Clinical trial results:
Phase II randomized, observer-blind, placebocontrolled, multi-country study in healthy non-pregnant women 18-45 years of age to evaluate the safety, reactogenicity and immunogenicity of a 1st intramuscular dose of GSK Biologicals' investigational RSV maternal vaccine (GSK388550A) when given alone and given in co-administration with a single intramuscular dose of Boostrix (US formulation SB776423 or ex-US formulation SB263855) and to evaluate the safety, reactogenicity and immunogenicity of a 2nd dose of the RSV maternal vaccine.

Summary

EudraCT number	2019-002258-22
Trial protocol	BE
Global end of trial date	22 November 2021

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	209141

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	GSK Response Center, GlaxoSmithKline, 20 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 20 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 February 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 November 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Safety:
• To evaluate the safety and reactogenicity of 2 dose levels (60 and 120 µg) of RSVPreF3 when given alone or co-administered with dTpa from Vaccination up to Day 31.
• To evaluate the safety of a 2nd dose of RSVPreF3 given from 12 up to 18 months post 1st dose up to Day 31 days post 2nd dose vaccination.
Immunogenicity:
• To evaluate the humoral immune response to 2 dose levels (60 and 120 µg) of RSVPreF3 when given alone and co-administered with dTpa, at Screening, Day 8 and Day 31 post 1st dose vaccination.

Protection of trial subjects:

All subjects were supervised/observed for 60 minutes after vaccination with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that have no contraindications to any components of the vaccines. Subjects were followed-up for 181 days after each vaccination.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 November 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 257
Country: Number of subjects enrolled	Belgium: 146
Country: Number of subjects enrolled	Canada: 106
Worldwide total number of subjects	509
EEA total number of subjects	146

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	509
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Data reported in the participant flow, baseline characteristics and the immunogenicity outcome measures of the Extension Study were only analyzed for pooled groups, as the two formulations of dTpa vaccine (containing 300 micrograms(µg) or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies.

Period 1

Period 1 title	Primary Study
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	RSV120_dTpa_RSV120(Pooled)

Arm description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and either one dose of 300 µg or 500 µg dTpa (Boostrix) vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Arm type	Experimental
Investigational medicinal product name	RSVPreF3 formulation 3 (120 µg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Investigational medicinal product name	dTpa - US formulation
Investigational medicinal product code	
Other name	Boostrix - US formulation
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Investigational medicinal product name	dTpa - ex-US formulation
Investigational medicinal product code	
Other name	Boostrix - ex-US formulation
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Arm title	RSV120_Placebo_RSV120(Pooled)

Arm description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months

post 1st vaccination and were followed up until the study end.

Arm type	Placebo
Investigational medicinal product name	RSVPreF3 formulation 3 (120 µg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Investigational medicinal product name	NaCl
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Arm title	RSV60_dTpa_RSV120(Pooled)

Arm description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and either one dose of 300 µg or 500 µg dTpa vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Arm type	Experimental
Investigational medicinal product name	RSVPreF3 formulation 2 (60 µg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Investigational medicinal product name	dTpa - US formulation
Investigational medicinal product code	
Other name	Boostrix - US formulation
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Investigational medicinal product name	dTpa - ex-US formulation
Investigational medicinal product code	
Other name	Boostrix - ex-US formulation
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Arm title	RSV60_Placebo_RSV120(Pooled)

Arm description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Arm type	Placebo

Investigational medicinal product name	RSVPreF3 formulation 2 (60 µg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Investigational medicinal product name	NaCl
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Arm title	dTpa_Placebo_RSV120(Pooled)

Arm description:

Subjects received one dose of Placebo and either one dose of 300 µg or 500 µg dTpa vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Arm type	Placebo
Investigational medicinal product name	dTpa - ex-US
Investigational medicinal product code	
Other name	Boostrix - ex-US formulation
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Investigational medicinal product name	NaCl
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Investigational medicinal product name	dTpa - US
Investigational medicinal product code	
Other name	Boostrix - US formulation
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Number of subjects in period 1	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)
Started	101	101	103
Completed	95	93	100
Not completed	6	8	3
ELIGIBILITY CRITERIA NOT FULFILLED	3	4	2
Lost to follow-up	3	4	1

Number of subjects in period 1	RSV60_Placebo_RSV120(Pooled)	dTpa_Placebo_RSV120(Pooled)
Started	102	102
Completed	100	98
Not completed	2	4
ELIGIBILITY CRITERIA NOT FULFILLED	1	-
Lost to follow-up	1	4

Period 2

Period 2 title	Extension Study
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	RSV120_dTpa_RSV120(Pooled)

Arm description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and either one dose of 300 µg or 500 µg dTpa (Boostrix) vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Arm type	Experimental
Investigational medicinal product name	RSVPreF3 formulation 3 (120 µg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Arm title	RSV120_Placebo_RSV120(Pooled)

Arm description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Arm type	Placebo

Investigational medicinal product name	RSVPreF3 formulation 3 (120 µg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Arm title	RSV60_dTpa_RSV120(Pooled)

Arm description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and either one dose of 300 µg or 500 µg dTpa vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Arm type	Experimental
Investigational medicinal product name	RSVPreF3 formulation 3 (120 µg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Arm title	RSV60_Placebo_RSV120(Pooled)

Arm description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Arm type	Placebo
Investigational medicinal product name	RSVPreF3 formulation 3 (120 µg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Arm title	dTpa_Placebo_RSV120(Pooled)

Arm description:

Subjects received one dose of Placebo and either one dose of 300 µg or 500 µg dTpa vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Arm type	Placebo
Investigational medicinal product name	RSVPreF3 formulation 3 (120 µg)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5mL dose administered in the deltoid muscle.

Number of subjects in period 2[1]	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)
Started	39	41	46
Completed	38	39	45
Not completed	1	2	1
Lost to follow-up	1	2	1

Number of subjects in period 2[1]	RSV60_Placebo_RSV120(Pooled)	dTpa_Placebo_RSV120(Pooled)
Started	41	46
Completed	41	45
Not completed	0	1
Lost to follow-up	-	1

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

Baseline characteristics

Reporting groups	
Reporting group title	RSV120_dTpa_RSV120(Pooled)
Reporting group description:	
Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and either one dose of 300 µg or 500 µg dTpa (Boostrix) vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.	
Reporting group title	RSV120_Placebo_RSV120(Pooled)
Reporting group description:	
Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.	
Reporting group title	RSV60_dTpa_RSV120(Pooled)
Reporting group description:	
Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and either one dose of 300 µg or 500 µg dTpa vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.	
Reporting group title	RSV60_Placebo_RSV120(Pooled)
Reporting group description:	
Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.	
Reporting group title	dTpa_Placebo_RSV120(Pooled)
Reporting group description:	
Subjects received one dose of Placebo and either one dose of 300 µg or 500 µg dTpa vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.	

Reporting group values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)
Number of subjects	101	101	103
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	101	101	103
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Age, Primary Study			
Units: Years			
arithmetic mean	31.4	31.0	30.8
standard deviation	± 7.6	± 8.0	± 8.4

Sex/Gender, Customized			
Sex/Gender, Primary Study			
Units: Participants			
Female	101	101	103
Male	0	0	0
Race/Ethnicity, Customized			
Race/Ethnicity, Primary Study			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	3	0	1
ASIAN	1	3	2
BLACK OR AFRICAN AMERICAN	4	6	8
OTHER Not specified	2	2	2
WHITE	91	90	90

Reporting group values	RSV60_Placebo_RSV120(Pooled)	dTpa_Placebo_RSV120(Pooled)	Total
Number of subjects	102	102	509
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	102	102	509
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Age, Primary Study			
Units: Years			
arithmetic mean	30.5	30.4	
standard deviation	± 8.3	± 7.9	-
Sex/Gender, Customized			
Sex/Gender, Primary Study			
Units: Participants			
Female	102	102	509
Male	0	0	0
Race/Ethnicity, Customized			
Race/Ethnicity, Primary Study			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	1	0	5
ASIAN	4	4	14
BLACK OR AFRICAN AMERICAN	3	4	25
OTHER Not specified	2	3	11
WHITE	92	91	454

Subject analysis sets

Subject analysis set title	RSV120_dTpa_RSV120(EX-US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine (12 to 18 months post 1st vaccination) and were followed up until the study end.

Subject analysis set title	RSV120_Placebo_RSV120(EX-US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_dTpa_RSV120(EX-US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_Placebo_RSV120(EX-US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	dTpa_Placebo_RSV120(EX-US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of Placebo and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_dTpa_RSV120(US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_Placebo_RSV120(US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_dTpa_RSV120(US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_Placebo_RSV120(US)-SSS-Primary Study

Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	dTpa_Placebo_RSV120(US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of Placebo and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_dTpa_RSV120(EX-US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine (12 to 18 months post 1st vaccination) and were followed up until the study end.

Subject analysis set title	RSV120_Placebo_RSV120(EX-US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_dTpa_RSV120(EX-US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_Placebo_RSV120(EX-US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	dTpa_Placebo_RSV120(EX-US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of Placebo and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_dTpa_RSV120(US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_Placebo_RSV120(US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1

of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_dTpa_RSV120(US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_Placebo_RSV120(US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	dTpa_Placebo_RSV120(US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of Placebo and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine (12 to 18 months post 1st vaccination) and were followed up until the study end.

Subject analysis set title	RSV120_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of Placebo and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_dTpa_RSV120(US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_Placebo_RSV120(US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_dTpa_RSV120(US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_Placebo_RSV120(US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	dTpa_Placebo_RSV120(US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of Placebo and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group values	RSV120_dTpa_RSV120(EX-US)-SSS-Primary Study	RSV120_Placebo_RSV120(EX-US)-SSS-Primary Study	RSV60_dTpa_RSV120(EX-US)-SSS-Primary Study
Number of subjects	50	49	51
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	50	49	51
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Age, Primary Study			
Units: Years arithmetic mean			

standard deviation	±	±	±

Sex/Gender, Customized			
Sex/Gender, Primary Study			
Units: Participants			
Female			
Male			
Race/Ethnicity, Customized			
Race/Ethnicity, Primary Study			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE			
ASIAN			
BLACK OR AFRICAN AMERICAN			
OTHER Not specified			
WHITE			

Reporting group values	RSV60_Placebo_RSV120(EX-US)-SSS-Primary Study	dTpa_Placebo_RSV120(EX-US)-SSS-Primary Study	RSV120_dTpa_RSV120(US)-SSS-Primary Study
Number of subjects	51	49	51
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	51	49	51
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Age, Primary Study			
Units: Years			
arithmetic mean			
standard deviation	±	±	±
Sex/Gender, Customized			
Sex/Gender, Primary Study			
Units: Participants			
Female			
Male			
Race/Ethnicity, Customized			
Race/Ethnicity, Primary Study			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE			
ASIAN			
BLACK OR AFRICAN AMERICAN			
OTHER Not specified			

WHITE			

Reporting group values	RSV120_Placebo_RSV120(US)-SSS-Primary Study	RSV60_dTpa_RSV120(US)-SSS-Primary Study	RSV60_Placebo_RSV120(US)-SSS-Primary Study
Number of subjects	52	52	51
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	51	52	51
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Age, Primary Study			
Units: Years			
arithmetic mean			
standard deviation	±	±	±
Sex/Gender, Customized			
Sex/Gender, Primary Study			
Units: Participants			
Female			
Male			
Race/Ethnicity, Customized			
Race/Ethnicity, Primary Study			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE			
ASIAN			
BLACK OR AFRICAN AMERICAN			
OTHER Not specified			
WHITE			

Reporting group values	dTpa_Placebo_RSV120(US)-SSS-Primary Study	RSV120_dTpa_RSV120(EX-US) - ES-Primary Study	RSV120_Placebo_RSV120(EX-US) - ES-Primary Study
Number of subjects	50	50	49
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0

Adults (18-64 years)	50	52	51
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Age, Primary Study			
Units: Years			
arithmetic mean			
standard deviation	±	±	±
Sex/Gender, Customized			
Sex/Gender, Primary Study			
Units: Participants			
Female			
Male			
Race/Ethnicity, Customized			
Race/Ethnicity, Primary Study			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE			
ASIAN			
BLACK OR AFRICAN AMERICAN			
OTHER Not specified			
WHITE			

Reporting group values	RSV60_dTpa_RSV120(EX-US) - ES-Primary Study	RSV60_Placebo_RSV120(EX-US) - ES-Primary Study	dTpa_Placebo_RSV120(EX-US) - ES-Primary Study
Number of subjects	51	51	51
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	51	49	48
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Age, Primary Study			
Units: Years			
arithmetic mean			
standard deviation	±	±	±
Sex/Gender, Customized			
Sex/Gender, Primary Study			
Units: Participants			
Female			
Male			
Race/Ethnicity, Customized			
Race/Ethnicity, Primary Study			
Units: Subjects			

AMERICAN INDIAN OR ALASKA NATIVE			
ASIAN			
BLACK OR AFRICAN AMERICAN			
OTHER Not specified			
WHITE			

Reporting group values	RSV120_dTpa_RSV120(US) - ES-Primary Study	RSV120_Placebo_RSV120(US) - ES-Primary Study	RSV60_dTpa_RSV120(US) - ES-Primary Study
Number of subjects	51	52	52
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	50	49	50
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Age, Primary Study			
Units: Years			
arithmetic mean			
standard deviation	±	±	±
Sex/Gender, Customized			
Sex/Gender, Primary Study			
Units: Participants			
Female			
Male			
Race/Ethnicity, Customized			
Race/Ethnicity, Primary Study			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE			
ASIAN			
BLACK OR AFRICAN AMERICAN			
OTHER Not specified			
WHITE			

Reporting group values	RSV60_Placebo_RSV120(US) - ES-Primary Study	dTpa_Placebo_RSV120(US) - ES-Primary Study	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study
Number of subjects	51	51	49
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0

Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	49	50	48
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Age, Primary Study			
Units: Years			
arithmetic mean			
standard deviation	±	±	±
Sex/Gender, Customized			
Sex/Gender, Primary Study			
Units: Participants			
Female	49		
Male	0		
Race/Ethnicity, Customized			
Race/Ethnicity, Primary Study			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE			
ASIAN			
BLACK OR AFRICAN AMERICAN			
OTHER Not specified			
WHITE			

Reporting group values	RSV120_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_Placebo_RSV120(EX-US) - PPS-Primary Study
Number of subjects	51	51	51
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	49	51	49
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Age, Primary Study			
Units: Years			
arithmetic mean			
standard deviation	±	±	±
Sex/Gender, Customized			
Sex/Gender, Primary Study			
Units: Participants			
Female			
Male			

Race/Ethnicity, Customized			
Race/Ethnicity, Primary Study			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE ASIAN BLACK OR AFRICAN AMERICAN OTHER Not specified WHITE			

Reporting group values	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study	RSV120_Placebo_RSV120(US) - PPS-Primary Study
Number of subjects	51	51	51
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	24	31	32
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Age, Primary Study			
Units: Years arithmetic mean standard deviation	±	±	±
Sex/Gender, Customized			
Sex/Gender, Primary Study			
Units: Participants			
Female Male			
Race/Ethnicity, Customized			
Race/Ethnicity, Primary Study			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE ASIAN BLACK OR AFRICAN AMERICAN OTHER Not specified WHITE			

Reporting group values	RSV60_dTpa_RSV120(US) - PPS-Primary Study	RSV60_Placebo_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study
Number of subjects	52	51	51
Age categorical Units: Subjects			
In utero	0	0	0

Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	29	31	14
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Age, Primary Study			
Units: Years			
arithmetic mean			
standard deviation	±	±	±
Sex/Gender, Customized			
Sex/Gender, Primary Study			
Units: Participants			
Female			
Male			
Race/Ethnicity, Customized			
Race/Ethnicity, Primary Study			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE			
ASIAN			
BLACK OR AFRICAN AMERICAN			
OTHER Not specified			
WHITE			

End points reporting groups

Reporting group title	RSV120_dTpa_RSV120(Pooled)

Reporting group description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and either one dose of 300 µg or 500 µg dTpa (Boostrix) vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group title	RSV120_Placebo_RSV120(Pooled)

Reporting group description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group title	RSV60_dTpa_RSV120(Pooled)

Reporting group description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and either one dose of 300 µg or 500 µg dTpa vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group title	RSV60_Placebo_RSV120(Pooled)

Reporting group description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group title	dTpa_Placebo_RSV120(Pooled)

Reporting group description:

Subjects received one dose of Placebo and either one dose of 300 µg or 500 µg dTpa vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group title	RSV120_dTpa_RSV120(Pooled)

Reporting group description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and either one dose of 300 µg or 500 µg dTpa (Boostrix) vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group title	RSV120_Placebo_RSV120(Pooled)

Reporting group description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group title	RSV60_dTpa_RSV120(Pooled)

Reporting group description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and either one dose of 300 µg or 500 µg dTpa vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group title	RSV60_Placebo_RSV120(Pooled)

Reporting group description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group title	dTpa_Placebo_RSV120(Pooled)

Reporting group description:

Subjects received one dose of Placebo and either one dose of 300 µg or 500 µg dTpa vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_dTpa_RSV120(EX-US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine (12 to 18 months post 1st vaccination) and were followed up until the study end.

Subject analysis set title	RSV120_Placebo_RSV120(EX-US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_dTpa_RSV120(EX-US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_Placebo_RSV120(EX-US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	dTpa_Placebo_RSV120(EX-US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of Placebo and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_dTpa_RSV120(US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_Placebo_RSV120(US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_dTpa_RSV120(US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The

subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_Placebo_RSV120(US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	dTpa_Placebo_RSV120(US)-SSS-Primary Study
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one dose of Placebo and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_dTpa_RSV120(EX-US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine (12 to 18 months post 1st vaccination) and were followed up until the study end.

Subject analysis set title	RSV120_Placebo_RSV120(EX-US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_dTpa_RSV120(EX-US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_Placebo_RSV120(EX-US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	dTpa_Placebo_RSV120(EX-US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of Placebo and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_dTpa_RSV120(US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_Placebo_RSV120(US) - ES-Primary Study

Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_dTpa_RSV120(US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_Placebo_RSV120(US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	dTpa_Placebo_RSV120(US) - ES-Primary Study
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received one dose of Placebo and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine (12 to 18 months post 1st vaccination) and were followed up until the study end.

Subject analysis set title	RSV120_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of Placebo and one dose of 500 µg dTpa vaccine (Ex-US formulation) on Day

1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_dTpa_RSV120(US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV120_Placebo_RSV120(US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_dTpa_RSV120(US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	RSV60_Placebo_RSV120(US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Subject analysis set title	dTpa_Placebo_RSV120(US) - PPS-Primary Study
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one dose of Placebo and one dose of 300 µg dTpa vaccine (US formulation) on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Primary: Percentage of subjects with any solicited local adverse event (AEs) [Primary Study]

End point title	Percentage of subjects with any solicited local adverse event (AEs) [Primary Study][1]

End point description:

Assessed solicited local AEs are: erythema, pain and swelling. Any = occurrence of the adverse event regardless of intensity grade. Any erythema and swelling = adverse event reported with a surface diameter greater than 0 millimeters.
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the safety response to RSVPreF3.
The analysis was performed on the Solicited Safety Set (SSS) - Primary Study which consisted of all subjects from the Exposed set (ES) - Primary Study for whom solicited safety data were available.

End point type	Primary

End point timeframe:

From Day 1 to Day 8

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	100	103	102
Units: Percentage of participants				
number (confidence interval 95%)				
RSVPreF3 (Left Arm), Erythema	5.9 (2.2 to 12.5)	5 (1.6 to 11.3)	5.8 (2.2 to 12.2)	5.9 (2.2 to 12.4)
RSVPreF3 (Left Arm), Pain	51.5 (41.3 to 61.6)	54 (43.7 to 64)	52.4 (42.4 to 62.4)	58.8 (48.6 to 68.5)
RSVPreF3 (Left Arm), Swelling	2 (0.2 to 7)	7 (2.9 to 13.9)	2.9 (0.6 to 8.3)	4.9 (1.6 to 11.1)
dTpa (Right Arm), Erythema	4 (1.1 to 9.8)	1 (0 to 5.4)	4.9 (1.6 to 11)	1 (0 to 5.3)
dTpa (Right Arm), Pain	81.2 (72.2 to 88.3)	25 (16.9 to 34.7)	76.7 (67.3 to 84.5)	18.6 (11.6 to 27.6)
dTpa (Right Arm), Swelling	5 (1.6 to 11.2)	0 (0 to 3.6)	1.9 (0.2 to 6.8)	1 (0 to 5.3)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	99			
Units: Percentage of participants				
number (confidence interval 95%)				
RSVPreF3 (Left Arm), Erythema	0 (0 to 3.7)			
RSVPreF3 (Left Arm), Pain	19.2 (12 to 28.3)			
RSVPreF3 (Left Arm), Swelling	0 (0 to 3.7)			
dTpa (Right Arm), Erythema	6.1 (2.3 to 12.7)			
dTpa (Right Arm), Pain	78.8 (69.4 to 86.4)			
dTpa (Right Arm), Swelling	4 (1.1 to 10)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with any solicited general AEs [Primary Study]

End point title	Percentage of subjects with any solicited general AEs [Primary Study][2]

End point description:

Assessed solicited general AEs are: fatigue, gastrointestinal symptoms, headache and fever (body temperature ≥ 38 degree Celcius/100.4 degree Fahrenheit). Any = occurrence of the adverse event regardless of intensity grade or relation to study vaccination.

The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the safety response to RSVPreF3.
The analysis was performed on the SSS - Primary Study which consisted of all subjects from the ES - Primary Study for whom solicited safety data were available.

End point type	Primary

End point timeframe:

From Day 1 to Day 8

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	101	103	102
Units: Percentage of participants				
number (confidence interval 95%)				
Fatigue	40.6 (30.9 to 50.8)	39.6 (30 to 49.8)	37.9 (28.5 to 48)	32.4 (23.4 to 42.3)
Gastrointestinal symptoms	23.8 (15.9 to 33.3)	28.7 (20.1 to 38.6)	27.2 (18.9 to 36.8)	28.4 (19.9 to 38.2)
Headache	44.6 (34.7 to 54.8)	45.5 (35.6 to 55.8)	35 (25.8 to 45)	39.2 (29.7 to 49.4)
Temperature	2 (0.2 to 7)	4 (1.1 to 9.8)	2.9 (0.6 to 8.3)	3.9 (1.1 to 9.7)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	99			
Units: Percentage of participants				
number (confidence interval 95%)				
Fatigue	38.4 (28.8 to 48.7)			
Gastrointestinal symptoms	28.3 (19.7 to 38.2)			
Headache	37.4 (27.9 to 47.7)			
Temperature	7.1 (2.9 to 14)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with any unsolicited AEs [Primary Study]

End point title	Percentage of subjects with any unsolicited AEs [Primary

	Study][3]

End point description:

An unsolicited AE is any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is to be reported as an unsolicited AE.
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the safety response to RSVPreF3.
The analysis was performed on the ES - Primary Study which consisted of all subjects who received at least 1 dose of the study treatment.

End point type	Primary

End point timeframe:

From Day 1 to Day 31

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	101	103	102
Units: Percentage of participants				
number (confidence interval 95%)	38.6 (29.1 to 48.8)	34.7 (25.5 to 44.8)	33 (24.1 to 43)	37.3 (27.9 to 47.4)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	102			
Units: Percentage of participants				
number (confidence interval 95%)	32.4 (23.4 to 42.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any SAEs [Primary Study]

End point title	Number of subjects with any SAEs [Primary Study][4]

End point description:

A SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization or results in disability/incapacity or is a congenital anomaly/birth defect in the offspring of a study subject. Any is defined as any occurrence of SAE regardless of intensity grade or relation to study vaccination.
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the safety response to

RSVPreF3.
The analysis was performed on the ES - Primary Study which consisted of all subjects who received at least 1 dose of the study treatment.

End point type	Primary

End point timeframe:

From Day 1 to Day 31

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	101	103	102
Units: Participants	0	0	0	0

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	102			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with any solicited local AEs [Extension Study]

End point title	Percentage of subjects with any solicited local AEs [Extension Study][5]

End point description:

Assessed solicited local AEs are: erythema, pain and swelling. Any = occurrence of the adverse event regardless of intensity grade. Any erythema and swelling = adverse event reported with a surface diameter greater than 0 millimeters.
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies.The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the safety response to RSVPreF3.
The analysis was performed on the SSS - Extension Study which consisted of all subjects from the ES - Extension Study for whom solicited safety data were available.

End point type	Primary

End point timeframe:

From the Day of 2nd vaccination to Day 8 post 2nd vaccination

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	39	46	41
Units: Percentage of participants				
number (confidence interval 95%)				
Erythema	17.9 (7.5 to 33.5)	10.3 (2.9 to 24.2)	8.7 (2.4 to 20.8)	14.6 (5.6 to 29.2)
Pain	87.2 (72.6 to 95.7)	87.2 (72.6 to 95.7)	80.4 (66.1 to 90.6)	85.4 (70.8 to 94.4)
Swelling	12.8 (4.3 to 27.4)	7.7 (1.6 to 20.9)	8.7 (2.4 to 20.8)	4.9 (0.6 to 16.5)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	44			
Units: Percentage of participants				
number (confidence interval 95%)				
Erythema	2.3 (0.1 to 12)			
Pain	38.6 (24.4 to 54.5)			
Swelling	2.3 (0.1 to 12)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects any solicited general AEs [Extension Period]

End point title	Percentage of subjects any solicited general AEs [Extension Period][6]

End point description:

Assessed solicited general AEs are: fatigue, gastrointestinal symptoms, headache and fever(body temperature ≥ 38 degree Celcius/100.4 degree Fahrenheit). Any = occurrence of the adverse event regardless of intensity grade or relation to study vaccination.
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the safety response to RSVPreF3.
The analysis was performed on the SSS - Extension Study which consisted of all subjects from the ES - Extension Study for whom solicited safety data were available.

End point type	Primary

End point timeframe:

From the Day of 2nd vaccination to Day 8 post 2nd vaccination

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	39	46	41
Units: Percentage of participants				
number (confidence interval 95%)				
Fatigue	25.6 (13 to 42.1)	33.3 (19.1 to 50.2)	37 (23.2 to 52.5)	46.3 (30.7 to 62.6)
Gastrointestinal symptoms	10.3 (2.9 to 24.2)	20.5 (9.3 to 36.5)	15.2 (6.3 to 28.9)	24.4 (12.4 to 40.3)
Headache	28.2 (15 to 44.9)	33.3 (19.1 to 50.2)	32.6 (19.5 to 48)	56.1 (39.7 to 71.5)
Temperature	0 (0 to 9)	0 (0 to 9)	2.2 (0.1 to 11.5)	9.8 (2.7 to 23.1)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	44			
Units: Percentage of participants				
number (confidence interval 95%)				
Fatigue	34.1 (20.5 to 49.9)			
Gastrointestinal symptoms	13.6 (5.2 to 27.4)			
Headache	31.8 (18.6 to 47.6)			
Temperature	2.3 (0.1 to 12)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with any unsolicited AEs [Extension Period]

End point title	Percentage of subjects with any unsolicited AEs [Extension Period][7]

End point description:

An unsolicited AE is any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is to be reported as an unsolicited AE.
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the safety response to RSVPreF3.
The analysis was performed on ES - Extension Study which consisted of all subjects who received at least 2 doses of the study treatment.

End point type	Primary

End point timeframe:

From the Day of 2nd vaccination to Day 31 post 2nd vaccination

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	46	41
Units: Percentage of participants				
number (confidence interval 95%)	18 (8 to 34)	20 (9 to 35)	20 (9 to 34)	29 (16 to 46)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	46			
Units: Percentage of participants				
number (confidence interval 95%)	20 (9 to 34)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any SAEs [Extension Period]

End point title	Number of subjects with any SAEs [Extension Period][8]

End point description:

A SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization or results in disability/incapacity or is a congenital anomaly/birth defect in the offspring of a study subject. Any is defined as any occurrence of SAE regardless of intensity grade or relation to study vaccination.
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the safety response to RSVPreF3.
The analysis was performed on ES - Extension Study which consisted of all subjects who received at least 2 doses of the study treatment.

End point type	Primary

End point timeframe:

From the Day of 2nd vaccination to Day 31 post 2nd vaccination

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	46	41
Units: Participants	0	0	0	1

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	46			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Primary: RSV A neutralizing antibody Geometric Mean Titers (GMTs) at Screening [Primary Study]

End point title	RSV A neutralizing antibody Geometric Mean Titers (GMTs) at Screening [Primary Study][9]

End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay and titers are expressed in ED60 (Estimated Dilution 60).
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the immunogenicity response to RSVPreF3.
The analysis was performed on the Per Protocol Set (PPS) - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Primary

End point timeframe:

At Screening (Day -7 to Day 1)

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	100	103	102
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	875 (745 to 1027)	1022 (856 to 1222)	1135 (959 to 1342)	771 (673 to 883)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	102			
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	1050 (896 to 1231)			

Statistical analyses

No statistical analyses for this end point

Primary: RSV A neutralizing antibody GMTs at Day 8 [Primary Study]

End point title	RSV A neutralizing antibody GMTs at Day 8 [Primary Study][10]

End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay and titers are expressed in ED60.
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the immunogenicity response to RSVPreF3.
The analysis was performed on the Per Protocol Set (PPS) - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Primary

End point timeframe:

At Day 8

Notes:

[10] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Poole d)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	99	100	102
Units: Titers (ED 60)				
geometric mean (confidence interval 95%)	14166 (12213 to 16431)	14285 (11999 to 17008)	10185 (8514 to 12183)	10590 (8994 to 12469)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	100			

Units: Titers (ED 60)				
geometric mean (confidence interval 95%)	783 (661 to 929)			

Statistical analyses

No statistical analyses for this end point

Primary: RSV A neutralizing antibody GMTs at Day 31 [Primary Study]

End point title	RSV A neutralizing antibody GMTs at Day 31 [Primary

End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay and titers are expressed in ED60.
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the immunogenicity response to RSVPreF3.
The analysis was performed on the Per Protocol Set (PPS) - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Primary

End point timeframe:

At Day 31

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	97	102	99
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	9836 (8252 to 11725)	11038 (9160 to 13301)	9214 (7806 to 10876)	8739 (7561 to 10101)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	845 (705 to 1013)			

Statistical analyses

No statistical analyses for this end point

Primary: RSV PreF3 IgG antibody Geometric Mean Concentration (GMCs) at Screening [Primary Study]

End point title	RSV PreF3 IgG antibody Geometric Mean Concentration (GMCs) at Screening [Primary Study][12]

End point description:

Serological assays for the determination of IgG antibodies against RSV PreF3 were performed by Enzyme-linked immunosorbent assay (ELISA).
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the immunogenicity response to RSVPreF3.
The analysis was performed on the Per Protocol Set (PPS) - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Primary

End point timeframe:

At Screening (Day -7 to Day 1)

Notes:

[12] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	100	103	102
Units: ELISA Units per milliliter (EU/mL)				
geometric mean (confidence interval 95%)	6611 (5857 to 7461)	6751 (5982 to 7620)	7449 (6534 to 8492)	6172 (5570 to 6840)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	102			
Units: ELISA Units per milliliter (EU/mL)				
geometric mean (confidence interval 95%)	6454 (5771 to 7217)			

Statistical analyses

No statistical analyses for this end point

Primary: RSV PreF3 IgG GMCs at Day 8 [Primary Study]

End point title	RSV PreF3 IgG GMCs at Day 8 [Primary Study][13]

End point description:

Serological assays for the determination of IgG antibodies against RSV PreF3 were performed by Enzyme-linked immunosorbent assay (ELISA).
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the immunogenicity response to RSVPreF3.
The analysis was performed on the Per Protocol Set (PPS) - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Primary

End point timeframe:

At Day 8

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99	99	100	102
Units: EU/mL				
geometric mean (confidence interval 95%)	156568 (137244 to 178613)	146708 (128639 to 167315)	101662 (89783 to 115113)	118670 (106004 to 132850)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: EU/mL				
geometric mean (confidence interval 95%)	5780 (5145 to 6494)			

Statistical analyses

No statistical analyses for this end point

Primary: RSV PreF3 IgG GMCs at Day 31 [Primary Study]

End point title	RSV PreF3 IgG GMCs at Day 31 [Primary Study][14]

End point description:

Serological assays for the determination of IgG antibodies against RSV PreF3 were performed by Enzyme-linked immunosorbent assay (ELISA).
Analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the immunogenicity response to RSVPreF3.
The analysis was performed on the Per Protocol Set (PPS) - Primary Study which consisted of all

subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Primary

End point timeframe:

At Day 31

Notes:

[14] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	97	102	99
Units: EU/mL				
geometric mean (confidence interval 95%)	101813 (89290 to 116092)	106082 (93597 to 120231)	86273 (77415 to 96145)	88938 (79738 to 99200)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: EU/mL				
geometric mean (confidence interval 95%)	6149 (5474 to 6908)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with any solicited local adverse event (AEs) by each Boostrix formulation [Primary Study]

End point title	Percentage of subjects with any solicited local adverse event (AEs) by each Boostrix formulation [Primary Study]

End point description:

Assessed solicited local AEs are: erythema, pain and swelling. Any = occurrence of the adverse event regardless of intensity grade. Any erythema and swelling = adverse event reported with a surface diameter greater than 0 millimeters.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum), as the objective of this endpoint was to analyze the impact of co-administration of RSVPreF3 with either 300 µg or 500 µg of dTpa (Boostrix) formulation on the safety response to RSVPreF3.
The analysis was performed on the SSS - Primary Study which consisted of all subjects from the ES - Primary Study for whom solicited safety data were available.

End point type	Secondary

End point timeframe:

From Day 1 to Day 8

End point values	RSV120_dTpa_RSV120(EX-US)-SSS-Primary Study	RSV120_Placebo_RSV120(EX-US)-SSS-Primary Study	RSV60_dTpa_RSV120(EX-US)-SSS-Primary Study	RSV60_Placebo_RSV120(EX-US)-SSS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	50	49	51	51
Units: Percentage of participants				
number (confidence interval 95%)				
Left Arm, Erythema	6 (1.3 to 16.5)	4.1 (0.5 to 14)	5.9 (1.2 to 16.2)	2 (0 to 10.4)
Left Arm, Pain	46 (31.8 to 60.7)	53.1 (38.3 to 67.5)	52.9 (38.5 to 67.1)	60.8 (46.1 to 74.2)
Left Arm, Swelling	2 (0.1 to 10.6)	6.1 (1.3 to 16.9)	3.9 (0.5 to 13.5)	2 (0 to 10.4)
Right Arm, Erythema	4 (0.5 to 13.7)	2 (0.1 to 10.9)	2 (0 to 10.4)	2 (0 to 10.4)
Right Arm, Pain	86 (73.3 to 94.2)	18.4 (8.8 to 32)	88.2 (76.1 to 95.6)	23.5 (12.8 to 37.5)
Right Arm, Swelling	6 (1.3 to 16.5)	0 (0 to 7.3)	3.9 (0.5 to 13.5)	2 (0 to 10.4)

End point values	dTpa_Placebo_RSV120(EX-US)-SSS-Primary Study	RSV120_dTpa_RSV120(US)-SSS-Primary Study	RSV120_Placebo_RSV120(US)-SSS-Primary Study	RSV60_dTpa_RSV120(US)-SSS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	51	51	52
Units: Percentage of participants				
number (confidence interval 95%)				
Left Arm, Erythema	0 (0 to 7.3)	5.9 (1.2 to 16.2)	5.9 (1.2 to 16.2)	5.8 (1.2 to 15.9)
Left Arm, Pain	16.3 (7.3 to 29.7)	56.9 (42.2 to 70.7)	54.9 (40.3 to 68.9)	51.9 (37.6 to 66)
Left Arm, Swelling	0 (0 to 7.3)	2 (0 to 10.4)	7.8 (2.2 to 18.9)	1.9 (0 to 10.3)
Right Arm, Erythema	6.1 (1.3 to 16.9)	3.9 (0.5 to 13.5)	0 (0 to 7)	7.7 (2.1 to 18.5)
Right Arm, Pain	79.6 (65.7 to 89.8)	76.5 (62.5 to 87.2)	31.4 (19.1 to 45.9)	65.4 (50.9 to 78)
Right Arm, Swelling	6.1 (1.3 to 16.9)	3.9 (0.5 to 13.5)	0 (0 to 7)	0 (0 to 6.8)

End point values	RSV60_Placebo_RSV120(US)-SSS-Primary Study	dTpa_Placebo_RSV120(US)-SSS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51	50		
Units: Percentage of participants				
number (confidence interval 95%)				

Left Arm, Erythema	9.8 (3.3 to 21.4)	0 (0 to 7.1)		
Left Arm, Pain	56.9 (42.2 to 70.7)	22 (11.5 to 36)		
Left Arm, Swelling	7.8 (2.2 to 18.9)	0 (0 to 7.1)		
Right Arm, Erythema	0 (0 to 7)	6 (1.3 to 16.5)		
Right Arm, Pain	13.7 (5.7 to 26.3)	78 (64 to 88.5)		
Right Arm, Swelling	0 (0 to 7)	2 (0.1 to 10.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with any solicited general AEs by each Boostrix formulation [Primary Study]

End point title	Percentage of subjects with any solicited general AEs by each Boostrix formulation [Primary Study]

End point description:

Assessed solicited general AEs are: fatigue, gastrointestinal symptoms, headache and fever(body temperature ≥ 38 degree Celcius/100.4 degree Fahrenheit). Any = occurrence of the adverse event regardless of intensity grade or relation to study vaccination.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum), as the objective of this endpoint was to analyze the impact of co-administration of RSVPreF3 with either 300 µg or 500 µg of dTpa (Boostrix) formulation on the safety response to RSVPreF3.
The analysis was performed on the SSS - Primary Study which consisted of all subjects from the ES - Primary Study for whom solicited safety data were available.

End point type	Secondary

End point timeframe:

From Day 1 to Day 8

End point values	RSV120_dTpa_RSV120(EX-US)-SSS-Primary Study	RSV120_Placebo_RSV120(EX-US)-SSS-Primary Study	RSV60_dTpa_RSV120(EX-US)-SSS-Primary Study	RSV60_Placebo_RSV120(EX-US)-SSS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	50	49	51	51
Units: Percentage of participants				
number (confidence interval 95%)				
Fatigue	36 (22.9 to 50.8)	36.7 (23.4 to 51.7)	39.2 (25.8 to 53.9)	29.4 (17.5 to 43.8)
Gastrointestinal symptoms	22 (11.5 to 36)	28.6 (16.6 to 43.3)	23.5 (12.8 to 37.5)	29.4 (17.5 to 43.8)
Headache	46 (31.8 to 60.7)	38.8 (25.2 to 53.8)	31.4 (19.1 to 45.9)	45.1 (31.1 to 59.7)
Temperature	4 (0.5 to 13.7)	6.1 (1.3 to 16.9)	3.9 (0.5 to 13.5)	5.9 (1.2 to 16.2)

End point values	dTpa_Placebo_RSV120(EX-US)-SSS-Primary Study	RSV120_dTpa_RSV120(US)-SSS-Primary Study	RSV120_Placebo_RSV120(US)-SSS-Primary Study	RSV60_dTpa_RSV120(US)-SSS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	51	52	52
Units: Percentage of participants				
number (confidence interval 95%)				
Fatigue	34.7 (21.7 to 49.6)	45.1 (31.1 to 59.7)	42.3 (28.7 to 56.8)	36.5 (23.6 to 51)
Gastrointestinal symptoms	30.6 (18.3 to 45.4)	25.5 (14.3 to 39.6)	28.8 (17.1 to 43.1)	30.8 (18.7 to 45.1)
Headache	40.8 (27 to 55.8)	43.1 (29.3 to 57.8)	51.9 (37.6 to 66)	38.5 (25.3 to 53)
Temperature	12.2 (4.6 to 24.8)	0 (0 to 7)	1.9 (0 to 10.3)	1.9 (0 to 10.3)

End point values	RSV60_Placebo_RSV120(US)-SSS-Primary Study	dTpa_Placebo_RSV120(US)-SSS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51	50		
Units: Percentage of participants				
number (confidence interval 95%)				
Fatigue	35.3 (22.4 to 49.9)	42 (28.2 to 56.8)		
Gastrointestinal symptoms	27.5 (15.9 to 41.7)	26 (14.6 to 40.3)		
Headache	33.3 (20.8 to 47.9)	34 (21.2 to 48.8)		
Temperature	2 (0 to 10.4)	2 (0.1 to 10.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with any unsolicited AEs by each Boostrix formulation [Primary Study]

End point title	Percentage of subjects with any unsolicited AEs by each Boostrix formulation [Primary Study]

End point description:

An unsolicited AE is any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is to be reported as an unsolicited AE.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum), as the objective of this endpoint was to analyze the impact of co-administration of RSVPreF3 with either 300 µg or 500 µg of dTpa (Boostrix) formulation on the safety response to RSVPreF3.
The analysis was performed on the ES - Primary Study which consisted of all subjects who received at least 1 dose of the study treatment.

End point type	Secondary

End point timeframe:

From Day 1 to Day 31

End point values	RSV120_dTpa_RSV120(EX-US) - ES-Primary Study	RSV120_Placebo_RSV120(EX-US) - ES-Primary Study	RSV60_dTpa_RSV120(EX-US) - ES-Primary Study	RSV60_Placebo_RSV120(EX-US) - ES-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	50	49	51	51
Units: Percentage of participants				
number (confidence interval 95%)	38 (24.7 to 52.8)	36.7 (23.4 to 51.7)	39.2 (25.8 to 53.9)	43.1 (29.3 to 57.8)

End point values	dTpa_Placebo_RSV120(EX-US) - ES-Primary Study	RSV120_dTpa_RSV120(US) - ES-Primary Study	RSV120_Placebo_RSV120(US) - ES-Primary Study	RSV60_dTpa_RSV120(US) - ES-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	51	51	52	52
Units: Percentage of participants				
number (confidence interval 95%)	33.3 (20.8 to 47.9)	39.2 (25.8 to 53.9)	32.7 (20.3 to 47.1)	26.9 (15.6 to 41)

End point values	RSV60_Placebo_RSV120(US) - ES-Primary Study	dTpa_Placebo_RSV120(US) - ES-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51	51		
Units: Percentage of participants				
number (confidence interval 95%)	31.4 (19.1 to 45.9)	31.4 (19.1 to 45.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any SAEs by each Boostrix formulation [Primary Study]

End point title	Number of subjects with any SAEs by each Boostrix formulation [Primary Study]

End point description:

A SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization or results in disability/incapacity or is a congenital anomaly/birth defect in the offspring of a study subject. Any is defined as any occurrence of SAE regardless of intensity grade or relation to study vaccination.

The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum), as the objective of this endpoint was to analyze the impact of co-administration of RSVPreF3 with either 300 µg or 500 µg of dTpa (Boostrix) formulation on the safety response to RSVPreF3.
The analysis was performed on the ES - Primary Study which consisted of all subjects who received at least 1 dose of the study treatment.

End point type	Secondary

End point timeframe:

From Day 1 to Day 31

End point values	RSV120_dTpa_RSV120(EX-US) - ES-Primary Study	RSV120_Placebo_RSV120(EX-US) - ES-Primary Study	RSV60_dTpa_RSV120(EX-US) - ES-Primary Study	RSV60_Placebo_RSV120(EX-US) - ES-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	50	49	51	51
Units: Participants	0	0	0	0

End point values	dTpa_Placebo_RSV120(EX-US) - ES-Primary Study	RSV120_dTpa_RSV120(US) - ES-Primary Study	RSV120_Placebo_RSV120(US) - ES-Primary Study	RSV60_dTpa_RSV120(US) - ES-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	51	51	52	52
Units: Participants	0	0	0	0

End point values	RSV60_Placebo_RSV120(US) - ES-Primary Study	dTpa_Placebo_RSV120(US) - ES-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51	51		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any SAEs from 1st vaccination to Day 181 [Primary Study]

End point title	Number of subjects with any SAEs from 1st vaccination to Day 181 [Primary Study]

End point description:

A SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization or results in disability/incapacity or is a congenital anomaly/birth defect in the offspring of a study subject. Any is defined as any occurrence of

SAE regardless of intensity grade or relation to study vaccination.
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the safety response to RSVPreF3.
The analysis was performed on the ES - Primary Study which consisted of all subjects who received at least 1 dose of the study treatment.

End point type	Secondary

End point timeframe:

From Day 1 to Day 181

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	101	103	102
Units: Participants	1	0	0	0

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	102			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any SAEs from 1st vaccination to Day 181 by each Boostrix formulation [Primary Study]

End point title	Number of subjects with any SAEs from 1st vaccination to Day 181 by each Boostrix formulation [Primary Study]

End point description:

A SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization or results in disability/incapacity or is a congenital anomaly/birth defect in the offspring of a study subject. Any is defined as any occurrence of SAE regardless of intensity grade or relation to study vaccination.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum), as the objective of this endpoint was to analyze the impact of co-administration of RSVPreF3 with either 300 µg or 500 µg of dTpa (Boostrix) formulation on the safety response to RSVPreF3.
The analysis was performed on the ES - Primary Study which consisted of all subjects who received at least 1 dose of the study treatment.

End point type	Secondary

End point timeframe:

From Day 1 to Day 181

End point values	RSV120_dTpa_RSV120(EX-US) - ES-Primary Study	RSV120_Placebo_RSV120(EX-US) - ES-Primary Study	RSV60_dTpa_RSV120(EX-US) - ES-Primary Study	RSV60_Placebo_RSV120(EX-US) - ES-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	50	49	51	51
Units: Participants	1	0	0	0

End point values	dTpa_Placebo_RSV120(EX-US) - ES-Primary Study	RSV120_dTpa_RSV120(US) - ES-Primary Study	RSV120_Placebo_RSV120(US) - ES-Primary Study	RSV60_dTpa_RSV120(US) - ES-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	51	51	52	52
Units: Participants	0	0	0	0

End point values	RSV60_Placebo_RSV120(US) - ES-Primary Study	dTpa_Placebo_RSV120(US) - ES-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51	51		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any SAEs from 2nd vaccination to Day 181 post 2nd vaccination [Extension Period]

End point title	Number of subjects with any SAEs from 2nd vaccination to Day 181 post 2nd vaccination [Extension Period]

End point description:

A SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization or results in disability/incapacity or is a congenital anomaly/birth defect in the offspring of a study subject. Any is defined as any occurrence of SAE regardless of intensity grade or relation to study vaccination.
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies, as the objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the safety response to RSVPreF3.
The analysis was performed on ES - Extension Study which consisted of all subjects who received at least 2 doses of the study treatment.

End point type	Secondary

End point timeframe:

From the Day of 2nd vaccination to Day 181 post 2nd vaccination

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	46	41
Units: Participants	0	0	0	1

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	46			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: RSV A neutralizing GMTs at Screening by each Boostrix formulation [Primary Study]

End point title	RSV A neutralizing GMTs at Screening by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay and titers are expressed in ED60.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum), as the objective of this endpoint was to analyze the impact of co-administration of RSVPreF3 with either 300 µg or 500 µg of dTpa (Boostrix) formulation on the immunogenicity response to RSVPreF3.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Screening (Day -7 to Day 1)

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV120_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	49	51	51
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	777 (625 to 966)	1009 (798 to 1277)	989 (749 to 1307)	777 (631 to 956)

End point values	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study	RSV120_Placebo_RSV120(US) - PPS-Primary Study	RSV60_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	51	51	51	52
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	956 (740 to 1236)	981 (773 to 1245)	1035 (786 to 1362)	1298 (1070 to 1574)

End point values	RSV60_Placebo_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51	51		
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	765 (638 to 917)	1154 (952 to 1399)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV A neutralizing GMTs at Day 8 by each Boostrix formulation [Primary Study]

End point title	RSV A neutralizing GMTs at Day 8 by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay and titers are expressed in ED60.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum), as the objective of this endpoint was to analyze the impact of co-administration of RSVPreF3 with either 300 µg or 500 µg of dTpa (Boostrix) formulation on the immunogenicity response to RSVPreF3.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Day 8

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV120_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	48	50	51
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	14523 (11831 to 17827)	15458 (12424 to 19231)	10677 (8146 to 13993)	11128 (8885 to 13939)

End point values	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study	RSV120_Placebo_RSV120(US) - PPS-Primary Study	RSV60_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	51	49	51	50
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	698 (530 to 918)	13818 (11070 to 17248)	13264 (10075 to 17462)	9715 (7612 to 12400)

End point values	RSV60_Placebo_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51	49		
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	10077 (7897 to 12858)	884 (722 to 1082)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV A neutralizing GMTs at Day 31 by each Boostrix formulation [Primary Study]

End point title	RSV A neutralizing GMTs at Day 31 by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay and titers are expressed in ED60.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum), as the objective of this endpoint was to analyze the impact of co-

administration of RSVPreF3 with either 300 µg or 500 µg of dTpa (Boostrix) formulation on the immunogenicity response to RSVPreF3.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Day 31

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV120_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	48	51	50
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	9838 (7987 to 12118)	10800 (8675 to 13446)	8754 (6821 to 11236)	8141 (6545 to 10125)

End point values	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study	RSV120_Placebo_RSV120(US) - PPS-Primary Study	RSV60_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	49	49	51
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	767 (575 to 1023)	9834 (7354 to 13152)	11276 (8283 to 15351)	9698 (7735 to 12159)

End point values	RSV60_Placebo_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	49	49		
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	9395 (7726 to 11425)	930 (740 to 1168)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV A neutralizing GMTs at single time point between 12 to 18 months post 1st vaccination by each Boostrix formulation [Primary Study]

End point title	RSV A neutralizing GMTs at single time point between 12 to 18

	months post 1st vaccination by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay and titers are expressed in ED60.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum), as the objective of this endpoint was to analyze the impact of co-administration of RSVPreF3 with either 300 µg or 500 µg of dTpa (Boostrix) formulation on the immunogenicity response to RSVPreF3.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At a single timepoint between 12 to 18 months post 1st vaccination

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV120_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	24	31	32	29
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	2034 (1458 to 2836)	2869 (1998 to 4119)	3086 (2143 to 4445)	2200 (1522 to 3180)

End point values	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study	RSV120_Placebo_RSV120(US) - PPS-Primary Study	RSV60_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	31	14	9	14
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	675 (495 to 920)	2014 (1190 to 3411)	2960 (1190 to 7362)	2474 (1741 to 3517)

End point values	RSV60_Placebo_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	15		
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	2569 (1586 to 4160)	969 (602 to 1560)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV A neutralizing GMTs at single time point between 12 to 18 months post 1st vaccination [Primary Study]

End point title	RSV A neutralizing GMTs at single time point between 12 to 18 months post 1st vaccination [Primary Study]

End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay and titers are expressed in ED60.
Analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the immunogenicity response to RSVPreF3.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At a single timepoint between 12 to 18 months post 1st vaccination

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	40	46	41
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	2027 (1546 to 2656)	2889 (2086 to 4001)	2885 (2204 to 3778)	2302 (1730 to 3064)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	46			
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	759 (588 to 980)			

Statistical analyses

No statistical analyses for this end point

Secondary: RSV A neutralizing GMTs at Day 31 post 2nd vaccination [Extension Study]

End point title	RSV A neutralizing GMTs at Day 31 post 2nd vaccination [Extension Study]

End point description:

Serological assays for the determination of antibodies against RSV-A were performed by neutralization assay and titers are expressed in ED60.
The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies, as the objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the immunogenicity response to RSVPreF3.
The analysis was performed on the PPS - Extension Study which consisted of all subjects from the ES - Extension Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Day 31 post 2nd vaccination

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	37	44	39
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	3892 (3016 to 5022)	5071 (3848 to 6683)	4779 (3747 to 6094)	4920 (3886 to 6231)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	42			
Units: Titers (ED60)				
geometric mean (confidence interval 95%)	8200 (6380 to 10539)			

Statistical analyses

No statistical analyses for this end point

Secondary: RSV PreF3 IgG GMCs at Screening by each Boostrix formulation [Primary Study]

End point title	RSV PreF3 IgG GMCs at Screening by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of IgG antibodies against RSV PreF3 were performed by ELISA. The corresponding antibody concentration is expressed in EU/mL. The cut-off value for the assay is 25 EU/mL.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum), as the objective of this endpoint was to analyze the impact of co-administration of RSVPreF3 with either 300 µg or 500 µg of dTpa (Boostrix) formulation on the immunogenicity response to RSVPreF3.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results

were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Screening (Day -7 to Day 1)

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV120_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	49	51	51
Units: EU/mL				
geometric mean (confidence interval 95%)	6240 (5159 to 7548)	6524 (5597 to 7604)	7237 (5905 to 8869)	6106 (5275 to 7067)

End point values	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study	RSV120_Placebo_RSV120(US) - PPS-Primary Study	RSV60_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	51	51	51	52
Units: EU/mL				
geometric mean (confidence interval 95%)	5907 (5077 to 6873)	6987 (5975 to 8170)	6978 (5764 to 8447)	7662 (6447 to 9107)

End point values	RSV60_Placebo_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51	51		
Units: EU/mL				
geometric mean (confidence interval 95%)	6240 (5375 to 7245)	7051 (5973 to 8324)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV PreF3 IgG GMCs at Day 8 by each Boostrix formulation [Primary Study]

End point title	RSV PreF3 IgG GMCs at Day 8 by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of IgG antibodies against RSV PreF3 were performed by ELISA.

The corresponding antibody concentration is expressed in EU/mL. The cut-off value for the assay is 25 EU/mL. The analysis of this outcome measure was reported for each formulation of the Boostrix (300 µg or 500 µg of aluminum). The objective of this endpoint was to analyze the impact of co-administration of RSVPreF3 with either 300 µg or 500 µg of Boostrix formulation on the immunogenicity response to RSVPreF3.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Day 8

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV120_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	48	50	51
Units: EU/mL				
geometric mean (confidence interval 95%)	155721 (133435 to 181728)	143104 (126138 to 162352)	100064 (84699 to 118216)	123475 (107405 to 141950)

End point values	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study	RSV120_Placebo_RSV120(US) - PPS-Primary Study	RSV60_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	51	50	51	50
Units: EU/mL				
geometric mean (confidence interval 95%)	5523 (4700 to 6490)	157403 (126554 to 195772)	150184 (119250 to 189142)	103286 (85400 to 124919)

End point values	RSV60_Placebo_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51	49		
Units: EU/mL				
geometric mean (confidence interval 95%)	114053 (95089 to 136799)	6061 (5097 to 7207)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV PreF3 IgG GMCs at Day 31 by each Boostrix formulation [Primary Study]

End point title	RSV PreF3 IgG GMCs at Day 31 by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of IgG antibodies against RSV PreF3 were performed by ELISA. The corresponding antibody concentration is expressed in EU/mL. The cut-off value for the assay is 25 EU/mL.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum), as the objective of this endpoint was to analyze the impact of co-administration of RSVPreF3 with either 300 µg or 500 µg of dTpa (Boostrix) formulation on the immunogenicity response to RSVPreF3.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Day 31

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV120_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	48	51	49
Units: EU/mL				
geometric mean (confidence interval 95%)	94254 (80742 to 110026)	95113 (83282 to 108624)	84509 (72281 to 98805)	81915 (70291 to 95460)

End point values	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study	RSV120_Placebo_RSV120(US) - PPS-Primary Study	RSV60_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	49	49	51
Units: EU/mL				
geometric mean (confidence interval 95%)	5600 (4777 to 6565)	109978 (88643 to 136446)	118052 (95525 to 145892)	88075 (75406 to 102872)

End point values	RSV60_Placebo_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	49	49		
Units: EU/mL				
geometric mean (confidence interval 95%)	96727 (82608 to 113258)	6739 (5678 to 7999)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV PreF3 IgG GMCs at single time point between 12 to 18 months post 1st vaccination by each Boostrix formulation [Primary Study]

End point title	RSV PreF3 IgG GMCs at single time point between 12 to 18 months post 1st vaccination by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of IgG antibodies against RSV PreF3 were performed by ELISA. The corresponding antibody concentration is expressed in EU/mL. The cut-off value for the assay is 25 EU/mL. The analysis of this outcome measure was reported for each formulation of the Boostrix (300 µg or 500 µg of aluminum). The objective of this endpoint was to analyze the impact of co-administration of RSVPreF3 with either 300 µg or 500 µg of Boostrix formulation on the immunogenicity response to RSVPreF3.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At a single timepoint between 12 to 18 months post 1st vaccination

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV120_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_Placebo_RSV120(EX-US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	24	31	32	29
Units: EU/mL				
geometric mean (confidence interval 95%)	18832 (15141 to 23423)	20894 (16466 to 26512)	23189 (18629 to 28864)	20720 (16689 to 25726)

End point values	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study	RSV120_Placebo_RSV120(US) - PPS-Primary Study	RSV60_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	31	14	9	14
Units: EU/mL				
geometric mean (confidence interval 95%)	5014 (3932 to 6392)	18127 (10969 to 29958)	19641 (9143 to 42195)	22905 (17801 to 29471)

End point values	RSV60_Placebo_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	15		
Units: EU/mL				
geometric mean (confidence interval 95%)	22233 (15931 to 31029)	6811 (5005 to 9269)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV PreF3 IgG GMCs at single time point between 12 to 18 months post 1st vaccination [Primary Study]

End point title	RSV PreF3 IgG GMCs at single time point between 12 to 18 months post 1st vaccination [Primary Study]

End point description:

Serological assays for the determination of IgG antibodies against RSV PreF3 were performed by ELISA. The corresponding antibody concentration is expressed in EU/mL. The cut-off value for the assay is 25 EU/mL.
Analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies. The objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the immunogenicity response to RSVPreF3.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At a single timepoint between 12 to 18 months post 1st vaccination

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	40	46	41
Units: EU/mL				
geometric mean (confidence interval 95%)	18570 (14961 to 23049)	20605 (16333 to 25995)	23102 (19586 to 27249)	21152 (17777 to 25168)

End point values	dTpa_Placebo_RSV120(Pooled)			

Subject group type	Reporting group			
Number of subjects analysed	46			
Units: EU/mL				
geometric mean (confidence interval 95%)	5540 (4581 to 6700)			

Statistical analyses

No statistical analyses for this end point

Secondary: RSV PreF3 IgG GMCs at Day 31 post 2nd vaccination [Extension Study]

End point title	RSV PreF3 IgG GMCs at Day 31 post 2nd vaccination [Extension Study]

End point description:

Serological assays for the determination of IgG antibodies against RSV PreF3 were performed by ELISA. The analysis of this outcome measure was reported for the Pooled groups as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies, as the objective of this endpoint was to analyze the impact of the co-administration of RSVPreF3 with dTpa (Boostrix) (both formulations together) on the immunogenicity response to RSVPreF3.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Day 31 post 2nd vaccination

End point values	RSV120_dTpa_RSV120(Pooled)	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	37	44	39
Units: (IU/mL)				
geometric mean (confidence interval 95%)	41399 (34806 to 49241)	42943 (37226 to 49537)	43977 (38784 to 49865)	45680 (38574 to 54094)

End point values	dTpa_Placebo_RSV120(Pooled)			
Subject group type	Reporting group			
Number of subjects analysed	42			
Units: (IU/mL)				
geometric mean (confidence interval 95%)	86934 (75442 to 100177)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pertussis toxoid (anti-PT), Filamentous hemagglutinin (anti-FHA) and Pertactin (anti-PRN) GMCs at Screening by each Boostrix formulation [Primary Study]

End point title	Pertussis toxoid (anti-PT), Filamentous hemagglutinin (anti-FHA) and Pertactin (anti-PRN) GMCs at Screening by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of IgG antibodies against Bordetella pertussis: anti-PT, anti-FHA and anti-PRN were performed by ELISA.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum).
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Screening (Day -7 to Day 1)

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	51	51	51
Units: International Units Per mL (IU/mL)				
geometric mean (confidence interval 95%)				
anti-PT	7.39 (5.11 to 10.68)	7.64 (5.47 to 10.66)	6.65 (4.66 to 9.47)	7.55 (5.34 to 10.66)
anti-FHA	32.8 (23 to 46.7)	34.5 (24.3 to 49.1)	29.3 (22 to 38.9)	31 (22.7 to 42.4)
anti-PRN	43.2 (27.9 to 66.7)	39 (25.3 to 60.1)	28.1 (18.2 to 43.4)	42.1 (27.6 to 64.2)

End point values	RSV60_dTpa_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	52	51		
Units: International Units Per mL (IU/mL)				
geometric mean (confidence interval 95%)				
anti-PT	5.66 (4.06 to 7.88)	7.17 (4.94 to 10.41)		
anti-FHA	29.6 (22.5 to 38.9)	28 (21 to 37.4)		

anti-PRN	40.1 (26.9 to 60)	28.7 (17.9 to 46.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pertussis toxoid (anti-PT), Filamentous hemagglutinin (anti-FHA) and Pertactin (anti-PRN) GMCs at Day 31 by each Boostrix formulation [Primary Study]

End point title	Pertussis toxoid (anti-PT), Filamentous hemagglutinin (anti-FHA) and Pertactin (anti-PRN) GMCs at Day 31 by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of IgG antibodies against Bordetella pertussis: anti-PT, anti-FHA and anti-PRN were performed by ELISA.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum).
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Day 31

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	51	48	49
Units: (IU/mL)				
geometric mean (confidence interval 95%)				
anti-PT	57.36 (41.82 to 78.69)	54.95 (44.78 to 67.44)	79.16 (62.67 to 99.98)	43.76 (34.1 to 56.17)
anti-FHA	237.1 (194.1 to 289.5)	210.6 (168.5 to 263.1)	303.6 (241.6 to 381.5)	186.5 (149.8 to 232.3)
anti-PRN	309.5 (226.7 to 422.6)	214.7 (166.8 to 276.4)	395.1 (290.3 to 537.6)	217.7 (153.7 to 308.3)

End point values	RSV60_dTpa_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51	49		
Units: (IU/mL)				
geometric mean (confidence interval				

95%)				
anti-PT	36.98 (28.25 to 48.42)	44.99 (34.81 to 58.15)		
anti-FHA	176.7 (139.3 to 224.1)	232.9 (182.2 to 297.8)		
anti-PRN	228.1 (161.9 to 321.5)	331.4 (238.4 to 460.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Diphtheria (Anti-D) GMC at Screening by each Boostrix formulation [Primary Study]

End point title	Diphtheria (Anti-D) GMC at Screening by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of IgG antibodies against anti-D were performed by ELISA.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum).
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Screening (Day -7 to Day 1)

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	51	49	49
Units: (IU/mL)				
geometric mean (confidence interval 95%)	0.26 (0.18 to 0.39)	0.27 (0.17 to 0.42)	0.23 (0.16 to 0.32)	0.46 (0.33 to 0.64)

End point values	RSV60_dTpa_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	52	50		
Units: (IU/mL)				
geometric mean (confidence interval 95%)	0.55 (0.42 to 0.73)	0.58 (0.43 to 0.78)		

Statistical analyses

No statistical analyses for this end point

Secondary: Diphtheria (Anti-D) GMCs at Day 31 by each Boostrix formulation [Primary Study]

End point title	Diphtheria (Anti-D) GMCs at Day 31 by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of IgG antibodies against anti-D were performed by ELISA.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum).
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Day 31

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	51	48	47
Units: (IU/mL)				
geometric mean (confidence interval 95%)	1.3 (0.97 to 1.73)	1.18 (0.85 to 1.63)	1.76 (1.25 to 2.48)	2.11 (1.61 to 2.76)

End point values	RSV60_dTpa_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	48	49		
Units: (IU/mL)				
geometric mean (confidence interval 95%)	2.2 (1.72 to 2.81)	3.29 (2.62 to 4.14)		

Statistical analyses

No statistical analyses for this end point

Secondary: Tetanus (Anti-T) GMCs at Screening by each Boostrix formulation [Primary Study]

End point title	Tetanus (Anti-T) GMCs at Screening by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of IgG antibodies against anti-T were performed by ELISA.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum).
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Screening (Day -7 to Day 1)

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	51	51	51
Units: (IU/mL)				
geometric mean (confidence interval 95%)	1.14 (0.87 to 1.5)	1.1 (0.78 to 1.54)	0.88 (0.64 to 1.22)	1.35 (1.01 to 1.81)

End point values	RSV60_dTpa_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	52	51		
Units: (IU/mL)				
geometric mean (confidence interval 95%)	1.56 (1.27 to 1.92)	1.68 (1.29 to 2.19)		

Statistical analyses

No statistical analyses for this end point

Secondary: Tetanus (Anti-T) GMCs at Day 31 by each Boostrix formulation [Primary Study]

End point title	Tetanus (Anti-T) GMCs at Day 31 by each Boostrix formulation [Primary Study]

End point description:

Serological assays for the determination of IgG antibodies against anti-T were performed by ELISA.
The analysis of this outcome measure was reported for each formulation of the dTpa (Boostrix) vaccine (300 µg or 500 µg of aluminum).

The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Day 31

End point values	RSV120_dTpa_RSV120(EX-US) - PPS-Primary Study	RSV60_dTpa_RSV120(EX-US) - PPS-Primary Study	dTpa_Placebo_RSV120(EX-US) - PPS-Primary Study	RSV120_dTpa_RSV120(US) - PPS-Primary Study
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	51	48	49
Units: (IU/mL)				
geometric mean (confidence interval 95%)	5.57 (4.64 to 6.7)	5.3 (4.52 to 6.21)	6.74 (5.79 to 7.84)	6.09 (4.98 to 7.45)

End point values	RSV60_dTpa_RSV120(US) - PPS-Primary Study	dTpa_Placebo_RSV120(US) - PPS-Primary Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51	49		
Units: (IU/mL)				
geometric mean (confidence interval 95%)	6.27 (5.29 to 7.44)	8.32 (6.88 to 10.05)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pertussis toxoid (anti-PT), Filamentous hemagglutinin (anti-FHA) and Pertactin (anti-PRN) GMCs at Screening [Primary Study]

End point title	Pertussis toxoid (anti-PT), Filamentous hemagglutinin (anti-FHA) and Pertactin (anti-PRN) GMCs at Screening [Primary Study][15]

End point description:

Serological assays for the determination of IgG antibodies against Bordetella pertussis: anti-PT, anti-FHA and anti-PRN were performed by ELISA.
Analysis of this outcome measure was reported for the Pooled groups [RSV120_dTpa_RSV120(Pooled), RSV60_dTpa_RSV120(Pooled) and dTpa_Placebo_RSV120(Pooled)] as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Screening (Day -7 to Day 1)

Notes:

[15] - 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 analysis was only performed on the groups that received the dTpa vaccine.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	dTpa_Placebo_RSV120(Pooled)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	100	103	102	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-PT	7.47 (5.83 to 9.57)	6.56 (5.20 to 8.28)	6.90 (5.36 to 8.89)	
Anti-FHA	31.9 (25.3 to 40.2)	31.9 (25.6 to 39.8)	28.6 (23.5 to 34.9)	
Anti-PRN	42.6 (31.6 to 57.4)	39.6 (29.6 to 52.9)	28.4 (20.7 to 38.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Pertussis toxoid (anti-PT), Filamentous hemagglutinin (anti-FHA) and Pertactin (anti-PRN) GMCs at Day 31 [Primary Study]

End point title	Pertussis toxoid (anti-PT), Filamentous hemagglutinin (anti-FHA) and Pertactin (anti-PRN) GMCs at Day 31 [Primary Study][16]

End point description:

Serological assays for the determination of IgG antibodies against Bordetella pertussis: anti-PT, anti-FHA and anti-PRN were performed by ELISA.
Analysis of this outcome measure was reported for the Pooled groups [RSV120_dTpa_RSV120(Pooled), RSV60_dTpa_RSV120(Pooled) and dTpa_Placebo_RSV120(Pooled)] as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Day 31

Notes:

[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: The analysis was only performed on the groups that received the dTpa vaccine.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	dTpa_Placebo_RSV120(Pooled)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	98	102	97	
Units: IU/mL				
geometric mean (confidence interval				

95%)				
Anti-PT	50.10 (41.04 to 61.17)	45.08 (38.00 to 53.48)	59.51 (49.71 to 71.23)	
Anti-FHA	210.3 (181.4 to 243.8)	192.9 (164.2 to 226.6)	265.6 (224.7 to 313.8)	
Anti-PRN	259.6 (205.8 to 327.4)	221.3 (179.5 to 272.9)	361.1 (289.1 to 451.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Diphtheria (Anti-D) GMCs at Screening [Primary Study]

End point title	Diphtheria (Anti-D) GMCs at Screening [Primary Study][17]

End point description:

Serological assays for the determination of IgG antibodies against anti-D were performed by ELISA.
Analysis of this outcome measure was reported for the Pooled groups [RSV120_dTpa_RSV120(Pooled), RSV60_dTpa_RSV120(Pooled) and dTpa_Placebo_RSV120(Pooled)] as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Screening (Day -7 to Day 1)

Notes:

[17] - 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 analysis was only performed on the groups that received the dTpa vaccine.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	dTpa_Placebo_RSV120(Pooled)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	98	103	99	
Units: IU/mL				
geometric mean (confidence interval 95%)	0.35 (0.27 to 0.45)	0.39 (0.30 to 0.51)	0.36 (0.28 to 0.47)	

Statistical analyses

No statistical analyses for this end point

Secondary: Diphtheria (Anti-D) GMC at Day 31 [Primary Study]

End point title	Diphtheria (Anti-D) GMC at Day 31 [Primary Study][18]

End point description:

Serological assays for the determination of IgG antibodies against anti-D were performed by ELISA.
Analysis of this outcome measure was reported for the Pooled groups [RSV120_dTpa_RSV120(Pooled), RSV60_dTpa_RSV120(Pooled) and dTpa_Placebo_RSV120(Pooled)] as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles

in previous studies.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Day 31

Notes:

[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: The analysis was only performed on the groups that received the dTpa vaccine.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	dTpa_Placebo_RSV120(Pooled)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	96	99	97	
Units: IU/mL				
geometric mean (confidence interval 95%)	1.65 (1.35 to 2.01)	1.59 (1.29 to 1.97)	2.42 (1.96 to 2.99)	

Statistical analyses

No statistical analyses for this end point

Secondary: Tetanus (Anti-T) GMCs at Screening [Primary Study]

End point title	Tetanus (Anti-T) GMCs at Screening [Primary Study][19]

End point description:

Serological assays for the determination of IgG antibodies against anti-T were performed by ELISA.
Analysis of this outcome measure was reported for the Pooled groups [RSV120_dTpa_RSV120(Pooled), RSV60_dTpa_RSV120(Pooled) and dTpa_Placebo_RSV120(Pooled)] as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Screening (Day -7 to Day 1)

Notes:

[19] - 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 analysis was only performed on the groups that received the dTpa vaccine.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	dTpa_Placebo_RSV120(Pooled)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	100	103	102	
Units: IU/mL				
geometric mean (confidence interval 95%)	1.24 (1.02 to 1.51)	1.31 (1.08 to 1.60)	1.22 (0.98 to 1.51)	

Statistical analyses

No statistical analyses for this end point

Secondary: Tetanus (Anti-T) GMCs at Day 31 [Primary Study]

End point title	Tetanus (Anti-T) GMCs at Day 31 [Primary Study][20]

End point description:

Serological assays for the determination of IgG antibodies against anti-T were performed by ELISA.
Analysis of this outcome measure was reported for the Pooled groups [RSV120_dTpa_RSV120(Pooled), RSV60_dTpa_RSV120(Pooled) and dTpa_Placebo_RSV120(Pooled)] as the two formulations of the dTpa vaccine (containing 300 µg or 500 µg of aluminum) showed similar immunogenicity and safety profiles in previous studies.
The analysis was performed on the PPS - Primary Study which consisted of all subjects from the ES - Primary Study, who complied with protocol defined procedures and for whom immunogenicity results were available for the specified assay and time point.

End point type	Secondary

End point timeframe:

At Day 31

Notes:

[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: The analysis was only performed on the groups that received the dTpa vaccine.

End point values	RSV120_dTpa_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	dTpa_Placebo_RSV120(Pooled)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	98	102	97	
Units: IU/mL				
geometric mean (confidence interval 95%)	5.83 (5.10 to 6.66)	5.76 (5.13 to 6.47)	7.49 (6.64 to 8.46)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Solicited adverse events(AEs) were collected during the 7-day follow-up period and unsolicited AEs during the 30-day follow-up period after any vaccination. Serious AEs were collected from Day 1 (Primary Study) to the Study End (Day 181, Extension Study).

Adverse event reporting additional description:

As per the analysis plan, AEs were reported for the pooled groups, as the 2 formulations of dTpa vaccine showed similar safety profiles in previous studies. Total number of subjects affected by Other AEs were obtained from the rows with the maximum number of events.Results of Other AEs were summarized by two periods (Primary & Extension Study).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	RSV120_dTpa_RSV120(Pooled)

Reporting group description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and either one dose of 300 µg or 500 µg dTpa (Boostrix) vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group title	dTpa_Placebo_RSV120(Pooled)

Reporting group description:

Subjects received one dose of Placebo and either one dose of 300 µg or 500 µg dTpa vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group title	RSV60_Placebo_RSV120(Pooled)

Reporting group description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group title	RSV120_Placebo_RSV120(Pooled)

Reporting group description:

Subjects received one dose of 120 µg RSVPreF3 formulation 3 vaccine and one dose of Placebo on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received a second dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Reporting group title	RSV60_dTpa_RSV120(Pooled)

Reporting group description:

Subjects received one dose of 60 µg RSVPreF3 formulation 2 vaccine and either one dose of 300 µg or 500 µg dTpa vaccine on Day 1 of the Primary Study and were followed up until Day 181. The subjects that agreed to participate in the Extension Study received one dose of 120 µg RSVPreF3 formulation 3 vaccine 12 to 18 months post 1st vaccination and were followed up until the study end.

Serious adverse events	RSV120_dTpa_RSV120(Pooled)	dTpa_Placebo_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	1 / 102 (0.98%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Radius fracture			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pyelonephritis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Radius fracture			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Wrist fracture			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pyelonephritis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	RSV120_dTpa_RSV120(Pooled)	dTpa_Placebo_RSV120(Pooled)	RSV60_Placebo_RSV120(Pooled)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	92 / 101 (91.09%)	89 / 102 (87.25%)	82 / 102 (80.39%)
Vascular disorders			
Hypertension - Extension Study			
subjects affected / exposed[1]	0 / 39 (0.00%)	1 / 46 (2.17%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Injection site pain - Primary Study			
subjects affected / exposed	86 / 101 (85.15%)	81 / 102 (79.41%)	60 / 102 (58.82%)
occurrences (all)	204	170	128
Fatigue - Primary Study			
subjects affected / exposed	42 / 101 (41.58%)	38 / 102 (37.25%)	34 / 102 (33.33%)
occurrences (all)	86	77	69
Injection site erythema - Primary Study			
subjects affected / exposed	7 / 101 (6.93%)	6 / 102 (5.88%)	7 / 102 (6.86%)
occurrences (all)	18	12	14
Injection site swelling - Primary Study			
subjects affected / exposed	5 / 101 (4.95%)	4 / 102 (3.92%)	6 / 102 (5.88%)
occurrences (all)	12	8	12
Pyrexia - Primary Study			

subjects affected / exposed	2 / 101 (1.98%)	7 / 102 (6.86%)	4 / 102 (3.92%)
occurrences (all)	4	14	8
Injection site bruising - Primary Study			
subjects affected / exposed	2 / 101 (1.98%)	2 / 102 (1.96%)	1 / 102 (0.98%)
occurrences (all)	4	4	2
Administration site erythema - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	1
Administration site pain - Primary Study			
subjects affected / exposed	2 / 101 (1.98%)	1 / 102 (0.98%)	1 / 102 (0.98%)
occurrences (all)	2	1	1
Injection site pruritus - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	3 / 102 (2.94%)	1 / 102 (0.98%)
occurrences (all)	2	6	2
Injection site haemorrhage - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	2
Administration site swelling - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	1	0	0
Vaccination site nodule - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	2	2	0
Malaise - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	2	0	0
Pain - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	1 / 102 (0.98%)
occurrences (all)	2	2	2
Injection site warmth - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	2 / 102 (1.96%)	0 / 102 (0.00%)
occurrences (all)	0	4	0

Axillary pain - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	2	0	2
Chills - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	2
Injection site induration - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	2	2	0
Influenza like illness - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	2
Feeling cold - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Hangover - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	0	2	0
Injection site rash - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	0	2	0
Injection site pain - Extension Study			
subjects affected / exposed[2]	34 / 39 (87.18%)	18 / 46 (39.13%)	35 / 41 (85.37%)
occurrences (all)	68	38	70
Fatigue - Extension Study			

subjects affected / exposed[3]	10 / 39 (25.64%)	16 / 46 (34.78%)	19 / 41 (46.34%)
occurrences (all)	23	32	39
Injection site erythema - Extension Study			
subjects affected / exposed[4]	7 / 39 (17.95%)	1 / 46 (2.17%)	6 / 41 (14.63%)
occurrences (all)	14	2	12
Pyrexia - Extension Study			
subjects affected / exposed[5]	0 / 39 (0.00%)	1 / 46 (2.17%)	5 / 41 (12.20%)
occurrences (all)	0	2	10
Injection site swelling - Extension Study			
subjects affected / exposed[6]	5 / 39 (12.82%)	1 / 46 (2.17%)	2 / 41 (4.88%)
occurrences (all)	10	2	4
Injection site pruritus - Extension Study			
subjects affected / exposed[7]	0 / 39 (0.00%)	0 / 46 (0.00%)	2 / 41 (4.88%)
occurrences (all)	0	0	4
Malaise - Extension Study			
subjects affected / exposed[8]	1 / 39 (2.56%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Administration site pain - Extension Study			
subjects affected / exposed[9]	1 / 39 (2.56%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Injection site induration - Extension Study			
subjects affected / exposed[10]	1 / 39 (2.56%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Inflammation - Extension Study			
subjects affected / exposed[11]	0 / 39 (0.00%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Influenza like illness - Extension Study			
subjects affected / exposed[12]	0 / 39 (0.00%)	0 / 46 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2
Injection site haemorrhage - Extension Study			
subjects affected / exposed[13]	0 / 39 (0.00%)	0 / 46 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2

Pain - Extension Study			
subjects affected / exposed[14]	0 / 39 (0.00%)	0 / 46 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2
Administration site swelling - Extension Study			
subjects affected / exposed[15]	0 / 39 (0.00%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Injection site lymphadenopathy - Extension Study			
subjects affected / exposed[16]	0 / 39 (0.00%)	1 / 46 (2.17%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
Immune system disorders			
Drug hypersensitivity - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	2	0	0
Seasonal allergy - Extension Study			
subjects affected / exposed[17]	0 / 39 (0.00%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	2	0	2
Vaginal discharge - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea - Extension Study			
subjects affected / exposed[18]	0 / 39 (0.00%)	0 / 46 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain - Primary Study			
subjects affected / exposed	3 / 101 (2.97%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	8	0	2
Cough - Primary Study			

subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	2 / 102 (1.96%)
occurrences (all)	0	0	4
Rhinorrhoea - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	2
Nasal congestion - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain - Extension Study			
subjects affected / exposed[19]	0 / 39 (0.00%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Nasal congestion - Extension Study			
subjects affected / exposed[20]	0 / 39 (0.00%)	0 / 46 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2
Rhinorrhoea - Extension Study			
subjects affected / exposed[21]	0 / 39 (0.00%)	1 / 46 (2.17%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
Insomnia - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	2
Affect lability - Extension Study			
subjects affected / exposed[22]	0 / 39 (0.00%)	0 / 46 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2
Poor quality sleep - Extension Study			
subjects affected / exposed[23]	0 / 39 (0.00%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Procedural pain - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	2	0	0
Thermal burn - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	2	2	0
Muscle strain - Extension Study			

subjects affected / exposed[24]	0 / 39 (0.00%)	0 / 46 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2
Contusion - Extension Study			
subjects affected / exposed[25]	0 / 39 (0.00%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	2
Nervous system disorders			
Headache - Primary Study			
subjects affected / exposed	47 / 101 (46.53%)	37 / 102 (36.27%)	42 / 102 (41.18%)
occurrences (all)	105	76	92
Dizziness - Primary Study			
subjects affected / exposed	2 / 101 (1.98%)	1 / 102 (0.98%)	1 / 102 (0.98%)
occurrences (all)	4	2	2
Disturbance in attention - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	2	0	0
Migraine - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Sciatica - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	2	0	0
Head discomfort - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	0	2	0
Neuralgia - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	0	2	0
Sleep deficit - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	2
Post-traumatic headache - Primary Study			

subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Headache - Extension Study			
subjects affected / exposed[26]	11 / 39 (28.21%)	16 / 46 (34.78%)	23 / 41 (56.10%)
occurrences (all)	24	34	50
Migraine with aura - Extension Study			
subjects affected / exposed[27]	0 / 39 (0.00%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	2 / 102 (1.96%)
occurrences (all)	2	0	4
Lymphadenitis - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	2	0	0
Ear and labyrinth disorders			
Ear pain - Extension Study			
subjects affected / exposed[28]	0 / 39 (0.00%)	0 / 46 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2
Eye disorders			
Vision blurred - Extension Study			
subjects affected / exposed[29]	0 / 39 (0.00%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Gastrointestinal disorder - Primary Study			
subjects affected / exposed	24 / 101 (23.76%)	28 / 102 (27.45%)	29 / 102 (28.43%)
occurrences (all)	50	56	58
Nausea - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	2	0	2
Dyspepsia - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	2	2	0
Toothache - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0

Abdominal distension - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Diarrhoea - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Hyperchlorhydria - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	2
Abdominal pain - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder - Extension Study			
subjects affected / exposed[30]	4 / 39 (10.26%)	7 / 46 (15.22%)	10 / 41 (24.39%)
occurrences (all)	9	14	20
Oesophageal spasm - Extension Study			
subjects affected / exposed[31]	0 / 39 (0.00%)	1 / 46 (2.17%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
Abdominal pain - Extension Study			
subjects affected / exposed[32]	1 / 39 (2.56%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Diarrhoea - Extension Study			
subjects affected / exposed[33]	1 / 39 (2.56%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Vomiting - Extension Study			
subjects affected / exposed[34]	1 / 39 (2.56%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Rash - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	0	2	0
Dermatitis - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	2	0	0
Dermatitis allergic - Primary Study			

subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	2	0	0
Night sweats - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	2
Night sweats - Extension Study			
subjects affected / exposed[35]	0 / 39 (0.00%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Rash - Extension Study			
subjects affected / exposed[36]	0 / 39 (0.00%)	1 / 46 (2.17%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Myalgia - Primary Study			
subjects affected / exposed	2 / 101 (1.98%)	0 / 102 (0.00%)	4 / 102 (3.92%)
occurrences (all)	4	0	8
Back pain - Primary Study			
subjects affected / exposed	2 / 101 (1.98%)	2 / 102 (1.96%)	2 / 102 (1.96%)
occurrences (all)	4	4	4
Neck pain - Primary Study			
subjects affected / exposed	2 / 101 (1.98%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	4	2	0
Arthralgia - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	2 / 102 (1.96%)
occurrences (all)	0	0	4
Muscle tightness - Primary Study			
subjects affected / exposed	2 / 101 (1.98%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	4	0	0
Pain in extremity - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal pain - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal stiffness - Primary Study			

subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	2
Pain in jaw - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	0	2	0
Limb discomfort - Extension Study			
subjects affected / exposed[37]	1 / 39 (2.56%)	1 / 46 (2.17%)	0 / 41 (0.00%)
occurrences (all)	2	2	0
Arthralgia - Extension Study			
subjects affected / exposed[38]	1 / 39 (2.56%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Myalgia - Extension Study			
subjects affected / exposed[39]	0 / 39 (0.00%)	1 / 46 (2.17%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Upper respiratory tract infection - Primary Study			
subjects affected / exposed	8 / 101 (7.92%)	5 / 102 (4.90%)	2 / 102 (1.96%)
occurrences (all)	16	10	4
Nasopharyngitis - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	3 / 102 (2.94%)	7 / 102 (6.86%)
occurrences (all)	2	6	14
Urinary tract infection - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	2 / 102 (1.96%)	1 / 102 (0.98%)
occurrences (all)	2	4	2
Sinusitis - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	2 / 102 (1.96%)	3 / 102 (2.94%)
occurrences (all)	0	4	6
Rhinitis - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	1 / 102 (0.98%)
occurrences (all)	2	2	2
Gastroenteritis - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	2 / 102 (1.96%)
occurrences (all)	0	2	4
Pharyngitis - Primary Study			

subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	2	0	2
Tooth infection - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	2	2	0
Conjunctivitis - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Pharyngitis bacterial - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Viral infection - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Chlamydial infection - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	0	2	0
Bacterial vaginosis - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	0 / 102 (0.00%)
occurrences (all)	0	2	0
Ear infection - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	2
Cystitis - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	2
Gingivitis - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	1 / 102 (0.98%)
occurrences (all)	0	0	2
Oral herpes - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0

Otitis media - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Otitis media acute - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Vaginitis chlamydial - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 102 (0.00%)	0 / 102 (0.00%)
occurrences (all)	0	0	0
Pharyngitis - Extension Study			
subjects affected / exposed[40]	0 / 39 (0.00%)	0 / 46 (0.00%)	2 / 41 (4.88%)
occurrences (all)	0	0	4
Nasopharyngitis - Extension Study			
subjects affected / exposed[41]	0 / 39 (0.00%)	0 / 46 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2
Bronchitis - Extension Study			
subjects affected / exposed[42]	0 / 39 (0.00%)	0 / 46 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2
Ear infection - Extension Study			
subjects affected / exposed[43]	0 / 39 (0.00%)	0 / 46 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2
Gastroenteritis - Extension Study			
subjects affected / exposed[44]	0 / 39 (0.00%)	0 / 46 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2
Pyelonephritis - Extension Study			
subjects affected / exposed[45]	0 / 39 (0.00%)	0 / 46 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Respiratory tract infection - Extension Study			
subjects affected / exposed[46]	0 / 39 (0.00%)	1 / 46 (2.17%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
Tonsillitis - Extension Study			

subjects affected / exposed[47]	0 / 39 (0.00%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Sinusitis - Extension Study			
subjects affected / exposed[48]	0 / 39 (0.00%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection - Extension Study			
subjects affected / exposed[49]	0 / 39 (0.00%)	0 / 46 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	RSV120_Placebo_RSV120(Pooled)	RSV60_dTpa_RSV120(Pooled)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	90 / 101 (89.11%)	91 / 103 (88.35%)	
Vascular disorders			
Hypertension - Extension Study			
subjects affected / exposed[1]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Injection site pain - Primary Study			
subjects affected / exposed	62 / 101 (61.39%)	84 / 103 (81.55%)	
occurrences (all)	136	200	
Fatigue - Primary Study			
subjects affected / exposed	40 / 101 (39.60%)	39 / 103 (37.86%)	
occurrences (all)	83	79	
Injection site erythema - Primary Study			
subjects affected / exposed	6 / 101 (5.94%)	8 / 103 (7.77%)	
occurrences (all)	12	18	
Injection site swelling - Primary Study			
subjects affected / exposed	8 / 101 (7.92%)	3 / 103 (2.91%)	
occurrences (all)	16	6	
Pyrexia - Primary Study			
subjects affected / exposed	4 / 101 (3.96%)	3 / 103 (2.91%)	
occurrences (all)	8	6	
Injection site bruising - Primary Study			

subjects affected / exposed	2 / 101 (1.98%)	4 / 103 (3.88%)	
occurrences (all)	6	8	
Administration site erythema - Primary Study			
subjects affected / exposed	3 / 101 (2.97%)	4 / 103 (3.88%)	
occurrences (all)	3	4	
Administration site pain - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	3 / 103 (2.91%)	
occurrences (all)	1	3	
Injection site pruritus - Primary Study			
subjects affected / exposed	2 / 101 (1.98%)	0 / 103 (0.00%)	
occurrences (all)	4	0	
Injection site haemorrhage - Primary Study			
subjects affected / exposed	2 / 101 (1.98%)	1 / 103 (0.97%)	
occurrences (all)	4	2	
Administration site swelling - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	4 / 103 (3.88%)	
occurrences (all)	0	4	
Vaccination site nodule - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	2 / 103 (1.94%)	
occurrences (all)	0	4	
Malaise - Primary Study			
subjects affected / exposed	2 / 101 (1.98%)	0 / 103 (0.00%)	
occurrences (all)	4	0	
Pain - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Injection site warmth - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Axillary pain - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	

Chills - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Injection site induration - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Influenza like illness - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	
Feeling cold - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Hangover - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Injection site discomfort - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Injection site haematoma - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Injection site discolouration - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Injection site rash - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Injection site pain - Extension Study			
subjects affected / exposed[2]	36 / 41 (87.80%)	37 / 46 (80.43%)	
occurrences (all)	74	74	
Fatigue - Extension Study			
subjects affected / exposed[3]	15 / 41 (36.59%)	17 / 46 (36.96%)	
occurrences (all)	31	35	
Injection site erythema - Extension Study			

subjects affected / exposed[4]	4 / 41 (9.76%)	4 / 46 (8.70%)	
occurrences (all)	8	8	
Pyrexia - Extension Study			
subjects affected / exposed[5]	0 / 41 (0.00%)	1 / 46 (2.17%)	
occurrences (all)	0	2	
Injection site swelling - Extension Study			
subjects affected / exposed[6]	3 / 41 (7.32%)	4 / 46 (8.70%)	
occurrences (all)	6	8	
Injection site pruritus - Extension Study			
subjects affected / exposed[7]	1 / 41 (2.44%)	0 / 46 (0.00%)	
occurrences (all)	2	0	
Malaise - Extension Study			
subjects affected / exposed[8]	0 / 41 (0.00%)	1 / 46 (2.17%)	
occurrences (all)	0	2	
Administration site pain - Extension Study			
subjects affected / exposed[9]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Injection site induration - Extension Study			
subjects affected / exposed[10]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Inflammation - Extension Study			
subjects affected / exposed[11]	1 / 41 (2.44%)	0 / 46 (0.00%)	
occurrences (all)	2	0	
Influenza like illness - Extension Study			
subjects affected / exposed[12]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Injection site haemorrhage - Extension Study			
subjects affected / exposed[13]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Pain - Extension Study			
subjects affected / exposed[14]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Administration site swelling -			

Extension Study			
subjects affected / exposed[15]	0 / 41 (0.00%)	1 / 46 (2.17%)	
occurrences (all)	0	1	
Injection site lymphadenopathy - Extension Study			
subjects affected / exposed[16]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Drug hypersensitivity - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Seasonal allergy - Extension Study			
subjects affected / exposed[17]	0 / 41 (0.00%)	1 / 46 (2.17%)	
occurrences (all)	0	2	
Reproductive system and breast disorders			
Dysmenorrhoea - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Vaginal discharge - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	
Intermenstrual bleeding - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	
Dysmenorrhoea - Extension Study			
subjects affected / exposed[18]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain - Primary Study			
subjects affected / exposed	2 / 101 (1.98%)	1 / 103 (0.97%)	
occurrences (all)	4	2	
Cough - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	1 / 103 (0.97%)	
occurrences (all)	2	2	
Rhinorrhoea - Primary Study			

subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Nasal congestion - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	2 / 103 (1.94%)	
occurrences (all)	0	4	
Oropharyngeal pain - Extension Study			
subjects affected / exposed[19]	3 / 41 (7.32%)	1 / 46 (2.17%)	
occurrences (all)	6	2	
Nasal congestion - Extension Study			
subjects affected / exposed[20]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea - Extension Study			
subjects affected / exposed[21]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Insomnia - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	1 / 103 (0.97%)	
occurrences (all)	2	2	
Affect lability - Extension Study			
subjects affected / exposed[22]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Poor quality sleep - Extension Study			
subjects affected / exposed[23]	0 / 41 (0.00%)	1 / 46 (2.17%)	
occurrences (all)	0	2	
Injury, poisoning and procedural complications			
Procedural pain - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Thermal burn - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Muscle strain - Extension Study			
subjects affected / exposed[24]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Contusion - Extension Study			

subjects affected / exposed[25]	0 / 41 (0.00%)	1 / 46 (2.17%)	
occurrences (all)	0	2	
Cardiac disorders			
Palpitations - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Headache - Primary Study			
subjects affected / exposed	47 / 101 (46.53%)	38 / 103 (36.89%)	
occurrences (all)	101	81	
Dizziness - Primary Study			
subjects affected / exposed	2 / 101 (1.98%)	0 / 103 (0.00%)	
occurrences (all)	4	0	
Disturbance in attention - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Migraine - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Sciatica - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Head discomfort - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Neuralgia - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Sleep deficit - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Post-traumatic headache - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	
Headache - Extension Study			

subjects affected / exposed[26]	15 / 41 (36.59%)	15 / 46 (32.61%)	
occurrences (all)	31	32	
Migraine with aura - Extension Study			
subjects affected / exposed[27]	0 / 41 (0.00%)	1 / 46 (2.17%)	
occurrences (all)	0	2	
Blood and lymphatic system disorders			
Lymphadenopathy - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	2 / 103 (1.94%)	
occurrences (all)	0	4	
Lymphadenitis - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Ear pain - Extension Study			
subjects affected / exposed[28]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Vision blurred - Extension Study			
subjects affected / exposed[29]	0 / 41 (0.00%)	1 / 46 (2.17%)	
occurrences (all)	0	2	
Gastrointestinal disorders			
Gastrointestinal disorder - Primary Study			
subjects affected / exposed	29 / 101 (28.71%)	28 / 103 (27.18%)	
occurrences (all)	60	57	
Nausea - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	
Dyspepsia - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Toothache - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	1 / 103 (0.97%)	
occurrences (all)	2	2	
Abdominal distension - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	

Diarrhoea - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Hyperchlorhydria - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Abdominal pain - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	
Gastrointestinal disorder - Extension Study			
subjects affected / exposed[30]	10 / 41 (24.39%)	7 / 46 (15.22%)	
occurrences (all)	20	14	
Oesophageal spasm - Extension Study			
subjects affected / exposed[31]	0 / 41 (0.00%)	1 / 46 (2.17%)	
occurrences (all)	0	2	
Abdominal pain - Extension Study			
subjects affected / exposed[32]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Diarrhoea - Extension Study			
subjects affected / exposed[33]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Vomiting - Extension Study			
subjects affected / exposed[34]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Rash - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	1 / 103 (0.97%)	
occurrences (all)	2	2	
Dermatitis - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Dermatitis allergic - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Night sweats - Primary Study			

subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Night sweats - Extension Study			
subjects affected / exposed[35]	1 / 41 (2.44%)	0 / 46 (0.00%)	
occurrences (all)	2	0	
Rash - Extension Study			
subjects affected / exposed[36]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Myalgia - Primary Study			
subjects affected / exposed	4 / 101 (3.96%)	1 / 103 (0.97%)	
occurrences (all)	8	2	
Back pain - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	
Neck pain - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	
Arthralgia - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Muscle tightness - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Pain in extremity - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	
Musculoskeletal pain - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal stiffness - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Pain in jaw - Primary Study			

subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Limb discomfort - Extension Study			
subjects affected / exposed[37]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Arthralgia - Extension Study			
subjects affected / exposed[38]	0 / 41 (0.00%)	0 / 46 (0.00%)	
occurrences (all)	0	0	
Myalgia - Extension Study			
subjects affected / exposed[39]	1 / 41 (2.44%)	0 / 46 (0.00%)	
occurrences (all)	2	0	
Infections and infestations			
Upper respiratory tract infection - Primary Study			
subjects affected / exposed	9 / 101 (8.91%)	4 / 103 (3.88%)	
occurrences (all)	18	8	
Nasopharyngitis - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Urinary tract infection - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	
Sinusitis - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Rhinitis - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Gastroenteritis - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Pharyngitis - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	
Tooth infection - Primary Study			

subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Pharyngitis bacterial - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Pharyngitis streptococcal - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Viral infection - Primary Study			
subjects affected / exposed	1 / 101 (0.99%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Chlamydial infection - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Bacterial vaginosis - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Ear infection - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Cystitis - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Gingivitis - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	0 / 103 (0.00%)	
occurrences (all)	0	0	
Oral herpes - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	
Otitis media - Primary Study			
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	2	

Otitis media acute - Primary Study				
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)		
occurrences (all)	0	2		
Vaginitis chlamydial - Primary Study				
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)		
occurrences (all)	0	2		
Vulvovaginal mycotic infection - Primary Study				
subjects affected / exposed	0 / 101 (0.00%)	1 / 103 (0.97%)		
occurrences (all)	0	2		
Pharyngitis - Extension Study				
subjects affected / exposed[40]	0 / 41 (0.00%)	0 / 46 (0.00%)		
occurrences (all)	0	0		
Nasopharyngitis - Extension Study				
subjects affected / exposed[41]	0 / 41 (0.00%)	1 / 46 (2.17%)		
occurrences (all)	0	2		
Bronchitis - Extension Study				
subjects affected / exposed[42]	0 / 41 (0.00%)	0 / 46 (0.00%)		
occurrences (all)	0	0		
Ear infection - Extension Study				
subjects affected / exposed[43]	0 / 41 (0.00%)	0 / 46 (0.00%)		
occurrences (all)	0	0		
Gastroenteritis - Extension Study				
subjects affected / exposed[44]	0 / 41 (0.00%)	0 / 46 (0.00%)		
occurrences (all)	0	0		
Pyelonephritis - Extension Study				
subjects affected / exposed[45]	0 / 41 (0.00%)	0 / 46 (0.00%)		
occurrences (all)	0	0		
Respiratory tract infection - Extension Study				
subjects affected / exposed[46]	0 / 41 (0.00%)	0 / 46 (0.00%)		
occurrences (all)	0	0		
Tonsillitis - Extension Study				
subjects affected / exposed[47]	1 / 41 (2.44%)	0 / 46 (0.00%)		
occurrences (all)	2	0		
Sinusitis - Extension Study				

subjects affected / exposed[48]	0 / 41 (0.00%)	1 / 46 (2.17%)	
occurrences (all)	0	2	
Upper respiratory tract infection - Extension Study			
subjects affected / exposed[49]	0 / 41 (0.00%)	1 / 46 (2.17%)	
occurrences (all)	0	2	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[13] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[14] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[15] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[16] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[17] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[18] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[19] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[20] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[21] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[22] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[23] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[24] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[25] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in

the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[26] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[27] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[28] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[29] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[30] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[31] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[32] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[33] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[34] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[35] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[36] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[37] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[38] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

[39] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[40] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[41] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[42] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[43] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[44] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[45] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[46] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[47] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[48] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).
[49] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Out of 509 subjects who completed the Primary Study, 296 subjects did not participate in the Extension Study due to non-compliance of protocol requirements (e.g. completion of the diary card, return for follow-up visits, no willingness/no informed consent obtained).

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 January 2020	The amendment has following changes: To collect immunogenicity data to 12 months post dosing. Long term persistence data will be useful to inform the boosting schedule for women entering successive pregnancies. Unblinding after Day 181 will still occur and the extended study (epoch 4) will be open label. In addition, several discrepancies with the protocol with the study procedures manual were aligned.
03 April 2020	The sponsor has decided not to implement the 6-month extension for prolonged immunogenicity described under Amendment 2. The rationale for taking this decision is that the sponsor intends to submit an amendment that will enrol new participants (Cohort 2) to allow a more robust assessment of non-inferiority of Boostrix response in co-administration with RSVPreF3. An assessment of antibody persistence will be included in these newly enrolled subjects. Hence the evaluation of prolonged immunogenicity in Cohort 1 has become redundant. Changes not related to the study design of the extension phase in Amendment 2 were not removed for this amendment.
28 August 2020	This study has been amended to administer a 2nd dose of the 120 µg RSVPreF3 Maternal investigational vaccine to all consenting subjects within a 6-month period from the beginning of 12 months to the beginning of 18 months following initial immunization (≥12 to <18 months).This extension part of the study will use non-pregnant women as a proxy for women who may require additional dosing in successive pregnancies. Specifically, this extension will provide information on: long term immunogenicity of a 1st dose of 60 µg or 120 µg RSVPreF3 vaccine and safety and immunogenicity of 2nd dose of 120 µg RSVPreF3 vaccine. In addition, this protocol amendment outlines measures that may be applicable during special circumstances (e.g., COVID-19 pandemic). The purpose of the amendment is to protect the subject's welfare, and as far as possible ensure the potential benefit to the subject and promote data integrity.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported