Clinical trial results:
A Phase 3, Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a 20-Valent Pneumococcal Conjugate Vaccine Given in A Series of 3 Infant Doses And 1 Toddler Dose in Infants in India and Taiwan

Summary

EudraCT number	2025-000542-25
Trial protocol	Outside EU/EEA
Global end of trial date	20 September 2025

Results information

Result version number	v1 (current)
This version publication date	25 June 2026
First version publication date	25 June 2026

Trial information

Trial identification

Sponsor protocol code	B7471024

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05512819
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	66 Hudson Boulevard East, New York, United States, NY 10001
Public contact	PfizerClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	PfizerClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.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	13 January 2026
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 September 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the safety profile of the 20-valent pneumococcal conjugate vaccine (20vPnC) in healthy infants in India and Taiwan, separately by country. To describe the immunogenicity of 20vPnC in healthy infants in India after Dose 4.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 September 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	India: 351
Country: Number of subjects enrolled	Taiwan: 190
Worldwide total number of subjects	541
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	541
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted across India and Taiwan. A total of 541 participants (351: India and 190: Taiwan) were enrolled to receive 20vPnC or 13vPnC and one participant randomized to "India participants: 13vPnC" did not receive the vaccination.

Pre-assignment

Screening details:

Data from 100 participants at a single study site were excluded from the analysis due to a quality event impacting that site. The exclusion of this data does not change the overall conclusions of the study regarding the benefit-risk profile of PCV20 or PCV13 in children.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	India participants: 20vPnC (Excluding Site 1012)

Arm description:

Infants from India (Excluding Site 1012) aged 42 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 5 milliliter (mL) of 20vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 6, 10 and 14 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.

Arm type	Experimental
Investigational medicinal product name	20vPnC
Investigational medicinal product code	PF-06482077
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants were administered 0.5 mL 20vPnC intramuscularly into the anterolateral thigh muscle of the left leg.

Arm title	India participants: 13vPnC (Excluding Site 1012)

Arm description:

Infants from India (Excluding Site 1012) aged 42 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 mL of 13vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 6, 10 and 14 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.

Arm type	Active comparator
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants were administered 0.5 mL 13vPnC intramuscularly into the anterolateral thigh muscle of the left leg.

Arm title	Taiwan participants: 20vPnC

Arm description:

Infants from Taiwan aged 56 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 mL of 20vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 8, 16, and 24 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.

Arm type	Experimental
Investigational medicinal product name	20vPnC
Investigational medicinal product code	PF-06482077
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants were administered 0.5 mL 20vPnC intramuscularly into the anterolateral thigh muscle of the left leg.

Arm title	Taiwan participants: 13vPnC

Arm description:

Infants from Taiwan aged 56 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 mL of 13vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 8, 16, and 24 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.

Arm type	Active comparator
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants were administered 0.5 mL 13vPnC intramuscularly into the anterolateral thigh muscle of the left leg.

Number of subjects in period 1[1]	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)	Taiwan participants: 20vPnC
Started	125	125	94
Dose 1	125	125	94
Dose 2	121	120	93
Dose 3	121	120	92
Dose 4	118	108	90
Completed	117	107	89
Not completed	8	18	5
Physician decision	-	1	-
Adverse event, non-fatal	-	-	1
No longer met eligibility criteria	1	5	2
Lost to follow-up	2	4	-
Withdrawal by parent/guardian	3	3	2
Protocol deviation	2	5	-

Number of subjects in period 1[1]	Taiwan participants: 13vPnC
Started	96
Dose 1	96
Dose 2	96
Dose 3	96
Dose 4	94
Completed	93
Not completed	3
Physician decision	-
Adverse event, non-fatal	-
No longer met eligibility criteria	3
Lost to follow-up	-
Withdrawal by parent/guardian	-
Protocol deviation	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: The total number of participants enrolled worldwide was 541, of whom 440 were included in the baseline period. Data from 100 participants at a single study site were excluded from the analysis due to a quality event affecting that site. Additionally, one participant randomized to the "India participants: 13vPnC" group did not receive the vaccination.

Baseline characteristics

Reporting groups	
Reporting group title	India participants: 20vPnC (Excluding Site 1012)
Reporting group description:	
Infants from India (Excluding Site 1012) aged 42 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 5 milliliter (mL) of 20vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 6, 10 and 14 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.	
Reporting group title	India participants: 13vPnC (Excluding Site 1012)
Reporting group description:	
Infants from India (Excluding Site 1012) aged 42 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 mL of 13vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 6, 10 and 14 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.	
Reporting group title	Taiwan participants: 20vPnC
Reporting group description:	
Infants from Taiwan aged 56 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 mL of 20vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 8, 16, and 24 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.	
Reporting group title	Taiwan participants: 13vPnC
Reporting group description:	
Infants from Taiwan aged 56 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 mL of 13vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 8, 16, and 24 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.	

Reporting group values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)	Taiwan participants: 20vPnC
Number of subjects	125	125	94
Age Categorical Units: Subjects			
Age continuous Units: days			
arithmetic mean	50.2	50.9	67.5
standard deviation	± 7.24	± 6.98	± 4.79
Gender categorical Units: Subjects			
Male	59	62	43
Female	66	63	51
Race Units: Subjects			
Asian	125	125	94
American Indian or Alaska Native	0	0	0
Black or African American	0	0	0
White	0	0	0
Not Reported	0	0	0
Ethnicity Units: Subjects			
Not Hispanic or Latino	125	125	94

Hispanic or Latino	0	0	0

Reporting group values	Taiwan participants: 13vPnC	Total	
Number of subjects	96	440	
Age Categorical Units: Subjects			
Age continuous Units: days			
arithmetic mean	67.3		
standard deviation	± 5.17	-	
Gender categorical Units: Subjects			
Male	57	221	
Female	39	219	
Race Units: Subjects			
Asian	96	440	
American Indian or Alaska Native	0	0	
Black or African American	0	0	
White	0	0	
Not Reported	0	0	
Ethnicity Units: Subjects			
Not Hispanic or Latino	96	440	
Hispanic or Latino	0	0	

End points

End points reporting groups

Reporting group title	India participants: 20vPnC (Excluding Site 1012)

Reporting group description:

Infants from India (Excluding Site 1012) aged 42 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 5 milliliter (mL) of 20vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 6, 10 and 14 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.

Reporting group title	India participants: 13vPnC (Excluding Site 1012)

Reporting group description:

Infants from India (Excluding Site 1012) aged 42 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 mL of 13vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 6, 10 and 14 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.

Reporting group title	Taiwan participants: 20vPnC

Reporting group description:

Infants from Taiwan aged 56 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 mL of 20vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 8, 16, and 24 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.

Reporting group title	Taiwan participants: 13vPnC

Reporting group description:

Infants from Taiwan aged 56 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 mL of 13vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 8, 16, and 24 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.

Primary: Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 1- India Participants (Excluding Site 1012)

End point title	Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 1- India Participants (Excluding Site 1012)[1][2]

End point description:

Local reactions included redness, swelling and pain at the injection site and were recorded by parents/legal guardians of participants using an electronic diary (e-diary). Redness and swelling were measured and recorded in measuring device units (mdu), where 1 mdu = 0.5 centimeter (cm). Redness and swelling were graded as mild (>0 to 2.0 cm), moderate (>2.0 to 7.0 cm) and severe (>7.0 cm). Pain at injection site was graded as mild (hurt if gently touched [example: whimpered, winced, protested, or withdrew]), moderate (hurt if gently touched, with crying), and severe (caused limitation of limb movement). Any local reaction: any redness and swelling >0.0 cm and any pain at the injection site. 95% CI was based on Clopper and Pearson method. Safety population included all the participants who received at least 1 dose of the study intervention and had safety data assessed after any dose. 'Number of Participants Analyzed' = number of participants with any e-diary data reported after Dose 1.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 1 (Day 1=day of Dose 1 administration)

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: This endpoint was summarized for specified reporting arms only.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124	125		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	8.9 (4.5 to 15.3)	9.6 (5.1 to 16.2)		
Redness: Mild	5.6 (2.3 to 11.3)	8.0 (3.9 to 14.2)		
Redness: Moderate	3.2 (0.9 to 8.1)	1.6 (0.2 to 5.7)		
Redness: Severe	0 (0.0 to 2.9)	0 (0.0 to 2.9)		
Swelling: Any	12.1 (6.9 to 19.2)	16.8 (10.7 to 24.5)		
Swelling: Mild	5.6 (2.3 to 11.3)	12.0 (6.9 to 19.0)		
Swelling: Moderate	6.5 (2.8 to 12.3)	4.8 (1.8 to 10.2)		
Swelling: Severe	0 (0.0 to 2.9)	0 (0.0 to 2.9)		
Pain at the injection site: Any	58.1 (48.9 to 66.9)	68.0 (59.1 to 76.1)		
Pain at the injection site: Mild	33.9 (25.6 to 42.9)	40.0 (31.3 to 49.1)		
Pain at the injection site: Moderate	23.4 (16.3 to 31.8)	26.4 (18.9 to 35.0)		
Pain at the injection site: Severe	0.8 (0.0 to 4.4)	1.6 (0.2 to 5.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 1- Taiwan Participants

End point title	Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 1- Taiwan Participants[3][4]

End point description:

Local reactions included redness, swelling and pain at the injection site and were recorded by parents/legal guardians of participants using an e-diary. Redness and swelling were measured and recorded in mdu, where 1 mdu = 0.5 cm. Redness and swelling were graded as mild (>0 to 2.0 cm), moderate (>2.0 to 7.0 cm) and severe (>7.0 cm). Pain at injection site was graded as mild (hurt if gently touched [example: whimpered, winced, protested, or withdrew]), moderate (hurt if gently touched, with crying), and severe (caused limitation of limb movement). Any local reaction: any redness and swelling >0.0 cm and any pain at the injection site. 95% CI was based on Clopper and Pearson method. Safety population included all the participants who received at least 1 dose of the study intervention and had safety data assessed after any dose.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 1 (Day 1=day of Dose 1 administration)

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: This endpoint was summarized for specified reporting arms only.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	94	96		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	17.0 (10.1 to 26.2)	15.6 (9.0 to 24.5)		
Redness: Mild	13.8 (7.6 to 22.5)	12.5 (6.6 to 20.8)		
Redness: Moderate	3.2 (0.7 to 9.0)	3.1 (0.6 to 8.9)		
Redness: Severe	0 (0.0 to 3.8)	0 (0.0 to 3.8)		
Swelling: Any	9.6 (4.5 to 17.4)	15.6 (9.0 to 24.5)		
Swelling: Mild	9.6 (4.5 to 17.4)	12.5 (6.6 to 20.8)		
Swelling: Moderate	0 (0.0 to 3.8)	3.1 (0.6 to 8.9)		
Swelling: Severe	0 (0.0 to 3.8)	0 (0.0 to 3.8)		
Pain at injection site: Any	19.1 (11.8 to 28.6)	17.7 (10.7 to 26.8)		
Pain at injection site: Mild	13.8 (7.6 to 22.5)	9.4 (4.4 to 17.1)		
Pain at injection site: Moderate	5.3 (1.7 to 12.0)	8.3 (3.7 to 15.8)		
Pain at injection site: Severe	0 (0.0 to 3.8)	0 (0.0 to 3.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 2- India Participants (Excluding Site 1012)

End point title	Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 2- India Participants (Excluding Site 1012)[5][6]

End point description:

Local reactions included redness, swelling and pain at the injection site and were recorded by parents/legal guardians of participants using an e-diary. Redness and swelling were measured and recorded in mdu, where 1 mdu = 0.5 cm. Redness and swelling were graded as mild (>0 to 2.0 cm), moderate (>2.0 to 7.0 cm) and severe (>7.0 cm). Pain at injection site was graded as mild (hurt if gently touched [example: whimpered, winced, protested, or withdrew]), moderate (hurt if gently touched, with crying), and severe (caused limitation of limb movement). Any local reaction: any redness and swelling >0.0 cm and any pain at the injection site. 95% CI was based on Clopper and Pearson method. Safety population included all the participants who received at least 1 dose of the study intervention and had safety data assessed after any dose. 'Number of Participants Analyzed' = number of participants with any e-diary data reported after Dose 2.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 2 (Day 1=day of Dose 2 administration)

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: This endpoint was summarized for specified reporting arms only.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	121	120		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	5.8 (2.4 to 11.6)	8.3 (4.1 to 14.8)		
Redness: Mild	4.1 (1.4 to 9.4)	8.3 (4.1 to 14.8)		
Redness: Moderate	1.7 (0.2 to 5.8)	0 (0.0 to 3.0)		
Redness: Severe	0 (0.0 to 3.0)	0 (0.0 to 3.0)		
Swelling: Any	13.2 (7.8 to 20.6)	16.7 (10.5 to 24.6)		
Swelling: Mild	8.3 (4.0 to 14.7)	13.3 (7.8 to 20.7)		
Swelling: Moderate	5.0 (1.8 to 10.5)	3.3 (0.9 to 8.3)		
Swelling: Severe	0 (0.0 to 3.0)	0 (0.0 to 3.0)		
Pain at the injection site: Any	50.4 (41.2 to 59.6)	56.7 (47.3 to 65.7)		
Pain at the injection site: Mild	32.2 (24.0 to 41.3)	35.0 (26.5 to 44.2)		
Pain at the injection site: Moderate	18.2 (11.8 to 26.2)	21.7 (14.7 to 30.1)		
Pain at the injection site: Severe	0 (0.0 to 3.0)	0 (0.0 to 3.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 2- Taiwan Participants

End point title	Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 2- Taiwan Participants [7][8]

End point description:

Local reactions included redness, swelling and pain at the injection site and were recorded by parents/legal guardians of participants using an e-diary. Redness and swelling were measured and recorded in mdu, where 1 mdu = 0.5 cm. Redness and swelling were graded as mild (>0 to 2.0 cm), moderate (>2.0 to 7.0 cm) and severe (>7.0 cm). Pain at injection site was graded as mild (hurt if gently touched [example: whimpered, winced, protested, or withdrew]), moderate (hurt if gently touched, with crying), and severe (caused limitation of limb movement). Any local reaction: any redness and swelling >0.0 cm and any pain at the injection site. 95% CI was based on Clopper and Pearson method. Safety population included all the participants who received at least 1 dose of the study intervention and had safety data assessed after any dose. 'Number of Participants Analyzed' = number of participants with any e-diary data reported after Dose 2.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 2 (Day 1=day of Dose 2 administration)

Notes:

[7] - 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: This endpoint was summarized for specified reporting arms only.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	93	96		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	29.0 (20.1 to 39.4)	25.0 (16.7 to 34.9)		
Redness: Mild	24.7 (16.4 to 34.8)	16.7 (9.8 to 25.6)		
Redness: Moderate	4.3 (1.2 to 10.6)	7.3 (3.0 to 14.4)		
Redness: Severe	0 (0.0 to 3.9)	1.0 (0.0 to 5.7)		
Swelling: Any	24.7 (16.4 to 34.8)	22.9 (15.0 to 32.6)		
Swelling: Mild	19.4 (11.9 to 28.9)	15.6 (9.0 to 24.5)		
Swelling: Moderate	5.4 (1.8 to 12.1)	7.3 (3.0 to 14.4)		
Swelling: Severe	0 (0.0 to 3.9)	0 (0.0 to 3.8)		
Pain at injection site: Any	23.7 (15.5 to 33.6)	22.9 (15.0 to 32.6)		
Pain at injection site: Mild	17.2 (10.2 to 26.4)	13.5 (7.4 to 22.0)		
Pain at injection site: Moderate	6.5 (2.4 to 13.5)	9.4 (4.4 to 17.1)		
Pain at injection site: Severe	0 (0.0 to 3.9)	0 (0.0 to 3.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 3- India Participants (Excluding Site 1012)

End point title	Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 3- India Participants (Excluding Site 1012)[9][10]

End point description:

Local reactions included redness, swelling and pain at the injection site and were recorded by parents/legal guardians of participants using an e-diary. Redness and swelling were measured and recorded in mdu, where 1 mdu = 0.5 cm. Redness and swelling were graded as mild (>0 to 2.0 cm), moderate (>2.0 to 7.0 cm) and severe (>7.0 cm). Pain at injection site was graded as mild (hurt if gently touched [example: whimpered, winced, protested, or withdrew]), moderate (hurt if gently touched, with crying), and severe (caused limitation of limb movement). Any local reaction: any redness

and swelling >0.0 cm and any pain at the injection site. 95% CI was based on Clopper and Pearson method. Safety population included all the participants who received at least 1 dose of the study intervention and had safety data assessed after any dose. 'Number of Participants Analyzed' = number of participants with any e-diary data reported after Dose 3.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 3 (Day 1=day of Dose 3 administration)

Notes:

[9] - 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: This endpoint was summarized for specified reporting arms only.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	118	120		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	8.5 (4.1 to 15.0)	9.2 (4.7 to 15.8)		
Redness: Mild	6.8 (3.0 to 12.9)	7.5 (3.5 to 13.8)		
Redness: Moderate	1.7 (0.2 to 6.0)	1.7 (0.2 to 5.9)		
Redness: Severe	0 (0.0 to 3.1)	0 (0.0 to 3.0)		
Swelling: Any	15.3 (9.3 to 23.0)	9.2 (4.7 to 15.8)		
Swelling: Mild	9.3 (4.7 to 16.1)	5.0 (1.9 to 10.6)		
Swelling: Moderate	5.9 (2.4 to 11.8)	4.2 (1.4 to 9.5)		
Swelling: Severe	0 (0.0 to 3.1)	0 (0.0 to 3.0)		
Pain at the injection site: Any	49.2 (39.8 to 58.5)	50.0 (40.7 to 59.3)		
Pain at the injection site: Mild	38.1 (29.4 to 47.5)	32.5 (24.2 to 41.7)		
Pain at the injection site: Moderate	11.0 (6.0 to 18.1)	17.5 (11.2 to 25.5)		
Pain at the injection site: Severe	0 (0.0 to 3.1)	0 (0.0 to 3.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 3- Taiwan Participants

End point title	Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 3- Taiwan Participants[11][12]

End point description:

Local reactions included redness, swelling and pain at the injection site and were recorded by parents/legal guardians of participants using an e-diary. Redness and swelling were measured and recorded in mdu, where 1 mdu = 0.5 cm. Redness and swelling were graded as mild (>0 to 2.0 cm), moderate (>2.0 to 7.0 cm) and severe (>7.0 cm). Pain at injection site was graded as mild (hurt if gently touched [example: whimpered, winced, protested, or withdrew]), moderate (hurt if gently touched, with crying), and severe (caused limitation of limb movement). Any local reaction: any redness and swelling >0.0 cm and any pain at the injection site. 95% CI was based on Clopper and Pearson method. Safety population included all the participants who received at least 1 dose of the study intervention and had safety data assessed after any dose. 'Number of Participants Analyzed' = number of participants with any e-diary data reported after Dose 3.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 3 (Day 1=day of Dose 3 administration)

Notes:

[11] - 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: This endpoint was summarized for specified reporting arms only.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	96		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	26.1 (17.5 to 36.3)	24.0 (15.8 to 33.7)		
Redness: Mild	19.6 (12.0 to 29.1)	17.7 (10.7 to 26.8)		
Redness: Moderate	6.5 (2.4 to 13.7)	6.3 (2.3 to 13.1)		
Redness: Severe	0 (0.0 to 3.9)	0 (0.0 to 3.8)		
Swelling: Any	21.7 (13.8 to 31.6)	30.2 (21.3 to 40.4)		
Swelling: Mild	14.1 (7.7 to 23.0)	22.9 (15.0 to 32.6)		
Swelling: Moderate	7.6 (3.1 to 15.1)	7.3 (3.0 to 14.4)		
Swelling: Severe	0 (0.0 to 3.9)	0 (0.0 to 3.8)		
Pain at injection site: Any	17.4 (10.3 to 26.7)	22.9 (15.0 to 32.6)		
Pain at injection site: Mild	14.1 (7.7 to 23.0)	16.7 (9.8 to 25.6)		
Pain at injection site: Moderate	3.3 (0.7 to 9.2)	6.3 (2.3 to 13.1)		
Pain at injection site: Severe	0 (0.0 to 3.9)	0 (0.0 to 3.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 4- India Participants (Excluding Site 1012)

End point title	Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 4- India Participants (Excluding Site 1012)[13][14]

End point description:

Local reactions included redness, swelling and pain at the injection site and were recorded by parents/legal guardians of participants using an e-diary. Redness and swelling were measured and recorded in mdu, where 1 mdu = 0.5 cm. Redness and swelling were graded as mild (>0 to 2.0 cm), moderate (>2.0 to 7.0 cm) and severe (>7.0 cm). Pain at injection site was graded as mild (hurt if gently touched [example: whimpered, winced, protested, or withdrew]), moderate (hurt if gently touched, with crying), and severe (caused limitation of limb movement). Any local reaction: any redness and swelling >0.0 cm and any pain at the injection site. 95% CI was based on Clopper and Pearson method. Safety population included all the participants who received at least 1 dose of the study intervention and had safety data assessed after any dose. 'Number of Participants Analyzed' = number of participants with any e-diary data reported after Dose 4.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 4 (Day 1=day of Dose 4 administration)

Notes:

[13] - 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: This endpoint was summarized for specified reporting arms only.

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	118	108		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	0.8 (0.0 to 4.6)	5.6 (2.1 to 11.7)		
Redness: Mild	0 (0.0 to 3.1)	4.6 (1.5 to 10.5)		
Redness: Moderate	0.8 (0.0 to 4.6)	0.9 (0.0 to 5.1)		
Redness: Severe	0 (0.0 to 3.1)	0 (0.0 to 3.4)		
Swelling: Any	2.5 (0.5 to 7.3)	4.6 (1.5 to 10.5)		
Swelling: Mild	1.7 (0.2 to 6.0)	3.7 (1.0 to 9.2)		
Swelling: Moderate	0.8 (0.0 to 4.6)	0.9 (0.0 to 5.1)		
Swelling: Severe	0 (0.0 to 3.1)	0 (0.0 to 3.4)		
Pain at the injection site: Any	32.2 (23.9 to 41.4)	35.2 (26.2 to 45.0)		
Pain at the injection site: Mild	25.4 (17.9 to 34.3)	30.6 (22.1 to 40.2)		
Pain at the injection site: Moderate	6.8 (3.0 to 12.9)	4.6 (1.5 to 10.5)		
Pain at the injection site: Severe	0 (0.0 to 3.1)	0 (0.0 to 3.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 4- Taiwan Participants

End point title	Percentage of Participants Reporting Local Reactions Within 7 Days After Dose 4- Taiwan Participants[15][16]

End point description:

Local reactions included redness, swelling and pain at the injection site and were recorded by parents/legal guardians of participants using an e-diary. Redness and swelling were measured and recorded in mdu, where 1 mdu = 0.5 cm. Redness and swelling were graded as mild (>0 to 2.0 cm), moderate (>2.0 to 7.0 cm) and severe (>7.0 cm). Pain at injection site was graded as mild (hurt if gently touched [example: whimpered, winced, protested, or withdrew]), moderate (hurt if gently touched, with crying), and severe (caused limitation of limb movement). Any local reaction: any redness and swelling >0.0 cm and any pain at the injection site. 95% CI was based on Clopper and Pearson method. Safety population included all the participants who received at least 1 dose of the study intervention and had safety data assessed after any dose. 'Number of Participants Analyzed' = number of participants with any e-diary data reported after Dose 4.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 4 (Day 1=day of Dose 4 administration)

Notes:

[15] - 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: This endpoint was summarized for specified reporting arms only.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	90	94		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	23.3 (15.1 to 33.4)	17.0 (10.1 to 26.2)		
Redness: Mild	11.1 (5.5 to 19.5)	12.8 (6.8 to 21.2)		
Redness: Moderate	12.2 (6.3 to 20.8)	4.3 (1.2 to 10.5)		
Redness: Severe	0 (0.0 to 4.0)	0 (0.0 to 3.8)		
Swelling: Any	27.8 (18.9 to 38.2)	18.1 (10.9 to 27.4)		
Swelling: Mild	14.4 (7.9 to 23.4)	16.0 (9.2 to 25.0)		
Swelling: Moderate	13.3 (7.1 to 22.1)	2.1 (0.3 to 7.5)		
Swelling: Severe	0 (0.0 to 4.0)	0 (0.0 to 3.8)		
Pain at injection site: Any	22.2 (14.1 to 32.2)	12.8 (6.8 to 21.2)		
Pain at injection site: Mild	20.0 (12.3 to 29.8)	11.7 (6.0 to 20.0)		
Pain at injection site: Moderate	2.2 (0.3 to 7.8)	1.1 (0.0 to 5.8)		
Pain at injection site: Severe	0 (0.0 to 4.0)	0 (0.0 to 3.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 1- India Participants (Excluding Site 1012)

End point title	Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 1- India Participants (Excluding Site 1012)[17][18]

End point description:

Systemic events were recorded by parents/legal guardians of participant's using an e-diary. Fever= temperature >= 38.0 degree Celsius (deg C) and categorized as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Decreased appetite was graded as mild: decreased interest in eating, moderate: decreased oral intake and severe: refusal to feed. Drowsiness/increased sleep was graded as mild: increased or prolonged sleeping bouts, moderate: slightly subdued, interfered with daily activity and severe: disabling, not interested in usual daily activity. Irritability was graded as mild: easily consolable, moderate: required increased attention and severe: inconsolable, crying could not be comforted. Any systemic event: any fever >=38 deg C, any decreased appetite, any drowsiness, any irritability. 95% CI based on Clopper and Pearson method. Safety population was used. Number of Participants Analyzed=number of participants with any e-diary data reported after Dose 1.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 1 (Day 1=day of Dose 1 administration)

Notes:

[17] - 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: This endpoint was summarized for specified reporting arms only.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124	125		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 deg C	18.5 (12.1 to 26.5)	15.2 (9.4 to 22.7)		
Fever: >=38.0 deg C to 38.4 deg C	13.7 (8.2 to 21.0)	8.8 (4.5 to 15.2)		
Fever: >38.4 deg C to 38.9 deg C	3.2 (0.9 to 8.1)	5.6 (2.3 to 11.2)		
Fever: >38.9 deg C to 40.0 deg C	1.6 (0.2 to 5.7)	0.8 (0.0 to 4.4)		
Fever: >40.0 deg C	0 (0.0 to 2.9)	0 (0.0 to 2.9)		
Decreased appetite: Any	21.8 (14.9 to 30.1)	24.8 (17.5 to 33.3)		

Decreased appetite: Mild	14.5 (8.8 to 22.0)	15.2 (9.4 to 22.7)		
Decreased appetite: Moderate	7.3 (3.4 to 13.3)	7.2 (3.3 to 13.2)		
Decreased appetite: Severe	0 (0.0 to 2.9)	2.4 (0.5 to 6.9)		
Drowsiness: Any	32.3 (24.1 to 41.2)	33.6 (25.4 to 42.6)		
Drowsiness: Mild	15.3 (9.5 to 22.9)	12.8 (7.5 to 20.0)		
Drowsiness: Moderate	16.1 (10.1 to 23.8)	19.2 (12.7 to 27.2)		
Drowsiness: Severe	0.8 (0.0 to 4.4)	1.6 (0.2 to 5.7)		
Irritability: Any	66.1 (57.1 to 74.4)	67.2 (58.2 to 75.3)		
Irritability: Mild	36.3 (27.8 to 45.4)	41.6 (32.9 to 50.8)		
Irritability: Moderate	28.2 (20.5 to 37.0)	23.2 (16.1 to 31.6)		
Irritability: Severe	1.6 (0.2 to 5.7)	2.4 (0.5 to 6.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 1- Taiwan Participants

End point title	Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 1- Taiwan Participants[19][20]

End point description:

Systemic events were recorded by parents/legal guardians of participant's using an e-diary. Fever= temperature >= 38.0 deg C and categorized as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Decreased appetite was graded as mild: decreased interest in eating, moderate: decreased oral intake and severe: refusal to feed. Drowsiness/increased sleep was graded as mild: increased or prolonged sleeping bouts, moderate: slightly subdued, interfered with daily activity and severe: disabling, not interested in usual daily activity. Irritability was graded as mild: easily consolable, moderate: required increased attention and severe: inconsolable, crying could not be comforted. Any systemic event: any fever >=38 deg C, any decreased appetite, any drowsiness, any irritability. 95% CI based on Clopper and Pearson method. Safety population was used.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 1 (Day 1=day of Dose 1 administration)

Notes:

[19] - 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: This endpoint was summarized for specified reporting arms only.

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	94	96		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 deg C	4.3 (1.2 to 10.5)	6.3 (2.3 to 13.1)		
Fever: >=38.0 deg C to 38.4 deg C	2.1 (0.3 to 7.5)	5.2 (1.7 to 11.7)		
Fever: >38.4 deg C to 38.9 deg C	2.1 (0.3 to 7.5)	1.0 (0.0 to 5.7)		
Fever: >38.9 deg C to 40.0 deg C	0 (0.0 to 3.8)	0 (0.0 to 3.8)		
Fever: >40.0 deg C	0 (0.0 to 3.8)	0 (0.0 to 3.8)		
Decreased appetite: Any	31.9 (22.7 to 42.3)	28.1 (19.4 to 38.2)		
Decreased appetite: Mild	10.6 (5.2 to 18.7)	12.5 (6.6 to 20.8)		
Decreased appetite: Moderate	21.3 (13.5 to 30.9)	14.6 (8.2 to 23.3)		
Decreased appetite: Severe	0 (0.0 to 3.8)	1.0 (0.0 to 5.7)		
Drowsiness: Any	52.1 (41.6 to 62.5)	47.9 (37.6 to 58.4)		
Drowsiness: Mild	44.7 (34.4 to 55.3)	42.7 (32.7 to 53.2)		
Drowsiness: Moderate	7.4 (3.0 to 14.7)	4.2 (1.1 to 10.3)		
Drowsiness: Severe	0 (0.0 to 3.8)	1.0 (0.0 to 5.7)		
Irritability: Any	42.6 (32.4 to 53.2)	40.6 (30.7 to 51.1)		
Irritability: Mild	14.9 (8.4 to 23.7)	13.5 (7.4 to 22.0)		
Irritability: Moderate	22.3 (14.4 to 32.1)	25.0 (16.7 to 34.9)		
Irritability: Severe	5.3 (1.7 to 12.0)	2.1 (0.3 to 7.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 2- India Participants (Excluding Site 1012)

End point title	Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 2- India Participants (Excluding Site 1012)[21][22]

End point description:

Systemic events were recorded by parents/legal guardians of participant's using an e-diary. Fever= temperature >= 38.0 deg C and categorized as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Decreased appetite was graded as mild: decreased interest in eating, moderate: decreased oral intake and severe: refusal to feed. Drowsiness/increased sleep was graded as mild: increased or prolonged sleeping bouts, moderate: slightly subdued, interfered with daily activity and severe: disabling, not interested in usual daily activity. Irritability was graded as mild: easily consolable, moderate: required increased attention and severe: inconsolable, crying could not be comforted. Any systemic event: any fever >=38 deg C, any decreased appetite, any drowsiness, any irritability. 95% CI based on Clopper and Pearson method. Safety population was used. Number of Participants Analyzed=number of participants with any e-diary data reported after Dose 2.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 2 (Day 1=day of Dose 2 administration)

Notes:

[21] - 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: This endpoint was summarized for specified reporting arms only.

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	121	120		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 deg C	11.6 (6.5 to 18.7)	9.2 (4.7 to 15.8)		
Fever: >=38.0 deg C to 38.4 deg C	9.9 (5.2 to 16.7)	5.8 (2.4 to 11.6)		
Fever: >38.4 deg C to 38.9 deg C	0.8 (0.0 to 4.5)	2.5 (0.5 to 7.1)		
Fever: >38.9 deg C to 40.0 deg C	0.8 (0.0 to 4.5)	0.8 (0.0 to 4.6)		
Fever: >40.0 deg C	0 (0.0 to 3.0)	0 (0.0 to 3.0)		
Decreased appetite: Any	13.2 (7.8 to 20.6)	15.8 (9.8 to 23.6)		
Decreased appetite: Mild	6.6 (2.9 to 12.6)	13.3 (7.8 to 20.7)		
Decreased appetite: Moderate	6.6 (2.9 to 12.6)	2.5 (0.5 to 7.1)		
Decreased appetite: Severe	0 (0.0 to 3.0)	0.0 (0.0 to 3.0)		
Drowsiness: Any	21.5 (14.5 to 29.9)	18.3 (11.9 to 26.4)		
Drowsiness: Mild	14.0 (8.4 to 21.5)	13.3 (7.8 to 20.7)		
Drowsiness: Moderate	7.4 (3.5 to 13.7)	5.0 (1.9 to 10.6)		
Drowsiness: Severe	0 (0.0 to 3.0)	0 (0.0 to 3.0)		
Irritability: Any	54.5 (45.2 to 63.6)	50.0 (40.7 to 59.3)		
Irritability: Mild	35.5 (27.0 to 44.8)	29.2 (21.2 to 38.2)		
Irritability: Moderate	18.2 (11.8 to 26.2)	20.8 (14.0 to 29.2)		
Irritability: Severe	0.8 (0.0 to 4.5)	0 (0.0 to 3.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Systemic Events Within 7 Days After

Dose 2- Taiwan Participants

End point title	Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 2- Taiwan Participants[23][24]

End point description:

Systemic events were recorded by parents/legal guardians of participant's using an e-diary. Fever= temperature >= 38.0 deg C and categorized as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Decreased appetite was graded as mild: decreased interest in eating, moderate: decreased oral intake and severe: refusal to feed. Drowsiness/increased sleep was graded as mild: increased or prolonged sleeping bouts, moderate: slightly subdued, interfered with daily activity and severe: disabling, not interested in usual daily activity. Irritability was graded as mild: easily consolable, moderate: required increased attention and severe: inconsolable, crying could not be comforted. Any systemic event: any fever >=38 deg C, any decreased appetite, any drowsiness, any irritability. 95% CI based on Clopper and Pearson method. Safety population was used. Number of Participants Analyzed=number of participants with any e-diary data reported after Dose 2.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 2 (Day 1=day of Dose 2 administration)

Notes:

[23] - 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: This endpoint was summarized for specified reporting arms only.

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	93	96		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 deg C	15.1 (8.5 to 24.0)	11.5 (5.9 to 19.6)		
Fever: >=38.0 deg C to 38.4 deg C	8.6 (3.8 to 16.2)	8.3 (3.7 to 15.8)		
Fever: >38.4 deg C to 38.9 deg C	4.3 (1.2 to 10.6)	2.1 (0.3 to 7.3)		
Fever: >38.9 deg C to 40.0 deg C	1.1 (0.0 to 5.8)	1.0 (0.0 to 5.7)		
Fever: >40.0 deg C	1.1 (0.0 to 5.8)	0 (0.0 to 3.8)		
Decreased appetite: Any	36.6 (26.8 to 47.2)	30.2 (21.3 to 40.4)		
Decreased appetite: Mild	21.5 (13.7 to 31.2)	8.3 (3.7 to 15.8)		
Decreased appetite: Moderate	14.0 (7.7 to 22.7)	21.9 (14.1 to 31.5)		
Decreased appetite: Severe	1.1 (0.0 to 5.8)	0 (0.0 to 3.8)		
Drowsiness: Any	48.4 (37.9 to 59.0)	50.0 (39.6 to 60.4)		
Drowsiness: Mild	40.9 (30.8 to 51.5)	43.8 (33.6 to 54.3)		
Drowsiness: Moderate	7.5 (3.1 to 14.9)	6.3 (2.3 to 13.1)		
Drowsiness: Severe	0 (0.0 to 3.9)	0 (0.0 to 3.8)		
Irritability: Any	43.0 (32.8 to 53.7)	46.9 (36.6 to 57.3)		
Irritability: Mild	14.0 (7.7 to 22.7)	11.5 (5.9 to 19.6)		

Irritability: Moderate	25.8 (17.3 to 35.9)	31.3 (22.2 to 41.5)		
Irritability: Severe	3.2 (0.7 to 9.1)	4.2 (1.1 to 10.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 3- India Participants (Excluding Site 1012)

End point title	Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 3- India Participants (Excluding Site 1012)[25][26]

End point description:

Systemic events were recorded by parents/legal guardians of participant's using an e-diary. Fever= temperature >= 38.0 deg C and categorized as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Decreased appetite was graded as mild: decreased interest in eating, moderate: decreased oral intake and severe: refusal to feed. Drowsiness/increased sleep was graded as mild: increased or prolonged sleeping bouts, moderate: slightly subdued, interfered with daily activity and severe: disabling, not interested in usual daily activity. Irritability was graded as mild: easily consolable, moderate: required increased attention and severe: inconsolable, crying could not be comforted. Any systemic event: any fever >=38 deg C, any decreased appetite, any drowsiness, any irritability. 95% CI based on Clopper and Pearson method. Safety population was used. Number of Participants Analyzed=number of participants with any e-diary data reported after Dose 3.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 3 (Day 1=day of Dose 3 administration)

Notes:

[25] - 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: This endpoint was summarized for specified reporting arms only.

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	118	120		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 deg C	2.5 (0.5 to 7.3)	3.3 (0.9 to 8.3)		
Fever: >=38.0 deg C to 38.4 deg C	1.7 (0.2 to 6.0)	2.5 (0.5 to 7.1)		
Fever: >38.4 deg C to 38.9 deg C	0.8 (0.0 to 4.6)	0.8 (0.0 to 4.6)		
Fever: >38.9 deg C to 40.0 deg C	0 (0.0 to 3.1)	0 (0.0 to 3.0)		
Fever: >40.0 deg C	0 (0.0 to 3.1)	0 (0.0 to 3.0)		
Decreased appetite: Any	10.2 (5.4 to 17.1)	10.8 (5.9 to 17.8)		
Decreased appetite: Mild	7.6 (3.5 to 14.0)	9.2 (4.7 to 15.8)		
Decreased appetite: Moderate	2.5 (0.5 to 7.3)	1.7 (0.2 to 5.9)		

Decreased appetite: Severe	0 (0.0 to 3.1)	0 (0.0 to 3.0)		
Drowsiness: Any	20.3 (13.5 to 28.7)	11.7 (6.5 to 18.8)		
Drowsiness: Mild	14.4 (8.6 to 22.1)	6.7 (2.9 to 12.7)		
Drowsiness: Moderate	5.9 (2.4 to 11.8)	5.0 (1.9 to 10.6)		
Drowsiness: Severe	0 (0.0 to 3.1)	0 (0.0 to 3.0)		
Irritability: Any	46.6 (37.4 to 56.0)	49.2 (39.9 to 58.4)		
Irritability: Mild	30.5 (22.4 to 39.7)	34.2 (25.8 to 43.4)		
Irritability: Moderate	15.3 (9.3 to 23.0)	15.0 (9.1 to 22.7)		
Irritability: Severe	0.8 (0.0 to 4.6)	0 (0.0 to 3.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 3- Taiwan Participants

End point title	Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 3- Taiwan Participants[27][28]

End point description:

Systemic events were recorded by parents/legal guardians of participant's using an e-diary. Fever= temperature >= 38.0 deg C and categorized as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Decreased appetite was graded as mild: decreased interest in eating, moderate: decreased oral intake and severe: refusal to feed. Drowsiness/increased sleep was graded as mild: increased or prolonged sleeping bouts, moderate: slightly subdued, interfered with daily activity and severe: disabling, not interested in usual daily activity. Irritability was graded as mild: easily consolable, moderate: required increased attention and severe: inconsolable, crying could not be comforted. Any systemic event: any fever >=38 deg C, any decreased appetite, any drowsiness, any irritability. 95% CI based on Clopper and Pearson method. Safety population was used. Number of Participants Analyzed=number of participants with any e-diary data reported after Dose 3.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 3 (Day 1=day of Dose 3 administration)

Notes:

[27] - 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: This endpoint was summarized for specified reporting arms only.

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	96		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 deg C	7.6 (3.1 to 15.1)	13.5 (7.4 to 22.0)		

Fever: >=38.0 deg C to 38.4 deg C	4.3 (1.2 to 10.8)	8.3 (3.7 to 15.8)		
Fever: >38.4 deg C to 38.9 deg C	3.3 (0.7 to 9.2)	3.1 (0.6 to 8.9)		
Fever: >38.9 deg C to 40.0 deg C	0 (0.0 to 3.9)	2.1 (0.3 to 7.3)		
Fever: >40.0 deg C	0 (0.0 to 3.9)	0 (0.0 to 3.8)		
Decreased appetite: Any	23.9 (15.6 to 33.9)	26.0 (17.6 to 36.0)		
Decreased appetite: Mild	16.3 (9.4 to 25.5)	12.5 (6.6 to 20.8)		
Decreased appetite: Moderate	7.6 (3.1 to 15.1)	13.5 (7.4 to 22.0)		
Decreased appetite: Severe	0 (0.0 to 3.9)	0 (0.0 to 3.8)		
Drowsiness: Any	35.9 (26.1 to 46.5)	37.5 (27.8 to 48.0)		
Drowsiness: Mild	31.5 (22.2 to 42.0)	30.2 (21.3 to 40.4)		
Drowsiness: Moderate	4.3 (1.2 to 10.8)	7.3 (3.0 to 14.4)		
Drowsiness: Severe	0 (0.0 to 3.9)	0 (0.0 to 3.8)		
Irritability: Any	41.3 (31.1 to 52.1)	38.5 (28.8 to 49.0)		
Irritability: Mild	14.1 (7.7 to 23.0)	9.4 (4.4 to 17.1)		
Irritability: Moderate	25.0 (16.6 to 35.1)	28.1 (19.4 to 38.2)		
Irritability: Severe	2.2 (0.3 to 7.6)	1.0 (0.0 to 5.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 4- India Participants (Excluding Site 1012)

End point title	Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 4- India Participants (Excluding Site 1012)[29][30]

End point description:

Systemic events were recorded by parents/legal guardians of participant's using an e-diary. Fever= temperature >= 38.0 deg C and categorized as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Decreased appetite was graded as mild: decreased interest in eating, moderate: decreased oral intake and severe: refusal to feed. Drowsiness/increased sleep was graded as mild: increased or prolonged sleeping bouts, moderate: slightly subdued, interfered with daily activity and severe: disabling, not interested in usual daily activity. Irritability was graded as mild: easily consolable, moderate: required increased attention and severe: inconsolable, crying could not be comforted. Any systemic event: any fever >=38 deg C, any decreased appetite, any drowsiness, any irritability. 95% CI based on Clopper and Pearson method. Safety population was used. Number of Participants Analyzed=number of participants with any e-diary data reported after Dose 4.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 4 (Day 1=day of Dose 4 administration)

Notes:

[29] - 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: This endpoint was summarized for specified reporting arms only.

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline

period.

Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	118	108		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 deg C	1.7 (0.2 to 6.0)	2.8 (0.6 to 7.9)		
Fever: >=38.0 deg C to 38.4 deg C	0.8 (0.0 to 4.6)	0.9 (0.0 to 5.1)		
Fever: >38.4 deg C to 38.9 deg C	0.8 (0.0 to 4.6)	0.9 (0.0 to 5.1)		
Fever: >38.9 deg C to 40.0 deg C	0 (0.0 to 3.1)	0.9 (0.0 to 5.1)		
Fever: >40.0 deg C	0 (0.0 to 3.1)	0 (0.0 to 3.4)		
Decreased appetite: Any	8.5 (4.1 to 15.0)	10.2 (5.2 to 17.5)		
Decreased appetite: Mild	5.9 (2.4 to 11.8)	5.6 (2.1 to 11.7)		
Decreased appetite: Moderate	2.5 (0.5 to 7.3)	4.6 (1.5 to 10.5)		
Decreased appetite: Severe	0 (0.0 to 3.1)	0 (0.0 to 3.4)		
Drowsiness: Any	6.8 (3.0 to 12.9)	6.5 (2.6 to 12.9)		
Drowsiness: Mild	5.1 (1.9 to 10.7)	3.7 (1.0 to 9.2)		
Drowsiness: Moderate	1.7 (0.2 to 6.0)	2.8 (0.6 to 7.9)		
Drowsiness: Severe	0 (0.0 to 3.1)	0 (0.0 to 3.4)		
Irritability: Any	18.6 (12.1 to 26.9)	19.4 (12.5 to 28.2)		
Irritability: Mild	15.3 (9.3 to 23.0)	12.0 (6.6 to 19.7)		
Irritability: Moderate	3.4 (0.9 to 8.5)	7.4 (3.3 to 14.1)		
Irritability: Severe	0 (0.0 to 3.1)	0 (0.0 to 3.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 4-Taiwan Participants

End point title	Percentage of Participants Reporting Systemic Events Within 7 Days After Dose 4-Taiwan Participants[31][32]

End point description:

Systemic events were recorded by parents/legal guardians of participant's using an e-diary. Fever= temperature >= 38.0 deg C and categorized as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Decreased appetite was graded as mild: decreased interest in eating, moderate: decreased oral intake and severe: refusal to feed. Drowsiness/increased sleep was graded as mild: increased or prolonged sleeping bouts, moderate: slightly subdued, interfered with daily activity and severe: disabling, not interested in usual daily activity. Irritability was graded as mild: easily consolable, moderate: required increased attention and severe: inconsolable, crying could not be comforted. Any systemic event: any fever >=38 deg C, any decreased appetite, any drowsiness, any

irritability. 95% CI based on Clopper and Pearson method. Safety population was used. Number of Participants Analyzed=number of participants with any e-diary data reported after Dose 4.

End point type	Primary

End point timeframe:

From Day 1 through Day 7 after Dose 4 (Day 1=day of Dose 4 administration)

Notes:

[31] - 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: This endpoint was summarized for specified reporting arms only.

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	90	94		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 deg C	15.6 (8.8 to 24.7)	13.8 (7.6 to 22.5)		
Fever: >=38.0 deg C to 38.4 deg C	7.8 (3.2 to 15.4)	8.5 (3.7 to 16.1)		
Fever: >38.4 deg C to 38.9 deg C	6.7 (2.5 to 13.9)	4.3 (1.2 to 10.5)		
Fever: >38.9 deg C to 40.0 deg C	1.1 (0.0 to 6.0)	1.1 (0.0 to 5.8)		
Fever: >40.0 deg C	0 (0.0 to 4.0)	0 (0.0 to 3.8)		
Decreased appetite: Any	20.0 (12.3 to 29.8)	20.2 (12.6 to 29.8)		
Decreased appetite: Mild	7.8 (3.2 to 15.4)	11.7 (6.0 to 20.0)		
Decreased appetite: Moderate	12.2 (6.3 to 20.8)	7.4 (3.0 to 14.7)		
Decreased appetite: Severe	0 (0.0 to 4.0)	1.1 (0.0 to 5.8)		
Drowsiness: Any	23.3 (15.1 to 33.4)	33.0 (23.6 to 43.4)		
Drowsiness: Mild	21.1 (13.2 to 31.0)	27.7 (18.9 to 37.8)		
Drowsiness: Moderate	2.2 (0.3 to 7.8)	5.3 (1.7 to 12.0)		
Drowsiness: Severe	0 (0.0 to 4.0)	0 (0.0 to 3.8)		
Irritability: Any	31.1 (21.8 to 41.7)	35.1 (25.5 to 45.6)		
Irritability: Mild	14.4 (7.9 to 23.4)	19.1 (11.8 to 28.6)		
Irritability: Moderate	16.7 (9.6 to 26.0)	13.8 (7.6 to 22.5)		
Irritability: Severe	0 (0.0 to 4.0)	2.1 (0.3 to 7.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Adverse Events (AEs) From Dose 1 to 1 Month After Dose 3- India Participants (Excluding Site 1012)

End point title	Percentage of Participants With Adverse Events (AEs) From Dose 1 to 1 Month After Dose 3- India Participants (Excluding Site 1012)[33][34]

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. 95% CI was based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this outcome measure. Safety population included all participants who received at least 1 dose of the study intervention and had safety data assessed after any dose.

End point type	Primary

End point timeframe:

From Day 1 of Dose 1 to 1 Month After Dose 3

Notes:

[33] - 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: This endpoint was summarized for specified reporting arms only.

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	125	125		
Units: Percentage of participants				
number (confidence interval 95%)	16.8 (10.7 to 24.5)	22.4 (15.4 to 30.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With AEs From Dose 1 to 1 Month After Dose 3- Taiwan Participants

End point title	Percentage of Participants With AEs From Dose 1 to 1 Month After Dose 3- Taiwan Participants[35][36]

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. 95% CI was based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this outcome measure. Safety population included all participants who received at least 1 dose of the study intervention and had safety data assessed after any dose.

End point type	Primary

End point timeframe:

From Day 1 of Dose 1 to 1 Month After Dose 3

Notes:

[35] - 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: This endpoint was summarized for specified reporting arms only.

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	94	96		
Units: Percentage of participants				
number (confidence interval 95%)	46.8 (36.4 to 57.4)	45.8 (35.6 to 56.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With AEs From Dose 4 to 1 Month After Dose 4- India Participants (Excluding Site 1012)

End point title	Percentage of Participants With AEs From Dose 4 to 1 Month After Dose 4- India Participants (Excluding Site 1012)[37][38]

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. 95% CI was based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this outcome measure. Safety population included all participants who received at least 1 dose of the study intervention and had safety data assessed after any dose. Number of Participants Analyzed=number of participants who received Dose 4.

End point type	Primary

End point timeframe:

From Day 1 of Dose 4 to 1 month after Dose 4

Notes:

[37] - 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: This endpoint was summarized for specified reporting arms only.

[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	118	108		
Units: Percentage of participants				
number (confidence interval 95%)	6.8 (3.0 to 12.9)	3.7 (1.0 to 9.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With AEs From Dose 4 to 1 Month After Dose 4- Taiwan Participants

End point title	Percentage of Participants With AEs From Dose 4 to 1 Month After Dose 4- Taiwan Participants[39][40]

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. 95% CI was based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this outcome measure. Safety population included all participants who received at least 1 dose of the study intervention and had safety data assessed after any dose. Here, 'Number of Participants Analyzed' = number of participants who received Dose 4.

End point type	Primary

End point timeframe:

From Day 1 of Dose 4 to 1 month after Dose 4

Notes:

[39] - 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: This endpoint was summarized for specified reporting arms only.

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	90	94		
Units: Percentage of participants				
number (confidence interval 95%)	12.2 (6.3 to 20.8)	17.0 (10.1 to 26.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With SAEs From Dose 1 to 1 Month After Dose 4- Taiwan Participants

End point title	Percentage of Participants With SAEs From Dose 1 to 1 Month After Dose 4- Taiwan Participants[41][42]

End point description:

An SAE was any untoward medical occurrence that, at any dose met at least of the following criteria: resulted in death; required inpatient hospitalization or prolongation of existing hospitalization; was life-

threatening; resulted in persistent or significant disability/ incapacity; congenital anomaly/birth defect and other important medical events. 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention and had safety data assessed after any dose.

End point type	Primary

End point timeframe:

From Day 1 of Dose 1 to 1 month after Dose 4

Notes:

[41] - 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: This endpoint was summarized for specified reporting arms only.

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	94	96		
Units: Percentage of participants				
number (confidence interval 95%)	19.1 (11.8 to 28.6)	12.5 (6.6 to 20.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Serious Adverse Events (SAEs) From Dose 1 to 1 Month After Dose 4- India Participants (Excluding Site 1012)

End point title	Percentage of Participants With Serious Adverse Events (SAEs) From Dose 1 to 1 Month After Dose 4- India Participants (Excluding Site 1012)[43][44]

End point description:

An SAE was any untoward medical occurrence that, at any dose met at least of the following criteria: resulted in death; required inpatient hospitalization or prolongation of existing hospitalization; was life-threatening; resulted in persistent or significant disability/ incapacity; congenital anomaly/birth defect and other important medical events. 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention and had safety data assessed after any dose.

End point type	Primary

End point timeframe:

From Day 1 of Dose 1 to 1 month after Dose 4

Notes:

[43] - 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: This endpoint was summarized for specified reporting arms only.

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	125	125		
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 2.9)	1.6 (0.2 to 5.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for the 20-Valent Pneumococcal Conjugate Vaccine (20vPnC) Serotypes at 1 Month After Dose 4- India Participants Only (Excluding Site 1012)

End point title	Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for the 20-Valent Pneumococcal Conjugate Vaccine (20vPnC) Serotypes at 1 Month After Dose 4- India Participants Only (Excluding Site 1012)[45][46]

End point description:

Concentrations of IgG for 20 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, 8, 10A, 11A, 12F, 15B, 22F, and 33F) were determined by multiplex Luminex immunoassay. GMCs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of concentrations and corresponding CIs based on Student's t distribution. Assay results below lower limit of quantification (LLOQ) was set to 0.5*LLOQ. Dose 4 evaluable immunogenicity population: eligible participants with specified age on day of Dose 1 and who received all 4 randomized vaccinations with Dose 4 received within 365-455 days of age, had at least 1 valid immunogenicity result after Dose 4, had blood collection within 27 to 56 days after Dose 4, had no other major protocol deviations as determined by the clinician. Number of Participants Analyzed=participants evaluable for this outcome measure and n= number of participants with valid IgG concentrations for the specified serotype at 1 month after Dose 4.

End point type	Primary

End point timeframe:

1 Month After Dose 4

Notes:

[45] - 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: This endpoint was summarized for specified reporting arms only.

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	112	104		
Units: Microgram per milliliter				
geometric mean (confidence interval 95%)				
Serotype 1 (n= 112,104)	3.31 (2.76 to 3.98)	5.05 (4.26 to 5.98)		

Serotype 3 (n= 112,104)	1.19 (1.00 to 1.40)	1.83 (1.56 to 2.14)		
Serotype 4 (n= 112,104)	8.80 (7.21 to 10.74)	12.21 (10.12 to 14.74)		
Serotype 5 (n= 112,104)	3.74 (3.10 to 4.52)	6.01 (5.10 to 7.09)		
Serotype 6A (n= 112,104)	13.65 (10.83 to 17.20)	23.45 (19.50 to 28.19)		
Serotype 6B (n= 112,104)	7.84 (6.30 to 9.74)	13.65 (11.20 to 16.64)		
Serotype 7F (n= 112,104)	5.35 (4.59 to 6.23)	7.03 (6.06 to 8.16)		
Serotype 9V (n= 112,104)	5.53 (4.35 to 7.03)	7.36 (5.95 to 9.09)		
Serotype 14 (n= 112,104)	10.30 (8.04 to 13.21)	13.51 (10.60 to 17.23)		
Serotype 18C (n= 112,104)	5.07 (4.29 to 5.99)	6.38 (5.33 to 7.63)		
Serotype 19A (n= 112,104)	8.66 (6.93 to 10.81)	11.87 (10.08 to 13.97)		
Serotype 19F (n= 111,104)	11.18 (9.05 to 13.82)	17.96 (14.85 to 21.72)		
Serotype 23F (n= 112,104)	5.26 (4.16 to 6.65)	8.31 (6.54 to 10.57)		
Serotype 8 (n= 112,104)	6.76 (5.29 to 8.64)	0.14 (0.10 to 0.20)		
Serotype 10A (n= 112,104)	7.24 (5.70 to 9.21)	0.03 (0.02 to 0.05)		
Serotype 11A (n= 112,104)	4.90 (3.84 to 6.24)	0.04 (0.03 to 0.06)		
Serotype 12F (n= 112,104)	2.86 (2.30 to 3.55)	0.02 (0.01 to 0.02)		
Serotype 15B (n= 112,104)	17.92 (13.27 to 24.20)	0.05 (0.04 to 0.07)		
Serotype 22F (n= 112,104)	9.50 (6.87 to 13.15)	0.03 (0.02 to 0.05)		
Serotype 33F (n= 112,104)	11.69 (9.30 to 14.70)	0.04 (0.03 to 0.07)		

Statistical analyses

No statistical analyses for this end point

Secondary: IgG GMCs for the 20vPnC Serotypes at 1 Month After Dose 3- India Participants (Excluding Site 1012)

End point title	IgG GMCs for the 20vPnC Serotypes at 1 Month After Dose 3- India Participants (Excluding Site 1012)[47]

End point description:

Concentrations of IgG for the 20 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, 8, 10A, 11A, 12F, 15B, 22F, and 33F) were determined using the multiplex Luminex immunoassay. GMCs and 2-sided CIs were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs based on the Student's t distribution. Assay result below LLOQ was set to 0.5*LLOQ. Dose 3 evaluable immunogenicity population: randomized participants aged >=42 to <=84 days in India on day of Dose 1, received the first 3 doses of assigned vaccination, had at least 1 valid immunogenicity result 1 month after Dose 3, had blood collection within 27 to 56 days after Dose 3, had no major protocol deviations. "Number of Participants Analyzed"= participants evaluable for this outcome measure and n= number of participants with valid IgG concentrations for the specified serotype at 1 month after Dose 3.

End point type	Secondary

End point timeframe:

1 Month After Dose 3

Notes:

[47] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	119	116		
Units: Microgram per milliliter				
geometric mean (confidence interval 95%)				
Serotype 1 (n= 118,116)	1.17 (0.95 to 1.44)	1.61 (1.35 to 1.92)		
Serotype 3 (n= 119,116)	0.73 (0.65 to 0.83)	0.97 (0.83 to 1.13)		
Serotype 4 (n= 119,116)	1.32 (1.06 to 1.64)	1.60 (1.32 to 1.94)		
Serotype 5 (n= 119,116)	0.83 (0.63 to 1.09)	1.16 (0.91 to 1.49)		
Serotype 6A (n= 119,116)	1.18 (0.89 to 1.58)	1.73 (1.32 to 2.27)		
Serotype 6B (n= 119,114)	0.39 (0.27 to 0.57)	0.61 (0.44 to 0.83)		
Serotype 7F (n= 119,116)	1.95 (1.65 to 2.32)	2.20 (1.88 to 2.58)		
Serotype 9V (n= 119,116)	1.57 (1.24 to 1.97)	2.06 (1.66 to 2.56)		
Serotype 14 (n= 119,116)	1.67 (1.30 to 2.14)	1.76 (1.34 to 2.32)		
Serotype 18C (n= 119,116)	1.59 (1.26 to 2.00)	1.79 (1.47 to 2.19)		
Serotype 19A (n= 119,116)	1.99 (1.63 to 2.43)	2.26 (1.86 to 2.74)		
Serotype 19F (n= 119,116)	2.63 (2.18 to 3.16)	2.96 (2.48 to 3.54)		
Serotype 23F (n= 119,116)	1.11 (0.85 to 1.45)	1.60 (1.26 to 2.04)		
Serotype 8 (n= 119,116)	2.36 (1.92 to 2.90)	0.04 (0.03 to 0.05)		
Serotype 10A (n= 119,116)	0.48 (0.34 to 0.69)	0.03 (0.02 to 0.04)		
Serotype 11A (n= 119,116)	3.58 (2.93 to 4.39)	0.04 (0.03 to 0.05)		
Serotype 12F (n= 119,116)	0.44 (0.31 to 0.62)	0.01 (0.01 to 0.02)		
Serotype 15B (n= 119,116)	6.31 (5.06 to 7.87)	0.05 (0.04 to 0.07)		
Serotype 22F (n= 119,116)	4.00 (3.09 to 5.18)	0.01 (0.01 to 0.02)		
Serotype 33F (n= 119,116)	1.44 (1.10 to 1.89)	0.06 (0.04 to 0.08)		

Statistical analyses

No statistical analyses for this end point

Secondary: IgG GMCs for the 20vPnC Serotypes at 1 Month After Dose 3- Taiwan Participants

End point title	IgG GMCs for the 20vPnC Serotypes at 1 Month After Dose 3-Taiwan Participants[48]

End point description:

Concentrations of IgG for the 20 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, 8, 10A, 11A, 12F, 15B, 22F, and 33F) were determined using the multiplex Luminex immunoassay. GMCs and 2-sided CIs were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs based on the Student's t distribution. Assay result below LLOQ was set to 0.5*LLOQ. Dose 3 evaluable immunogenicity population: randomized participants aged >=56 to <=84 days in Taiwan on day of Dose 1, received the first 3 doses of assigned vaccination, had at least 1 valid immunogenicity result 1 month after Dose 3, had blood collection within 27 to 56 days after Dose 3, had no major protocol deviations. "Number of Participants Analyzed"= participants evaluable for this outcome measure and n= number of participants with valid IgG concentrations for the specified serotype at 1 month after Dose 3.

End point type	Secondary

End point timeframe:

1 Month After Dose 3

Notes:

[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	94		
Units: Microgram per milliliter				
geometric mean (confidence interval 95%)				
Serotype 1 (n= 92, 94)	2.76 (2.32 to 3.27)	3.00 (2.42 to 3.72)		
Serotype 3 (n= 92, 94)	1.05 (0.92 to 1.21)	1.22 (1.04 to 1.42)		
Serotype 4 (n= 92, 94)	3.90 (3.27 to 4.64)	3.92 (3.16 to 4.87)		
Serotype 5 (n= 92, 94)	3.37 (2.82 to 4.01)	3.49 (2.80 to 4.35)		
Serotype 6A (n= 92, 94)	5.28 (4.42 to 6.31)	6.13 (5.08 to 7.40)		
Serotype 6B (n= 91, 94)	1.85 (1.50 to 2.28)	2.53 (2.06 to 3.09)		
Serotype 7F (n= 92, 94)	4.26 (3.65 to 4.98)	4.90 (4.05 to 5.93)		
Serotype 9V (n= 92, 94)	3.17 (2.67 to 3.75)	3.69 (3.01 to 4.52)		

Serotype 14 (n= 92, 94)	6.56 (5.56 to 7.74)	5.59 (4.30 to 7.25)		
Serotype 18C (n= 92, 94)	3.94 (3.44 to 4.51)	4.04 (3.26 to 5.01)		
Serotype 19A (n= 92, 94)	1.74 (1.50 to 2.03)	2.21 (1.85 to 2.64)		
Serotype 19F (n= 92, 94)	4.40 (3.80 to 5.10)	5.61 (4.78 to 6.59)		
Serotype 23F (n= 92, 94)	2.93 (2.44 to 3.52)	3.71 (3.05 to 4.53)		
Serotype 8 (n= 92, 86)	4.61 (4.03 to 5.28)	0.02 (0.02 to 0.03)		
Serotype 10A (n= 92, 94)	3.27 (2.60 to 4.11)	0.01 (0.01 to 0.01)		
Serotype 11A (n= 92, 94)	5.28 (4.50 to 6.18)	0.01 (0.01 to 0.01)		
Serotype 12F (n= 92, 94)	2.05 (1.72 to 2.43)	0.01 (0.01 to 0.01)		
Serotype 15B (n= 92, 94)	14.76 (12.49 to 17.44)	0.02 (0.02 to 0.03)		
Serotype 22F (n= 92, 94)	14.55 (12.42 to 17.04)	0.00 (0.00 to 0.01)		
Serotype 33F (n= 92, 94)	4.04 (3.18 to 5.14)	0.02 (0.02 to 0.02)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Predefined Serotype-specific IgG Concentrations for the 20vPnC Serotypes at 1 Month After Dose 3- India Participants (Excluding Site 1012)

End point title	Percentage of Participants With Predefined Serotype-specific IgG Concentrations for the 20vPnC Serotypes at 1 Month After Dose 3- India Participants (Excluding Site 1012)[49]

End point description:

Percentage of participants with predefined serotype-specific IgG concentrations (serotype 5: >=0.23 microgram per milliliter [mcg/mL]: serotype 6B: >=0.10 mcg/mL: serotype 19A: >=0.12 mcg/mL and serotypes 1, 3, 4, 6A, 7F, 9V, 14, 18C, 19F, 23F, 8, 10A, 11A, 12F, 15B, 22F and 33F: >=0.35 mcg/mL) is reported in this outcome measure. Dose 3 evaluable immunogenicity population: randomized participants aged >=42 to <=84 days in India on day of Dose 1, received the first 3 doses of assigned vaccination, had at least 1 valid immunogenicity result 1 month after Dose 3, had blood collection within 27 to 56 days after Dose 3, had no major protocol deviations. Here, "Number of Participants Analyzed" signifies number of participants evaluable for this outcome measure and n = number of participants with valid assay for the specified serotype.

End point type	Secondary

End point timeframe:

1 Month After Dose 3

Notes:

[49] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	119	116		
Units: Percentage of participants				
number (confidence interval 95%)				
Serotype 1 (n=118,116)	88.1 (80.9 to 93.4)	94.8 (89.1 to 98.1)		
Serotype 3 (n=119,116)	84.9 (77.2 to 90.8)	87.1 (79.6 to 92.6)		
Serotype 4 (n=119,116)	89.1 (82.0 to 94.1)	92.2 (85.8 to 96.4)		
Serotype 5 (n=119,116)	82.4 (74.3 to 88.7)	88.8 (81.6 to 93.9)		
Serotype 6A (n=119,116)	78.2 (69.6 to 85.2)	87.1 (79.6 to 92.6)		
Serotype 6B (n=119,114)	76.5 (67.8 to 83.8)	85.1 (77.2 to 91.1)		
Serotype 7F (n=119, 116)	96.6 (91.6 to 99.1)	97.4 (92.6 to 99.5)		
Serotype 9V (n=119,116)	89.9 (83.0 to 94.7)	88.8 (81.6 to 93.9)		
Serotype 14 (n=119,116)	86.6 (79.1 to 92.1)	87.9 (80.6 to 93.2)		
Serotype 18C (n=119,116)	87.4 (80.1 to 92.8)	88.8 (81.6 to 93.9)		
Serotype 19A (119,116)	98.3 (94.1 to 99.8)	100.0 (96.9 to 100.0)		
Serotype 19F (119,116)	96.6 (91.6 to 99.1)	95.7 (90.2 to 98.6)		
Serotype 23F (n=119,116)	84.0 (76.2 to 90.1)	88.8 (81.6 to 93.9)		
Serotype 8 (n=119,116)	95.8 (90.5 to 98.6)	9.5 (4.8 to 16.3)		
Serotype 10A (n=119,116)	57.1 (47.7 to 66.2)	8.6 (4.2 to 15.3)		
Serotype 11A (n=119,116)	97.5 (92.8 to 99.5)	8.6 (4.2 to 15.3)		
Serotype 12F (n=1119,116)	59.7 (50.3 to 68.6)	6.0 (2.5 to 12.0)		
Serotype 15B (n=119,116)	97.5 (92.8 to 99.5)	9.5 (4.8 to 16.3)		
Serotype 22F (119,116)	95.0 (89.3 to 98.1)	6.9 (3.0 to 13.1)		
Serotype 33F (n=119,116)	86.6 (79.1 to 92.1)	11.2 (6.1 to 18.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Predefined Serotype-specific IgG Concentrations for the 20vPnC Serotypes at 1 Month After Dose 3- Taiwan Participants

End point title	Percentage of Participants With Predefined Serotype-specific IgG Concentrations for the 20vPnC Serotypes at 1 Month After Dose 3- Taiwan Participants[50]

End point description:

Percentage of participants with predefined serotype-specific IgG concentrations (serotype 5: >=0.23 microgram per milliliter [mcg/mL]: serotype 6B: >=0.10 mcg/mL: serotype 19A: >=0.12 mcg/mL and serotypes1, 3, 4, 6A, 7F, 9V, 14, 18C, 19F, 23F, 8, 10A, 11A, 12F, 15B, 22F and 33F: >=0.35 mcg/mL) is reported in this outcome measure. Dose 3 evaluable immunogenicity population: randomized participants aged >=56 to <=84 days in Taiwan on day of Dose 1, received the first 3 doses of assigned vaccination, had at least 1 valid immunogenicity result 1 month after Dose 3, had blood collection within 27 to 56 days after Dose 3, had no major protocol deviations. "Number of Participants Analyzed (N)"= participants evaluable for this outcome measure and n = number of participants with valid assay for the specified serotype.

End point type	Secondary

End point timeframe:

1 Month After Dose 3

Notes:

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	94		
Units: Percentage of participants				
number (confidence interval 95%)				
Serotype 1 (n=92,94)	100.0 (96.1 to 100.0)	98.9 (94.2 to 100.0)		
Serotype 3 (n=92,94)	97.8 (92.4 to 99.7)	96.8 (91.0 to 99.3)		
Serotype 4 (n=92,94)	100.0 (96.1 to 100.0)	96.8 (91.0 to 99.3)		
Serotype 5 (n=92,94)	100.0 (96.1 to 100.0)	98.9 (94.2 to 100.0)		
Serotype 6A (n=92,94)	98.9 (94.1 to 100.0)	98.9 (94.2 to 100.0)		
Serotype 6B (n=91,94)	100.0 (96.0 to 100.0)	98.9 (94.2 to 100.0)		
Serotype 7F (n=92,94)	100.0 (96.1 to 100.0)	98.9 (94.2 to 100.0)		
Serotype 9V (n=92,94)	98.9 (94.1 to 100.0)	98.9 (94.2 to 100.0)		
Serotype 14 (n=92,94)	98.9 (94.1 to 100.0)	94.7 (88.0 to 98.3)		
Serotype 18C (n=92,94)	100.0 (96.1 to 100.0)	98.9 (94.2 to 100.0)		
Serotype 19A (n=92,94)	100.0 (96.1 to 100.0)	100.0 (96.2 to 100.0)		
Serotype 19F (n=92,94)	100.0 (96.1 to 100.0)	100.0 (96.2 to 100.0)		
Serotype 23F (n=92,94)	100.0 (96.1 to 100.0)	98.9 (94.2 to 100.0)		
Serotype 8 (n=92,86)	100.0 (96.1 to 100.0)	0 (0.0 to 4.2)		
Serotype 10A (n=92,94)	96.7 (90.8 to 99.3)	0.0 (0.0 to 3.8)		
Serotype 11A (n=92,94)	100.0 (96.1 to 100.0)	0.0 (0.0 to 3.8)		

Serotype 12F (n=92,94)	97.8 (92.4 to 99.7)	0.0 (0.0 to 3.8)		
Serotype 15B (n=92,94)	100.0 (96.1 to 100.0)	1.1 (0.0 to 5.8)		
Serotype 22F (n=92,94)	100.0 (96.1 to 100.0)	0.0 (0.0 to 3.8)		
Serotype 33F (n=92,94)	97.8 (92.4 to 99.7)	0.0 (0.0 to 3.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: IgG GMC for the 20vPnC Serotypes at 1 Month After Dose 4- Taiwan Participants only

End point title	IgG GMC for the 20vPnC Serotypes at 1 Month After Dose 4- Taiwan Participants only[51]

End point description:

Concentrations of IgG for the 20 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, 8, 10A, 11A, 12F, 15B, 22F, and 33F) were determined using the multiplex Luminex immunoassay. GMCs and 2-sided CIs were calculated by exponentiating the mean logarithm of the concentrations and corresponding CIs based on Student's t distribution. Assay result below LLOQ was set to 0.5*LLOQ. Dose 4 evaluable immunogenicity population: eligible participants with specified age on day of Dose 1 and who received all 4 randomized vaccinations with Dose 4 received within 365-455 days of age, had at least 1 valid immunogenicity result after Dose 4, had blood collection within 27 to 56 days after Dose 4, had no other major protocol deviations as determined by the clinician. N= participants evaluable for this outcome measure. n= number of participants with valid IgG concentrations for the specified serotype reported at 1 month after Dose 4.

End point type	Secondary

End point timeframe:

1 Month After Dose 4

Notes:

[51] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	92		
Units: Microgram per milliliter				
geometric mean (confidence interval 95%)				
Serotype 1 (n=88,92)	4.10 (3.41 to 4.94)	4.60 (3.74 to 5.67)		
Serotype 3 (n=88,92)	1.56 (1.28 to 1.90)	1.71 (1.43 to 2.05)		
Serotype 4 (n=88,92)	7.83 (6.41 to 9.57)	8.13 (6.69 to 9.88)		
Serotype 5 (n=88,92)	5.48 (4.50 to 6.68)	5.69 (4.62 to 7.01)		
Serotype 6A (n=88,92)	14.72 (12.13 to 17.87)	15.34 (12.52 to 18.80)		
Serotype 6B (n=88,92)	7.10 (5.78 to 8.71)	8.63 (6.79 to 10.96)		

Serotype 7F (n=88,92)	8.08 (6.74 to 9.67)	9.51 (7.82 to 11.56)		
Serotype 9V (n=88,92)	6.61 (5.47 to 8.00)	7.98 (6.53 to 9.75)		
Serotype 14 (n=88,92)	11.39 (9.53 to 13.61)	9.82 (8.21 to 11.75)		
Serotype 18C (n=88,92)	9.07 (7.48 to 10.99)	9.83 (7.93 to 12.18)		
Serotype 19A (n=88,92)	5.60 (4.55 to 6.90)	6.62 (5.53 to 7.91)		
Serotype 19F (n=88,92)	8.12 (6.60 to 9.99)	10.23 (8.52 to 12.27)		
Serotype 23F (n=88,92)	10.35 (8.22 to 13.04)	12.49 (9.94 to 15.69)		
Serotype 8 (n=88,85)	8.29 (6.88 to 9.99)	0.04 (0.03 to 0.05)		
Serotype 10A (n=88,92)	13.75 (11.21 to 16.86)	0.01 (0.01 to 0.02)		
Serotype 11A (n=88,92)	7.25 (6.00 to 8.77)	0.01 (0.01 to 0.01)		
Serotype 12F (n=88,92)	3.96 (3.19 to 4.92)	0.01 (0.01 to 0.01)		
Serotype 15B (n=88,92)	23.35 (19.33 to 28.20)	0.03 (0.02 to 0.03)		
Serotype 22F (n=88,92)	26.05 (21.22 to 31.98)	0.01 (0.00 to 0.01)		
Serotype 33F (n=88,92)	14.95 (12.22 to 18.30)	0.01 (0.01 to 0.01)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Predefined Serotype-specific IgG Concentration for the 20vPnC Serotypes at 1 Month after Dose 4- India Participants (Excluding Site 1012)

End point title	Percentage of Participants with Predefined Serotype-specific IgG Concentration for the 20vPnC Serotypes at 1 Month after Dose 4- India Participants (Excluding Site 1012)[52]

End point description:

Percentage of participants with predefined serotype-specific IgG concentrations (serotype 5: >=0.23 microgram per milliliter [mcg/mL]: serotype 6B: >=0.10 mcg/mL: serotype 19A: >=0.12 mcg/mL and serotypes 1, 3, 4, 6A, 7F, 9V, 14, 18C, 19F, 23F, 8, 10A, 11A, 12F, 15B, 22F and 33F: >=0.35 mcg/mL) is reported in this outcome measure. Dose 4 evaluable immunogenicity population: eligible participants with specified age on day of Dose 1 and who received all 4 randomized vaccinations with Dose 4 received within 365-455 days of age, had at least 1 valid immunogenicity result after Dose 4, had blood collection within 27 to 56 days after Dose 4, had no other major protocol deviations as determined by the clinician. N= participants evaluable for this outcome measure and n= number of participants with valid assay results for the specified serotype.

End point type	Secondary

End point timeframe:

1 Month after Dose 4

Notes:

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	112	104		
Units: Percentage of Participants				
number (confidence interval 95%)				
Serotype 1 (n=112, 104)	98.2 (93.7 to 99.8)	100.0 (96.5 to 100.0)		
Serotype 3 (n=112, 104)	90.2 (83.1 to 95.0)	100.0 (96.5 to 100.0)		
Serotype 4 (n=112, 104)	100.0 (96.8 to 100.0)	100.0 (96.5 to 100.0)		
Serotype 5 (n=112, 104)	98.2 (93.7 to 99.8)	100.0 (96.5 to 100.0)		
Serotype 6A (n=112, 104)	99.1 (95.1 to 100.0)	100.0 (96.5 to 100.0)		
Serotype 6B (n=112, 104)	100.0 (96.8 to 100.0)	100.0 (96.5 to 100.0)		
Serotype 7F (n=112, 104)	100.0 (96.8 to 100.0)	100.0 (96.5 to 100.0)		
Serotype 9V (n=112, 104)	96.4 (91.1 to 99.0)	99.0 (94.8 to 100.0)		
Serotype 14 (n=112, 104)	97.3 (92.4 to 99.4)	98.1 (93.2 to 99.8)		
Serotype 18C (n=112, 104)	98.2 (93.7 to 99.8)	100.0 (96.5 to 100.0)		
Serotype 19A (n=112, 104)	99.1 (95.1 to 100.0)	100.0 (96.5 to 100.0)		
Serotype 19F (n=111, 104)	98.2 (93.6 to 99.8)	99.0 (94.8 to 100.0)		
Serotype 23F (n=112, 104)	96.4 (91.1 to 99.0)	97.1 (91.8 to 99.4)		
Serotype 8 (n=112, 104)	94.6 (88.7 to 98.0)	29.8 (21.2 to 39.6)		
Serotype 10A (n=112, 104)	97.3 (92.4 to 99.4)	10.6 (5.4 to 18.1)		
Serotype 11A (n=112, 104)	96.4 (91.1 to 99.0)	19.2 (12.2 to 28.1)		
Serotype 12F (n=112, 104)	97.3 (92.4 to 99.4)	9.6 (4.7 to 17.0)		
Serotype 15B (n=112, 104)	92.9 (86.4 to 96.9)	10.6 (5.4 to 18.1)		
Serotype 22F (n=112, 104)	92.0 (85.3 to 96.3)	14.4 (8.3 to 22.7)		
Serotype 33F (n=112, 104)	98.2 (93.7 to 99.8)	18.3 (11.4 to 27.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Predefined Serotype-specific IgG Concentration for the 20vPnC Serotypes at 1 Month after Dose 4- Taiwan Participants

End point title	Percentage of Participants with Predefined Serotype-specific IgG Concentration for the 20vPnC Serotypes at 1 Month after Dose 4- Taiwan Participants [53]

End point description:

Percentage of participants with predefined serotype-specific IgG concentrations (serotype 5: >=0.23 microgram per milliliter [mcg/mL]: serotype 6B: >=0.10 mcg/mL: serotype 19A: >=0.12 mcg/mL and serotypes 1, 3, 4, 6A, 7F, 9V, 14, 18C, 19F, 23F, 8, 10A, 11A, 12F, 15B, 22F and 33F: >=0.35 mcg/mL) is reported in this outcome measure. Dose 4 evaluable immunogenicity population: eligible participants with specified age on day of Dose 1 and who received all 4 randomized vaccinations with Dose 4 received within 365-455 days of age, had at least 1 valid immunogenicity result after Dose 4, had blood collection within 27 to 56 days after Dose 4, had no other major protocol deviations as determined by the clinician. N= participants evaluable for this outcome measure and n= number of participants with valid assay for the specified serotype.

End point type	Secondary

End point timeframe:

1 Month after Dose 4

Notes:

[53] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was summarized for specified reporting arms only.

End point values	Taiwan participants: 20vPnC	Taiwan participants: 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	92		
Units: Percentage of Participants				
number (confidence interval 95%)				
Serotype 1 (n=88,92)	100.0 (95.9 to 100.0)	100.0 (96.1 to 100.0)		
Serotype 3 (n=88,92)	95.5 (88.8 to 98.7)	97.8 (92.4 to 99.7)		
Serotype 4 (n=88,92)	100.0 (95.9 to 100.0)	100.0 (96.1 to 100.0)		
Serotype 5 (n=88,92)	100.0 (95.9 to 100.0)	100.0 (96.1 to 100.0)		
Serotype 6A (n=88,92)	100.0 (95.9 to 100.0)	98.9 (94.1 to 100.0)		
Serotype 6B (n=88,92)	100.0 (95.9 to 100.0)	98.9 (94.1 to 100.0)		
Serotype 7F (n=88,92)	100.0 (95.9 to 100.0)	100.0 (96.1 to 100.0)		
Serotype 9V (n=88,92)	100.0 (95.9 to 100.0)	100.0 (96.1 to 100.0)		
Serotype 14 (n=88,92)	100.0 (95.9 to 100.0)	100.0 (96.1 to 100.0)		
Serotype 18C (n=88,92)	100.0 (95.9 to 100.0)	100.0 (96.1 to 100.0)		
Serotype 19A (n=88,92)	100.0 (95.9 to 100.0)	100.0 (96.1 to 100.0)		
Serotype 19F (n=88,92)	100.0 (95.9 to 100.0)	100.0 (96.1 to 100.0)		
Serotype 23F (n=88,92)	100.0 (95.9 to 100.0)	98.9 (94.1 to 100.0)		
Serotype 8 (n=88,85)	100.0 (95.9 to 100.0)	4.7 (1.3 to 11.6)		
Serotype 10A (n=88,92)	100.0 (95.9 to 100.0)	1.1 (0.0 to 5.9)		
Serotype 11A (n=88,92)	100.0 (95.9 to 100.0)	1.1 (0.0 to 5.9)		

Serotype 12F (n=88,92)	100.0 (95.9 to 100.0)	0 (0.0 to 3.9)		
Serotype 15B (n=88,92)	100.0 (95.9 to 100.0)	3.3 (0.7 to 9.2)		
Serotype 22F (n=88,92)	100.0 (95.9 to 100.0)	1.1 (0.0 to 5.9)		
Serotype 33F (n=88,92)	100.0 (95.9 to 100.0)	1.1 (0.0 to 5.9)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Local reactions and systemic events (systematic assessment): From Day 1 through Day 7 after each dose; non-systematic assessment (SAEs: from Dose (D)1 up to 1 month after D4; other AEs: from D1 up to 1 month after D3 and from D4 up to 1 month after D4)

Adverse event reporting additional description:

Same events may appear as both an SAE and a non-SAE. However, what are presented are distinct events. An event may be classified as serious in 1 participant and as non-serious in another participant, or 1 participant may have experienced both a SAE and non-SAE during the study. Safety population was used.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	28.1

Reporting groups

Reporting group title	India participants: 20vPnC (Excluding Site 1012)

Reporting group description:

Infants from India (Excluding Site 1012) aged 42 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 5 mL of 20vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 6, 10 and 14 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.

Reporting group title	India participants: 13vPnC (Excluding Site 1012)

Reporting group description:

Infants from India (Excluding Site 1012) aged 42 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 mL of 13vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 6, 10 and 14 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.

Reporting group title	Taiwan participants: 20vPnC

Reporting group description:

Infants from Taiwan aged 56 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 mL of 20vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 8, 16, and 24 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.

Reporting group title	Taiwan participants: 13vPnC

Reporting group description:

Infants from Taiwan aged 56 to 84 days at the time of enrolment were randomized to receive 4 doses of 0.5 mL of 13vPnC intramuscularly. Participants were administered infant doses (dose 1 to dose 3) at approximately 8, 16, and 24 weeks of age. Toddler dose (dose 4) was given at approximately 12 to 15 months of age.

Serious adverse events	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)	Taiwan participants: 20vPnC
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 125 (0.00%)	2 / 125 (1.60%)	18 / 94 (19.15%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Congenital, familial and genetic disorders			

Enteric duplication	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Scalp haematoma	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	0 / 94 (0.00%)
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			
Enterocolitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Diarrhoea infectious	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	1 / 125 (0.80%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	1 / 125 (0.80%)	0 / 94 (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	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	5 / 94 (5.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	0 / 94 (0.00%)
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	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		

subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	2 / 94 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	0 / 94 (0.00%)
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	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	0 / 94 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	1 / 94 (1.06%)
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 salmonella	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	0 / 94 (0.00%)
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 respiratory syncytial viral	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	1 / 94 (1.06%)
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 parainfluenzae viral	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	1 / 94 (1.06%)
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	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	2 / 94 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		

subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	0 / 94 (0.00%)
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 infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	3 / 94 (3.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic viral infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	0 / 94 (0.00%)
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	Taiwan participants: 13vPnC		
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 96 (12.50%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Congenital, familial and genetic disorders			
Enteric duplication	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Scalp haematoma	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	1 / 96 (1.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Enterocolitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Diarrhoea infectious	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	1 / 96 (1.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		

subjects affected / exposed	2 / 96 (2.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Campylobacter gastroenteritis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	1 / 96 (1.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	3 / 96 (3.13%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Exanthema subitum	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis salmonella	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	1 / 96 (1.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia respiratory syncytial viral	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia parainfluenzae viral	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	1 / 96 (1.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Influenza	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		

subjects affected / exposed	0 / 96 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus bronchiolitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	1 / 96 (1.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	1 / 96 (1.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Systemic viral infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	1 / 96 (1.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	India participants: 20vPnC (Excluding Site 1012)	India participants: 13vPnC (Excluding Site 1012)	Taiwan participants: 20vPnC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	123 / 125 (98.40%)	122 / 125 (97.60%)	93 / 94 (98.94%)
Investigations			
SARS-CoV-2 antibody test positive	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	4 / 94 (4.26%)
occurrences (all)	0	0	4
SARS-CoV-2 test positive	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	6 / 94 (6.38%)
occurrences (all)	0	0	6
Nervous system disorders			
Hypersomnia (INCREASED SLEEP)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			
subjects affected / exposed	55 / 125 (44.00%)	53 / 125 (42.40%)	73 / 94 (77.66%)
occurrences (all)	55	53	73
General disorders and administration site conditions			
Injection site pain (PAIN AT INJECTION SITE)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			
subjects affected / exposed	109 / 125 (87.20%)	107 / 125 (85.60%)	40 / 94 (42.55%)
occurrences (all)	109	107	40
Pyrexia (FEVER)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			
subjects affected / exposed	36 / 125 (28.80%)	32 / 125 (25.60%)	31 / 94 (32.98%)
occurrences (all)	36	32	31
Swelling (SWELLING)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			
subjects affected / exposed	37 / 125 (29.60%)	34 / 125 (27.20%)	47 / 94 (50.00%)
occurrences (all)	37	34	47
Gastrointestinal disorders			
Diarrhoea	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	4 / 125 (3.20%)	0 / 94 (0.00%)
occurrences (all)	0	4	0
Skin and subcutaneous tissue disorders			
Erythema (REDNESS)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			

subjects affected / exposed	20 / 125 (16.00%)	25 / 125 (20.00%)	46 / 94 (48.94%)
occurrences (all)	20	25	46
Dermatitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	6 / 94 (6.38%)
occurrences (all)	0	0	7
Dermatitis atopic	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	4 / 94 (4.26%)
occurrences (all)	0	0	4
Eczema	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	6 / 94 (6.38%)
occurrences (all)	0	0	6
Dermatitis diaper	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	2 / 94 (2.13%)
occurrences (all)	0	0	2
Dermatitis contact	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	1 / 94 (1.06%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	0 / 94 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability (IRRITABILITY)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			
subjects affected / exposed	105 / 125 (84.00%)	106 / 125 (84.80%)	65 / 94 (69.15%)
occurrences (all)	105	106	65
Infections and infestations			
Upper respiratory tract infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	11 / 125 (8.80%)	16 / 125 (12.80%)	6 / 94 (6.38%)
occurrences (all)	12	17	6
Viral infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	4 / 125 (3.20%)	4 / 125 (3.20%)	0 / 94 (0.00%)
occurrences (all)	4	4	0
Bronchiolitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	2 / 94 (2.13%)
occurrences (all)	0	0	2
COVID-19	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		

subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	8 / 94 (8.51%)
occurrences (all)	0	0	8
Otitis media acute	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	0 / 94 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	10 / 94 (10.64%)
occurrences (all)	0	0	11
Hand-foot-and-mouth disease	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 125 (0.00%)	0 / 125 (0.00%)	3 / 94 (3.19%)
occurrences (all)	0	0	3
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			
subjects affected / exposed	40 / 125 (32.00%)	46 / 125 (36.80%)	58 / 94 (61.70%)
occurrences (all)	40	46	58

Non-serious adverse events	Taiwan participants: 13vPnC		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	95 / 96 (98.96%)		
Investigations			
SARS-CoV-2 antibody test positive	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences (all)	0		
SARS-CoV-2 test positive	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	10 / 96 (10.42%)		
occurrences (all)	10		
Nervous system disorders			
Hypersomnia (INCREASED SLEEP)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			
subjects affected / exposed	73 / 96 (76.04%)		
occurrences (all)	73		
General disorders and administration site conditions			
Injection site pain (PAIN AT INJECTION SITE)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			

subjects affected / exposed	38 / 96 (39.58%)		
occurrences (all)	38		
Pyrexia (FEVER)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			
subjects affected / exposed	35 / 96 (36.46%)		
occurrences (all)	35		
Swelling (SWELLING)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			
subjects affected / exposed	47 / 96 (48.96%)		
occurrences (all)	47		
Gastrointestinal disorders			
Diarrhoea	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Erythema (REDNESS)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			
subjects affected / exposed	43 / 96 (44.79%)		
occurrences (all)	43		
Dermatitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	6 / 96 (6.25%)		
occurrences (all)	6		
Dermatitis atopic	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	6 / 96 (6.25%)		
occurrences (all)	6		
Eczema	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	4 / 96 (4.17%)		
occurrences (all)	5		
Dermatitis diaper	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	3 / 96 (3.13%)		
occurrences (all)	3		
Dermatitis contact	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	3 / 96 (3.13%)		
occurrences (all)	3		
Seborrhoeic dermatitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		

subjects affected / exposed	4 / 96 (4.17%)		
occurrences (all)	4		
Psychiatric disorders			
Irritability (IRRITABILITY)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			
subjects affected / exposed	67 / 96 (69.79%)		
occurrences (all)	67		
Infections and infestations			
Upper respiratory tract infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	11 / 96 (11.46%)		
occurrences (all)	12		
Viral infection	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences (all)	0		
Bronchiolitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	3 / 96 (3.13%)		
occurrences (all)	3		
COVID-19	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	8 / 96 (8.33%)		
occurrences (all)	8		
Otitis media acute	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	4 / 96 (4.17%)		
occurrences (all)	4		
Nasopharyngitis	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	15 / 96 (15.63%)		
occurrences (all)	15		
Hand-foot-and-mouth disease	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
subjects affected / exposed	0 / 96 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)	Additional description: MedDRA v 26.1 for Taiwan and MedDRA v 28.1 for India		
alternative assessment type: Systematic			
subjects affected / exposed	58 / 96 (60.42%)		
occurrences (all)	58		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 November 2023	Amendment 1: Added a primary immunogenicity objective, outcome measure, and estimand specific to the participants in India after Dose 4.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported