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Statistical Analysis Plan

Interim Analysis Day 208, Interim Analysis Day 365 and Final Analysis

ALTERNATIVE SCHEDULE STUDY FOR VLA15, A MULTIVALENT RECOMBINANT OSPA BASED VACCINE CANDIDATE AGAINST LYME BORRELIOSIS, IN HEALTHY ADULTS AGED 18 TO 65 YEARS - A RANDOMIZED, CONTROLLED, OBSERVER-BLIND PHASE 2 STUDY.

Protocol: VLA15-202

Confidential

Sponsor: Valneva Austria GmbH

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Name	Role	Date	Signature
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List of Abbreviations

AE	Adverse Event
AESI	Adverse Event of Special Interest
Alum	Al(OH)3, Aluminum Hydroxide
ATC	Anatomical Therapeutic Chemical Classification System
B.b. s.l.	Borrelia burgdorferi sensu lato
BDRM	Blinded Data Review Meeting
DSMB	Data Safety Monitoring Board
ELISA	Enzyme-Linked Immunosorbent Assay
EOS	End of Study
GMFR	Geometric Mean Fold Rise
GMT	Geometric Mean Titer
I.M.	Intramuscular
IA	Interim Analysis
IgG	Immunoglobulin G
MedDRA	Dictionary for Regulatory Activities
mITT	Modified Intent-to-Treat
OspA	Outer surface protein A
PBS	Phosphate Buffered Saline
PP	Per-protocol
SAE	Serious Adverse Event
SBA	Serum Bactericidal Assay
SCR	Seroconversion Rate
SOP	Standard Operating Procedure
ST	Serotype
TLF	Table, Listing and Figures
WHO	World Health Organization

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1. OVERVIEW

1.1 Study Objectives

1.1.1 Primary Objective

- To investigate the immune response to VLA15 when used in an alternative immunization schedule (i.e. Month 0-2-6) at Day 208 (Month 7, i.e. 1 month after the third immunization) in healthy adults aged 18 - 65 years.

1.1.2 Secondary Objectives

Immunogenicity:

- To investigate the immune response of VLA15 when used in an alternative immunization schedule (i.e. Month 0-2-6) in healthy adults aged 18 – 65 years up to Month 18 (i.e. 12 months after the third immunization).

Safety:

- To investigate the safety profile of VLA15 when used in an alternative immunization schedule (i.e. Month 0-2-6) in healthy adults aged 18 – 65 years up to Month 18 (i.e. 12 months after the third immunization).

1.2 Study Design

This is a randomized, observer-blind (subject, sponsor and investigator/site staff involved in clinical evaluation of subjects are blinded), placebo controlled, multicenter Phase 2 study (Figure 1).

A total of approx. 250 subjects are randomized stratified by study site, age group and baseline Borrelia burgdorferi sensu lato *(B.b.* s.l.) serostatus 2:2:1 to receive 135 µg VLA15 w/ alum (100 subjects), 180 µg VLA15 w/ alum (100 subjects), or placebo (50 subjects). Selection of the two VLA15 dose groups was performed in a parallel Phase 2 study (i.e. VLA15-201), that evaluated three treatment groups (90 µg, 135 µg and 180 µg of VLA15 w/ alum) in its run-in phase prior to starting study VLA15-202. Vaccinations are administered as intramuscular (I.M.) vaccinations on Day 1 (Month 0), Day 57 (Month 2) and Day 180 (Month 6). Dosing is adjusted by injection volume (see Table 1).

Table 1: Treatment Groups and Vaccinations

Group	Treatment	Injection Volume [mL]	Days of Vaccination
135 µg	VLA15 135 µg w/ alum	0.75	1, 57, 180
180 µg	VLA15 180 µg w/ alum	1.00	1, 57, 180
Placebo	PBS	1.00	1, 57, 180

1.3 Endpoints

1.3.1 Primary Endpoint

- GMTs (Geometric Mean Titers) for Immunoglobulin G (IgG) against each Outer surface protein A (OspA) serotype ST1 to ST6, determined by Enzyme-Linked Immunosorbent Assay (ELISA) at Day 208 (Month 7).

1.3.2 Secondary Endpoints

Immunogenicity:

- GMTs for IgG against each OspA serotype (ST1 to ST6), determined by ELISA, at Day 1 (Month 0), 29 (Month 1), 57 (Month 2), 85 (Month 3), 180 (Month 6), 365 (Month 12), and 545 (Month 18).
- SCRs (Seroconversion Rate) for each OspA serotype specific IgG (ST1 to ST6), determined by ELISA, at Day 29 (Month 1), 57 (Month 2), 85 (Month 3), 180 (Month 6), 208 (Month 7), 365 (Month 12), and 545 (Month 18).
- GMFR (Geometric Mean of the fold rise) as compared to baseline for IgG against each OspA serotype (ST1 to ST6), determined by ELISA, at Day 29 (Month 1), 57 (Month 2), 85 (Month 3), 180 (Month 6), 208 (Month 7), 365 (Month 12), and 545 (Month 18).
- GMTs, SCRs and GMFRs for IgG against each OspA serotype (ST1 to ST6), determined by ELISA, at Day 1 (Month 0), 29 (Month 1), 57 (Month 2), 85 (Month 3), 180 (Month 6), 208 (Month 7), 365 (Month 12), and 545 (Month 18) stratified by age group.

Safety:

- Frequency of SAEs during the entire study;
- Frequency of related SAEs during the entire study;
- Frequency of AESIs during the entire study;
- Frequency of related AESIs during the entire study;
- Frequency of unsolicited AEs during the entire study (incl. clinically relevant laboratory parameters);
- Frequency of related unsolicited AEs during the entire study (incl. clinically relevant laboratory parameters);
- Frequency of solicited local and solicited systemic AEs within 7 days after each and after any vaccination.
- Frequency of SAEs, AESIs, solicited and unsolicited AEs during the entire study stratified by age group.

1.4 Sample Size Calculation

The sample size in study VLA15-202 has been selected to provide a sufficient safety database and for determining the optimal dose (VLA15 w/ alum 135 µg or VLA15 w/ alum 180 µg) in the alternative schedule before advancing the vaccine candidate into Phase 3. Upon completion of the study, the total number of subjects exposed to the dose used for Phase 3 trials would be approximately N=310, taken together both Phase 2 studies that are performed with VLA15 (VLA15-201 and VLA15-202). A total of N=100 subjects will have received the selected dose for Phase

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3 in the alternative immunization schedule Day 1-57-180 (Month 0-2-6). The database would thus allow 95 % confidence that a given reaction would not be observed at a higher rate than 1:(100/3) rate, i.e. 3 %, if it is not observed in this trial using selected dose and a vaccination schedule of Day 1-57-180 (Month 0-2-6).

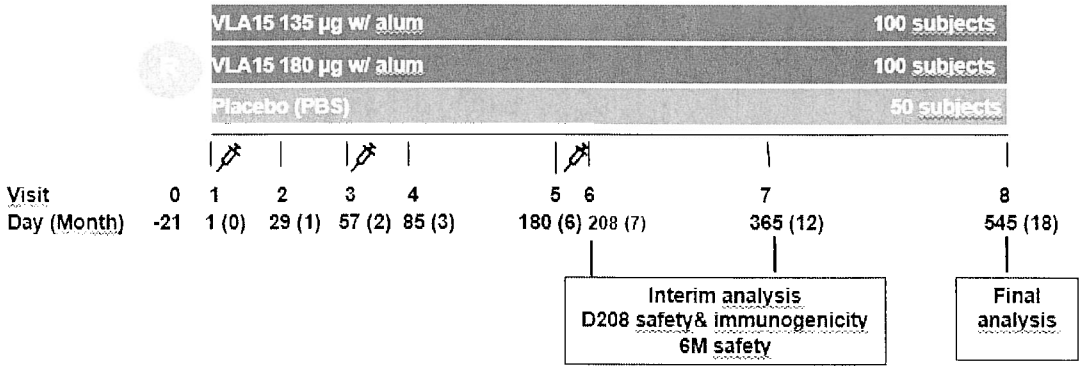
With respect to the primary endpoint, GMTs for ST1-6 specific IgGs on Day 208: In the absence of an established protective titer and without an estimate for the GMTs with a longer immunization schedule, sample size calculation is based on somewhat arbitrary differences in GMTs between VLA15 treatment groups, in order to demonstrate which titer levels could be distinguished with the proposed sample size. Titers observed in Phase 1 using an immunization schedule Day 1-29-57 were used as basis: In the 90 µg w/ alum group (i.e. the lowest possible dose group used in the present Phase 2 study), a GMT of 61.3 was observed for ST1 (i.e. the serotype with lowest titers in Phase 1) with a Standard Deviation (LOG10) of 0.51. A total of 100 randomized subjects (90 evaluable subjects assuming a 10% drop-out rate for Day 208) per group will provide 80% power at a two-sided alpha level of 5 % to distinguish a GMT of 61.3 in one treatment group from a putative higher GMT of 100.4 in another treatment group. An approximately 1.6 fold higher titer could thus be distinguished, which is considered a relevant difference.

The overall sample size of 50 subjects in the placebo group has been selected to allow for the internal validation of both safety and immunogenicity results.

1.5 Flowchart

1.5.1 Study Design

Figure 1: Study Design



1.5.2 Study Schedule

Table 2: Table of Events

Visit	V0	V1	V2	V3	V4	V5	V6	V7	V8	Early Termination
Timing Day (D) Month (M)	**D-21**	**D1 M0**	**D29 M1**	**D57 M2**	**D85 M3**	**D180 M6**	**D208 M7**	**D365 M12**	**D545 M18**	**before V8**
Time windows	**-21to -1**	**0**	**+/- 4**	**+/- 4**	**+/- 4**	**+/- 7**	**+4/-10**	**+7/- 14**	**+/- 28**	**n/a**
Visit type	in-person	in-person	in-person	in-person	in-person	in-person	in-person or remotely (2)	in-person or remotely (2)	in-person or remotely (2)	in-person or remotely (2)
Informed consent (3)	X									
Inclusion/exclusion criteria	X	X (Review)								
Vaccination delay criteria		X		X		X				
Demographic data	X									
Medical history incl. vaccinations	X	X (4)								
Concomitant medications/ treatments incl. vaccinations	X	X	X	X	X	X	X	X	X	X
Physical examination (5), ECG	X									
Vital signs (6)	X	X		X		X				
Evaluation of oral body temperature	X	X (7)		X (7)		X (7)				
HIV test [3.5 mL] (8)	X (9)									
Bb s.l. screening test [4mL] (10)	X (9)								X (11)	X (11)
Baseline serology Sample [5.0 mL] (12)	X (9)									
Serum Pregnancy test [3.5 mL] (13)	X (9)									
Urine Pregnancy test (13)		X (14)	X	X (14)	X	X (14)	X (11)	X (11)	X (11)	X (11)
Clinical chemistry [8.5 mL] (15)	X (9)		X	X (14)	X	X (14)	X (11)		X (11)	
Hematology [4 mL] (16)	X (9)		X	X (14)	X	X (14)	X (11)		X (11)	
Coagulation blood sample [4.5 mL] (17)	X (9)									
Urinalysis (18)	X		X	X (14)	X	X (14)	X (11)		X (11)	
Immunogenicity blood sample (19)		X (14) [54 mL]	X [27 mL]	X (14) [27 mL]	X [54 mL]	X (14) [27 mL]	X (11) [54 mL]	X (11), (20) [54 mL]	X (11), (20) [54 mL]	
Randomization (21)		X								
VACCINATION (22)		X		X		X				
Check for AEs following vaccination		X		X		X				
Symptom-driven physical exam (24)		X (25)	X	X (25)	X	X (25)	X (11)	X (11)	X (11)	X (11)
Inspection of injection site of previous vaccinations			X		X		X (23)			X (11), (28)
Distribute and explain Subject Diary (26)		X		X		X				
Review and collect Subject Diary			X		X		X (27)			X(27), (28)
Distribute and explain Memory Aid			X		X		X (11)	X (11)		
Review and collect Memory Aid				X		X		X (11), (27)	X (11), (27)	X(27), (28)

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Visit	V0	V1	V2	V3	V4	V5	V6	V7	V8	Early Termination
Timing Day (D) Month (M)	**D-21**	**D1 M0**	**D29 M1**	**D57 M2**	**D85 M3**	**D180 M6**	**D208 M7**	**D365 M12**	**D545 M18**	**before V8**
Time windows	**-21to -1**	**0**	**+/- 4**	**+/- 4**	**+/- 4**	**+/- 7**	**+4/-10**	**+7/- 14**	**+/- 28**	**n/a**
Visit type	in-person	in-person	in-person	in-person	in-person	in-person	in-person or remotely (2)	in-person or remotely (2)	in-person or remotely (2)	in-person or remotely (2)
AE/ SAE/ AESI Assessment (29)		X	X	X	X	X	X	X	X	X
Blood Volume [mL]	33 (13); 29.5 (30)	54.0	39.5	39.5	66.5	39.5	66.5	54.0	70.5	4.0

(1) Every effort should be made to have discontinued subjects complete the early termination visit. If the subject is unwilling to perform an ET visit or an in-person ET visit is not possible due to circumstances of the ongoing COVID-19 situation, a phone-call should be made to follow-up on Adverse Events and Concomitant Medications/ Vaccinations. Note: If a subject presents at a regular study visit and informs that it discontinues the study after this visit, the study visit is not performed as an ET visit, but is performed and documented as a regular study visit including all events that are described for the respective study visit; in addition. In this case, a Lyme borreliosis screening test is performed in addition.

(2) Visit should preferably be conducted as an in-person visit. If an in-person is not feasible due to COVID-19, e.g. travel restrictions, local recommendations, circumstances at the study site's location that prohibit an in-person visit, or if the PI believes that the subject's safety and well-being might be jeopardized with an in-person visit at the study site due to COVID-19, the visit should be conducted remotely (e.g., phone/ video call).

(3) Occurs before screening and prior to any study-related procedures.

(4) Symptoms noted at Visit 1 (prior to first vaccination) are not considered AEs but are recorded as medical history.

(5) Physical examination includes, but is not limited to assessment of general appearance and skin, head/ eyes/ ears/ nose/ throat, cardiovascular system, respiratory system, abdominal and gastrointestinal system, musculoskeletal system, neurological system and lymph nodes. If applicable, physical examination as well as ECG performed within the study VLA15-201 is acceptable for study VLA15-202 if within the specified visit window.

(6) Vital signs (Systolic and diastolic blood pressure, pulse rate while seated and at rest) to be measured prior to vaccination (if applicable) and in addition prior to discharge in case subject reports any complaints.

(7) To be performed prior to vaccination.

(8) The results of negative HIV tests that are performed up to 30 days before Visit 0 are acceptable (blood: HIV test 3.5 mL). Positive HIV test obtained by ELISA has to be confirmed by a second method (e.g. Westernblot or PCR).

(9) If applicable, HIV test, Lyme borreliosis screening test, serum pregnancy test, clinical chemistry tests, hematology tests, and coagulation tests performed at the study site within the study VLA15-201 is acceptable for study VLA15-202 if within the specified visit window. As such, if test results are available, respective blood samples do not need to be collected again for the present study. Similar, if applicable, a baseline serology sample collected at the study site within the study VLA15-201 is acceptable for study VLA15-202 if within the specified visit window.

(10) A commercially available C6 ELISA assay (VlsE ELISA) is performed (blood: 4 mL). Serum samples that are tested positive have to be verified by a confirmatory immunoblot. LB test results need to be available before randomization and remain valid for 4 weeks.

(11) For in-person study visits only.

(12) A baseline serology sample is taken at the screening visit and might be used for retrospective work-up of suspected AESIs (e.g. analysis of Rheumatoid factor (RF), anti citrullinated protein antibodies (ACPA) etc., as appropriate). (blood: 5.0 mL). If applicable, a baseline serology sample collected at the study site within the study VLA15-201 is acceptable for study VLA15-202 if within the specified visit window.

(13) In women of childbearing potential. A woman is considered of childbearing potential if fertile, following menarche and until becoming post-menopausal unless permanently sterile. A woman who is considered of non-childbearing potential must be e.g. surgically sterilized for at least 3 months prior to Visit 1 (e.g. by hysterectomy,

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bilateral salpingectomy, bilateral oophorectomy, trans cervical sterilization), or postmenopausal for at least one year prior to Visit 1.
For serum pregnancy test: tests that were performed in study laboratory within visit window and where results are available at study visit are acceptable.

(14) At vaccination visits, all samples have to be obtained before vaccination. Pregnancy results and urinalysis must be available before vaccination.
(15) Creatinine, sodium, potassium, calcium, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase, bilirubin, CRP (blood: 8.5 mL). Test results from this study visit do not need to be available before vaccination. Tests that were performed in study laboratory within visit window and where results are available at study visit are acceptable.
(16) Hemoglobin, hematocrit, erythrocyte count, white blood count, platelets (EDTA blood: 4 mL). Test results from this study visit do not need to be available before vaccination. Tests that were performed in study laboratory within visit window and where results are available at study visit are acceptable.
(17) Prothrombin time, aPTT, fibrinogen (blood: 4.5 mL). Tests that were performed in study laboratory within visit window and where results are available at study visit are acceptable.
(18) Standard urine dipstick: pH, specific gravity, leucocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes. Tests that were performed in study laboratory within visit window and where results are available at study visit are acceptable.
(19) Blood is collected for immunogenicity testing by ELISA and for supportive functional antibody analysis by serum bactericidal assay or animal protection models..
(20) In case subject visit is performed remotely, if the COVID-19 situation allows, the immunogenicity sample should be taken in an unscheduled visit as early as possible, within a maximum time window of 2 months after the remote study visit.
(21) To be performed by study staff otherwise not involved with study conduct to keep the study observer-blinded (i.e. unblinded study staff).
(22) Study vaccine has to be administered by study staff otherwise not involved with study conduct to keep the study observer-blinded. Subjects should be observed for at least 30 min after vaccination for treatment of any immediate reactions.
(23) In case subject visit is performed remotely ask subject to describe the appearance of the injection site, to understand whether there is any residual local reaction. If yes, document as AE.
(24) Except for Visit 1: Body systems for which the subject reports any symptoms should be evaluated and relevant abnormal findings documented as AEs. At vaccination days the symptom-driven physical exam is to be performed before administration of the vaccination.
(25) If subject has any complaints after vaccination, a second symptom-driven physical examination will be performed by the investigator prior to discharge. Subject will only be discharged if in the opinion of the investigator no further concerns exist.
(26) At Visit 1, the subjects are provided with thermometer and measuring tapes. The subjects assess solicited local and systemic AEs themselves over a period of seven consecutive days after each vaccination.
(27) In case visit is performed remotely ask subject to read through diary/memory aid during call, or to mail or email pictures of the diary/memory aid entries to aid the discussion. Instruct subject to continue using the diary/memory aid for documenting AEs and to bring the diary/memory aid along for the next study visit, if applicable.
(28) Unreturned Subject Diaries/ Memory Aids should be collected at the Early Termination Visit. For Early Terminations prior to Visit 6, the previous injection site should be inspected.
(29) AEs, SAEs and AESIs are collected throughout study conduct. Symptoms noted at Visit 1 (prior to vaccination) are not considered adverse events but will be recorded as medical history.
(30) Women of non-childbearing potential and male subjects.

2. GENERAL CONSIDERATIONS

2.1 Conduct of Analysis

Two interim analyses on safety and immunogenicity data are performed. The first interim analysis (IA D208) is performed once all subjects have completed Visit 6 (i.e. Day 208/Month 7, four weeks after the last vaccination) covering safety and immunogenicity data up to Visit 6 including the primary Endpoint. The second interim analysis (IA D365) will be performed once all subjects have completed Visit 7 (i.e. Day 365, six months after the last vaccination), covering all safety data collected up to this time point. Final analysis of safety and immunogenicity data is performed once all subjects have completed the follow-up period up to Visit 8 (i.e. Month 18, 12 months after the last vaccination).

2.2 Statistical Software and Quality Control

All statistical analyses are performed using SAS® version 9.3 or higher. Tables, figures and data listings are generated in Microsoft® Word® as well as PDF® format.

Quality control of SAS® programs include a review of the whole process of result generation:

- Review of all analysis SAS® programs
- Review of SAS® log for errors, warnings and other notes that could indicate mistakes in the programs
- Review of all tables, listings and figures for completeness and correctness

As additional quality control measure, independent re-programming are performed as described in SOP SAS04.

2.3 Applicable Standard Operating Procedures

The applicable Standard Operating Procedures (SOPs) of [redacted] for this study are:

STAT03	Statistical Analysis Plan
STAT04	Interim Analysis
STAT05	Randomization and Unblinding
STAT06	Data Review Meeting
STAT07	Report Writing
SAS01	SAS General Principles
SAS04	Handling of Statistical Analyses
SAS06	CDISC- ADaM
SAS07	CDISC - Quality Control

2.4 Blinding and Randomization

Subjects are allocated to treatment groups via the EDC system. Eligible subjects are randomized 2:2:1 stratified by study site, age group and baseline *B.b.* s.l. serostatus according to a randomization list created by a statistician. Date and time of enrolment are defined as the time point at which the subject is registered in the system and the subject is allocated to a treatment group.

The study is an observer-blinded trial, which will be conducted in a blinded manner for the study investigators, the sponsor including laboratory personnel, and the subjects. Only designated study staff who randomize subjects into treatment groups and perform preparation and application of the vaccinations is unblinded. These unblinded study staff members are not involved with trial conduct otherwise. An overview of persons who are unblinded is provided below:

Unblinded:

- Designated study site staff who randomize subjects to treatment groups and are concerned with IMP handling (i.e. perform preparation and administration of the study vaccine, maintain drug dispensing log detailing the dates and quantities of IMP administered to each subject). These unblinded study staff members are not involved with trial conduct otherwise.
- CRAs responsible for monitoring of IMP handling and related data for verifying drug accountability during the study and performing overall drug accountability.
- Statistical team at the CRO performing statistical analyses for generation of safety data tables for the Data Safety Monitoring Board (DSMB).
- DSMB members.

Blinded:

- Study participants
- Investigators and other study staff involved in general study conduct and safety assessments.
- All other CRAs (responsible for monitoring study data apart from IMP handling/drug accountability).
- All other sponsor and CRO staff including laboratory personnel at the sponsor's labs for immunogenicity assessments.

The study sponsor and trial statisticians are unblinded at the time of the Interim Analysis (IA D208), after the respective database snapshot has been performed.

2.5 Descriptive Analyses

In general, descriptive analyses of continuous variables (summary statistics) are described with the number of non-missing observations, arithmetic mean, standard deviation (±SD), median, quartiles (Q1 and Q3) and range (minimum and maximum).

Descriptive analyses of continuous immunogenicity variables (i.e. tables for the GMT and GMFR) are described with the number of non-missing observations, geometric mean, confidence intervals for the geometric mean, standard deviation of logarithmic values, median, quartiles (Q1 and Q3) and range (minimum and maximum).

Categorical variables (frequency statistics) are described with the number of non-missing observations and percentages (%). Percentages are calculated on the total number of non-missing observations, if not stated otherwise.

2.6 Center and Country Effect and Stratification Variables

As all centers are located in the US no country effect has to be considered. The center effect is taken into account and estimated by adding study site in ANOVA models. Also other covariates are used as described in Section 5.3.

Furthermore, selected tables are presented by stratification factors baseline *B.b.* s.l. serostatus and age group. A separate column in the List of Tables (Section 7) defines which tables are stratified by baseline *B.b. s.l.* serostatus at Visit 0 and by age group.

2.7 Handling Missing Data

Generally, missing values of immunogenicity variables are not imputed, and the analyses are limited to observed values. For missing data in Adverse Event (AE) evaluation (e.g. missing information if serious, medically attended, about severity or causality) a worst case approach is applied. In case of missing assignment to solicited or unsolicited, this AE is neither counted in tables for solicited AEs nor in tables for unsolicited AEs but in tables for all AEs.

2.8 Protocol Deviations

A Blind Data Review Meeting (BDRM) is conducted prior to database snapshot for IA D208 on all available data to review protocol deviations, to discuss specific unforeseeable data issues, and to allocate the subjects to the analysis sets. During the review of the protocol deviations, two classifications are performed:

1. Protocol deviations are classified as "not relevant" or "relevant" deviations, based on the potential influence on the immunogenicity analysis. Protocol deviation classification are made on a case by case decision. "Relevant" protocol violations that lead to exclusion from the PP Population (see Section 2.10.3) include the following but are not limited to:
    - Subjects who received less than three vaccinations (Day 1, 57, 180)
    - Subjects who received the wrong study medication
    - Subjects with substantial time window violations on vaccination visits (Visits 3 and 5)
        - Visit 3 (Day 57): +/- 10 days
        - Visit 5 (Day 180): +/- 14 days
    - Subjects who fulfill exclusion criteria 2, 8, 9 and 14
    - Subjects with other deviations that may affect immune response

    Protocol violations classified as "relevant" are described in the CSR (Clinical Study Report).

2. Protocol deviations according to the GCP (E3) definition are outlined in the CSR.

The associated decisions are documented and approved in the BDRM Report.

2.9 Exclusion of Time Points in the Per-Protocol Analysis

In the PP analysis immunogenicity samples that are outside the predefined time windows described below are excluded at the respective visit (exclusion of subjects from the PP Population is described in Section 2.8):

- Visit 2 (Day 29): +/- 7 days
- Visit 3 (Day 57): +/- 10 days
- Visit 4 (Day 85): +/- 10 days
- Visit 5 (Day 180): +/- 14 days
- Visit 6 (Day 208): +/- 14 days
- Visit 7 (Day 365): +/- 21 days
- Visit 8 (Day 545): +/- 28 days

2.10 Analysis Populations

2.10.1 Safety Population

The safety population includes all subjects who entered into the study and received at least one vaccination. The safety population is used for all safety analyses. All analysis based on the safety population are carried out using the actual treatment received. Subjects with vaccination errors are allocated to a treatment group for safety analyses after a case-by-case review in the BDRM; applying the following general rules:

- If a subject received different VLA15 doses at different visits, the minimum dose received decides the treatment group of the subject for safety analysis;
- If a subject received both VLA15 and placebo, the subject is analyzed in a VLA15 group (dose decided by the first rule)

2.10.2 Modified Intent-to-Treat (mITT) Population

The mITT population is defined to include all subjects enrolled who received at least one vaccination. Subjects are analyzed according to the treatment group they had been allocated to, rather than by the actual treatment, they received. If the Safety and mITT Population are identical (i.e. no mis-randomization) the analysis is performed for the Safety Population and the mITT Population together, labeled with "Safety/mITT Population".

2.10.3 Per-Protocol (PP) Population

The Per-Protocol (PP) Population excludes all subjects that fulfilled at least one of the relevant protocol deviation criteria as defined in in Section 2.8. The PP Population is defined in the BDRM that is conducted before IA Day 208. A second DRM is planned prior to the final analysis to review protocol deviations after this interim analysis.

2.11 Subject Data Listings

All vaccinated subjects are included in the listings if not stated otherwise. Data listings include the subject number as identifier (and parameter and/or visit if available) and are sorted by subject ID (and parameter and/or visit if available). A column showing the treatment group is shown in all listings. Additionally, a column indicating if a subject is in the PP Population is shown in all immunogenicity listings.

2.12 Columns in Tables

All tables are presented by treatment group, i.e. every treatment group is shown in a separate column. Tables described at overall study information (Section 3), baseline evaluation (Section 4) and safety analysis (Section 6) show one column per treatment group (i.e. 135 µg, 180 µg and Placebo) a column for the two VLA15 treatment groups pooled and a column for all subjects pooled. Tables defined in Section 5 show one column for each treatment group.

2.13 Medical Coding

Adverse events, medical history and concomitant procedures are coded using Medical Dictionary for Regulatory Activities (MedDRA) and concomitant medications and vaccination history are coded using WHO Drug Reference List and Anatomical Therapeutic Chemical (ATC) Classification System as described in the Coding Guideline.

Events reported in the adverse events log are combined with solicited symptoms from the diary section. Solicited symptoms are coded as described in Section 6.1.2.2.

2.14 Changes in the Conduct of the Study or Planned Analysis

All statistical analyses are performed according to the CSP. In case of analyses deviate from SAP, all changes are described and justified in the CSR.

2.15 Effect of COVID-19

In particular, instead of in-person visits, visits can be conducted remotely (e.g., phone/video call) for time points after Visit 5 (Day 180) as described in the CSP version 3.0. It is tabulated and listed whether visits were performed remotely due to COVID-19.

Further, it might be possible that the source data verification (SDV) is not fully performed for all entered data for IA D208 and IA D365. In case such PDs are added at the rescheduled SDV, these PDs are reviewed prior the IA D365 Analysis. Furthermore, subject diaries might be not returned at the time point of the IA D208 and not all solicited AEs are reported in the database. Therefore, the solicited AE analyses is repeated in the IA D365. For unsolicited AEs, AEs up to Day 208 and up to Day 365 are analyzed in separate tables.

3. OVERALL STUDY INFORMATION

Analyses are performed for the Safety Population, mITT Population and PP Population. If the Safety and mITT Populations are identical, the analysis is performed for the Safety Population and the mITT Population together, labeled "Safety/mITT Population".

3.1 Data Points

The following information is analyzed descriptively and corresponding details on the subject level are provided in data listings:

- Subject overview
- Screening failures and reasons
- Randomization
- Violated inclusion/exclusion criteria (will only be listed)
- Study vaccination details
- Visits log
- Attendance status and early termination details
- Protocol deviations
- Visits performed remotely due to Covid-19

3.2 Definition

- Screening failures are defined as subjects not eligible for study enrolment.
- For IA D208, early terminations up to Day 208 are analyzed. This is stated in the table header.
- For IA D365, early terminations up to Day 365 are analyzed. This is stated in the table header.
- Early terminations up to Day 208 are detected by calculating the last attended scheduled visit for subjects with visit attendance status "early termination" on the End of Study (EOS) page in the eCRF. The derivation of early terminations up to Day 365 is determined analogously.
- For Final Analysis, all early terminations are analyzed.

4. BASELINE EVALUATION

Baseline data is presented for the Safety, mITT and PP Population. If the Safety and mITT Population are identical (i.e. no mis-randomization) the analysis is performed for the Safety Population and the mITT Population together, labeled with "Safety/mITT Population".

4.1 Data Points

The following information is analyzed descriptively and corresponding details on the subject level are provided in data listings:

- Demographic Information (gender, childbearing potential, age [years], race, body height [cm], body weight [kg] and body mass index [kg/m^2])
- Physical examination (is only listed)
- ECG
- Vaccination history
- Medical History
- Prior/Concomitant Medications

- Prior/Concomitant Procedures
- HIV (is only listed)

4.2 Definitions

- Baseline for non-immunogenicity analyses is defined as Visit 0.
- Body height is analyzed in centimeters (cm). Body height documented in inch (in) is converted to cm using the following rule: height [cm] = height [in] × 2.54.
- Body weight is analyzed in kg. Body weight documented in pounds (lbs) is converted to kilogram [kg] using the following rule: weight [kg] = weight [lbs] × 0.45359237
- The Body Mass Index [kg/m^2] is calculated as (kg/cm^2) × 10,000
- Medications stopped prior (<) to Day 1 (Visit 1) are considered prior medications, all other medications are considered to be concomitant. Medications with a missing or incomplete end date where it cannot clearly be decided if the end date was before or after Day 1 (Visit 1) are considered concomitant.
- Procedures stopped prior (<) to Day 1 (Visit 1) are considered prior procedures, all other procedures are considered to be concomitant. Procedures with a missing or incomplete stop date where it cannot clearly be decided if the stop date was before or after Day 1 (Visit 1) are considered concomitant.
- For IA D208, all medications and procedures started up to Day 208 are analyzed. This is stated in the table header.
- For IA D365, all medications and procedures started up to Day 365 are analyzed. This is stated in the table header.
- Medications/procedures are considered to have started up to Day 208 if the start date of the medication/procedure is before or on study Day 208 (Visit 6). In case of an incomplete start date where it cannot clearly be decided if the medication/procedure started up to Day 208 or not, the medication/procedure is considered to have started up to Day 208. The derivation of medications/procedures started before or on Day 365 are determined analogously.
- For Final Analysis, all medications and procedures are analyzed.
- Medical history not stopped prior (<) to informed consent is considered ongoing at study entry, Entries with a missing or incomplete stop date where it cannot clearly be decided if the stop date was before or after informed consent are considered ongoing at study entry.

5. IMMUNOGENICITY ANALYSIS

All tables and figures are provided for the PP Population. Specific tables and figures are repeated for the mITT Population and are also repeated stratified by baseline *B.b.* s.l. serostatus and by age group as marked in the list of TLFs in Section 7. Listings include all subjects from the mITT Population. IA D208 covers time points Day 1 (Visit 1), Day 85 (Visit 4) and Day 208 (Visit 6) for ELISA and Day 1 (Visit 1) and Day 208 (Visit 6) for SBA. No immunogenicity analysis is performed for IA Day 365. All immunogenicity time points for ELISA and available time points for SBA (Day 1, Day 208, Day 365 (if results available), Day 545 (if results available) are analyzed in the final analysis.

5.1 Data Points

5.1.1 Tables and Listings

The following information is analyzed separately for ELISA and functional antibody testing (SBA), if not stated otherwise. Corresponding details on subject level are provided in data listings:

Summary tables for categorical immunogenicity variables:

- Immunogenicity blood sample availability by time point
- ELISA:
  - Immunogenicity results/serostatus (report concentration/negative;) by OspA serotype by time point (including baseline serology status)
  - Subjects by OspA specific IgG serostatus at baseline
  - SCRs for OspA specific IgG titer by visit
    - each OspA serotype (separate tables for ST1 to ST6)
    - all six OspA serotypes combined
    - ST1 and ST2 combined
  - Subjects reaching an at least 4-fold or a 10- fold increase from Day 1 (Visit 1) in OspA-specific titer by visit (separate tables for each OspA serotype ST1 to ST6)
- SBA:
  - Immunogenicity results/serostatus (SBA: positive/negative/pre-dilution) by OspA serotype by time point (including baseline serology status)
  - Subjects by SBA serostatus at baseline
  - SCRs for SBA titer by visit
    - each OspA serotype (separate tables for ST1 to ST6)
    - all six OspA serotypes combined
    - ST1 and ST2 combined

Summary tables for continuous immunogenicity variables are provided:

- ELISA:
  - GMTs for IgG against each OspA serotype (ST1 to ST6) by visit (separate table for each OspA serotype).
  - GMFRs as compared to Visit 1 (Day 1) for IgG against each OspA serotype by visit (separate tables for each OspA serotype)
- SBA:
  - GMTs for SBA titer against each OspA serotype (ST1 to ST6) by visit (separate table for each OspA serotype).
  - GMFRs as compared to Visit 1 (Day 1) for each OspA serotype by visit (separate tables for each OspA serotype)

Correlation Analysis:

- ELISA:
  - Correlation analyses for each OspA Specific IgG titer with each other OspA specific IgG titer, respectively, at Day 208 (15 comparisons in total)
- SBA:
  - Correlation analyses for each SBA titer with each other SBA titer, respectively, at Day 208 (15 comparisons in total)
- Correlation analysis ELISA vs. SBA:
  - For each serotype separately, correlation analysis for ELISA titers vs. respective SBA titers at Day 1, Day 208, Day 365 (SBA measurement only performed if deemed meaningful based on analysis of ELISA data) and Day 545 (SBA measurement only performed if deemed meaningful based on ELISA data), (pooled VLA15 groups and for each VLA15 group separately).
  - For each serotype separately, the ELISA threshold above which 50, 60, 70, 80 or 90 % of subjects are SBA seroconverted (for all VLA15 groups pooled and for each VLA15 group separately, all serotypes are shown in the same table).

Inferential analysis will be performed as described in Section 5.3. Details are specified in Section 7.

5.1.2 Figures for ELISA and SBA

- ELISA:
  - Bar charts: OspA-specific IgG antibodies (GMT) including standard deviation vs OspA serotypes by treatment group for each time point separately (y-axis: GMT; x-axis: OspA STs per treatment groups)
  - Bar charts: OspA-specific antibodies (GMT) including standard deviation by serotype over time for treatment groups 135 µg and 180 µg separately (y-axis: GMT; x-axis: serotypes)
  - Bar charts: OspA-specific antibodies (GMT) including standard deviation by serotype, baseline B.b. s.l. serostatus and age group at Day 208 for treatment groups 135 µg and 180 µg separately (y-axis: GMT; x-axis: serotypes)
  - Bar charts Seroconversion Rate:
    - Seroconversion Rate by OspA-specific IgG and treatment group (for each time point separately, y-axis: percentage of subjects, x-axis: OspA STs per treatment groups)
    - Seroconversion Rate for all OspA-specific IgG serotypes combined over time vs. treatment group (y axis: percentage of subjects, x axis: visits per treatment groups)
    - Seroconversion Rate for OspA-specific IgG serotypes ST1 and ST2 combined over time vs. treatment group(y axis: percentage of subjects, x axis: visits per treatment groups)
  - Line charts (y-axis: GMT, x-axis: study days): OspA-specific IgG antibodies (GMT) over time vs. treatment group for each ST1-6 separately

- Line charts (y-axis: GMT, x-axis: study days): OspA-specific IgG antibodies (GMT) over time vs. serotype for each treatment group separately
- For each OspA serotype and treatment group: Reverse cumulative distribution curves for percentage of subjects reaching certain OspA specific IgG titer (for each treatment group and each serotype separately)
- Scatter plots representing the correlation between OspA IgG antibody GMTs for each combination of two different OspA serotypes for all treatment groups pooled.

- SBA:
  - Bar charts: SBA titer (GMT) including standard deviation vs OspA serotypes by treatment group for each time point separately (y-axis: GMT; x-axis: OspA STs per treatment groups)
  - Bar charts: SBA titer (GMT) including standard deviation by serotype over time for treatment groups 135 µg and 180 separately µg (y-axis: GMT; x-axis: serotypes)
  - Bar charts: SBA titer (GMT) including standard deviation by serotype, baseline B.b. s.l. serostatus and age group at Day 208 for treatment groups 135 µg and 180 separately µg (y-axis: GMT; x-axis: serotypes)
  - Bar Charts: SBA Seroconversion Rate by OspA serotype and treatment group (for each time point separately, y-axis: percentage of subjects, x-axis: OspA STs per treatment groups) as well as for ST1-ST6 combined and ST1+ST2 combined
  - Line charts (y-axis: GMT, x-axis: study days): SBA titer (GMT) over time vs. treatment group for each ST1-6 separately
  - Line charts (y-axis: GMT, x-axis: study days): SBA titer (GMT) over time vs. serotype for each treatment group separately
  - For each OspA serotype and treatment group: Reverse cumulative distribution curves: percentage of subjects vs. SBA titer (for each treatment group and each serotype separately)
  - Scatter plots representing the correlation between SBA titer for each combination of two different OspA serotypes for all treatment groups pooled
- ELISA and SBA:
  - Scatter plots representing the correlation between ELISA and SBA titer for each OspA serotype at Day 1, Day 208, Day 365 and Day 545 (if measurement performed)..

5.2 Derivations and Definitions

- Baseline for immunogenicity analysis is defined as Visit 1.
- A subject reaches a 4-fold increase in ELISA if the value at a certain visit after Day 1 is at least 4-times higher than the value at Day 1. A 10-fold increase is derived analogously.

5.2.1 ELISA

- Baseline OspA IgG seropositive/seronegative for ELISA is defined as follows:

- ELISA samples scored as "negative" or below the quantitation limit of the ELISA (40 U/mL) is replaced by 20 U/mL.
- Subjects with Day 1 (Visit 1) values below the quantitation limit of the ELISA (40 U/mL) and samples scored as "negative" (i.e. replaced by 20 U/mL) are considered "baseline OspA IgG seronegative" for each serotype.
  - Subjects with Day 1 (Visit 1) values of 40 U/mL and above are considered "baseline OspA IgG seropositive" for each serotype.

- Seroconversion for ELISA is defined as:
  - For subjects that are seronegative at Visit 1 (baseline): a change from seronegative at Visit 1 to seropositive (i.e. antibody titer of ≥40 U/mL) at a certain time point.
  - For subjects that are seropositive Visit 1 (baseline): a ≥ 4-fold rise in IgG antibody titer from Visit 1.
  - In case of missing values (missing at baseline or current time point), seroconversion is not calculated.

5.2.2 SBA

- SBA samples scored as "negative" or below the quantitation limit of the SBA [redacted] SBA [redacted] and Serotype [redacted] SBA [redacted] are replaced with half of the quantitation limit (ST1, 2, 4, 5, 6 by SBA titer of [redacted] and [redacted]
- SBA results for
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- Definition of SBA seronegative and seropositive:
  - SBA samples scored as "negative" in the data source or below the quantitation limit are considered as "seronegative" for each serotype
  - [redacted]
- Seroconversion for SBA is defined as
  - For subjects that are seronegative at Day 1 (Visit 1): a change from baseline seronegative to seropositive at a certain time point.

- [redacted]
- In case of missing values (missing at baseline or current time point), SBA seroconversion is not calculated

- The ELISA threshold is defined as the minimum of the ELISA titer for which 50, 60, 70, 80 or 90 % of subjects are SBA seroconverted

5.3 Inferential analysis

- In general, all statistical tests comparing treatment groups in the immunogenicity analysis include the VLA15 135 µg group, the 180 µg group and the placebo group.
- ANOVAs with factors treatment group and study sites are performed for the comparison between the VLA15 135 µg, 180 µg and Placebo group for each OspA ST1 to ST6 respectively. The primary immunogenicity analysis is the ANOVA for ELISA GMTs at Day 208 in the PP Population
- This is done using log10 transformed data and taking the anti-log of the resulting point estimates for the least squares means, least squares means differences and the corresponding 95 % CIs. Tukey's HSD test is applied for pair-wise comparisons.
- ELISA:
  - ANOVAs are performed for GMTs as well as GMFRs at all available time points.
  - Sensitivity analyses for GMTs and GMFRs are performed for ANOVAs with factors study site, treatment group, study site*treatment group, age, and baseline *B.b.* s.l serostatus for Day 85 and Day 208, Day 365 and Day 545.
  - Summary tables for the OspA- specific IgG titer against each OspA serotype and summary tables for the geometric mean fold-rise against each OspA serotype are amended by an overall test (Kruskal-Wallis).
  - SCRs are compared using Fisher-Freeman-Halton tests, a significant overall test is amended by pair-wise tests (Fisher's exact test). The same is done for rates of subjects reaching a 4- or 10- fold Increase from Day 1 (Visit 1) in ELISA titer.
  - A non-parametric correlation analysis (Spearman) between OspA IgG antibodies GMTs for each combination of two different OspA specific IgG types are performed for Day 208, VLA15 treatment group separately as well as for all VLA15 treatment groups together (pooled analysis).

- SBA:
  - ANOVAs are performed for GMTs at all available time points.
  - Sensitivity analyses for GMTs are performed for ANOVAs with factors study site, treatment group, study site*treatment group, age, and baseline *B.b.* s.l serostatus.
  - Summary tables for the IgG titer against each OspA serotype and summary tables for the geometric mean fold-rise against each OspA serotype are amended by an overall test (Kruskal-Wallis).

- SCRs are compared using Fisher-Freeman-Halton tests, a significant overall test is amended by pair-wise tests (Fisher's exact test).
- A non-parametric correlation analysis (Spearman) between SBA GMTs for each combination of two different OspA serotypes are performed for Day 208, VLA15 treatment group separately as well as for all VLA15 treatment groups together (pooled analysis).
-

- ELISA and SBA correlation:
  - A non-parametric correlation analysis (Spearman between ELISA and SBA titer for each OspA serotype at Day 1, Day 208, Day 365 and Day 545 (if measurement performed).

6. SAFETY ANALYSIS

Safety Analysis is performed for the Safety Population. Data from the unscheduled visits is only listed but not tabulated.

6.1 Adverse Events

Solicited adverse events are documented in the subject diary. Serious solicited AEs are also reported in the Adverse Event Log. Unsolicited adverse events are documented in the AE log.

6.1.1 Data Points

The following information is analyzed descriptively and corresponding details on the subject level are provided in data listings:

- Adverse Events Overview (solicited and unsolicited AEs)
- Adverse Events Overview (solicited and unsolicited AEs) stratified by age group and baseline b.b. s.l. serostatus
- Serious Adverse Events (solicited and unsolicited) by SOC and PT
- Medically attended Adverse Events (solicited and unsolicited) by SOC and PT
- Adverse Events (solicited and unsolicited) leading to withdrawal from further vaccination by SOC and PT
- Adverse Events (solicited and unsolicited) leading to withdrawal from study by SOC and PT
- Non-Serious solicited or unsolicited AE by SOC and PT for PTs with Frequency >5 % in any treatment group
- Non-Serious solicited or unsolicited AE by SOC and PT for PTs with Frequency >10 % in any treatment group

Solicited AE Tables (eCRF Section "Subject Diary")

- Solicited Adverse Events after any vaccination (by symptom, by maximum severity)
- Solicited Local Adverse Events reaching FDA grading after any Vaccination by Symptom
- Solicited Local Adverse Events reaching FDA grading by Symptom and Vaccination Period
- Solicited Adverse Events by Vaccination Period (by symptom, by maximum severity)
- Solicited Adverse Events by Diary Day (overall and by symptom)
- Mean Duration (in days) of solicited Adverse Events

- Greatest Single Diameter (in cm) for Present Erythema, Swelling and Induration
- Body Temperature (in °C) for case of fever

Unsolicited AE Tables (eCRF Section "Adverse Event Log) for specific types of AEs (e.g. any unsolicited AE, any unsolicited SAE)

- Unsolicited Adverse Events by SOC and PT
- Unsolicited Adverse Events by Vaccination Period
- Unsolicited Adverse Event by Maximum Severity (overall and for specific types of AEs)
- Unsolicited Adverse Event by Causality (overall and for specific types of AEs)

The following figures are provided:

- Bar chart: The number and percentage of subjects with solicited local Adverse Events by symptom and overall, by treatment group and grade for the diary period after each vaccination and for the whole treatment period.

Inferential analysis is performed as described in Section 6.1.3. Details are specified in Section 7.

6.1.2 Derivations and Definitions

6.1.2.1 General Principles for Analysis of Adverse Event

- In general, for tables summarizing solicited AEs, only the Subject Diary is used. For tables for all AEs (solicited and unsolicited) in general the unsolicited AEs are taken from the eCRF section "AE-log" and the solicited AEs are only taken from the eCRF section "Subject Diary".
- Tables showing "severe" events include events with grade 3 or 4 (or missing grade).
- For tables by maximum severity and worst causality, subjects are only counted once in highest grading category and events are counted in each reported grading category.
- Percentages in tables that do not present data by time periods are based on N (treatment group totals).
- For the IA Day 208 all AEs from the eCRF section "Subject Diary" and AEs from the eCRF section "AE log" that started up to Day 208 (Visit 6) are analyzed. It is stated in the table header that AEs up to Day 208 will be analyzed.
- For the IA Day 365 all AEs from the eCRF section "Subject Diary" and AEs from the eCRF section "AE log" that started up to Day 365 (Visit 7) are analyzed. It is stated in the table header that AEs up to Day 365 are analyzed.
- AEs in the AE log are considered to have started up to Day 208 if the start date of the AE is before or on study Day 208 (Visit 6). In case of an incomplete start date where it cannot clearly be decided if the AE started up to Day 208 or not, the AE is considered to have started up to Day 208. The derivation of AEs started before or on Day 365 are determined analogously.
- For analyzation of non-serious solicited (eCRF section "Subject Diary") and non-serious unsolicited (eCRF section "Adverse Event log") AEs only AEs for which the question "Serious adverse event" ticked with "no"

in the eCRF are included. Adverse Events are only included for this analysis if their occurrence by PT in at least one treatment group in the Safety Population is 5 % or over 10 %, respectively.

6.1.2.2 Principles for Solicited Adverse Events

Solicited AEs comprise reactions at the injection site or systemic reactions that are typical for vaccinations:

- Solicited local AEs: pain, tenderness, induration/ hardening, swelling and erythema/ redness
- Solicited systemic AEs: headache, myalgia (muscle pain), arthralgia (joint pain), fever (oral body temperature), flu-like symptoms, nausea, vomiting and fatigue
- Solicited AEs are per definition regarded as related to IMP.
- For tables that summarize solicited AEs over several diary days / diary periods from the Subject Diary, the worst severity of all diary days / diary periods is taken as the events severity.
- Percentages in tables for solicited AEs by diary period /diary day are based on the number of subjects with available information (diary completed or symptom present on at least one day). In particular, if a symptom was not assessed at a certain diary day and the symptom is reported as not present on the other days, the subject is not included in the table of the respective symptom and diary period.
- For the derivation of the duration of solicited Adverse Events by symptom and vaccination period the difference of the first occurrence and the last occurrence of the concerning event in the respective vaccination period is taken, no matter if the event is continuous or not. Therefore, also the end-date if ongoing after day 6 is considered. If the AE was ongoing after day 6 but has a missing or incomplete end-date, the date of last attended visit is used as end date.
- For swelling, redness and induration, the maximum diameter per diary period in cm is derived as taking the maximum of all diameters reported in that period for that symptom and converting via [cm] = [in] × 2.54.
- The maximum body temperature per diary period for present symptom fever is derived as taking the maximum temperature of all temperatures reported in that period and converting via [°C] = ([°F] – 32) × 5/9.
- Adverse Events from the Subject Diary are coded according to the table below:

Event	SOC name	SOC code	PT name	PT code
Arthralgia	Musculoskeletal and connective tissue disorders	10028395	Arthralgia	10003239
Fatigue	General disorders and administration site conditions	10018065	Fatigue	10016256
Fever	General disorders and administration site conditions	10018065	Pyrexia	10037660

Event	SOC name	SOC code	PT name	PT code
Flu like symptom	General disorders and administration site conditions	10018065	Influenza like illness	10022004
Headache	Nervous system disorders	10029205	Headache	10019211
Myalgia	Musculoskeletal and connective tissue disorders	10028395	Myalgia	10028411
Nausea	Gastrointestinal disorders	10017947	Nausea	10028813
Vomiting	Gastrointestinal disorders	10017947	Vomiting	10047700
Erythema/Redness	General disorders and administration site conditions	10018065	Injection site erythema	10022061
Induration/Hardening	General disorders and administration site conditions	10018065	Injection site induration	10022075
Pain	General disorders and administration site conditions	10018065	Injection site pain	10022086
Swelling	General disorders and administration site conditions	10018065	Injection site swelling	10053425
Tenderness	General disorders and administration site conditions	10018065	Injection site pain	10022086

6.1.2.3 Principles for Unsolicited Adverse Events

- AEs in the AE log are coded using the MedDRA version that is current at time point of the respective data snapshots and database closure. The version used is indicated in the respective tables and listings and is documented in the CSR.
- Adverse events in the AE log are considered related if the causality to IMP is reported as "probable" or "possible" (or missing causality)
- An AE in the AE-log is considered as "leading to withdrawal from further vaccination" if for "action taken on IMP", "second dose not administered" or "third dose not administered" is ticked.
- An AE in the AE-log is considered as "leading to withdrawal from study" if in section "other action taken" the question "Withdrawn from study", is answered with "yes".
- Percentages in tables for unsolicited events or all events (solicited and unsolicited) over the whole study are based on N (treatment group totals).
- For presentation of AEs by vaccination period, unsolicited AEs are assigned as follows:

- 1st vaccination period: AE with start date/time at or after date/time of 1st vaccination and within 28 days of 1st vaccination. If no AE start time is given, the AE is included if the start date is at or after the date of 1st vaccination and within 28 days of 1st vaccination.
- 2nd and 3rd vaccination period are defined analogously
- If a subject did not receive a certain vaccination, the respective vaccination period is not defined.

6.1.3 Inferential Analysis for Adverse Events

95 % confidence intervals according to Altman are generally provided for all AE rates. Differences between the three treatment groups are assessed for significance using Fisher's exact (Fisher-Freeman-Halton) test, whereby a significant overall test is amended by pair-wise tests.

It is stated in detail in Section 7 for which tables such comparisons are made.

6.2 Laboratory Parameters

Laboratory data from scheduled visits is tabulated. Listings include results from unscheduled visits and scheduled visits.

6.2.1 Data Points

The following parameters are assessed in the study and are included in the statistical analysis:

- Hematology
  - Hemoglobin
  - Hematocrit
  - Erythrocyte count
  - White blood count
  - Platelets
- Coagulation
  - Prothrombin time
  - Activated partial thromboplastin time
  - Fibrinogen
- Clinical Chemistry
  - Creatinine
  - Sodium
  - Potassium
  - Calcium
  - Aspartate aminotransferase
  - Alanine aminotransferase
  - Alkaline phosphatase
  - Bilirubin
  - C-reactive protein

- Urinalysis
  - Specific gravity
  - pH
  - Leukocytes
  - Nitrite
  - Protein
  - Glucose
  - Ketones
  - Urobilinogen
  - Bilirubin
  - Erythrocytes

The following variables are analyzed descriptively by time point:

- Absolute values (summary statistics for hematology, coagulation and clinical chemistry)
- Absolute change from Visit 0 (summary statistics for hematology and clinical chemistry)
- Number of subjects with values above/below normal range (for hematology, clinical chemistry and coagulation)
- Urinalysis results (frequency statistics)
- Abnormal pH and specific gravity values (frequency statistics)
- Subjects with values reaching grading by severity (for parameters with grading defined in Section 6.3.2.1)

One set of data listings shows graded laboratory parameters (hematology, and clinical chemistry) and parameters outside normal range (hematology, coagulation and clinical chemistry).

6.2.2 *Derivations and Definitions*

6.2.2.1 Severity Grading

For statistical analysis, hematology and clinical chemistry laboratory assessments are graded according to the grading scale provided below. In particular, all values lying in the range of the severity grades are assigned to the respective grade and all abnormal values that were not assigned in this way are labelled "Grade 0". All values that neither lie in the range of a severity grade nor are abnormal are not assigned to a grade.

[redacted]

Table 3: Grading Scale for Abnormal Laboratory Assessments

	Mild (Grade 1)[1]	Moderate (Grade 2)	Severe (Grade 3)	Potentially life threatening (Grade 4)[2]
Hematology Parameters				
Hemoglobin (Female) - gm/dL	11.0 - 12.0	9.5 - 10.9	8.0 - 9.4	<8.0
Hemoglobin (Male) - gm/dL	12.5 - 13.5	10.5 - 12.4	8.5 - 10.4	<8.5
Hematocrit	Outside normal range[3]			
Erythrocyte count	Outside normal range[3]			
WBC Increase - cell/mm³	10,800 - 15,000	15,001 - 20,000	20,001 - 25, 000	>25,000
WBC Decrease - cell/mm³	2,500 - 3,500	1,500 - 2,499	1,000 - 1,499	<1,000
Neutrophils Decrease - cell/mm³	1,500 - 2,000	1,000 - 1,499	500 - 999	<500
Platelets Decreased - cell/mm³	125,000 - 140,000	100,000 - 124,000	25,000 - 99,000	<25,000
Clinical Chemistry Parameters				
Creatinine – mg/dL	1.5 – 1.7	1.8 – 2.0	2.1 – 2.5	>2.5 or requires dialysis
Sodium – Hyponatremia mEq/L	132 – 134	130 – 131	125 – 129	<125
Sodium – Hypernatremia mEq/L	144 – 145	146 – 147	148 – 150	>150
Potassium – Hyperkalemia mEq/L	5.1 – 5.2	5.3 – 5.4	5.5 – 5.6	> 5.6
Potassium – /Hypokalemia mEq/L	3.5 – 3.6	3.3 – 3.4	3.1 – 3.2	<3.1
Calcium – hypocalcemia mg/dL	8.0 – 8.4	7.5 – 7.9	7.0 – 7.4	<7.0
Calcium – hypercalcemia mg/dL	10.5 – 11.0	11.1 – 11.5	11.6 – 12.0	>12.0
AST – increase by factor	1.1 – 2.5 x ULN[4]	2.6 – 5.0 x ULN	5.1 – 10 x ULN	>10 x ULN
ALT – increase by factor	1.1 – 2.5 x ULN	2.6 – 5.0 x ULN	5.1 – 10 x ULN	>10 x ULN
Alkaline phosphatase – increase by factor	1.1 – 2.0 x ULN	2.1 – 3.0 x ULN	3.1 – 10 x ULN	>10 x ULN
Bilirubin – when accompanied by any increase in Liver Function Test increase by factor	1.1 – 1.25 x ULN	1.26 – 1.5 x ULN	1.51 – 1.75 x ULN	>1.75 x ULN
Bilirubin – when Liver Function Test is normal; increase by factor	1.1 – 1.5 x ULN	1.6 – 2.0 x ULN	2.0 – 3.0 x ULN	> 3.0 x ULN
CRP	Outside normal range[3]			

1 In case local laboratory normal ranges and absolute Grade 1 limits overlap, Grade 1 limits prevail, i.e. the value is classified as Grade 1 abnormality even if it is within local laboratory normal ranges. Values between the local laboratory normal ranges and absolute Grade 1 limits are reported as no abnormality (Grade 0).

2 The clinical signs or symptoms associated with laboratory abnormalities might result in characterization of the laboratory abnormalities as Potentially Life Threatening (Grade 4). For example, a low sodium value that falls within a grade 3 parameter (125-129 mE/L) should be recorded as a grade 4 hyponatremia unsolicited AE if the subject had a new seizure associated with the low sodium value.

3 As the FDA Scale does not provide any grading for Hematocrit, Erythrocyte count and CRP, these are only analyzed as "outside normal range", as determined by local laboratory standards without further differentiation.

4 "ULN" is the upper limit of the normal range

Increase liver function exists if AST or ALT are above normal range at the same visit as Bilirubin fulfills one of the FDA grading criteria.

If a laboratory value lies between two grades (e.g. after conversion to the unit used for grading the value has several decimal places), the higher grade is assigned to the value.

6.2.2.2 Conversion of Units

Conversion of laboratory parameters from a study site specific laboratory unit into the unit to be used in the statistical analysis for severity grading (Section 6.3.2.1) or for summary tables are performed via the following formula:

Value in unit for severity grading or for analysis = value in study site specific unit * conversion factor

Parameter	Standard Unit/ Unit for Analysis
Clinical chemistry	
Alanine Aminotransferase	U/L
Alkaline Phosphatase	U/L
Aspartate Aminotransferase	U/L
Bilirubin	µmol/L
C Reactive Protein	nmol/L
Calcium	mmol/L
Creatinine	µmol/L
Potassium	mmol/L
Sodium	mmol/L
Coagulation	
Fibrinogen	g/L
Activated partial thromboplastin time	s
Hematology	
Erythrocyte count	T/L
Hemoglobin	g/L
White blood count	G/L
Hematocrit	%
Platelets	G/L

Prothrombin Time is analyzed using the reported unit (i.e. in seconds or percent).

6.3 Lyme borreliosis Screening

Lyme borreliosis screening is analyzed and is used as stratification factor.

6.4 Other Safety Parameters

The following information is analyzed descriptively and corresponding details on the subject level are provided in data listings:

- Systolic blood pressure by time point incl. measurements after vaccinations (summary statistics)
- Diastolic blood pressure by time point incl. measurements after vaccinations (summary statistics)
- Pulse rate by time point incl. measurements after vaccinations (summary statistics)
- Body temperature by time point (summary statistics)

The following information will only be listed:

- Physical Examination
- Pregnancy Test
- Injection Site Inspection
- Assessment after Vaccination
- Vaccination delay criteria

7. LIST OF TABLES, DATA LISTINGS AND FIGURES

7.1 List of Tables

7.1.1 Overall Study Information

IA D208 No	IA D365 No	FA No	Legend	Content/Comment
14.1.1.1.1	14.2.1.1.1	14.3.1.1.1	Subject Overview	Overall
14.1.1.1.2	14.2.1.1.2	14.3.1.1.2	Subjects by Treatment Groups and Overall (Safety Population)	
14.1.1.1.3	14.2.1.1.3	14.3.1.1.3	Subjects by Visit (Safety Population)	Incl. information whether • Visits 6, 7, 8 and Early Termination Visit were performed on site or remotely due to Covid-19.
14.1.1.1.4	14.2.1.1.4	14.3.1.1.4	Early Termination Details (Safety Population)	
14.1.1.1.5	14.2.1.1.5	14.3.1.1.5	Vaccination Details (Safety Population)	
14.1.1.1.6	14.2.1.1.6	14.3.1.1.6	Protocol Deviations by Deviation Type (Safety Population)	• PDs concerning PP Population • PDs concerning ICH E3
14.1.1.1.7	14.2.1.1.7	14.3.1.1.7	Number of Screening Failures and Reason	
14.1.1.2.2-6	14.2.1.2.2-6	14.3.1.2.2-6	Repeat Table 2-6 for mITT Population	
14.1.1.3.2-6	14.2.1.3.2-6	14.3.1.3.2-6	Repeat Table 2-6 for PP Population	

7.1.2 Baseline

IA D208 No	IA D2365 No	FA No	Legend	Content/Comment
14.1.2.1.1	14.2.2.1.1	14.3.2.1.1	Summary Table of Demographic Data (Safety Population)	Overall and stratified by age group and baseline B.b. s.l. serostatus
14.1.2.1.2	14.2.2.1.2	14.3.2.1.2	ECG Results at Screening (Safety Population)	
14.1.2.1.3	14.2.2.1.3	14.3.2.1.3	Medical History by SOC and PT (Safety Population)	
14.1.2.1.4	14.2.2.1.4	14.3.2.1.4	Medical History Ongoing at Visit 1 by SOC and PT (Safety Population)	

[redacted]

IA D208 No	IA D2365 No	FA No	Legend	Content/Comment
14.1.2.1.5	14.2.2.1.5	14.3.2.1.5	Prior Medications by ATC Level 2 and ATC Level 3 (Safety Population)	
14.1.2.1.6	14.2.2.1.6	14.3.2.1.6	Concomitant Medications by ATC Level 2 and ATC Level 3 (Safety Population)	
14.1.2.1.7	14.2.2.1.7	14.3.2.1.7	Prior Procedures by SOC and PT (Safety Population)	
14.1.2.1.8	14.2.2.1.8	14.3.2.1.8	Concomitant Procedures by SOC and PT (Safety Population)	
14.1.2.1.9	14.2.2.1.9	14.3.2.1.9	Vaccination History by ATC Level 3 (Safety Population)	
14.1.2.2.1-9	14.2.2.2.1-9	14.3.2.2.1-9	Repeat all tables for mITT Population	
14.1.2.3. 1-9	14.2.2.3. 1-9	14.3.2.3. 1-9	Repeat all tables for PP Population	

7.1.3 Immunogenicity

IA D208 No	FA No	Legend	Content/Comment
14.1.3.1.1	14.3.3.1.1	Number of Immunogenicity Blood Samples by Visit (PP Population)	Incl. number of subjects which performed V6-8 and ET remotely and respective corresponding unscheduled visit for blood draws
14.1.3.1.2	14.3.3.1.2	ELISA: Number of Immunogenicity Results by OspA Serotype (PP Population)	
14.1.3.1.3	14.3.3.1.3	ELISA: Number and Percentage of Subjects Stratified by OspA IgG Serostatus at Baseline (Visit 1) and baseline B.b. s.l. serostatus by OspA baseline status by Serotype (PP Population)	Overall and stratified by age group
14.1.3.1.4	14.3.3.1.4	ELISA: GMTs for OspA ST1-specific IgG by Visit (PP Population)	Overall and stratified by age group and baseline B.b. s.l. serostatus
14.1.3.1.5	14.3.3.1.5	ELISA: GMTs for OspA ST2-specific IgG by Visit (PP Population)	Overall and stratified by age group and baseline B.b. s.l. serostatus

IA D208 No	FA No	Legend	Content/Comment
14.1.3.1.6	14.3.3.1.6	ELISA: GMTs for OspA ST3-specific IgG by Visit (PP Population)	Overall and stratified by age group and baseline B.b. s.l. serostatus
14.1.3.1.7	14.3.3.1.7	ELISA: GMTs for OspA ST4-specific IgG by Visit (PP Population)	Overall and stratified by age group and baseline B.b. s.l. serostatus
14.1.3.1.8	14.3.3.1.8	ELISA: GMTs for OspA ST5-specific IgG by Visit (PP Population)	Overall and stratified by age group and baseline B.b. s.l. serostatus
14.1.3.1.9	14.3.3.1.9	ELISA: GMTs for OspA ST6-specific IgG by Visit (PP Population)	Overall and stratified by age group and baseline B.b. s.l. serostatus
14.1.3.1.10	14.3.3.1.10	ELISA: GMFRs (as compared to Day 1) for OspA ST1-specific IgG by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.11	14.3.3.1.11	ELISA: GMFRs (as compared to Day 1) for OspA ST2-specific IgG by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.12	14.3.3.1.12	ELISA: GMFRs (as compared to Day 1) for OspA ST3-specific IgG by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.13	14.3.3.1.13	ELISA: GMFRs (as compared to Day 1) for OspA ST4-specific IgG by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.14	14.3.3.1.14	ELISA: GMFRs (as compared to Day 1) for OspA ST5-specific IgG by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.15	14.3.3.1.15	ELISA: GMFRs (as compared to Day 1) for OspA ST6-specific IgG by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.16	14.3.3.1.16	ELISA: SCR for OspA ST1-specific IgG by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.17	14.3.3.1.17	ELISA: SCR for OspA ST2-specific IgG by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.18	14.3.3.1.18	ELISA: SCR for OspA ST3-specific IgG by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.19	14.3.3.1.19	ELISA: SCR for OspA ST4-specific IgG by Visit (PP Population)	Overall and stratified by age group

IA D208 No	FA No	Legend	Content/Comment
14.1.3.1.20	14.3.3.1.20	ELISA: SCR for OspA ST5-specific IgG by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.21	14.3.3.1.21	ELISA: SCR for OspA ST6-specific IgG by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.22	14.3.3.1.22	ELISA: SCR for OspA-specific IgG against OspA serotypes ST1 to ST6 combined by visit (PP Population)	
14.1.3.1.23	14.3.3.1.23	ELISA: SCR for OspA-specific IgG against ST1 and ST2 combined by visit (PP Population)	
14.1.3.1.24	14.3.3.1.24	ELISA: Subjects Achieving a >=4 or >=10-fold increase from Day 1 (Visit 1) in OspA ST1-specific IgG Titer by visit (PP Population)	
14.1.3.1.25	14.3.3.1.25	ELISA: Subjects Achieving a >=4 or >=10-fold increase from Day 1 (Visit 1) in OspA ST2-specific IgG Titer by visit (PP Population)	
14.1.3.1.26	14.3.3.1.26	ELISA: Subjects Achieving a >=4 or >=10-fold increase from Day 1 (Visit 1) in OspA ST3-specific IgG Titer by visit (PP Population)	
14.1.3.1.27	14.3.3.1.27	ELISA: Subjects Achieving a >=4 or >=10-fold increase from Day 1 (Visit 1) in OspA ST4-specific IgG Titer by visit (PP Population)	
14.1.3.1.28	14.3.3.1.28	ELISA: Subjects Achieving a >=4 or >=10-fold increase from Day 1 (Visit 1) in OspA ST5-specific IgG Titer by visit (PP Population)	
14.1.3.1.29	14.3.3.1.29	ELISA: Subjects Achieving a >=4 or >=10-fold increase from Day 1 (Visit 1) in OspA ST6-specific IgG Titer by visit (PP Population)	

IA D208 No	FA No	Legend	Content/Comment
14.1.3.1.30	14.3.3.1.30	ELISA:ANOVA (Factors: Treatment Group, Study Site) for GMT of OspA ST1-specific IgG by Visit (PP Population)	To be repeated for mITT population
14.1.3.1.31	14.3.3.1.31	ELISA:ANOVA (Factors: Treatment Group, Study Site) for GMT of OspA ST2-specific IgG by Visit (PP Population)	To be repeated for mITT population
14.1.3.1.32	14.3.3.1.32	ELISA:ANOVA (Factors: Treatment Group, Study Site) for GMT of OspA ST3-specific IgG by Visit (PP Population)	To be repeated for mITT population
14.1.3.1.33	14.3.3.1.33	ELISA:ANOVA (Factors: Treatment Group, Study Site) for GMT of OspA ST4-specific IgG by Visit (PP Population)	To be repeated for mITT population
14.1.3.1.34	14.3.3.1.34	ELISA:ANOVA (Factors: Treatment Group, Study Site) for GMT of OspA ST5-specific IgG by Visit (PP Population)	To be repeated for mITT population
14.1.3.1.35	14.3.3.1.35	ELISA:ANOVA (Factors: Treatment Group, Study Site) for GMT of OspA ST6-specific IgG by Visit (PP Population)	To be repeated for mITT population
14.1.3.1.36	14.3.3.1.36	ELISA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMT of OspA ST1-specific IgG at Day 85, Day 208, Day 365 and Day 545 (PP Population)	To be repeated for mITT population
14.1.3.1.37	14.3.3.1.37	ELISA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMT of OspA ST2-specific IgG at Day 85, Day 208, Day 365 and Day 545 (PP Population)	To be repeated for mITT population
14.1.3.1.38	14.3.3.1.38	ELISA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMT of OspA ST3-specific IgG at Day 85, Day	To be repeated for mITT population

IA D208 No	FA No	Legend	Content/Comment
		208, Day 365 and Day 545 (PP Population)	
14.1.3.1.39	14.3.3.1.39	ELISA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMT of OspA ST4-specific IgG at Day 85, Day 208, Day 365 and Day 545 (PP Population)	To be repeated for mITT population
14.1.3.1.40	14.3.3.1.40	ELISA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMT of OspA ST5-specific IgG at Day 85, Day 208, Day 365 and Day 545 (PP Population)	To be repeated for mITT population
14.1.3.1.41	14.3.3.1.41	ELISA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMT of OspA ST6-specific IgG at Day 85, Day 208, Day 365 and Day 545 (PP Population)	To be repeated for mITT population
14.1.3.1.42	14.3.3.1.42	ELISA: ANOVA (Factors: Treatment Group, Study Site) for GMFR from Day 1 of OspA ST1-specific IgG by Visit (PP Population)	
14.1.3.1.43	14.3.3.1.43	ELISA: ANOVA (Factors: Treatment Group, Study Site) for GMFR from Day 1 of OspA ST2-specific IgG by Visit (PP Population)	
14.1.3.1.44	14.3.3.1.44	ELISA: ANOVA (Factors: Treatment Group, Study Site) for GMFR from Day 1 of OspA ST3-specific IgG by Visit (PP Population)	
14.1.3.1.45	14.3.3.1.45	ELISA: ANOVA (Factors: Treatment Group, Study Site) for GMFR from Day 1 of OspA ST4-specific IgG by Visit (PP Population)	
14.1.3.1.46	14.3.3.1.46	ELISA: ANOVA (Factors: Treatment Group, Study Site)	

IA D208 No	FA No	Legend	Content/Comment
		for GMFR from Day 1 of OspA ST5-specific IgG by Visit (PP Population)	
14.1.3.1.47	14.3.3.1.47	ELISA: ANOVA (Factors: Treatment Group, Study Site) for GMFR from Day 1 of OspA ST6-specific IgG by Visit (PP Population)	
14.1.3.1.48	14.3.3.1.48	ELISA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMFR of OspA ST1-specific IgG at Day 85, Day 208, Day 365 and Day 545 (PP Population)	
14.1.3.1.49	14.3.3.1.49	ELISA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMFR of OspA ST2-specific IgG at Day 85, Day 208, Day 365 and Day 545 (PP Population)	
14.1.3.1.50	14.3.3.1.50	ELISA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMFR of OspA ST3-specific IgG at Day 85, Day 208, Day 365 and Day 545 (PP Population)	
14.1.3.1.51	14.3.3.1.51	ELISA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMFR of OspA ST4-specific IgG at Day 85, Day 208, Day 365 and Day 545 (PP Population)	
14.1.3.1.52	14.3.3.1.52	ELISA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMFR of OspA ST5-specific IgG at Day 85, Day 208, Day 365 and Day 545 (PP Population)	

[redacted]

IA D208 No	FA No	Legend	Content/Comment
14.1.3.1.53	14.3.3.1.53	ELISA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, baseline B.b. s.l. serostatus) for GMFR of OspA ST6-specific IgG at Day 85, Day 208, Day 365 and Day 545 (PP Population)	
14.1.3.1.54	14.3.3.1.54	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST1 vs ST2 at Day 208(PP Population)	
14.1.3.1.55	14.3.3.1.55	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST1 vs ST3 at Day 208 (PP Population)	
14.1.3.1.56	14.3.3.1.56	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST1 vs ST4 at Day 208(PP Population)	
14.1.3.1.57	14.3.3.1.57	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST1 vs ST5 at Day 208 (PP Population)	
14.1.3.1.58	14.3.3.1.58	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST1 vs ST6 at Day 208 (PP Population)	
14.1.3.1.59	14.3.3.1.59	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST2 vs ST3 at Day 208 (PP Population)	
14.1.3.1.60	14.3.3.1.60	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST2 vs ST4 at Day 208 (PP Population)	
14.1.3.1.61	14.3.3.1.61	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST2 vs ST5 at Day 208 (PP Population)	
14.1.3.1.62	14.3.3.1.62	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST2 vs ST6 at Day 208 (PP Population)	
14.1.3.1.63	14.3.3.1.63	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for	

IA D208 No	FA No	Legend	Content/Comment
		ST3 vs ST4 at Day 208 (PP Population)	
14.1.3.1.64	14.3.3.1.64	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST3 vs ST5 at Day 208 (PP Population)	
14.1.3.1.65	14.3.3.1.65	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST3 vs ST6 at Day 208 (PP Population)	
14.1.3.1.66	14.3.3.1.66	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST4 vs ST5 at Day 208 (PP Population)	
14.1.3.1.67	14.3.3.1.67	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST4 vs ST6 at Day 208 (PP Population)	
14.1.3.1.68	14.3.3.1.68	ELISA: Correlation Analysis for GMTs of OspA Specific IgG for ST5 vs ST6 at Day 208 (PP Population)	
14.1.3.1.69	14.3.3.1.69	SBA: Number of Immunogenicity Results by OspA Serotype (PP Population)	
14.1.3.1.70	14.3.3.1.70	SBA: Number and Percentage of Subjects Stratified by SBA Serostatus at Baseline (Visit 1) by Serotype (PP Population)	Overall and stratified by age group
14.1.3.1.71	14.3.3.1.71	SBA: GMTs for ST1 SBA Titer by Visit (PP Population)	Overall and stratified by age group and baseline B.b. s.l. serostatus
14.1.3.1.72	14.3.3.1.72	SBA: GMTs for ST2 SBA Titer by Visit (PP Population)	Overall and stratified by age group and baseline B.b. s.l. serostatus
14.1.3.1.73	14.3.3.1.73	SBA: GMTs for ST3 SBA Titer by Visit (PP Population)	Overall and stratified by age group and baseline B.b. s.l. serostatus
14.1.3.1.74	14.3.3.1.74	SBA: GMTs for ST4 SBA Titer by Visit (PP Population)	Overall and stratified by age group and baseline B.b. s.l. serostatus
14.1.3.1.75	14.3.3.1.75	SBA: GMTs for ST5 SBA Titer by Visit (PP Population)	Overall and stratified by age group and baseline B.b. s.l. serostatus

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IA D208 No	FA No	Legend	Content/Comment
14.1.3.1.76	14.3.3.1.76	SBA: GMTs for ST6 SBA Titer by Visit (PP Population)	Overall and stratified by age group and baseline B.b. s.l. serostatus
14.1.3.1.77	14.3.3.1.77	SBA: GMFRs (as compared to Day 1) for ST1 SBA Titer by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.78	14.3.3.1.78	SBA: GMFRs (as compared to Day 1) for ST2 SBA Titer by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.79	14.3.3.1.79	SBA: GMFRs (as compared to Day 1) for ST3 SBA Titer by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.80	14.3.3.1.80	SBA: GMFRs (as compared to Day 1) for ST4 SBA Titer by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.81	14.3.3.1.81	SBA: GMFRs (as compared to Day 1) for ST5 SBA Titer by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.82	14.3.3.1.82	SBA: GMFRs (as compared to Day 1) for ST6 SBA Titer by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.83	14.3.3.1.83	SBA: SCR for ST1 specific SBA Titer by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.84	14.3.3.1.84	SBA: SCR for ST2 specific SBA Titer by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.85	14.3.3.1.85	SBA: SCR for ST3 specific SBA Titer by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.86	14.3.3.1.86	SBA: SCR for ST4 specific SBA Titer by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.87	14.3.3.1.87	SBA: SCR for ST5 specific SBA Titer by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.88	14.3.3.1.88	SBA: SCR for ST6 specific SBA Titer by Visit (PP Population)	Overall and stratified by age group
14.1.3.1.89	14.3.3.1.89	SBA: SCR for SBA titer ST1 to ST6 combined by visit (PP Population)	
14.1.3.1.90	14.3.3.1.90	SBA: SCR for SBA titer ST1 and ST2 combined by visit (PP Population)	
14.1.3.1.91	14.3.3.1.91	SBA: ANOVA (Factors: Treatment Group, Study Site)	

IA D208 No	FA No	Legend	Content/Comment
		for GMT of ST1 specific SBA Titer by Visit (PP Population)	
14.1.3.1.92	14.3.3.1.92	SBA: ANOVA (Factors: Treatment Group, Study Site) for GMT of ST2 specific SBA Titer by Visit (PP Population)	
14.1.3.1.93	14.3.3.1.93	SBA: ANOVA (Factors: Treatment Group, Study Site) for GMT of ST3 specific SBA Titer by Visit (PP Population)	
14.1.3.1.94	14.3.3.1.94	SBA: ANOVA (Factors: Treatment Group, Study Site) for GMT of ST4 specific SBA Titer by Visit (PP Population)	
14.1.3.1.95	14.3.3.1.95	SBA: ANOVA (Factors: Treatment Group, Study Site) for GMT of ST5 specific SBA Titer by Visit (PP Population)	
14.1.3.1.96	14.3.3.1.96	SBA: ANOVA (Factors: Treatment Group, Study Site) for GMT of ST6 specific SBA Titer by Visit (PP Population)	
14.1.3.1.97	14.3.3.1.97	SBA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMT of ST1 specific SBA Titer at Day 208 (PP Population)	
14.1.3.1.98	14.3.3.1.98	SBA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMT of ST2 specific SBA Titer at Day 208 (PP Population)	
14.1.3.1.99	14.3.3.1.99	SBA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMT of ST3 specific SBA Titer at Day 208 (PP Population)	
14.1.3.1.100	14.3.3.1.100	SBA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l.	

IA D208 No	FA No	Legend	Content/Comment
		serostatus) for GMT of ST4 specific SBA Titer at Day 208 (PP Population)	
14.1.3.1.101	14.3.3.1.101	SBA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMT of ST5 specific SBA Titer at Day 208 (PP Population)	
14.1.3.1.102	14.3.3.1.102	SBA: ANOVA (Factors: Treatment Group, Study Site, Study Site*Treatment Group, Age group, and baseline B.b. s.l. serostatus) for GMT of ST6 specific SBA Titer at Day 208 (PP Population)	
14.1.3.1.103	14.3.3.1.103	SBA: Correlation Analysis for GMTs of SBA titer for ST1 vs ST2 at Day 208 (PP Population)	
14.1.3.1.104	14.3.3.1.104	SBA: Correlation Analysis for GMTs of SBA titer for ST1 vs ST3 at Day 208 (PP Population)	
14.1.3.1.105	14.3.3.1.105	SBA: Correlation Analysis for GMTs of SBA titer for ST1 vs ST4 at Day 208 (PP Population)	
14.1.3.1.106	14.3.3.1.106	SBA: Correlation Analysis for GMTs of SBA titer for ST1 vs ST5 at Day 208 (PP Population)	
14.1.3.1.107	14.3.3.1.107	SBA: Correlation Analysis for GMTs of SBA titer for ST1 vs ST6 at Day 208 (PP Population)	
14.1.3.1.108	14.3.3.1.108	SBA: Correlation Analysis for GMTs of SBA titer for ST2 vs ST3 at Day 208 (PP Population)	
14.1.3.1.109	14.3.3.1.109	SBA: Correlation Analysis for GMTs of SBA titer for ST2 vs ST4 at Day 208 (PP Population)	
14.1.3.1.110	14.3.3.1.110	SBA: Correlation Analysis for GMTs of SBA titer for ST2 vs ST5 at Day 208 (PP Population)	

IA D208 No	FA No	Legend	Content/Comment
14.1.3.1.111	14.3.3.1.111	SBA: Correlation Analysis for GMTs of SBA titer for ST2 vs ST6 at Day 208 (PP Population)	
14.1.3.1.112	14.3.3.1.112	SBA: Correlation Analysis for GMTs of SBA titer for ST3 vs ST4 at Day 208 (PP Population)	
14.1.3.1.113	14.3.3.1.113	SBA: Correlation Analysis for GMTs of SBA titer for ST3 vs ST5 at Day 208 (PP Population)	
14.1.3.1.114	14.3.3.1.114	SBA: Correlation Analysis for GMTs of SBA titer for ST3 vs ST6 at Day 208 (PP Population)	
14.1.3.1.115	14.3.3.1.115	SBA: Correlation Analysis for GMTs of SBA titer for ST4 vs ST5 at Day 208 (PP Population)	
14.1.3.1.116	14.3.3.1.116	SBA: Correlation Analysis for GMTs of SBA titer for ST4 vs ST6 at Day 208 (PP Population)	
14.1.3.1.117	14.3.3.1.117	SBA: Correlation Analysis for GMTs of SBA titer for ST5 vs ST6 at Day 208 (PP Population)	
14.1.3.1.118	14.3.3.1.118	Correlation for ELISA OspA ST1-specific IgG vs. ST1- SBA Titer for Day 1 (PP Population)	
14.1.3.1.119	14.3.3.1.119	Correlation for ELISA OspA ST2-specific IgG vs. ST2- specific SBA Titer for Day 1 (PP Population)	
14.1.3.1.120	14.3.3.1.120	Correlation for ELISA OspA ST3-specific IgG vs. ST3- SBA Titer for Day 1 (PP Population)	
14.1.3.1.121	14.3.3.1.121	Correlation for ELISA OspA ST4-specific IgG vs. ST4- SBA Titer for Day 1 (PP Population)	
14.1.3.1.122	14.3.3.1.122	Correlation for ELISA OspA ST5-specific IgG vs. ST5- SBA Titer for Day 1 (PP Population)	
14.1.3.1.123	14.3.3.1.123	Correlation for ELISA OspA ST6-specific IgG vs. ST6- SBA Titer for Day 1 (PP Population)	
14.1.3.1.124	14.3.3.1.124	Correlation for ELISA OspA ST1-specific IgG vs. ST1- SBA Titer for Day 208 (PP Population)	

IA D208 No	FA No	Legend	Content/Comment
14.1.3.1.125	14.3.3.1.125	Correlation for ELISA OspA ST2-specific IgG vs. ST2- specific SBA Titer for Day 208 (PP Population)	
14.1.3.1.126	14.3.3.1.126	Correlation for ELISA OspA ST3-specific IgG vs. ST3- SBA Titer for Day 208 (PP Population)	
14.1.3.1.127	14.3.3.1.127	Correlation for ELISA OspA ST4-specific IgG vs. ST4- SBA Titer for Day 208 (PP Population)	
14.1.3.1.128	14.3.3.1.128	Correlation for ELISA OspA ST5-specific IgG vs. ST5- SBA Titer for Day 208 (PP Population)	
14.1.3.1.129	14.3.3.1.129	Correlation for ELISA OspA ST6-specific IgG vs. ST6- SBA Titer for Day 208 (PP Population)	
14.1.3.1.130	14.3.3.1.130	Correlation for ELISA OspA ST1-specific IgG vs. ST1- SBA Titer for Day 365 (PP Population)	
14.1.3.1.131	14.3.3.1.131	Correlation for ELISA OspA ST2-specific IgG vs. ST2- SBA Titer for Day 365 (PP Population)	
14.1.3.1.132	14.3.3.1.132	Correlation for ELISA OspA ST3-specific IgG vs. ST3- SBA Titer for Day 365 (PP Population)	
14.1.3.1.133	14.3.3.1.133	Correlation for ELISA OspA ST4-specific IgG vs. ST4- SBA Titer for Day 365 (PP Population)	
14.1.3.1.134	14.3.3.1.134	Correlation for ELISA OspA ST5-specific IgG vs. ST5- SBA Titer for Day 365 (PP Population)	
14.1.3.1.135	14.3.3.1.135	Correlation for ELISA OspA ST6-specific IgG vs. ST6- SBA Titer for Day 365 (PP Population)	
14.1.3.1.136	14.3.3.1.136	Correlation for ELISA OspA ST1-specific IgG vs. ST1- SBA Titer for Day 545 (PP Population)	
14.1.3.1.137	14.3.3.1.137	Correlation for ELISA OspA ST2-specific IgG vs. ST2- SBA Titer for Day 545 (PP Population)	
14.1.3.1.138	14.3.3.1.138	Correlation for ELISA OspA ST3-specific IgG vs. ST3- SBA Titer for Day 545 (PP Population)	

IA D208 No	FA No	Legend	Content/Comment
14.1.3.1.139	14.3.3.1.139	Correlation for ELISA OspA ST4-specific IgG vs. ST4- SBA Titer for Day 545 (PP Population)	
14.1.3.1.140	14.3.3.1.140	Correlation for ELISA OspA ST5-specific IgG vs. ST5- SBA Titer for Day 545 (PP Population)	
14.1.3.1.141	14.3.3.1.141	Correlation for ELISA OspA ST6-specific IgG vs. ST6- SBA Titer for Day 545 (PP Population)	
14.1.3.1.142	14.3.3.1.142	ELISA IgG titer Above Which 50, 60, 70, 80 or 90% of Subjects are SBA Seroconverted	
14.1.3.2.x	14.3.3.2.x	Repeat selected tables for mITT Population (only tables marked in comment column above)	

7.1.4 Safety

IA D208 No	IA D365 No	FA No	Legend	Content/Comment
14.1.4.1	14.2.4.1.1	N/A	Summary Table of Adverse Events up to Day 208 (solicited and unsolicited) (Safety Population)	Including statistical test • Any AE, related AE, severe AE, related severe AE, SAE, related SAE, medically attended AE, related medically attended AE, AE leading to withdrawal from study, AE leading to withdrawal from further vaccination • Any solicited AE, severe solicited AE, solicited local AE, severe solicited local AE, solicited systemic AE, severe solicited systemic AE • Any unsolicited AE, related unsolicited AE, severe solicited AE, related severe solicited AE, unsolicited SAE, medically attended unsolicited AE, related medically attended unsolicited AE, unsolicited AE leading to withdrawal from study, unsolicited AE leading to withdrawal from further vaccination, AE of special interest, related AE of special interest

IA D208 No	IA D365 No	FA No	Legend	Content/Comment
N/A	14.2.4.1.2	N/A	Summary Table of Adverse Events up to Day 365 (solicited and unsolicited) (Safety Population)	Including statistical test Content see table 14.x.4.1
N/A	N/A	14.3.4.1	Summary Table of Adverse Events During Entire Study (solicited and unsolicited) (Safety Population)	Including statistical test Content see table 14.x.4.1
14.1.4.2	14.2.4.2.1	N/A	Summary Table of Adverse Events by Age group up to Day 208 (solicited and unsolicited) (Safety Population)	Including statistical test Content see table 14.x.4.1
N/A	14.2.4.2.2	N/A	Summary Table of Adverse Events up to Day 365 by Age group (solicited and unsolicited) (Safety Population)	Including statistical test Content see table 14.x.4.1
N/A	N/A	14.3.4.2	Summary Table of Adverse Events During Entire Study by Age group (solicited and unsolicited) (Safety Population)	Including statistical test Content see table 14.x.4.1
14.1.4.3	14.2.4.3.1	N/A	Summary Table of Adverse Events up to Day 208 by baseline B.b. s.l. serostatus (solicited and unsolicited) (Safety Population)	Including statistical test Content see table 14.x.4.1
N/A	14.2.4.3.2	N/A	Summary Table of Adverse Events up to Day 365 by baseline B.b. s.l. serostatus (solicited and unsolicited) (Safety Population)	Including statistical test Content see table 14.x.4.1
N/A	N/A	14.3.4.3	Summary Table of Adverse Events During Entire Study by baseline B.b. s.l. serostatus (solicited and unsolicited) (Safety Population)	Including statistical test Content see table 14.x.4.1
14.1.4.4	14.2.4.4.1	N/A	Summary Table of Adverse Events up to Day 208 (solicited and unsolicited) by Vaccination Period (Safety Population)	Including statistical test Content see table 14.x.4.1
N/A	14.2.4.4.2	N/A	Summary Table of Adverse Events up to Day 365 (solicited and unsolicited) by Vaccination Period (Safety Population)	Including statistical test Content see table 14.x.4.1
N/A	N/A	14.3.4.4	Summary Table of Adverse Events During Entire Study (solicited and unsolicited) by Vaccination Period (Safety Population)	Including statistical test Content see table 14.x.4.1
14.1.4.5	14.2.4.5.1	N/A	Subjects with Solicited and Unsolicited Serious Adverse Events	Including statistical test

IA D208 No	IA D365 No	FA No	Legend	Content/Comment
			up to Day 208 by SOC and PT (Safety Population)	
N/A	14.2.4.5.2	N/A	Subjects with Solicited and Unsolicited Serious Adverse Events up to Day 365 by SOC and PT (Safety Population)	Including statistical test
N/A	14.2.4.5	14.3.4.5	Subjects with Solicited and Unsolicited Serious Adverse Events During Entire Study by SOC and PT (Safety Population)	Including statistical test
14.1.4.6	14.2.4.6.1	N/A	Subjects with Solicited and Unsolicited Related Serious Adverse Events up to Day 208 by SOC and PT (Safety Population)	Including statistical test
N/A	14.2.4.6.2	N/A	Subjects with Solicited and Unsolicited Related Serious Adverse Events up to Day 365 by SOC and PT (Safety Population)	Including statistical test
N/A	N/A	14.3.4.6	Subjects with Solicited and Unsolicited Related Serious Adverse Events During Entire Study by SOC and PT (Safety Population)	Including statistical test
14.1.4.7	14.2.4.7.1	N/A	Subjects with Solicited and Unsolicited Medically Attended Adverse Events up to Day 208 by SOC and PT (Safety Population)	Including statistical test
N/A	14.2.4.7.2	N/A	Subjects with Solicited and Unsolicited Medically Attended Adverse up to Day 365 by SOC and PT (Safety Population)	Including statistical test
N/A	N/A	14.3.4.7	Subjects with Solicited and Unsolicited Medically Attended Adverse Events During Entire Study by SOC and PT (Safety Population)	Including statistical test
14.1.4.8	14.2.4.8.1	N/A	Subjects with Solicited and Unsolicited Related Medically Attended Adverse Events up to Day 208 by SOC and PT (Safety Population)	Including statistical test
N/A	14.2.4.8.2	N/A	Subjects with Solicited and Unsolicited Related Medically Attended Adverse Events up to Day 365 by SOC and PT (Safety Population)	Including statistical test

IA D208 No	IA D365 No	FA No	Legend	Content/Comment
N/A	N/A	14.3.4.8	Subjects with Solicited and Unsolicited Related Medically Attended Adverse During Entire Study by SOC and PT (Safety Population)	Including statistical test
14.1.4.9	14.2.4.9.1	N/A	Subjects with Solicited and Unsolicited Adverse Events up to Day 208 Leading to Withdrawal from Further Vaccination by SOC and PT (Safety Population)	Including statistical test
N/A	14.2.4.9.2	N/A	Subjects with Solicited and Unsolicited Adverse Events up to Day 365 Leading to Withdrawal from Further Vaccination by SOC and PT (Safety Population)	Including statistical test
N/A	N/A	14.3.4.9	Subjects with Solicited and Unsolicited Adverse Events During Entire Study Leading to Withdrawal from Further Vaccination by SOC and PT (Safety Population)	Including statistical test
14.1.4.10	14.2.4.10.	N/A	Subjects with Solicited and Unsolicited Adverse Events up to Day 208 Leading to Withdrawal from Study by SOC and PT (Safety Population)	Including statistical test
N/A	14.2.4.10.2	N/A	Subjects with Solicited and Unsolicited Adverse Events up to Day 365 Leading to Withdrawal from Study by SOC and PT (Safety Population)	Including statistical test
N/A	N/A	14.3.4.10	Subjects with Solicited and Unsolicited Adverse Events During Entire Study Leading to Withdrawal from Study by SOC and PT (Safety Population)	Including statistical test
14.1.4.11	14.2.4.11.1	N/A	Subjects with any Non-Serious Adverse Events up to Day 208 by SOC and PT for PTs with Frequency >5% in any Treatment Group (eCRF Section 'AE Log' for Unsolicited AEs and 'Subject Diary' for Solicited AEs, Safety Population)	Including statistical test
N/A	14.2.4.11.2	N/A	Subjects with any Non-Serious Adverse Events up to Day 365 by SOC and PT for PTs with Frequency >5% in any Treatment Group (eCRF Section 'AE Log' for Unsolicited AEs	Including statistical test

IA D208 No	IA D365 No	FA No	Legend	Content/Comment
			and 'Subject Diary' for Solicited AEs, Safety Population)	
N/A	N/A	14.3.4.11	Subjects with any Non-Serious Adverse Events During Entire Study by SOC and PT for PTs with Frequency >5% in any Treatment Group (eCRF Section 'AE Log' for Unsolicited AEs and 'Subject Diary' for Solicited AEs, Safety Population)	Including statistical test
14.1.4.12	14.2.4.12.1	N/A	Subjects with any Non-Serious Adverse Events up to Day 208 by SOC and PT for PTs with Frequency >10% in any Treatment Group (eCRF Section 'AE Log' for Unsolicited AEs and 'Subject Diary' for Solicited AEs, Safety Population)	Including statistical test
N/A	14.2.4.12.2	N/A	Subjects with any Non-Serious AEs up to Day 365 by SOC and Adverse Events for PTs with Frequency >10% in any Treatment Group (eCRF Section 'AE Log' for Unsolicited AEs and 'Subject Diary' for Solicited AEs, Safety Population)	Including statistical test
N/A	N/A	14.3.4.12	Subjects with any Non-Serious AEs During Entire Study by SOC and PT for PTs with Frequency >10% in any Treatment Group (eCRF Section 'AE Log' for Unsolicited AEs and 'Subject Diary' for Solicited AEs, Safety Population)	Including statistical test
14.1.4.13	14.2.4.13	14.3.4.13	Subjects with Solicited Adverse Events after any Vaccination (Safety Population)	Including statistical test
14.1.4.14	14.2.4.14	14.3.4.14	Subjects with Severe Solicited Adverse Events after any Vaccination by Symptom (Safety Population)	Including statistical test
14.1.4.15	14.2.4.15	14.3.4.15	Subjects with Solicited Local Adverse Events after any Vaccination by Symptom (Safety Population)	Including statistical test
14.1.4.16	14.2.4.16	14.3.4.16	Subjects with Solicited Local Adverse Events reaching FDA	Including statistical test

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IA D208 No	IA D365 No	FA No	Legend	Content/Comment
			grading after any Vaccination by Symptom (Safety Population)	
14.1.4.17	14.2.4.17	14.3.4.17	Subjects with Solicited Local Adverse Events after any Vaccination by Symptom and Age Group (Safety Population)	Including statistical test
14.1.4.18	14.2.4.18	14.3.4.18	Subjects with Solicited Local Adverse Events after any Vaccination by Symptom and baseline B.b. s.l. serostatus (Safety Population)	Including statistical test
14.1.4.19	14.2.4.19	14.3.4.19	Subjects with Solicited Systemic Adverse Events after any Vaccination by Symptom (Safety Population)	Including statistical test
14.1.4.20	14.2.4.20	14.3.4.20	Subjects with Solicited Systemic Adverse Events after any Vaccination by Symptom and Age Group (Safety Population)	Including statistical test
14.1.4.21	14.2.4.21	14.3.4.21	Subjects with Solicited Systemic Adverse Events after any Vaccination by Symptom and baseline B.b. s.l. serostatus (Safety Population)	Including statistical test
14.1.4.22	14.2.4.22	14.3.4.22	Subjects with Solicited Adverse Events after any Vaccination Classified by Maximum Severity (Safety Population)	Including statistical test
14.1.4.23	14.2.4.23	14.3.4.23	Subjects with Solicited Local Adverse Events after any Vaccination by Symptom Classified by Maximum Severity (Safety Population)	Including statistical test
14.1.4.24	14.2.4.24	14.3.4.24	Subjects with Solicited Local Adverse Events after any Vaccination by Symptom and Age Group Classified by Maximum Severity (Safety Population)	Including statistical test
14.1.4.25	14.2.4.25	14.3.4.25	Subjects with Solicited Local Adverse Events after any Vaccination by Symptom and baseline B.b. s.l. serostatusClassified by Maximum Severity (Safety Population)	Including statistical test
14.1.4.26	14.2.4.26	14.3.4.26	Subjects with Solicited Systemic Adverse Events after any	Including statistical test

IA D208 No	IA D365 No	FA No	Legend	Content/Comment
			Vaccination by Symptom Classified by Maximum Severity (Safety Population)	
14.1.4.27	14.2.4.27	14.3.4.27	Subjects with Solicited Systemic Adverse Events after any Vaccination by Symptom and Age Group Classified by Maximum Severity (Safety Population)	Including statistical test
14.1.4.28	14.2.4.28	14.3.4.28	Subjects with Solicited Systemic Adverse Events after any Vaccination by Symptom and baseline B.b. s.l. serostatusClassified by Maximum Severity (Safety Population)	Including statistical test
14.1.4.29	14.2.4.29	14.3.4.29	Subjects with Solicited Adverse Events by Vaccination Period (Safety Population)	Including statistical test
14.1.4.30	14.2.4.30	14.3.4.30	Subjects with Solicited Local Adverse Events by Symptom and by Vaccination Period (Safety Population)	Including statistical test
14.1.4.31	14.2.4.31	14.3.4.31	Subjects with Solicited Local Adverse Events reaching FDA grading by Symptom and Vaccination Period (Safety Population)	Including statistical test
14.1.4.32	14.2.4.32	14.3.4.32	Subjects with Solicited Systemic Adverse Events by Symptom and by Vaccination Period (Safety Population)	Including statistical test
14.1.4.33	14.2.4.33	14.3.4.33	Subjects with Solicited Adverse Events by Vaccination Period Classified by Maximum Severity (Safety Population)	Including statistical test
14.1.4.34	14.2.4.34	14.3.4.34	Subjects with Solicited Local Adverse Events by Vaccination Period Classified by Maximum Severity (Safety Population)	Including statistical test
14.1.4.35	14.2.4.35	14.3.4.35	Subjects with Solicited Systemic Adverse Events by Vaccination Period Classified by Maximum Severity (Safety Population)	Including statistical test
14.1.4.36	14.2.4.36	14.3.4.36	Subjects with Solicited Local Adverse Events by Symptom and Vaccination Period Classified by	Including statistical test

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IA D208 No	IA D365 No	FA No	Legend	Content/Comment
			Maximum Severity (Safety Population)	
14.1.4.37	14.2.4.37	14.3.4.37	Subjects with Solicited Systemic Adverse Events by Symptom and Vaccination Period Classified by Maximum Severity (Safety Population)	Including statistical test
14.1.4.38	14.2.4.38	14.3.4.38	Subjects with Solicited Adverse Events by Diary Day (Safety Population)	Including statistical test
14.1.4.39	14.2.4.39	14.3.4.39	Subjects with Solicited Local Adverse Events by Diary Day (Safety Population)	Including statistical test
14.1.4.40	14.2.4.40	14.3.4.40	Subjects with Solicited Systemic Adverse Events by Diary Day (Safety Population)	Including statistical test
14.1.4.41	14.2.4.41	14.3.4.41	Greatest Diameter for Present Local Reactions after each Vaccination, by Symptom (Safety Population)	
14.1.4.42	14.2.4.42	14.3.4.42	Maximum Fever after each Vaccination (Safety Population)	
14.1.4.43	14.2.4.43	14.3.4.43	Number of Days with Solicited Local AE by Diary Period (Safety Population)	
14.1.4.44	14.2.4.44	14.3.4.44	Number of Days with Solicited Systemic AE by Diary Period (Safety Population)	
14.1.4.43	14.2.4.45.1	N/A	Subjects with Unsolicited Adverse Events up to Day 208 by SOC and PT (Safety Population)	Including statistical test
N/A	14.2.4.45.2	N/A	Subjects with Unsolicited Adverse Events up to Day 365 by SOC and PT (Safety Population)	Including statistical test
N/A	N/A	14.3.4.45	Subjects with Unsolicited Adverse Events During Entire Study by SOC and PT (Safety Population)	Including statistical test
14.1.4.46	14.2.4.46.1	N/A	Subjects with Related Unsolicited Adverse Events up to Day 208 by SOC and PT (Safety Population)	Including statistical test
N/A	14.2.4.46.2	N/A	Subjects with Related Unsolicited Adverse Events up to Day 365 by SOC and PT (Safety Population)	Including statistical test

IA D208 No	IA D365 No	FA No	Legend	Content/Comment
N/A	N/A	14.3.4.46	Subjects with Related Unsolicited Adverse Events During Entire Study by SOC and PT (Safety Population)	Including statistical test
14.1.4.47	14.2.4.47.1	N/A	Subjects with Severe Unsolicited Adverse Events up to Day 208 by SOC and PT (Safety Population)	Including statistical test
N/A	14.2.4.47.2	N/A	Subjects with Severe Unsolicited Adverse Events up to Day 365 by SOC and PT (Safety Population)	Including statistical test
N/A	N/A	14.3.4.47	Subjects with Severe Unsolicited Adverse Events During Entire Study by SOC and PT (Safety Population)	Including statistical test
14.1.4.48	14.2.4.48.1	N/A	Subjects with Related Severe Unsolicited Adverse Events up to Day 208 by SOC and PT (Safety Population)	Including statistical test
N/A	14.2.4.48.2	N/A	Subjects with Related Severe Unsolicited Adverse Events up to Day 365 by SOC and PT (Safety Population)	Including statistical test
N/A	N/A	14.3.4.48	Subjects with Related Severe Unsolicited Adverse Events During Entire Study by SOC and PT (Safety Population)	Including statistical test
14.1.4.49	14.2.4.49.1	N/A	Subjects with Adverse Events of Special Interest up to Day 208 by SOC and PT (Safety Population)	Including statistical test
N/A	14.2.4.49.2	N/A	Subjects with Adverse Events of Special Interest up to Day 365 by SOC and PT (Safety Population)	Including statistical test
N/A	N/A	14.3.4.49	Subjects with Adverse Events of Special Interest During Entire Study by SOC and PT (Safety Population)	Including statistical test
14.1.4.50	14.2.4.50.1	N/A	Subjects with Related Adverse Events of Special Interest up to Day 208 by SOC and PT (Safety Population)	Including statistical test
N/A	14.2.4.50.2	N/A	Subjects with Related Adverse Events of Special Interest up to Day 365 by SOC and PT (Safety Population)	Including statistical test
N/A	N/A	14.3.4.50	Subjects with Related Adverse Events of Special Interest During	Including statistical test

IA D208 No	IA D365 No	FA No	Legend	Content/Comment
			Entire Study by SOC and PT (Safety Population)	
14.1.4.51	14.2.4.51.1	N/A	Subjects with at least one Unsolicited Adverse Event up to Day 208 by Maximum Severity (Safety Population)	Including statistical test
N/A	14.2.4.51.2	N/A	Subjects with at least one Unsolicited Adverse Event up to Day 365 by Maximum Severity (Safety Population)	Including statistical test
N/A	N/A	14.3.4.51	Subjects with at least one Unsolicited Adverse Event During Entire Study by Maximum Severity (Safety Population)	Including statistical test
14.1.4.52	14.2.4.52.1	N/A	Subjects with at least one Medically Attended Unsolicited Adverse Event up to Day 208 by Maximum Severity (Safety Population)	Including statistical test
N/A	14.2.4.52.2	N/A	Subjects with at least one Medically Attended Unsolicited Adverse Event up to Day 365 by Maximum Severity (Safety Population)	Including statistical test
N/A	N/A	14.3.4.52	Subjects with at least one Medically Attended Unsolicited Adverse Event During Entire Study by Maximum Severity (Safety Population)	Including statistical test
14.1.4.53	14.2.4.53.1	N/A	Subjects with at least one Adverse Event of Special Interest up to Day 208 by Maximum Severity (Safety Population)	Including statistical test
N/A	14.2.4.53.2	N/A	Subjects with at least one Adverse Event of Special Interest up to Day 365 by Maximum Severity (Safety Population)	Including statistical test
N/A	N/A	14.3.4.53	Subjects with at least one Adverse Event of Special Interest During Entire Study by Maximum Severity (Safety Population)	Including statistical test
14.1.4.54	14.2.4.54.1	N/A	Subjects with at least one Unsolicited Adverse Event up to Day 208 by Causality (Safety Population)	Including statistical test

IA D208 No	IA D365 No	FA No	Legend	Content/Comment
N/A	14.2.4.54.2	N/A	Subjects with at least one Unsolicited Adverse Event up to Day 365 by Causality (Safety Population)	Including statistical test
N/A	N/A	14.3.4.54	Subjects with at least one Unsolicited Adverse Event During Entire Study by Causality (Safety Population)	Including statistical test
14.1.4.55	14.2.4.55.1	N/A	Subjects with at least one Medically Attended Unsolicited Adverse Event up to Day 208 by Causality (Safety Population)	Including statistical test
N/A	14.2.4.55.2	N/A	Subjects with at least one Medically Attended Unsolicited Adverse Event up to Day 365 by Causality (Safety Population)	Including statistical test
N/A	N/A	14.3.4.55	Subjects with at least one Medically Attended Unsolicited Adverse Event During Entire Study by Causality (Safety Population)	Including statistical test
14.1.4.56	14.2.4.56.1	N/A	Subjects with at least one Adverse Event of Special Interest up to Day 208 by Causality (Safety Population)	Including statistical test
N/A	14.2.4.56.2	N/A	Subjects with at least one Adverse Event of Special Interest up to Day 365 by Causality (Safety Population)	Including statistical test
N/A	N/A	14.3.4.56	Subjects with at least one Adverse Event of Special Interest During Entire Study by Causality (Safety Population)	Including statistical test
14.1.4.57	14.2.4.57	14.3.4.57	Absolute Values for Hematology Parameters by Parameter and Visit (Safety Population)	
14.1.4.58	14.2.4.58	14.3.4.58	Absolute Values for Clinical Chemistry Parameters by Parameter and Visit (Safety Population)	
14.1.4.59	14.2.4.59	14.3.4.59	Absolute Changes from Baseline for Hematology Parameters by Parameter and Visit (Safety Population)	
14.1.4.60	14.2.4.60	14.3.4.60	Absolute Changes from Baseline for Clinical Chemistry Parameters	

IA D208 No	IA D365 No	FA No	Legend	Content/Comment
			by Parameter and Visit (Safety Population)	
14.1.4.61	14.2.4.61	14.3.4.61	Subjects with Hematology Parameters Outside Normal Range by Parameter and Visit (Safety Population)	
14.1.4.62	14.2.4.62	14.3.4.62	Subjects with Clinical Chemistry Parameters Outside Normal Range by Parameter and Visit (Safety Population)	
14.1.4.63	14.2.4.63	14.3.4.63	Subjects with Coagulation Parameters Outside Normal Range by Parameter (Safety Population)	
14.1.4.64	14.2.4.64	14.3.4.64	Urine Laboratory Results by Parameter and Visit (Safety Population)	
14.1.4.65	14.2.4.65	14.3.4.65	Subjects with Abnormal pH and Specific Gravity Values by Parameter and Visit (Safety Population)	
14.1.4.66	14.2.4.66	14.3.4.66	Subjects Reaching Severity Grading for Hematology Parameters by Parameter and Visit (Safety Population)	
14.1.4.67	14.2.4.67	14.3.4.67	Subjects Reaching Severity Grading for Clinical Chemistry Parameters by Parameter and Visit (Safety Population)	
14.1.4.68	14.2.4.68	14.3.4.68	Systolic Blood Pressure [mmHg] by Visit (Safety Population)	
14.1.4.69	14.2.4.69	14.3.4.69	Diastolic Blood Pressure [mmHg] by Visit (Safety Population)	
14.1.4.70	14.2.4.70	14.3.4.70	Pulse Rate [beats/min] by Visit (Safety Population)	
14.1.4.71	14.2.4.71	14.3.4.71	Oral Temperature [°C] by Visit (Safety Population)	

7.2 List of Data Listings

7.2.1 Overall Study Information

IA D208 No	IA D365 No	FA No	Legend	Content
16.2.1.1.1	16.2.2.1.1	16.2.3.1.1	Subject overview	Subject ID, Country, Site Name, Study Part, Date of signed informed consent, Subject eligible to be randomized, Reason not randomized, Planned Treatment, Actual Treatment, Safety/mITT Population, Reason not in Safety/mITT Population, PP Population, Reason not in PP Population
16.2.1.1.2	16.2.2.1.2	16.2.3.1.2	Screening Failure with Reason	Subject ID, Withdrawal of consent, In/Ex criteria not met, Other reason screening failure, Specification of other reason for screening failure
16.2.1.1.3	16.2.2.1.3	16.2.3.1.3	In/Exclusion Criteria that were not Met	Subject ID, Visit, Criterion ID not met, Criterion description
16.2.1.1.4	16.2.2.1.4	16.2.3.1.4	Study Vaccination (Vaccinated Subjects)	Subject ID, Group, Visit, Vaccination administered, Reason if not Administered, Date, Time, Kit number, Location, Other location (specification/reason)
16.2.1.1.5	16.2.2.1.5	16.2.3.1.5	Visit Log (Vaccinated Subjects)	Subject ID, Group, Visit, Visit performed, Visit Date, Reason visit not performed, Deviation from time window [days], Reason outside time window, Age, Reason for unscheduled visit, Type of contact (ET visit)
16.2.1.1.6	16.2.2.1.6	16.2.3.1.6	Missed Visits, Missed Vaccinations, Early Terminations: Part I (Vaccinated Subjects)	Subject ID, Group, Visit attendance, All vaccinations administered, Primary reason treatment discontinuation, Other reason for treatment discontinuation, AE Term (treatment discontinuation), Reason for recommended withdrawal (treatment discontinuation), Individual stopping criteria, AE Term (stopping criteria)
16.2.1.1.7	16.2.2.1.7	16.2.3.1.7	Missed Visits, Missed Vaccinations, Early Terminations: Part II (Vaccinated Subjects)	Subject ID, Group, Is the primary reason for treatment discontinuation the same as for early termination, Primary reason for early termination, Other reason for early

IA D208 No	IA D365 No	FA No	Legend	Content
				termination, AE Term (early termination), Reason for recommended withdrawal (early termination), Death date, Primary cause of death, Date of ET, Last attended scheduled visit before ET
16.2.1.1.8	16.2.2.1.8	16.2.3.1.8	Protocol Deviations (Vaccinated Subjects)	Subject ID, Group, PD Category, PD Description, Severity (PP Population), Reason for classification, Severity (ICH E3), Severity (Monitoring)
16.2.1.1.9	16.2.2.1.9	16.2.3.1.9	Visits Performed as Phone Call Due to Covid-19 (Vaccinated Subjects)	Subject ID, Group, Visit, Visit performed, Visit Date, Reason visit not performed, Deviation from time window [days], Reason outside time window, Age, Reason for unscheduled visit, Type of contact (ET visit)

7.2.2 Baseline

IA D208 No	IA D365 No	FA No	Legend	Content
16.2.1.2.1	16.2.2.2.1	16.2.3.2.1	Demographics (Vaccinated Subjects)	Subject ID, Group, Gender, Childbearing potential, Reason no childbearing potential (other), Year of birth, Age at Screening [years], Age group, Race (other), Body height [cm], Body weight [kg], BMI [kg/m2]
16.2.1.2.2	16.2.2.2.2	16.2.3.2.2	Physical Examination at Screening (Vaccinated Subjects)	Subject ID, Group, Visit, Physical examination performed, Reason not performed, Examination Date
16.2.1.2.3	16.2.2.2.3	16.2.3.2.3	ECG (Vaccinated Subjects)	Subject ID, Group, ECG performed, Date, Reason ECG not performed, ECG Result, ECG clinically relevant
16.2.1.2.4	16.2.2.2.4	16.2.3.2.4	HIV Test (Vaccinated Subjects)	Subject ID, Group, Test performed, Reason test not performed, Date, Result
16.2.1.2.5	16.2.2.2.5	16.2.3.2.5	Medical History (Vaccinated Subjects)	Subject ID, Group, Condition, MedDRA PT (version), MedDRA SOC (version), Start Date, End Date, Ongoing at study entry

IA D208 No	IA D365 No	FA No	Legend	Content
16.2.1.2.6	16.2.2.2.6	16.2.3.2.6	Prior Medications (Vaccinated Subjects)	Subject ID, Group, Medication or therapy, Start Date, End Date, ATC term level 2 (version), ATC term level 3 (version), Dose Unit, Dose Form, Frequency, Route, Indication category, Indication
16.2.1.2.7	16.2.2.2.7	16.2.3.2.7	Concomitant Medications (Vaccinated Subjects)	Subject ID, Group, Medication or therapy, Start Date, End Date, ATC term level 2 (version), ATC term level 3 (version), Dose Unit, Dose Form, Frequency, Route, Indication category, Indication
16.2.1.2.8	16.2.2.2.8	16.2.3.2.8	Prior Procedures (Vaccinated Subjects)	Subject ID, Group, Procedure, Start Date, CP ongoing at study end, End Date, Indication category, Indication, MedDRA PT (version), MedDRA SOC (version)
16.2.1.2.9	16.2.2.2.9	16.2.3.2.9	Concomitant Procedures (Vaccinated Subjects)	Subject ID, Group, Procedure, Start Date, CP ongoing at study end, End Date, Indication category, Indication, MedDRA PT (version), MedDRA SOC (version)
16.2.1.2.10	16.2.2.2.10	16.2.3.2.10	Vaccination History (Vaccinated Subjects)	Subject ID, Group, Date of Vaccination, Vaccination (indication or trade name, ATC term level 3 (version)

7.2.3 *Immunogenicity*

IA D208 No	FA No	Legend	Content
16.2.1.3.1	16.2.3.3.1	ELISA: Immunogenicity Results Part 1 (Treated Subjects)	Subject number, Planned Treatment (mITT), Sample included in PP analysis, Visit, Date of visit, Time of visit, Sample drawn, Reason for not drawn, Sample ID, Plate ID, Antigen, IgG titer [U/mL] (measured), Sample Status, IgG titer [U/mL] (analysis), Fold increase from Day 1, ELISA Seroconversion since V1
16.2.1.3.2	16.2.3.3.2	ELISA: Immunogenicity Results Part 2 (Treated Subjects)	Subject number, Planned Treatment (mITT), Sample included in PP analysis, Visit, Date of visit, Time of visit, Seroconversion for all six serotypes ST1-6, Seroconversion for ST1 and ST2

IA D208 No	FA No	Legend	Content
16.2.1.3.3	16.2.3.3.3	SBA: Immunogenicity Results Part 1 (Treated Subjects)	Subject number, Planned Treatment (mITT), Sample included in PP analysis, Visit, Date of visit, Time of visit, Sample drawn, Reason for not drawn, Sample ID, Plate ID, SBA titer (measured), Sample Status, titer (analysis), Fold increase from Day 1, Seroconversion since V1
16.2.1.3.4	16.2.3.3.4	SBA: Immunogenicity Results Part 2 (Treated Subjects)	Subject number, Planned Treatment (mITT), Sample included in PP analysis, Visit, Date of visit, Time of visit, Seroconversion for all six serotypes ST1-6, Seroconversion for ST1 and ST2

7.2.4 Safety

IA D208 No	IA D365 No	FA No	Legend	Content
16.2.1.4.1.1	16.2.2.4.1.1	16.2.3.4.1.1	Unsolicited Adverse Events Part I (Vaccinated Subjects)	Subject number, Group, Adverse Event, MedDRA PT (version), MedDRA SOC(version), Start date, Start time, Study day of onset, Onset after vacc., Onset (relative to previous vacc.) [days], End Date, End time, Duration of AE [days]
16.2.1.4.1.2	16.2.2.4.1.2	16.2.3.4.1.2	Unsolicited Adverse Events Part II (Vaccinated Subjects)	Subject number, Group, Adverse Event, Event considered as AESI, Specialist work-up performed, Medically attended, Serious adverse event, SAE criteria, Severity, Causality, Action taken on IMP, Action taken general, Outcome
16.2.1.4.1.3	16.2.2.4.1.3	16.2.3.4.1.3	Related Unsolicited Adverse Events Part I (Vaccinated Subjects)	See Listing 16.2.1.4.1.1
16.2.1.4.1.4	16.2.2.4.1.4	16.2.3.4.1.4	Related Unsolicited Adverse Events Part II (Vaccinated Subjects)	See Listing 16.2.1.4.1.2
16.2.1.4.1.5	16.2.2.4.1.5	16.2.3.4.1.5	Severe Unsolicited Adverse Events Part I (Vaccinated Subjects)	See Listing 16.2.1.4.1.1
16.2.1.4.1.6	16.2.2.4.1.6	16.2.3.4.1.6	Severe Unsolicited Adverse Events Part II (Vaccinated Subjects)	See Listing 16.2.1.4.1.2

IA D208 No	IA D365 No	FA No	Legend	Content
16.2.1.4.1.7	16.2.2.4.1.7	16.2.3.4.1.7	Serious Adverse Events Part I (Vaccinated Subjects)	See Listing 16.2.1.4.1.1
16.2.1.4.1.8	16.2.2.4.1.8	16.2.3.4.1.8	Serious Adverse Events Part II (Vaccinated Subjects)	Subject number, Group, Adverse Event, Type of AE, Event considered as AESI, Specialist work-up performed, Medically attended, Serious, SAE criteria, Severity, Causality, Action taken on IMP, Action taken general, Outcome
16.2.1.4.1.9	16.2.2.4.1.9	16.2.3.4.1.9	Medically Attended Adverse Events Part I (Vaccinated Subjects)	See Listing 16.2.1.4.1.1
16.2.1.4.1.10	16.2.2.4.1.10	16.2.3.4.1.10	Medically Attended Adverse Events Part II (Vaccinated Subjects)	See Listing 16.2.1.4.1.8
16.2.1.4.1.11	16.2.2.4.1.11	16.2.3.4.1.11	Adverse Events Resulting in Death Part I (Vaccinated Subjects)	See Listing 16.2.1.4.1.1
16.2.1.4.1.12	16.2.2.4.1.12	16.2.3.4.1.12	Adverse Events Resulting in Death Part II (Vaccinated Subjects)	See Listing 16.2.1.4.1.8
16.2.1.4.1.13	16.2.2.4.1.13	16.2.3.4.1.13	Adverse Events Leading to Withdrawal from Further Vaccination (Vaccinated Subjects)	Subject number, Group, Adverse event term, MedDRA PT (version), MedDRA SOC(version), Severity, Causality, Start date, Withdrawn from further vacc. after vacc., Onset (relative to previous vacc.)[days], Estimated Duration of AE (incl. missing stop date) [days]
16.2.1.4.1.14	16.2.2.4.1.14	16.2.3.4.1.14	Adverse Events Leading to Withdrawal from the Study (Vaccinated Subjects)	Subject number, Group, Adverse event term, MedDRA PT (version), MedDRA SOC(version), Severity, Causality, Start date, Withdrawn from study after vacc., Onset (relative to previous vacc.) [days], Estimated Duration of AE (incl. missing stop date) [days]
16.2.1.4.1.15	16.2.2.4.1.15	16.2.3.4.1.15	Adverse Events with Missing Assessment (eCRF Section "AE log") Part I (Vaccinated Subjects)	See Listing 16.2.1.4.1.1

IA D208 No	IA D365 No	FA No	Legend	Content
16.2.1.4.1.16	16.2.2.4.1.16	16.2.3.4.1.16	Adverse Events with Missing Assessment (eCRF Section "AE log") Part II (Vaccinated Subjects)	See Listing 16.2.1.4.1.8
16.2.1.4.1.17	16.2.2.4.1.17	16.2.3.4.1.17	Solicited Adverse Events by Diary Day (Vaccinated Subjects)	Subject number, Group, Symptom, Present after vaccination, Serious, Medically attended, Taken any medication due to symptom, Withdrawn from further vaccination, Withdrawn from study, Time point, Symptom ongoing after Day 6, Meets FDA Toxicity Grading Scale, Grade per diary day (incl. not present), Size [cm], Oral body temperature [°C]
16.2.1.4.1.18	16.2.2.4.1.18	16.2.3.4.1.18	Severe Solicited Adverse Events by Diary Day (Vaccinated Subjects)	See Listing 16.2.1.4.1.17
16.2.1.4.1.19	16.2.2.4.1.19	16.2.3.4.1.19	Solicited Adverse Events with Missing Assessments by Diary Day (Vaccinated Subjects)	See Listing 16.2.1.4.1.17
16.2.1.4.1.20	16.2.2.4.1.20	16.2.3.4.1.20	Solicited Adverse Events by Diary Period (Vaccinated Subjects)	Subject number, Group, Symptom, Present after vaccination, Serious, Medically attended, Taken any medication due to symptom, Withdrawn from furthervaccination, Withdrawn from study, Onset (relative to previous vacc.) [days], Stop day (relative to previous vacc.) [days], Maximum severity (grade 0-4 and n/p)
16.2.1.4.1.21	16.2.2.4.1.21	16.2.3.4.1.21	Severe Solicited Adverse Events by Diary Period (Vaccinated Subjects)	See Listing 16.2.1.4.1.21
16.2.1.4.2.1	16.2.2.4.2.1	16.2.3.4.2.1	Hematology Values Outside Normal Range or Meeting FDA Grading Scale for Lab Assessments (Vaccinated Subjects)	Subject number, Group, Visit, Date, Time, Parameter, FDA Grading, Result, Unit, Lower Limit, Upper Limit, Result (converted), Unit (converted), Lower limit (converted), Upper limit (converted), Out of normal

IA D208 No	IA D365 No	FA No	Legend	Content
				range, Clinically relevant, Likely cause (if available)
16.2.1.4.2.2	16.2.2.4.2.2	16.2.3.4.2.2	Clinical Chemistry Values Outside Normal Range or Meeting FDA Grading Scale for Lab Assessments (Vaccinated Subjects)	See Listing 16.2.1.4.2.1
16.2.1.4.2.3	16.2.2.4.2.3	16.2.3.4.2.3	Coagulation Values Outside Normal Range (Vaccinated Subjects)	Subject number, Group, Visit, Date, Parameter, Result, Unit, Lower Limit, Upper Limit, Result (converted), Unit (converted), Lower limit (converted), Upper limit (converted), Out of normal range, Clinically relevant, Likely cause (if available)
16.2.1.4.2.4	16.2.2.4.2.4	16.2.3.4.2.4	Urinalysis Values Outside Normal Range (Vaccinated Subjects)	Subject number, Group, Visit, Date, Time, Test, Result, Clinically relevant, Likely cause (if available)
16.2.1.4.3.1	16.2.2.4.3.1	16.2.3.4.3.1	Vital Signs by Visit (Vaccinated Subjects)	Subject number, Group, Visit, Specifier, Date, Time, Systolic Blood Pressure [mmHg], Diastolic Blood Pressure [mmHg], Pulse Rate [beats/min], Oral body temperature [°C]
16.2.1.4.3.2	16.2.2.4.3.2	16.2.3.4.3.2	Physical Examination (Vaccinated Subjects)	Subject number, Group, Visit, Specifier, Examination Date, Examination Time, Type of physical examination, Physical examination performed, Reason physical examination/observation not performed
16.2.1.4.3.3	16.2.2.4.3.3	16.2.3.4.3.3	Pregnancy Test (Vaccinated Female Subjects)	Subject number, Group, Visit, Date, Time, Pregnancy test performed, Reason not performed, Type, Result
16.2.1.4.3.4	16.2.2.4.3.4	16.2.3.4.3.4	Injection Site Inspection (Vaccinated Subjects)	Subject number, Group, Visit, Date, Time, Inspection of injection site performed, Reason not performed, Any findings
16.2.1.4.3.5	16.2.2.4.3.5	16.2.3.4.3.5	Body Temperature in Case of Fever (Vaccinated Subjects)	Subject number, Group, Visit, Time point, Body temperature [°C]

IA D208 No	IA D365 No	FA No	Legend	Content
16.2.1.4.3.6	16.2.2.4.3.6	16.2.3.4.3.6	Lyme Borreliosis Screening (Vaccinated Subjects)	Subject number, Group, Visit, Date, Sample analysis performed, Reason not collected/performed, Result (C6 ELISA assay), Confirmatory immunoblot performed, Reason conf. immunoblot not done, IgM Result (Immunoblot), IgG Result (Immunoblot), *B.b. s.l.* serostatus
16.2.1.4.3.7	16.2.2.4.3.7	16.2.3.4.3.7	Vaccination Delay Criteria (Vaccinated Subjects)	Subject number, Group, Visit, Checklist question, Answer

7.3 List of Figures

7.3.1 Immunogenicity

IA D208 No	FA No	Legend
14.1.3.1.1	14.3.3.1.1	Bar Chart: ELISA OspA- Specific IgG Antibodies (GMT) by OspA Serotype and Treatment Group, Day 1 (PP Population)
N/A	14.3.3.1.2	Bar Chart: ELISA OspA- Specific IgG Antibodies (GMT) by OspA Serotype and Treatment Group, Day 29 (PP Population)
N/A	14.3.3.1.3	Bar Chart: ELISA OspA- Specific IgG Antibodies (GMT) by OspA Serotype and Treatment Group, Day 57 (PP Population)
14.1.3.1.4	14.3.3.1.4	Bar Chart: ELISA OspA- Specific IgG Antibodies (GMT) by OspA Serotype and Treatment Group, Day 85 (PP Population)
N/A	14.3.3.1.5	Bar Chart: ELISA OspA- Specific IgG Antibodies (GMT) by OspA Serotype and Treatment Group, Day 180 (PP Population)
14.1.3.1.6	14.3.3.1.6	Bar Chart: ELISA OspA- Specific IgG Antibodies (GMT) by OspA Serotype and Treatment Group, Day 208 (PP Population)
N/A	14.3.3.1.7	Bar Chart: ELISA OspA- Specific IgG Antibodies (GMT) by OspA Serotype and Treatment Group, Day 365 (PP Population)
N/A	14.3.3.1.8	Bar Chart: ELISA OspA- Specific IgG Antibodies (GMT) by OspA Serotype and Treatment Group, Day 545 (PP Population)
N/A	14.3.3.1.9	Bar Chart: ELISA Seroconversion Rate by OspA Serotype and Treatment Group at Day 29 (PP Population)
N/A	14.3.3.1.10	Bar Chart: ELISA Seroconversion Rate by OspA Serotype and Treatment Group at Day 57 (PP Population)
14.1.3.1.11	14.3.3.1.11	Bar Chart: ELISA Seroconversion Rate by OspA Serotype and Treatment Group at Day 85 (PP Population)

[redacted]

IA D208 No	FA No	Legend
N/A	14.3.3.1.12	Bar Chart: ELISA Seroconversion Rate by OspA Serotype and Treatment Group at Day 180 (PP Population)
14.1.3.1.13	14.3.3.1.13	Bar Chart: ELISA Seroconversion Rate by OspA Serotype and Treatment Group at Day 208 (PP Population)
N/A	14.3.3.1.14	Bar Chart: ELISA Seroconversion Rate by OspA Serotype and Treatment Group at Day 365 (PP Population)
N/A	14.3.3.1.15	Bar Chart: ELISA Seroconversion Rate by OspA Serotype and Treatment Group at Day 545 (PP Population)
14.1.3.1.16	14.3.3.1.16	Bar Chart: ELISA Seroconversion Rate for OspA STs 1-6 Combined over Time vs. Treatment Group (PP Population)
14.1.3.1.17	14.3.3.1.17	Bar Chart: ELISA Seroconversion Rate for OspA Serotypes ST1 and ST2 Combined over Time vs. Treatment Group (PP Population)
14.1.3.1.18	14.3.3.1.18	Line Chart: ELISA OspA- Specific IgG Antibodies (GMT) over Time vs. Treatment Group for ST1 (PP Population)
14.1.3.1.19	14.3.3.1.19	Line Chart: ELISA OspA- Specific IgG Antibodies (GMT) over Time vs. Treatment Group for ST2 (PP Population)
14.1.3.1.20	14.3.3.1.20	Line Chart: ELISA OspA- Specific IgG Antibodies (GMT) over Time vs. Treatment Group for ST3 (PP Population)
14.1.3.1.21	14.3.3.1.21	Line Chart: ELISA OspA- Specific IgG Antibodies (GMT) over Time vs. Treatment Group for ST4 (PP Population)
14.1.3.1.22	14.3.3.1.22	Line Chart: ELISA OspA- Specific IgG Antibodies (GMT) over Time vs. Treatment Group for ST5 (PP Population)
14.1.3.1.23	14.3.3.1.23	Line Chart: ELISA OspA- Specific IgG Antibodies (GMT) over Time vs. Treatment Group for ST6 (PP Population)
14.1.3.1.24	14.3.3.1.24	Line Chart: ELISA OspA- Specific IgG Antibodies (GMT) over Time per OspA serotype, Group VLA15 135 µg (PP Population)
14.1.3.1.25	14.3.3.1.25	Line Chart: ELISA OspA- Specific IgG Antibodies (GMT) over Time per OspA serotype, Group VLA15 180 µg (PP Population)
14.1.3.1.26	14.3.3.1.26	Reverse Cumulative Distribution Curves for ELISA Group 135 µg: Percentage of Subjects vs. OspA ST1-Specific IgG Antibodies (GMT) by Visit (PP Population)
14.1.3.1.27	14.3.3.1.27	Reverse Cumulative Distribution Curves for ELISA Group 180 µg: Percentage of Subjects vs. OspA ST1-Specific IgG Antibodies (GMT) by Visit (PP Population)
14.1.3.1.28	14.3.3.1.28	Reverse Cumulative Distribution Curves for ELISA Group 135 µg: Percentage of Subjects vs. OspA ST2-Specific IgG Antibodies (GMT) by Visit (PP Population)
14.1.3.1.29	14.3.3.1.29	Reverse Cumulative Distribution Curves for ELISA Group 180 µg: Percentage of Subjects vs. OspA ST2-Specific IgG Antibodies (GMT) by Visit (PP Population)

IA D208 No	FA No	Legend
14.1.3.1.30	14.3.3.1.30	Reverse Cumulative Distribution Curves for ELISA Group 135 µg: Percentage of Subjects vs. OspA ST3-Specific IgG Antibodies (GMT) by Visit (PP Population)
14.1.3.1.31	14.3.3.1.31	Reverse Cumulative Distribution Curves for ELISA Group 180 µg: Percentage of Subjects vs. OspA ST3-Specific IgG Antibodies (GMT) by Visit (PP Population)
14.1.3.1.32	14.3.3.1.32	Reverse Cumulative Distribution Curves for ELISA Group 135 µg: Percentage of Subjects vs. OspA ST4-Specific IgG Antibodies (GMT) by Visit (PP Population)
14.1.3.1.33	14.3.3.1.33	Reverse Cumulative Distribution Curves for ELISA Group 180 µg: Percentage of Subjects vs. OspA ST4-Specific IgG Antibodies (GMT) by Visit (PP Population)
14.1.3.1.34	14.3.3.1.34	Reverse Cumulative Distribution Curves for ELISA Group 135 µg: Percentage of Subjects vs. OspA ST5-Specific IgG Antibodies (GMT) by Visit (PP Population)
14.1.3.1.35	14.3.3.1.35	Reverse Cumulative Distribution Curves for ELISA Group 180 µg: Percentage of Subjects vs. OspA ST5-Specific IgG Antibodies (GMT) by Visit (PP Population)
14.1.3.1.36	14.3.3.1.36	Reverse Cumulative Distribution Curves for ELISA Group 135 µg: Percentage of Subjects vs. OspA ST6-Specific IgG Antibodies (GMT) by Visit (PP Population)
14.1.3.1.37	14.3.3.1.37	Reverse Cumulative Distribution Curves for ELISA Group 180 µg: Percentage of Subjects vs. OspA ST6-Specific IgG Antibodies (GMT) by Visit (PP Population)
14.1.3.1.38	14.3.3.1.38	Scatterplot: ELISA OspA ST1 IgG Antibodies vs. OspA ST2 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.39	14.3.3.1.39	Scatterplot: ELISA OspA ST1 IgG Antibodies vs. OspA ST3 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.40	14.3.3.1.40	Scatterplot: ELISA OspA ST1 IgG Antibodies vs. OspA ST4 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.41	14.3.3.1.41	Scatterplot: ELISA OspA ST1 IgG Antibodies vs. OspA ST5 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.42	14.3.3.1.42	Scatterplot: ELISA OspA ST1 IgG Antibodies vs. OspA ST6 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.43	14.3.3.1.43	Scatterplot: ELISA OspA ST2 IgG Antibodies vs. OspA ST3 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.44	14.3.3.1.44	Scatterplot: ELISA OspA ST2 IgG Antibodies vs. OspA ST4 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.45	14.3.3.1.45	Scatterplot: ELISA OspA ST2 IgG Antibodies vs. OspA ST5 IgG Antibodies at Day 208 (PP Population)

IA D208 No	FA No	Legend
14.1.3.1.46	14.3.3.1.46	Scatterplot: ELISA OspA ST2 IgG Antibodies vs. OspA ST6 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.47	14.3.3.1.47	Scatterplot: ELISA OspA ST3 IgG Antibodies vs. OspA ST4 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.48	14.3.3.1.48	Scatterplot: ELISA OspA ST3 IgG Antibodies vs. OspA ST5 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.49	14.3.3.1.49	Scatterplot: ELISA OspA ST3 IgG Antibodies vs. OspA ST6 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.50	14.3.3.1.50	Scatterplot: ELISA OspA ST4 IgG Antibodies vs. OspA ST5 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.51	14.3.3.1.51	Scatterplot: ELISA OspA ST4 IgG Antibodies vs. OspA ST6 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.52	14.3.3.1.52	Scatterplot: ELISA OspA ST5 IgG Antibodies vs. OspA ST6 IgG Antibodies at Day 208 (PP Population)
14.1.3.1.53	14.3.3.1.53	Bar Chart: ELISA OspA- Specific IgG Antibodies (GMT) by Serotype Over Time for Group 135 µg (PP Population)
14.1.3.1.54	14.3.3.1.54	Bar Chart: ELISA OspA- Specific IgG Antibodies (GMT) by Serotype Over Time for Group 180 µg (PP Population)
14.1.3.1.55	14.3.3.1.55	Bar Chart: ELISA OspA- Specific IgG Antibodies (GMT) by baseline B.b. s.l. serostatus and age group at Day 208 (PP Population, 135 µg)
14.1.3.1.56	14.3.3.1.56	Bar Chart: ELISA OspA- Specific IgG Antibodies (GMT) by baseline B.b. s.l. serostatusand age group at Day 208 (PP Population, 180 µg)
14.1.3.1.57	14.3.3.1.57	Bar Chart: SBA Titer (GMT) by OspA Serotype and Treatment Group, Day 1 (PP Population)
14.1.3.1.58	14.3.3.1.58	Bar Chart: SBA Titer (GMT) by OspA Serotype and Treatment Group, Day 208 (PP Population)
N/A	14.3.3.1.59	Bar Chart: SBA Titer (GMT) by OspA Serotype and Treatment Group, Day 365 (PP Population)
N/A	14.3.3.1.60	Bar Chart: SBA Titer (GMT) by OspA Serotype and Treatment Group, Day 545 (PP Population)
N/A	14.3.3.1.61	Bar Chart: SBA Seroconversion Rate by OspA Serotype and Treatment Group at Day 208 (PP Population)
N/A	14.3.3.1.62	Bar Chart: SBA Seroconversion Rate by OspA Serotype and Treatment Group at Day 365 (PP Population)
N/A	14.3.3.1.63	Bar Chart: SBA Seroconversion Rate by OspA Serotype and Treatment Group at Day 545 (PP Population)
14.1.3.1.64	14.3.3.1.64	Bar Chart: SBA Seroconversion Rate for OspA STs 1-6 Combined over Time vs. Treatment Group (PP Population)

IA D208 No	FA No	Legend
14.1.3.1.65	14.3.3.1.65	Bar Chart: SBA Seroconversion Rate for OspA Serotypes ST1 and ST2 Combined over Time vs. Treatment Group (PP Population)
14.1.3.1.66	14.3.3.1.66	Line Chart: OspA ST1–specific SBA Titer (GMT) over Time vs. Treatment Group (PP Population)
14.1.3.1.67	14.3.3.1.67	Line Chart: OspA ST2–specific SBA Titer (GMT) over Time vs. Treatment Group for ST2 (PP Population)
14.1.3.1.68	14.3.3.1.68	Line Chart: OspA ST3–specific SBA Titer (GMT) over Time vs. Treatment Group for ST3 (PP Population)
14.1.3.1.69	14.3.3.1.69	Line Chart: OspA ST4–specific SBA Titer (GMT) over Time vs. Treatment Group for ST4 (PP Population)
14.1.3.1.70	14.3.3.1.70	Line Chart: OspA ST5–specific SBA Titer (GMT) over Time vs. Treatment Group for ST5 (PP Population)
14.1.3.1.71	14.3.3.1.71	Line Chart: OspA ST6–specific SBA Titer (GMT) over Time vs. Treatment Group for ST6 (PP Population)
14.1.3.1.72	14.3.3.1.72	Line Chart: OspA –specific SBA Titer (GMT) over Time per OspA serotype, Group VLA15 135 µg (PP Population)
14.1.3.1.73	14.3.3.1.73	Line Chart: OspA ST1–specific SBA Titer (GMT) over Time per OspA serotype, Group VLA15 180 µg (PP Population)
14.1.3.1.74	14.3.3.1.74	Reverse Cumulative Distribution Curves for SBA Group 135 µg: Percentage of Subjects vs. OspA ST1 SBA Titer (GMT) by Visit (PP Population)
14.1.3.1.75	14.3.3.1.75	Reverse Cumulative Distribution Curves for SBA Group 180 µg: Percentage of Subjects vs. OspA ST1 SBA Titer (GMT) by Visit (PP Population)
14.1.3.1.76	14.3.3.1.76	Reverse Cumulative Distribution Curves for SBA Group 135 µg: Percentage of Subjects vs. OspA ST2 SBA Titer Antibodies (GMT) by Visit (PP Population)
14.1.3.1.77	14.3.3.1.77	Reverse Cumulative Distribution Curves for SBA Group 180 µg: Percentage of Subjects vs. OspA ST2 SBA Titer Antibodies (GMT) by Visit (PP Population)
14.1.3.1.78	14.3.3.1.78	Reverse Cumulative Distribution Curves for SBA Group 135 µg: Percentage of Subjects vs. OspA ST3 SBA Titer Antibodies (GMT) by Visit (PP Population)
14.1.3.1.79	14.3.3.1.79	Reverse Cumulative Distribution Curves for SBA Group 180 µg: Percentage of Subjects vs. OspA ST3 SBA Titer Antibodies (GMT) by Visit (PP Population)
14.1.3.1.80	14.3.3.1.80	Reverse Cumulative Distribution Curves for SBA Group 135 µg: Percentage of Subjects vs. OspA ST4 SBA Titer Antibodies (GMT) by Visit (PP Population)

IA D208 No	FA No	Legend
14.1.3.1.81	14.3.3.1.81	Reverse Cumulative Distribution Curves for SBA Group 180 µg: Percentage of Subjects vs. OspA ST4 SBA Titer Antibodies (GMT) by Visit (PP Population)
14.1.3.1.82	14.3.3.1.82	Reverse Cumulative Distribution Curves for SBA Group 135 µg: Percentage of Subjects vs. OspA ST5 SBA Titer Antibodies (GMT) by Visit (PP Population)
14.1.3.1.83	14.3.3.1.83	Reverse Cumulative Distribution Curves for SBA Group 180 µg: Percentage of Subjects vs. OspA ST5 SBA Titer Antibodies (GMT) by Visit (PP Population)
14.1.3.1.84	14.3.3.1.84	Reverse Cumulative Distribution Curves for SBA Group 135 µg: Percentage of Subjects vs. OspA ST6 SBA Titer Antibodies (GMT) by Visit (PP Population)
14.1.3.1.85	14.3.3.1.85	Reverse Cumulative Distribution Curves for SBA Group 180 µg: Percentage of Subjects vs. OspA ST6 SBA Titer Antibodies (GMT) by Visit (PP Population)
14.1.3.1.86	14.3.3.1.86	Scatterplot: SBA OspA ST1 Titer vs. OspA ST2 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.87	14.3.3.1.87	Scatterplot: SBA OspA ST1 Titer vs. OspA ST3 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.88	14.3.3.1.88	Scatterplot: SBA OspA ST1 Titer vs. OspA ST4 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.89	14.3.3.1.89	Scatterplot: SBA OspA ST1 Titer vs. OspA ST5 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.90	14.3.3.1.90	Scatterplot: SBA OspA ST1 Titer vs. OspA ST6 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.91	14.3.3.1.91	Scatterplot: SBA OspA ST2 Titer vs. OspA ST3 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.92	14.3.3.1.92	Scatterplot: SBA OspA ST2 Titer vs. OspA ST4 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.93	14.3.3.1.93	Scatterplot: SBA OspA ST2 Titer vs. OspA ST5 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.94	14.3.3.1.94	Scatterplot: SBA OspA ST2 Titer vs. OspA ST6 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.95	14.3.3.1.95	Scatterplot: SBA OspA ST3 Titer vs. OspA ST4 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.96	14.3.3.1.96	Scatterplot: SBA OspA ST3 Titer vs. OspA ST5 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.97	14.3.3.1.97	Scatterplot: SBA OspA ST3 Titer vs. OspA ST6 Titer Antibodies at Day 208 (PP Population)

IA D208 No	FA No	Legend
14.1.3.1.98	14.3.3.1.98	Scatterplot: SBA OspA ST4 Titer vs. OspA ST5 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.99	14.3.3.1.99	Scatterplot: SBA OspA ST4 Titer vs. OspA ST6 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.100	14.3.3.1.100	Scatterplot: SBA OspA ST5 Titer vs. OspA ST6 Titer Antibodies at Day 208 (PP Population)
14.1.3.1.101	14.3.3.1.101	Bar Chart: SBA Titer (GMT) by Serotype Over Time for Group 135 µg (PP Population)
14.1.3.1.102	14.3.3.1.102	Bar Chart: SBA Titer (GMT) by Serotype Over Time for Group 180 µg (PP Population)
14.1.3.1.103	14.3.3.1.103	Bar Chart: SBA Titer (GMT) by baseline B.b. s.l. serostatus and age group at Day 208 (PP Population, 135 µg)
14.1.3.1.104	14.3.3.1.104	Bar Chart: SBA Titer (GMT) by baseline B.b. s.l. serostatus and age group at Day 208 (PP Population, 180 µg)
14.1.3.1.105	14.3.3.1.105	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST1 at Day 1
14.1.3.1.106	14.3.3.1.106	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST2 at Day 1 (PP Population)
14.1.3.1.107	14.3.3.1.107	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST3 at Day 1 (PP Population)
14.1.3.1.108	14.3.3.1.108	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST4 at Day 1 (PP Population)
14.1.3.1.109	14.3.3.1.109	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST5 at Day 1 (PP Population)
14.1.3.1.110	14.3.3.1.110	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST6 at Day 1 (PP Population)
14.1.3.1.105	14.3.3.1.105	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST1 at Day 208
14.1.3.1.106	14.3.3.1.106	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST2 at Day 208 (PP Population)
14.1.3.1.107	14.3.3.1.107	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST3 at Day 208 (PP Population)

IA D208 No	FA No	Legend
14.1.3.1.108	14.3.3.1.108	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST4 at Day 208 (PP Population)
14.1.3.1.109	14.3.3.1.109	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST5 at Day 208 (PP Population)
14.1.3.1.110	14.3.3.1.110	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST6 at Day 208 (PP Population)
N/A	14.3.3.1.111	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST1 at Day 365 (PP Population)
N/A	14.3.3.1.112	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST2 at Day 365 (PP Population)
N/A	14.3.3.1.113	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST3 at Day 365 (PP Population)
N/A	14.3.3.1.114	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST4 at Day 365 (PP Population)
N/A	14.3.3.1.115	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST5 at Day 365 (PP Population)
N/A	14.3.3.1.116	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST6 at Day 365 (PP Population)
N/A	14.3.3.1.117 (if deemed meaningful)	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST1 at Day 545 (PP Population)
N/A	14.3.3.1.118 (if deemed meaningful)	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST2 at Day 545 (PP Population)
N/A	14.3.3.1.119 (if deemed meaningful)	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST3 at Day 545 (PP Population)

IA D208 No	FA No	Legend
N/A	14.3.3.1.120 (if deemed meaningful)	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST4 at Day 545 (PP Population)
N/A	14.3.3.1.121 (if deemed meaningful)	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST5 at Day 545 (PP Population)
N/A	14.3.3.1.122 (if deemed meaningful)	Scatter Plot: Correlation between ELISA and SBA titer for OspA ST6 at Day 545 (PP Population)

7.3.2 Safety

IA D208 No	IA D365 No	FA No	Legend
14.1.4.1	14.2.4.1	14.3.4.1	Bar Chart for Rate of Subjects with Solicited Local Adverse Events by Symptom and Maximum Severity after any Vaccination (Safety Population)
14.1.4.2	14.2.4.2	14.3.4.2	Bar Chart for Rate of Subjects with Solicited Local Adverse Events by Symptom, Maximum Severity and Age Group after any Vaccination (Safety Population)
14.1.4.3	14.2.4.3	14.3.4.3	Bar Chart for Rate of Subjects with Solicited Local Adverse Events by Symptom, Maximum Severity and baseline B.b. s.l. serostatus after any Vaccination (Safety Population)
14.1.4.4	14.2.4.4	14.3.4.4	Bar Chart for Rate of Subjects with Solicited Local Adverse Events by Symptom, Maximum Severity and Vaccination Period (Safety Population)
14.1.4.5	14.2.4.5	14.3.4.5	Bar Chart for Rate of Subjects with Solicited Systemic Adverse Events by Symptom, Maximum Severity after any Vaccination (Safety Population)
14.1.4.6	14.2.4.6	14.3.4.6	Bar Chart for Rate of Subjects with Solicited Systemic Adverse Events by Symptom, Maximum Severity and Age Group after any Vaccination (Safety Population)
14.1.4.7	14.2.4.7	14.3.4.7	Bar Chart for Rate of Subjects with Solicited Systemic Adverse Events by Symptom, Maximum Severity and baseline B.b. s.l. serostatus after any Vaccination (Safety Population)
14.1.4.8	14.2.4.8	14.3.4.8	Bar Chart for Rate of Subjects with Solicited Systemic Adverse Events by Symptom, Maximum Severity and Vaccination Period (Safety Population)

8. SHELLS OF TABLES, DATA LISTINGS AND FIGURES

For this analysis, no table shells or mock tables are produced, but analysis drafts of TLFs are generated based on dummy group allocation (dummy randomization list) and dummy immunogenicity data. These drafts are reviewed by the sponsor prior to SAP finalization and database snapshot.