



Clinical trial results:

A Phase 3, Randomized, Double-blind, Active Comparator-controlled, Multicenter Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of V114 in Recipients of Allogeneic Hematopoietic Stem Cell Transplant (PNEU-STEM)

Summary

EudraCT number	2018-000066-11
Trial protocol	DE FR BE SE
Global end of trial date	04 November 2021

Results information

Result version number	v1
This version publication date	05 May 2022
First version publication date	05 May 2022

Trial information

Trial identification

Sponsor protocol code	V114-022
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03565900
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 November 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 November 2021
Global end of trial reached?	Yes
Global end of trial date	04 November 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study is designed 1) to describe the safety, tolerability, and immunogenicity of V114 and Prevna[®] 13[™] in pneumococcal vaccine-naïve adult and pediatric recipients of allogeneic hematopoietic stem cell transplant (HSCT), and 2) to describe the safety and tolerability of PNEUMOVAX[™]23 when administered 12 months after HSCT.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 September 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 18
Country: Number of subjects enrolled	Belgium: 72
Country: Number of subjects enrolled	Brazil: 10
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Colombia: 27
Country: Number of subjects enrolled	France: 39
Country: Number of subjects enrolled	Germany: 26
Country: Number of subjects enrolled	Mexico: 17
Country: Number of subjects enrolled	Sweden: 26
Country: Number of subjects enrolled	United States: 37
Worldwide total number of subjects	277
EEA total number of subjects	163

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	9
Adolescents (12-17 years)	5
Adults (18-64 years)	215
From 65 to 84 years	48
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study recruited male and female participants at least 3 years of age who have received allogeneic HSCT.

Pre-assignment

Screening details:

263 adult participants and 14 pediatric participants (3 to 18 years of age) were randomized 1:1 to receive either V114 or Prevnar 13™ on Day 1.

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

Blinding implementation details:

Study was double-blinded with in-house blinding procedures.

Arms

Are arms mutually exclusive?	Yes
Arm title	V114

Arm description:

Participants received single 0.5 mL intramuscular (IM) injection of V114 on Day 1, Day 30 and Day 60 and a single 0.5 mL IM injection of PNEUMOVAX™23 at 12 months after HSCT. Participants received HSCT 90 to 180 days prior to Day 1. Those who developed chronic graft-versus-host-disease (GVHD) during the first year after HSCT received V114 instead of PNEUMOVAX™23 as their fourth dose.

Arm type	Experimental
Investigational medicinal product name	V114
Investigational medicinal product code	
Other name	Pneumococcal 15-valent Conjugate Vaccine, VAXNEUVANCE™
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

15-valent pneumococcal conjugate vaccine containing 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F) present in Prevnar 13™ plus 2 additional serotypes (22F, 33F) in each 0.5 mL dose

Investigational medicinal product name	PNEUMOVAX™23
Investigational medicinal product code	
Other name	23-valent pneumococcal polysaccharide vaccine (PPV23)
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

23-valent pneumococcal polysaccharide vaccine containing 23 serotypes (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F) in each 0.5 mL dose

Arm title	Prevnar 13™
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Arm description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1, Day 30 and Day 60 and a single 0.5 mL IM injection of PNEUMOVAX™23 at 12 months after HSCT. Participants will have received HSCT 90 to 180 days prior to Day 1. Those who developed chronic GVHD during the first year after HSCT received Prevnar 13™ instead of PNEUMOVAX™23 as their fourth dose.

Arm type	Active comparator
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Investigational medicinal product name	PNEUMOVAX™23
Investigational medicinal product code	
Other name	23-valent pneumococcal polysaccharide vaccine (PPV23)
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

23-valent pneumococcal polysaccharide vaccine containing 23 serotypes (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F) in each 0.5 mL dose

Investigational medicinal product name	Pprevnar 13™
Investigational medicinal product code	
Other name	13-valent pneumococcal conjugate vaccine (PCV13)
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

13-valent pneumococcal conjugate vaccine containing 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F) in each 0.5 mL dose

Number of subjects in period 1	V114	Pprevnar 13™
Started	139	138
Dose 1 - (Day 1)	139	135
Dose 2 - (Day 30)	135	128
Dose 3 - (Day 60)	130	124
Completed	115	111
Not completed	24	27
Adverse event, serious fatal	9	7
Consent withdrawn by subject	4	5
Physician decision	7	11
unknown	4	1
Withdrawal By Parent/Guardian	-	1
Randomized By Mistake	-	2

Baseline characteristics

Reporting groups

Reporting group title	V114
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Reporting group description:

Participants received single 0.5 mL intramuscular (IM) injection of V114 on Day 1, Day 30 and Day 60 and a single 0.5 mL IM injection of PNEUMOVAX™23 at 12 months after HSCT. Participants received HSCT 90 to 180 days prior to Day 1. Those who developed chronic graft-versus-host-disease (GVHD) during the first year after HSCT received V114 instead of PNEUMOVAX™23 as their fourth dose.

Reporting group title	Prevnar 13™
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Reporting group description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1, Day 30 and Day 60 and a single 0.5 mL IM injection of PNEUMOVAX™23 at 12 months after HSCT. Participants will have received HSCT 90 to 180 days prior to Day 1. Those who developed chronic GVHD during the first year after HSCT received Prevnar 13™ instead of PNEUMOVAX™23 as their fourth dose.

Reporting group values	V114	Prevnar 13™	Total
Number of subjects	139	138	277
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	5	4	9
Adolescents (12-17 years)	3	2	5
Adults (18-64 years)	108	107	215
From 65-84 years	23	25	48
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	47.9	46.3	-
standard deviation	± 16.0	± 18.3	-
Gender Categorical Units: Subjects			
Female	57	62	119
Male	82	76	158
Race Units: Subjects			
American Indian or Alaska Native	4	3	7
Asian	2	4	6
Black or African American	6	1	7
Multiple	5	15	20
White	122	115	237
Ethnicity Units: Subjects			
Hispanic or Latino	30	29	59
Not Hispanic or Latino	104	104	208
Not Reported	3	4	7

Unknown	2	1	3
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End points

End points reporting groups

Reporting group title	V114
Reporting group description: Participants received single 0.5 mL intramuscular (IM) injection of V114 on Day 1, Day 30 and Day 60 and a single 0.5 mL IM injection of PNEUMOVAX™23 at 12 months after HSCT. Participants received HSCT 90 to 180 days prior to Day 1. Those who developed chronic graft-versus-host-disease (GVHD) during the first year after HSCT received V114 instead of PNEUMOVAX™23 as their fourth dose.	
Reporting group title	Pevnar 13™
Reporting group description: Participants received a single 0.5 mL IM injection of Pevnar 13™ on Day 1, Day 30 and Day 60 and a single 0.5 mL IM injection of PNEUMOVAX™23 at 12 months after HSCT. Participants will have received HSCT 90 to 180 days prior to Day 1. Those who developed chronic GVHD during the first year after HSCT received Pevnar 13™ instead of PNEUMOVAX™23 as their fourth dose.	
Subject analysis set title	V114 (Adult)
Subject analysis set type	Safety analysis
Subject analysis set description: All randomized adult participants who received at least 1 dose of V114	
Subject analysis set title	Pevnar 13™ (Adult)
Subject analysis set type	Safety analysis
Subject analysis set description: All randomized adult participants who received at least 1 dose of Pevnar 13™	
Subject analysis set title	V114 (Pediatric)
Subject analysis set type	Safety analysis
Subject analysis set description: All randomized pediatric participants who received at least 1 dose of V114	
Subject analysis set title	Pevnar 13™ (Pediatric)
Subject analysis set type	Safety analysis
Subject analysis set description: All randomized pediatric participants who received at least 1 dose of Pevnar 13™	

Primary: Adult Participants: Percentage of Participants With a Solicited Injection-site Adverse Event Following Any of the First 3 Doses With V114 or Pevnar 13™

End point title	Adult Participants: Percentage of Participants With a Solicited Injection-site Adverse Event Following Any of the First 3 Doses With V114 or Pevnar 13™ ^[1]
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End point description:

An adverse event (AE) is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. The percentage of adult participants with solicited injection-site AEs was assessed. The solicited injection-site AEs were erythema, pain, and swelling. All randomized participants who received at least 1 dose of study vaccination were analyzed.

End point type	Primary
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End point timeframe:

Up to 5 days after any of the Day 1, Day 30, or Day 60 vaccinations (V114 or Pevnar 13™)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses were planned for this endpoint.

End point values	V114 (Adult)	Pprevnar 13™ (Adult)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	131	129		
Units: Percentage of Participants				
number (confidence interval 95%)				
Injection site erythema	20.6 (14.0 to 28.6)	14.0 (8.5 to 21.2)		
Injection site pain	88.5 (81.8 to 93.4)	74.4 (66.0 to 81.7)		
Injection site swelling	32.1 (24.2 to 40.8)	17.8 (11.7 to 25.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Pediatric Participants: Percentage of Participants With a Solicited Injection-site Adverse Event Following Any of the First 3 Doses With V114 or Pprevnar 13™

End point title	Pediatric Participants: Percentage of Participants With a Solicited Injection-site Adverse Event Following Any of the First 3 Doses With V114 or Pprevnar 13™ ^[2]
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End point description:

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. The percentage of pediatric participants with solicited injection-site AEs was assessed. The solicited injection-site AEs were erythema, induration, pain, and swelling. All randomized participants who received at least 1 dose of study vaccination were analyzed.

End point type	Primary
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End point timeframe:

Up to 14 days after any of the Day 1, Day 30, or Day 60 vaccinations (V114 or Pprevnar 13™)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses were planned for this endpoint.

End point values	V114 (Pediatric)	Pprevnar 13™ (Pediatric)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	6		
Units: Percentage of Participants				
number (confidence interval 95%)				
Injection site erythema	0.0 (0.0 to 36.9)	33.3 (4.3 to 77.7)		
Injection site induration	12.5 (0.3 to 52.7)	33.3 (4.3 to 77.0)		
Injection site pain	75.0 (34.9 to 96.8)	83.3 (35.9 to 99.6)		
Injection site swelling	25.0 (3.2 to 65.1)	50.0 (11.8 to 88.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Adult Participants: Percentage of Participants With a Solicited Systemic Adverse Event Following Any of the First 3 Doses With V114 or Pevnar 13™

End point title	Adult Participants: Percentage of Participants With a Solicited Systemic Adverse Event Following Any of the First 3 Doses With V114 or Pevnar 13™ ^[3]
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End point description:

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. The percentage of adult participants with solicited systemic AEs was assessed. The solicited systemic AEs assessed were arthralgia, fatigue, headache, and myalgia. All randomized participants who received at least 1 dose of study vaccination were analyzed.

End point type	Primary
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End point timeframe:

Up to 14 days after any of the Day 1, Day 30, or Day 60 vaccinations (V114 or Pevnar 13™)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses were planned for this endpoint.

End point values	V114 (Adult)	Pevnar 13™ (Adult)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	131	129		
Units: Percentage of Participants				
number (confidence interval 95%)				
Arthralgia	16.0 (10.2 to 23.5)	18.6 (12.3 to 26.4)		
Fatigue	45.0 (36.3 to 54.0)	40.3 (31.8 to 49.3)		
Headache	29.0 (21.4 to 37.6)	31.0 (23.2 to 39.7)		
Myalgia	48.9 (40.0 to 57.7)	34.9 (26.7 to 43.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Pediatric Participants: Percentage of Participants With a Solicited Systemic Adverse Event Following Any of the First 3 Doses With V114 or Pevnar 13™

End point title	Pediatric Participants: Percentage of Participants With a Solicited Systemic Adverse Event Following Any of the First 3 Doses With V114 or Pevnar 13™ ^[4]
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End point description:

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. The percentage of pediatric participants with solicited systemic AEs was assessed. The solicited systemic AEs assessed were arthralgia, fatigue, headache, and myalgia. All randomized participants who received at least 1 dose of study vaccination were analyzed.

End point type	Primary
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End point timeframe:

Up to 14 days after any of the Day 1, Day 30, or Day 60 vaccinations (V114 or Prevnar 13™)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses were planned for this endpoint.

End point values	V114 (Pediatric)	Prevnar 13™ (Pediatric)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	6		
Units: Percentage of Participants				
number (confidence interval 95%)				
Arthralgia	12.5 (0.3 to 52.7)	0.0 (0.0 to 45.9)		
Fatigue	25.0 (3.2 to 65.1)	16.7 (0.4 to 64.1)		
Headache	12.5 (0.3 to 52.7)	16.7 (0.4 to 64.1)		
Myalgia	50.0 (15.7 to 84.3)	16.7 (0.4 to 64.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With a Vaccine-related Serious Adverse Event Up to Month 12 After Allogeneic HSCT

End point title	Percentage of Participants With a Vaccine-related Serious Adverse Event Up to Month 12 After Allogeneic HSCT ^[5]
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End point description:

A serious adverse event (SAE) is an AE that is life-threatening, requires or prolongs an existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, or is another important medical event deemed such by medical or scientific judgment. The percentage of participants with a vaccine-related SAE following dose 1 (with either V114 or Prevnar 13™) was reported. Vaccine-related SAEs were counted starting after vaccine dose 1 up to 12 months post-HSCT, which could be up to 9 months post-vaccine dose 1. All randomized participants who received at least 1 dose of the relevant study vaccination for the timepoint of interest were analyzed.

End point type	Primary
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End point timeframe:

Up to 9 months

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses were planned for this endpoint.

End point values	V114 (Adult)	Prevnar 13™ (Adult)	V114 (Pediatric)	Prevnar 13™ (Pediatric)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	129	8	6
Units: Percentage of Participants				
number (confidence interval 95%)	0.8 (0.0 to 4.2)	0.0 (0.0 to 2.8)	0.0 (0.0 to 36.9)	0.0 (0.0 to 45.9)

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Concentration (GMC) of Serotype-specific Immunoglobulin G (IgG) at 30 Days Following Dose 3 With V114 or Prevnar 13™ (Day 90)

End point title	Geometric Mean Concentration (GMC) of Serotype-specific Immunoglobulin G (IgG) at 30 Days Following Dose 3 With V114 or Prevnar 13™ (Day 90) ^[6]
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End point description:

The GMC of serotype-specific IgG for the serotypes contained in V114 (13 serotypes shared with Prevnar 13™ and 2 serotypes unique to V114) was determined using an electrochemiluminescence assay. All randomized participants without protocol deviations that could have substantially impacted the results of the immunogenicity endpoint and who had sufficient data to perform the analyses were analyzed.

End point type	Primary
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End point timeframe:

Day 90 (30 days after the Day 60 vaccinations with V114 or Prevnar 13™)

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses were planned for this endpoint.

End point values	V114	Prevnar 13™		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	135		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 1 (Shared) (n=105, 88)	2.97 (2.22 to 3.99)	1.90 (1.34 to 2.69)		
Serotype 3 (Shared) (n=105, 88)	0.80 (0.63 to 1.02)	0.52 (0.38 to 0.71)		
Serotype 4 (Shared) (n=105, 88)	1.61 (1.23 to 2.11)	1.52 (1.04 to 2.20)		
Serotype 5 (Shared) (n=105, 88)	2.85 (2.13 to 3.81)	1.91 (1.32 to 2.77)		
Serotype 6A (Shared) (n=105, 88)	3.40 (2.42 to 4.76)	2.79 (1.78 to 4.38)		
Serotype 6B (Shared) (n=105, 88)	3.49 (2.45 to 4.98)	2.86 (1.82 to 4.49)		
Serotype 7F (Shared) (n=105, 88)	3.20 (2.38 to 4.30)	3.01 (2.07 to 4.36)		
Serotype 9V (Shared) (n=105, 88)	2.56 (1.94 to 3.38)	1.83 (1.26 to 2.65)		
Serotype 14 (Shared) (n=105, 87)	6.50 (4.94 to 8.57)	4.61 (3.17 to 6.69)		
Serotype 18C (Shared) (n=105, 88)	3.84 (2.83 to 5.22)	2.58 (1.76 to 3.79)		
Serotype 19A (Shared) (n=105, 88)	5.03 (3.88 to 6.53)	4.31 (3.00 to 6.20)		

Serotype 19F (Shared) (n=105, 88)	5.03 (3.72 to 6.79)	3.67 (2.53 to 5.33)		
Serotype 23F (Shared) (n=105, 88)	3.59 (2.64 to 4.88)	2.62 (1.66 to 4.15)		
Serotype 22F (Unique to V114) (n=105, 86)	4.09 (3.02 to 5.54)	0.15 (0.11 to 0.20)		
Serotype 33F (Unique to V114) (n=105, 88)	3.40 (2.58 to 4.48)	0.39 (0.29 to 0.53)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adult Participants: Percentage of Participants With a Solicited Injection-site Adverse Event Following Vaccination With PNEUMOVAX™23

End point title	Adult Participants: Percentage of Participants With a Solicited Injection-site Adverse Event Following Vaccination With PNEUMOVAX™23
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End point description:

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. Following a single dose vaccination with PNEUMOVAX™23, the percentage of adult participants with solicited injection-site AEs was assessed. The solicited injection-site AEs were erythema, pain, and swelling. All randomized participants who received at least 1 dose of study vaccination were analyzed. Forty-seven participants in the V114 group and 58 participants in the Prevnar 13™ group did not receive PNEUMOVAX™23 and therefore were not included in the analysis for this end point.

End point type	Secondary
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End point timeframe:

Up to 5 days after the PNEUMOVAX™23 vaccination (12 months after HSCT and approximately 6 to 9 months after Day 1)

End point values	V114 (Adult)	Prevnar 13™ (Adult)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	84	71		
Units: Percentage of Participants				
number (confidence interval 95%)				
Injection site erythema	17.9 (10.4 to 27.7)	22.5 (13.5 to 34.0)		
Injection site pain	67.9 (56.8 to 77.6)	57.7 (45.4 to 69.4)		
Injection site swelling	21.4 (13.2 to 31.7)	23.9 (14.6 to 35.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pediatric Participants: Percentage of Participants With a Solicited

Injection-site Adverse Event Following Vaccination With PNEUMOVAX™23

End point title	Pediatric Participants: Percentage of Participants With a Solicited Injection-site Adverse Event Following Vaccination With PNEUMOVAX™23
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End point description:

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. Following single dose vaccination with PNEUMOVAX™23, the percentage of pediatric participants with solicited injection-site AEs was assessed. The solicited injection-site AEs were induration, pain, and swelling. All randomized participants who received at least 1 dose of study vaccination were analyzed. Three participants in the V114 group and two participants in the Prevnar 13™ group did not receive PNEUMOVAX™23 and therefore were not included in the analysis for this end point.

End point type	Secondary
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End point timeframe:

Up to 14 days after the PNEUMOVAX™23 vaccination (12 months after HSCT and approximately 6 to 9 months after Day 1)

End point values	V114 (Pediatric)	Prevnar 13™ (Pediatric)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	5	4		
Units: Percentage of Participants				
number (confidence interval 95%)				
Injection site induration	0.0 (0.0 to 52.2)	25.0 (0.6 to 80.6)		
Injection site pain	60.0 (14.7 to 94.7)	50.0 (6.8 to 93.2)		
Injection site swelling	20.0 (0.5 to 71.6)	25.0 (0.6 to 80.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adult Participants: Percentage of Participants With a Solicited Systemic Adverse Event Following Vaccination With PNEUMOVAX™23

End point title	Adult Participants: Percentage of Participants With a Solicited Systemic Adverse Event Following Vaccination With PNEUMOVAX™23
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End point description:

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. Following a single dose vaccination with PNEUMOVAX™23, the percentage of adult participants with solicited systemic AEs was assessed. The solicited systemic AEs were arthralgia, fatigue, headache, and myalgia. All randomized participants who received at least 1 dose of study vaccination were analyzed. Forty-seven participants in the V114 group and 58 participants in the Prevnar 13™ group did not receive PNEUMOVAX™23 and therefore were not included in the analysis for this end point.

End point type	Secondary
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End point timeframe:

Up to 14 days after the PNEUMOVAX™23 vaccination (12 months after HSCT and approximately 6 to 9 months after Day 1)

End point values	V114 (Adult)	Pprevnar 13™ (Adult)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	84	71		
Units: Percentage of Participants				
number (confidence interval 95%)				
Arthralgia	7.1 (2.7 to 14.9)	8.5 (3.2 to 17.5)		
Fatigue	22.6 (14.2 to 33.0)	16.9 (9.0 to 27.7)		
Headache	21.4 (13.2 to 31.7)	19.7 (11.2 to 30.9)		
Myalgia	32.1 (22.4 to 43.2)	26.8 (16.9 to 38.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pediatric Participants: Percentage of Participants With a Solicited Systemic Adverse Event Following Vaccination With PNEUMOVAX™23

End point title	Pediatric Participants: Percentage of Participants With a Solicited Systemic Adverse Event Following Vaccination With PNEUMOVAX™23
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End point description:

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. Following a single dose vaccination with PNEUMOVAX™23, the percentage of pediatric participants with solicited systemic AEs was assessed. The solicited systemic AEs were fatigue, headache, and myalgia. All randomized participants who received at least 1 dose of study vaccination were analyzed. Three participants in the V114 group and two participants in the Pprevnar 13™ group did not receive PNEUMOVAX™23 and therefore were not included in the analysis for this end point.

End point type	Secondary
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End point timeframe:

Up to 14 days after the PNEUMOVAX™23 vaccination (12 months after HSCT and approximately 6 to 9 months after Day 1)

End point values	V114 (Pediatric)	Pprevnar 13™ (Pediatric)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	5	4		
Units: Percentage of Participants				
number (confidence interval 95%)				
Fatigue	20.0 (0.5 to 71.6)	0.0 (0.0 to 60.2)		
Headache	20.0 (0.5 to 71.6)	0.0 (0.0 to 60.2)		

Myalgia	40.0 (5.3 to 85.3)	0.0 (0.0 to 60.2)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Vaccine-related Serious Adverse Event Following Vaccination With PNEUMOVAX™23

End point title	Percentage of Participants With a Vaccine-related Serious Adverse Event Following Vaccination With PNEUMOVAX™23
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End point description:

A SAE is an AE that is life-threatening, requires or prolongs an existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, or is another important medical event deemed such by medical or scientific judgment. The percentage of participants with a vaccine-related SAE following a single dose vaccination with PNEUMOVAX™23 was reported. All randomized participants who received at least 1 dose of the relevant study vaccination for the timepoint of interest were analyzed. Forty-seven adult participants in the V114 group, 58 adult participants in the Prevnar 13™ group, 3 pediatric participants in the V114 group, and 2 pediatric participants in the Prevnar 13™ group did not receive PNEUMOVAX™23 and therefore were not included in the analysis for this end point.

End point type	Secondary
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End point timeframe:

Up to 1 month after PNEUMOVAX™23 vaccination (12 months after HSCT and approximately 6 to 10 months after Day 1)

End point values	V114 (Adult)	Prevnar 13™ (Adult)	V114 (Pediatric)	Prevnar 13™ (Pediatric)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	84	71	5	4
Units: Percentage of Participants				
number (confidence interval 95%)	1.2 (0.0 to 6.5)	0.0 (0.0 to 5.1)	0.0 (0.0 to 52.2)	0.0 (0.0 to 60.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Adult Participants With GVHD: Percentage of Participants With a Solicited Injection-site Adverse Event Following Dose 4 With V114 or Prevnar 13™

End point title	Adult Participants With GVHD: Percentage of Participants With a Solicited Injection-site Adverse Event Following Dose 4 With V114 or Prevnar 13™
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End point description:

This end point applies to adult participants who developed GVHD within 12 months of HSCT and received V114 or Prevnar 13™ as the fourth vaccination. An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. Following dose 4 with V114 or Prevnar 13™, the percentage

of adult participants with solicited injection-site AEs was assessed. The solicited injection-site AEs were erythema, pain, and swelling. All randomized participants who received at least 1 dose of study vaccination were analyzed. One hundred four participants in the V114 group and 93 participants in the Prevnar 13™ group did not receive a fourth dose of V114 or Prevnar 13™ and therefore were not included in the analysis for this end point.

End point type	Secondary
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End point timeframe:

Up to 5 days after the fourth V114 or Prevnar 13™ vaccination (12 months after HSCT and approximately 6 to 9 months after Day 1)

End point values	V114 (Adult)	Prevnar 13™ (Adult)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	27	36		
Units: Percentage of Participants				
number (confidence interval 95%)				
Injection site erythema	3.7 (0.1 to 19.0)	8.3 (1.8 to 22.5)		
Injection site pain	77.8 (57.7 to 91.4)	61.1 (43.5 to 76.9)		
Injection site swelling	22.2 (8.6 to 42.3)	13.9 (4.7 to 29.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pediatric Participants With GVHD: Percentage of Participants With a Solicited Injection-site Adverse Event Following Dose 4 With V114 or Prevnar 13™

End point title	Pediatric Participants With GVHD: Percentage of Participants With a Solicited Injection-site Adverse Event Following Dose 4 With V114 or Prevnar 13™
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End point description:

This end point applies to pediatric participants who developed GVHD within 12 months of HSCT and received V114 or Prevnar 13™ as the fourth vaccination dose. An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. Following dose 4 with V114 or Prevnar 13™, the percentage of pediatric participants with solicited injection-site AEs was assessed. The solicited injection-site AE was pain. All randomized participants who received at least 1 dose of study vaccination were analyzed. Six participants in the V114 group and 5 participants in the Prevnar 13™ group did not receive a fourth dose of V114 or Prevnar 13™ and therefore were not included in the analysis for this end point.

End point type	Secondary
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End point timeframe:

Up to 14 days after the fourth V114 or Prevnar 13™ vaccination (12 months after HSCT and approximately 6 to 9 months after Day 1)

End point values	V114 (Pediatric)	Pprevnar 13™ (Pediatric)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	1		
Units: Percentage of Participants				
number (confidence interval 95%)				
Injection site pain	50.0 (1.3 to 98.7)	0.0 (0.0 to 97.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adult Participants With GVHD: Percentage of Participants With a Solicited Systemic Adverse Event Following Dose 4 With V114 or Pprevnar 13™

End point title	Adult Participants With GVHD: Percentage of Participants With a Solicited Systemic Adverse Event Following Dose 4 With V114 or Pprevnar 13™
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End point description:

This end point applies to adult participants who developed GVHD within 12 months of HSCT and received V114 or Pprevnar 13™ as the fourth vaccination dose. An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. Following dose 4 with V114 or Pprevnar 13™, the percentage of adult participants with solicited systemic AEs was assessed. The solicited systemic AEs were arthralgia, fatigue, headache, and myalgia. All randomized participants who received at least 1 dose of study vaccination were analyzed. One hundred four participants in the V114 group and 93 participants in the Pprevnar 13™ group did not receive a fourth dose of V114 or Pprevnar 13™ and therefore were not included in the analysis for this end point.

End point type	Secondary
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End point timeframe:

Up to 14 days after the fourth V114 or Pprevnar 13™ vaccination (12 months after HSCT and approximately 6 to 9 months after Day 1)

End point values	V114 (Adult)	Pprevnar 13™ (Adult)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	27	36		
Units: Percentage of Participants				
number (confidence interval 95%)				
Arthralgia	11.1 (2.4 to 29.2)	8.3 (1.8 to 22.5)		
Fatigue	29.6 (13.8 to 50.2)	16.7 (6.4 to 32.8)		
Headache	22.2 (8.6 to 42.3)	11.1 (3.1 to 26.1)		
Myalgia	29.6 (13.8 to 50.2)	22.2 (10.1 to 39.2)		

Statistical analyses

Secondary: Pediatric Participants With GVHD: Percentage of Participants With a Solicited Systemic Adverse Event Following Dose 4 With V114 or Pevnar 13™

End point title	Pediatric Participants With GVHD: Percentage of Participants With a Solicited Systemic Adverse Event Following Dose 4 With V114 or Pevnar 13™
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End point description:

This end point applies to pediatric participants who developed GVHD within 12 months of HSCT and received V114 or Pevnar 13™ as the fourth vaccination. An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. Following dose 4 with V114 or Pevnar 13™, the percentage of pediatric participants with solicited systemic AEs was assessed. There were no solicited systemic AEs. All randomized participants who received at least 1 dose of study vaccination were analyzed. Six participants in the V114 group and 5 participants in the Pevnar 13™ group did not receive a fourth dose of V114 or Pevnar 13™ and therefore were not included in the analysis for this end point.

End point type	Secondary
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End point timeframe:

Up to 14 days after the fourth V114 or Pevnar 13™ vaccination (12 months after HSCT and approximately 6 to 9 months after Day 1)

End point values	V114 (Pediatric)	Pevnar 13™ (Pediatric)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	1		
Units: Percentage of Participants				
number (not applicable)	0.0	0.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Participants With GVHD: Percentage of Participants With a Vaccine-related Serious Adverse Event Following Dose 4 With V114 or Pevnar 13™

End point title	Participants With GVHD: Percentage of Participants With a Vaccine-related Serious Adverse Event Following Dose 4 With V114 or Pevnar 13™
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End point description:

This end point applies to participants who developed GVHD within 12 months of HSCT and received V114 or Pevnar 13™ as vaccine dose 4. An SAE is an AE that is life-threatening, requires or prolongs an existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, or is another important medical event deemed such by medical or scientific judgment. The percentage of participants with a vaccine-related SAE following dose 4 with V114 or Pevnar 13™ through completion of study was reported. All randomized participants who received at least 1 dose of relevant study vaccination for the timepoint of interest were analyzed. 104 adult participants in the V114 group, 93 adult participants in the Pevnar 13™ group, 6 pediatric participants in the V114 group, and 5 pediatric participants in the Pevnar 13™ group did not receive a fourth dose of V114 or Pevnar 13™ and therefore were not included in the analysis for this end point.

End point type	Secondary
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End point timeframe:

Up to 6 months after the fourth V114 or Pevnar 13™ vaccination (12 months after HSCT and approximately 6 to 15 months after Day 1)

End point values	V114 (Adult)	Prevnar 13™ (Adult)	V114 (Pediatric)	Prevnar 13™ (Pediatric)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	36	2	1
Units: Percentage of Participants				
number (confidence interval 95%)	0.0 (0.0 to 12.8)	0.0 (0.0 to 9.7)	0.0 (0.0 to 84.2)	0.0 (0.0 to 97.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer of Serotype-specific Opsonophagocytic Activity at 30 Days Following Dose 3 With V114 or Prevnar 13™ (Day 90)

End point title	Geometric Mean Titer of Serotype-specific Opsonophagocytic Activity at 30 Days Following Dose 3 With V114 or Prevnar 13™ (Day 90)
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End point description:

The GMT of serotype-specific OPA for the serotypes contained in V114 (13 serotypes shared with Prevnar 13™ and 2 serotypes unique to V114) was determined using a multiplexed opsonophagocytic assay. All randomized participants without protocol deviations that could have substantially impacted the results of the immunogenicity endpoint and who had sufficient data to perform the analyses were analyzed.

End point type	Secondary
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End point timeframe:

Up to Day 90 (30 days after the Day 60 vaccinations with V114 or Prevnar 13™)

End point values	V114	Prevnar 13™		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	135		
Units: Titers				
geometric mean (confidence interval 95%)				
Serotype 1 (Shared) (n=92, 68)	90.9 (60.8 to 135.9)	59.3 (37.8 to 93.1)		
Serotype 3 (Shared) (n=92, 67)	152.1 (114.6 to 201.7)	128.5 (89.6 to 184.4)		
Serotype 4 (Shared) (n=92, 68)	1008.4 (684.3 to 1486.2)	1357.7 (786.7 to 2343.1)		
Serotype 5 (Shared) (n=92, 68)	317.6 (206.7 to 487.9)	169.1 (106.1 to 269.6)		
Serotype 6A (Shared) (n=91, 68)	2494.5 (1731.4 to 3593.8)	2295.0 (1463.8 to 3598.4)		
Serotype 6B (Shared) (n=90, 68)	2280.2 (1500.8 to 3464.3)	3000.4 (1800.0 to 5001.3)		

Serotype 7F (Shared) (n=92, 68)	1945.3 (1278.5 to 2960.0)	3076.9 (1958.1 to 4834.7)		
Serotype 9V (Shared) (n=92, 66)	1059.4 (743.0 to 1510.5)	1050.0 (659.5 to 1671.6)		
Serotype 14 (Shared) (n=91, 68)	1953.6 (1296.9 to 2942.9)	1689.2 (995.0 to 2867.6)		
Serotype 18C (Shared) (n=92, 67)	1146.6 (833.6 to 1577.2)	714.6 (439.3 to 1162.3)		
Serotype 19A (Shared) (n=92, 68)	1365.6 (960.4 to 1941.8)	1201.6 (724.0 to 1994.2)		
Serotype 19F (Shared) (n=92, 67)	965.6 (675.3 to 1380.8)	1065.6 (707.8 to 1604.3)		
Serotype 23F (Shared) (n=91, 65)	1158.3 (784.1 to 1711.1)	2065.2 (1144.3 to 3727.4)		
Serotype 22F (Unique to V114) (n=89, 67)	1127.5 (717.9 to 1770.7)	19.0 (11.9 to 30.2)		
Serotype 33F (Unique to V114) (n=91, 68)	4441.7 (2966.6 to 6650.2)	173.6 (97.0 to 310.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Geometric Mean Fold Rises (GMFR) ≥ 4 in Serotype-specific IgG at 30 Days Following Dose 3 With V114 or Pevnar 13™ (Day 90)

End point title	Percentage of Participants With Geometric Mean Fold Rises (GMFR) ≥ 4 in Serotype-specific IgG at 30 Days Following Dose 3 With V114 or Pevnar 13™ (Day 90)
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End point description:

The GMFR of serotype-specific IgG for the serotypes contained in V114 (13 serotypes shared with Pevnar 13™ and 2 serotypes unique to V114) was determined using an electrochemiluminescence assay. All randomized participants without protocol deviations that could have substantially impacted the results of the immunogenicity endpoint and who had sufficient data to perform the analyses were analyzed.

End point type	Secondary
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End point timeframe:

Day 1 (Baseline) and Day 90 (30 days after the Day 60 vaccinations with V114 or Pevnar 13™)

End point values	V114	Pevnar 13™		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	135		
Units: Percentage of Participants				
geometric mean (confidence interval 95%)				
Serotype 1 (Shared) (n=103, 84)	69.9 (60.1 to 78.5)	64.3 (53.1 to 74.4)		
Serotype 3 (Shared) (n=103, 84)	62.1 (52.0 to 71.5)	48.8 (37.7 to 60.0)		

Serotype 4 (Shared) (n=103, 84)	73.8 (64.2 to 82.0)	70.2 (59.3 to 79.7)		
Serotype 5 (Shared) (n=103, 84)	60.2 (50.1 to 69.7)	60.7 (49.5 to 71.2)		
Serotype 6A (Shared) (n=103, 84)	73.8 (64.2 to 82.0)	69.0 (58.0 to 78.7)		
Serotype 6B (Shared) (n=103, 84)	71.8 (62.1 to 80.3)	69.0 (58.0 to 78.7)		
Serotype 7F (Shared) (n=103, 84)	69.9 (60.1 to 78.5)	70.2 (59.3 to 79.7)		
Serotype 9V (Shared) (n=103, 84)	65.0 (55.0 to 74.2)	63.1 (51.9 to 73.4)		
Serotype 14 (Shared) (n=103, 83)	51.5 (41.4 to 61.4)	50.6 (39.4 to 61.8)		
Serotype 18C (Shared) (n=103, 84)	67.0 (57.0 to 75.9)	61.9 (50.7 to 72.3)		
Serotype 19A (Shared) (n=103, 84)	55.3 (45.2 to 65.1)	48.8 (37.7 to 60.0)		
Serotype 19F (Shared) (n=103, 84)	63.1 (53.0 to 72.4)	61.9 (50.7 to 72.3)		
Serotype 23F (Shared) (n=103, 84)	61.2 (51.1 to 70.6)	61.9 (50.7 to 72.3)		
Serotype 22F (Unique to V114) (n=103, 83)	74.8 (65.2 to 82.8)	1.2 (0.0 to 6.5)		
Serotype 33F (Unique to V114) (n=103, 84)	54.4 (44.3 to 64.2)	4.8 (1.3 to 11.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With GMFR ≥ 4 in Serotype-specific OPA at 30 Days Following Dose 3 With V114 or Prevnar 13™ (Day 90)

End point title	Percentage of Participants With GMFR ≥ 4 in Serotype-specific OPA at 30 Days Following Dose 3 With V114 or Prevnar 13™ (Day 90)
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End point description:

Activity for the 15 serotypes contained in V114 vaccine were determined using a Multiplex Opsonophagocytic Assay. The GMFR of serotype-specific OPA for the serotypes contained in V114 (13 serotypes shared with Prevnar 13™ and 2 serotypes unique to V114) was determined using multiplexed opsonophagocytic assay. All randomized participants without protocol deviations that could have substantially impacted the results of the immunogenicity endpoint and who had sufficient data to perform the analyses were analyzed.

End point type	Secondary
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End point timeframe:

Time Frame: Day 1 (Baseline) and Day 90 (30 days after the Day 60 vaccinations with V114 or Prevnar 13™)

End point values	V114	Prevnam 13™		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	135		
Units: Percentage of Participants				
number (confidence interval 95%)				
Serotype 1 (Shared) (n=88, 61)	65.9 (55.0 to 75.7)	54.1 (40.8 to 66.9)		
Serotype 3 (Shared) (n=88, 61)	58.0 (47.0 to 68.4)	55.7 (42.4 to 68.5)		
Serotype 4 (Shared) (n=87, 59)	71.3 (60.6 to 80.5)	78.0 (65.3 to 87.7)		
Serotype 5 (Shared) (n=88, 62)	70.5 (59.8 to 79.7)	53.2 (40.1 to 66.0)		
Serotype 6A (Shared) (n=87, 61)	64.4 (53.4 to 74.4)	68.9 (55.7 to 80.1)		
Serotype 6B (Shared) (n=85, 60)	69.4 (58.5 to 79.0)	73.3 (60.3 to 83.9)		
Serotype 7F (Shared) (n=86, 60)	68.6 (57.7 to 78.2)	71.7 (58.6 to 82.5)		
Serotype 9V (Shared) (n=88, 60)	54.5 (43.6 to 65.2)	53.3 (40.0 to 66.3)		
Serotype 14 (Shared) (n=86, 62)	54.7 (43.5 to 65.4)	58.1 (44.8 to 70.5)		
Serotype 18C (Shared) (n=88, 60)	69.3 (58.6 to 78.7)	46.7 (33.7 to 60.0)		
Serotype 19A (Shared) (n=86, 61)	64.0 (52.9 to 74.0)	59.0 (45.7 to 71.7)		
Serotype 19F (Shared) (n=88, 61)	61.4 (50.4 to 71.6)	68.9 (55.7 to 80.1)		
Serotype 23F (Shared) (n=85, 55)	63.5 (52.4 to 73.7)	69.1 (55.2 to 80.9)		
Serotype 22F (Unique to V114) (n=84, 58)	70.2 (59.3 to 79.7)	3.4 (0.4 to 11.9)		
Serotype 33F (Unique to V114) (n=86, 62)	61.6 (50.5 to 71.9)	11.3 (4.7 to 21.9)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Non-serious AEs: Up to 14 days after each vaccination; SAEs and deaths (all-causes): Through 6 months after dose 4 with V114 or Prevnar13™ (up to 15 months total) or through 1 month after single dose vaccination with PNEUMOVAX™23 (up to 10 months total).

Adverse event reporting additional description:

The analysis population for deaths (all-causes) included all randomized participants. The analysis population for AEs included all randomized participants who received at least 1 dose of study vaccination.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	V114 (Following Any of First 3 Doses of PCV) Adults
Reporting group description: -	
Reporting group title	Prevnar 13™ (Following Any of First 3 Doses of PCV) Adults
Reporting group description: -	
Reporting group title	V114 (Following PPV23) Adults
Reporting group description: -	
Reporting group title	Prevnar 13™ (Following PPV23) Adults
Reporting group description: -	
Reporting group title	V114 (Following Dose 4 of PCV) Adults
Reporting group description: -	
Reporting group title	Prevnar 13™ (Following Dose 4 of PCV) Adults
Reporting group description: -	
Reporting group title	Prevnar 13™ (Following Any of First 3 Doses of PCV) Pediatric
Reporting group description: -	
Reporting group title	V114 (Following Any of First 3 Doses of PCV) Pediatric
Reporting group description: -	
Reporting group title	V114 (Following PPV23) Pediatric
Reporting group description: -	
Reporting group title	V114 (Following Dose 4 of PCV) Pediatric
Reporting group description: -	
Reporting group title	Prevnar 13™ (Following PPV23) Pediatric
Reporting group description: -	
Reporting group title	Prevnar 13™ (Following Dose 4 of PCV) Pediatric
Reporting group description: -	

Serious adverse events	V114 (Following Any of First 3 Doses of PCV) Adults	Prevnar 13™ (Following Any of First 3 Doses of PCV) Adults	V114 (Following PPV23) Adults
Total subjects affected by serious adverse events			
subjects affected / exposed	38 / 131 (29.01%)	48 / 129 (37.21%)	2 / 84 (2.38%)
number of deaths (all causes)	6	9	1
number of deaths resulting from	0	0	0

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Acute lymphocytic leukaemia recurrent			
subjects affected / exposed	2 / 131 (1.53%)	7 / 129 (5.43%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia recurrent			
subjects affected / exposed	2 / 131 (1.53%)	3 / 129 (2.33%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Central nervous system leukaemia			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Chronic lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (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
Chronic myeloid leukaemia			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Leukaemia recurrent			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Lymphocytic leukaemia			

subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Metastases to meninges			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Myelodysplastic syndrome			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post transplant lymphoproliferative disorder			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 131 (0.76%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Malaise			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (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
Mucosal inflammation			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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

Polyserositis			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Pyrexia			
subjects affected / exposed	0 / 131 (0.00%)	3 / 129 (2.33%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	1 / 131 (0.76%)	2 / 129 (1.55%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic graft versus host disease			
subjects affected / exposed	0 / 131 (0.00%)	2 / 129 (1.55%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease			
subjects affected / exposed	4 / 131 (3.05%)	5 / 129 (3.88%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Graft versus host disease in gastrointestinal tract			
subjects affected / exposed	2 / 131 (1.53%)	0 / 129 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease in liver			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (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
Graft versus host disease in lung			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Epiglottic cyst			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Organising pneumonia			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Pleurisy			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (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
Pneumothorax			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (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
Pulmonary embolism			
subjects affected / exposed	1 / 131 (0.76%)	2 / 129 (1.55%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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 failure			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (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
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Injury, poisoning and procedural complications			
Cervical vertebral fracture			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Transfusion microchimerism			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Cardiac arrest			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (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
Myocardial infarction			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Myocarditis			

subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Pericarditis			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Headache			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Hemiparesis			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Ischaemic stroke			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (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
Sciatica			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Febrile neutropenia			

subjects affected / exposed	2 / 131 (1.53%)	2 / 129 (1.55%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Immune thrombocytopenia			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Methaemoglobinaemia			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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			
Colitis			
subjects affected / exposed	0 / 131 (0.00%)	2 / 129 (1.55%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Diarrhoea			
subjects affected / exposed	3 / 131 (2.29%)	2 / 129 (1.55%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			

subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Intestinal ischaemia			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Large intestine polyp			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Vomiting			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Gallbladder obstruction			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Hepatic failure			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Cystitis haemorrhagic			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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			
Myositis			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Bronchiolitis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (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
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	1 / 131 (0.76%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Clostridium colitis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (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

Clostridium difficile colitis			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Cytomegalovirus colitis			
subjects affected / exposed	1 / 131 (0.76%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection reactivation			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Enterobacter bacteraemia			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Erysipelas			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Gastroenteritis			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Herpes zoster			
subjects affected / exposed	0 / 131 (0.00%)	2 / 129 (1.55%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			

subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Infection			
subjects affected / exposed	1 / 131 (0.76%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Influenza			
subjects affected / exposed	1 / 131 (0.76%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Neutropenic sepsis			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nocardia sepsis			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Parainfluenzae virus infection			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Pneumocystis jirovecii pneumonia			

subjects affected / exposed	2 / 131 (1.53%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	3 / 131 (2.29%)	6 / 129 (4.65%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia parainfluenzae viral			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (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 pneumococcal			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (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
Pulmonary sepsis			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Sepsis			
subjects affected / exposed	0 / 131 (0.00%)	2 / 129 (1.55%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Septic shock			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Sinusitis fungal			

subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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
Urinary tract infection			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 131 (0.76%)	0 / 129 (0.00%)	0 / 84 (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			
Hyperammonaemia			
subjects affected / exposed	0 / 131 (0.00%)	1 / 129 (0.78%)	0 / 84 (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

Serious adverse events	Prevnar 13™ (Following PPV23) Adults	V114 (Following Dose 4 of PCV) Adults	Prevnar 13™ (Following Dose 4 of PCV) Adults
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 71 (5.63%)	6 / 27 (22.22%)	7 / 36 (19.44%)
number of deaths (all causes)	0	2	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Acute lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 71 (0.00%)	2 / 27 (7.41%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute myeloid leukaemia recurrent			

subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Central nervous system leukaemia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Chronic lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Leukaemia recurrent			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Lymphocytic leukaemia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Metastases to meninges			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Myelodysplastic syndrome			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Post transplant lymphoproliferative disorder			

subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Malaise			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Polyserositis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Pyrexia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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

Chronic graft versus host disease subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Graft versus host disease subjects affected / exposed	0 / 71 (0.00%)	1 / 27 (3.70%)	2 / 36 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease in gastrointestinal tract subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Graft versus host disease in liver subjects affected / exposed	1 / 71 (1.41%)	0 / 27 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease in lung subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Respiratory, thoracic and mediastinal disorders Acute respiratory failure subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Chronic obstructive pulmonary disease subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Epiglottic cyst			

subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Organising pneumonia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Pleurisy			
subjects affected / exposed	1 / 71 (1.41%)	0 / 27 (0.00%)	0 / 36 (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
Pneumothorax			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Pulmonary oedema			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Respiratory failure			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Injury, poisoning and procedural complications			

Cervical vertebral fracture			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Transfusion microchimerism			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Cardiac arrest			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Myocarditis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Pericarditis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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

Headache			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Hemiparesis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Ischaemic stroke			
subjects affected / exposed	0 / 71 (0.00%)	1 / 27 (3.70%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sciatica			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Febrile neutropenia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 27 (0.00%)	0 / 36 (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
Haemolytic anaemia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Immune thrombocytopenia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Methaemoglobinaemia			

subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Constipation			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Diarrhoea			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Food poisoning			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Intestinal ischaemia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Large intestine perforation			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Large intestine polyp			

subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Vomiting			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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			
Cholecystitis acute			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Gallbladder obstruction			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Hepatic failure			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Cystitis haemorrhagic			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Musculoskeletal and connective tissue disorders			
Myositis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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

Infections and infestations Appendicitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 71 (0.00%) 0 / 0 0 / 0	 0 / 27 (0.00%) 0 / 0 0 / 0	 0 / 36 (0.00%) 0 / 0 0 / 0
Bronchiolitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 71 (0.00%) 0 / 0 0 / 0	 1 / 27 (3.70%) 0 / 1 0 / 0	 0 / 36 (0.00%) 0 / 0 0 / 0
Bronchopulmonary aspergillosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 71 (0.00%) 0 / 0 0 / 0	 0 / 27 (0.00%) 0 / 0 0 / 0	 0 / 36 (0.00%) 0 / 0 0 / 0
COVID-19 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 71 (0.00%) 0 / 0 0 / 0	 0 / 27 (0.00%) 0 / 0 0 / 0	 0 / 36 (0.00%) 0 / 0 0 / 0
Clostridium colitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 71 (0.00%) 0 / 0 0 / 0	 1 / 27 (3.70%) 0 / 1 0 / 0	 0 / 36 (0.00%) 0 / 0 0 / 0
Clostridium difficile colitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 71 (0.00%) 0 / 0 0 / 0	 0 / 27 (0.00%) 0 / 0 0 / 0	 0 / 36 (0.00%) 0 / 0 0 / 0
Cytomegalovirus colitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 71 (0.00%) 0 / 0 0 / 0	 0 / 27 (0.00%) 0 / 0 0 / 0	 0 / 36 (0.00%) 0 / 0 0 / 0
Cytomegalovirus infection reactivation subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 71 (0.00%) 0 / 0 0 / 0	 0 / 27 (0.00%) 0 / 0 0 / 0	 0 / 36 (0.00%) 0 / 0 0 / 0

Enterobacter bacteraemia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Erysipelas			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Gastroenteritis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Herpes zoster			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Infected skin ulcer			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Infection			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Influenza			

subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Klebsiella bacteraemia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Neutropenic sepsis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Nocardia sepsis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 71 (0.00%)	1 / 27 (3.70%)	0 / 36 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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			
subjects affected / exposed	1 / 71 (1.41%)	1 / 27 (3.70%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia parainfluenzae viral			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			

subjects affected / exposed	1 / 71 (1.41%)	0 / 27 (0.00%)	0 / 36 (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
Pulmonary sepsis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Sepsis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Sinusitis fungal			
subjects affected / exposed	0 / 71 (0.00%)	1 / 27 (3.70%)	0 / 36 (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
Urinary tract infection			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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
Metabolism and nutrition disorders			
Hyperammonaemia			

subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (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	Prevnar 13™ (Following Any of First 3 Doses of PCV) Pediatric	V114 (Following Any of First 3 Doses of PCV) Pediatric	V114 (Following PPV23) Pediatric
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 6 (16.67%)	2 / 8 (25.00%)	0 / 5 (0.00%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Acute lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 6 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute myeloid leukaemia recurrent			
subjects affected / exposed	1 / 6 (16.67%)	0 / 8 (0.00%)	0 / 5 (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
Central nervous system leukaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Chronic lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Chronic myeloid leukaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Leukaemia recurrent			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Lymphocytic leukaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Metastases to meninges			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Myelodysplastic syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Post transplant lymphoproliferative disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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

Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Mucosal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Polyserositis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Chronic graft versus host disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Graft versus host disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Graft versus host disease in gastrointestinal tract			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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

Graft versus host disease in liver subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Graft versus host disease in lung subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Epiglottic cyst			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Organising pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Pleurisy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Pneumothorax			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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

Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Pulmonary oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Injury, poisoning and procedural complications			
Cervical vertebral fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Transfusion microchimerism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Cardiac arrest			

subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Myocardial infarction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Myocarditis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Pericarditis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Ischaemic stroke			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Sciatica			

subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Haemolytic anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Immune thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Methaemoglobinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Diarrhoea			

subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Food poisoning			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Intestinal ischaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Large intestine perforation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Large intestine polyp			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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			
Cholecystitis acute			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Gallbladder obstruction			

subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Cystitis haemorrhagic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Musculoskeletal and connective tissue disorders			
Myositis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Bronchiolitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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

COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Clostridium colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Clostridium difficile colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Cytomegalovirus colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Enterobacter bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Erysipelas			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Gastroenteritis rotavirus			

subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	1 / 8 (12.50%)	0 / 5 (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
Infected skin ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Klebsiella bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Neutropenic sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Nocardia sepsis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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			
subjects affected / exposed	0 / 6 (0.00%)	1 / 8 (12.50%)	0 / 5 (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
Pneumonia parainfluenzae viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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 pneumococcal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Pulmonary sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Sepsis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Septic shock			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Sinusitis fungal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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
Metabolism and nutrition disorders			
Hyperammonaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (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	V114 (Following Dose 4 of PCV) Pediatric	Prevnar 13™ (Following PPV23) Pediatric	Prevnar 13™ (Following Dose 4 of PCV) Pediatric
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Acute lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Acute myeloid leukaemia recurrent			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Central nervous system leukaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Chronic lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Leukaemia recurrent			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Lymphocytic leukaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Metastases to meninges			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Myelodysplastic syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Post transplant lymphoproliferative disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Mucosal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Polyserositis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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

Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Chronic graft versus host disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Graft versus host disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Graft versus host disease in gastrointestinal tract			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Graft versus host disease in liver			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Graft versus host disease in lung			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Epiglottic cyst			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Organising pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Pleurisy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Pulmonary oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Respiratory failure			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Injury, poisoning and procedural complications			
Cervical vertebral fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Transfusion microchimerism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Cardiac arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Myocardial infarction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Myocarditis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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

Pericarditis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Hemiparesis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Ischaemic stroke			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Sciatica			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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

Haemolytic anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Immune thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Methaemoglobinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Food poisoning			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Intestinal ischaemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Large intestine perforation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Large intestine polyp			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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			
Cholecystitis acute			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Gallbladder obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Hepatic failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Cystitis haemorrhagic			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Musculoskeletal and connective tissue disorders			
Myositis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Bronchiolitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Clostridium colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Clostridium difficile colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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

Cytomegalovirus colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Enterobacter bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Erysipelas			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Infected skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Influenza			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Klebsiella bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Neutropenic sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Nocardia sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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 parainfluenzae viral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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 pneumococcal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Pulmonary sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Septic shock			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Sinusitis fungal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Urinary tract infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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
Metabolism and nutrition disorders			
Hyperammonaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (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

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

Non-serious adverse events	V114 (Following Any of First 3 Doses of PCV) Adults	Prevnar 13™ (Following Any of First 3 Doses of PCV) Adults	V114 (Following PPV23) Adults
Total subjects affected by non-serious adverse events			
subjects affected / exposed	125 / 131 (95.42%)	108 / 129 (83.72%)	65 / 84 (77.38%)
Nervous system disorders			
Headache			
subjects affected / exposed	38 / 131 (29.01%)	40 / 129 (31.01%)	18 / 84 (21.43%)
occurrences (all)	73	67	20
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	59 / 131 (45.04%)	52 / 129 (40.31%)	19 / 84 (22.62%)
occurrences (all)	105	111	21
Injection site erythema			
subjects affected / exposed	27 / 131 (20.61%)	18 / 129 (13.95%)	15 / 84 (17.86%)
occurrences (all)	37	22	15
Injection site hypersensitivity			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Injection site induration			

subjects affected / exposed occurrences (all)	0 / 131 (0.00%) 0	0 / 129 (0.00%) 0	0 / 84 (0.00%) 0
Injection site pain subjects affected / exposed occurrences (all)	116 / 131 (88.55%) 284	97 / 129 (75.19%) 237	57 / 84 (67.86%) 57
Injection site swelling subjects affected / exposed occurrences (all)	42 / 131 (32.06%) 64	23 / 129 (17.83%) 35	18 / 84 (21.43%) 18
Pyrexia subjects affected / exposed occurrences (all)	1 / 131 (0.76%) 1	2 / 129 (1.55%) 2	5 / 84 (5.95%) 5
Immune system disorders Chronic graft versus host disease in skin subjects affected / exposed occurrences (all)	0 / 131 (0.00%) 0	0 / 129 (0.00%) 0	0 / 84 (0.00%) 0
Graft versus host disease in eye subjects affected / exposed occurrences (all)	0 / 131 (0.00%) 0	0 / 129 (0.00%) 0	0 / 84 (0.00%) 0
Graft versus host disease in gastrointestinal tract subjects affected / exposed occurrences (all)	0 / 131 (0.00%) 0	4 / 129 (3.10%) 4	0 / 84 (0.00%) 0
Graft versus host disease in skin subjects affected / exposed occurrences (all)	0 / 131 (0.00%) 0	3 / 129 (2.33%) 3	0 / 84 (0.00%) 0
Eye disorders Conjunctival hyperaemia subjects affected / exposed occurrences (all)	1 / 131 (0.76%) 2	0 / 129 (0.00%) 0	0 / 84 (0.00%) 0
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	2 / 131 (1.53%) 3	6 / 129 (4.65%) 6	0 / 84 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 131 (0.76%) 1	0 / 129 (0.00%) 0	0 / 84 (0.00%) 0
Diarrhoea			

subjects affected / exposed	12 / 131 (9.16%)	5 / 129 (3.88%)	2 / 84 (2.38%)
occurrences (all)	15	6	2
Odynophagia			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	4 / 131 (3.05%)	3 / 129 (2.33%)	0 / 84 (0.00%)
occurrences (all)	4	3	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	1 / 131 (0.76%)	1 / 129 (0.78%)	0 / 84 (0.00%)
occurrences (all)	1	1	0
Skin and subcutaneous tissue disorders			
Prurigo			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	21 / 131 (16.03%)	24 / 129 (18.60%)	6 / 84 (7.14%)
occurrences (all)	33	38	6
Myalgia			
subjects affected / exposed	64 / 131 (48.85%)	45 / 129 (34.88%)	27 / 84 (32.14%)
occurrences (all)	111	77	30
Infections and infestations			
Pharyngitis			
subjects affected / exposed	0 / 131 (0.00%)	2 / 129 (1.55%)	0 / 84 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			

Decreased appetite subjects affected / exposed occurrences (all)	0 / 131 (0.00%) 0	2 / 129 (1.55%) 5	0 / 84 (0.00%) 0
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Non-serious adverse events	Prevnam 13™ (Following PPV23) Adults	V114 (Following Dose 4 of PCV) Adults	Prevnam 13™ (Following Dose 4 of PCV) Adults
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 71 (74.65%)	22 / 27 (81.48%)	26 / 36 (72.22%)
Nervous system disorders			
Headache			
subjects affected / exposed	14 / 71 (19.72%)	6 / 27 (22.22%)	4 / 36 (11.11%)
occurrences (all)	16	7	4
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	12 / 71 (16.90%)	8 / 27 (29.63%)	6 / 36 (16.67%)
occurrences (all)	16	9	6
Injection site erythema			
subjects affected / exposed	16 / 71 (22.54%)	1 / 27 (3.70%)	3 / 36 (8.33%)
occurrences (all)	16	1	3
Injection site hypersensitivity			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 71 (0.00%)	0 / 27 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	41 / 71 (57.75%)	21 / 27 (77.78%)	22 / 36 (61.11%)
occurrences (all)	42	21	23
Injection site swelling			
subjects affected / exposed	17 / 71 (23.94%)	6 / 27 (22.22%)	5 / 36 (13.89%)
occurrences (all)	17	7	5
Pyrexia			
subjects affected / exposed	1 / 71 (1.41%)	1 / 27 (3.70%)	2 / 36 (5.56%)
occurrences (all)	1	1	2
Immune system disorders			
Chronic graft versus host disease in skin			

subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Graft versus host disease in eye subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Graft versus host disease in gastrointestinal tract subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Graft versus host disease in skin subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Eye disorders Conjunctival hyperaemia subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Odynophagia subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Rhinorrhoea subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Skin and subcutaneous tissue disorders			

Prurigo subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Myalgia subjects affected / exposed occurrences (all)	6 / 71 (8.45%) 6 19 / 71 (26.76%) 20	3 / 27 (11.11%) 3 8 / 27 (29.63%) 8	3 / 36 (8.33%) 3 8 / 36 (22.22%) 8
Infections and infestations Pharyngitis subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 27 (0.00%) 0	0 / 36 (0.00%) 0

Non-serious adverse events	Prevna 13™ (Following Any of First 3 Doses of PCV) Pediatric	V114 (Following Any of First 3 Doses of PCV) Pediatric	V114 (Following PPV23) Pediatric
Total subjects affected by non-serious adverse events subjects affected / exposed	6 / 6 (100.00%)	7 / 8 (87.50%)	3 / 5 (60.00%)
Nervous system disorders Headache subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 2	1 / 8 (12.50%) 1	1 / 5 (20.00%) 2
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	1 / 6 (16.67%)	2 / 8 (25.00%)	1 / 5 (20.00%)
occurrences (all)	1	5	2
Injection site erythema			
subjects affected / exposed	2 / 6 (33.33%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	5	0	0
Injection site hypersensitivity			
subjects affected / exposed	1 / 6 (16.67%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Injection site induration			
subjects affected / exposed	2 / 6 (33.33%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	3	1	0
Injection site pain			
subjects affected / exposed	5 / 6 (83.33%)	6 / 8 (75.00%)	3 / 5 (60.00%)
occurrences (all)	8	13	3
Injection site swelling			
subjects affected / exposed	3 / 6 (50.00%)	2 / 8 (25.00%)	1 / 5 (20.00%)
occurrences (all)	5	3	1
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Chronic graft versus host disease in skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Graft versus host disease in eye			
subjects affected / exposed	1 / 6 (16.67%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Graft versus host disease in gastrointestinal tract			
subjects affected / exposed	1 / 6 (16.67%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Graft versus host disease in skin			
subjects affected / exposed	1 / 6 (16.67%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Eye disorders			

Conjunctival hyperaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0	0 / 5 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Odynophagia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 8 (12.50%) 2	0 / 5 (0.00%) 0
Skin and subcutaneous tissue disorders			
Prurigo subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Psychiatric disorders			
Depression subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Endocrine disorders			
Adrenal insufficiency subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 8 (0.00%) 0	0 / 5 (0.00%) 0
Musculoskeletal and connective tissue disorders			

Arthralgia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 8 (12.50%) 2	0 / 5 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	4 / 8 (50.00%) 8	2 / 5 (40.00%) 2
Infections and infestations Pharyngitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 8 (25.00%) 2	0 / 5 (0.00%) 0

Non-serious adverse events	V114 (Following Dose 4 of PCV) Pediatric	Prevnar 13™ (Following PPV23) Pediatric	Prevnar 13™ (Following Dose 4 of PCV) Pediatric
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 2 (50.00%)	3 / 4 (75.00%)	0 / 1 (0.00%)
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Injection site erythema subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Injection site hypersensitivity subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Injection site induration subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 4 (25.00%) 1	0 / 1 (0.00%) 0
Injection site pain			

subjects affected / exposed	1 / 2 (50.00%)	2 / 4 (50.00%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Injection site swelling			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Chronic graft versus host disease in skin			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Graft versus host disease in eye			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Graft versus host disease in gastrointestinal tract			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Graft versus host disease in skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival hyperaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Odynophagia			

subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Skin and subcutaneous tissue disorders Prurigo subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Infections and infestations Pharyngitis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 June 2018	Amendment 01: Primary reason for amendment was to incorporate revisions to the collection of medical device incidents from the protocol.
16 November 2018	Amendment 03: Primary reason for amendment was to incorporate revisions to add a pediatric cohort (≥ 3 years of age) to the existing study.
05 April 2019	Amendment 04: Primary reason for amendment was to adjust the stratification factor for steroid use and clarify the definition and reporting time frame for specific events of interest.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported