



Clinical trial results:

A Phase 2, Randomized, Partially Double-Blind Trial to Evaluate the Safety, Tolerability, and Immunogenicity of a Multivalent Pneumococcal Conjugate Vaccine Administered in Healthy Toddlers 12 Through 15 Months of age

Summary

EudraCT number	2025-000101-16
Trial protocol	Outside EU/EEA
Global end of trial date	08 February 2026

Results information

Result version number	v1 (current)
This version publication date	22 August 2026
First version publication date	22 August 2026

Trial information

Trial identification

Sponsor protocol code	C4931010
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT06531538
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	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.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)	Yes
EMA paediatric investigation plan number(s)	EMA-000023-PIP39-67
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	08 May 2026
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	08 February 2026
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability profile of fourth-generation multivalent pneumococcal conjugate vaccine (PG4) administered to toddlers greater than or equal to ($\geq$)12 to less than or equal to ($\leq$)15 months of age.

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	30 July 2024
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 191
Country: Number of subjects enrolled	Puerto Rico: 32
Worldwide total number of subjects	223
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)	223
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:

A total of 225 participants were enrolled and randomized in this study, of whom 223 participants received study vaccination.

Pre-assignment

Screening details:

Participants were randomized to receive either 1 or 2 doses of PG4 or 1 dose of the control vaccine 20-valent pneumococcal conjugate vaccine (20vPnC).

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	Subject, Investigator, Monitor, Assessor

Blinding implementation details:

Study is partially blinded as 2 of the 3 groups are blinded and 1 is unblinded.

Arms

Are arms mutually exclusive?	Yes
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Arm title	2-Dose PG4
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Arm description:

Participants aged ≥ 12 to ≤ 15 months received 2 doses of PG4 0.5 milliliter (mL) each intramuscularly. Dose 1 was administered at Day 1 (Dose 1 Visit [Vaccination 1]) and Dose 2 was administered 56 to 70 days after Dose 1 (Dose 2 Visit [Vaccination 2]).

Arm type	Experimental
Investigational medicinal product name	PG4
Investigational medicinal product code	PF-07872412
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 2 doses of PG4 0.5 mL intramuscularly each at Dose 1 visit and Dose 2 visit.

Arm title	1-Dose PG4
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Arm description:

Participants aged ≥ 12 to ≤ 15 months received 1 dose of PG4 0.5 mL intramuscularly. Dose 1 was administered at Day 1 (Dose 1 Visit [Vaccination 1]).

Arm type	Experimental
Investigational medicinal product name	PG4
Investigational medicinal product code	PF-07872412
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 1 dose of PG4 0.5 mL intramuscularly at Dose 1 visit.

Arm title	1-Dose 20vPnC
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Arm description:

Participants aged ≥ 12 to ≤ 15 months received 1 dose of 20vPnC 0.5 mL intramuscularly. Dose 1 was administered at Day 1 (Dose 1 Visit [Vaccination 1]).

Arm type	Active comparator
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Investigational medicinal product name	20vPnC
Investigational medicinal product code	PF-06482077
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 1 dose of 20vPnC 0.5 mL intramuscularly at Dose 1 visit.

Number of subjects in period 1	2-Dose PG4	1-Dose PG4	1-Dose 20vPnC
Started	89	89	45
Completed	79	88	41
Not completed	10	1	4
Withdrawal by Parent/Guardian	7	-	2
Lost to follow-up	2	-	2
Protocol deviation	1	1	-

Baseline characteristics

Reporting groups

Reporting group title	2-Dose PG4
Reporting group description: Participants aged ≥ 12 to ≤ 15 months received 2 doses of PG4 0.5 milliliter (mL) each intramuscularly. Dose 1 was administered at Day 1 (Dose 1 Visit [Vaccination 1]) and Dose 2 was administered 56 to 70 days after Dose 1 (Dose 2 Visit [Vaccination 2]).	
Reporting group title	1-Dose PG4
Reporting group description: Participants aged ≥ 12 to ≤ 15 months received 1 dose of PG4 0.5 mL intramuscularly. Dose 1 was administered at Day 1 (Dose 1 Visit [Vaccination 1]).	
Reporting group title	1-Dose 20vPnC
Reporting group description: Participants aged ≥ 12 to ≤ 15 months received 1 dose of 20vPnC 0.5 mL intramuscularly. Dose 1 was administered at Day 1 (Dose 1 Visit [Vaccination 1]).	

Reporting group values	2-Dose PG4	1-Dose PG4	1-Dose 20vPnC
Number of subjects	89	89	45
Age categorical			
Units: Subjects			
In Utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days - 23 months)	89	89	45
Children (2 - 11 years)	0	0	0
12 - 17 years	0	0	0
Adults (18 - 64 years)	0	0	0
From 65 - 84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: months			
arithmetic mean	12.7	12.7	12.9
standard deviation	± 1.09	± 1.02	± 1.24
Gender categorical			
Units: Subjects			
Male	50	53	24
Female	39	36	21
Race			
Units: Subjects			
White	68	70	33
Black or African American	8	11	5
Asian	2	0	1
American Indian or Alaska Native	1	0	0
Multiracial	6	5	2
Not reported	4	3	4
Ethnicity			
Units: Subjects			
Hispanic/Latino/Spanish origin	45	52	26

Non-Hispanic/non-Latino/non-Spanish origin	44	37	19
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Reporting group values	Total		
Number of subjects	223		
Age categorical Units: Subjects			
In Utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days - 23 months)	223		
Children (2 - 11 years)	0		
12 - 17 years	0		
Adults (18 - 64 years)	0		
From 65 - 84 years	0		
85 years and over	0		
Age continuous Units: months arithmetic mean standard deviation	-		
Gender categorical Units: Subjects			
Male	127		
Female	96		
Race Units: Subjects			
White	171		
Black or African American	24		
Asian	3		
American Indian or Alaska Native	1		
Multiracial	13		
Not reported	11		
Ethnicity Units: Subjects			
Hispanic/Latino/Spanish origin	123		
Non-Hispanic/non-Latino/non-Spanish origin	100		

End points

End points reporting groups

Reporting group title	2-Dose PG4
Reporting group description: Participants aged ≥ 12 to ≤ 15 months received 2 doses of PG4 0.5 milliliter (mL) each intramuscularly. Dose 1 was administered at Day 1 (Dose 1 Visit [Vaccination 1]) and Dose 2 was administered 56 to 70 days after Dose 1 (Dose 2 Visit [Vaccination 2]).	
Reporting group title	1-Dose PG4
Reporting group description: Participants aged ≥ 12 to ≤ 15 months received 1 dose of PG4 0.5 mL intramuscularly. Dose 1 was administered at Day 1 (Dose 1 Visit [Vaccination 1]).	
Reporting group title	1-Dose 20vPnC
Reporting group description: Participants aged ≥ 12 to ≤ 15 months received 1 dose of 20vPnC 0.5 mL intramuscularly. Dose 1 was administered at Day 1 (Dose 1 Visit [Vaccination 1]).	

Primary: Percentage of Participants With Any Local Reactions Within 7 Days After the Last Vaccination

End point title	Percentage of Participants With Any Local Reactions Within 7 Days After the Last Vaccination ^[1]
End point description: Local reactions included redness, swelling and pain at injection site, reported in the electronic diary (e-diary) and/or case report form (CRF) after vaccination. Redness and swelling were measured and recorded in measuring device (caliper) units, where 1 measuring device unit=0.5 centimeter (cm) and graded as mild: >0 to 2.0 cm, moderate: >2.0 to 7.0 cm, severe: >7 cm, Grade 4: necrosis (redness and swelling) or exfoliative dermatitis (redness). Pain at injection site was graded as mild: hurts if gently touched, moderate: hurts if gently touched with crying, severe: causes limitation of limb movement, Grade 4: emergency room visit or hospitalization for severe injection site pain. Percentage of participants with any local reactions of any severity were reported. Safety analysis set included all participants who received at least 1 dose of the study intervention. Here, "Subjects Analyzed" signifies number of participants who received last vaccination in the specified arms.	
End point type	Primary
End point timeframe: Day 1 through Day 7 after last vaccination (last vaccination = vaccination on Day 1 for "1-Dose PG4" and "1-Dose 20vPnC" arms, and Dose 2 for "2-Dose PG4" arm)	
Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: No statistical analysis was planned for this endpoint	

End point values	2-Dose PG4	1-Dose PG4	1-Dose 20vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	75	89	45	
Units: Percentage of participants				
number (confidence interval 95%)	57.3 (45.4 to 68.7)	59.6 (48.6 to 69.8)	48.9 (33.7 to 64.2)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Any Local Reactions Within 7 Days After Dose 1: 2-Dose PG4

End point title	Percentage of Participants With Any Local Reactions Within 7 Days After Dose 1: 2-Dose PG4 ^{[2][3]}
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End point description:

Local reactions included redness, swelling and pain at injection site, reported in the e-diary and/or CRF after vaccination. Redness and swelling were measured and recorded in measuring device (caliper) units, where 1 measuring device unit= 0.5 cm and graded as mild: >0 to 2.0 cm, moderate: >2.0 to 7.0 cm, severe: >7 cm, Grade 4: necrosis (redness and swelling) or exfoliative dermatitis (redness). Pain at injection site was graded as mild: hurts if gently touched, moderate: hurts if gently touched with crying, severe: causes limitation of limb movement, Grade 4: emergency room visit or hospitalization for severe injection site pain. In this outcome measure, percentage of participants with any local reactions of any severity were reported. Safety analysis set included all participants who received at least 1 dose of the study intervention.

End point type	Primary
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End point timeframe:

Day 1 through Day 7 after Dose 1

Notes:

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

Justification: No statistical analysis was planned for this endpoint

[3] - 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: The end point is reporting statistics for the arms specified

End point values	2-Dose PG4			
Subject group type	Reporting group			
Number of subjects analysed	89			
Units: Percentage of participants				
number (confidence interval 95%)	51.7 (40.8 to 62.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Any Systemic Events Within 7 Days After the Last Vaccination

End point title	Percentage of Participants With Any Systemic Events Within 7 Days After the Last Vaccination ^[4]
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End point description:

Systemic events: fever, decreased appetite, drowsiness, and irritability, reported in e-diary and/or CRF after vaccination. Fever measured in degree Celsius and ranged: mild (≥ 38.0 -38.4), moderate (>38.4 -38.9), severe (>38.9 -40.0), Grade 4: >40.0 . Decreased appetite graded as: mild (decreased interest in eating), moderate (decreased oral intake), severe (refusal to feed); drowsiness graded as: mild (increased or prolonged sleeping bouts), moderate (slightly subdued, interfered with daily activity), severe (disabling, not interested in usual daily activity); irritability graded as: mild (easily consolable), moderate (required increased attention), severe (inconsolable; crying could be comforted). Grade 4: emergency room visit or hospitalization. Percentage of participants with any systemic events of any severity were reported. Safety analysis set was used. Here, "Subjects Analyzed" signifies number of participants who received last vaccination in the specified arms.

End point type	Primary
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End point timeframe:

Day 1 through Day 7 after last vaccination (last vaccination = vaccination on Day 1 for "1-Dose PG4" and "1-Dose 20vPnC" arms, and Dose 2 for "2-Dose PG4" arm)

Notes:

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

Justification: No statistical analysis was planned for this endpoint

End point values	2-Dose PG4	1-Dose PG4	1-Dose 20vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	76	89	45	
Units: Percentage of participants				
number (confidence interval 95%)	52.6 (40.8 to 64.2)	66.3 (55.5 to 76.0)	55.6 (40.0 to 70.4)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Any Systemic Events Within 7 Days After Dose 1: 2-Dose PG4

End point title	Percentage of Participants With Any Systemic Events Within 7 Days After Dose 1: 2-Dose PG4 ^[5] ^[6]
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End point description:

Systemic events: fever, decreased appetite, drowsiness, and irritability, reported in e-diary and/or CRF after vaccination. Fever measured in degree Celsius and ranged: mild (≥ 38.0 -38.4), moderate (>38.4 -38.9), severe (>38.9 -40.0), Grade 4: >40.0 . Decreased appetite graded as: mild (decreased interest in eating), moderate (decreased oral intake), severe (refusal to feed); drowsiness graded as: mild (increased or prolonged sleeping bouts), moderate (slightly subdued, interfered with daily activity), severe (disabling, not interested in usual daily activity); irritability graded as: mild (easily consolable), moderate (required increased attention), severe (inconsolable; crying could be comforted). Grade 4: emergency room visit or hospitalization. Percentage of participants with any systemic events of any severity were reported. Safety analysis set included all participants who received at least 1 dose of the study intervention.

End point type	Primary
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End point timeframe:

Day 1 through Day 7 after dose 1

Notes:

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

Justification: No statistical analysis was planned for this endpoint

[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: The end point is not reporting statistics for all the arms

End point values	2-Dose PG4			
Subject group type	Reporting group			
Number of subjects analysed	89			
Units: Percentage of participants				
number (confidence interval 95%)	60.7 (49.7 to 70.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Adverse Events (AEs) From the Last Vaccination to 1 Month After the Last Vaccination

End point title	Percentage of Participants With Adverse Events (AEs) From the Last Vaccination to 1 Month After the Last Vaccination ^[7]
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End point description:

An AE was defined as 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. AEs included both serious AEs (SAEs) and all other AEs (non-SAEs). An SAE was defined as any untoward medical occurrence that, at any dose, met one or more of the following criteria - resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect and other important medical events per protocol of the study. Events collected by systematic assessment (local reactions and systemic events) were excluded from evaluation. Safety analysis set included all participants who had received at least 1 dose of the study intervention. Here, "Subjects Analyzed" signifies number of participants who received last vaccination in the specified arms.

End point type	Primary
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End point timeframe:

From the last vaccination to 1 Month after the last vaccination (last vaccination = vaccination on Day 1 for "1-Dose PG4" and "1-Dose 20vPnC" arms, and Dose 2 for "2-Dose PG4" arm)

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: No statistical analysis was planned for this endpoint

End point values	2-Dose PG4	1-Dose PG4	1-Dose 20vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	79	89	45	
Units: Percentage of participants				
number (confidence interval 95%)	19.0 (11.0 to 29.4)	25.8 (17.1 to 36.2)	28.9 (16.4 to 44.3)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Serious Adverse Events (SAEs) From Dose 1 Through 6 Months After the Last Vaccination

End point title	Percentage of Participants With Serious Adverse Events (SAEs) From Dose 1 Through 6 Months After the Last Vaccination ^[8]
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End point description:

An SAE was defined as any untoward medical occurrence that, at any dose, met one or more of the following criteria - resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect and other important medical events per protocol of the study. Safety

analysis set included all participants who had received at least 1 dose of the study intervention.

End point type	Primary
End point timeframe:	
From Dose 1 on Day 1 through 6 months after the last vaccination (6 months after Dose 1 for 1-Dose PG4 and 1-Dose 20vPnC, and 6 months after Dose 2 for 2-Dose PG4)	
Notes:	
[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.	
Justification: No statistical analysis was planned for this endpoint	

End point values	2-Dose PG4	1-Dose PG4	1-Dose 20vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	89	89	45	
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 4.1)	3.4 (0.7 to 9.5)	0 (0.0 to 7.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations (GMCs) of Pneumococcal Immunoglobulin G (IgG) at 1 Month After the Last Vaccination

End point title	Geometric Mean Concentrations (GMCs) of Pneumococcal Immunoglobulin G (IgG) at 1 Month After the Last Vaccination
End point description:	
GMCs of pneumococcal IgG were reported for 25 serotypes: 20vPnC (1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33F) and 5 additional (15A, 23A, 23B, 24F and 35B) serotypes in this outcome measure. GMCs and 2-sided 95% confidence intervals (CIs) were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs (based on the student t distribution). Evaluable immunogenicity population included all randomized participants who were eligible, received the study interventions to which they were randomly assigned, had at least 1 valid immunogenicity result within 27 to 56 days, inclusive, after the last vaccination, and had no other major protocol deviations as determined by the clinician. Here, "number analyzed" signifies participants evaluable for specified rows.	
End point type	Secondary
End point timeframe:	
1 Month after the last vaccination (last vaccination = vaccination on Day 1 for "1-Dose PG4" and "1-Dose 20vPnC" arms, and Dose 2 for "2-Dose PG4" arm)	

End point values	2-Dose PG4	1-Dose PG4	1-Dose 20vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	78	40	
Units: Microgram/milliliter (mcg/mL)				
number (confidence interval 95%)				
20vPnC: 1 (n= 72, 77, 40)	2.22 (1.79 to 2.74)	2.66 (2.28 to 3.11)	4.24 (3.31 to 5.44)	
20vPnC: 3 (n= 72, 77, 40)	6.46 (5.01 to 8.32)	4.21 (3.32 to 5.34)	1.21 (0.95 to 1.53)	
20vPnC: 4 (n= 72, 77, 40)	3.22 (2.56 to 4.04)	4.97 (4.11 to 6.02)	5.65 (4.56 to 7.01)	

20vPnC: 5 (n= 72, 77, 40)	1.92 (1.48 to 2.48)	2.73 (2.24 to 3.34)	3.43 (2.66 to 4.41)	
20vPnC: 6A (n= 72, 77, 40)	8.99 (7.32 to 11.05)	11.41 (9.50 to 13.69)	16.11 (12.59 to 20.61)	
20vPnC: 6B (n= 72, 77, 40)	6.83 (5.48 to 8.51)	9.48 (7.63 to 11.77)	9.99 (7.17 to 13.92)	
20vPnC: 7F (n= 72, 77, 40)	5.07 (4.24 to 6.07)	5.13 (4.44 to 5.92)	5.57 (4.49 to 6.90)	
20vPnC: 8 (n= 72, 77, 40)	3.82 (3.23 to 4.52)	4.86 (4.06 to 5.81)	5.89 (4.74 to 7.31)	
20vPnC: 9V (n= 72, 77, 40)	3.64 (2.90 to 4.56)	4.54 (3.81 to 5.41)	6.00 (4.65 to 7.74)	
20vPnC: 10A (n= 72, 77, 40)	8.68 (6.71 to 11.22)	9.36 (7.50 to 11.68)	12.64 (9.24 to 17.29)	
20vPnC: 11A (n= 72, 77, 40)	2.80 (2.32 to 3.38)	4.14 (3.37 to 5.09)	4.31 (3.42 to 5.42)	
20vPnC: 12F (n= 72, 77, 40)	2.23 (1.76 to 2.84)	2.37 (1.93 to 2.93)	3.19 (2.49 to 4.08)	
20vPnC: 14 (n= 72, 77, 40)	5.40 (4.36 to 6.69)	7.98 (6.29 to 10.12)	10.70 (8.05 to 14.22)	
20vPnC: 15B (n= 72, 77, 40)	23.54 (19.40 to 28.55)	32.97 (27.58 to 39.40)	26.80 (20.87 to 34.41)	
20vPnC: 18C (n= 72, 77, 40)	4.68 (3.50 to 6.26)	4.96 (4.07 to 6.06)	6.17 (4.53 to 8.41)	
20vPnC: 19A (n= 72, 77, 40)	3.65 (3.00 to 4.44)	4.61 (3.79 to 5.60)	5.81 (4.46 to 7.57)	
20vPnC: 19F (n= 72, 77, 40)	6.02 (4.71 to 7.70)	7.68 (6.19 to 9.54)	9.32 (7.09 to 12.24)	
20vPnC: 22F (n= 72, 77, 40)	11.71 (9.27 to 14.78)	11.04 (9.20 to 13.25)	16.21 (12.62 to 20.81)	
20vPnC: 23F (n= 72, 77, 40)	8.16 (6.13 to 10.87)	7.90 (6.02 to 10.37)	6.57 (4.72 to 9.15)	
20vPnC: 33F (n= 72, 77, 40)	10.60 (8.24 to 13.64)	9.60 (7.82 to 11.80)	13.35 (10.12 to 17.62)	
5 Additional: 15A (n= 73, 78, 40)	1.61 (1.24 to 2.08)	1.84 (1.39 to 2.44)	0.39 (0.26 to 0.60)	
5 Additional: 23A (n= 73, 78, 39)	2.35 (1.72 to 3.20)	0.53 (0.35 to 0.81)	0.07 (0.03 to 0.14)	
5 Additional: 23B (n= 73, 78, 40)	6.41 (4.69 to 8.76)	3.10 (2.02 to 4.75)	1.05 (0.57 to 1.94)	
5 Additional: 24F (n= 73, 78, 36)	3.49 (2.42 to 5.03)	0.21 (0.14 to 0.33)	0.00 (0.00 to 0.01)	
5 Additional: 35B (n= 72, 75, 40)	2.09 (1.56 to 2.81)	0.87 (0.59 to 1.29)	0.01 (0.01 to 0.02)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Systematic assessment (local reactions, systemic events): D1 through D7 after each vaccination; Non-systematic assessment: serious AEs, all-cause mortality-D1 of vaccination up to 6 months after last vaccination; other AEs-1 month after last vaccination.

Adverse event reporting additional description:

Same event may appear as both non-SAE and SAE. However, what is presented are distinct events. An event may be categorized as serious in one participant and as non-serious in another participant, or one participant may have experienced both a serious and non-serious event during the study.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	28.1
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Reporting groups

Reporting group title	2-Dose PG4: Dose 1 to Dose 2
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Reporting group description:

Participants aged ≥ 12 to ≤ 15 months received 2 doses of PG4 0.5 mL each intramuscularly. Dose 1 was administered at Day 1 (Dose 1 Visit [Vaccination 1]) and Dose 2 was administered 56 to 70 days after Dose 1 (Dose 2 Visit [Vaccination 2]).

Reporting group title	2-Dose PG4: After Dose 2
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Reporting group description:

Participants aged ≥ 12 to ≤ 15 months received 2 doses of PG4 0.5 mL each intramuscularly. Dose 1 was administered at Day 1 (Dose 1 Visit [Vaccination 1]) and Dose 2 was administered 56 to 70 days after Dose 1 (Dose 2 Visit [Vaccination 2]). In this arm AEs reported after Dose 2 up to 6 months.

Reporting group title	1-Dose PG4
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Reporting group description:

Participants aged ≥ 12 to ≤ 15 months received 1 dose of PG4 0.5 mL intramuscularly. Dose 1 was administered at Day 1 (Dose 1 Visit [Vaccination 1]).

Reporting group title	1-Dose 20vPnC
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Reporting group description:

Participants aged ≥ 12 to ≤ 15 months received 1 dose of 20vPnC 0.5 mL intramuscularly. Dose 1 was administered at Day 1 (Dose 1 Visit [Vaccination 1]).

Serious adverse events	2-Dose PG4: Dose 1 to Dose 2	2-Dose PG4: After Dose 2	1-Dose PG4
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 89 (0.00%)	0 / 79 (0.00%)	3 / 89 (3.37%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 89 (0.00%)	0 / 79 (0.00%)	1 / 89 (1.12%)
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			

Bronchiolitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 79 (0.00%)	2 / 89 (2.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	1-Dose 20vPnC		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 45 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	2-Dose PG4: Dose 1 to Dose 2	2-Dose PG4: After Dose 2	1-Dose PG4
Total subjects affected by non-serious adverse events			
subjects affected / exposed	72 / 89 (80.90%)	57 / 79 (72.15%)	74 / 89 (83.15%)
Nervous system disorders			
Hypersomnia (INCREASED SLEEP)			
alternative assessment type: Systematic			
subjects affected / exposed	36 / 89 (40.45%)	24 / 79 (30.38%)	40 / 89 (44.94%)
occurrences (all)	36	24	40
General disorders and administration site conditions			
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 89 (8.99%)	4 / 79 (5.06%)	7 / 89 (7.87%)
occurrences (all)	8	4	7

Injection site pain (PAIN) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	37 / 89 (41.57%) 37	30 / 79 (37.97%) 30	44 / 89 (49.44%) 44
Injection site erythema (REDNESS) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	26 / 89 (29.21%) 26	23 / 79 (29.11%) 23	25 / 89 (28.09%) 25
Injection site swelling (SWELLING) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	16 / 89 (17.98%) 16	16 / 79 (20.25%) 16	21 / 89 (23.60%) 21
Psychiatric disorders Irritability (IRRITABILITY) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	38 / 89 (42.70%) 38	28 / 79 (35.44%) 28	42 / 89 (47.19%) 42
Infections and infestations Otitis media subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all)	6 / 89 (6.74%) 8 8 / 89 (8.99%) 8	4 / 79 (5.06%) 4 3 / 79 (3.80%) 3	4 / 89 (4.49%) 4 6 / 89 (6.74%) 6
Metabolism and nutrition disorders Decreased appetite (DECREASED APPETITE) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	22 / 89 (24.72%) 22	11 / 79 (13.92%) 11	20 / 89 (22.47%) 20

Non-serious adverse events	1-Dose 20vPnC		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 45 (73.33%)		
Nervous system disorders Hypersomnia (INCREASED SLEEP) alternative assessment type: Systematic			

subjects affected / exposed occurrences (all)	12 / 45 (26.67%) 12		
General disorders and administration site conditions Pyrexia (FEVER) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	2 / 45 (4.44%) 2		
Injection site pain (PAIN) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	18 / 45 (40.00%) 18		
Injection site erythema (REDNESS) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	10 / 45 (22.22%) 10		
Injection site swelling (SWELLING) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	7 / 45 (15.56%) 7		
Psychiatric disorders Irritability (IRRITABILITY) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	18 / 45 (40.00%) 18		
Infections and infestations Otitis media subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 45 (4.44%) 2		
Metabolism and nutrition disorders Decreased appetite (DECREASED APPETITE) alternative assessment type: Systematic			

subjects affected / exposed	5 / 45 (11.11%)		
occurrences (all)	5		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

PIP number: EMA/PE/0000233967

Notes: