



Clinical trial results:

A Master Protocol to Investigate the Efficacy and Safety of Tirzepatide Once Weekly in Participants who have Obstructive Sleep Apnea and Obesity: A Randomized, Double-Blind, Placebo-Controlled Trial (SURMOUNT-OSA)

Summary

EudraCT number	2021-004552-41
Trial protocol	CZ
Global end of trial date	29 March 2024

Results information

Result version number	v2 (current)
This version publication date	30 April 2025
First version publication date	27 March 2025
Version creation reason	• Correction of full data set Correction of full data set

Trial information

Trial identification

Sponsor protocol code	I8F-MC-GPIF
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05412004
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-285-4559,

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	29 March 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	29 March 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that QW (once weekly) tirzepatide at the MTD (maximum-tolerated dose) (10 mg or 15 mg) is superior to placebo for mean percent decrease in AHI (Apnea-Hypopnea Index).

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 June 2022
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	United States: 149
Country: Number of subjects enrolled	China: 37
Country: Number of subjects enrolled	Japan: 20
Country: Number of subjects enrolled	Taiwan: 16
Country: Number of subjects enrolled	Brazil: 84
Country: Number of subjects enrolled	Mexico: 69
Country: Number of subjects enrolled	Australia: 25
Country: Number of subjects enrolled	Germany: 46
Country: Number of subjects enrolled	Czechia: 23
Worldwide total number of subjects	469
EEA total number of subjects	69

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)	418
From 65 to 84 years	51
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Not applicable

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
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Arm title	Tirzepatide MTD_GPI1
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Arm description:

Participants not on positive airway pressure (PAP) therapy received a maximum tolerated dose (MTD) of 10 milligrams (mg) or 15 mg of Tirzepatide once weekly (QW) as a subcutaneous (SC) injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks.

Arm type	Experimental
Investigational medicinal product name	Tirzepatide
Investigational medicinal product code	LY3298176
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants not on PAP therapy received 10 mg or 15 mg Tirzepatide QW after initial titration of 2.5 mg every 4 weeks as SC injection for 52 weeks.

Arm title	Placebo_GPI1
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Arm description:

Participants not on PAP therapy received placebo QW as an SC injection for 52 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants not on PAP therapy received placebo QW as SC injection for 52 weeks.

Arm title	TZP MTD_GPI2
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Arm description:

Participants who are on PAP therapy received an MTD of 10 mg or 15 mg of Tirzepatide QW as an SC injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks.

Arm type	Experimental
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Investigational medicinal product name	Tirzepatide
Investigational medicinal product code	LY3298176
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants who are on PAP therapy received 10 mg or 15 mg Tirzepatide QW after initial titration of 2.5 mg every 4 weeks as SC injection for 52 weeks.

Arm title	Placebo_GPI2
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Arm description:

Participants who are on PAP therapy received placebo QW as SC injection for 52 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants who are on PAP therapy received placebo QW as SC injection for 52 weeks.

Number of subjects in period 1	Tirzepatide MTD_GPI1	Placebo_GPI1	TZP MTD_GPI2
Started	114	120	120
Received at Least One Dose of Study Drug	114	120	119
Completed	101	86	113
Not completed	13	34	7
Consent withdrawn by subject	4	19	4
Physician decision	-	1	-
Participant quit treatment due to their schedule	-	-	-
Screen Failure	-	-	-
Adverse event, non-fatal	-	2	1
Patient could not assist to site	-	1	-
Pregnancy	-	1	-
Protocol Violation	1	-	-
Lost to follow-up	3	-	-
Assigned Treatment by Mistake	5	10	2

Number of subjects in period 1	Placebo_GPI2
Started	115
Received at Least One Dose of Study Drug	114
Completed	89
Not completed	26
Consent withdrawn by subject	14

Physician decision	-
Participant quit treatment due to their schedule	1
Screen Failure	1
Adverse event, non-fatal	5
Patient could not assist to site	-
Pregnancy	-
Protocol Violation	-
Lost to follow-up	-
Assigned Treatment by Mistake	5

Baseline characteristics

Reporting groups

Reporting group title	Tirzepatide MTD_GPI1
Reporting group description:	
Participants not on positive airway pressure (PAP) therapy received a maximum tolerated dose (MTD) of 10 milligrams (mg) or 15 mg of Tirzepatide once weekly (QW) as a subcutaneous (SC) injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks.	
Reporting group title	Placebo_GPI1
Reporting group description:	
Participants not on PAP therapy received placebo QW as an SC injection for 52 weeks.	
Reporting group title	TZP MTD_GPI2
Reporting group description:	
Participants who are on PAP therapy received an MTD of 10 mg or 15 mg of Tirzepatide QW as an SC injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks.	
Reporting group title	Placebo_GPI2
Reporting group description:	
Participants who are on PAP therapy received placebo QW as SC injection for 52 weeks.	

Reporting group values	Tirzepatide MTD_GPI1	Placebo_GPI1	TZP MTD_GPI2
Number of subjects	114	120	120
Age categorical			
Units: Subjects			
<50years	63	62	54
>=50years	51	58	66
Age continuous			
Units: years			
arithmetic mean	47.3	48.4	47.3
standard deviation	± 11.0	± 11.9	± 11.0
Gender categorical			
All randomized participants.			
Units: Subjects			
Female	36	41	33
Male	78	79	87
Ethnicity (NIH/OMB)			
All randomized participants.			
Units: Subjects			
Hispanic or Latino	51	47	38
Not Hispanic or Latino	63	69	82
Unknown or Not Reported	0	4	0
Race (NIH/OMB)			
All randomized participants.			
Units: Subjects			
American Indian or Alaska Native	9	9	10
Asian	23	24	17
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	7	8
White	74	80	85
More than one race	2	0	0

Unknown or Not Reported	0	0	0
Region of Enrollment			
All randomized participants.			
Units: Subjects			
United States	35	36	41
China	14	14	4
Japan	3	4	7
Taiwan	5	4	4
Brazil	24	25	18
Mexico	20	19	14
Australia	1	5	10
Germany	7	7	16
Czechia	5	6	6
Baseline apnea-hypopnea index (AHI)			
AHI is the number of apneas or hypopneas recorded via polysomnography during the study per hour of sleep. Apnea is defined as a cessation of airflow lasting at least 10 seconds, and hypopnea as a decrease in airflow by at least 30% from baseline for at least 10 seconds occurring with a drop in oxygen saturation (SpO ₂) by at least 4%. AHI values are categorized as 5-15 episodes/hr = mild; 15-<30 episodes/hr = moderate; and ≥ 30 episodes/h = severe. A significant reduction in values indicates a positive outcome.0			
Units: events per hour			
arithmetic mean	52.86	50.13	46.08
standard deviation	± 30.50	± 31.47	± 22.35

Reporting group values	Placebo_GPI2	Total	
Number of subjects	115	469	
Age categorical			
Units: Subjects			
<50years	45	224	
≥50years	70	245	
Age continuous			
Units: years			
arithmetic mean	48.4	-	
standard deviation	± 11.9	-	
Gender categorical			
All randomized participants.			
Units: Subjects			
Female	32	142	
Male	83	327	
Ethnicity (NIH/OMB)			
All randomized participants.			
Units: Subjects			
Hispanic or Latino	38	174	
Not Hispanic or Latino	76	290	
Unknown or Not Reported	1	5	
Race (NIH/OMB)			
All randomized participants.			
Units: Subjects			
American Indian or Alaska Native	9	37	
Asian	16	80	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	3	24	

White	86	325	
More than one race	0	2	
Unknown or Not Reported	1	1	
Region of Enrollment			
All randomized participants.			
Units: Subjects			
United States	37	149	
China	5	37	
Japan	6	20	
Taiwan	3	16	
Brazil	17	84	
Mexico	16	69	
Australia	9	25	
Germany	16	46	
Czechia	6	23	
Baseline apnea-hypopnea index (AHI)			
AHI is the number of apneas or hypopneas recorded via polysomnography during the study per hour of sleep. Apnea is defined as a cessation of airflow lasting at least 10 seconds, and hypopnea as a decrease in airflow by at least 30% from baseline for at least 10 seconds occurring with a drop in oxygen saturation (SpO) by at least 4%. AHI values are categorized as 5-15 episodes/hr = mild; 15-<30 episodes/hr = moderate; and ≥ 30 episodes/h = severe. A significant reduction in values indicates a positive outcome.0			
Units: events per hour			
arithmetic mean	53.10		
standard deviation	± 30.23	-	

End points

End points reporting groups

Reporting group title	Tirzepatide MTD_GPI1
Reporting group description: Participants not on positive airway pressure (PAP) therapy received a maximum tolerated dose (MTD) of 10 milligrams (mg) or 15 mg of Tirzepatide once weekly (QW) as a subcutaneous (SC) injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks.	
Reporting group title	Placebo_GPI1
Reporting group description: Participants not on PAP therapy received placebo QW as an SC injection for 52 weeks.	
Reporting group title	TZP MTD_GPI2
Reporting group description: Participants who are on PAP therapy received an MTD of 10 mg or 15 mg of Tirzepatide QW as an SC injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks.	
Reporting group title	Placebo_GPI2
Reporting group description: Participants who are on PAP therapy received placebo QW as SC injection for 52 weeks.	

Primary: Change From Baseline in Apnea-Hypopnea Index (AHI)

End point title	Change From Baseline in Apnea-Hypopnea Index (AHI)
End point description: AHI, Apnea-Hypopnea Index, is the number of apneas or hypopneas recorded via polysomnography during the study per hour of sleep. Apnea is defined as a cessation of airflow lasting at least 10 seconds, and hypopnea as a decrease in airflow by at least 30% from baseline for at least 10 seconds occurring with a drop in oxygen saturation (SpO ₂) by at least 4%. AHI values are categorized as 5-15 events/hr = mild; 15-<30 events/hr = moderate; and ≥ 30 events/hr = severe. A significant reduction in values indicates a positive outcome. Analysis Population Description (APD): Modified intent-to-treat (mITT) population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome.	
End point type	Primary
End point timeframe: Baseline, Week 52	

End point values	Tirzepatide MTD_GPI1	Placebo_GPI1	TZP MTD_GPI2	Placebo_GPI2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	86	110	87
Units: events/hour				
least squares mean (standard error)	-25.25 (± 2.06)	-5.25 (± 2.11)	-29.27 (± 1.99)	-5.51 (± 2.21)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Tirzepatide MTD_GPI1 v Placebo_GPI1

Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[1]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-20.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.82
upper limit	-14.2

Notes:

[1] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Statistical analysis title	Statistical Analysis 2
Comparison groups	TZP MTD_GPI2 v Placebo_GPI2
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[2]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-23.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.61
upper limit	-17.93

Notes:

[2] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Secondary: Percent Change From Baseline in AHI

End point title	Percent Change From Baseline in AHI
End point description:	
Percent Change From Baseline in AHI was evaluated. APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome.	
End point type	Secondary
End point timeframe:	
Baseline, Week 52	

End point values	Tirzepatide MTD_GPI1	Placebo_GPI1	TZP MTD_GPI2	Placebo_GPI2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	86	110	87
Units: percentage change				
least squares mean (standard error)	-50.68 ($\pm$ 5.90)	-3.03 ($\pm$ 7.07)	-58.72 ($\pm$ 5.28)	-2.50 ($\pm$ 6.95)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Tirzepatide MTD_GPI1 v Placebo_GPI1
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[3]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-47.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-65.76
upper limit	-29.55

Notes:

[3] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Statistical analysis title	Statistical Analysis 2
Comparison groups	TZP MTD_GPI2 v Placebo_GPI2
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[4]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-56.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-73.73
upper limit	-38.7

Notes:

[4] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Secondary: Percentage of Participants With $\geq 50\%$ AHI Reduction From Baseline

End point title	Percentage of Participants With $\geq 50\%$ AHI Reduction From Baseline
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End point description:

The percentage of participants achieving $\geq 50\%$ AHI reduction from baseline to Week 52 was evaluated.

APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome.

End point type	Secondary
End point timeframe:	
Week 52	

End point values	Tirzepatide MTD_GPI1	Placebo_GPI1	TZP MTD_GPI2	Placebo_GPI2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	86	110	87
Units: Percentage of participants				
number (not applicable)	61.22	18.96	72.40	23.25

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Tirzepatide MTD_GPI1 v Placebo_GPI1
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	42.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	30.76
upper limit	54.79

Statistical analysis title	Statistical Analysis 2
Comparison groups	TZP MTD_GPI2 v Placebo_GPI2
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	48.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	36.55
upper limit	60.65

Secondary: Percentage of Participants With AHI <5 or With AHI 5-14 With Epworth Sleepiness Scale (ESS) ≤10

End point title	Percentage of Participants With AHI <5 or With AHI 5-14 With Epworth Sleepiness Scale (ESS) ≤10
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End point description:

The percentage of participants with OSA remission (AHI <5 events per hour of sleep) or with mild OSA without excessive daytime sleepiness (AHI 5-14 events per hour of sleep with ESS ≤10) at Week 52 was evaluated. The ESS is used to assess improvements in excessive daytime sleepiness from baseline to Week 52. The ESS is an 8-item, participant-completed measure that asks the participant to rate, on a scale of 0 (no chance of dozing) to 3 (high chance of dozing), their usual chances of dozing in 8 different daytime situations, with a recall period of "in recent times." The ESS total score is the sum of the 8-item scores and ranges from 0 to 24, with higher scores indicating greater daytime sleepiness.

End point type	Secondary
End point timeframe:	
Week 52	

End point values	Tirzepatide MTD_GPI1	Placebo_GPI1	TZP MTD_GPI2	Placebo_GPI2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	86	110	87
Units: percentage of participants				
number (not applicable)	42.17	15.88	50.24	14.33

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Tirzepatide MTD_GPI1 v Placebo_GPI1
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	28.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.27
upper limit	39.22

Statistical analysis title	Statistical Analysis 2
Comparison groups	TZP MTD_GPI2 v Placebo_GPI2

Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	33.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.12
upper limit	44.31

Secondary: Change From Baseline in Sleep Apnea-Specific Hypoxic Burden (SASHB) (% Min/Hour)

End point title	Change From Baseline in Sleep Apnea-Specific Hypoxic Burden (SASHB) (% Min/Hour)
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End point description:

SASHB is determined by measuring the respiratory event-associated area under the curve for oxygen desaturation from pre-event baseline and represents the cumulative burden of intermittent hypoxia caused by OSA-related sleep-disordered breathing at sleep. Percent change in SASHB from baseline to Week 52 was evaluated. APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome.

End point type	Secondary
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End point timeframe:

Baseline, Week 52

End point values	Tirzepatide MTD_GPI1	Placebo_GPI1	TZP MTD_GPI2	Placebo_GPI2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	86	110	87
Units: %.min/hr				
least squares mean (standard error)	-95.19 (± 4.081)	-25.07 (± 9.804)	-102.98 (± 3.758)	-41.69 (± 11.313)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Tirzepatide MTD_GPI1 v Placebo_GPI1

Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Median difference (net)
Point estimate	-70.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-90.94
upper limit	-49.31
Variability estimate	Standard error of the mean
Dispersion value	10.619

Statistical analysis title	Statistical Analysis 2
Comparison groups	TZP MTD_GPI2 v Placebo_GPI2
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Median difference (net)
Point estimate	-61.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-84.66
upper limit	-37.93
Variability estimate	Standard error of the mean
Dispersion value	11.921

Secondary: Change From Baseline in Patient-Reported Outcomes Measurement Information System (PROMIS) Short Form Sleep-Related Impairment 8a (PROMIS SRI) and PROMIS Short Form Sleep Disturbance 8b (PROMIS SD)

End point title	Change From Baseline in Patient-Reported Outcomes Measurement Information System (PROMIS) Short Form Sleep-Related Impairment 8a (PROMIS SRI) and PROMIS Short Form Sleep Disturbance 8b (PROMIS SD)
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End point description:

PROMIS SRI consists of 8 items that assess self-reported perceptions of alertness, sleepiness, and tiredness during usual waking hours and perceived functional impairments associated with sleep problems. PROMIS SRI has a recall period of "in the past 7 days" and each item is rated on a 5-point scale from "not at all" to "very much." PROMIS SD consists of 8 items that assess self-reported perceptions of sleep quality, sleep depth, and restoration associated with sleep. PROMIS SD has a recall period of "in the past 7 days" and each item is rated on a 5-point scale ranging from "not at all" to "very much," "never" to "always," or "very poor" to "very good." For both PROMIS SRI and PROMIS SD, item responses are used to generate T-scores which are standardized scores with a mean of 50 and a standard deviation of 10 (score range cannot be specified for T-scores). Higher T-scores indicate worse outcomes; more sleep-related impairment (PROMIS SRI) or more sleep disturbance (PROMIS SD).

End point type	Secondary
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End point timeframe:

Baseline, Week 52

APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome.

End point values	Tirzepatide MTD_GPI1	Placebo_GPI1	TZP MTD_GPI2	Placebo_GPI2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	79	93	79
Units: score on a scale				
least squares mean (standard error)				
Sleep Disturbance	-4.47 (± 0.69)	-2.44 (± 0.70)	-6.98 (± 0.82)	-3.08 (± 0.88)
Sleep-Related Impairment	-6.57 (± 0.83)	-3.13 (± 0.80)	-8.18 (± 0.95)	-3.91 (± 1.03)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Sleep Disturbance	
Comparison groups	Tirzepatide MTD_GPI1 v Placebo_GPI1
Number of subjects included in analysis	169
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.037 ^[5]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-2.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.95
upper limit	-0.12

Notes:

[5] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Sleep Related Impairment	
Comparison groups	Tirzepatide MTD_GPI1 v Placebo_GPI1
Number of subjects included in analysis	169
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 ^[6]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-3.43

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.69
upper limit	-1.17

Notes:

[6] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Statistical analysis title	Statistical Analysis 3
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Statistical analysis description:

Sleep Disturbance

Comparison groups	TZP MTD_GPI2 v Placebo_GPI2
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[7]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-3.9

Confidence interval

level	95 %
sides	2-sided
lower limit	-6.21
upper limit	-1.58

Notes:

[7] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Statistical analysis title	Statistical Analysis 4
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Statistical analysis description:

Sleep Related Impairment

Comparison groups	TZP MTD_GPI2 v Placebo_GPI2
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 ^[8]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-4.26

Confidence interval

level	95 %
sides	2-sided
lower limit	-6.97
upper limit	-1.56

Notes:

[8] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Secondary: Percent Change From Baseline in Body Weight

End point title	Percent Change From Baseline in Body Weight
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End point description:

Percent Change from Baseline in Body Weight is evaluated. APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome.

End point type	Secondary
End point timeframe:	
Baseline, Week 52	

End point values	Tirzepatide MTD_GPI1	Placebo_GPI1	TZP MTD_GPI2	Placebo_GPI2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	87	113	90
Units: Percent change				
least squares mean (standard deviation)	-17.65 ($\pm$ 0.69)	-1.56 ($\pm$ 0.68)	-19.62 ($\pm$ 0.71)	-2.34 ($\pm$ 0.74)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo_GPI1 v Tirzepatide MTD_GPI1
Number of subjects included in analysis	188
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[9]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-16.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.99
upper limit	-14.19

Notes:

[9] - ANCOVA model was used with baseline, geographic region, sex, baseline OSA severity Group, treatment (Type III sum of squares) as covariates.

Statistical analysis title	Statistical Analysis 2
Comparison groups	TZP MTD_GPI2 v Placebo_GPI2
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[10]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-17.28

Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.29
upper limit	-15.28

Notes:

[10] - ANCOVA model was used with baseline, geographic region, sex, baseline OSA severity Group, treatment (Type III sum of squares) as covariates.

Secondary: Change From Baseline in High Sensitivity C Reactive Protein (hsCRP) Concentration

End point title	Change From Baseline in High Sensitivity C Reactive Protein (hsCRP) Concentration
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End point description:

HsCRP is a marker for inflammation and was measured from blood samples to identify the presence of inflammation, to determine its severity, and to monitor response to treatment. APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome.

End point type	Secondary
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End point timeframe:

Baseline, Week 52

End point values	Tirzepatide MTD_GPI1	Placebo_GPI1	TZP MTD_GPI2	Placebo_GPI2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	95	84	102	82
Units: mg (milligram)/L (liter)				
least squares mean (standard error)	-1.42 (± 0.151)	-0.70 (± 0.203)	-1.37 (± 0.130)	-0.33 (± 0.236)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Tirzepatide MTD_GPI1 v Placebo_GPI1
Number of subjects included in analysis	179
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.752 ^[11]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.21
upper limit	-0.22
Variability estimate	Standard error of the mean
Dispersion value	0.253

Notes:

[11] - ANCOVA model was used with baseline, geographic region, sex, baseline OSA severity Group, treatment (Type III sum of squares) as covariates.

Statistical analysis title	Statistical Analysis 2
Comparison groups	TZP MTD_GPI2 v Placebo_GPI2
Number of subjects included in analysis	184
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.35 ^[12]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.57
upper limit	-0.51
Variability estimate	Standard error of the mean
Dispersion value	0.269

Notes:

[12] - ANCOVA model was used with baseline, geographic region, sex, baseline OSA severity Group, treatment (Type III sum of squares) as covariates.

Secondary: Change From Baseline in Systolic Blood Pressure (SBP)

End point title	Change From Baseline in Systolic Blood Pressure (SBP)
End point description:	
Change in systolic blood pressure from baseline to Week 48 is evaluated. APD: mITT population consisting of all randomized participants who are exposed to at least 1 dose of study intervention and have evaluable data for this outcome.	
End point type	Secondary
End point timeframe:	
Baseline, Week 48	

End point values	Tirzepatide MTD_GPI1	Placebo_GPI1	TZP MTD_GPI2	Placebo_GPI2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	89	112	91
Units: mmHg				
least squares mean (standard error)	-9.46 (± 1.02)	-1.84 (± 1.03)	-7.64 (± 1.03)	-3.94 (± 1.18)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Tirzepatide MTD_GPI1 v Placebo_GPI1

Number of subjects included in analysis	189
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[13]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-7.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.48
upper limit	-4.77

Notes:

[13] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Statistical analysis title	Statistical Analysis 2
Comparison groups	TZP MTD_GPI2 v Placebo_GPI2
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.017 ^[14]
Method	ANCOVA
Parameter estimate	LS Mean Change difference
Point estimate	-3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.75
upper limit	-0.65

Notes:

[14] - ANCOVA model was used with baseline, geographic region, sex, treatment (Type III sum of squares) as covariates.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All randomized participants are exposed to at least 1 dose of study intervention. Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

Adverse event reporting additional description:

As per the prespecified statistical analysis plan, adverse events were analyzed as per the treatment regimen.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Tirzepatide MTD_GPI1
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Reporting group description:

Participants not on PAP therapy received an MTD of 10 mg or 15 mg of Tirzepatide QW as an SC injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks.

Reporting group title	Placebo_GPI2
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Reporting group description:

Participants who are on PAP therapy received placebo QW as an SC injection for 52 weeks.

Reporting group title	Placebo_GPI1
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Reporting group description:

Participants not on PAP therapy received placebo QW as an SC injection for 52 weeks.

Reporting group title	Tirzepatide MTD_GPI2
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Reporting group description:

Participants who are on PAP therapy received an MTD of 10 mg or 15 mg of Tirzepatide QW as an SC injection for 52 weeks, including the initial dose escalation by 2.5 mg every 4 weeks.

Serious adverse events	Tirzepatide MTD_GPI1	Placebo_GPI2	Placebo_GPI1
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 114 (7.89%)	12 / 114 (10.53%)	7 / 120 (5.83%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
clear cell renal cell carcinoma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric cancer			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (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
malignant melanoma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (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
plasma cell myeloma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (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
prostate cancer metastatic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed ^[1]	0 / 78 (0.00%)	1 / 82 (1.22%)	0 / 79 (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
tonsil cancer metastatic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
aortic stenosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (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
hypotension			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
nephrectomy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
abnormal uterine bleeding			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed ^[2]	0 / 36 (0.00%)	1 / 32 (3.13%)	0 / 41 (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			
asthmatic crisis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (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

mood swings			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
road traffic accident			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (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
upper limb fracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (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
atrial fibrillation			

alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	2 / 120 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (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
Nervous system disorders			
cerebral haemorrhage			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (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
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gallbladder polyp			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hydronephrosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthritis			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
loose body in joint alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (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
spinal osteoarthritis alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
appendicitis alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dengue fever alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (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
gastroenteritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
hypokalaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Tirzepatide MTD_GPI2		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 119 (5.88%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
clear cell renal cell carcinoma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
gastric cancer			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
malignant melanoma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
plasma cell myeloma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
prostate cancer metastatic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed ^[1]	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
tonsil cancer metastatic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
aortic stenosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hypotension			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
nephrectomy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
abnormal uterine bleeding			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed ^[2]	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
asthmatic crisis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

mood swings alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 119 (0.00%) 0 / 0 0 / 0			
suicide attempt alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 119 (0.00%) 0 / 0 0 / 0			
Injury, poisoning and procedural complications road traffic accident alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 119 (0.84%) 0 / 1 0 / 0			
tendon injury alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 119 (0.00%) 0 / 0 0 / 0			
upper limb fracture alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 119 (0.00%) 0 / 0 0 / 0			
Cardiac disorders acute myocardial infarction alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 119 (0.00%) 0 / 0 0 / 0			
atrial fibrillation				

alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
coronary artery disease			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
cerebral haemorrhage			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
coma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
presyncope			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
pancreatitis acute			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 119 (0.84%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
gallbladder polyp			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
hydronephrosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
nephrolithiasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
arthritis			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
intervertebral disc protrusion alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
loose body in joint alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
osteoarthritis alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
spinal osteoarthritis alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
appendicitis alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
dengue fever alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 119 (0.84%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
gastroenteritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
pneumonia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
hypokalaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

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

Non-serious adverse events	Tirzepatide MTD_GPI1	Placebo_GPI2	Placebo_GPI1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	91 / 114 (79.82%)	82 / 114 (71.93%)	91 / 120 (75.83%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adrenal adenoma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0

benign neoplasm of skin alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
colorectal adenoma alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
enchondromatosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
metastasis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
melanocytic naevus alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
neoplasm skin alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
seborrhoeic keratosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 2	0 / 120 (0.00%) 0
squamous cell carcinoma of skin alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
Vascular disorders			

aortic occlusion alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
haematoma alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
hypertension alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	2 / 114 (1.75%) 2	8 / 120 (6.67%) 9
hypotension alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	3 / 114 (2.63%) 3	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
internal haemorrhage alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
Surgical and medical procedures cochlea implant alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
fascia release alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
intraocular lens implant alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
phlebectomy alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
tooth extraction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	3	0	1
ureteral stent insertion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
administration site reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	4	0	0
application site pruritus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
application site reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	3	0	0
asthenia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
chest discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	1	1	0
chest pain			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
fatigue			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	2	1	0
feeling cold			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences (all)	0	1	1
injection site bruising			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	3 / 114 (2.63%)	1 / 120 (0.83%)
occurrences (all)	1	3	1
injection site erythema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
injection site pruritus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0

injection site rash			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
injection site reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	8 / 114 (7.02%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	70	0	2
injection site urticaria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
local reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	2	0	0
malaise			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
oedema peripheral			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	2 / 114 (1.75%)	1 / 120 (0.83%)
occurrences (all)	0	3	1
pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
peripheral swelling			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	2 / 120 (1.67%)
occurrences (all)	0	0	3
pyrexia			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed occurrences (all)	2 / 114 (1.75%) 2	1 / 114 (0.88%) 1	2 / 120 (1.67%) 2
temperature intolerance alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
thirst alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
Immune system disorders anaphylactic reaction alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
drug hypersensitivity alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
seasonal allergy alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 4	0 / 114 (0.00%) 0	2 / 120 (1.67%) 2
Reproductive system and breast disorders benign prostatic hyperplasia alternative dictionary used: MedDRA 26.1 subjects affected / exposed ^[3] occurrences (all)	0 / 78 (0.00%) 0	1 / 82 (1.22%) 1	0 / 79 (0.00%) 0
cervical cyst alternative dictionary used: MedDRA 26.1 subjects affected / exposed ^[4] occurrences (all)	1 / 36 (2.78%) 1	0 / 32 (0.00%) 0	0 / 41 (0.00%) 0
cervical polyp alternative dictionary used: MedDRA 26.1			

subjects affected / exposed ^[5] occurrences (all)	0 / 36 (0.00%) 0	0 / 32 (0.00%) 0	0 / 41 (0.00%) 0
prostatitis alternative dictionary used: MedDRA 26.1 subjects affected / exposed ^[6] occurrences (all)	1 / 78 (1.28%) 1	1 / 82 (1.22%) 1	0 / 79 (0.00%) 0
vaginal haemorrhage alternative dictionary used: MedDRA 26.1 subjects affected / exposed ^[7] occurrences (all)	0 / 36 (0.00%) 0	0 / 32 (0.00%) 0	1 / 41 (2.44%) 1
Respiratory, thoracic and mediastinal disorders			
asthma alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	3 / 120 (2.50%) 3
cough alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	4 / 114 (3.51%) 4	2 / 114 (1.75%) 2	2 / 120 (1.67%) 3
diaphragmatic disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
epistaxis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
nasal congestion alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	2 / 114 (1.75%) 2	0 / 120 (0.00%) 0
oropharyngeal pain alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
paranasal cyst			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
pleurisy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
productive cough			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
respiratory disorder			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
pulmonary mass			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
rhinorrhoea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
rhinitis allergic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
sinus congestion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0

snoring alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
tonsillar inflammation alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
vasomotor rhinitis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
wheezing alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
Psychiatric disorders anxiety disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
anxiety alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	2 / 114 (1.75%) 2	2 / 114 (1.75%) 2	4 / 120 (3.33%) 4
bruxism alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
confusional state alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 3
depression alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	3 / 114 (2.63%)	2 / 114 (1.75%)	1 / 120 (0.83%)
occurrences (all)	3	2	1
hallucination			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
insomnia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 114 (2.63%)	0 / 114 (0.00%)	2 / 120 (1.67%)
occurrences (all)	4	0	2
libido decreased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
mood altered			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
panic attack			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
rapid eye movement sleep behaviour disorder			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
sleep disorder			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
Product issues			
device physical property issue			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
albumin urine present			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	2	0	0
amylase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	4 / 114 (3.51%)	3 / 120 (2.50%)
occurrences (all)	1	5	3
blood bicarbonate increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
blood calcitonin increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	2 / 120 (1.67%)
occurrences (all)	0	0	2
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
blood pressure decreased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
blood osmolarity decreased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
blood glucose increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences (all)	0	2	1
blood creatinine increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	1	1	0
blood pressure increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	2 / 114 (1.75%)	1 / 120 (0.83%)
occurrences (all)	0	2	1
blood urea increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
blood testosterone decreased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
blood pressure measurement			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0

cardiac murmur			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
coronavirus test positive			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	1	0	1
creatinine urine increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
electrocardiogram t wave inversion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
heart rate increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	5 / 114 (4.39%)	0 / 114 (0.00%)	2 / 120 (1.67%)
occurrences (all)	5	0	2
lipids abnormal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
lipase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 114 (2.63%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	4	0	0
mean cell volume increased			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
occult blood positive			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
pancreatic enzymes increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
protein urine present			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
sars-cov-2 test positive			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	2	0	0
transaminases increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
weight decreased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
vitamin d decreased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
white blood cell count decreased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0

weight increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	2 / 120 (1.67%) 2
Injury, poisoning and procedural complications			
animal bite alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
bone contusion alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
breast injury alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
contusion alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	3 / 114 (2.63%) 3	0 / 120 (0.00%) 0
epicondylitis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
eye contusion alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
fall alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	3 / 114 (2.63%) 5	1 / 120 (0.83%) 1
foot fracture alternative dictionary used:			

MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
head injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	2 / 120 (1.67%)
occurrences (all)	0	0	2
hand fracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	1	1	0
iatrogenic injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
injection related reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
joint injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences (all)	0	1	1
lower limb fracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
limb injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	2 / 114 (1.75%)	1 / 120 (0.83%)
occurrences (all)	1	3	1
ligament sprain			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	3 / 114 (2.63%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	3	0	1
meniscus injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
muscle strain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences (all)	0	1	1
muscle rupture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
nail avulsion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
overdose			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	4 / 114 (3.51%)	2 / 114 (1.75%)	2 / 120 (1.67%)
occurrences (all)	4	2	2
road traffic accident			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
skin laceration			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
soft tissue injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0

spinal column injury alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
viiiith nerve injury alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
wrist fracture alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	2 / 114 (1.75%) 2	0 / 120 (0.00%) 0
Cardiac disorders angina pectoris alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	2 / 114 (1.75%) 2	0 / 120 (0.00%) 0
aortic valve incompetence alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
arrhythmia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
atrioventricular block second degree alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
atrial fibrillation alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	1 / 120 (0.83%) 1
bradycardia alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
bundle branch block right			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
coronary artery disease			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
extrasystoles			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
mitral valve incompetence			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
sinus arrhythmia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
supraventricular extrasystoles			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
supraventricular tachycardia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
tachycardia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	2	0	1

ventricular extrasystoles alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
Nervous system disorders			
carotid arteriosclerosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
carpal tunnel syndrome alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 2	0 / 120 (0.00%) 0
dizziness alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	2 / 114 (1.75%) 4	3 / 114 (2.63%) 5	2 / 120 (1.67%) 2
dysgeusia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
headache alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	4 / 114 (3.51%) 4	1 / 114 (0.88%) 1	3 / 120 (2.50%) 6
hypoesthesia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
hypotonia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
lethargy alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	2 / 120 (1.67%)
occurrences (all)	0	1	2
memory impairment			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
migraine			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	2 / 120 (1.67%)
occurrences (all)	0	3	2
neuralgia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
ophthalmic migraine			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
presyncope			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	2 / 120 (1.67%)
occurrences (all)	0	1	2
somnolence			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0

taste disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
tremor alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
Blood and lymphatic system disorders			
anaemia macrocytic alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
anaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	2 / 114 (1.75%) 2	0 / 120 (0.00%) 0
leukopenia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
macrocytosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
lymphadenitis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
microcytic anaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
neutropenia alternative dictionary used: MedDRA 26.1			

subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
sudden hearing loss			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
tinnitus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
vertigo			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
Eye disorders			
dry eye			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
photopsia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
vitreous haemorrhage			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
vitreous degeneration			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	5 / 114 (4.39%)	2 / 114 (1.75%)	1 / 120 (0.83%)
occurrences (all)	10	2	1
abdominal discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	2 / 114 (1.75%)	1 / 120 (0.83%)
occurrences (all)	3	2	1
abdominal pain upper			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	4 / 114 (3.51%)	2 / 114 (1.75%)	2 / 120 (1.67%)
occurrences (all)	4	2	6
abdominal pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	7 / 114 (6.14%)	2 / 114 (1.75%)	4 / 120 (3.33%)
occurrences (all)	7	2	4
aphthous ulcer			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
barrett's oesophagus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
colon dysplasia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
constipation			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	18 / 114 (15.79%)	5 / 114 (4.39%)	3 / 120 (2.50%)
occurrences (all)	25	7	4
diarrhoea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	30 / 114 (26.32%)	10 / 114 (8.77%)	15 / 120 (12.50%)
occurrences (all)	69	15	21
diverticulum intestinal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
dyspepsia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	5 / 114 (4.39%)	1 / 114 (0.88%)	2 / 120 (1.67%)
occurrences (all)	5	1	4
epigastric discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
enterocolitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
enteritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
eructation			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	9 / 114 (7.89%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	11	1	0
erosive oesophagitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0

flatulence			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 114 (2.63%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences (all)	4	1	1
frequent bowel movements			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences (all)	0	1	1
gastric polyps			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	1	1	0
gastritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	2 / 114 (1.75%)	0 / 120 (0.00%)
occurrences (all)	1	2	0
gastrointestinal hypermotility			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	2
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	9 / 114 (7.89%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	13	0	1
haemorrhoids			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	2	1	0
hiatus hernia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
inguinal hernia			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
large intestine polyp			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
malocclusion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	3	0	0
mouth ulceration			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
nausea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	29 / 114 (25.44%)	6 / 114 (5.26%)	12 / 120 (10.00%)
occurrences (all)	59	7	15
oesophagitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
pancreatitis acute			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
pelvic floor dysfunction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
salivary gland cyst			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0

toothache alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	2 / 114 (1.75%) 2	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
vomiting alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	20 / 114 (17.54%) 34	1 / 114 (0.88%) 1	5 / 120 (4.17%) 6
Hepatobiliary disorders cholelithiasis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
gallbladder polyp alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
hepatic function abnormal alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
hepatic steatosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	2 / 114 (1.75%) 2	1 / 120 (0.83%) 1
Skin and subcutaneous tissue disorders actinic keratosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
acne alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
alopecia			

alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	5 / 114 (4.39%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences (all)	5	1	1
angioedema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
dermatitis allergic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	1	0	1
dermal cyst			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
erythema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	2	0	0
hand dermatitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
night sweats			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
pigmentation disorder			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	2	0	0
psoriasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
rash pruritic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
sebaceous hyperplasia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
skin lesion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
urticaria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			
diabetic nephropathy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
glomerulonephropathy			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 114 (0.88%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	1	1	0
haematuria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
hydronephrosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
hypertonic bladder			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
microalbuminuria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
nephrolithiasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 114 (2.63%)	0 / 114 (0.00%)	2 / 120 (1.67%)
occurrences (all)	3	0	2
nephropathy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
pollakiuria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
proteinuria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0

renal colic alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
urethral stenosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
urinary incontinence alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
urinary retention alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
Endocrine disorders autoimmune thyroid disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
goitre alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
hyperparathyroidism alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
thyroid mass alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
Musculoskeletal and connective tissue disorders			

arthritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
arthralgia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 114 (2.63%)	5 / 114 (4.39%)	6 / 120 (5.00%)
occurrences (all)	3	5	6
back pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	5 / 114 (4.39%)	2 / 120 (1.67%)
occurrences (all)	1	5	2
bursitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
extremity contracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
joint swelling			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
muscle contracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
muscle spasms			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
musculoskeletal stiffness			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
musculoskeletal pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
musculoskeletal chest pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
muscle tightness			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences (all)	0	1	1
myalgia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	2	1	0
myositis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
neck pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	1	0	1
osteoarthritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	2 / 114 (1.75%)	1 / 120 (0.83%)
occurrences (all)	0	3	1

pain in extremity			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences (all)	2	1	1
plantar fasciitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	3 / 120 (2.50%)
occurrences (all)	0	0	6
sacroiliac joint dysfunction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
spinal osteoarthritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	2	0	0
spinal pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
tendon disorder			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
tendonitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences (all)	1	1	2
trigger finger			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
torticollis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
vertebral foraminal stenosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
acute sinusitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	2 / 114 (1.75%)	0 / 120 (0.00%)
occurrences (all)	1	3	0
bronchitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	7 / 114 (6.14%)	0 / 120 (0.00%)
occurrences (all)	0	7	0
covid-19			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	6 / 114 (5.26%)	11 / 114 (9.65%)	10 / 120 (8.33%)
occurrences (all)	6	12	11
conjunctivitis viral			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
conjunctivitis bacterial			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences (all)	0	1	1
cystitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	2 / 120 (1.67%)
occurrences (all)	0	0	2
dengue fever			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
diverticulitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
erysipelas			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
epstein-barr virus infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
fungus infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
fungus foot infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0

fungal skin infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
gastroenteritis viral alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
gastroenteritis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	3 / 114 (2.63%) 3	1 / 114 (0.88%) 1	4 / 120 (3.33%) 4
gastrointestinal infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	2 / 114 (1.75%) 2	0 / 120 (0.00%) 0
helicobacter infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
herpes zoster alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
hordeolum alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	2 / 120 (1.67%) 2
herpes virus infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
influenza alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	4 / 114 (3.51%)	3 / 114 (2.63%)	8 / 120 (6.67%)
occurrences (all)	5	3	8
lower respiratory tract infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	1	0	1
nasopharyngitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 114 (2.63%)	12 / 114 (10.53%)	8 / 120 (6.67%)
occurrences (all)	3	17	8
onychomycosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
oral candidiasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
otitis externa			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
otitis media acute			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
parasitic gastroenteritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
paronychia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0

pharyngitis streptococcal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
pneumonia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	1 / 114 (0.88%)	2 / 120 (1.67%)
occurrences (all)	2	1	2
post procedural infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
postoperative wound infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
pseudomembranous colitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 114 (2.63%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	3	0	1
pyelonephritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
respiratory tract infection viral			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
rhinitis			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 114 (0.00%)	2 / 114 (1.75%)	0 / 120 (0.00%)
occurrences (all)	0	2	0
sinusitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	5 / 114 (4.39%)	2 / 120 (1.67%)
occurrences (all)	2	5	2
tonsillitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	2 / 114 (1.75%)	0 / 120 (0.00%)
occurrences (all)	2	2	0
tinea pedis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
tooth abscess			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	1	1	0
tooth infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	7 / 114 (6.14%)	8 / 114 (7.02%)	10 / 120 (8.33%)
occurrences (all)	10	9	11
urinary tract infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 114 (1.75%)	1 / 114 (0.88%)	2 / 120 (1.67%)
occurrences (all)	2	1	2
viral infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0

viral upper respiratory tract infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	1 / 120 (0.83%) 1
Metabolism and nutrition disorders dehydration alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
decreased appetite alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	4 / 114 (3.51%) 4	3 / 114 (2.63%) 3	0 / 120 (0.00%) 0
diabetes mellitus alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
dyslipidaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	2 / 114 (1.75%) 2	3 / 120 (2.50%) 3
gout alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	2 / 114 (1.75%) 6	0 / 114 (0.00%) 0	0 / 120 (0.00%) 0
glucose tolerance impaired alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	2 / 120 (1.67%) 2
hypertriglyceridaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 114 (0.88%) 1	2 / 120 (1.67%) 2
hyperuricaemia alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	2 / 114 (1.75%)	4 / 114 (3.51%)	4 / 120 (3.33%)
occurrences (all)	3	5	4
hyperglycaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences (all)	0	1	1
hyperkalaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	2 / 114 (1.75%)	0 / 120 (0.00%)
occurrences (all)	1	2	0
hyperlipidaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	2 / 120 (1.67%)
occurrences (all)	1	0	2
hypoglycaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
hyponatraemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
increased appetite			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 114 (0.88%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
iron deficiency			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 114 (0.00%)	3 / 114 (2.63%)	2 / 120 (1.67%)
occurrences (all)	0	3	2

vitamin d deficiency alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	1 / 114 (0.88%) 1	0 / 120 (0.00%) 0
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Non-serious adverse events	Tirzepatide MTD_GPI2		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	98 / 119 (82.35%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adrenal adenoma alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
benign neoplasm of skin alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
colorectal adenoma alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
enchondromatosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
metastasis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
melanocytic naevus alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
neoplasm skin alternative dictionary used: MedDRA 26.1			

subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
seborrhoeic keratosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
squamous cell carcinoma of skin alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
Vascular disorders aortic occlusion alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 haematoma alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 hypertension alternative dictionary used: MedDRA 26.1 subjects affected / exposed 2 / 119 (1.68%) occurrences (all) 2 hypotension alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 internal haemorrhage alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
Surgical and medical procedures cochlea implant alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
fascia release			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
intraocular lens implant			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
phlebectomy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
tooth extraction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
ureteral stent insertion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
administration site reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
application site pruritus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
application site reaction			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
asthenia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	2		
chest discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
chest pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
fatigue			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	4 / 119 (3.36%)		
occurrences (all)	22		
feeling cold			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	2		
influenza like illness			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
injection site bruising			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 119 (1.68%)		
occurrences (all)	2		

injection site erythema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 119 (1.68%)		
occurrences (all)	13		
injection site pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
injection site pruritus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 119 (1.68%)		
occurrences (all)	13		
injection site rash			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
injection site reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	6 / 119 (5.04%)		
occurrences (all)	44		
injection site urticaria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
local reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	8		
malaise			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
oedema peripheral			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
pain alternative dictionary used: MedDRA 26.1 subjects affected / exposed 2 / 119 (1.68%) occurrences (all) 2			
peripheral swelling alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
pyrexia alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
temperature intolerance alternative dictionary used: MedDRA 26.1 subjects affected / exposed 2 / 119 (1.68%) occurrences (all) 2			
thirst alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
Immune system disorders anaphylactic reaction alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
drug hypersensitivity alternative dictionary used: MedDRA 26.1 subjects affected / exposed 1 / 119 (0.84%) occurrences (all) 1			
seasonal allergy alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed ^[3]	0 / 87 (0.00%)		
occurrences (all)	0		
cervical cyst			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed ^[4]	0 / 32 (0.00%)		
occurrences (all)	0		
cervical polyp			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed ^[5]	1 / 32 (3.13%)		
occurrences (all)	1		
prostatitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed ^[6]	0 / 87 (0.00%)		
occurrences (all)	0		
vaginal haemorrhage			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed ^[7]	0 / 32 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
cough			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 119 (2.52%)		
occurrences (all)	3		
diaphragmatic disorder			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
epistaxis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
nasal congestion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	4 / 119 (3.36%)		
occurrences (all)	4		
oropharyngeal pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
paranasal cyst			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
pleurisy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
productive cough			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
respiratory disorder			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
pulmonary mass			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		

rhinorrhoea alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
rhinitis allergic alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
sinus congestion alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
snoring alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
tonsillar inflammation alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
vasomotor rhinitis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
wheezing alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
Psychiatric disorders anxiety disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) anxiety alternative dictionary used: MedDRA 26.1	0 / 119 (0.00%) 0		

subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
bruxism			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
confusional state			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
depression			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
hallucination			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
insomnia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 119 (1.68%)		
occurrences (all)	2		
libido decreased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
mood altered			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
panic attack			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		

rapid eye movement sleep behaviour disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 sleep disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
Product issues device physical property issue alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
Investigations alanine aminotransferase increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 albumin urine present alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 amylase increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed 1 / 119 (0.84%) occurrences (all) 2 blood creatine phosphokinase increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed 1 / 119 (0.84%) occurrences (all) 1 blood bicarbonate increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			

blood calcitonin increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
blood cholesterol increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
blood alkaline phosphatase increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
blood pressure decreased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
blood osmolarity decreased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
blood glucose increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
blood creatinine increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
blood pressure increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
blood urea increased alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
blood testosterone decreased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
blood pressure measurement			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
cardiac murmur			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
coronavirus test positive			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
creatinine urine increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
electrocardiogram t wave inversion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
heart rate increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	2		

lipids abnormal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
lipase increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	4 / 119 (3.36%)		
occurrences (all)	5		
mean cell volume increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
occult blood positive			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
pancreatic enzymes increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
protein urine present			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
sars-cov-2 test positive			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
transaminases increased			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
weight decreased			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed occurrences (all) 1 / 119 (0.84%) 1			
vitamin d decreased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) 0 / 119 (0.00%) 0			
white blood cell count decreased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) 1 / 119 (0.84%) 1			
weight increased alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) 0 / 119 (0.00%) 0			
Injury, poisoning and procedural complications animal bite alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) 0 / 119 (0.00%) 0 bone contusion alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) 1 / 119 (0.84%) 1 breast injury alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) 0 / 119 (0.00%) 0 contusion alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all) 1 / 119 (0.84%) 1 epicondylitis alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
eye contusion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
fall			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
foot fracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
head injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
hand fracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
iatrogenic injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
injection related reaction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
joint injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		

lower limb fracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
limb injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
ligament sprain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
meniscus injury			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
muscle strain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
muscle rupture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
nail avulsion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
overdose			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	2		
road traffic accident			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
skin laceration alternative dictionary used: MedDRA 26.1 subjects affected / exposed 2 / 119 (1.68%) occurrences (all) 2			
soft tissue injury alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
spinal column injury alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
viiiith nerve injury alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
wrist fracture alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
Cardiac disorders angina pectoris alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
aortic valve incompetence alternative dictionary used: MedDRA 26.1 subjects affected / exposed 1 / 119 (0.84%) occurrences (all) 1			
arrhythmia alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
atrioventricular block second degree			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
atrial fibrillation			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
bradycardia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
bundle branch block right			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
coronary artery disease			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
extrasystoles			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
mitral valve incompetence			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
sinus arrhythmia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		

supraventricular extrasystoles alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
supraventricular tachycardia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
tachycardia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
ventricular extrasystoles alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
Nervous system disorders carotid arteriosclerosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
carpal tunnel syndrome alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
dizziness alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 2		
dysgeusia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
headache alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
hypoaesthesia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
hypotonia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
lethargy			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
memory impairment			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
migraine			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
neuralgia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
ophthalmic migraine			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
presyncope			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		

sciatica alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
somnolence alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
syncope alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
taste disorder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
tremor alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
Blood and lymphatic system disorders anaemia macrocytic alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
anaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
leukopenia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
macrocytosis alternative dictionary used: MedDRA 26.1			

subjects affected / exposed 1 / 119 (0.84%) occurrences (all) 1			
lymphadenitis alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
microcytic anaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
neutropenia alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
Ear and labyrinth disorders ear pain alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 sudden hearing loss alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 tinnitus alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 vertigo alternative dictionary used: MedDRA 26.1 subjects affected / exposed 1 / 119 (0.84%) occurrences (all) 1			
Eye disorders dry eye alternative dictionary used: MedDRA 26.1			

subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 photopsia alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 vitreous haemorrhage alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 vitreous degeneration alternative dictionary used: MedDRA 26.1 subjects affected / exposed 1 / 119 (0.84%) occurrences (all) 1			
Gastrointestinal disorders abdominal distension alternative dictionary used: MedDRA 26.1 subjects affected / exposed 4 / 119 (3.36%) occurrences (all) 4 abdominal discomfort alternative dictionary used: MedDRA 26.1 subjects affected / exposed 1 / 119 (0.84%) occurrences (all) 1 abdominal pain upper alternative dictionary used: MedDRA 26.1 subjects affected / exposed 7 / 119 (5.88%) occurrences (all) 8 abdominal pain alternative dictionary used: MedDRA 26.1 subjects affected / exposed 5 / 119 (4.20%) occurrences (all) 8 aphthous ulcer alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
barrett's oesophagus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
colon dysplasia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
constipation			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	18 / 119 (15.13%)		
occurrences (all)	19		
diarrhoea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	26 / 119 (21.85%)		
occurrences (all)	56		
diverticulum intestinal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
dyspepsia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	11 / 119 (9.24%)		
occurrences (all)	11		
epigastric discomfort			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
enterocolitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		

enteritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
eructation			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	10 / 119 (8.40%)		
occurrences (all)	26		
erosive oesophagitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
flatulence			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
frequent bowel movements			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
gastric polyps			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
gastritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 119 (1.68%)		
occurrences (all)	2		
gastrointestinal hypermotility			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	6 / 119 (5.04%)		
occurrences (all)	8		
haemorrhoids			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 119 (1.68%)		
occurrences (all)	2		
hiatus hernia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
inguinal hernia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
large intestine polyp			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
malocclusion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
mouth ulceration			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
nausea			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	26 / 119 (21.85%)		
occurrences (all)	58		
oesophagitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		

pancreatitis acute alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
pelvic floor dysfunction alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
salivary gland cyst alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
toothache alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
vomiting alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	11 / 119 (9.24%) 18		
Hepatobiliary disorders cholelithiasis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	2 / 119 (1.68%) 2		
gallbladder polyp alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
hepatic function abnormal alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
hepatic steatosis alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	2 / 119 (1.68%)		
occurrences (all)	2		
Skin and subcutaneous tissue disorders			
actinic keratosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
acne			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
alopecia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	5 / 119 (4.20%)		
occurrences (all)	5		
angioedema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
dermatitis allergic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
dermal cyst			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
erythema			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
hand dermatitis			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
night sweats			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
pigmentation disorder			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
pruritus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
psoriasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
rash pruritic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
sebaceous hyperplasia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
skin lesion			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		

urticaria alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
Renal and urinary disorders diabetic nephropathy alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
glomerulonephropathy alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
haematuria alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
hydronephrosis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
hypertonic bladder alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
microalbuminuria alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
nephrolithiasis alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	3 / 119 (2.52%) 4		
nephropathy alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
pollakiuria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
proteinuria			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
renal colic			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
urethral stenosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
urinary incontinence			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
urinary retention			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
Endocrine disorders			
autoimmune thyroid disorder			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
goitre			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
hyperparathyroidism alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
thyroid mass alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0			
Musculoskeletal and connective tissue disorders arthritis alternative dictionary used: MedDRA 26.1 subjects affected / exposed 1 / 119 (0.84%) occurrences (all) 1 arthralgia alternative dictionary used: MedDRA 26.1 subjects affected / exposed 4 / 119 (3.36%) occurrences (all) 4 back pain alternative dictionary used: MedDRA 26.1 subjects affected / exposed 1 / 119 (0.84%) occurrences (all) 1 bursitis alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 extremity contracture alternative dictionary used: MedDRA 26.1 subjects affected / exposed 0 / 119 (0.00%) occurrences (all) 0 intervertebral disc protrusion alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
joint swelling			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
muscle contracture			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
muscle spasms			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
musculoskeletal stiffness			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
musculoskeletal pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
musculoskeletal chest pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
muscle tightness			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
myalgia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		

myositis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
neck pain			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
osteoarthritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
pain in extremity			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
plantar fasciitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
sacroiliac joint dysfunction			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
rotator cuff syndrome			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
spinal osteoarthritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
spinal pain			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
tendon disorder			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
tendonitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
trigger finger			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
torticollis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
vertebral foraminal stenosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
Infections and infestations			
acute sinusitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
bronchitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 119 (2.52%)		
occurrences (all)	3		
covid-19			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	8 / 119 (6.72%)		
occurrences (all)	8		
conjunctivitis viral			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
conjunctivitis bacterial			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
conjunctivitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 119 (1.68%)		
occurrences (all)	2		
cystitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
dengue fever			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
diverticulitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
ear infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
erysipelas			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		

epstein-barr virus infection			
alternative dictionary used:			
MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
fungal infection			
alternative dictionary used:			
MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
fungal foot infection			
alternative dictionary used:			
MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
fungal skin infection			
alternative dictionary used:			
MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
gastroenteritis viral			
alternative dictionary used:			
MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
gastroenteritis			
alternative dictionary used:			
MedDRA 26.1			
subjects affected / exposed	7 / 119 (5.88%)		
occurrences (all)	8		
gastrointestinal infection			
alternative dictionary used:			
MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
helicobacter infection			
alternative dictionary used:			
MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
herpes zoster			
alternative dictionary used:			
MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
hordeolum			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
herpes virus infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
influenza			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	3 / 119 (2.52%)		
occurrences (all)	3		
lower respiratory tract infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
nasopharyngitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	15 / 119 (12.61%)		
occurrences (all)	24		
onychomycosis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
oral candidiasis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
otitis externa			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		

otitis media acute			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
parasitic gastroenteritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
paronychia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
pharyngitis streptococcal			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
pneumonia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
post procedural infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
postoperative wound infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
pseudomembranous colitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
respiratory tract infection			
alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
pyelonephritis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
respiratory tract infection viral			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
rhinitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
sinusitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 119 (1.68%)		
occurrences (all)	2		
tonsillitis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
tinea pedis			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
tooth abscess			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
tooth infection			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	2 / 119 (1.68%)		
occurrences (all)	2		

upper respiratory tract infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	5 / 119 (4.20%) 7		
urinary tract infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
viral infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
viral upper respiratory tract infection alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
Metabolism and nutrition disorders			
dehydration alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	1 / 119 (0.84%) 1		
decreased appetite alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	3 / 119 (2.52%) 3		
diabetes mellitus alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
dyslipidaemia alternative dictionary used: MedDRA 26.1 subjects affected / exposed occurrences (all)	0 / 119 (0.00%) 0		
gout alternative dictionary used: MedDRA 26.1			

subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
glucose tolerance impaired			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
hypertriglyceridaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
hyperuricaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
hyperglycaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
hyperkalaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
hyperlipidaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		
hypoglycaemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
hyponatraemia			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	1 / 119 (0.84%)		
occurrences (all)	1		

increased appetite			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
iron deficiency			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		
vitamin d deficiency			
alternative dictionary used: MedDRA 26.1			
subjects affected / exposed	0 / 119 (0.00%)		
occurrences (all)	0		

Notes:

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender-specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 September 2022	Protocol Amendment (b): 1) The secondary objective "Change in AHI." was added. 2) The endpoint for key secondary objective "Change in SBP" has been updated to Week 48 from Week 52. 3) The endpoint for the other secondary objective, "Change in Diastolic Blood Pressure (DBP)," has been updated to Week 48 from Week 52. 4) Changes have been made to the Schedule of Activities to reflect the synchronization of timing of the Columbia-Suicide Severity Rating Scale (C-SSRS) to the Patient Health Questionnaire-9 (PHQ-9).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported