GlaxoSmithKline	**Statistical Analysis Plan**
Detailed Title:	A Phase 1/2, randomized, observer-blind, controlled, multi-center, dose-escalation study to evaluate safety, reactogenicity and immunogenicity of GSK Biologicals' respiratory syncytial virus (RSV) investigational vaccine based on the RSV viral proteins F, N and M2-1 encoded by chimpanzee-derived adenovector (ChAd155-RSV) (GSK3389245A), when administered intramuscularly according to a 0, 1-month schedule to RSV-seropositive infants aged 12 to 23 months
eTrack study number and Abbreviated Title	204838 (RSV PED-002)
Scope:	All data pertaining to the above study.
Date of Statistical Analysis Plan	Final: 28-Mar-2018
Co-ordinating author:	PPD (Study Statistician)
Reviewed by:	PPD (Clinical and Epidemiology Project Lead) PPD (Clinical Research and Development Lead) PPD (Lead statistician) PPD (Lead statistical analyst) PPD (Scientific writer) PPD (Regulatory Affairs) PPD (SERM physician) Mandatory (Public disclosure representative) PPD (Head CLS) PPD (Senior Manager, Immuno Lab Platform3) PPD (Expert Scientist, Biology Molecular) PPD (Lead ADaM CEO Head)
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APP 9000058193 Statistical Analysis Plan Template (Effective date: 14 April 2017)

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LIST OF ABBREVIATIONS

AE	Adverse event
AESI	Adverse Events of Special Interest
ChAd155-RSV	Investigational recombinant chimpanzee adenovirus Type 155-vectored RSV vaccine
CI	Confidence Interval
CMI	Cell-mediated immunity
CTRS	Clinical Trial Registry Summary
ERD	Enhanced RSV disease
ES	Exposed Set
GMC	Geometric mean antibody concentration
GMT	Geometric mean antibody titer
ICH	International Conference on Harmonisation
IDMC	Independent Data Monitoring Committee
iSRC	Internal Safety Review Committee
LL	Lower Limit of the confidence interval
LLOQ	Lower Limit of Quantification
LRTI	Lower respiratory tract infection
MedDRA	Medical Dictionary for Regulatory Activities
N.A.	Not Applicable
PCA	Palivizumab Competing Antibodies
PPS	Per Protocol Set
RR	Respiratory rate
RSV	Respiratory syncytial virus
RSV-Hd	High dose ChAd155-RSV vaccine (5×10^{10} vp)
RSV-Ld	Low dose ChAd155-RSV vaccine (5×10^{9} vp)
RSV-Md	Middle dose ChAd155-RSV vaccine (1.5×10^{10} vp)
RSV-RTI	Respiratory tract infection associated with RSV infection
RTI	Respiratory tract infection
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SHS	Study Headline Summary

SR	Study Report
TFL	Tables Figures and Listings
TOC	Table of Content
UL	Upper Limit of the confidence interval

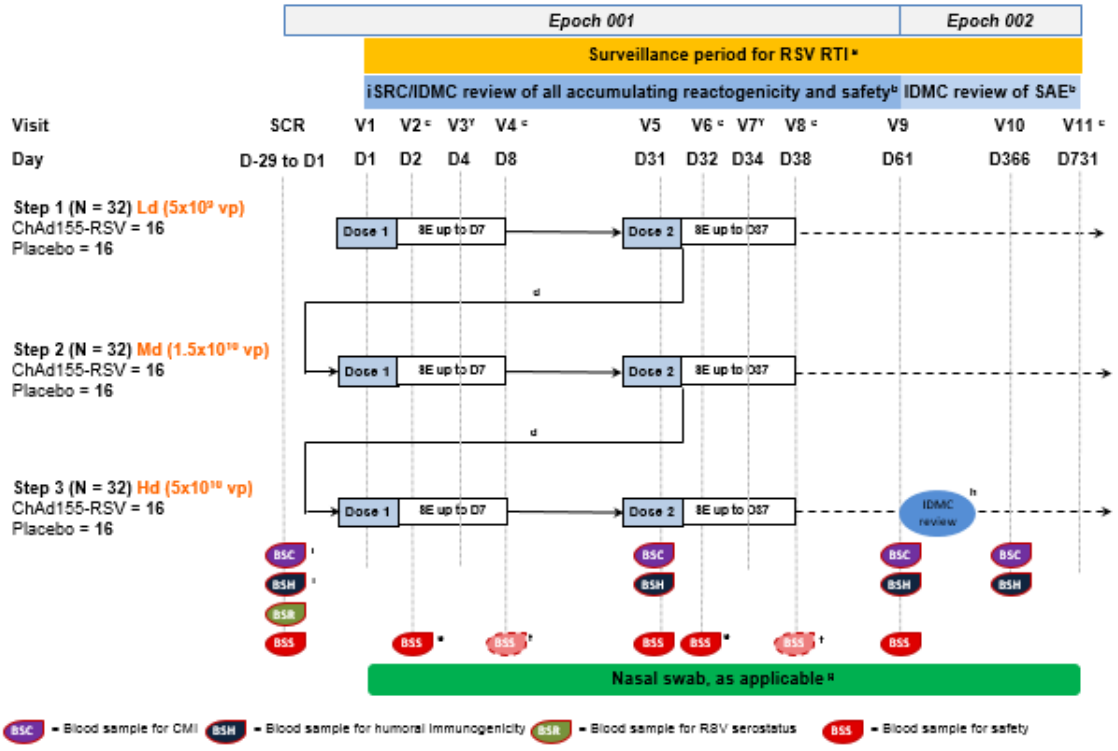
1. DOCUMENT HISTORY

Date	Description	Protocol Version
28-MAR-2018	Final version	Amendment 4 - 10-DEC-2017

2. STUDY DESIGN

Figure 1 Study design

Please note that for the analysis for D61, D366 and D731, the study will be converted in cDISC standard. To avoid confusion between analysis planned and table template, all the text and figures have been changed into cDISC, i.e, Day 'DX' is changed to Day 'DX+1'.



Hd: High dose; IDMC: Independent Data Monitoring Committee; iSRC: Internal Safety Review Committee; Ld: low dose; Md: middle dose; RSV: respiratory syncytial virus; SCR: screening; SE: safety evaluation

Hd: High dose; **IDMC:** Independent Data Monitoring Committee; **iSRC:** Internal Safety Review Committee; **Ld:** low dose; **Md:** middle dose; **RSV:** respiratory syncytial virus; **SCR:** Screening; **SE:** solicited events; **vp:** viral particles.

¥ On Day 4 and Day 34, a visit may take place at the investigators clinical facility or the investigator/clinical staff may call the subjects' parent(s)/LAR(s), as appropriate to the circumstances in the judgment of the investigator.

a Surveillance for RSV-RTI comprises monthly nasal swab collected to detect asymptomatic RSV infections during RSV season and active and passive surveillance contacts for RSV symptomatic RTI (see Section 9.2 of the protocol). Data about RSV–RTI incidence will be reviewed monthly by an IDMC.

b Within each step, an iSRC will review all accumulating safety data three weeks after the start of vaccination and then about every three weeks (until the IDMC has reviewed all safety data up to 30 days after administration of Dose 2 in Step 3 i.e. Day 61). The IDMC will review all accumulating reactogenicity and safety data monthly throughout the period of vaccination (up to 30 days after administration of Dose 2 in Step 3, i.e. Day 61) and accumulating SAEs until Day 731. Refer to Sections 9.10.2 and 9.10.3 of the protocol.

c Visit 2 (Day 2), Visit 4 (Day 8), Visit 6 (Day 32), Visit 8 (Day 38) and Visit 11 (Day 731) may take place in the subject's home or at the investigators clinical facility as appropriate to the circumstances in the judgment of the investigator.

d Dose escalation will proceed after administration of two doses of the vaccine to 32 subjects in Step 1. However, in the absence of a significant safety concern detected in the regular monitoring of accumulating safety data on at least 16 subjects, the IDMC may allow for dose escalation to proceed without the requirement of enrolling and evaluating the full group size of 32 subjects. A subsequent dose escalation (from Step 2 to Step 3) will proceed after administration of two doses of the vaccine to between a maximum of 32 to a minimum of 16 subjects in the absence of a significant safety concern detected by the IDMC in the regular monitoring of accumulating safety data. Thus, upon review of the accumulating safety data on a minimum of 16 subjects after administration of two doses of the vaccine, the IDMC may decide that based on the evolving safety profile, sufficient information has been accumulated to allow safe progression to the next sequential dose level. It will be ensured that, as a minimum the IDMC will have reviewed safety data of at least 16 subjects for two doses and given their formal approval prior to enrolling subjects to the next dose level.

e Only for hematology.

f Day 8 hematology testing will be performed if any ≥ Grade 1 for platelet decrease is detected on Day 1 after vaccination; to ensure its resolution. Similarly, hematology testing on Day 38 will be performed if any ≥ Grade 1 for platelet decrease is detected on Day 32.

g Refer to Section 6.6.11.3 of the protocol

h The IDMC will perform a review when all safety data up to 30 days after administration of Dose 2 in Step 3 (i.e. Day 61) are available.

i Blood samples for CMI and for humoral immunogenicity may be postponed until after the RSV serostatus is known and eligibility is confirmed up to or on Day 1 (but before vaccination).

- **Experimental design**: Phase I/II, observer-blind, randomized, placebo-controlled, multi-centric, study with two parallel groups per step in a 3-step staggered design
- **Duration of the study**: approximately 24 months:
  - Epoch 001: primary starting at the Screening visit and ending at Visit 9 (Day 61)
  - Epoch 002: follow-up starting at Visit 10 (Day 366) and ending at Visit 11 (Day 731)

  Any safety, immunogenicity and disease surveillance data collected beyond Visit 9 (Day 61) will be collected in Epoch 002
- **Primary completion Date**: Visit 9 (Day 61).
- **End of Study**: Last testing results released of samples collected at Visit 11 (Day 731). *

  * Up to Visit 11 (Day 731), there will be monthly nasal swab to detect asymptomatic RSV infections during the RSV season and if following active or a passive surveillance contacts, subject presents symptoms of RTI, a nasal swab will be collected.
- **Study groups**: Throughout the three steps, infants will be randomized in two groups to receive either ChAd155-RSV vaccine or placebo.

Table 1 Study groups and epochs foreseen in the study

Step	Study groups	Number of subjects*	Age (Min/Max)	Epochs	
				Epoch 001	Epoch 002
1	RSV-Ld	~ 16	12 months - 23 months	X	x
	Placebo-Ld	~ 16	12 months - 23 months	X	x
2	RSV-Md	~ 16	12 months - 23 months	X	x
	Placebo-Md	~ 16	12 months - 23 months	X	x
3	RSV-Hd	~ 16	12 months - 23 months	X	x
	Placebo-Hd	~ 16	12 months - 23 months	X	x

RSV-Ld: low dose ChAd155-RSV vaccine (5 x 10^9 vp); **RSV-Md**: middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp); **RSV-Hd**: high dose ChAd155-RSV vaccine (5 x 10^{10} vp).

*The target will be to enroll up to 96 RSV-seropositive infants aged 12 to 23 months at the time of first vaccination (unless the dose escalation IDMC decision can be made based on the evaluation of accumulating safety data on fewer subjects) to ensure that at least 64 infants receive two doses of study vaccine (ChAd155-RSV or Placebo) (see Section **Error! Reference source not found.**). Then the number of subjects at each step will be at least 16 (approximately 8 subjects per group) at steps 1 and 2 and 32 (approximately 16 subjects per group at step 3)

- **Vaccination schedule**: two IM vaccine doses administered according to a 0, 1-month schedule (i.e. at Day 1 and Day 31)
- **Treatment allocation**: infants will be randomized using a randomization system on internet (SBIR) at first vaccination
- **Blinding**: observer-blind in Epoch 001 and single-blind in Epoch 002
- **Sampling schedule**:

  Blood samples for biochemistry will be taken from all infants at Screening (up to 29 days before first vaccination to Day 1) and on Day 31, and Day 61 (refer to Table 11 of the protocol for the list of parameters to be tested). Blood samples for hematology will be taken from all infants at Screening (up to 29 days before first vaccination to Day 1) and on Day 1, Day 31, Day 32, and Day 61 (refer to Table 11of the protocol for the list of parameters to be tested). Day 8 hematology testing will be performed if any ≥ Grade 1 for platelet decrease is detected on Day 2 after vaccination, to ensure its resolution. Similarly, hematology testing on Day 38 will be performed if any ≥ Grade 1 for platelet decrease is detected on Day 32. A clinical examination with special attention given to detection of spontaneous bleeding or easy bruising and evidence of bruising or petechiae will be performed by the investigator/study staff on Day 2, Day 4 and Day 8 after each vaccination (i.e. Day 2, Day 4, Day 8, Day 32, Day 34, and Day 38. The visits on Day 4 and Day 34 may be replaced by a phone call by the investigator/study staff to inquire of the infants' general health and to solicit reports of a rash, spontaneous bleeding or easy bruising. On Day 2, and Day 32, special attention will also be given to the detection of petechiae or evidence of petechiae induced by the tourniquet. This special attention to detection of petechiae or evidence of petechiae induced by the tourniquet will also be given on Day 8 and/or Day 38 in case hematology testing will be performed on that day. Further testing may be required to investigate a finding or guide subject management based on the investigators clinical judgment. Subjects' parent(s)/LAR(s) will be instructed to contact the investigator/study staff if their child presents symptoms of spontaneous bleeding or easy bruising or if their child develops a rash in the month following vaccination, in order to detect any thrombocytopenic petechiae or purpura. The

investigator will, based on his/her medical judgement, appropriately investigate infants with clinical suspicion of low platelets

- Blood sample for **RSV serostatus** will be taken from all infants at Screening.
- Blood samples for **CMI** are limited to those in investigational sites with a laboratory in proximity capable to perform WBS necessary for the CMI assay. In those sites, samples will be taken from all subjects at Screening and on Day 31, Day 61, and Day 366**.**

  Note: Blood samples for CMI taken on Day 8 and Day 38 for subjects enrolled under protocol amendment 1 will still be assessed for CMI.
- Blood samples for **humoral immunogenicity** will be taken from all subjects at Screening and on Day 31, Day 61, and Day 366.
- Blood sample for **assessment of mechanism of illness (potential ERD)** will be taken from subjects hospitalized for LRTI (only for RSV-positive subjects using a locally available RSV test).
- Nasal swab: there will be monthly nasal swab to detect asymptomatic RSV infections during the RSV season and if following active or a passive surveillance contacts, a subject present symptom of RTI, a nasal swab will be collected.

- **Study visits**: Visit 1 (Day 1), Visit 5 (Day 31), Visit 9 (Day 61) and Visit 10 (Day 366) must be performed at the investigators clinical facility. Visit 2 (Day 2), Visit 4 (Day 8), Visit 6 (Day 32), Visit 8 (Day 38) and Visit 11 (Day 731) (no blood sampling for immune response and no vaccine administration) may take place in the subject's home or at the investigators clinical facility as appropriate to the circumstances in the judgment of the investigator. Visit 3 (Day 4) and Visit 7 (Day 34) may take place at the investigators clinical facility or the investigator/clinical staff may call the subjects' parent(s)/LAR(s), as appropriate to the circumstances in the judgment of the investigator.
- **Surveillance for RSV-RTI, difficulty in breathing and wheezing episodes.**

  Surveillance period will be carried out from Visit 1 (after Dose 1) until Visit 11 (Day 731). In order to detect asymptomatic RSV-RTI, monthly nasal swabs for analysis at sponsor laboratory will be performed for all subjects during the RSV season. In order to timely detect RSV-RTI and to ensure cases are timely captured by the study sites, both active and passive surveillance will be conducted:

  - **Passive surveillance**: Parent(s)/LAR(s) are instructed to contact the investigator/study staff as soon as the subject experiences new RTI symptoms (cough, runny nose or blocked nose) or worsening of RTI symptoms, or in case of difficulty in breathing or wheezing.
  - **Active surveillance**: parent(s)/LAR(s) of all the subjects will be contacted by the investigator/study staff on a regular basis (weekly during the RSV season and every month outside the RSV season) to identify any potential RSV-RTI and to remind the parent(s)/LAR(s) of the subjects to report any new occurrence of RTI symptoms (cough, runny nose, blocked nose) or worsening of RTI symptoms, or in case of difficulty in breathing or wheezing as soon as possible.

3. OBJECTIVES

3.1. Primary objective

- To evaluate the safety and reactogenicity of three dose levels of the RSV investigational vaccine when administered as two IM doses according to a 0, 1-month schedule, up to 30 days after Dose 2 (i.e. Day 61) in RSV-seropositive infants aged 12 to 23 months

3.2. Secondary objectives

- To evaluate the safety of two IM doses of three dose levels of the RSV investigational vaccine when administered according to a 0, 1-month schedule from study start (Day 1) up to study conclusion (Day 731) in RSV-seropositive infants aged 12 to 23 months
- To evaluate the occurrence of RSV respiratory tract infections in RSV-seropositive infants from Visit 1 (Day 1, after Dose 1) up to study conclusion (Day 731)
- To evaluate the magnitude of the CMI induced by two IM doses of three dose levels of the RSV investigational vaccine when administered according to a 0, 1-month schedule, up to Day 366 in RSV-seropositive infants aged 12 to 23 months.
- To evaluate the humoral immunogenicity induced by two IM doses of three dose levels of the RSV investigational vaccine when administered according to a 0, 1-month schedule, up to Day 366 in RSV-seropositive infants aged 12 to 23 months

3.3. Tertiary objectives

- To further evaluate the CMI profile induced by two IM doses of three dose levels of the RSV investigational vaccine when administered according to a 0, 1-month schedule, up to Day 366 in RSV-seropositive infants aged 12 to 23 months
- If deemed necessary, to further characterize the immune response of the RSV investigational vaccine when two IM doses are administered according to a 0, 1-month schedule in RSV-seropositive infants.

4. ENDPOINTS

4.1. Primary endpoints

- Occurrence of AEs from first vaccination (Day 1) up to Day 61.
  - Occurrence of each solicited local and general AE, during a 7-day follow-up period after each vaccination (i.e. the day of vaccination and 6 subsequent days).
  - Occurrence of any unsolicited AE, during a 30-day follow-up period after each vaccination (i.e. the day of vaccination and 29 subsequent days).

- Occurrence of any SAE from Day 1 up to Day 61.
- Occurrence of episode of spontaneous or excessive bleeding (AE of specific interest), during a 30-day follow-up period after each vaccination.
- Occurrence of any hematological (hemoglobin level, white blood cells and platelets) laboratory abnormalities at Screening, Day 1, Day 8, Day 31, Day 32, Day 38, and Day 61.
- Occurrence of any biochemical (alanine aminotransferase, aspartate aminotransferase and creatinine) laboratory abnormalities at Screening, Day 31, and Day 61

4.2. Secondary endpoints

- Occurrence of SAEs from study start (Day 1) up to Day 366.
- Occurrence of RSV-LRTI (AE of specific interest) as from Dose 1 administration up to Day 366.
- Occurrence of RSV-RTI, RSV-LRTI, severe RSV-LRTI (according to standardized case definitions) as from Dose 1 administration up to Day 366.
- Occurrence of SAEs from study start (Day 1) up to study conclusion (Day 731).
- Occurrence of RSV-LRTI (AE of specific interest) as from Dose 1 administration up to study conclusion (Day 731).
- Occurrence of RSV-RTI, RSV-LRTI, severe RSV-LRTI (according to standardized case definitions) as from Dose 1 administration up to study conclusion (Day 731).
- Magnitude of the CMI response to the investigational RSV vaccine, pre-vaccination (Screening), post-Dose 1 (Day 31) and post-Dose 2 (Day 61 and Day 366).
  - CD3+/CD4+ T-cells expressing at least two markers among CD40L, IL-2, TNF-α, and IFN-γ upon stimulation with F, N and M2-1 peptide pools.
- Humoral response to the investigational RSV vaccine, pre-vaccination (Screening), post-Dose 1 (Day 31) and post-Dose 2 (Day 61 and Day 366):
  - Neutralizing antibody titers against RSV-A.
  - RSV F antibody concentrations.
- Humoral response to the investigational RSV vaccine, pre-vaccination (Screening), post-Dose 1 (Day 31) and post-Dose 2 (Day 61):
  - Palivizumab-competing antibody concentrations.

4.3. Tertiary endpoints

- CMI response profile (Th1, Th2, Th17) to the investigational RSV vaccine, pre-vaccination (Screening), post-Dose 1 (Day 31) and post-Dose 2 (Day 61 and Day 366).
  - CD3+/CD4+ and/or CD3+/CD8+ T-cells expressing at least one or any combination of immune marker(s) among CD40L, 41BB, IL-2, TNF-α, IFN-γ, IL-13 and IL-17 upon stimulation with F, N and M2-1 peptide pools.
- Any further exploratory immunology to detect disease-related or vaccine-related immune responses, such as but not limited to:
  - Anti-vector immunity: neutralization. (Analysis for this endpoint will be described in another SAP/AAR).

5. ANALYSIS SETS

5.1. Definition

5.1.1. Total vaccinated cohort

The total vaccinated cohort (TVC) will include all subjects with at least one study vaccine administration documented.

- A safety analysis based on the TVC will include all vaccinated subjects.
- An immunogenicity analysis based on the TVC will include all vaccinated subjects for whom immunogenicity data are available.

The TVC analysis will be performed per treatment actually administered at Dose 1.

5.1.2. According-to-protocol cohort for analysis of immunogenicity

The ATP cohort for analysis of immunogenicity will be defined by timepoint and will consist of all subjects from the TVC who complied with eligibility criteria, study procedures up to the end of the study and had immunogenicity results in the epoch as described below.

More specifically, the ATP cohort for analysis of immunogenicity up to Visit 9 (Day 61)/at Visit 10 (Day 366) will include all evaluable subjects:

- Who met all eligibility criteria (i.e. no protocol violation linked to the inclusion/exclusion criteria, including age).
- Who received two dose of study vaccine.
- For whom the administration route and site of the vaccine was as according to protocol.

- Who received the vaccine according to protocol procedures.
- Who complied with the vaccination schedule, as specified in Table 5 of the protocol.
- Who did not receive a concomitant medication/product leading to exclusion from an ATP analysis, as described in Section 7.6.2 of the protocol, up to Visit 9 (Day 61)/up to Visit 10 (Day 366).
- Who complied with the timings of the post vaccination blood sampling for immune response evaluation, up to Visit 9 (Day 61) /at Visit 10 (Day 366), as specified in Table 5 of the protocol.
- For whom post-vaccination immunogenicity results are available for at least one assay up to Visit 9 (Day 61) /at Visit 10 (Day 366).

Note that in order to align to ICH and cDISC terminology the Total Vaccinated Cohort and the According to Protocol cohort have been renamed Exposed Set (ES) and Per-Protocol Set (PPS) respectively.

5.2. Criteria for eliminating data from Analysis Sets

Elimination codes are used to identify subjects to be eliminated from analysis. Detail is provided below for each set.

5.2.1. Elimination from Exposed Set (ES)

Code 1030 (Study vaccine not administered at all) and code 900 (invalid informed consent or fraud data) will be used for identifying subjects eliminated from ES

5.2.2. Elimination from Per-protocol analysis Set (PPS)

5.2.2.1. Excluded subjects

A subject will be excluded from the PPS for analysis of immunogenicity at Day 61 and Day 366 under the following conditions

Code	Condition under which the code is used
900	Invalid informed consent or fraud data (*Subjects receiving a code 900 should not receive any other elimination codes)*
1030	Study vaccine not administered at all (*Subjects receiving a code 1030 should not receive any other elimination codes)*
1050	Randomization failure
1070$	Subjects got vaccinated with the correct vaccine but containing a lower volume
1070$	Administration not according to protocol for reason specified by the investigator, other than side, site and route
1070$	Site or route of study vaccine administration wrong or unknown
1070$	Wrong replacement or study vaccine administered (not compatible with the vaccine regimen associated to the treatment number)
1070$	Administered study vaccine reported as being the correct one but is not compatible with the vaccine regimen associated to the treatment number
1080	Vaccine temperature deviation
1090	Expired vaccine administered
1500$	Subjects who have received only one dose of vaccination
2010	Protocol violation (inclusion/exclusion criteria)
2080	Subjects did not comply with vaccination schedule (DOSE 1 to DOSE 2 = 23-36 (days)

[$]*Attribution of code to a subject requires CRDL confirmation*
Please note that all the elimcode has to be checked for the subject under schedule 1.

5.2.2.2. Right censored Data

Data from visit X and subsequent visit will be censored for the PPS analysis under the following conditions. The code ****.Vx will be used to identify subjects whose immunogenicity data should be eliminated from a specific visit onwards. Vx will be V9 and V10 with respect to PPS defined up to Visit 9 and Visit 10, respectively.

Code	Decode → Condition under which the code is used
1040*.Vx	Administration of concomitant vaccine(s) forbidden in the protocol → A vaccine not foreseen by the study protocol administered from dose 1and ending 30 days after the last dose of vaccines administration • Applicable visits – For Day 61 PP, to check from Dose 1 up to Day 61 – For Day 366 PP, to check from Dose 1 up to Day 366
1060	Randomization code was broken

* Attribution of these elimcodes are responsibility of CRDL following review of individual data listings
Please note that all the elimcode has to be checked for the subject under schedule 1 who have received vaccination.

5.2.2.3. Visit-specific censored Data

Data at visit X will be censored for the PPS analysis under the following conditions. The code ****.Vx will also be used to identify study withdrawal at visit X. Vx will be V9 and V10 with respect to PPS defined up to Visit 9 and Visit 10, respectively.

Code	Decode → Condition under which the code is used
2040*.Vx	• Administration of any medication forbidden by the protocol→ – Any investigational or non-registered product (drug or vaccine) other than the study vaccines used during the study period. – Immunosuppressants or other immune-modifying drugs administered chronically (i.e., more than 14 days) during the study period. – Immunoglobulins and/or any blood products administered during the study period – Administration of long-acting immune-modifying drugs during the study period. • Applicable visits – For Day 61 PP (V9), check from Dose 1 up to Day 61 BS – For Day 366 PP (V10), check from Dose 1 up to Day 366 BS
2050*.Vx	• Underlying medical condition forbidden by the protocol • Applicable visits – For Day 61 PP, to check from Dose 1 up to Day 61 – For Day 366 PP, to check from Dose 1 up to Day 366
2060*.Vx	Concomitant infection related to the vaccine which may influence immune response • Applicable visits – For Day 61 PP (V9), to check from Dose 1 up to Day 61 – For Day 366 PP (V10), to check from Dose 1 up to Day 366
2070*.Vx	Concomitant infection not related to the vaccine which may influence immune response • Applicable visits – For Day 61 PP, to check from Dose 1 up to Day 61 – For Day 366 PP, to check from Dose 1 up to Day 366
2090.Vx	Subjects did not comply with immunological blood sample schedule Applicable visits – For Day 61 PP, to check for Dose 1 to Visit 5 BS = 23-36 days and Dose 2 to Visit 9 BS = 28-35 days] – For Day 366 PP, to check for Dose 1 to Visit 10 BS = 335-395 days]

Code	Decode → Condition under which the code is used
2100.Vx	Serological results not available post-vaccination→ No immunological result at all for the specific blood sample collection timepoint • Applicable visits – For Day 61 PP, check for availability of atleast one assay [CMI (ICS), Neutra, RSV F IgG or PCA result] at Day 31 and Day 61 – For Day 366 PP, check for availability of atleast one assay [CMI (ICS), Neutra, RSV F IgG or PCA result] at Day 366
2120[!@].Vx	Obvious incoherence or abnormality or error in data → Incoherence between CRF and results, wrong sample labelling, Central/internal/external lab deviations; incorrect spinning/processing of sample including processing within the time required by protocol; temperature deviations from range defined in protocol and/or SPM - room temperature/refrigerator/freezer; an assessment was completed, but was not completed according to protocol or SPM. • Applicable visits – For Day 61 PP, check on Day 31 and Day 61 CMI (ICS), Neutra, RSV F IgG or PCA result – For Day 366 PP, check on Day 366 CMI (ICS), Neutra, RSV F IgG or PCA result

* Attribution of these elimcodes are responsibility of CRDL following review of individual data listings
Please note that all the elimcode has to be checked for the subject under schedule 1 who is vaccinated.
@this code need confirmation from lab expert of particular test performed
! Attribution of code to a subject requires CRDL confirmation

5.3. Important protocol deviation not leading to elimination from per-protocol analysis set

The following important protocol deviations will be reported by groups:

- Forced randomization: In case of supplies shortage for the next assigned vaccine according to the randomization schedule at the clinical site, the randomization system will use the forced randomization procedure in order to continue to enrol and vaccinate subjects. The system moves seamlessly to the next treatment/randomization number for which vaccine supplies are available. The site will not be aware of the forced randomization event.
- Short follow-up: subjects who completed the last study contact before the minimum length of follow-up requirement
- In case unexpected vaccinations at study start were granted due to regulatory recommendation or medical need, the subjects who had such vaccination could be mentioned.

6. STATISTICAL ANALYSES

Note that standard data derivation rule and stat methods are described in annex 1 and will not be repeated below.

6.1. Demography

6.1.1. Analysis of demographics/baseline characteristics planned in the protocol

The analysis of demographics will be performed on the Exposed Set and on the PPS for analysis of immunogenicity at Day 61 and Day 366 analysis. The analysis of demography will be performed on Exposed Set at Day 731.

Demographic characteristics (age at first vaccination in months, gender, race, country), weight, height or length, and vital signs, and cohort description will be summarized by group using descriptive statistics:

- Frequency tables will be generated for categorical variable such as race.
- Mean, median, standard error and range will be provided for continuous data such as age.

The above analysis will also be done at Day 366 and Day 731 with age at the visit in months.

The weight for age Z score (WAZ) and height or length for age Z score (HAZ) at first vaccination, Day 366 and Day 731 will be calculated on ES. The distribution of subjects will be tabulated as a whole and per group.

Withdrawal status will be summarized by group using descriptive statistics.

- The numbers of withdrawn subjects will be tabulated according to the reason for withdrawal on ES.
- The number of subjects enrolled into the study as well as the number of subjects excluded from PPS analyses will be tabulated.

6.2. Immunogenicity

6.2.1. Analysis of immunogenicity planned in the protocol

The primary analysis will be performed on the PPS for analysis of immunogenicity and a complementary analysis will be performed on Exposed Set. All the immune analysis is within group only.

6.2.1.1. CMI analysis

The analysis will be performed on each group separately, pooled placebo group and pooled RSV group. All the CMI analysis will be performed for each peptide pool (F, N, M2-1) separately and taking all the peptide pool together for subjects who has data available for the three peptide pools.

With respect to secondary objectives, the following parameters will be summarized by group using descriptive statistics (N, geometric mean [GM], minimum [min], 1st quartile [Q1], median, third quartile [Q3], maximum [max]), at each timepoint during which blood samples are collected for CMI in investigational sites with a laboratory in proximity capable to perform WBS necessary for the CMI assay:

- Frequency of CD4+ T-cells expressing at least two markers among CD40L, IL-2, TNF-α, and IFN-γ upon stimulation with F, N and M2-1.
- Box plot with individual data for CD4+ T-cells expressing at least two markers among CD40L, IL-2, TNF-α, and IFN-γ upon stimulation with F, N and M2-1 and combined peptide pool will be presented.

With respect to tertiary objectives, the cellular immune response will be further characterized using descriptive analysis of the frequency of CD8+ T-cells and CD4+ T-helper cell profile (Th1, Th2, Th17) expressing at least one or any combination of marker(s) among CD40L, 41BB, IL-2, TNF-α, IFN-γ, IL-13, and IL-17.

The following parameters will be summarized by group using description statistics (N, GM, min, Q1, median, Q3, max), at each timepoint during which blood samples are collected for CMI:

- Frequency of CD4+ and CD8+ T-cells expressing at least one or any combination of immune marker(s) among CD40L, 41BB, IL-2, TNF-α, IFN-γ, IL-13 and IL-17 upon stimulation with F, N and M2-1 peptide pools.
- Tabular presentation of T-helper cell ‘Th1’ profile - Frequency of CD4+ T-cells expressing at least IFN-γ but no IL-13 upon stimulation with F, N and M2-1 peptide pools.
- Tabular presentation of T-helper cell ‘Th2’ profile: Frequency of CD4+ T-cells expressing at least IL-13 but no IFN-γ upon stimulation with F, N and M2-1 peptide pools.
- Tabular presentation of T-helper cell ‘Th17’ profile - Frequency of CD4+ T-cell expressing atleast IL17 upon stimulation with F, N and M2-1 peptide pools.
- Calculation of ‘Th2/Th1 ratio’ = Frequency of Th2 T-cells / frequency of Th1 T-cells.
- Separate box plot with individual data for CD4+ and CD8+ T-cells expressing at least one marker among CD40L, 41BB, IL-2, TNF-α, IFN-γ, IL-13 and IL-17 upon stimulation with F, N and M2-1 and combined peptide pools will be presented.

- Separate box plot with individual data for CD4+ T-cells expressing at least IFN-γ but no IL-13 (Th1 profile) upon stimulation with F, N and M2-1 and combined peptide pools will be presented.
- Separate box plot with individual data for CD4+ T-cells expressing at least IL-13 but no IFN-γ (Th2 profile) upon stimulation with F, N and M2-1 and combined peptide pools will be presented.
- Separate box plot with individual data for CD4+ T-cells expressing at least IL17(Th17 profile) upon stimulation with F, N and M2-1 and combined peptide pools will be presented.

The need to generate co-expression profile graph for any combination for CD4+ and CD8+ will be evaluated after looking at the descriptive tables.

6.2.1.2. Humoral immune response

For each group, at each timepoint that blood samples are collected for humoral immune response against the investigational RSV vaccine (neutralizing antibody titers against RSV-A, RSV F antibody concentrations, and palivizumab-competing antibody concentrations):

- GMTs/GMCs will be tabulated with 95% CI and represented graphically.
- Percentage of subjects above the seropositivity threshold will be tabulated with exact 95% CI.
- Antibody titers/concentrations will be displayed using reverse cumulative curves.
- The distributions of neutralizing antibody titers/concentrations will be tabulated (< 128, 128-256, > 256-512, > 512-1024, > 1024-2048, > 2048-4096, > 4096)
- Percentage of responders in terms of RSV-A neutralizing antibody titers will be tabulated with exact 95% CI.
- Individual post-vaccination versus pre-vaccination results will be plotted using scatter plots. Results of the Placebo groups will be used as a reference.
- Geometric mean of ratios of antibody titers/concentrations at each post-vaccination timepoint over pre-vaccination will be tabulated with 95% CI.
- Distribution of the fold increase of the neutralizing antibody titers will be tabulated by pre-vaccination titer category (percentage of subjects with a fold increase equal to or above 1, 2, 2.5, 3, 4, 6, 8 10, 11 and 12 by pre-vaccination titre category: (< 128, 128-256, > 256-512, > 512-1024, > 1024-2048, > 2048-4096, > 4096, and by cumulative category: <128, ≥128, ≥256, ≥512, ≥1024, ≥2048, ≥4096.).
- The kinetics of individual antibody titer/antibody concentration results will be plotted as a function of time for subjects with results available at all timepoints.

If available, any further exploratory immunology results (including, but not limited to anti-vector immunity) will be reported by group and timepoint using descriptive summary statistics will be described separately in Additional analysis request (AAR).

6.3. Analysis of RSV incidence

The assessment of RSV analysis incidence and severity will be performed on the Exposed Set on RSV groups, placebo groups, pooled RSV and pooled Placebo groups separately for first RSV season (Day 1-366) and second RSV season (Days 367-731) and overall (Days 1-731).

The analysis will be performed according to all case definitions presented in Table 5.

The proportion of subjects with at least one RSV infection and number of infections experienced by subjects meeting each of the case definition in Table 5 (with 95 % CI) will be calculated by group.

The number of RSV infections within each group and the maximum disease severity of the event will be tabulated. The number of RSV infections within each group and frequency of hospitalization will be tabulated. The number of infections in each group and descriptive analysis of the viral load associated with the maximum disease severity of the event will be tabulated (mean, median, min, max). Descriptive analysis on maximum viral load per subject based on qRT-PCR confirmed RSV infection of maximum severity will be performed.

The viruses identified in the Respiratory Viral Panel will be tabulated to those events where RSV-RTI was identified to describe frequency of co-infections and responsible viruses. These tables will be repeated limited to RVP results of cases of confirmed LRTI and RSV-LRTI.

After looking at the frequency of coinfection of all confirmed LRTI and RSV-LRTI, if there will be more than 10% coinfections (RSV infection with identification of another viral pathogen on RVP), tables will be reproduced including those RSV episodes where co-infection was present and those where no other respiratory viral pathogen was identified. The descriptive analysis on viral load table will not be repeated on subject with at least one episode with maximum viral load.

Listing will be presented for all cases of RSV infection until Day 731 with the details of gender, age at episode, country, site, day of event (i.e days since first visit), classification according to maximum severity of episode as RSV RTI/RSV LRTI/ RSV severe LRTI and RSV very severe LRTI, RSV hospitalization ‘Yes/No’, SpO2 value, respiratory rate, result of RSV qRT-PCR and RVP result will be presented.

Listings will be generated at Day 731 for all hospitalized cases with gender, age at episode, classification according to maximum severity of episode as (RSV RTI/RSV LRTI/ RSV severe LRTI and RSV very severe LRTI), RVP result, total number of calendar days on which the child was hospitalized, days requiring monitoring/nursing observation, days requiring nasogastric or intravenous fluids, days requiring supplemental oxygen, days requiring respiratory support excluding mechanical ventilation, days requiring mechanical ventilation and days requiring pediatric intensive care unit management.

6.4. Analysis of safety

6.4.1. Analysis of safety planned in the protocol

6.4.1.1. Within groups assessment

The analysis will be based on the ES on each treatment groups separately.

The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 7-day or 30-day follow-up period will be tabulated with exact 95% confidence interval (CI) after each vaccine dose and overall. The percentage of doses followed by at least one local AE (solicited and unsolicited), by at least one general AE (solicited and unsolicited) and by any AE during the 7-day or 30-day follow-up period will be tabulated, overall vaccination course, with exact 95% CI. The same computations will be done for Grade 3 AEs, for any AEs considered related to vaccination and for any Grade 3 AEs considered related to vaccination.

The percentage of subjects reporting each individual solicited local AE (any grade, Grade 2, Grade 3, resulting in a medically attended visit) and solicited general AE (any grade, Grade 2, Grade 3, any related, Grade 2 related, Grade 3 related, resulting in medically attended visit) during the 7-day follow-up period (Day 1-7) will be tabulated for each group after each vaccine dose and overall. Similarly, the percentage of doses followed by each individual solicited local and general AE and their sub-categories, will be tabulated, overall vaccination course, with exact 95% CI.

For fever, the number and percentage of subjects reporting fever by half degree (°C) cumulative increments during the 7-day follow-up period (Day 0-6) will be tabulated for each group after each vaccine dose and overall. Similar tabulations will be performed for any fever with a causal relationship to vaccination, Grade 3 (> 39.5°C) causally related fever and for any fever resulting in a medically attended visit. In addition, the prevalence of any and Grade 3 fever will be presented graphically over time after vaccination.

The percentage of subjects with unsolicited AEs within 30 days (Day 1-30) after each vaccine dose (overall doses) with its exact 95% CI will be tabulated by group and by MedDRA preferred term. Similar tabulation will be done for Grade 3 unsolicited AEs, for any causally related unsolicited AEs, for Grade 3 causally related unsolicited AEs and for unsolicited AEs resulting in a medically attended visit. The verbatim reports of unsolicited AEs will be reviewed by a physician and the signs and AEs will be coded according to the MedDRA Dictionary Version 20 for Adverse Reaction Terminology. Every verbatim term will be matched with the appropriate Preferred Term.

The percentage of subject with episode of spontaneous or excessive bleeding (AE of specific interest), during a 30-day follow-up period after each vaccination will be tabulated by group according to associated PT code presented in Section 12. The percentage of subjects with RSV-LRTI (AE of specific interest) from Dose 1 up to Day 365 and from Dose 1 up to study conclusion (Day 730) will be tabulated by group according to associated PT code presented in Section 12.

The percentage of subjects with SAE within 30 days (Day 1-30) after each vaccine dose with its exact 95% CI will be tabulated by group and by MedDRA preferred term. Similar table will be generated for SAE from Dose 1 up to Day 61, from Dose 1 up to Day 366 and from Dose 1 up to Day 731.

SAEs reported throughout the study and AE of specific interest will be described in detail.

The percentage of subjects using concomitant medication (any medication, any antipyretic/ analgesic and any antipyretic taken prophylactically, respectively) during the 7-day follow-up period (Day 1-7) and during the 30-day follow-up period (Day 1-30) will be summarized by group after each vaccine dose and overall.

For each group and for each hematology and biochemistry parameter:

- The percentage of subjects having hematology and biochemistry results below/above/within the local laboratory normal ranges will be tabulated by timepoint and toxicity grading scale.
- The maximum grading from Screening up to Visit 9 (Day 61) will be tabulated by grading the safety laboratory values according to toxicity criteria Grading scale adapted from [Division of AIDS, 2003], [Division of AIDS, 2004] and [Division of AIDS, 2007].
- For eosinophils, basophils, and monocytes, summary statistics (min, max, standard deviation, mean and median) will be presented as there is no grading provided for these parameters.

6.4.1.2. Between groups assessment

Exploratory comparisons between the investigational RSV groups and the Placebo groups will be done in terms of the percentage of subjects, overall doses, reporting any Grade 2/3 AE during the 7-day follow-up period (Day 1-7) after vaccination, and/ or any fever >38.5°C during the 7-day follow-up period (Day 1-7) after vaccination, and/ or any vaccine-related SAE during the 7-day follow-up period (Day 1-7) after vaccination.

The standardized asymptotic 95% CI for the following differences will be computed:

- RSV_Ld minus Placebo_Ld
- RSV_Md minus Placebo_Md
- RSV_Hd minus Placebo_Hd

6.4.2. Additional considerations

6.4.2.1. Additional safety analysis

For the analysis of safety, the percentage of subjects reporting each individual solicited local AE (any, each grade, resulting in medically attended visit) during the 7-day follow-up period after vaccination will be tabulated based on maximum intensity per subject for each study vaccine for each group. The percentage of subjects reporting each individual solicited general AE (any, each grade, any related, any Grade 2 related, any Grade 3 related, resulting in medically attended visit) during the 7-day follow-up period after vaccination will be based on maximum intensity per subject for each study vaccine for each group.

6.4.2.2. Exclusion of implausible solicited Adverse Event

Some local and systemic adverse events will be directly measured by the subject and will not be subject to a reconciliation process, even if they are biologically implausible. Therefore, these implausible measurements will be removed from the analysis but included in listings. Implausible measurements are summarized in the table below:

Table 2 Implausible Solicited Adverse Events

Parameter	Implausible measurements
Body temperature	≤ 33°C or ≥ 42°C
Swelling	For subjects < 6 years: Measurements < 0 mm

6.4.2.3. Combined Solicited and Unsolicited Adverse Events

A summary of subjects with all combined solicited (regardless of their duration) and unsolicited adverse events will be provided. Solicited adverse events will be coded by MedDRA as per the following codes

Solicited symptom	Lower level term name	Lower level term code	Corresponding Primary Term code
Pain	Pain	10033371	10033371
Redness	Erythema	10015150	10015150
Swelling	Swelling	10042674	10042674
Drowsiness	Drowsiness	10013649	10013649
Fever	Fever	10016558	10016558
Irritability/Fussiness	Irritability	10022998	10022998
Loss of appetite	Appetite lost	10003028	10003028

For clintrial.gov and EudraCT posting purposes, a summary of combined solicited and unsolicited non-serious adverse events will be produced by System Organ Class and preferred terms and according to occurrence of each event.

7. ANALYSIS INTERPRETATION

All analyses are descriptive. Comparative analyses will be descriptive with the aim to characterize the difference in safety/reactogenicity between groups and should be interpreted with caution considering that there is no adjustment for multiplicity and that group sizes are small for these comparisons.

8. CONDUCT OF ANALYSES

8.1. Sequence of analyses

The statistical analyses will be performed in 3 steps:

A first analysis will be performed when all data (safety and immunogenicity) up to Day 61 (i.e. data that are as clean as possible) are available. Additional safety data available at the time of this analysis will be described. At this point, the statistician will be unblinded (i.e. individual subject treatment assignments will be available) and the study will be conducted in a single-blind manner, with patients remaining blinded up to study end (Day 731). Summary results may unblind some specific subjects but no individual listings will be provided and the investigators will not have access to the treatment allocation up to study end (Day 731), except in case of emergency unblinding (see Section 9.8 of the protocol).

An analysis will be performed when all data (safety and immunogenicity) up to Visit 10 (Day 366; i.e. data that are as clean as possible) are available. No individual listings will be provided.

The final analysis will be performed when all data up to study conclusion (Day 731) are available. An integrated clinical study report containing all data will be written and made available to the investigators at that time.

If the data for tertiary endpoints (additional exploratory analyses) become available at a later stage, (an) additional analysis/ analyses will be performed. These data will be documented in amendments to the study report and will be made available to the investigators at that time.

Description	**Analysis ID**	**Disclosure Purpose (CTRS=public posting, SR=study report, internal)**	**Dry run review needed (Y/N)**	***Study Headline Summary (SHS)*requiring expedited communication to upper management (Yes/No)**	**Reference for TFL**
Final Analysis	E1_01	SR	N	*Yes*	
Analysis of epoch 1	E1_0X	CTRS	Y	Yes	
Up to D366	E1_0X+1		N	No	All tables from TFL dated xxxxxx

Table 3 Endpoints assessed at different analysis time points

Analysis	Analysis ID	Safety	Immuno	RSV/RTI
Epoch 1 (Day 60)		Solicited AE, Unsolicited AE, haematology and biochemistry, AESI(bleeding), SAE from D1-Day 61	All CMI and Humoral readout from D1-D61	
Up to D366		SAE, AESI – D1-D366	All CMI and Humoral response at D366	RSV analysis for 1st season – D1-D366
Final (Day 731)		SAE, AESI – D1-D731	None	RSV 2nd season – D367-D731; Overall (D1-D731)

8.2. Statistical considerations for interim analyses

No interim analysis is planned.

9. CHANGES FROM PLANNED ANALYSES

Following are the changes in the planned analysis:-

- The naming of the cohort has been changed per cDISC standards.
- Per cDISC standard, the day of first vaccination is now changed from Day 0 to Day 1.
- The study design diagram has been adapted as per cDISC format
- In secondary endpoints, specific safety endpoints for Day 1 up to D366 has been added as follows: -
  - Occurrence of SAEs from study start (Day 1) up to Day 366.
  - Occurrence of RSV-LRTI (AE of specific interest) as from Dose 1 administration up to Day 366.
  - Occurrence of RSV-RTI, RSV-LRTI, severe RSV-LRTI (according to standardized case definitions) as from Dose 1 administration up to Day 366.
- For the immunogenicity analysis, the analysis will be performed on both PPS and ES without any condition on percentage of subjects excluded
- For inclusion of subjects in PPS for analysis of immunogenicity, subjects should have received both the doses and not atleast one dose.

10. LIST OF FINAL REPORT TABLES, LISTINGS AND FIGURES

The TFL TOC provides the list of tables/listings and figures needed for the study report. It also identifies the tables eligible for each analyses and their role (synopsis, in-text, post-text, SHS, CTRS,…). Note that all TFL aimed to be included as post-text are noted as post-text even if these are tabulation of individual data such as listing of SAE. The post-text material contains all source material for the study report and accordingly a post-text table may be redundant with an in-text table.

The mock tables referred under column named 'layout' can be found in legacy-GSK SDD dedicated folder for standard tables and in Section 12 (Annex 2) for study specific mock table/figure/listing. The latter table/figure/listing are identified by the prefix SS_ in the TFL Toc.

The following group names and pooled group names will be used in the TFLs, to be in line with the T-domains:

Group order in tables	Group label in tables	Group definition for footnote	Pooled Groups label in tables	Pooled definition for footnote
1	RSV-Ld	Low dose ChAd155-RSV vaccine (5 x 10^9 vp)	RSV	ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
2	RSV-Md	Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)	RSV	ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
3	RSV-Hd	High dose ChAd155-RSV vaccine (5 x 10^{10} vp)	RSV	ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
4	Placebo-Ld	Non-active control (0.5 ml)	Placebo	Non active control (0.15/0.5 ml pooled groups)
5	Placebo-Md	Non-active control (0.15 ml)	Placebo	Non active control (0.15/0.5 ml pooled groups)
6	Placebo-Hd	Non-active control (0.5 ml)	Placebo	Non active control (0.15/0.5 ml pooled groups)
7^	Pooled	Pooled RSV + Placebo	Pooled	Pooled RSV + Placebo

^The pooled group is not in the treatment dataset but will be created for generating some tables during D366 analysis.

11. ANNEX 1 STANDARD DATA DERIVATION RULE AND STATISTICAL METHODS

11.1. cDISC specification

The analysis planned at D61, D366 and D731 is planned in cDISC format. In cDISC format, the day of vaccination is mentioned as Day 1 rather than Day 0 per protocol. Accordingly, all the timepoint will be mentioned as Day X +1. The analysis will be performed adjusting for it so that correct interval will be selected.

11.2. Statistical Method References

The exact two-sided 95% CIs for a proportion within a group will be the Clopper-Pearson exact CI [Clopper CJ, Pearson ES. The use of confidence or fiducial limits illustrated in the case of binomial. *Biometrika*. 1934; 26:404-413].

The standardised asymptotic two-sided 95% CI for the group difference in proportions is based on the method described in the following paper: Robert G. Newcombe, interval estimation for the difference between independent proportions: comparison of eleven methods, *Statist Med.* 1998; 17, 873-890]. The standardised asymptotic method used is the method six.

11.3. Standard data derivation

11.3.1. Date derivation

- SAS date derived from a character date: In case day is missing, 15 is used. In case day & month are missing, 30June is used.
- Onset day for an event (ae, medication, vaccination, …): The onset day is the number of days between the last study vaccination & the onset/start date of the event. This is 1 for an event starting on the same day as a vaccination. See SAS date derived in case the start date of the event is incomplete.
- Duration: Duration of an event is expressed in days. It is the number of days between the start & the stop dates + 1. Therefore, duration is 1 day for an event starting & ending on the same day.
- Association of an event to the primary epoch: An adverse event belongs to the primary epoch, if the onset date is before and including Visit 9 (Day 60). Any safety data collected beyond Visit 9 (Day 60) will be collected in Epoch 002.

11.3.2. Dose number

- The study dose number is defined in reference to the number of study visits at which vaccination occurred. More specifically dose 1 refers to all vaccines administered at the first vaccination visit while dose 2 corresponds to all vaccinations administered at the second vaccination visit even if this is the first time a product is administered to the subject.
- Relative dose: the relative dose for an event (AE, medication, vaccination) is the most recent study dose given before an event. In case the event takes place on the day a study dose is given, the related dose will be that of the study dose, even if the event actually took place before vaccination. For instance, if an adverse event begins on the day of the study vaccination but prior to administration of the vaccine, it will be assigned to this dose. In case a study dose is not administered and an event occurs after the subsequent study dose (eg 2^{nd} study dose), the relative dose of the event will be study dose associated to the subsequent study dose (eg dose 2).
- The number of doses for a product is the number of times the product was administered to a subject.
- The incidence per dose is the number of vaccination visits at which an event was reported among all vaccination visits.

11.3.3. Demography

- Age: Age at the reference activity, computed as the number of units between the date of birth and the reference activity. Note that due to incomplete date, the derived age may be incorrect by 1 month when month is missing from the birthdate. This may lead to apparent inconsistency between the derived age and the eligibility criteria/the age category used for randomization.
- Conversion of weight to kg: The following conversion rule is used:

  Weight in Kilogramm= weight in Pounds / 2.2

  Weight in Kilogramm =weight in oncs / 35.27

  The result is rounded to 2 decimals.
- Conversion of height to cm: The following conversion rule is used:

  Height in Centimetres = Height in Feet * 30.48

  Height in Centimetres = Height in Inch * 2.54

  The result is rounded to the unit (ie no decimal).
- Conversion of temperature to °C: The following conversion rule is used:

  Temperature in °Celsius = ((Temperature in °Fahrenheit -32) *5)/9

  The result is rounded to 1 decimal.

- Calculation of weight for age Z-score (WAZ) for each subject (rounded to 2 decimal):

  WAZ = (Weight of subject -median weight)/Standard deviation for weight

- Calculation of height for age Z-score (HAZ) for each subject (rounded to 2 decimal):

  HAZ = (Height of subject -median height)/Standard deviation for height

11.3.4. Immunogenicity

- For a given subject and given immunogenicity measurement, missing or non-evaluable measurements will not be replaced. Therefore, an analysis will exclude subjects with missing or non-evaluable measurements. Kinetics will be plotted on subjects with results available at all timepoints.
- The Geometric Mean Concentrations/Titres (GMC/Ts) calculations are performed by taking the anti-log of the mean of the log titre transformations. Antibody titres below the cut-off of the assay will be given an arbitrary value of half the cut-off of the assay for the purpose of GMT calculation.
- The 95% CI for the mean of log-transformed titer will be first obtained assuming that log-transformed values were normally distributed with unknown variance. The 95% CI for the GMTs/GMCs will be then obtained by exponential-transformation of the 95% CI for the mean of log-transformed titer.
- A seronegative subject is a subject whose antibody titre is below the cut-off value of the assay. A seropositive subject is a subject whose antibody titre is greater than or equal to the cut-off value of the assay.
- An exploratory definition of vaccine response to the RSV neutralising antibodies will be as:
  - At least a 4-fold increase from pre-vaccination if pre-vaccination neutralising antibody titre <128.
  - At least a 3-fold increase from pre-vaccination if pre-vaccination neutralising antibody titre in [128-256].
  - At least a 2.5-fold increase from pre-vaccination if pre-vaccination neutralising antibody titre in]256-1024].
  - At least 1-fold from pre-vaccination if pre-vaccination neutralising antibody titre >1024

  Please note that other definition of vaccine response will be also be explored but interest might be limited considering this is not target population.
- Assay cut-off for the humoral immunity will be per the following table

Component	Method	Unit	Cut-off
Respiratory Syncytial Virus A Ab	NEUTRALIZATION	ED60	8
Respiratory Syncytial Virus F protein Ab.IgG (Anti-RSV PreF antibody)	ELISA	EU/ml	10
Respiratory Syncytial Virus F protein Ab.IgG (Palivizumab competing Ab)	ELISA	µg/ml	9.6

- Considering the cut-off for the neutralising antibody against RSV-A is below the assay's LLOQ [32], the following rules will be applied for derivation of seropostivity status and GMT:

Assay	Raw result	Derivation for seropositivity status	Derivation for GMT calculation	Derivation for fold-increase between Post and Pre-vaccination titres
RSV-A neutralising Antibody	<cut-off	NEG	Cut-off/2	LLOQ/2
	[cut-off-LLOQ [	POS	Cut-Off	LLOQ/2
	≥LLOQ	POS	Exact value	Exact value

- The cut-off for the PCA assay is set at the level of the assay LLOQ (9.60 µg/mL). For results below the cut-off (LLOQ), an arbitrary value of half of the cut-off will be considered for calculation of GMC and fold increase.
- All CI computed will be two-sided 95% CI.
- CMI: CD4+ and/or CD8+ T-cells, by ICS using WBS
  - All results available in the database (events/per million of cells) will be dividing by 10000 in order to express the results in percentage (%).
  - The derived variable that will be used for the analysis will be:
    - the frequency of RSV F/N/M2-1 specific and combined (RSV F/N/M2-1) CD4+ T-cells expressing at least two marker among CD40L, IL-2, TNF-α, and IFN-γ;
    - the frequency of $CD4^+$ and $CD8^+$ T-cells expressing at least one or any combination of immune marker(s) among CD40L, 41BB, IL-2, TNF-α, IFN-γ, IL-13 and IL-17 upon stimulation with F, N and M2-1 peptide pools and combined peptide pools.
  - Those derived variables will be obtained as follows: sum of all specific responses of interest minus the sum of corresponding background responses. All values less or equal to zero will be set to 1 for the purpose of GM calculation.
  - Co-expression profile: for each CD4+/CD8+ any combination of markers, the RSV F/N/M2-1 specific response will be obtained by subtracting the background value to the RSV value (stimulation with RSV F/N/M2-1 peptides), and by setting to 1 all values less than or equal to zero for the purpose of GM calculation and graphical representation.
  - The log-transformation of the percentage of RSV F/N/M2-1specific CD4+/CD8+ T-cells will be applied, and the GM calculations will be performed by taking the anti-log of the mean of the log transformations.
  - For calculation of Th2/Th1 ratio has to be done by taking average of Th2 and Th1 profile at the individual level after adjusting on background.

11.3.5. Safety

- For a given subject and the analysis of solicited symptoms during the 7 day follow-up period after vaccination, missing or non-evaluable measurements will not be replaced. Therefore, the analysis of the solicited symptoms based on the ES will include only vaccinated subjects with documented safety data (*i.e.*, symptom screen completed). More specifically the following rules will be used:
  - Subjects who documented the absence of a solicited symptom after one dose will be considered not having that symptom after that dose.
    - Subjects who documented the presence of a solicited symptom and fully or partially recorded daily measurement over the solicited period will be included in the summaries at that dose and classified according to their maximum observed daily recording over the solicited period.
    - Subjects who documented the presence of a solicited symptom after one dose without having recorded any daily measurement will be considered as having symptom and will be considered in subjects who experiences the symptom but will not be considered in the specific information by grade.
    - Doses without symptom sheets documented will be excluded.
- For analysis of unsolicited AEs, SAEs and for the analysis of concomitant medications, all vaccinated subjects will be considered. Subjects who did not report an event or concomitant medication will be considered as subjects without the event or the concomitant medication respectively.
- Related dose: The related dose for an event (e.g., AE, medication, vaccination…) is the study dose given before an event. In case the event takes place on a day a study dose is given, the related dose will be that of the study dose even if the event actually took place before. For instance, for a conc. medication started on the day of study dose 2 but before dose 2 administrations, the related dose will be dose 2.
- The maximum intensity of local injection site redness and swelling will be scored at GSK Biologicals as follows:

  0 : None
  1 : < 5 mm
  2 : 5 to 20 mm
  3 : > 20 mm

- Fever is defined as temperature ≥ 37.5°C / 99.5°F for oral, axillary or tympanic route, or ≥ 38.0°C / 100.4°F for rectal route. The preferred route for recording temperature in this study will be axillary. For the analysis, temperatures will be coded as follows:

Grade	Temperature (oral, axillary or tympanic route)	Temperature (rectal route)
0	< 37.5°C	< 38°C
1	≥ 37.5°C - ≤ 38.5°C	≥ 38°C - ≤ 39°C
2	> 38.5°C - ≤ 39.5°C	> 39°C - ≤ 40°C
3	> 39.5°C	> 40°C

- **Conversion of temperature to °C**
  - Temperature in °Celsius = ((Temperature in °Fahrenheit -32) *5)/9.
  - The result is rounded to 1 decimal.
- Note that for all tables described in this section, the way the percentage of subjects will be derived will depend on the event analysed (see table below for details). As a result, the N value will differ from one table to another.

Event	N used for deriving % per subject for Vaccination phase	N used for deriving % per dose for Vaccination phase
Concomitant vaccination	All subjects with study vaccine administered	All study visits with study vaccine administered
Solicited general symptom	All subjects with at least one solicited general symptom documented as either present or absent (i.e., symptom screen completed)	All study visits with study vaccine administered and with at least one solicited general symptom documented as either present or absent (i.e., symptom screen completed)
Solicited local symptom	All subjects with at least one solicited local symptom documented as either present or absent (i.e., symptom screen completed)	All study visits with study vaccine administered and with at least one solicited local symptom documented as either present or absent (i.e., symptom screen completed)
Unsolicited symptom	All subjects with study vaccine administered	All study visits with study vaccine administered
Concomitant medication	All subjects with study vaccine administered	All study visits with study vaccine administered

- All CI computed will be two-sided 95% CI.
- Grading of haematological and biochemical parameters will be assessed as per the following tables: -

Table 4 Toxicity grading scales for hematology and biochemistry parameters applicable for this study

Component	Grade 1	Grade 2	Grade 3	Grade 4
Hemoglobin (g/dL)	9.0 to < 10.5	8.0 to < 9.0	7.0 to < 8.0	< 7.0
Leukocytes decreased (cell/mm^3)	2500 to < 3500	1500 to < 2500	1000 to < 1500	< 1000
Platelets decreased (cell//mm^3)	75000 to < 150000	50000 to < 75000	25000 to < 50000	< 25000
Alanine Aminotransferase (increase by factor)	1.1 to < 2.0 xULN	2.0 to < 3.0 xULN	3.00 to ≤ 8.0 xULN	> 8.0 xULN
Aspartate Aminotransferase (increase by factor)	1.1 to < 2.0 xULN	2.0 to < 3.0 xULN	3.00 to ≤ 8.0 xULN	> 8.0 xULN
Creatinine (mg/dL)	0.6 to < 0.9	0.9 to < 1.2	1.2 to ≤ 1.5	> 1.5
Absolute neutrophil count decreased (cell/mm³)	***1000 to < 1300***	***750 to < 1000***	***500 to < 750***	***< 500***
Absolute lymphocyte count decreased (cell/mm³)	***600 to < 650***	***500 to < 600***	***350 to < 500***	***< 350***
Eosinophil	N.A	N.A	N.A	N.A
Basophil	N.A	N.A	N.A	N.A
Monocyte	N.A	N.A	N.A	N.A

Grading scale adapted from [**Error! Reference source not found.**, 2003], [**Error! Reference source not found.**, 2004] and [**Error! Reference source not found.**, 2007].

ULN: upper limit of normal

11.3.6. RTI and LRTI

- For the analysis of RTI and LRTI, all cases will be definitively classified as either RSV-RTI, RSV-LRTI, RSV-severe LRTI or RSV-very severe LRTI according to standardized case definitions (see table below) based on the available WHO case definitions, and the association to RSV infection will be assessed by quantitative PCR as primary analysis.

Table 5 Case definition of RSV- RTI/LRTI

RSV infection	Symptomatic and/or asymptomatic RSV infection
RSV-RTI	Runny nose OR blocked nose OR cough AND Confirmed RSV infection [4]
RSV-LRTI	History of cough OR difficulty breathing [1] AND SpO_2 < 95% [2], OR RR increase [3] AND Confirmed RSV infection [4]
RSV-severe LRTI	Meeting the case definition of RSV-LRTI AND SpO_2 < 93% [2], OR lower chest wall in-drawing
RSV-very severe LRTI	Meeting the case definition of RSV-LRTI AND SpO_2 < 90% [2], OR inability to feed, OR failure to respond / unconscious
RSV hospitalization	Confirmed RSV infection [5] AND Hospitalized for acute medical condition [6]
All-cause LRTI	History of cough OR difficulty breathing [1] AND SpO_2 < 95% [2], OR RR increase [3]

Definition based on [Modjarrad, 2016]
LRTI = lower respiratory tract infections; RR = respiratory rate; RTI = respiratory tract infections;
SpO_2 = blood oxygen saturatin
[1] Based on history reported by parents/LARs and includes difficulty breathing (e.g. showing signs of wheezing or stridor, tachypnoea, flaring [of nostrils], chest in-drawing, apnoea) associated with nasal obstruction
[2] For blood oxygen saturation (SpO_2), the lowest value monitored will be used
[3] RR increase defined as ≥ 40/minute (12 months of age or above)
[4] RSV infection confirmed on nasal swab positive for RSV A or B by quantitative Reverse Transcription Polymerase Chain Reaction (qRT-PCR)
[5] RSV sampling and testing is based on medical judgment of medical practitioner or driven by algorithm
[6] Hospitalization is defined as a medical decision that the infant requires admission for observation or treatment

- For the analysis of RSV-RTI episode, the start date of an RTI episode will be defined as the first day of any occurrence of cough, runny nose, blocked nose, and a new case requires an interval of at least 7 symptom free days since the last episode of RTI that was diagnosed.
- For the analysis of RSV-LRTI or severe or very severe LRTI the start date of the LRTI episode is defined as the point at which the first symptoms of cough, or difficulty breathing were observed and a new case requires an interval of at least 7 symptom free days since the last episode of LRTI that was diagnosed.

- End date of the RTI episode is defined as the point at which the child is considered symptom-free of cough, runny nose, blocked nose, wheezing, and difficulty breathing.
- For molecular biology (qRT-PCR test), the following cut-off will be applied: -

System	Component	Method	Unit	Cut-off
Nasal swab	RSV-A RNA	Quantitative real-time PCR (qRT-PCR)	Copies/ml	1123
Nasal swab	RSV-B RNA	Quantitative real-time PCR (qRT-PCR)	Copies/ml	1467

- For calculation of viral load for RSV-A/B, all reported values will be included. Subject infected by either RSV-A or RSV-B or both will be included for calculation. Total viral load = Viral load for RSV-A + Viral load for RSV-B. LOD for RSV-A and RSV-B are 1123 and 1467 copies/ml, respectively. Following rule will be applied: -

Raw result	Derivation for positivity	Derivation for viral load calculation
<LOD	NEG	LOD/2
≥LOD	POS	Exact value

11.3.7. Number of decimals displayed

The following decimal description from the decision rules will be used for the demography, immunogenicity and safety/reactogenicity.

Display Table	Parameters	Number of decimal digits
Demographic characteristics	Mean, median age	1
Demographic characteristics	SD (age)	1
Reactogenicity	Mean, Min, Q1, Median, Q3, Max for duration	1
All summaries	% of count, including LL & UL of CI	1
All summaries	% of difference, including LL & UL of CI	2

12. ANNEX 2: RELEVANT PREFERRED TERMS FOR DETECTION OF AESI

Any of the below listed preferred term reported as an Expedited Adverse Event must be immediately escalated to the CRDL or Central Safety Physician to assess or confirm the need for an urgent IDMC review.

The list of preferred terms and associated PT codes is given below:

HAEMATOMA

Preferred term	PT code
abdominal wall haematoma	10067383
administration site haematoma	10075100
adrenal haematoma	10059194
aortic intramural haematoma	10067975
application site haematoma	10068317
arterial intramural haematoma	10074971
auricular haematoma	10003797
basal ganglia haematoma	10077031
brain stem haematoma	10073230
breast haematoma	10064753
broad ligament haematoma	10006375
bursal haematoma	10077818
catheter site haematoma	10055662
cephalhaematoma	10008014
cerebellar haematoma	10061038
cerebral haematoma	10053942
cervix haematoma uterine	10050020
chest wall haematoma	10076597
colonic haematoma	10009996
deep dissecting haematoma	10074718
extradural haematoma	10015769
eyelid haematoma	10064976
haematoma	10018852
haematoma evacuation	10060733
haematoma infection	10051564
hepatic haematoma	10019676
incision site haematoma	10059241
infusion site haematoma	10065463
injection site haematoma	10022066
instillation site haematoma	10073609
intestinal haematoma	10069829
intra-abdominal haematoma	10056457
intracerebral haematoma evacuation	10062025

intracranial haematoma	10059491
intraocular haematoma	10071934
laryngeal haematoma	10070885
lip haematoma	10066304
mediastinal haematoma	10049941
medical device site haematoma	10075577
mesenteric haematoma	10071557
nasal septum haematoma	10075027
oesophageal intramural haematoma	10077486
oral mucosa haematoma	10074779
ovarian haematoma	10033263
paranasal sinus haematoma	10069702
pelvic haematoma	10054974
penile haematoma	10070656
perineal haematoma	10034520
periorbital haematoma	10034544
periosteal haematoma	10077341
perirenal haematoma	10049450
peritoneal haematoma	10058095
pharyngeal haematoma	10068121
post procedural haematoma	10063188
pulmonary haematoma	10054991
renal haematoma	10038459
retroperitoneal haematoma	10058360
scrotal haematoma	10039749
spinal cord haematoma	10076051
spinal epidural haematoma	10050162
spinal subdural haematoma	10050164
splenic haematoma	10041646
spontaneous haematoma	10065304
subarachnoid haematoma	10076701
subcutaneous haematoma	10042345
subdural haematoma	10042361
subgaleal haematoma	10069510
subretinal haematoma	10071935
tongue haematoma	10043959
uterine haematoma	10063875
vaccination site haematoma	10069472
vaginal haematoma	10046909
vitreous haematoma	10071936
vulval haematoma	10047756

HAEMORRHAGE

Preferred term	PT code
abdominal wall haemorrhage	10067788
acute haemorrhagic conjunctivitis	10067817
administration site haemorrhage	10075101
adrenal haemorrhage	10001361
anal haemorrhage	10049555
anastomotic haemorrhage	10056346
angina bullosa haemorrhagica	10064223
application site haemorrhage	10072694
arterial haemorrhage	10060964
basal ganglia haemorrhage	10067057
bone marrow haemorrhage	10073581
brain stem haemorrhage	10006145
brain stem microhaemorrhage	10071205
breast haemorrhage	10006254
bronchial haemorrhage	10065739
catheter site haemorrhage	10051099
central nervous system haemorrhage	10072043
cerebellar haemorrhage	10008030
cerebellar microhaemorrhage	10071206
cerebral haemorrhage	10008111
cerebral microhaemorrhage	10067277
cervix haemorrhage uterine	10050022
ciliary body haemorrhage	10057417
conjunctival haemorrhage	10010719
diverticulitis intestinal haemorrhagic	10013541
diverticulum intestinal haemorrhagic	10013560
duodenitis haemorrhagic	10013865
ear haemorrhage	10014009
encephalitis haemorrhagic	10014589
gastric haemorrhage	10017788
gastroduodenal haemorrhage	10053768
gastrointestinal haemorrhage	10017955
genital haemorrhage	10061178
haemarthrosis	10018829
haematemesis	10018830
haematochezia	10018836
haematotympanum	10063013
haematuria	10018867
haemorrhage	10055798
haemorrhage coronary artery	10055803

haemorrhage intracranial	10018985
haemorrhage subcutaneous	10018999
haemorrhage subepidermal	10019001
haemorrhage urinary tract	10055847
haemorrhagic anaemia	10052293
haemorrhagic diathesis	10062713
haemorrhagic disorder	10019009
haemorrhagic infarction	10019013
haemorrhagic ovarian cyst	10060781
haemorrhagic pneumonia	10077933
haemorrhagic thyroid cyst	10072256
haemorrhagic urticaria	10059499
injection site haemorrhage	10022067
internal haemorrhage	10075192
intestinal haemorrhage	10059175
intra-abdominal haemorrhage	10061249
intraventricular haemorrhage	10022840
iris haemorrhage	10057418
joint microhaemorrhage	10077666
lacrimal haemorrhage	10069930
large intestinal haemorrhage	10052534
laryngeal haemorrhage	10065740
lip haemorrhage	10049297
lower gastrointestinal haemorrhage	10050953
lymph node haemorrhage	10074270
mediastinal haemorrhage	10056343
mesenteric haemorrhage	10060717
mouth haemorrhage	10028024
mucocutaneous haemorrhage	10076048
mucosal haemorrhage	10061298
muscle haemorrhage	10028309
myocardial haemorrhage	10048849
naevus haemorrhage	10062955
ocular retrobulbar haemorrhage	10057571
oesophageal haemorrhage	10030172
optic disc haemorrhage	10030919
optic nerve sheath haemorrhage	10030941
ovarian haemorrhage	10065741
pancreatic haemorrhage	10033625
papillary muscle haemorrhage	10059164
parathyroid haemorrhage	10059051
parotid gland haemorrhage	10051166

pelvic haemorrhage	10063678
penile haemorrhage	10034305
pericardial haemorrhage	10034476
periorbital haemorrhage	10071697
peritoneal haemorrhage	10034666
petechiae	10034754
pharyngeal haemorrhage	10034827
pituitary haemorrhage	10049760
post procedural haemorrhage	10051077
procedural haemorrhage	10071229
prostatic haemorrhage	10036960
pulmonary alveolar haemorrhage	10037313
pulmonary haemorrhage	10037394
putamen haemorrhage	10058940
rectal haemorrhage	10038063
renal haemorrhage	10038460
respiratory tract haemorrhage	10038727
retinal haemorrhage	10038867
retroperitoneal haemorrhage	10038980
scleral haemorrhage	10050508
skin haemorrhage	10064265
small intestinal haemorrhage	10052535
soft tissue haemorrhage	10051297
spermatic cord haemorrhage	10065742
spinal cord haemorrhage	10048992
spinal epidural haemorrhage	10049236
spinal subarachnoid haemorrhage	10073564
spinal subdural haemorrhage	10073563
splenic haemorrhage	10041647
spontaneous haemorrhage	10074557
subarachnoid haemorrhage	10042316
subdural haemorrhage	10042364
testicular haemorrhage	10051877
thalamus haemorrhage	10058939
thoracic haemorrhage	10062744
thyroid haemorrhage	10064224
tongue haemorrhage	10049870
tracheal haemorrhage	10062543
upper gastrointestinal haemorrhage	10046274
ureteric haemorrhage	10065743
urethral haemorrhage	10049710
urinary bladder haemorrhage	10046528

urogenital haemorrhage	10050058
uterine haemorrhage	10046788
vaccination site haemorrhage	10069475
vaginal haemorrhage	10046910
venous haemorrhage	10065441
vitreous haemorrhage	10047655
vulval haemorrhage	10063816

THROMBOCYTOPENIA

Preferred term	PT code
bleeding time abnormal	10049227
bleeding time prolonged	10005140
coagulation test abnormal	10063557
platelet count abnormal	10035526
platelet count decreased	10035528
platelet disorder	10035532
platelet dysfunction	10073391
thrombocytopenia	10043554
thrombocytopenic purpura	10043561

LOWER RESPIRATORY TRACT INFECTION

Preferred term	PT code
atypical pneumonia	10003757
bronchitis	10006451
bronchitis viral	10053160
haemorrhagic pneumonia	10077933
lower respiratory tract infection	10024968
lower respiratory tract infection viral	10065188
lung infection	10061229
pneumonia	10035664
pneumonia respiratory syncytial viral	10035732
pulmonary sepsis	10051739
respiratory syncytial virus bronchiolitis	10038718
respiratory syncytial virus bronchitis	10069811
respiratory tract infection	10062352
respiratory tract infection viral	10062106

13. ANNEX 3: STUDY SPECIFIC MOCK TFL

The data display, title and footnote is for illustration purpose and will be adapted to the study specificity as indicated in the TFL TOC. Note that there may be few changes between the study specific SAP mock TFL and the final TFLs as editorial/minor changes do not require a SAP amendment.

13.1. List of individual data listing

Following individual data listing will be generated

Appendix Table I.A - Elimination codes
Appendix Table I.B – Demography
Appendix Table IBii - Physical examination/vital signs
Appendix Table I.Ci - Dates of birth, Informed consent, Vaccination and blood sampling, Contact
Appendix Table I.Cii - Reason for visit not done
Appendix Table I.D - General medical history - Physical examination
Appendix Table I.Ei – Study Conclusion
Appendix Table I.Eii – Screening conclusion
Appendix Table I.F – Notes (this appendix is provided for info only and should not be used for the clinical report)
Appendix Table I.G / I.H - Vaccination procedure
Appendix Table I.I - Reason for not administration of vaccine
Appendix Table I.J - Reason for non-eligibility
Appendix Table I.Ki – Previous history of vaccination
Appendix Table I.Kii – Previous history of disease
Appendix Table II.Ai - Solicited local adverse events
Appendix Table II.B - Solicited general adverse events
Appendix Table II.Ci - Unsolicited adverse events within (30) days post-vaccination
Appendix Table II.Cii - Unsolicited adverse events after (30) days post-vaccination
Appendix Table II.Di - Concomitant medications
Appendix Table II.Dii - Concomitant vaccinations
Appendix Table III.A – Immunogenicity - HI
Appendix Table III.B – Immunogenicity- CMI
Appendix Table IV.A – Haematology and Biochemistry
Appendix Table IIIA – Altitude of the site
Appendix Table IIE –Detection of Episodes and Limb Examination
Appendix Table IIF - Surveillance Contact
Appendix Table IIG - Assessment of RTI Episode
Appendix Table IIH - RTI Symptoms
Appendix Table IIJ - Signs and Symptoms of RSV-LRTI
Appendix Table IIK - Chest X-Ray Observations
Appendix Table IIL- Inpatient Care
Appendix Table IIIA – Local RSV Result
Appendix Table IIIB – Nasal Swab (qRT-PCR Result)
Appendix IIIC – Blood culture result
Appendix IIID- Re-screening

13.2. Template of Tables and Figures

Template 1 Number of subjects by country and center <Exposed Set>

		<Each group> N=XXXX		<Each group> N=XXXX		Total N=XXXX	
Country	**Center**	**n**	**%**	**n**	**%**	**n**	**%**
<each country>	<each center >	XXX	XX.X	XXX	XX.X	XXX	XX.X
	All	XXX	XX.X	XXX	XX.X	XXX	XX.X

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
n = number of subjects in a given center or country
N = total number of subjects
% = n/N x 100
Center = GSK Biologicals assigned center number

Template 2 Number of subjects vaccinated, completed and withdrawn with reason for withdrawal – up to Day X <Exposed set>

	<Each group> N=XXXX	<Each group> N=XXXX	Total N=XXXX
	n	**n**	**n**
Number of subjects vaccinated	xxx	xxx	xxx
End of study status			
[EACH CATEGORY]	xxx	xxx	xxx
Reasons for withdrawal:			
[REASONS]	xxx	xxx	xxx

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
Vaccinated = number of subjects who were vaccinated in the study
Completed = number of subjects who completed last study visit
Withdrawn = number of subjects who did not come for the last study visit

Template 3 Visit attendance <Exposed set>

		<Each group> N=XXX	
Visit	**Status**	**n**	**%**
INFORMED CONSENT	Completed		
RANDOMIZATION	Completed		
<EACH VISIT>	Attended		
	Not attended yet		
	Permanent discontinuation prior to this visit		
	Not attended		
CONCLUSION	Completed		

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = Number of subjects in each group or in total
Conclusion = date of last visit or withdrawal

Template 4 Number of subjects enrolled into the study as well as the number of subjects excluded from the PPS analysis of immunogenicity at Day X with reasons for exclusion

	Total			*<each group>*	
Title	**n**	**s**	**%**	**n**	**s**
Enrolled Set					
Invalid informed consent or fraudulent data (code 900)					
Study vaccine dose not administered but subject number allocated (code 1030)					
Exposed set					
<*Reason for elimination & elimination code*>					
<*Reason for elimination & elimination code*>					
PPS for analysis of immunogenicity at Day X					

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
Note: Subjects may have more than one elimination code assigned
n = number of subjects with the elimination code assigned excluding subjects who have been assigned a lower elimination code number
s = number of subjects with the elimination code assigned
% = percentage of subjects in the considered PPS relative to the Exposed set

Template 5 Summary of demographic characteristics <Exposed set>

	<Each group> N=XXXX		<Each group> N=XXXX		Total N=XXXX	
	Value or n	**%**	**Value or n**	**%**	**Value or n**	**%**
Age in months at <timepoint>						
N with data	xxx		xxx		xxx	
Mean	xxx.x		xxx.x		xxx.x	
SD	xxx.x		xxx.x		xxx.x	
Median	xxx.x		xxx.x		xxx.x	
Minimum	xxx		xxx		xxx	
Maximum	xxx		xxx		xxx	
Gender						
<EACH GENDER>	xxx	xx.x	xxx	xx.x	xxx	xx.x
…	xxx	xx.x	xxx	xx.x	xxx	xx.x
Ethnicity						
<EACH ETHNICITY>	xxx	xx.x	xxx	xx.x	xxx	xx.x
…	xxx	xx.x	xxx	xx.x	xxx	xx.x
Geographic Ancestry						
<EACH GEOGRAPHIC ANCESTRY>	xxx	xx.x	xxx	xx.x	xxx	xx.x
…	xxx	xx.x	xxx	xx.x	xxx	xx.x
Country						
<EACH COUNTRY>	xxx	xx.x	xxx	xx.x	xxx	xx.x
…	xxx	xx.x	xxx	xx.x	xxx	xx.x

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
N with data = number of subjects with documentation of the corresponding data
SD = standard deviation

Template 6 Summary of vital signs characteristics <Exposed set>

			<each group> N =	Total N =
Visit	**Characteristics**	**Parameters**	**Value**	**Value**
<Each visit>	Height (Cm)	N with data		
		Mean		
		SD		
		Median		
		Minimum		
		Maximum		
	Weight (Kg)	N with data		
		Mean		
		SD		
		Median		
		Minimum		
		Maximum		
	Heart rate (Beats per minute)	N with data		
		Mean		
		SD		
		Median		
		Minimum		
		Maximum		
	Respiratory rate (Breadth per minute)	N with data		
		Mean		
		SD		
		Median		
		Minimum		
		Maximum		
	Temperature/(Axillary) (°C)	N with data		
		Mean		
		SD		
		Median		
		Minimum		
		Maximum		

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = total number of subjects
N with data = number of subjects with documentation of the corresponding data
Value = value of the considered parameter
SD = standard deviation

Template 7 Distribution of weight for age Z-score (WAZ) at vaccination <Exposed Set>

		Each group N =		Total N =	
Visit	**Characteristics**	**n**	**%**	**n**	**%**
Day 1	Normal (-1 < WAZ < 0)				
	Mildly underweight (-2<WAZ<-1)				
	Moderately underweight (-3<WAZ<-2)				
	Severely underweight (WAZ<-3)				
Day 366	Normal (-1 < WAZ < 0)				
	Mildly underweight (-2<WAZ<-1)				
	Moderately underweight (-3<WAZ<-2)				
	Severely underweight (WAZ<-3)				

<group>
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = Total number of subjects
n = number of subjects in each category
% = n / Number of subjects with available results x 100
For weight for age Z score calculation of each subject, median = XX and SD = YY

Template 8 Distribution of height for age Z-score (HAZ) at vaccination <Exposed Set>

		Each group N =		Total N =	
Visit	**Characteristics**	**n**	**%**	**n**	**%**
Day 1	Normal (-1 < HAZ < 0)				
	Mildly stunted (-2<HAZ<-1)				
	Moderately stunted (-3<HAZ<-2)				
	Severely stunted (HAZ<-3)				
Day 366	Normal (-1 < HAZ < 0)				
	Mildly stunted (-2<HAZ<-1)				
	Moderately stunted (-3<HAZ<-2)				
	Severely stunted (HAZ<-3)				

<group>
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = Total number of subjects
n = number of subjects in each category
% = n / Number of subjects with available results x 100
For height for age Z score calculation of each subject, median = XX and SD = YY

Template 9 Deviations from specifications for age and intervals between study visits up to Day X <Exposed Set>

		Age	SCR-Dose:1	Dose:1-VISIT3 (D4)	Dose:1-VISIT4 (D8)	Dose:1-Dose:2	Dose:2-VISIT7 (D34)	Dose:2-VISIT8 (D38)	Dose:2-VISIT9 (D61)	Dose:1-VISIT10 (D366)	Dose:1-VISIT11 (D731)
Group		**Protocol**	**Protocol**	**Protocol**	**Protocol**	**Protocol**	**Protocol**	**Protocol**	**Protocol**	**Protocol**	**Protocol**
		from 12 to 23 months	from 1 to 30 days	from 3 to 4 days	from 7 to 10 days	from 23 to 36 days	from 3 to 4 days	from 7 to 10 days	from 28 to 35 days	from 335 to 395 days	from 700 to 760 days
<each group>	N										
	n										
	%										
	range										

<each group (pooled groups)>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = total number of subjects with available results
n/% = number / percentage of subjects with results outside of the interval
range = minimum-maximum for age and intervals
Please note - On Day 3 and Day 33, a visit may take place at the investigators clinical facility or the investigator/clinical staff may call the subjects' parent(s)/LAR(s), as appropriate to the circumstances in the judgment of the investigator

Template 10 Study Population

	<Each group> N=XXXX	<Each group> N=XXXX	Total N=XXXX
Number of subjects			
Planned, N	xxx	xxx	xxx
Randomised, N <cohort name>	xxx	xxx	xxx
Completed, n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
<Unknown>	xxx	xxx	xxx
Demographics			
N <cohort name>	xxx	xxx	xxx
Females:Males	xxx:xxx	xxx:xxx	xxx:xxx
Mean Age, <unit> (SD)	xxx.x (xxx.x)	xxx.x (xxx.x)	xxx.x (xxx.x)
Median Age, <unit> (minimum, maximum)	xxx (xxx,xxx)	xxx (xxx,xxx)	xxx (xxx,xxx)
<MOST FREQUENT CATEGORY OF RACE>	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
<SECOND MOST FREQUENT CATEGORY OF RACE>	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
<THIRD MOST FREQUENT CATEGORY OF RACE>	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = Total number of subjects
SD = Standard deviation

Template 11 Number of enrolled subjects by country

	<*each group*> N =	Total N =
Characteristics	**n**	**n**
Country		

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = Number of enrolled subjects
n= number of enrolled subjects included in each group or in total for a given country or for all countries

Template 12 Number of enrolled subjects by age category

		<*each group*> N =	Total N =
Characteristics	**Categories**	**n**	**n**
Age category	1=Infants and toddlers (28 days-23 month)		
	Missing		

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = Number of enrolled subjects
n= number of enrolled subjects included in each group or in total for a given age category or for all age categories
Missing = age at dose 1 unknown

Template 13 Minimum and maximum activity dates <Exposed set>

		<each group>	<each group>	Overall
Visit Description	**Parameter**	**Date**	**Date**	**Date**
<each inform consent>	Minimum			
	Maximum			
[Randomisation]	Minimum			
	Maximum			
<each visit>	Minimum			
	Maximum			

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)

Template 14 Exposure to study vaccines <Exposed Set>

	<Each group> N=XXXX		<Each group> N=XXXX		Total N=XXXX	
Number of subjects receiving	**n**	**%**	**n**	**%**	**n**	**%**
Exactly 1 Dose						
Exactly 2 Doses						
…						
At least 1 Dose						
Total number of doses administered during the study						

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 109 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = number of subjects in each group or in total included in the considered cohort
n = number of subjects/doses in the given category
% = percentage of subjects in the given category

Template 15 Compliance in completing solicited symptoms information <Exposed Set>

		<each group>			<each group>		
DOSE	**Symptom information**	**N**	**n**	**Compliance (%)**	**N**	**n**	**Compliance (%)**
DOSE <each dose number>	General SS						
	Local SS						
TOTAL	General SS Local SS						

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 109 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N=Number of administered doses
n = number of doses with SS returned
General SS = Symptom screens used for the collection of general solicited AEs
Local SS = Symptom screens used for the collection of local solicited AEs
Compliance (%) = (n / N) X 100

Template 16 Incidence and nature of symptoms (solicited and unsolicited) reported during the 7-day post-vaccination period (Days 1-7) following each dose and overall <Exposed Set>

		<Each group>					<Each group>					Local symptoms				
					95% CI					95% CI					95% CI	
Dose	**Symptoms**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Dose 1	Any symptom															
	General symptoms															
	Local symptoms															
Dose 2	Any symptom															
	General symptoms															
	Local symptoms															
Overall/dose	Any symptom															
	General symptoms															
	Local symptoms															
Overall/subject	Any symptom															
	General symptoms															
	Local symptoms															

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
For each dose:
N = number of subjects with the corresponding documented dose
n/% = number/percentage of subjects presenting at least one type of symptom following the corresponding dose
For overall/dose:
N = number of documented dose
n/% = number/percentage of doses followed by at least one type of symptom
For overall/subject:
N = number of documented dose
n/% = number/percentage of subjects presenting at least one type of symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Template 17 Incidence of solicited local symptoms reported during the 7-day (Days 1-7) post-vaccination period following each dose and overall <Exposed Set>

			<each group>				
						95 % CI	
Dose	**Symptom**	**Type**	**N**	**n**	**%**	**LL**	**UL**
DOSE 1	Pain	All					
		≥ Grade 2					
		Grade 3					
		Medical advice					
	Redness (mm)	All					
		≥ 5					
		>20					
		Medical advice					
	Swelling (mm)	All					
		≥ 5					
		>20					
		Medical advice					
DOSE 2	Pain	…					
	Redness (mm)	…					
	Swelling (mm)	…					
OVERALL/DOSE	Pain	…					
	Redness (mm)	…					
	Swelling (mm)	…					
OVERALL/SUBJECT	Pain	…					
	Redness (mm)	…					
	Swelling (mm)	…					

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
For each dose:
N = number of subjects with the corresponding documented dose
n/% = number/percentage of subjects reporting the type of symptom at least once following the corresponding dose
For Overall/dose:
N = number of documented dose
n/% = number/percentage of doses followed by at least one type of symptom
For Overall/subject:
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the type of symptom at least once
95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit
The maximum intensity of local injection site redness/swelling was coded as follows:
1: > 0.1 mm to < 5 mm
2: ≥ 5 mm to ≤ 20 mm
3: > 20 mm

Template 18 Incidence of solicited local symptoms reported during the 7-day (Days 1-7) post-vaccination period following each dose and overall by maximum grading <Exposed Set>

			<each group>				
						95 % CI	
Dose	Symptom	Type	N	n	%	LL	UL
DOSE 1	Pain	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Medical advice					
	Redness (mm)	All					
		≥0.1 - <5.0					
		≥5.0 - ≤20.0					
		>20					
		Medical advice					
	Swelling (mm)	All					
		≥0.1 - <5.0					
		≥5.0 - ≤20.0					
		>20					
		Medical advice					
DOSE 2	Pain	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Medical advice					
	Redness (mm)	All					
		≥0.1 - <5.0					
		≥5.0 - ≤20.0					
		>20					
		Medical advice					
	Swelling (mm)	All					
		≥0.1 - <5.0					
		≥5.0 - ≤20.0					
		>20					
		Medical advice					
OVERALL/DOSE	Pain	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Medical advice					
	Redness (mm)	All					
		≥0.1 - <5.0					
		≥5.0 - ≤20.0					
		>20					
		Medical advice					
	Swelling (mm)	All					
		≥0.1 - <5.0					
		≥5.0 - ≤20.0					
		>20					
		Medical advice					

			<each group>				
						95 % CI	
Dose	**Symptom**	**Type**	**N**	**n**	**%**	**LL**	**UL**
OVERALL/SUBJECT	Pain	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Medical advice					
	Redness (mm)	All					
		≥0.1 - <5.0					
		≥5.0 - ≤20.0					
		>20					
		Medical advice					
	Swelling (mm)	All					
		≥0.1 - <5.0					
		≥5.0 - ≤20.0					
		>20					
		Medical advice					

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
For each dose:
N = number of subjects with the corresponding documented dose
n/% = number/percentage of subjects reporting the type of symptoms as maximum intensity during the follow-up period
For Overall/dose:
N = number of documented dose
n/% = number/percentage of doses followed by the type of symptom as maximum intensity during the follow-up period
For Overall/subject:
N = number of documented dose
n/% = number/percentage of subjects reporting the type of symptom as maximum intensity during the follow-up period
CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit
The maximum intensity of local injection site redness/swelling was coded as follows:
1: > 0.1 mm to < 5 mm
2: ≥ 5 mm to ≤ 20 mm
3: > 20 mm

Template 19 Incidence of solicited general symptoms reported during the 7-day (Days 1-7) post-vaccination period following each dose and overall <Exposed Set>

			<each group>				
						95 % CI	
Dose	**Symptom**	**Type**	**N**	**n**	**%**	**LL**	**UL**
DOSE 1	Drowsiness	All					
		≥ Grade 2					
		Grade 3					
		Related					
		≥ Grade 2*Related					
		Grade 3*Related					
		Medical advice					
	Irritability/Fussiness	All					
		≥ Grade 2					
		Grade 3					
		Related					
		≥ Grade 2*Related					
		Grade 3*Related					
		Medical advice					
	Loss of appetite	All					
		≥ Grade 2					
		Grade 3					
		Related					
		≥ Grade 2*Related					
		Grade 3*Related					
		Medical advice					
	Fever (Axillary) (°C)	All (≥37.5)					
		>37.5					
		>38.0					
		>38.5					
		>39.0					
		>39.5					
		Related					
		>38.5*Related					
		>39.5*Related					
		Medical advice					
DOSE 2	Drowsiness	…					
	Irritability/Fussiness	…					
	Loss of appetite	…					
	Fever (Axillary) (°C)	…					
OVERALL/DOSE	Drowsiness	…					
	Irritability/Fussiness	…					
	Loss of appetite	…					
	Fever (Axillary) (°C)	…					
OVERALL/SUBJECT	Drowsiness	…					
	Irritability/Fussiness	…					
	Loss of appetite	…					
	Fever (Axillary) (°C)	…					

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)

Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
For each dose:
N = number of subjects with the corresponding documented dose
n/% = number/percentage of subjects reporting the symptom at least once following the corresponding dose
For Overall/dose:
N = number of documented dose
n/% = number/percentage of doses followed by at least one type of symptom
For Overall/subject:
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the type of symptom at least once
95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit
Temperatures were coded as follows:
1: ≥ 37.5 °C to ≤ 38.5 °C
2: > 38.5 °C to ≤ 39.5°C
3: > 39.5°C

Template 20 Incidence of solicited general symptoms reported during the 7-day (Days 1-7) post-vaccination period following each dose and overall by maximum grading <Exposed Set>

			Each group				
						95 % CI	
Dose	Symptom	Type	N	n	%	LL	UL
DOSE 1	Drowsiness	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Related					
		Grade 2 Related					
		Grade 3 Related					
		Medical advice					
	Irritability / Fussiness	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Related					
		Grade 2 Related					
		Grade 3 Related					
		Medical advice					
	Loss Of Appetite	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Related					
		Grade 2 Related					
		Grade 3 Related					
		Medical advice					
	Temperature/(Axillary) (°C)	All					
		≥37.5 - ≤38.5					
		>38.5 - ≤39.5					
		>39.5					
		Related					
		>38.5 - ≤39.5*Related					
		>39.5*Related					
		Medical advice					
DOSE 2	Drowsiness	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Related					
		Grade 2 Related					
		Grade 3 Related					
		Medical advice					
	Irritability / Fussiness	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Related					
		Grade 2 Related					
		Grade 3 Related					
		Medical advice					

			Each group				
						95 % CI	
Dose	**Symptom**	**Type**	**N**	**n**	**%**	**LL**	**UL**
	Loss Of Appetite	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Related					
		Grade 2 Related					
		Grade 3 Related					
		Medical advice					
	Temperature/(Axillary) (°C)	All					
		≥37.5 - ≤38.5					
		>38.5 - ≤39.5					
		>39.5					
		Related					
		>38.5 - ≤39.5*Related					
		>39.5*Related					
		Medical advice					
OVERALL/DOSE	Drowsiness	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Related					
		Grade 2 Related					
		Grade 3 Related					
		Medical advice					
	Irritability / Fussiness	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Related					
		Grade 2 Related					
		Grade 3 Related					
		Medical advice					
	Loss Of Appetite	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Related					
		Grade 2 Related					
		Grade 3 Related					
		Medical advice					
	Temperature/(Axillary) (°C)	All					
		≥37.5 - ≤38.5					
		>38.5 - ≤39.5					
		>39.5					
		Related					
		>38.5 - ≤39.5*Related					
		>39.5*Related					
		Medical advice					
OVERALL/SUBJECT	Drowsiness	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Related					

			Each group				
						95 % CI	
Dose	**Symptom**	**Type**	**N**	**n**	**%**	**LL**	**UL**
		Grade 2 Related					
		Grade 3 Related					
		Medical advice					
	Irritability / Fussiness	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Related					
		Grade 2 Related					
		Grade 3 Related					
		Medical advice					
	Loss Of Appetite	All					
		Grade 1					
		Grade 2					
		Grade 3					
		Related					
		Grade 2 Related					
		Grade 3 Related					
		Medical advice					
	Temperature/(Axillary) (°C)	All					
		≥37.5 - ≤38.5					
		>38.5 - ≤39.5					
		>39.5					
		Related					
		>38.5 - ≤39.5*Related					
		>39.5*Related					
		Medical advice					

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
For each dose:
N = number of subjects with the corresponding documented dose
n/% = number/percentage of subjects reporting the type of symptom as maximum intensity during the follow-up period
For Overall/dose:
N = number of documented dose
n/% = number/percentage of doses followed by the type of symptoms as maximum intensity during the follow-up period
For Overall/subject:
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the type of symptoms as maximum intensity during the follow-up period
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit
Temperatures were coded as follows:
1: ≥ 37.5 °C to ≤ 38.5 °C
2: > 38.5 °C to ≤ 39.5°C
3: > 39.5°C

Template 21 Maximum Temperature reported during the 7-day (Days 1-7) post-vaccination period – dose X <Exposed Set>

		Each group N =				Total N =			
				95% CI				95% CI	
Characteristics	**Categories**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Maximum temperature	No fever								
	Unknown temperature								
	[37.5-37.9]								
	[38.0-38.4]								
	[38.5-38.9]								
	[39.0-39.4]								
	[39.5-39.9]								
	[40.0-….								

N = number of subjects with documented dose
n/% = number/percentage of subjects in a given category
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Template 22 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 30-day (Days 1-30) post-vaccination period <Exposed Set>

		Each group N =			
				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**
At least one symptom					
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)				
	Teething (10043183)				
	Vomiting (10047700)				
General disorders and administration site conditions (10018065)	Pyrexia (10037660)				
Immune system disorders (10021428)	Seasonal allergy (10048908)				
Infections and infestations (10021881)	Conjunctivitis (10010741)				
	Otitis media (10033078)				
	Paronychia (10034016)				
	Tonsillitis (10044008)				
	Tonsillitis streptococcal (10044013)				
	Viral upper respiratory tract infection (10047482)				
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)				
	Face injury (10050392)				
	Head injury (10019196)				
Skin and subcutaneous tissue disorders (10040785)	Miliaria (10027627)				

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects included in the considered cohort in each group
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Template 23 Number and percentage of subjects taking a concomitant medication during the 7- day (Days 1-7) post -vaccination period <Exposed Set>

		<each group>				
					95% CI	
Dose	**Type**	**N**	**n**	**%**	**LL**	**UL**
DOSE 1	Any					
	Any antipyretics					
	Prophylactic antipyretics					
DOSE 2	Any					
	Any antipyretics					
	Prophylactic antipyretics					
OVERALL/DOSE	Any					
	Any antipyretics					
	Prophylactic antipyretics					
OVERALL/SUBJECT	Any					
	Any antipyretics					
	Prophylactic antipyretics					

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
For each dose:
N = total number of subjects with the corresponding administered dose
n/% = number/percentage of subjects took the specified type of concomitant medication at least once during the considered period
For Overall/dose:
N = number of administered doses
n/% = number/percentage of doses after which the specified type of concomitant medication was taken at least once during the considered period
For Overall/subject:
N = total number of subjects with at least one administered dose
n/% = number/percentage of subjects who took the specified type of concomitant medication at least once during the considered period
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Template 24 Distribution of change from baseline in hematology and biochemistry with respect to normal laboratory ranges <Exposed Set>

				<each group >		
Laboratory parameter	**Timing**	**Range indicator at Baseline (SCR)**	**Range indicator at timing**	**N**	**n**	**%**
Alanine Aminotransferase	PI(D2)	Unknown	Unknown			
			Below			
			Within			
			Above			
		Below	Unknown			
			Below			
			Within			
			Above			
		Within	Unknown			
			Below			
			Within			
			Above			
		Above	Unknown			
			Below			
			Within			
			Above			
	PI (D8)	…				
	PI (D31)					
	PII (D32)	…				
	PII (D38)	…				
	PII (D61)	…				
	UNSCH1					
	UNSCH2					
	…	…				
Aspartate Aminotransferase	…	…				
Creatinine	…	…				
Hemoglobin						
Leukocytes (White Blood Cells)	…	…				
Neutrophil						
Platelets	…	…				

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = number of subjects with available results for the specified laboratory parameter and timing in a given baseline category
n/% = number/percentage of subjects in the specified category
Below = below the normal laboratory range defined for the specified laboratory parameter
Within = within the normal laboratory range defined for the specified laboratory parameter
Above = above the normal laboratory range defined for the specified laboratory parameter
SCR= Screening
PI (D2): Post-vaccination dose 1 at Day 2
PI (D8): Post-vaccination dose 1 at Day 8
PI (D31): Post-vaccination dose 1 at Day 31
PII (D32): Post-vaccination dose 2 at Day 32
PII (D38): Post-vaccination dose 2 at Day 38

PII (D61): Post-vaccination dose 2 at Day 61
UNSCH: Unscheduled visit for safety

Template 25 Summary of hematology and biochemistry results by maximum grade from VISIT X (DX) up to VISIT Y (DY) – post dose 1 of vaccination versus baseline <Exposed Set>

			<each group >		
Laboratory parameter	**Baseline (SCR)**	**Visit 2 to Visit X**	**N**	**n**	**%**
Hemoglobin (decrease)	Unknown	Unknown			
		Grade 0			
		Grade 1			
		Grade 2			
		Grade 3			
		Grade 4			
	Grade 0				
	Grade 1				
	Grade 2				
	Total				
Leukocytes (White Blood Cells) (decrease)	…				
Neutrophil (decrease)					
Platelets					
Alanine Aminotransferase					
Aspartate Aminotransferase					
Creatinine					

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 109 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 1010 vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 1010 vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = number of subjects with at least one available result for the specified laboratory parameter and follow-up period
n/% = number/percentage of subjects reporting at least once the laboratory event when the maximum grading over the follow-up period is considered
SCR=Screening

Template 26 Descriptive statistics table on eosinophils, basophils, and monocytes counts for subjects <Exposed Set>

			Each Group N=		
				95% CI	
Parameters	**Timing**	**Parameter**	**Value**	**LL**	**UL**
Eosinophils	SCR	n			
		Mean			
		95% CI			
		Q1			
		Median			
		Q3			
		Min/Max			
	PI(D2)				
	PI (D8)				
	PI (D31)				
	PII (D32)				
	PII (D38)				
Basophils					
Monocytes					

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = number of subjects in each group
n= Number of subjects with result available
SD=Standard Deviation
Q1, Q2 and Q3 = 1^{st} , 2^{nd} (median) and 3^{rd} quantiles
Min/Max = Minimum/Maximum
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Figure 2 Individuals results of hemoglobin levels in < *group*> <Exposed Set>

Note: This figure is shown as an example.

Template 27 Exploratory comparisons between groups in terms of percentage of subjects reported any Grade 2/3 AE and/or any fever >38.5°C and/or any vaccine-related SAE during the 7-day (Days 1-7) post-vaccination period <Exposed Set>

								Difference in percentage (Group 1 minus Group 2)			
										95 % CI	
Group 1	**N**	**n**	**%**	**Group 2**	**N**	**n**	**%**	**Difference**	**%**	**LL**	**UL**
RSV_Ld				Placebo_Ld				RSV_Ld – Placebo_Ld			
RSV_Md				Placebo_Md				RSV_Md – Placebo_Md			
RSV_Hd				Placebo_Hd				RSV_Hd – Placebo_Hd			

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = Number of subjects with the administered dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = Standardized asymptotic 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Template 28 Percentage of subjects reporting episode of spontaneous or excessive bleeding (AE of specific interest) classified by MedDRA Primary System Organ Class and Preferred Term within the 30-day (Days 1-30) post-vaccination period <Exposed Set>

		Each group N =				
					95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n***	**n**	**%**	**LL**	**UL**
At least one symptom						
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)					
	Teething (10043183)					
	Vomiting (10047700)					
General disorders and administration site conditions (10018065)	Pyrexia (10037660)					
Immune system disorders (10021428)	Seasonal allergy (10048908)					
Infections and infestations (10021881)	Conjunctivitis (10010741)					
	Otitis media (10033078)					
	Paronychia (10034016)					
	Tonsillitis (10044008)					
	Tonsillitis streptococcal (10044013)					
	Viral upper respiratory tract infection (10047482)					
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)					
	Face injury (10050392)					
	Head injury (10019196)					
Skin and subcutaneous tissue disorders (10040785)	Miliaria (10027627)					

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose
n* = number of events reported
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Template 29 Solicited and unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 30-day (Days 1-30) post-vaccination period including number of events - SAE excluded <Exposed Set>

		<each group> N =		
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n***	**n**	**%**
At least one symptom				
<each SOC>	<each PT term>			

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n* = number of events reported
n/% = number/percentage of subjects reporting the symptom at least once

Template 30 Number (%) of subjects with serious adverse events from vaccination dose 1 up to Day X/Study end including number of events reported <Exposed Set>

			<each group> N =		
Type of Event	**Primary System Organ Class**	**Preferred Term (CODE)**	**n***	**n**	**%**
SAE	At least one symptom				
	<each SOC>	<each PT term>			
Related SAE	At least one symptom				
	<each SOC>	<each PT term>			
Fatal SAE	At least one symptom				
	<each SOC>	<each PT term>			
Related fatal SAE	At least one symptom				
	<each SOC>	<each PT term>			

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = number of subjects with the administered dose
n* = number of events reported
n/% = number/percentage of subjects reporting the symptom at least once

Template 31 Listing of unscheduled safety visit from vaccination dose 1 up to Day X/study end <Exposed Set>

Group	Sub. No.	Gender	Country	Race	Age at visit (Month)	Date of sample	Date of previous safety sample	Timing	Laboratory parameter	Result	Unit	Grade
								<timepoint previous to unsched safety>	Hemoglobin			
									Platelet count			
								UNSCHED SAFETY 1	Hemoglobin			
									Platelet count			

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
Please note the listing will be generated on group blinded at D61 and D366 analysis

Template 32 Listing of SAEs reported from vaccination dose 1 up to Day X visit /study end <Exposed Set>

Group	Sub. No.	Sex	Country	Race	Age at onset (Month)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome	Seriousness criteria	Potential AESI (preferred term)

<each group>:

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
Potential AESI: AEs potentially related to spontaneous or excessive bleeding or LRTI will be identified based on the list of preferred terms described in section 11 –Annex
Please note the listing will be generated on group blinded at D61 and D366 analysis

Template 33 Listing of AEs related to LRTI and association to RSV infection from vaccination dose 1 up to Day X visit/study end <Exposed Set>

Group	Sub. No.	Age at onset (month)	Verbatim	Preferred term	MED type	Previous Dose	Day of onset	Start date	End date	Duration	Intensity	Causality	Outcome	Local RSV test result	Date of sample for local testing	Central test RSV A	Central test RSV B	Date of sample for central testing	AESI

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
AESI: AEs of Special Interest - LRTI identified by the Investigator
*AEs related to LRTI will be identified based on the list of preferred terms described in in section 12 –Annex 2

Template 34 Listing of RSV-RTI cases identified according to WHO case definitions and RSV-LRTI reported as AESI from vaccination dose 1 up to Day X visit /study end <Exposed Set>

Group	Sub. No.	Episode nb	Surveillance type	Start date of episode	End date of episode	SpO2	Respiratory rate	Local RSV test	Date of sample for local testing	Central test RSV A	Central test RSV B	Date of sample for central testing	RSV-RTI	RSV-LRTI	RSV-severe LRTI	RSV-very severe LRTI	All-cause LRTI	AESI	Hospitalization
													Yes/No	Yes/No	Yes/No	Yes/No	Yes/NO	Yes/No	Yes/No

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
Placebo-Ld = Non-active control (0.5 ml)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
Placebo-Md = Non-active control (0.15 ml)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Hd = Non-active control (0.5 ml)
AESI: AEs of Special Interest - LRTI identified by the Investigator

Template 35 Listing of AEs related to spontaneous or excessive bleeding together with hemoglobin and platelet count results from vaccination dose 1 up to Day 60 visit <Exposed Set>

Group	Sub. No.	Age at onset (month)	Verbatim	Preferred term*	Previous Dose	Day of onset	Duration	Intensity	Start date	End date	AESI	Date of sample	Laboratory parameter	Raw result	Unit
xx	xx		xx	xx	xx	xx			xx	xx		xx	Hemoglobin		
													Platelet count		
												xx	Hemoglobin		
													Platelet count		
												…			

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
*AEs related to spontaneous or excessive bleeding will be identified based on the list of preferred terms described in section 12 –Annex
AESI: AEs of Special Interest – Spontaneous or excessive bleeding identified by the Investigator

Template 36 Listing of adverse events, SAEs and solicited symptoms leading to withdrawal from the study or treatment from vaccination dose 1 up to Day X visit/study end <Exposed Set>

Group	Subject No.	Country	Gender	Race	AE Description	SAE	Causality	Outcome	Type of discontinuation

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)

Template 37 Number and percentage of subjects with anti-RSV-A neutralising antibody titre equal to or above <cut-off> and GMTs <PPS for analysis of immunogenicity at Day X>

				≥cut-off unit				GMT				
						95% CI			95% CI			
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**	**Min**	**Max**
Anti-RSV-A Neutralizing Antibody	<each group>	PRE										
		PI(D31)										
		PII(D61)										
		PII(D366)										

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
GMT = geometric mean antibody titre calculated on all subjects
N = Number of subjects with available results
95% CI = 95% confidence interval; LL = lower limit, UL = upper limit
n/% = number/percentage of subjects with titer equal to or above specified value
MIN/MAX = Minimum/Maximum
PRE= Pre-vaccination at Day 1
PI(D31) = Post-vaccination dose 1 at Day 31
PII(D61) = Post-vaccination dose 2 at Day 61
PII(D366) = Post-vaccination dose 2 at Day 366

Template 38 Vaccine response for anti-RSV-A neutralising antibody titre at each post-vaccination timepoint <PPS for analysis of immunogenicity at Day X>

			<Each Group>				
						95% CI	
Antibody	**Timing**	**Pre-vaccination status**	**N**	**n**	**%**	**LL**	**UL**
<each antibody>	PII(D61)	<128					
		≥128 - ≤256					
		>256-≤1024					
		>1024					
		Total					
	PII(D366)	<128					
		≥128 - ≤256					
		>256-≤1024					
		>1024					
		Total					

<each group>:

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
Total = all subjects with pre-and post- vaccination result available
Vaccine response defined as :
For subjects with pre-vaccination titer <128: antibody titer at post-vaccination>= 4 fold the pre-vaccination antibody titer
For subjects with pre-vaccination titer in ≥128 - ≤256: antibody titer at post-vaccination >= 3 fold the pre-vaccination antibody titer
For subjects with pre-vaccination titer in >256-≤1024: antibody titer at post-vaccination>= 2.5 fold the pre-vaccination antibody titer
For subjects with pre-vaccination titer >1024: antibody titer at post-vaccination >= 1 fold the pre-vaccination antibody titer
N = number of subjects with both pre- and post-vaccination results available
n/% = number/percentage of responders
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(D61) = Post-vaccination dose 2 at Day 61
PII(D366) = Post-vaccination dose 2 at Day 366

Template 39 Distribution of anti-RSV-A neutralising antibody titer <PPS for analysis of immunogenicity at Day X>

			Each group		
Antibody	**Timing**	**Titre**	**N**	**n**	**%**
Anti-RSV A Neutralizing Antibody	PRE	<128			
		≥128			
		≥256			
		≥512			
		≥1024			
		≥2048			
		≥4098			

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = number of subjects with available results
n/% = number/percentage of subjects with titre within the specified criterion
PRE = Pre-vaccination at Day 1
PI(D31) = Post-vaccination dose 1 at Day 31
PII(D61) = Post-vaccination dose 2 at Day 61
PII(D366) = Post-vaccination dose 2 at Day 366

Template 40 Distribution of fold of anti-RSV-A neutralising antibody titer by pre-vaccination titer category <PPS for analysis of immunogenicity at Day X>

				Each group		
Antibody	**Fold change**	**Pre-vaccination status**	**Timing**	**N**	**n**	**%**
Anti-RSV A Neutralizing Antibody	<1	<128	PI(D31)			
			PII(D61)			
			PII(D366)			
		≥128-≤256				
		>256-≤512				
		>1024-≤2048				
		>2048-≤4096				
		>4096				
		Total				
	≥1					
	≥2					
	≥2.5					
	≥3					
	≥4					
	≥6					
	≥8					
	≥10					
	≥11					
	≥12					

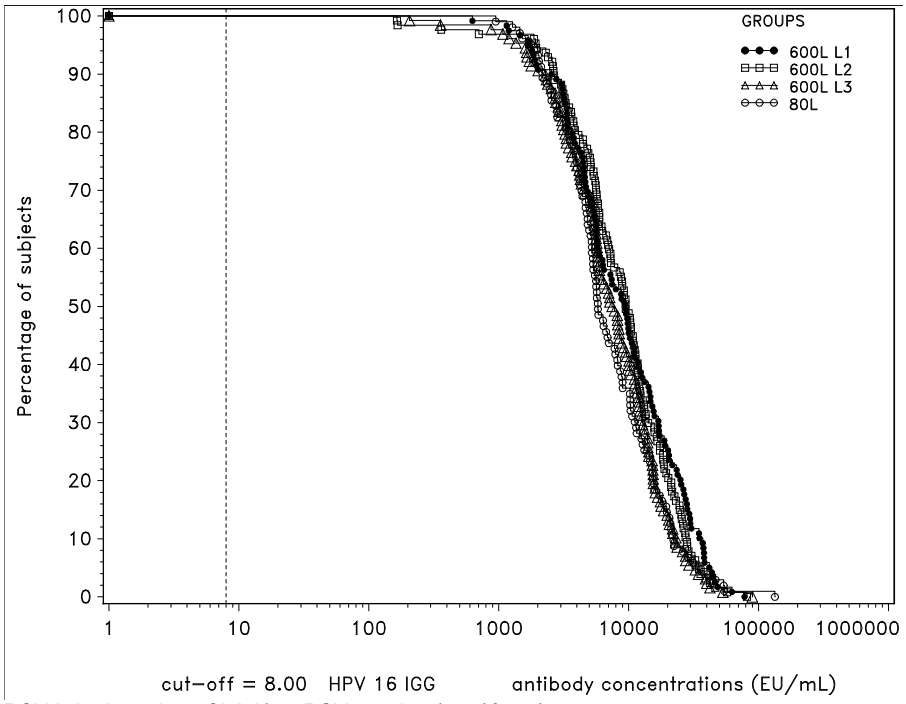
<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = number of subjects with pre and corresponding post-vaccination results available
n/% = number/percentage of subjects with titre fold change meeting the specified criterion
PI(D31) = Post-vaccination dose 1 at Day 31
PII(D61) = Post-vaccination dose 2 at Day 61
PII(D366) = Post-vaccination dose 2 at Day 366

Template 41 Geometric mean of the individual ratio of anti-RSV-A neutralising antibody titers at each post-vaccination timepoint compared to pre-vaccination with 95% CI <PPS for analysis of immunogenicity at Day X>

						GMT ratio			
								95% CI	
Group	**N**	**Time point description**	**GMT**	**Time point description**	**GMT**	**Ratio order**	**Value**	**LL**	**UL**
<*each group*>		PI(D31)		PRE		PI(D31) / PRE			
		PII(D61)		PRE		PII(D61) / PRE			
		PII(D366)		PRE		PII(D366) / PRE			

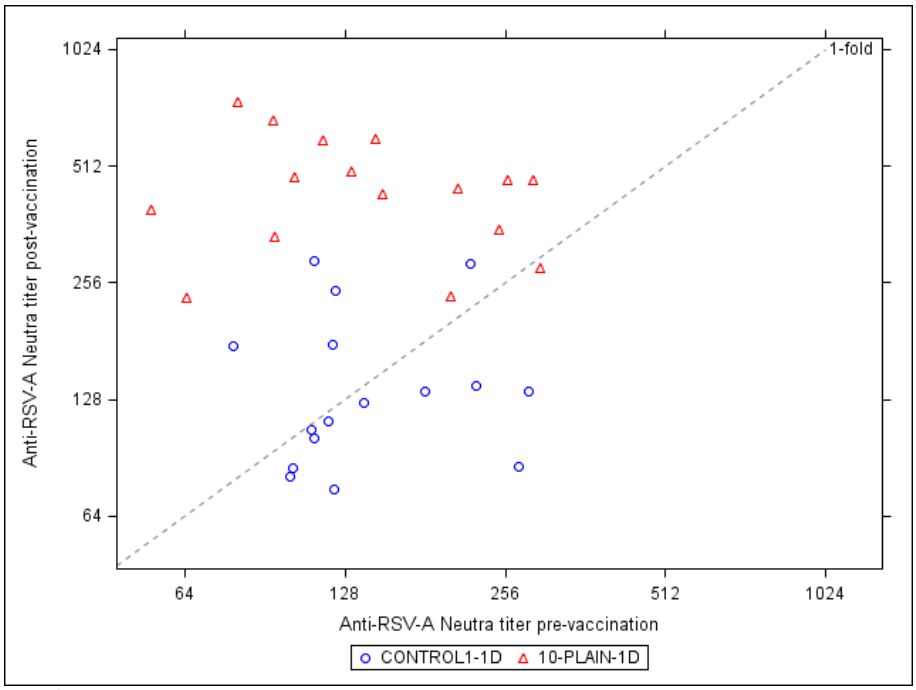
<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
GMT = geometric mean antibody titer
N = Number of subjects with available results at the two considered time points
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE= Pre-vaccination at Day 1
PI(D31) = Post-vaccination dose 1 at Day 31
PII(D61) = Post-vaccination dose 2 at Day 61
PII(D366) = Post-vaccination dose 2 at Day 366

Figure 3 Reverse cumulative distribution curves for anti-RSV-A neutralising antibody titres in each group at baseline and <D60/D365> <PPS for analysis of immunogenicity at Day X>



RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
Note: This graph is provided as an example. The same graph will be provided in colour for each time point and each assay comparing the values of the groups

Figure 4 **Individual results of anti-RSV-A neutralising antibody titre at Day <60/365> versus pre-vaccination in <each group> and Control group> <PPS for analysis of immunogenicity at Day X>**



<each group>:

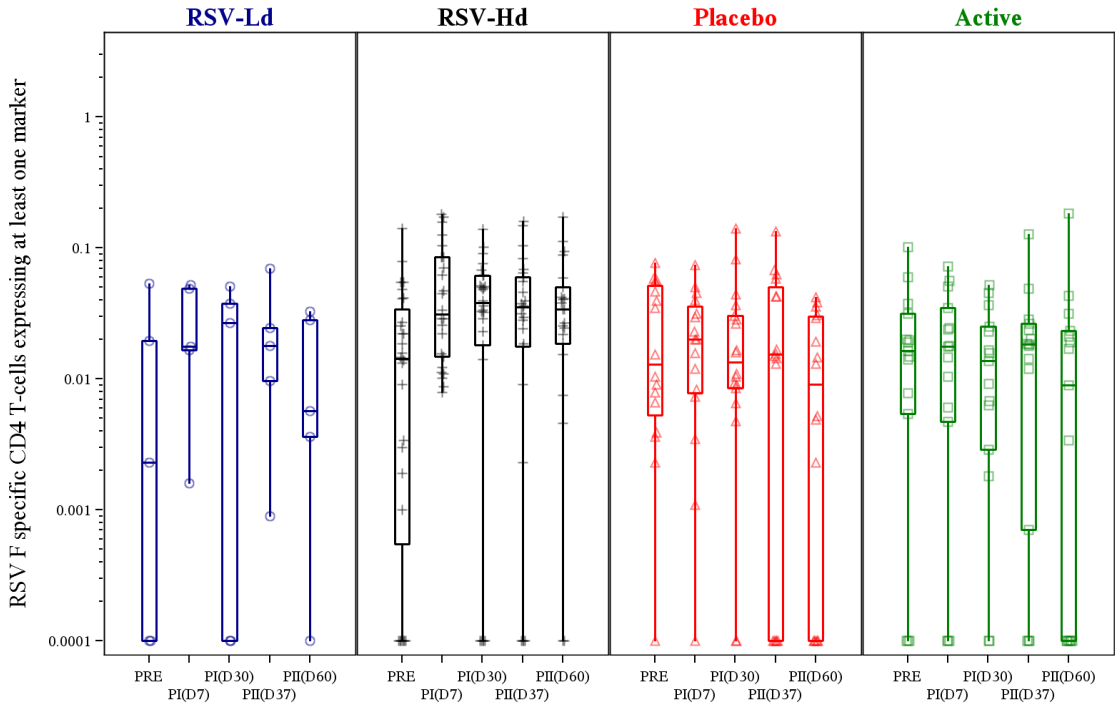
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
Note: This graph is provided as an example. The same graph will be generated for each assay and each timepoint separately (Days 61, 366):

Template 42 Descriptive statistics on the frequency of CD4+ T-cells expressing at least two markers among CD40L, IL-2, TNF-α, and IFN-γ upon stimulation with <RSV F/ N /M2-1/combined> peptide pool <PPS for analysis of immunogenicity at Day X>

				<each group>		
Stimulation	**Group**	**Timing**	**Paramter**	**Value**	**LL**	**UL**
IFNg protein – RSV F pool 15/11 Ag		PRE	n			
			NMiss			
			GM			
			Mean			
			SD			
			Min			
			Q1			
			Median			
			Q3			
			Max			
		PI(D31)				
		PII(D61)				
		PII(D366)				
IFNg protein – RSV N pool 15/11 Ag		PRE				
		PI(D31)				
		PII(D61)				
		PII(D366)				
IFNg protein – RSV M2-1 pool 15/11 Ag		PRE				
		PI(D31)				
		PII(D61)				
		PII(D366)				
Combined (F,N and M2-1)		PRE				
		PI(D31)				
		PII(D61)				
		PII(D366)				

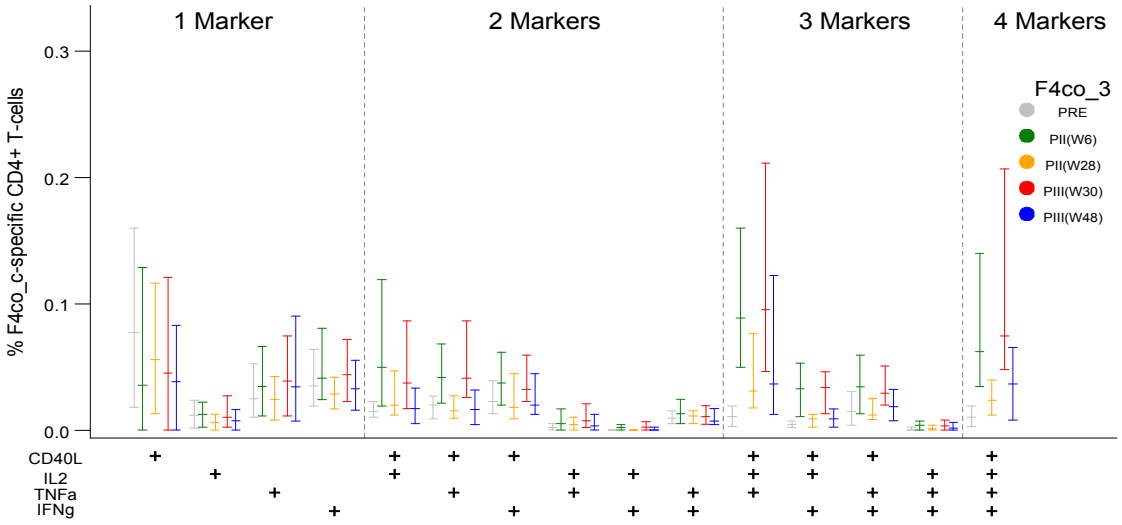
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
N = number of subjects with available results;
Nmiss = number of subjects with missing results
GM= Geometric Mean
SD = Standard Deviation
Q1,Q3 = First and third quartiles
Min/Max = Minimum/Maximum
PRE = Pre-vaccination at Day 1
PI(D31) = Post-vaccination dose 1 at Day 31
PII(D61) = Post-vaccination dose 2 at Day 61
PII(D366) = Post-vaccination dose 2 at Day 366
Please note that for combined peptide pool, we will only consider subjects who has data available for the three peptide pools

Figure 5 **Boxplots of individual data for CD4+ T-cells expressing at least two markers among CD40L, IL-2, TNF-α, and IFN-γ upon stimulation with <RSV F/ N /M2-1/combined> peptide pool <from pre-vaccination to Day 61/Day 366> <PPS for analysis of immunogenicity at Day X>**



RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
PRE= Pre-vaccination at Day 1
PI(D31) = Post-vaccination dose 1 at Day 31
PII(D61) = Post-vaccination dose 2 at Day 61
PII(D366) = Post-vaccination dose 2 at Day 366
Note: This graph is provided as an example. Template will be adapted to display the 3 RSV or 3Control groups together and the 4 timepoints: PRE, PI(D31), PII(D61) and PII(D366).
Please note – To present the information on pooled RSV and pooled Placebo after looking at the data of Day 61 analysis.

Figure 6 **Co-expression profile of the RSV <F/N/M2-1> specific <CD4+> T-cells expressing at least two markers among CD40L, IL-2, TNF-α, and IFN-γ in <RSV-Ld group> <PPS for analysis of immunogenicity at Day X>**



RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
Note: This graph is given as an example. Template will be adapted to display Q1-Median-Q3 for each combination of atleast 2 markers out of (CD40L, IL-2, TNF-α, and IFN-γ →11 combinations) for each timepoint: PRE, PI(D31), PII(D61) and PII(D366). It will be generated for each vaccine group and each RSV pool of peptides (RSV F/N/M2-1).

Template 43 Number and percentage of subjects with at least one RSV infection, RSV-RTI, RSV-LRTI, RSV-severe LRTI, RSV-very severe LRTI, All-cause LRTI and RSV hospitalization from vaccination dose 1 up to D366/D731 visit <Exposed Set>

	Group N =					Total N =				
				95% CI					95% CI	
Categories	**n****	**n**	**%**	**LL**	**UL**	**n****	**n**	**%**	**LL**	**UL**
No Infection										
RSV infection - symptomatic or asymptomatic*										
RSV-RTI										
RSV-LRTI										
RSV-severe LRTI										
RSV-very severe LRTI										
All-cause LRTI										
RSV hospitalization$										

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
RSV = ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
Placebo = Non-active control (0.5/0.15/0.5 ml pooled groups)
* Association to RSV based on central testing only for asymptomatic visit (no local test available)
$Confirmed RSV infection and hospitalized for acute medical condition
N = number of subjects in each group
n** = number of cases in each category
n/%= number/percentage of subjects reporting at least once the case
95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit
Please note – Single episode can be considered in multiple category depending on the symptom experienced

Template 44 Number and percentage of subjects reporting the RSV infection of different severity by number of events experienced between vaccination dose 1 up to D366/D731 visit <Exposed Set>

		<Each group> N=xx			
				95% CI	
Characteristics	**Categories**	**n**	**%**	**LL**	**UL**
RSV infection-symptomatic or asymptomatic*	0				
	1				
	2				
RSV-RTI	0				
	1				
RSV-LRTI	0				
	1				
	2				
RSV-Severe LRTI	0				
	1				
RSV-very severe LRTI	0				
	1				
All cause LRTI	0				
	1				
	2				
	3				
RSV hospitalization$	0				
	1				
	2				
	3				

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
RSV = ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
Placebo = Non-active control (0.5/0.15/0.5 ml pooled groups)
N = number of subjects in each group
n = number of subjects in a given category
% =100*n/N
LL, UL for percentage = Exact 95% Lower and Upper confidence limits
Please note – Single episode can be considered in multiple category depending on the symptom experienced
* Association to RSV based on central testing only for asymptomatic visit (no local test available)
$Confirmed RSV infection and hospitalized for acute medical condition

Template 45 Number and percentage of RSV infections and associated disease severity between vaccination dose 1 up to D366/D731 visit <Exposed Set>

	Group N =				Total N =			
			95% CI				95% CI	
Categories	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
RSV asymptomatic (Excluding RSV-RTI, LRTI, RSV-severe LRTI or RSV-very severe LRTI)								
RSV RTI (Excluding LRTI, RSV-severe or very severe LRTI)								
RSV LRTI (Excluding RSV-severe or very severe LRTI)								
RSV-severe LRTI (Excluding RSV-very severe LRTI)								
RSV-very severe LRTI								

RSV-Ld = Low dose ChAd155-RSV vaccine (5×10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5×10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5×10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
RSV = ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
Placebo = Non-active control (0.5/0.15/0.5 ml pooled groups)
* Association to RSV based on central testing only for asymptomatic visit (no local test available)
N = number of RSV positive samples in each group
n** = number of cases in each category
n/%= number/percentage of cases in each category
95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit
Please note – Single episode is considered in single category of highest severity based on the symptom experienced

Template 46 Number and percentage of RSV infections requiring hospitalization between vaccination dose 1 up to D366/D731 <Exposed Set>

	Group N =					Total N =				
				95% CI					95% CI	
Categories	**n****	**n**	**%**	**LL**	**UL**	**n****	**N**	**%**	**LL**	**UL**
RSV RTI*(Excluding LRTI, severe or very severe LRTI)										
RSV LRTI (Excluding severe or very severe LRTI)										
RSV-severe LRTI (Excluding very severe LRTI)										
RSV-very severe LRTI										

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
RSV = ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
Placebo = Non-active control (0.5/0.15/0.5 ml pooled groups)
N = number of RSV infections in each group
n** = number of cases in each category
n/%= number/percentage of subjects reporting at least once the case
95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit

Template 47 Descriptive statistics of viral load calculated on all qRT-PCR confirmed RSV infection episodes with varying disease severity from vaccination dose 1 up to D366/D731 <Exposed Set>

		Group N=		
Symptoms	**Parameters**	**Value**	**LL**	**UL**
RSV asymptomatic* (Excluding RSV-RTI, RSV-LRTI, RSV-severe LRTI or RSV-very severe LRTI)	n			
	GM			
	95% CI			
	SD			
	Q1			
	Median			
	Q3			
	Min/Max			
RSV RTI (Excluding RSV-LRTI, RSV-severe LRTI or RSV-very severe LRTI)				
RSV LRTI (Excluding RSV-severe or RSV-very severe LRTI)				
RSV-severe LRTI (Excluding RSV-very severe LRTI)				
RSV-very severe LRTI				
RSV hospitalization$				

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
RSV = ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
Placebo = Non-active control (0.5/0.15/0.5 ml pooled groups)
N = number of RSV infections episodes in each group
n= Number of events in each category
SD=Standard Deviation
Q1 and Q3 = 1st and 3rd quantiles
Min/Max = Minimum/Maximum
GM = Geometric mean
LL, UL for GM = Exact 95% Lower and Upper confidence limits
Total RSV viral load computed as RSV A Viral load + RSV B Viral load
* Association to RSV based on central testing only for asymptomatic visit (no local test available)
$Confirmed RSV infection and hospitalized for acute medical condition
Please note: each episode for a subject is considered to be independent. We may have multiple swab for one episode. We have considered the swab with maximum viral load from one episode for the table
Please note – Except for RSV hospitalization, single episode is considered in single category of highest severity based on the symptom experienced
Please check:- To check for cases where asymptomatic swab has been taken but the subject hasve symptoms of RTI or LRTI. In this case, asymptomatic is also considered as RSV RTI/LRTI and maximum viral load of all the episode should be considered.

Template 48 Descriptive statistics of maximum viral load per subjects based on qRT-PCR confirmed episode with varying disease severity form vaccination dose 1 up to D366/D731 <Exposed Set>

		Each Group N=		
			95% CI	
Symptoms	**Parameters**	**Value**	**LL**	**UL**
RSV asymptomatic* (Excluding RSV-RTI, RSV-LRTI, RSV-severe LRTI or RSV-very severe LRTI)	n			
	GM			
	95% CI			
	SD			
	Q1			
	Median			
	Q3			
	Min/Max			
RSV RTI (Excluding RSV-LRTI, RSV-severe or RSV-very severe LRTI)	…			
RSV LRTI (Excluding RSV-severe or RSV-very severe LRTI)	…			
RSV-severe LRTI (Excluding RSV-very severe LRTI)	…			
RSV-very severe LRTI	…			
RSV hospitalization$	…			

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
RSV = ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
Placebo = Non-active control (0.5/0.15/0.5 ml pooled groups)
N = number of RSV positive subjects in each group
n= Number of subjects in each category
SD=Standard Deviation
Q1 and Q3 = 1st and 3rd quantiles
Min/Max = Minimum/Maximum
GM = Geometric mean
LL, UL for GM = Exact 95% Lower and Upper confidence limits
Total RSV viral load computed as RSV A Viral load + RSV B Viral load
Please note: Except of RSV hospitalization, the subject has been considered only once in one of the category based on the maximum severity of event experienced
* Association to RSV based on central testing only for asymptomatic visit (no local test available)
$Confirmed RSV infection and hospitalized for acute medical condition

Template 49 Frequency of multiple respiratory pathogen for qRT-PCR confirmed RSV-RTI episodes from vaccination dose 1 up to D366/D731 visit <Exposed Set>

	Group N =				Total N =			
			95% CI				95% CI	
Categories	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Influenza Virus A/California/7/2009(H1N1)								
Adenovirus								
Human Coronavirus OC43								
Human Coronavirus 229E								
Human Coronavirus NL63								
Human Coronavirus HKU1								
Enterovirus + Rhinovirus								
Influenza Virus A								
Influenza Virus B								
Influenza Virus A (H1N1)								
Influenza Virus A (H3N2)								
Human bocavirus								
Human metapneumovirus								
Parainfluenza virus 1								
Parainfluenza virus 2								
Parainfluenza virus 3								
Parainfluenza virus 4								

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
RSV = ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
Placebo = Non-active control (0.5/0.15/0.5 ml pooled groups)
N = number of qRT-PCR confirmed RSV-RTI infection episodes in each group
n = number of episodes in a given category
% =100*n/N
LL, UL for percentage = Exact 95% Lower and Upper confidence limits

Template 50 Frequency of multiple respiratory pathogen for confirmed LRTI episodes from vaccination dose 1 up to D366/D731 visit <Exposed Set>

	Group N =				Total N =			
			95% CI				95% CI	
Categories	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Respiratory syncytial virus								
Influenza Virus A/California/7/2009(H1N1)								
Adenovirus								
Human Coronavirus OC43								
Human Coronavirus 229E								
Human Coronavirus NL63								
Human Coronavirus HKU1								
Enterovirus + Rhinovirus								
Influenza Virus A								
Influenza Virus B								
Influenza Virus A (H1N1)								
Influenza Virus A (H3N2)								
Human bocavirus								
Human metapneumovirus								
Parainfluenza virus 1								
Parainfluenza virus 2								
Parainfluenza virus 3								
Parainfluenza virus 4								

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
RSV = ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
Placebo = Non-active control (0.5/0.15/0.5 ml pooled groups)
N = number of confirmed LRTI infection episodes in each group
n = number of episodes in a given category
% =100*n/N
LL, UL for percentage = Exact 95% Lower and Upper confidence limits

Template 51 Listing of RSV-RTI cases identified according to case definitions <Exposed Set>

Group	Sub. No.	Sex	Age at episode(month)	Country	Site	Surveillance type	Episode nb	Dose	Dose nb.	Onset day	SpO2	Respiratory rate	Central test RSV A	Central test RSV B	RSV-RTI	RSV-LRTI	Severe RSV-LRTI	RSV-very severe LRTI	Hospitalization	RVP result
															Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
Placebo-Ld = Non-active control (0.5 ml)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
Placebo-Md = Non-active control (0.15 ml)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Hd = Non-active control (0.5 ml)
RSV-LM=ChAd155-RSV vaccine (low/ middle dose pooled groups)
Placebo-LM= Non-active control (0.5/0.15 ml pooled groups)
RSV = ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
Placebo = Non-active control (0.5/0.15/0.5 ml pooled groups)

Template 52 Listing of RSV-RTI requiring hospitalization and type of inpatient facility required <Exposed Set>

Group	Sub. No.	Sex	Age at episode(month)	Country	Classification of episode per WHO*	Total days hospitalized	No. of days of monitoring or nursing	No. of days of nasogastric or intravenous fluids given	No. of days oxygen administered	No. of days respiratory support given	No. of days mechanical ventilation given	No. of days child kept in paediatrics intensive care unit	RVP result	Pathogen identified in RVP
													Yes/No	

RSV-Ld = Low dose ChAd155-RSV vaccine (5×10^9 vp)
Placebo-Ld = Non-active control (0.5 ml)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5×10^{10} vp)
Placebo-Md = Non-active control (0.15 ml)
RSV-Hd = High dose ChAd155-RSV vaccine (5×10^{10} vp)
Placebo-Hd = Non-active control (0.5 ml)
RSV-LM=ChAd155-RSV vaccine (low/ middle dose pooled groups)
Placebo-LM= Non-active control (0.5/0.15 ml pooled groups)
RSV = ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
Placebo = Non-active control (0.5/0.15/0.5 ml pooled groups)
*subject will be classified per maximum severity experienced

Template 53 Number and percentage of subjects with highest associated severity of RSV infection from vaccination dose 1 up to D366/D731 visit <Exposed Set>

	Group N =					Total N =				
				95% CI					95% CI	
Categories	**n****	**n**	**%**	**LL**	**UL**	**n****	**n**	**%**	**LL**	**UL**
No Infection										
RSV asymptomatic (Excluding RSV-RTI, RSV-LRTI, RSV-severe LRTI or RSV-very severe LRTI)										
RSV RTI (Excluding RSV-LRTI, RSV-severe or very severe LRTI)										
RSV LRTI (Excluding RSV-severe or very severe LRTI)										
RSV-severe LRTI (Excluding RSV-very severe LRTI)										
RSV-very severe LRTI										

RSV-Ld = Low dose ChAd155-RSV vaccine (5×10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5×10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5×10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
RSV = ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
Placebo = Non-active control (0.5/0.15/0.5 ml pooled groups)
N = number of subjects in each group
n** = number of cases in each category
n/%= number/percentage of subjects reporting at least once the case
95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit
Please note – Single episode can be considered in single category depending on the highest severity symptom experienced

Template 54 Number and percentage of subjects reporting the RSV infection of maximum severity by number of events experienced between vaccination dose 1 up to D366/D731 visit <Exposed Set>

		Total				
					95% CI	
Characteristics	**Categories**	**N**	**n**	**%**	**LL**	**UL**
RSV asymptomatic (Excluding RSV-RTI, RSV-LRTI, RSV-severe LRTI or RSV-very severe LRTI)	0					
	1					
	2					
RSV-RTI (Excluding RSV-LRTI, RSV severe or very severe LRTI)	0					
	1					
RSV-LRTI (Excluding RSV severe or very severe LRTI)	0					
	1					
RSV-Severe LRTI Excluding RSV very severe LRTI)	0					
	1					
RSV-very severe LRTI	0					
	1					

RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
RSV = ChAd155-RSV vaccine (low/ middle/high dose pooled groups)
Placebo = Non-active control (0.5/0.15/0.5 ml pooled groups)
N = number of subjects in each group
n = number of subjects in a given category
% =100*n/N
LL, UL for percentage = Exact 95% Lower and Upper confidence limits
Please note – Single episode will be considered in single category depending on the maximum severity experienced

Template 55 Number (%) of subjects reported solicited local symptoms during the 7-day (Days 1-7) post-vaccination period following each dose and across doses <Exposed Set>

			<each group>				
						95 % CI	
Dose	**Symptom**	**Type**	**N**	**n**	**%**	**LL**	**UL**
DOSE 1	Pain	All					
		Grade 3					
	Redness (mm)	All					
		>20					
	Swelling (mm)	All					
		>20					
DOSE 2	Pain	…					
	Redness (mm)	…					
	Swelling (mm)	…					
ACROSS DOSEs	Pain	…					
	Redness (mm)	…					
	Swelling (mm)	…					

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
For each dose:
N = number of subjects with the corresponding documented dose
n/% = number/percentage of subjects reporting the type of symptom at least once following the corresponding dose
For Across dose:
N = number of documented doses
n/% = number/percentage of doses followed by at least one type of symptom
95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit
The maximum intensity of local injection site redness/swelling was coded as follows:
1: > 0.1 mm to < 5 mm
2: ≥ 5 mm to ≤ 20 mm
3: > 20 mm

Template 56 Number (%) of subjects reported solicited general symptoms during the 7-day (Days 1-7) post-vaccination period following each dose and across dose <Exposed Set>

			<each group>				
						95 % CI	
Dose	**Symptom**	**Type**	**N**	**n**	**%**	**LL**	**UL**
DOSE 1	Drowsiness	All					
		Grade 3					
		Related					
	Irritability/Fussiness	All					
		Grade 3					
		Related					
	Loss of appetite	All					
		Grade 3					
		Related					
	Fever (Axillary) (°C)	All (≥37.5)					
		>39.5					
		Related					
DOSE 2	Drowsiness	…					
	Irritability/Fussiness	…					
	Loss of appetite	…					
	Fever (Axillary) (°C)	…					
ACROSS DOSE	Drowsiness	…					
	Irritability/Fussiness	…					
	Loss of appetite	…					
	Fever (Axillary) (°C)	…					

<each group>:
RSV-Ld = Low dose ChAd155-RSV vaccine (5 x 10^9 vp)
RSV-Md = Middle dose ChAd155-RSV vaccine (1.5 x 10^{10} vp)
RSV-Hd = High dose ChAd155-RSV vaccine (5 x 10^{10} vp)
Placebo-Ld = Non-active control (0.5 ml)
Placebo-Md = Non-active control (0.15 ml)
Placebo-Hd = Non-active control (0.5 ml)
For each dose:
N = number of subjects with the corresponding documented dose
n/% = number/percentage of subjects reporting the symptom at least once following the corresponding dose
For Across dose:
N = number of documented doses
n/% = number/percentage of doses followed by at least one type of symptom
95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit
Temperatures were coded as follows:
1: ≥ 37.5 °C to ≤ 38.5 °C
2: > 38.5 °C to ≤ 39.5°C
3: > 39.5°C