical analysis description: Week 48	
Comparison groups	GT005 High dose [2E11 vg] v Untreated control

Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.488
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.049
upper limit	0.928
Variability estimate	Standard error of the mean
Dispersion value	0.2662

Statistical analysis title	GT005 Medium dose [5E10 vg] v Untreated control
Statistical analysis description: Week 72	
Comparison groups	GT005 Medium dose [5E10 vg] v Untreated control
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.307
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.248
upper limit	0.862
Variability estimate	Standard error of the mean
Dispersion value	0.3361

Statistical analysis title	GT005 High dose [2E11 vg] v Untreated control
Statistical analysis description: Week 72	
Comparison groups	GT005 High dose [2E11 vg] v Untreated control
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.503

Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.058
upper limit	1.063
Variability estimate	Standard error of the mean
Dispersion value	0.3392

Secondary: The change from baseline at Week 96 in geographic atrophy (GA)

End point title	The change from baseline at Week 96 in geographic atrophy (GA)
End point description: GA area as measured by fundus autofluorescence (FAF)	
End point type	Secondary
End point timeframe: Baseline, Week 96	

End point values	GT005 Medium dose [5E10 vg]	GT005 High dose [2E11 vg]	Untreated control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	39	32	
Units: mm2				
least squares mean (standard error)	4.414 (± 0.3109)	4.607 (± 0.3167)	3.769 (± 0.3286)	

Statistical analyses

Statistical analysis title	GT005 High dose [2E11 vg] v Untreated control
Statistical analysis description: Week 96	
Comparison groups	GT005 High dose [2E11 vg] v Untreated control
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.838
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.081
upper limit	1.594
Variability estimate	Standard error of the mean
Dispersion value	0.4577

Statistical analysis title	GT005 Medium dose [5E10 vg] v Untreated control
Statistical analysis description: Week 96	
Comparison groups	GT005 Medium dose [5E10 vg] v Untreated control
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.645
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.103
upper limit	1.393
Variability estimate	Standard error of the mean
Dispersion value	0.4527

Secondary: Summary of Adverse Events

End point title	Summary of Adverse Events

End point description:

An adverse event (AE) is any untoward medical occurrence (e.g. any unfavorable and unintended sign [including abnormal laboratory findings], symptom or disease) in a subject or clinical investigation subject.

A TEAE is defined as any AE that develops after randomization or any AE already present that worsens following randomization. The primary summaries of AEs are based on TEAEs.

AE = adverse event
SAE = serious adverse event
Rel = related
Trt = study treatment
Proc. = procedure
Disc. = discontinuation
AESI = AE of special interest
Surg. = surgical

End point type	Secondary

End point timeframe:

Adverse events are reported from randomization to the end of study, at Week 96, up to a maximum timeframe of approximately 96 weeks.

End point values	GT005 Medium dose [5E10 vg]	GT005 High dose [2E11 vg]	Untreated control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	87	86	82	
Units: Participants				
Subjects with >= 1 ocular AE for the study eye	66	65	15	
Subjects with >= 1 ocular AE for the fellow eye	32	35	14	
Subjects with >= 1 non-ocular AE	63	59	44	
n with >= 1 ocular AE rel. to trt. - study eye	13	21	0	
n with >= 1 non-ocular AE related to trt.	0	0	0	
n >= 1 ocular AE rel. to surg. proc.- study eye	48	48	0	
n with >= 1 non-ocular AE rela.to surgical proc.	0	0	0	
n >= 1 ocular AE rel. to study proc. - study eye	8	9	0	
n with >= 1 non-ocular AE related to study proc.	0	2	0	
n >= 1 ocular AE leading to disc. - study eye	0	0	0	
n with >= 1 non-ocular AE leading to disc.	5	2	1	
Subjects with >= 1 ocular AESI for the study eye	19	31	3	
n with >= 1 ocular AESI for the fellow eye	3	3	1	
Subjects with >= 1 ocular SAE for the study eye	2	5	0	
Subjects with >= 1 ocular SAE for the fellow eye	0	0	0	
Subjects with at least one non-ocular SAE	20	22	10	
n >= 1 ocular SAE rel. to trt. for the study eye	0	0	0	
n >= 1 non-ocular SAE related to study trt.	0	0	0	
n >= 1 ocular SAE rel. to surg proc - study eye	1	4	0	
n >= 1 e non-ocular SAE rel. to surgical proc.	0	0	0	
n >= 1 ocular SAE rel. to study proc - study eye	1	1	0	
n >= 1 non-ocular SAE related to study proc.	0	0	0	
n >= 1 ocular SAE leading to disc.- study eye	0	0	0	
n with >= 1 non-ocular SAE leading to disc.	5	2	1	
Deaths	4	1	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Ocular AEs occurring in ≥2% of subjects by primary system organ class and preferred term for the study eye

End point title	Ocular AEs occurring in ≥2% of subjects by primary system organ class and preferred term for the study eye

End point description:

An adverse event (AE) is any untoward medical occurrence (e.g. any unfavorable and unintended sign [including abnormal laboratory findings], symptom or disease) in a subject or clinical investigation subject.

A TEAE is defined as any AE that develops after randomization or any AE already present that worsens following randomization. The primary summaries of AEs are based on TEAEs.

System organ classes are sorted alphabetically, and preferred terms are sorted by decreasing overall frequency within system organ class.

End point type	Secondary

End point timeframe:

Adverse events are reported from randomization to the end of study, at Week 96, up to a maximum timeframe of approximately 96 weeks.

End point values	GT005 Medium dose [5E10 vg]	GT005 High dose [2E11 vg]	Untreated control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	87	86	82	
Units: Participants				
Subjects with at least one event	66	65	15	
Eye disorders	65	62	14	
-Cataract	21	20	3	
-Retinal pigmentation	12	22	0	
-Conjunctival haemorrhage	18	12	1	
-Retinal haemorrhage	8	10	2	
-Eye pain	5	7	0	
-Ocular hypertension	6	6	0	
-Punctate keratitis	6	6	0	
-Retinal tear	5	6	0	
-Dry eye	4	4	1	
-Posterior capsule opacification	3	4	2	
-Anterior chamber cell	4	4	0	
-Eye irritation	6	2	0	
-Vitreous haemorrhage	2	6	0	
-Choroidal neovascularisation	2	3	2	
-Vitreous floaters	3	4	0	
-Cataract nuclear	3	3	0	
-Retinal detachment	2	4	0	
-Corneal oedema	1	4	0	
-Diplopia	4	1	0	
-Eye pruritus	1	4	0	
-Foreign body sensation in eyes	3	2	0	
-Iritis	4	1	0	
-Visual impairment	2	3	0	
Investigations	11	2	0	

-Intraocular pressure increased	1	2	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Non-ocular AEs occurring in ≥2% of subjects

End point title	Non-ocular AEs occurring in ≥2% of subjects

End point description:

An adverse event (AE) is any untoward medical occurrence (e.g. any unfavorable and unintended sign [including abnormal laboratory findings], symptom or disease) in a subject or clinical investigation subject.

A TEAE is defined as any AE that develops after randomization or any AE already present that worsens following randomization. The primary summaries of AEs are based on TEAEs.

End point type	Secondary

End point timeframe:

Adverse events are reported from randomization to the end of study, at Week 96, up to a maximum timeframe of approximately 96 weeks.

End point values	GT005 Medium dose [5E10 vg]	GT005 High dose [2E11 vg]	Untreated control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	87	86	82	
Units: Participants	63	59	44	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in GA morphology from Baseline to Week 96 on multimodal imaging - Number of participants with increase in Fundus autofluorescence

End point title	Change in GA morphology from Baseline to Week 96 on multimodal imaging - Number of participants with increase in Fundus autofluorescence

End point description:

Change in retinal morphology on multimodal imaging.

End point type	Secondary

End point timeframe:

Baseline, Weeks 5, 12, 24, 36, 48, 72 and 96

End point values	GT005 Medium dose [5E10 vg]	GT005 High dose [2E11 vg]	Untreated control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	75	78	74	
Units: Participants				
Week 5 (n=23,24,0)	23	23	999	
Week 12 (n=75,73,74)	74	73	73	
Week 24 (n=75,78,72)	72	78	71	
Week 36 (n=70,70, 71)	66	69	70	
Week 48 (n=67,72,68)	67	71	68	
Week 72 (61, 62,59)	60	60	56	
Week 96 (n=52,49, 34)	50	48	33	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Best corrected visual acuity (BCVA) Score from Baseline through Week 96 via the early treatment for diabetic retinopathy (ETDRS) chart

End point title	Change in Best corrected visual acuity (BCVA) Score from Baseline through Week 96 via the early treatment for diabetic retinopathy (ETDRS) chart

End point description:

BCVA was assessed using Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity testing charts.

Min and max possible scores are 0-100 respectively. A higher score represents better visual functioning.

End point type	Secondary

End point timeframe:

Baseline, Weeks 1, 5, 8, 12, 24, 36, 48, 72 and 96

End point values	GT005 Medium dose [5E10 vg]	GT005 High dose [2E11 vg]	Untreated control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	79	73	
Units: Letters read				
least squares mean (standard error)				
Week 1 (n=81,78,0)	-2.0 (± 1.54)	-7.0 (± 1.56)	999 (± 999)	
Week 5 (n=81,78,0)	-0.8 (± 0.88)	-3.3 (± 0.89)	999 (± 999)	
Week 8 (n=79,77,0)	-0.1 (± 0.85)	-1.7 (± 0.86)	999 (± 999)	
Week 12 (n=79,79,73)	-1.1 (± 0.91)	-2.5 (± 0.91)	-0.7 (± 0.96)	
Week 24 (n=78,78,71)	-2.7 (± 1.03)	-6.3 (± 1.03)	-1.1 (± 1.09)	
Week 36 (75,74,72)	-2.5 (± 1.24)	-7.7 (± 1.25)	-3.0 (± 1.30)	
Week 48 (n=73,75,69)	-2.6 (± 1.48)	-7.3 (± 1.46)	-5.3 (± 1.54)	
Week 72 (n=63, 70, 58)	-4.1 (± 1.54)	-7.9 (± 1.50)	-8.8 (± 1.61)	
Week 96 (n=54,51,35)	-5.5 (± 1.78)	-10.0 (± 1.78)	-12.7 (± 2.02)	

Statistical analyses

Statistical analysis title	GT005 High dose [2E11 vg] v Untreated control
Statistical analysis description: Week 12	
Comparison groups	GT005 High dose [2E11 vg] v Untreated control
Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	-1.8
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4
upper limit	0.4
Variability estimate	Standard error of the mean
Dispersion value	1.32

Statistical analysis title	GT005 Medium dose [5E10 vg] v Untreated control
Statistical analysis description: Week 12	
Comparison groups	GT005 Medium dose [5E10 vg] v Untreated control
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	-0.5
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.6
upper limit	1.7
Variability estimate	Standard error of the mean
Dispersion value	1.33

Statistical analysis title	GT005 Medium dose [5E10 vg] v Untreated control

Statistical analysis description:	
Week 24	
Comparison groups	GT005 Medium dose [5E10 vg] v Untreated control
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	-1.6
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.1
upper limit	0.8
Variability estimate	Standard error of the mean
Dispersion value	1.5

Statistical analysis title	GT005 Medium dose [5E10 vg] v Untreated control
Statistical analysis description:	
Week 36	
Comparison groups	GT005 Medium dose [5E10 vg] v Untreated control
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.5
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.5
upper limit	3.5
Variability estimate	Standard error of the mean
Dispersion value	1.81

Statistical analysis title	GT005 High dose [2E11 vg] v Untreated control
Statistical analysis description:	
Week 24	
Comparison groups	GT005 High dose [2E11 vg] v Untreated control
Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	-5.3

Confidence interval	
level	90 %
sides	2-sided
lower limit	-7.7
upper limit	-2.8
Variability estimate	Standard error of the mean
Dispersion value	1.49

Statistical analysis title	GT005 High dose [2E11 vg] v Untreated control
Statistical analysis description: Week 36	
Comparison groups	GT005 High dose [2E11 vg] v Untreated control
Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	-4.7
Confidence interval	
level	90 %
sides	2-sided
lower limit	-7.7
upper limit	-1.7
Variability estimate	Standard error of the mean
Dispersion value	1.8

Statistical analysis title	GT005 Medium dose [5E10 vg] v Untreated control
Statistical analysis description: Week 48	
Comparison groups	GT005 Medium dose [5E10 vg] v Untreated control
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	2.6
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.9
upper limit	6.1
Variability estimate	Standard error of the mean
Dispersion value	2.14

Statistical analysis title	GT005 High dose [2E11 vg] v Untreated control
Statistical analysis description: Week 48	
Comparison groups	GT005 High dose [2E11 vg] v Untreated control
Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	-2.1
Confidence interval	
level	90 %
sides	2-sided
lower limit	-5.6
upper limit	1.4
Variability estimate	Standard error of the mean
Dispersion value	2.12

Statistical analysis title	GT005 Medium dose [5E10 vg] v Untreated control
Statistical analysis description: Week 72	
Comparison groups	GT005 Medium dose [5E10 vg] v Untreated control
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	4.7
Confidence interval	
level	90 %
sides	2-sided
lower limit	1
upper limit	8.4
Variability estimate	Standard error of the mean
Dispersion value	2.24

Statistical analysis title	GT005 High dose [2E11 vg] v Untreated control
Statistical analysis description: Week 72	
Comparison groups	GT005 High dose [2E11 vg] v Untreated control

Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	0.9
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.8
upper limit	4.5
Variability estimate	Standard error of the mean
Dispersion value	2.2

Statistical analysis title	GT005 Medium dose [5E10 vg] v Untreated control
Statistical analysis description: Week 96	
Comparison groups	GT005 Medium dose [5E10 vg] v Untreated control
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	7.1
Confidence interval	
level	90 %
sides	2-sided
lower limit	2.7
upper limit	11.6
Variability estimate	Standard error of the mean
Dispersion value	2.7

Statistical analysis title	GT005 High dose [2E11 vg] v Untreated control
Statistical analysis description: Week 96	
Comparison groups	GT005 High dose [2E11 vg] v Untreated control
Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	
Method	mixed model repeated measures
Parameter estimate	LS Mean Difference
Point estimate	2.6

Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.8
upper limit	7.1
Variability estimate	Standard error of the mean
Dispersion value	2.68

Secondary: Change in Low luminance difference (LLD) letter count from Baseline at Weeks 12, 24, 36, 48, 72 and 96, via early treatment for diabetic retinopathy (ETDRS) chart

End point title	Change in Low luminance difference (LLD) letter count from Baseline at Weeks 12, 24, 36, 48, 72 and 96, via early treatment for diabetic retinopathy (ETDRS) chart

End point description:

LLD was assessed using Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity testing charts.

The test was to be performed after BCVA testing, prior to pupil dilation, and distance refraction was to be carried out before Low Luminance Visual Acuity (LLVA) was measured.

LLVA was to be measured by placing a 2.0-log-unit neutral density filter over the front of each eye and having the subject read the normally illuminated ETDRS chart. The LLD was calculated as the difference between BCVA and LLVA.

Initially, letters were to be read at a distance of 4 metres from the chart. If <20 letters were read at 4 metres, testing at 1 metre should have been performed. LLD was to be reported as number of letters read correctly by the subject.

Min and max possible scores are 0-100 respectively. A higher score represents better visual functioning.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12, 24, 36, 48, 72 and 96

End point values	GT005 Medium dose [5E10 vg]	GT005 High dose [2E11 vg]	Untreated control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	79	76	74	
Units: Letters read				
arithmetic mean (standard deviation)				
Week 12	-0.6 (± 7.59)	-1.1 (± 9.63)	1.2 (± 9.51)	
Week 24 (n=78,75,71)	-0.6 (± 10.10)	-2.5 (± 12.73)	0.5 (± 12.01)	
Week 36 (75,72,71)	0.0 (± 9.90)	-2.6 (± 13.40)	-0.1 (± 11.12)	
Week 48 (n=73,73,69)	-0.5 (± 10.31)	-1.5 (± 15.18)	-0.4 (± 12.93)	
Week 72 (n=63,67,58)	-0.5 (± 13.15)	-5.2 (± 17.24)	-2.5 (± 14.93)	
Week 96 (n=54,49,35)	-3.1 (± 16.11)	-2.2 (± 13.48)	-5.9 (± 16.82)	

Statistical analyses

No statistical analyses for this end point

Secondary: Reading performance, measured as the MRS (words per minute), as assessed by Minnesota low-vision reading test (MNRead) chart: summary statistics for change from baseline by visit for the study eye

End point title	Reading performance, measured as the MRS (words per minute), as assessed by Minnesota low-vision reading test (MNRead) chart: summary statistics for change from baseline by visit for the study eye

End point description:

The maximum reading speed (MRS) represents the highest reading speed an individual can achieve when print size is not a limiting factor. Essentially, it measures how quickly a person can read text when the print is large enough to be easily readable.

A higher count represents better visual functioning.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12, 24, 36, 48, 72 and 96

End point values	GT005 Medium dose [5E10 vg]	GT005 High dose [2E11 vg]	Untreated control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	72	65	
Units: Words read per minute				
arithmetic mean (standard deviation)				
Week 24 (n=73,72,65)	-15.756 (± 32.7268)	-12.368 (± 43.2054)	-15.769 (± 40.5051)	
Week 36 (71,70,65)	-18.488 (± 54.7913)	-15.673 (± 31.7802)	-3.689 (± 94.1057)	
Week 48 (n=69,67,62)	-20.734 (± 36.4110)	-6.678 (± 49.0844)	-17.297 (± 56.8547)	
Week 72 (n=57,64,53)	-24.485 (± 45.8525)	-20.798 (± 39.6796)	-26.121 (± 40.8016)	
Week 96 (n=48,47,29)	-24.678 (± 44.7777)	-25.178 (± 39.7216)	-19.242 (± 45.0703)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline at Weeks 24, 36, 48, 72 and 96 in Functional reading independence (FRI) index

End point title	Change from Baseline at Weeks 24, 36, 48, 72 and 96 in Functional reading independence (FRI) index

End point description:

The FRI index is a patient-reported outcome measure developed specifically for use in GA patients. The FRI index evaluates the level of independence subjects have in performing everyday activities that require reading, such as writing a cheque or reading a prescription. Scores derived from the index range from 1 (unable to do) to 4 (total independence).

A higher score represents better visual functioning.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24, 36, 48, 72 and 96

End point values	GT005 Medium dose [5E10 vg]	GT005 High dose [2E11 vg]	Untreated control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	77	75	67	
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=77,75,67)	-0.4 (± 5.20)	-1.4 (± 4.74)	-0.1 (± 3.98)	
Week 36 (71,70,65)	-0.8 (± 4.64)	-1.1 (± 4.31)	-0.1 (± 4.67)	
Week 48 (n=70,73,65)	-0.3 (± 4.76)	-1.4 (± 4.87)	-0.2 (± 4.50)	
Week 72 (n=63,69,58)	-0.8 (± 4.93)	-1.3 (± 5.19)	-1.5 (± 5.37)	
Week 96 (n=54,51,32)	-1.4 (± 5.57)	-1.4 (± 4.41)	-1.1 (± 5.11)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline at Weeks 24, 36, 48, 72 and 96 in Patient Reported Outcomes (Visual Function Questionnaire-25) - Composite Score

End point title	Change From Baseline at Weeks 24, 36, 48, 72 and 96 in Patient Reported Outcomes (Visual Function Questionnaire-25) - Composite Score

End point description:

The National Eye Institute Visual Function Questionnaire-25 (NEI-VFQ-25) measures the influence of visual disability and visual symptoms on general health domains.

The NEI VFQ-25 consists of a base set of 25 vision-targeted questions representing 11 vision-related constructs, plus an additional single-item general health rating question. All items are scored so that a high score represents better visual functioning. Each item is then converted to a 0 to 100 scale so that the lowest and highest possible scores are set at 0 and 100 points, respectively. A composite score is derived based on the average of the 11 subscales.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24, 36, 48, 72 and 96

End point values	GT005 Medium dose [5E10 vg]	GT005 High dose [2E11 vg]	Untreated control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	77	78	67	
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=77,78,67)	-1.466 (± 12.8742)	-2.289 (± 12.3295)	-1.270 (± 11.2063)	

Week 36 (71,73,65)	-1.955 (± 11.5060)	-3.479 (± 12.0848)	-2.273 (± 12.2395)	
Week 48 (n=70,74,65)	-2.501 (± 12.9563)	-3.113 (± 11.9974)	-4.403 (± 14.2465)	
Week 72 (n=63,69,54)	-4.232 (± 14.6259)	-3.432 (± 11.3840)	-6.583 (± 15.5133)	
Week 96 (n=54,51,33)	-6.341 (± 14.4187)	-7.718 (± 10.9016)	-6.804 (± 15.4812)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events are reported from randomization to the end of study, at Week 96, up to a maximum timeframe of approximately 96 weeks.

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	GT005@Medium dose@[5E10 vg]

Reporting group description:

GT005@Medium dose@[5E10 vg]

Reporting group title	Overall

Reporting group description:

Overall

Reporting group title	Untreated control

Reporting group description:

Untreated control

Reporting group title	GT005@High dose@[2E11 vg]

Reporting group description:

GT005@High dose@[2E11 vg]

Serious adverse events	GT005@Medium dose@[5E10 vg]	Overall	Untreated control
Total subjects affected by serious adverse events			
subjects affected / exposed	22 / 87 (25.29%)	57 / 255 (22.35%)	10 / 82 (12.20%)
number of deaths (all causes)	4	6	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasma cell myeloma			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bladder neoplasm			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal adenoma			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal oncocytoma			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of head and neck			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcomatoid carcinoma of the lung			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			

subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Vascular stent stenosis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pulmonary mass			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Acute respiratory failure			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pneumonitis aspiration			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Psychiatric disorders			
Hallucination			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Dural tear			

subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	2 / 87 (2.30%)	3 / 255 (1.18%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial rupture			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open globe injury - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			

subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	3 / 87 (3.45%)	4 / 255 (1.57%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bundle branch block left			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			

subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Mitral valve incompetence			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery dissection			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic left ventricular failure			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Nervous system disorders			
Cerebral infarction			

subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Cervical radiculopathy			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Syncope			
subjects affected / exposed	2 / 87 (2.30%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vitreous haemorrhage - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment - Study eye			

subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hepatobiliary disorders			
Hepatic cirrhosis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 87 (0.00%)	3 / 255 (1.18%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urinary retention			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Diverticulitis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cystitis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endophthalmitis - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pneumonia serratia			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Sepsis			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	GT005@High dose@[2E11 vg]		
Total subjects affected by serious adverse events			
subjects affected / exposed	25 / 86 (29.07%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasma cell myeloma			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric cancer			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder neoplasm			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			

subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Adrenal adenoma				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal oncocytoma				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of head and neck				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sarcomatoid carcinoma of the lung				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Hypertension				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Death				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular stent stenosis				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary mass			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute respiratory failure			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonitis aspiration			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Psychiatric disorders			
Hallucination			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Dural tear			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hip fracture			

subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wrist fracture				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound dehiscence				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Synovial rupture				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural complication				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Open globe injury - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Joint dislocation				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Bradycardia				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				

subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Angina pectoris				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute myocardial infarction				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acute coronary syndrome				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Bundle branch block left				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Mitral valve incompetence				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Left ventricular failure				

subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery stenosis				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery dissection				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic left ventricular failure				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cerebral infarction				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Carotid artery stenosis				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				

subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular disorder				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical radiculopathy				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Embolic stroke				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Vitreous haemorrhage - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retinal detachment - Study eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Gastrointestinal haemorrhage				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				

subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Hepatobiliary disorders				
Hepatic cirrhosis				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Urinary retention				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue				

disorders				
Muscular weakness				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc disorder				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar spinal stenosis				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polymyalgia rheumatica				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Diverticulitis				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis infective				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

COVID-19				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Endophthalmitis - Study eye				
subjects affected / exposed	3 / 86 (3.49%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia serratia				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				

Hyponatraemia			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	GT005@Medium dose@[5E10 vg]	Overall	Untreated control
Total subjects affected by non-serious adverse events			
subjects affected / exposed	76 / 87 (87.36%)	201 / 255 (78.82%)	50 / 82 (60.98%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Eye naevus - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Basal cell carcinoma			
subjects affected / exposed	3 / 87 (3.45%)	5 / 255 (1.96%)	1 / 82 (1.22%)
occurrences (all)	4	6	1
Basal cell carcinoma - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Bladder cancer			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Thyroid cancer metastatic			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Squamous cell carcinoma of head and neck			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Squamous cell carcinoma			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	2	2	0

Seborrhoeic keratosis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Prostate cancer			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Lipoma			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Keratoacanthoma			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Lymphocele			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Orthostatic hypotension			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Aortic aneurysm			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Arteriosclerosis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Hypertension			
subjects affected / exposed	4 / 87 (4.60%)	9 / 255 (3.53%)	1 / 82 (1.22%)
occurrences (all)	4	9	1
Hypertensive crisis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Hypertensive emergency			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Hypotension			

subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	1 / 82 (1.22%)
occurrences (all)	1	3	1
Subclavian artery stenosis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Venous thrombosis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
White coat hypertension			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
General disorders and administration site conditions			
Illness			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Discomfort			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Facial pain			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Facial pain - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Fatigue			
subjects affected / exposed	0 / 87 (0.00%)	4 / 255 (1.57%)	1 / 82 (1.22%)
occurrences (all)	0	4	1
Pyrexia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Prosthetic cardiac valve stenosis			

subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Non-cardiac chest pain			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	1	2	1
Infusion site bruising			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	1	2	1
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Social circumstances			
Edentulous			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Reproductive system and breast disorders			
Prostatomegaly			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Prostatitis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Erectile dysfunction			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0

Dyspnoea			
subjects affected / exposed	1 / 87 (1.15%)	4 / 255 (1.57%)	2 / 82 (2.44%)
occurrences (all)	1	4	2
Cough			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	1 / 82 (1.22%)
occurrences (all)	1	3	1
Catarrh			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Oropharyngeal pain			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Pulmonary mass			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Paranasal sinus mucosal hypertrophy			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Pulmonary oedema			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			

Panic attack			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Mood altered			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Hallucination			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Charles Bonnet syndrome			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	1 / 82 (1.22%)
occurrences (all)	1	3	1
Product issues			
Device dislocation - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Hepatic steatosis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Cholelithiasis			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	1	2	1
Investigations			

Eosinophil count increased			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
C-reactive protein increased			
subjects affected / exposed	5 / 87 (5.75%)	9 / 255 (3.53%)	2 / 82 (2.44%)
occurrences (all)	6	10	2
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Glomerular filtration rate decreased			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Blood bilirubin increased			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 87 (2.30%)	4 / 255 (1.57%)	2 / 82 (2.44%)
occurrences (all)	2	4	2
Blood creatinine increased			
subjects affected / exposed	3 / 87 (3.45%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	3	3	0
Blood glucose increased			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Blood potassium decreased			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Blood pressure increased			
subjects affected / exposed	3 / 87 (3.45%)	6 / 255 (2.35%)	3 / 82 (3.66%)
occurrences (all)	4	7	3
Blood pressure systolic increased			

subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	1	2	1
Blood sodium decreased			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Blood urea increased			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Body temperature increased			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Full blood count abnormal			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Haemoglobin decreased			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Intraocular pressure increased - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Intraocular pressure increased - Study eye			
subjects affected / exposed	11 / 87 (12.64%)	13 / 255 (5.10%)	0 / 82 (0.00%)
occurrences (all)	12	14	0
Lipase increased			
subjects affected / exposed	2 / 87 (2.30%)	6 / 255 (2.35%)	0 / 82 (0.00%)
occurrences (all)	2	6	0
Liver function test increased			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Mean cell haemoglobin concentration decreased			

subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Neutrophil count increased			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	0	2	1
Platelet count decreased			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Red blood cell count decreased			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
White blood cell count increased			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Clavicle fracture			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Accidental exposure to product - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Chemical burns of eye - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Chemical burns of eye - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Contusion			

subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Pelvic fracture			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Craniofacial fracture - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Eye contusion - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Eyelid contusion - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Eyelid injury - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Fall			
subjects affected / exposed	0 / 87 (0.00%)	5 / 255 (1.96%)	2 / 82 (2.44%)
occurrences (all)	0	5	2
Foot fracture			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Hand fracture			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Humerus fracture			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Hyphaema - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	3	0
Joint injury			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			

subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Muscle strain			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Patella fracture			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Corneal abrasion - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Procedural nausea			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Vascular access site haematoma			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Product administered at inappropriate site - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Radius fracture			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Retinal tear - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Rib fracture			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Road traffic accident			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1

Skin abrasion			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Skin laceration			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Skin laceration - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Spinal compression fracture			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Splinter			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Stoma complication			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Suture related complication - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Tooth fracture			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Traumatic haematoma			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Procedural pain - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Wound			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			

Corneal dystrophy - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Adenomatous polyposis coli			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Corneal dystrophy - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Aortic valve calcification			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Aortic valve incompetence			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Arrhythmia			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Atrial fibrillation			
subjects affected / exposed	1 / 87 (1.15%)	6 / 255 (2.35%)	1 / 82 (1.22%)
occurrences (all)	1	6	1
Cardiac amyloidosis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Cardiac failure congestive			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	0	2	1
Coronary artery disease			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Left ventricular failure			

subjects affected / exposed	0 / 87 (0.00%)	3 / 255 (1.18%)	1 / 82 (1.22%)
occurrences (all)	0	3	1
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Cerebral small vessel ischaemic disease			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Cerebral atrophy			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	1	2	1
Amputation stump pain			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Balance disorder			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Altered state of consciousness			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Ageusia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Gerstmann's syndrome			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Tremor			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	0	2	1
Encephalopathy			

subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Cognitive disorder			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	1	2	1
Headache			
subjects affected / exposed	1 / 87 (1.15%)	6 / 255 (2.35%)	0 / 82 (0.00%)
occurrences (all)	1	6	0
Hypoaesthesia			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Ilioinguinal neuralgia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Nerve compression			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Neuralgia - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Neuropathy peripheral			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Post herpetic neuralgia			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Sciatica			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Seizure			

subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Syncope			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Essential tremor			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	0	2	1
Vertebral artery stenosis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
VIth nerve paralysis - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 87 (3.45%)	8 / 255 (3.14%)	2 / 82 (2.44%)
occurrences (all)	3	8	2
Leukocytosis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Blood loss anaemia			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Splenomegaly			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Spontaneous haematoma			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Ear and labyrinth disorders			
Meniere's disease			

subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Middle ear effusion			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Motion sickness			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Cataract nuclear - Study eye			
subjects affected / exposed	3 / 87 (3.45%)	6 / 255 (2.35%)	0 / 82 (0.00%)
occurrences (all)	3	7	0
Anterior capsule contraction - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Anterior capsule contraction - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Anterior chamber cell - Study eye			
subjects affected / exposed	4 / 87 (4.60%)	8 / 255 (3.14%)	0 / 82 (0.00%)
occurrences (all)	4	8	0
Anterior chamber flare - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Blepharitis - Fellow eye			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Blepharitis - Study eye			
subjects affected / exposed	3 / 87 (3.45%)	4 / 255 (1.57%)	0 / 82 (0.00%)
occurrences (all)	3	4	0
Borderline glaucoma - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Borderline glaucoma - Study eye			

subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Cataract - Fellow eye			
subjects affected / exposed	5 / 87 (5.75%)	17 / 255 (6.67%)	2 / 82 (2.44%)
occurrences (all)	5	17	2
Cataract - Study eye			
subjects affected / exposed	21 / 87 (24.14%)	44 / 255 (17.25%)	3 / 82 (3.66%)
occurrences (all)	21	44	3
Cataract nuclear - Fellow eye			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Cataract subcapsular - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Cataract subcapsular - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	1	3	0
Chalazion - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Chalazion - Study eye			
subjects affected / exposed	3 / 87 (3.45%)	4 / 255 (1.57%)	0 / 82 (0.00%)
occurrences (all)	3	4	0
Choroidal detachment - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Choroidal haemorrhage - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Corneal epithelial microcysts - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Choroidal neovascularisation - Study eye			

subjects affected / exposed	2 / 87 (2.30%)	7 / 255 (2.75%)	2 / 82 (2.44%)
occurrences (all)	2	8	2
Chromatopsia - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Conjunctival haemorrhage - Study eye			
subjects affected / exposed	18 / 87 (20.69%)	31 / 255 (12.16%)	1 / 82 (1.22%)
occurrences (all)	21	35	1
Conjunctival oedema - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Corneal defect - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Corneal disorder - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Choroidal neovascularisation - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	1 / 82 (1.22%)
occurrences (all)	1	3	1
Corneal erosion - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Corneal oedema - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Corneal oedema - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	5 / 255 (1.96%)	0 / 82 (0.00%)
occurrences (all)	1	5	0
Corneal striae - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Cystoid macular oedema - Study eye			

subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	1	3	0
Dermatochalasis - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Ectropion - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Diplopia - Fellow eye			
subjects affected / exposed	3 / 87 (3.45%)	4 / 255 (1.57%)	0 / 82 (0.00%)
occurrences (all)	3	4	0
Diplopia - Study eye			
subjects affected / exposed	4 / 87 (4.60%)	5 / 255 (1.96%)	0 / 82 (0.00%)
occurrences (all)	4	5	0
Dry age-related macular degeneration - Fellow eye			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Dry eye - Fellow eye			
subjects affected / exposed	2 / 87 (2.30%)	7 / 255 (2.75%)	1 / 82 (1.22%)
occurrences (all)	2	7	1
Dry eye - Study eye			
subjects affected / exposed	4 / 87 (4.60%)	9 / 255 (3.53%)	1 / 82 (1.22%)
occurrences (all)	4	9	1
Ectropion - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	3 / 255 (1.18%)	1 / 82 (1.22%)
occurrences (all)	0	3	1
Detachment of retinal pigment epithelium - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Eczema eyelids - Fellow eye			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Foreign body sensation in eyes - Study eye			

subjects affected / exposed	3 / 87 (3.45%)	5 / 255 (1.96%)	0 / 82 (0.00%)
occurrences (all)	3	5	0
Epiretinal membrane - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Exophthalmos - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Eye discharge - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Eye inflammation - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Eye irritation - Study eye			
subjects affected / exposed	6 / 87 (6.90%)	8 / 255 (3.14%)	0 / 82 (0.00%)
occurrences (all)	6	8	0
Eye pain - Study eye			
subjects affected / exposed	5 / 87 (5.75%)	12 / 255 (4.71%)	0 / 82 (0.00%)
occurrences (all)	6	13	0
Eye pruritus - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	5 / 255 (1.96%)	0 / 82 (0.00%)
occurrences (all)	1	5	0
Eyelid bleeding - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	2	3	0
Eyelid oedema - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Eyelid pain - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Eyelid ptosis - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Eyelids pruritus - Fellow eye			

subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Eyelids pruritus - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	2	3	0
Eczema eyelids - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Foveal degeneration - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Lagophthalmos - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Fuchs' syndrome - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Glare - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Glaucoma - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	1	3	0
Glaucoma - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	4 / 255 (1.57%)	0 / 82 (0.00%)
occurrences (all)	2	4	0
Hypotony of eye - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Iridocyclitis - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	4 / 255 (1.57%)	0 / 82 (0.00%)
occurrences (all)	1	4	0
Iritis - Study eye			
subjects affected / exposed	4 / 87 (4.60%)	5 / 255 (1.96%)	0 / 82 (0.00%)
occurrences (all)	4	5	0
Keratic precipitates - Study eye			

subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Keratitis - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Keratitis - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Lacrimation decreased - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Lacrimation decreased - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Lacrimation disorder - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Lacrimation increased - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Fuchs' syndrome - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Ocular discomfort - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	4 / 255 (1.57%)	0 / 82 (0.00%)
occurrences (all)	2	4	0
Optic ischaemic neuropathy - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Neovascular age-related macular degeneration - Fellow eye			
subjects affected / exposed	2 / 87 (2.30%)	5 / 255 (1.96%)	1 / 82 (1.22%)
occurrences (all)	2	5	1
Metamorphopsia - Study eye			

subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Metamorphopsia - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Macular oedema - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Macular hole - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Lenticular opacities - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	0	2	1
Lens dislocation - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Ocular hyperaemia - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Ocular hypertension - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Ocular hypertension - Study eye			
subjects affected / exposed	6 / 87 (6.90%)	12 / 255 (4.71%)	0 / 82 (0.00%)
occurrences (all)	6	12	0
Optic disc haemorrhage - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Optic ischaemic neuropathy - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Ocular discomfort - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0

Punctate keratitis - Fellow eye			
subjects affected / exposed	4 / 87 (4.60%)	10 / 255 (3.92%)	0 / 82 (0.00%)
occurrences (all)	4	10	0
Pterygium - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Posterior capsule opacification - Study eye			
subjects affected / exposed	3 / 87 (3.45%)	9 / 255 (3.53%)	2 / 82 (2.44%)
occurrences (all)	3	9	2
Posterior capsule opacification - Fellow eye			
subjects affected / exposed	5 / 87 (5.75%)	11 / 255 (4.31%)	2 / 82 (2.44%)
occurrences (all)	5	11	2
Photopsia - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	4 / 255 (1.57%)	0 / 82 (0.00%)
occurrences (all)	2	5	0
Photopsia - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Photophobia - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Periorbital pain - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Optic nerve sheath haemorrhage - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Punctate keratitis - Study eye			
subjects affected / exposed	6 / 87 (6.90%)	12 / 255 (4.71%)	0 / 82 (0.00%)
occurrences (all)	6	12	0
Retinal oedema - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Retinal haemorrhage - Study eye			

subjects affected / exposed	8 / 87 (9.20%)	20 / 255 (7.84%)	2 / 82 (2.44%)
occurrences (all)	9	21	2
Retinal haemorrhage - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	1	3	0
Retinal detachment - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	1	3	0
Retinal depigmentation - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Retinal depigmentation - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Retinal cyst - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Retinal pigmentation - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Vitreoretinal traction syndrome - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Retinal tear - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Retinal tear - Study eye			
subjects affected / exposed	5 / 87 (5.75%)	11 / 255 (4.31%)	0 / 82 (0.00%)
occurrences (all)	5	11	0
Retinal vein occlusion - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	1	2	1
Subretinal fluid - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0

Swelling of eyelid - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Tractional retinal detachment - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Trichiasis - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Vitreal cells - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Visual impairment - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	5 / 255 (1.96%)	0 / 82 (0.00%)
occurrences (all)	2	6	0
Visual impairment - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	1	3	0
Visual field defect - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Vision blurred - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Ulcerative keratitis - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Trichiasis - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Retinal pigmentation - Study eye			
subjects affected / exposed	12 / 87 (13.79%)	34 / 255 (13.33%)	0 / 82 (0.00%)
occurrences (all)	13	35	0
Vitreous detachment - Fellow eye			

subjects affected / exposed	1 / 87 (1.15%)	4 / 255 (1.57%)	2 / 82 (2.44%)
occurrences (all)	1	4	2
Vitreous floaters - Fellow eye			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Vitreous floaters - Study eye			
subjects affected / exposed	3 / 87 (3.45%)	7 / 255 (2.75%)	0 / 82 (0.00%)
occurrences (all)	3	8	0
Vitreous haemorrhage - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Vitreous haemorrhage - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	8 / 255 (3.14%)	0 / 82 (0.00%)
occurrences (all)	2	8	0
Vitreous opacities - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	3	4	0
Gastrointestinal disorders			
Gastric ulcer			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Abdominal discomfort			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Abdominal pain			
subjects affected / exposed	0 / 87 (0.00%)	3 / 255 (1.18%)	1 / 82 (1.22%)
occurrences (all)	0	3	1
Abdominal pain upper			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	0	2	1
Constipation			
subjects affected / exposed	1 / 87 (1.15%)	5 / 255 (1.96%)	0 / 82 (0.00%)
occurrences (all)	1	5	0

Dental caries			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Diarrhoea			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Diverticulum			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Duodenal ulcer			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Food poisoning			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Pancreatitis acute			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	3 / 87 (3.45%)	6 / 255 (2.35%)	0 / 82 (0.00%)
occurrences (all)	3	7	0
Irritable bowel syndrome			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	1	2	1
Inguinal hernia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Hiatus hernia			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Gastritis erosive			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0

Proctalgia			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Toothache			
subjects affected / exposed	1 / 87 (1.15%)	4 / 255 (1.57%)	0 / 82 (0.00%)
occurrences (all)	1	4	0
Vomiting			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	3	0
Oesophageal dysplasia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Decubitus ulcer			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Dermal cyst			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Sebaceous gland disorder			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Eczema asteatotic			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Lichenoid keratosis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Pruritus			

subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	0	2	1
Dermatitis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Skin irritation			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Skin lesion			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Skin mass - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Chronic kidney disease			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Renal impairment			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	2 / 82 (2.44%)
occurrences (all)	1	3	2
Glomerulosclerosis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Incontinence			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Microalbuminuria			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Nephrolithiasis			
subjects affected / exposed	1 / 87 (1.15%)	5 / 255 (1.96%)	2 / 82 (2.44%)
occurrences (all)	1	5	2

Renal cyst			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Acute kidney injury			
subjects affected / exposed	2 / 87 (2.30%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	2	3	0
Urinary tract obstruction			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Urinary retention			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Ureteric dilatation			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	1 / 82 (1.22%)
occurrences (all)	1	3	1
Musculoskeletal and connective tissue disorders			
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Arthritis			
subjects affected / exposed	1 / 87 (1.15%)	4 / 255 (1.57%)	1 / 82 (1.22%)
occurrences (all)	1	4	1
Flank pain			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Bursitis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Back pain			
subjects affected / exposed	4 / 87 (4.60%)	7 / 255 (2.75%)	2 / 82 (2.44%)
occurrences (all)	4	7	2
Foot deformity			

subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	0	2	1
Arthralgia			
subjects affected / exposed	2 / 87 (2.30%)	7 / 255 (2.75%)	2 / 82 (2.44%)
occurrences (all)	2	9	3
Groin pain			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	0	2	1
Muscle disorder			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Myalgia			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Muscle tightness			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Osteoarthritis			
subjects affected / exposed	0 / 87 (0.00%)	3 / 255 (1.18%)	3 / 82 (3.66%)
occurrences (all)	0	3	3
Osteoporosis			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	0	2	1
Pain in extremity			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 87 (0.00%)	3 / 255 (1.18%)	1 / 82 (1.22%)
occurrences (all)	0	4	2
Spinal stenosis			

subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Tendonitis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Rotator cuff syndrome			
subjects affected / exposed	1 / 87 (1.15%)	5 / 255 (1.96%)	2 / 82 (2.44%)
occurrences (all)	1	6	3
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 87 (2.30%)	5 / 255 (1.96%)	2 / 82 (2.44%)
occurrences (all)	2	5	2
Bacterial infection			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Appendicitis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Acute sinusitis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Abscess oral			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Abscess neck			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Abscess intestinal			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
COVID-19			
subjects affected / exposed	14 / 87 (16.09%)	35 / 255 (13.73%)	9 / 82 (10.98%)
occurrences (all)	14	36	10
Hordeolum - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0

Cellulitis			
subjects affected / exposed	2 / 87 (2.30%)	4 / 255 (1.57%)	0 / 82 (0.00%)
occurrences (all)	2	4	0
Conjunctivitis - Fellow eye			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0
Conjunctivitis - Study eye			
subjects affected / exposed	2 / 87 (2.30%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	2	3	0
Conjunctivitis bacterial - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	3 / 87 (3.45%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	6	6	0
Diverticulitis			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	2	3	1
Eye infection - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Eye infection - Study eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Herpes zoster			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Gingivitis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Gingival abscess			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Gastrointestinal infection			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0

Gastroenteritis salmonella			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Furuncle			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Eyelid infection - Fellow eye			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Candida infection			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Hordeolum - Study eye			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	1	2	1
Influenza			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	0	2	0
Intervertebral discitis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Kidney infection			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Leprosy			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Lyme disease			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 87 (1.15%)	5 / 255 (1.96%)	0 / 82 (0.00%)
occurrences (all)	3	7	0

Oral candidiasis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Otitis media acute			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Paronychia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Periodontitis			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	1	2	1
Pneumonia			
subjects affected / exposed	1 / 87 (1.15%)	6 / 255 (2.35%)	0 / 82 (0.00%)
occurrences (all)	1	6	0
Post-acute COVID-19 syndrome			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Pyelonephritis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Pyuria			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Root canal infection			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	1 / 87 (1.15%)	6 / 255 (2.35%)	1 / 82 (1.22%)
occurrences (all)	2	8	1
Skin bacterial infection			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0

Skin infection			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Tinea pedis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Tooth abscess			
subjects affected / exposed	0 / 87 (0.00%)	4 / 255 (1.57%)	1 / 82 (1.22%)
occurrences (all)	0	4	1
Tooth infection			
subjects affected / exposed	2 / 87 (2.30%)	3 / 255 (1.18%)	0 / 82 (0.00%)
occurrences (all)	2	3	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	2 / 82 (2.44%)
occurrences (all)	1	3	2
Urinary tract infection			
subjects affected / exposed	7 / 87 (8.05%)	13 / 255 (5.10%)	3 / 82 (3.66%)
occurrences (all)	7	13	3
Urinary tract infection pseudomonal			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Rhinitis			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
Glucose tolerance impaired			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia			
subjects affected / exposed	1 / 87 (1.15%)	3 / 255 (1.18%)	2 / 82 (2.44%)
occurrences (all)	1	3	2
Hyperkalaemia			

subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Hyperlipidaemia			
subjects affected / exposed	1 / 87 (1.15%)	4 / 255 (1.57%)	1 / 82 (1.22%)
occurrences (all)	1	4	1
Hypoglycaemia			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Vitamin D deficiency			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Vitamin B12 deficiency			
subjects affected / exposed	1 / 87 (1.15%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	1	1	0
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	1	2	1
Obesity			
subjects affected / exposed	0 / 87 (0.00%)	1 / 255 (0.39%)	0 / 82 (0.00%)
occurrences (all)	0	1	0
Iron deficiency			
subjects affected / exposed	0 / 87 (0.00%)	2 / 255 (0.78%)	1 / 82 (1.22%)
occurrences (all)	0	2	1
Hyponatraemia			
subjects affected / exposed	1 / 87 (1.15%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	1	2	0
Hypokalaemia			
subjects affected / exposed	2 / 87 (2.30%)	2 / 255 (0.78%)	0 / 82 (0.00%)
occurrences (all)	2	2	0

Non-serious adverse events	GT005@High dose@[2E11 vg]		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	75 / 86 (87.21%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Eye naevus - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Basal cell carcinoma				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Basal cell carcinoma - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Bladder cancer				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Thyroid cancer metastatic				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Squamous cell carcinoma of skin				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Squamous cell carcinoma of head and neck				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Squamous cell carcinoma				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Seborrhoeic keratosis				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Prostate cancer				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Lipoma				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Keratoacanthoma				

subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Vascular disorders			
Lymphocele			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Orthostatic hypotension			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Aortic aneurysm			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Arteriosclerosis			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	4 / 86 (4.65%)		
occurrences (all)	4		
Hypertensive crisis			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Hypertensive emergency			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Hypotension			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Subclavian artery stenosis			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Venous thrombosis			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
White coat hypertension			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		

General disorders and administration site conditions			
Illness			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Chest pain			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Discomfort			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Facial pain			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Facial pain - Study eye			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	3 / 86 (3.49%)		
occurrences (all)	3		
Pyrexia			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Prosthetic cardiac valve stenosis			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Infusion site bruising			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Influenza like illness			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Immune system disorders			

Seasonal allergy			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	2		
Social circumstances			
Edentulous			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Prostatomegaly			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Prostatitis			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Erectile dysfunction			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Dyspnoea			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Catarrh			

subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Pulmonary mass			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Pulmonary arterial hypertension			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Pleural effusion			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Paranasal sinus mucosal hypertrophy			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Pulmonary oedema			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Psychiatric disorders			
Panic attack			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Mood altered			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Hallucination			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		

Depression			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Charles Bonnet syndrome			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Anxiety			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Product issues			
Device dislocation - Study eye			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Hepatic steatosis			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Cholelithiasis			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Investigations			
Eosinophil count increased			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
C-reactive protein increased			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	2		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Glomerular filtration rate decreased			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		

Blood alkaline phosphatase increased				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Blood bilirubin increased				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Blood creatinine increased				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Blood glucose increased				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Blood potassium decreased				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Blood pressure increased				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Blood pressure systolic increased				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Blood sodium decreased				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	2			
Blood urea increased				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Body temperature increased				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Full blood count abnormal				

subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Haemoglobin decreased				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Hepatic enzyme increased				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	2			
Intraocular pressure increased - Fellow eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Intraocular pressure increased - Study eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Lipase increased				
subjects affected / exposed	4 / 86 (4.65%)			
occurrences (all)	4			
Liver function test increased				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Mean cell haemoglobin concentration decreased				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Neutrophil count increased				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Platelet count decreased				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Prostatic specific antigen increased				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Red blood cell count decreased				

subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Urine albumin/creatinine ratio increased			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
White blood cell count increased			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Clavicle fracture			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Accidental exposure to product - Study eye			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Chemical burns of eye - Fellow eye			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Chemical burns of eye - Study eye			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	2		
Pelvic fracture			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Craniofacial fracture - Fellow eye			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Eye contusion - Study eye			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Eyelid contusion - Study eye			

subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Eyelid injury - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Fall				
subjects affected / exposed	3 / 86 (3.49%)			
occurrences (all)	3			
Foot fracture				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Hand fracture				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Humerus fracture				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Hyphaema - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	3			
Joint injury				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Ligament sprain				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Limb injury				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Muscle strain				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Patella fracture				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Corneal abrasion - Study eye				

subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Procedural nausea				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Vascular access site haematoma				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Product administered at inappropriate site - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Radius fracture				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Retinal tear - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Rib fracture				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Road traffic accident				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Skin abrasion				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Skin laceration				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Skin laceration - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Spinal compression fracture				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			

Splinter			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Stoma complication			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Suture related complication - Study eye			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Tooth fracture			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Traumatic haematoma			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Procedural pain - Study eye			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Wound			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Congenital, familial and genetic disorders			
Corneal dystrophy - Study eye			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Adenomatous polyposis coli			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Corneal dystrophy - Fellow eye			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Aortic valve calcification			

subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Aortic valve incompetence			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Arrhythmia			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	2		
Atrial fibrillation			
subjects affected / exposed	4 / 86 (4.65%)		
occurrences (all)	4		
Cardiac amyloidosis			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Cardiac failure congestive			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Coronary artery disease			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Left ventricular failure			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	2		
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Cerebral small vessel ischaemic disease			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Cerebral atrophy			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Amputation stump pain			

subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Balance disorder				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Carpal tunnel syndrome				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Altered state of consciousness				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Ageusia				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Gerstmann's syndrome				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Tremor				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Encephalopathy				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Dizziness				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Dementia Alzheimer's type				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Cognitive disorder				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Headache				
subjects affected / exposed	5 / 86 (5.81%)			
occurrences (all)	5			
Hypoaesthesia				

subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Ilioinguinal neuralgia			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Nerve compression			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Neuralgia - Fellow eye			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Post herpetic neuralgia			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	2		
Seizure			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Syncope			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Essential tremor			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Vertebral artery stenosis			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
VIth nerve paralysis - Study eye			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	3 / 86 (3.49%)		
occurrences (all)	3		
Leukocytosis			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Iron deficiency anaemia			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Blood loss anaemia			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Splenomegaly			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Spontaneous haematoma			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Meniere's disease			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Middle ear effusion			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Motion sickness			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Eye disorders			
Cataract nuclear - Study eye			
subjects affected / exposed	3 / 86 (3.49%)		
occurrences (all)	4		
Anterior capsule contraction - Fellow eye			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Anterior capsule contraction - Study eye			

subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Anterior chamber cell - Study eye				
subjects affected / exposed	4 / 86 (4.65%)			
occurrences (all)	4			
Anterior chamber flare - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Blepharitis - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Blepharitis - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Borderline glaucoma - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Borderline glaucoma - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Cataract - Fellow eye				
subjects affected / exposed	10 / 86 (11.63%)			
occurrences (all)	10			
Cataract - Study eye				
subjects affected / exposed	20 / 86 (23.26%)			
occurrences (all)	20			
Cataract nuclear - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Cataract subcapsular - Fellow eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Cataract subcapsular - Study eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Chalazion - Fellow eye				

subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Chalazion - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Choroidal detachment - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Choroidal haemorrhage - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Corneal epithelial microcysts - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Choroidal neovascularisation - Study eye				
subjects affected / exposed	3 / 86 (3.49%)			
occurrences (all)	4			
Chromatopsia - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Conjunctival haemorrhage - Study eye				
subjects affected / exposed	12 / 86 (13.95%)			
occurrences (all)	13			
Conjunctival oedema - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Corneal defect - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Corneal disorder - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Choroidal neovascularisation - Fellow eye				

subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Corneal erosion - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Corneal oedema - Fellow eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Corneal oedema - Study eye				
subjects affected / exposed	4 / 86 (4.65%)			
occurrences (all)	4			
Corneal striae - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Cystoid macular oedema - Study eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Dermatochalasis - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Ectropion - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Diplopia - Fellow eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Diplopia - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Dry age-related macular degeneration - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Dry eye - Fellow eye				
subjects affected / exposed	4 / 86 (4.65%)			
occurrences (all)	4			

Dry eye - Study eye				
subjects affected / exposed	4 / 86 (4.65%)			
occurrences (all)	4			
Ectropion - Fellow eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Detachment of retinal pigment epithelium - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Eczema eyelids - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Foreign body sensation in eyes - Study eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Epiretinal membrane - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Exophthalmos - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Eye discharge - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Eye inflammation - Study eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Eye irritation - Study eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Eye pain - Study eye				
subjects affected / exposed	7 / 86 (8.14%)			
occurrences (all)	7			
Eye pruritus - Study eye				

subjects affected / exposed	4 / 86 (4.65%)			
occurrences (all)	4			
Eyelid bleeding - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Eyelid oedema - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Eyelid pain - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Eyelid ptosis - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Eyelids pruritus - Fellow eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Eyelids pruritus - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Eczema eyelids - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Foveal degeneration - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Lagophthalmos - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Fuchs' syndrome - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Glare - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Glaucoma - Fellow eye				

subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Glaucoma - Study eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Hypotony of eye - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Iridocyclitis - Study eye				
subjects affected / exposed	3 / 86 (3.49%)			
occurrences (all)	3			
Iritis - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Keratic precipitates - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Keratitis - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Keratitis - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Lacrimation decreased - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Lacrimation decreased - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Lacrimation disorder - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	2			
Lacrimation increased - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Fuchs' syndrome - Fellow eye				

subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Ocular discomfort - Study eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Optic ischaemic neuropathy - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Neovascular age-related macular degeneration - Fellow eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Metamorphopsia - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Metamorphopsia - Fellow eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Macular oedema - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Macular hole - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Lenticular opacities - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Lens dislocation - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Ocular hyperaemia - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Ocular hypertension - Fellow eye				

subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Ocular hypertension - Study eye				
subjects affected / exposed	6 / 86 (6.98%)			
occurrences (all)	6			
Optic disc haemorrhage - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Optic ischaemic neuropathy - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Ocular discomfort - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Punctate keratitis - Fellow eye				
subjects affected / exposed	6 / 86 (6.98%)			
occurrences (all)	6			
Pterygium - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Posterior capsule opacification - Study eye				
subjects affected / exposed	4 / 86 (4.65%)			
occurrences (all)	4			
Posterior capsule opacification - Fellow eye				
subjects affected / exposed	4 / 86 (4.65%)			
occurrences (all)	4			
Photopsia - Study eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	3			
Photopsia - Fellow eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Photophobia - Study eye				

subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	2			
Periorbital pain - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Optic nerve sheath haemorrhage - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Punctate keratitis - Study eye				
subjects affected / exposed	6 / 86 (6.98%)			
occurrences (all)	6			
Retinal oedema - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Retinal haemorrhage - Study eye				
subjects affected / exposed	10 / 86 (11.63%)			
occurrences (all)	10			
Retinal haemorrhage - Fellow eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Retinal detachment - Study eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Retinal depigmentation - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Retinal depigmentation - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Retinal cyst - Fellow eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Retinal pigmentation - Fellow eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			

Vitreoretinal traction syndrome - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Retinal tear - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Retinal tear - Study eye				
subjects affected / exposed	6 / 86 (6.98%)			
occurrences (all)	6			
Retinal vein occlusion - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Subretinal fluid - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Swelling of eyelid - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Tractional retinal detachment - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Trichiasis - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Vitreal cells - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Visual impairment - Study eye				
subjects affected / exposed	3 / 86 (3.49%)			
occurrences (all)	4			
Visual impairment - Fellow eye				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Visual field defect - Study eye				

subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Vision blurred - Study eye			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Ulcerative keratitis - Study eye			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Trichiasis - Study eye			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Retinal pigmentation - Study eye			
subjects affected / exposed	22 / 86 (25.58%)		
occurrences (all)	22		
Vitreous detachment - Fellow eye			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Vitreous floaters - Fellow eye			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Vitreous floaters - Study eye			
subjects affected / exposed	4 / 86 (4.65%)		
occurrences (all)	5		
Vitreous haemorrhage - Fellow eye			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Vitreous haemorrhage - Study eye			
subjects affected / exposed	6 / 86 (6.98%)		
occurrences (all)	6		
Vitreous opacities - Study eye			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Gastrointestinal disorders			
Gastric ulcer			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		

Gastritis				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Abdominal discomfort				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Abdominal pain				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Abdominal pain upper				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Constipation				
subjects affected / exposed	4 / 86 (4.65%)			
occurrences (all)	4			
Dental caries				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Diarrhoea				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Diverticulum				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Duodenal ulcer				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Food poisoning				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Pancreatitis acute				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Nausea				
subjects affected / exposed	3 / 86 (3.49%)			
occurrences (all)	4			

Irritable bowel syndrome subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Inguinal hernia subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Hiatus hernia subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Gastritis erosive subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Proctalgia subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Toothache subjects affected / exposed occurrences (all)	3 / 86 (3.49%) 3		
Vomiting subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Oesophageal dysplasia subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Skin and subcutaneous tissue disorders Actinic keratosis subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Decubitus ulcer subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Dermal cyst			

subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Sebaceous gland disorder			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Eczema			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Eczema asteatotic			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Lichenoid keratosis			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	2		
Pruritus			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Dermatitis			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Skin irritation			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Skin lesion			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Skin mass - Study eye			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Renal and urinary disorders			
Chronic kidney disease			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	2		

Renal impairment subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Glomerulosclerosis subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Incontinence subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Microalbuminuria subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Nephrolithiasis subjects affected / exposed occurrences (all)	2 / 86 (2.33%) 2		
Renal cyst subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Acute kidney injury subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Urinary tract obstruction subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Urinary retention subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Ureteric dilatation subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Musculoskeletal and connective tissue disorders			

Greater trochanteric pain syndrome				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Arthritis				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Flank pain				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Bursitis				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Back pain				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Foot deformity				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Arthralgia				
subjects affected / exposed	3 / 86 (3.49%)			
occurrences (all)	4			
Groin pain				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Muscle disorder				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Muscle spasms				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Myalgia				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Muscle tightness				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			

Osteoarthritis subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Osteoporosis subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Pain in extremity subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Polymyalgia rheumatica subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Spinal osteoarthritis subjects affected / exposed occurrences (all)	2 / 86 (2.33%) 2		
Spinal stenosis subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Tendonitis subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Rotator cuff syndrome subjects affected / exposed occurrences (all)	2 / 86 (2.33%) 2		
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Bacterial infection subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Appendicitis subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		
Acute sinusitis			

subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Abscess oral				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Abscess neck				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Abscess intestinal				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
COVID-19				
subjects affected / exposed	12 / 86 (13.95%)			
occurrences (all)	12			
Hordeolum - Fellow eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Cellulitis				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Conjunctivitis - Fellow eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Conjunctivitis - Study eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Conjunctivitis bacterial - Fellow eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Cystitis				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Diverticulitis				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Eye infection - Fellow eye				

subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Eye infection - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Herpes zoster				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Gingivitis				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Gingival abscess				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Gastrointestinal infection				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Gastroenteritis salmonella				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Furuncle				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Eyelid infection - Fellow eye				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Candida infection				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Hordeolum - Study eye				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	2 / 86 (2.33%)			
occurrences (all)	2			
Intervertebral discitis				

subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Kidney infection				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Leprosy				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Lower respiratory tract infection				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Lyme disease				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	4 / 86 (4.65%)			
occurrences (all)	4			
Oral candidiasis				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Otitis media acute				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Paronychia				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Periodontitis				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	5 / 86 (5.81%)			
occurrences (all)	5			
Post-acute COVID-19 syndrome				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Pyelonephritis				

subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Pyuria				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Root canal infection				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Sinusitis				
subjects affected / exposed	4 / 86 (4.65%)			
occurrences (all)	5			
Skin bacterial infection				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Skin infection				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Tinea pedis				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Tooth abscess				
subjects affected / exposed	3 / 86 (3.49%)			
occurrences (all)	3			
Tooth infection				
subjects affected / exposed	1 / 86 (1.16%)			
occurrences (all)	1			
Upper respiratory tract infection				
subjects affected / exposed	0 / 86 (0.00%)			
occurrences (all)	0			
Urinary tract infection				
subjects affected / exposed	3 / 86 (3.49%)			
occurrences (all)	3			
Urinary tract infection pseudomonal				

subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Rhinitis			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Glucose tolerance impaired			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Hypercholesterolaemia			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Hyperlipidaemia			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	2		
Hypoglycaemia			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Vitamin D deficiency			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Vitamin B12 deficiency			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 86 (0.00%)		
occurrences (all)	0		
Obesity			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		

Iron deficiency subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Hyponatraemia subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 86 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 November 2020	This protocol amendment included: study period extended to 2 years with the addition of Weeks 72 and 96. Revision of objectives to include the additional Week 72 and 96 timepoints, the addition of secondary objective: The change from baseline to Week 72 and Week 96 in geographic atrophy (GA) area as measured by fundus autofluorescence (FAF). Additional optical coherence tomography-angiography (OCT-A); OCT-A additional imaging assessments for CNV conversion. Genotyping ICF included as a separate statement. Protocol amendments classified as administrational changes, substantial amendments, and urgent amendments.
03 June 2021	Corrected the imaging modality for retinal anatomical measures. Clarification of OCT-A certification. Microperimetry imaging assessment requirements.
04 January 2022	This protocol amendment included randomisation of study eye, clarification of bleb number, GT005 deferral guidance, additional safety assessment with FAF at Week 5, and vital signs.
15 September 2022	This protocol amendment included: updated primary endpoint read-out timepoint from Week 48 to Week 72, several secondary endpoints have been changed to exploratory endpoints, updates to secondary and exploratory endpoints to be reported ‘through Week 96, updates to the statistical methods, study rationale, and dose rationale. Updated safety assessment guidance under Section 7.4.2.1 and updated the list of Adverse Events of Special Interest (AESI) to include RPE changes, updated recent information under ‘Risks associated with GT005. Updated guidance on the timing of cataract surgery during the study under Section 1.6.1.2, Risks Associated with the surgical and study procedures. Updates to Section 3.1 Study Overview, Section 3.4.1 Masking, and Section 5.5 Measures to Minimize Bias.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.nov for complete trial results.

Notes: