Statistical Analysis Plan

CureVac AG

Protocol number: CV-7202-104

A non-randomized, open label, controlled, dose-escalation, phase I clinical trial to evaluate the safety, reactogenicity and immunogenicity of one or two administrations of candidate rabies mRNA vaccine CV7202 in healthy adult subjects

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Approval

Upon review of this document, including the table, listing, and figure shells, the undersigned approves the statistical analysis plan. The analysis methods and data presentation are acceptable.

	Approvals / Date
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LIST OF ABBREVIATIONS

Abbreviation	Full Notation
AE	adverse event
AESI	adverse event of special interest
ATC	Anatomical Therapeutic Chemical
BLQ	Below limit of quantification
BMI	body mass index
eCRF	electronic case report form
FA	full analysis
GMT	geometric mean titer
IA	interim analysis
ICH	International Council for Harmonisation
Ig	immunoglobulin
i.m.	intramuscular
MAAE	medically attended adverse event
mRNA	messenger ribonucleic acid
PP	per protocol
PT	preferred term
QC	quality control
RABV-G	rabies virus glycoprotein
RNA	ribonucleic acid
SA	safety
SAE	serious adverse event
SOC	system organ class
TEAE	treatment-emergent adverse event
TLFs	tables, listings, and figures
VNT	virus-neutralizing antibody titer

1. INTRODUCTION

This document outlines the statistical methods to be implemented during the analyses of data collected within the scope of CureVac AG protocol CV-7202-104 [A non-randomized, open label, controlled, dose-escalation, phase I clinical trial to evaluate the safety, reactogenicity and immunogenicity of one or two administrations of candidate rabies mRNA vaccine CV7202 in healthy adult subjects]. The purpose of this plan is to provide specific guidelines from which the statistical analyses will proceed. Any deviations from this plan will be documented in the clinical trial report.

2. TRIAL DOCUMENTS

The following trial documents are used for the preparation of the statistical analysis plan:

- Protocol version 2.0, 30 April 2020
- Annotated electronic case report form (eCRF), Version 6.0, 28 November 2019
- Data management plan version 3.0, 14 June 2019
- Immunomonitoring analysis plan version 1.0, 14 January 2020

3. TRIAL OBJECTIVES

3.1 Primary Objective

The primary objective of the trial is to assess the safety and reactogenicity profile of CV7202 administered intramuscularly (i.m.) to healthy adults (18-40 years old), as a range of doses (1, 2 and 5 µg) in 1- or 2-dose regimens.

3.2 Secondary Objective

Secondary objectives include:

For safety

- To assess the safety profile of CV7202 administered i.m. to healthy adults (18-40 years old), as a range of doses (1, 2, and 5 µg) in 1- or 2-dose regimens in the period from 12 to 24 months after the last dose.

For the characterization of the humoral immune response

- To evaluate the potential protective immune responses to CV7202 and Rabipur® in healthy adults (18-40 years old), by assessing the percentages of subjects with Rabies Specific serum virus-neutralizing antibody titers (VNTs) ≥0.5 IU/ml.
- To evaluate the immunogenicity (VNTs) of CV7202 administered to healthy adults (18-40 years old), as a range of doses (1, 2, and 5 µg) in 1- or 2-dose regimens and the immunogenicity of Rabipur administered in a 3-dose regimen.

3.3 Exploratory Objectives

Exploratory objectives comprise:

For the evaluation of the innate immune response

- To evaluate the innate immune response to 1 or 2 doses of CV7202 compared with baseline.

For the evaluation of antigen specific T-cell response

- To evaluate the frequencies and functionalities of rabies virus glycoprotein (RABV-G)-specific T cells after 1 or 2 doses of CV7202 compared with baseline.

For the evaluation and characterization of the B-cell response

- To evaluate the frequencies of RABV-G-specific B cells after 1 or 2 doses of CV7202 compared with baseline.
- To evaluate the effect of vaccination on B-cell phenotype and activation after 1 or 2 doses of CV7202 compared with baseline.
- To evaluate the effect of vaccination on B-cell clonality after 1 or 2 doses of CV7202 compared with baseline.

For the characterization of the humoral immune response

- To evaluate RABV-G-specific antibody responses throughout the trial including the follow-up period by assessing immunoglobulin M (IgM), IgG, and IgA levels.
- To characterize the nature and quality of the RABV-G-specific antibody response, by measuring the serum affinity and avidity after 1 or 2 doses of CV7202 and the breadth of neutralization against heterologous lyssaviruses with variant epitopes.

4. TRIAL DESIGN AND PLAN

This is a non-randomized, open label, controlled, dose-escalation, phase I clinical trial to evaluate the safety, reactogenicity, and immunogenicity of 1 or 2 i.m. administrations of candidate rabies messenger ribonucleic acid (mRNA) vaccine CV7202 in healthy adult subjects.

Subjects will be enrolled in 2 trial sites, 1 in Germany, 1 in Belgium.

Approximately 52 subjects will be enrolled sequentially in up to 4 trial groups to receive either a dose of CV7202 containing different mRNA content or Rabipur. In a first CV7202 group, 10 subjects have received a dose containing 5 µg mRNA. A dose of 1 or 2 µg mRNA will be administered to 2 additional groups of 16 subjects each, of whom 8 in each group will be administered a second dose 28 days later. A control group of 10 subjects will receive 3 doses of the licensed vaccine Rabipur according to the manufacturer's recommendations. Safety and immunogenicity assessments will be made up to 2 years following the last dose administration.

Specified safety data will be reviewed by an internal safety review committee and a data safety monitoring board on a pre-defined schedule. At each planned safety review, safety data will be reviewed, and a GO/NO GO decision made accordingly for enrollment of further subjects and administration of subsequent doses.

Enrollment will be staggered in Groups 2 to 4 to ensure the safety of the participating subjects. Enrollment into Group 1 (1.0 ml Rabipur) will not be staggered, since the clinical safety of Rabipur is well established.

Subjects will be enrolled at pre-screening (Day -90 to -1) to receive either CV7202 starting on Day 1 as 1 dose or 2 doses (at least 28 days apart), or 3 doses of control vaccine (Rabipur). Follow-up for safety and immunogenicity is planned up to 24 months after the last dose; therefore, the expected duration of participation for each subject is approximately 24 months after the last dose.

Please refer to protocol section 5 for more details of trial design, protocol section 6 for trial population and protocol section 7 for discontinuation/withdrawal criteria.

5. DETERMINATION OF SAMPLE SIZE

No statistically based sample size estimation was performed.

6. GENERAL ANALYSIS CONSIDERATIONS

The statistical analyses will be reported using summary tables, listings, and figures (TLFs). The International Council for Harmonisation (ICH) numbering convention will be used for all TLFs. Due to the exploratory nature of this trial, only descriptive statistics will be used; therefore, no confirmatory statistical inference will be performed.

Continuous variables will be summarized with means, standard deviations, medians, minimums, maximums, and valid cases. Other summaries may be used as appropriate.

Categorical variables will be summarized by counts and by percentage of subjects in corresponding categories. Percentages for missing values are omitted and do not account for the percent calculation of other categories. Percentages are routinely based on the total category count excluding the missing category if not otherwise mentioned. Percentages showing a rate relative to the total number of subjects in this group are given in special tables (eg, adverse event [AE] tables). Footnotes will specify the percent basis in those cases.

All summary tables will be presented by vaccination group (in the tables denoted as ‘dosage/vaccine’). Baseline summaries will also include a total summary column. The CV7202 dose groups will be reported from the lowest to the highest dose. Selected tables will also display by dose regimen (in the tables denoted as ‘treatment group’).

Individual subject data obtained from the eCRFs or data from external sources like immunogenicity laboratory data and any derived data will be presented by subject in data listings. All post-baseline unscheduled assessments will be listed only. Only scheduled post-baseline safety measurements will be summarized, if appropriate. Should a repeat occur at a scheduled visit then only the last result per visit will be considered for the summary tables.

The analyses described in this plan are considered a priori, in that they have been defined prior to database lock. Any analyses performed subsequent to finalization of this statistical analysis plan will be considered post hoc and exploratory. Post hoc analyses will be labeled as such on the output and identified in the clinical trial report.

All analyses and tabulations will be performed using SAS® software Version 9.4 or higher. Tables, listings, and figures will be presented in rich text format. The process for SAS program validation and quality control (QC) for programs and outputs is documented in the Synteract working instruction "SAS programming quality control", and trial-specific QC requirements can be found in Appendix B: SAS Programming QC requirements.

6.1 Baseline Values

Unless otherwise noted, baseline is defined as the last nonmissing value recorded prior to the first administration of the trial product. Unscheduled visits will be used for the determination of baseline values, when applicable.

6.2 Adjustments for Covariates

Not applicable

6.3 Handling of Dropouts or Missing Data

Summaries will be based on a valid case basis, ie, on observed data only, unless specified otherwise.

Missing or incomplete dates of (unsolicited) AEs will be imputed to assess whether an AE occurred prior to or after the first vaccination dose. Imputed dates are only further used for classification, but no other calculation like durations will be done. Imputation will also be considered for missing or incomplete CMs dates to determine whether a CM is prior, concomitant or ongoing.

The most conservative approach will be systematically considered. If the AE onset date is missing/incomplete, it is assumed to have occurred during the trial vaccination phase (ie, considered a post-vaccination AE) except if the partial onset date or other data, such as the end date, indicate differently.

The following algorithms will be applied to missing and incomplete AE start and stop dates:

Start Dates

- If the day portion of the start date is missing, then the start date will be estimated to be equal to the date of first administration of trial product, provided the start month and year are the same as the administration of trial product and the stop date is either after the first administration of trial product or completely missing. Otherwise, the missing day portion will be estimated as "15."
- If both the day and month portions of the start date are missing, then the start date will be estimated to be equal to the date of first administration of trial product, provided the start year is the same as the first administration of trial product and the stop date is either after the first administration of trial product or completely missing. Otherwise, if the start year is lower than the year of first administration of the trial product, the event will be assumed to start on the mid-year point of the given year (eg, ??-???-2013 is estimated as 01-JUL-2013).
- If the start year is after the year of first administration of the trial product, the start date will be estimated as the first day of the year (ie, 01-JAN-YYYY).
- If the start date is completely missing and the stop date is either after the first administration of trial product or completely missing, the start date will be estimated to be the day of first administration of trial product. Otherwise, the start date will be estimated to be the first day of the same year as the stop date.

Stop Dates

- If only the day of resolution is unknown, the day will be assumed to be the last of the month (eg, ??-JAN-2013 will be treated as 31-JAN-2013) or at the date of last contact, if earlier.
- If both the day and month of resolution are unknown, the event will be assumed to have ceased on the last day of the year (eg, ??-???-2013 will be treated as 31-DEC-2013) or at the date of last contact, if earlier.
- If the stop date is completely missing or the event is continuing, the event will be assumed to be after the first administration of trial product and will be imputed using the the date of last contact.

6.4 Interim Analysis and Data Monitoring

One or more interim analyses (IAs) may be performed for this trial. The data will be cleaned for all subjects. The analyses will be based on a data snapshot. Analyses will be performed on the safety set or subsets of it based on the availability of data. No decision-making is planned for the IAs and no adjustments for the trial are planned based on the results.

It is not planned to discuss any difference between the IAs and the final analysis in the clinical trial report.

A first interim analysis was performed after 16 subjects had been vaccinated (10 subjects in the CV7202 5 µg group and 6 subjects in the Rabipur group) and observed until Visit 8. The first interim analysis focused on safety aspects only. It was planned in a standalone interim analysis plan, which was finalized on 6 February 2019.

The second interim analysis was performed after 53 subjects had been vaccinated (16 subjects in the CV7202 1 µg group, 16 subjects in the CV7202 2 µg group, 10 subjects in the CV7202 5 µg group and 11 subjects in the Rabipur group) and observed until Visit 12 (Day 57). The second interim analysis focused on safety and immunogenicity. The analysis was primarily based on the interim analysis plan as of 06 Febaruary 2019 and subsequent change requests for tables.

For details of data monitoring please refer to section 4.

6.5 Examination of Subgroups

No subgroup analysis other than by dose regimen (treatment group) is planned.

6.6 Multiple Comparison/Multiplicity

No adjustments for multiple testing will be made in this trial.

6.7 Multicenter Studies

This is a multicenter trial with 2 sites in 2 countries participating in the trial.
No comparison of the results by trial site is planned.

7. NOTATION OF VACCINATION GROUPS AND VISITS

Notation of vaccination groups

The following notation of **vaccination groups** will be used throughout the report:

Full notation (as used in the trial protocol)	***Notation as used throughout all tables, listings and figures***
Group 3 • *Group 3 without Group 3a* • *Group 3a*	CV7202 1 µg • *CV7202 1x1 µg* • *CV7202 2x1 µg*
Group 4 • *Group 4 without Group 4a* • *Group 4a*	CV7202 2 µg • *CV7202 1x2 µg* • *CV7202 2x2 µg*
Group 2	CV7202 5 µg
Group 1	Rabipur

The administration of a second dose to every 8 of the 16 subjects in groups 3 and 4 was done in a sequential manner at the sites. Therefore this analysis does not differentiate between planned and actual vaccination group and done regimen and all analyses will be based on the actually received vaccination group and dose regimen.

Visit terminology

Visit	***Notation as used throughout all tables, listings and figures***[1]
Visit 1 (Pre-screening Visit, Days -90 to -1)	V1 (Pre-screening)
Visit 2 (Screening Visit, Days -30 to -1)	V2 (Screening)
Visit 3 (Vaccination Dose 1 CV7202 or Rabipur, Day 1)	V3 (Day 1)
Visit 4 (Day 2 or 3*)	V4 (Day 2/3)
Phone call (Day 3)	Phone call 1 (Day 3)
Visit 5 (Vaccination Dose 2 Rabipur, Day 8)	V5 (Day 8)
Visit 6 (Day 10)	V6 (Day 10)
Visit 7 (Day 15)	V7 (Day 15)
Visit 8 (Vaccination Dose 2 CV7202 or Dose 3 Rabipur, Day 29)	V8 (Day 29)
Visit 9 (Day 30 or 31**)	V9 (Day 30/31)
Phone call (Day 31)	Phone call 2 (Day 31)
Visit 10 (Day 36)	V10 (Day 36)
Visit 11 (Day 43)	V11 (Day 43)
Visit 12 (Day 57)	V12 (Day 57)
Visit 13 (Day 91)	V13 (Day 91)
Visit 14 (Month 6: Day 181 [1-dose regimens]/ Day 209 [2-dose regimens and Group 1 {Rabipur}])	V14 (Month 6)
Optional Visit 14A***	V14A (M6+3)
Visit 15 (Month 12: Day 365 [1-dose regimens]/ Day 393 [2-dose regimens and Group 1 {Rabipur}])	V15 (Month 12)
Optional Visit 15A***	V15A (M12+3)
Visit 16 (Month 18: Day 547)	V16 (Month 18)
Optional Visit 16A***	V16A (M18+3)
Visit 17 (Trial End) (Month 24: Day 729)	V17 (Trial End/Month 24)
Optional Visit 17A***	V17A (M24+3)

* It should be noted that for subjects enrolled in the trial before Protocol Amendment 1 became effective, Visit 4 occurred on Day 3 as planned in the original protocol.

[1] Programming note: This visit notation should be applied in SDTM for the VISIT/VISITNUM variable. If VISIT is uppercased, then the preference is to assign a format to VISITNUM, display the formatted VISITNUM, order by the VISITNUM variable, and do not display VISIT.

** For some subjects already vaccinated with Rabipur before the last protocol amendment was issued, Visit 9 occurred on Day 31 as planned in the original protocol. For other subjects, the visit should occur on Day 30.
*** In case Visit 14, 15, 16, or 17 could not take place on site due to the public health emergency related to COVID-19, safety information should be collected via a phone call within the protocol-allowed time interval for that visit. In case Visit 14, 15, 16, or 17 was conducted as a phone call or not all procedures could be performed on site, Visits 14A, 15A, 16A, or 17A should be scheduled on site during a widened visit window starting the day after the expiry of the original visit window and lasting up to 3 months after the original projected visit date (+15-90 days).

8. ANALYSIS SETS

The following subject population will be used for safety analyses:

- **Safety analysis set** will include all subjects who have received at least 1 dose of the candidate rabies mRNA vaccine CV7202 or the active control Rabipur and for whom any post-Day 1 safety data are available. The statement that a subject had no AEs (on the Adverse Event eCRF) constitutes a valid safety assessment. The analysis of safety will be performed on this population.

The following subject populations will be used for analyses of immunogenicity objectives:

- **Full analysis (FA)** set is the subset of the safety analysis set with subjects who have the baseline sample and at least 1 additional blood sample available for VNT analysis. This analysis set is the primary analysis set for all immunogenicity objectives.

9. TRIAL POPULATION

9.1 Subject Disposition

Subject disposition information will be summarized for all subjects by vaccination group and dose regimen. Summaries will include the number of subjects screened, the number of subjects enrolled (ie, screened successfully), the number of subjects vaccinated, the number of subjects completing the trial, and the main reason for termination. The number of subjects per trial site/country will be summarized by vaccination group.

Subjects' data concerning screening failures will be listed.

9.2 Protocol Deviations

All potential protocol deviations will be assessed during a data review meeting.
Protocol deviations due to missed or delayed assessments or in other relation to COVID-19 will be categorized as such.
The impact of protocol deviations on the analysis will be discussed during the data review meeting.

Subjects having protocol deviations and the specification of their protocol deviations will be listed including type of deviation.

9.3 Eligibility

A listing of subjects not fulfilling any inclusion or exclusion criteria will be created.
Data on eligibility pre-screening, screening, and recheck will be listed.

9.4 Demographic and Baseline Characteristics

Demographic variables include age at signing informed consent, gender, child-bearing potential, and ethnic origin. Other baseline characteristics include height, weight, and body mass index (BMI) at screening and medical history at screening.

Descriptive statistics will be presented for age, height, weight, and BMI at screening. Frequency counts and percentages will be presented for gender, child-bearing potential, and ethnic origin. Demographic and baseline characteristics will be summarized for the safety analysis set and the FA set by vaccination group and dose regimen.

Medical history data will only be listed.

9.5 Prior, Ongoing and Concomitant Medications/Vaccinations

Prior, ongoing, and concomitant medications/vaccinations verbatim terms in the eCRFs will be mapped to Anatomical/Therapeutic/Chemical (ATC) class and Preferred Names using the WHODrug Global (version March 01, 2018 or higher).

Prior, ongoing, and concomitant medications/vaccinations will be listed including all information documented under this section. A flagging will show if medication/vaccination is classified as prior, ongoing, or concomitant.

Medication/vaccination definitions and their start and stop dates are as follows and imputed dates (see section 6.3) will be used for classification into each category:

- Prior medications/vaccinations are defined with a start date prior to screening and stop date before the date of first administration of the trial product.
- Ongoing medications/vaccinations are defined as any medication/vaccination used prior to screening with stop date at/after date of first administration of the trial product, or which are ongoing from screening.
- Concomitant medications/vaccinations are defined as any medication/vaccination with start date at/after date of first administration of the trial product.
- If the allocation to prior, ongoing, or concomitant is not clear, the medication/vaccination will be considered as concomitant.

Ongoing and concomitant medications/vaccinations will be summarized for each vaccination group by World Health Organization ATC class (level 2) and preferred name. These summaries will present the number and percentage of subjects using each medication. Subjects may have more than 1 medication per ATC class and preferred name. At each level of subject summarization, a subject is counted once if he/ she reported 1 or more medications at that level. Each summary will be ordered by descending order of incidence of ATC class and preferred name within each ATC class.

Prior medications/vaccinations will only be listed.

10. IMMUNOGENICITY ANALYSES

The immunogenicity analyses will be based on the FA set..

Details of analytical procedures, acceptance criteria, data analysis and reporting for immunogenicity data are described in the immunomonitoring analysis plan.

10.1 Immunogenicity Endpoints and Variables

10.1.1 Secondary Immunogenicity Endpoint

For the characterization of the humoral immune response

- Percentages of subjects with Rabies Specific serum VNTs ≥0.5 IU/ml by trial group on Days 1 (pre-vaccination), 15 and 43 and 12, 18*, and 24* months after the last dose.
- Serum geometric mean titers (GMTs) of VNTs by trial group on Days 1, 8, 15, 29, 36, 43, 57, and 91 and 6, 12, 18*, and 24* months after the last dose.

* Will be performed only in subjects with detectable RABV-G-specific IgG at 6 months after the last vaccination.

10.1.2 Exploratory Immunogenicity Endpoints

For the evaluation of the innate immune response:

- Serum cytokine concentrations* including but not limited to chemokine (C-X-C motif) ligand 10, chemokine (CC motif) ligand 3, interleukin-6, tumor necrosis factor-α and interferon-γ at pre-vaccination and 4 hours after vaccination on Day 1, and Days 2 or 3** and 8 after each vaccination.
- Transcriptome profiling* on the day of vaccination at pre-vaccination, and Days 2 or 3** and 8 after each vaccination.

* Will be performed in the first 5 subjects in Group 2 (** on Day 3) and all subjects in Groups 3 and 4 (** on Day 2). Note that Day 3 was planned in the original protocol and only applies to subjects in Groups 1 and 2 who were already enrolled and vaccinated before the last protocol amendment was issued. Day 2 applies to all other subjects.

For the evaluation of antigen specific T-cell response:

- The frequencies and functionalities of RABV-G-specific T cells in peripheral blood from the first 5 subjects in Group 2 and all subjects in Groups 3 and 4 on Days 1, 8, 36, and 91* and 6* and 12* months after the last dose.

* For groups that have shown a significant T-cell response at Day 8 or 36 compared to baseline.

For the evaluation and characterization of the B-cell response

- The frequencies of RABV-G-specific B cells in peripheral blood from the first 5 subjects in Group 2 and all subjects in Groups 3 and 4 on Days 1, 8, 36, and 91* and 6* and 12* months after the last dose.
- The frequencies and activation status of phenotypically distinct subsets of B-cell populations, including but not limited to naïve and memory B cells, plasmablasts, and plasma cells for the first 5 subjects in Group 2 and all subjects in Groups 3 and 4 on Days 1, 8, 36, and 91* and 6* and 12* months after the last dose.
- Sequencing of B-cell receptors of circulating B cells on Days 1, 8, 29, 36, 57, and 91* and 6* and 12* months after the last dose.

* For groups that have shown a significant B-cell response at Day 8 or 36 compared to baseline.

For the characterization of the humoral immune response:

- RABV-G-specific IgM, IgG, and IgA levels measured by enzyme-linked immunosorbent assay on Days 1, 8, 15, 29, 36, 43, 57, and 91 and 6 and 12 months after the last dose.
- RABV-G-specific IgG levels measured by enzyme-linked immunosorbent assay 18* and 24* months after the last dose.
- Identification of epitopes recognized by vaccine-induced antibodies on Days 1, 15, and 43 and 12 months after the last dose**.
- Measurement of RABV-G-specific antibody avidity and affinity on Days 1, 15, and 43 and 12 months after the last dose**.
- Measurement of VNTs against additional heterologous lyssaviruses on Days 1, 15, and 43 and 12 months after the last dose**.

* Will be performed only in subjects with detectable RABV-G-specific IgG at 6 months after the last vaccination.

** Will be performed only on selected samples with VNT >0.5 IU/ml.

10.2 Secondary Immunogenicity Analysis

The number and percentage of subjects with Rabies Specific serum VNTs ≥ 0.5 IU/ml will be determined for each visit and displayed by vaccination group and dose regimen including 95% exact confidence limits. The percentages will be based on subjects providing data for the respective visit.

For evaluation of values below the limit of quantification (=BLQ values) for tables and figures, the following conventions will be made:

- Values <0.1 are identified as BLQ values.
- All concentration values marked as BLQ will be set to 0.5*LLOQ (= 0.1 IU/ml) = 0.05 IU/ml
- Missing post-dose values will not be replaced.

Absolute (raw untransformed) serum VNT values will be summarized for each visit by vaccination group and dose regimen.

Serum VNT values will be log-transformed and the mean , SD and 95% confidence interval of the log-transformed values will be calculated. The serum GMTs (= antilog mean of log-transformed data) and the corresponding 95% confidence intervals for the GMTs (=antilog lower and upper 95% confidence bound of log-transformed data) as well as geometric SD, median, minimum and maximum will be tabulated by vaccination group and dose regimen for baseline and each postbaseline visit.

10.3 Exploratory Analyses

10.3.1 Immunoglobulin

The number and percentage of subjects with detectable RABV-G-specific immunoglobulin (> LLOQ: IgM ≥ 780 U/ml, IgA ≥ 195.5 U/ml and IgG ≥ 780 U/ml) levels will be determined for each visit and displayed by vaccination group and dose regimen including 95% exact confidence limits. The percentages will be based on subjects providing data for the respective visit.
For evaluation of values below the limit of quantification (=BLQ values) for tables and figures, the following conventions will be made:

- Values <LLOQ are identified as BLQ values.
- All concentration values marked as BLQ will be set to 0.5*LLOQ (LLOQs: IgM 780 U/ml, IgA 195.5 U/ml, IgG ≥ 780 U/ml)
- Missing post-dose values will not be replaced.

Absolute (raw untransformed) RABV-G-specific IgM, IgG and IgA levels will be summarized for each visit by vaccination group and dose regimen.

RABV-G-specific immunoglobulin levels will be log-transformed and the mean and 95% confidence interval of the log-transformed values will be calculated. The GMTs (= antilog mean of log-transformed data) and the corresponding 95% confidence intervals for the GMTs (=antilog lower and upper 95% confidence bound of log-transformed data) as well as geometric SD, median, minimum and maximum will be tabulated by vaccination group and dose regimen for baseline and each postbaseline visit.

10.3.2 Cellular Immune Response

Cellular immune response results will be summarized using descriptive statistics by parameter, vaccination group, and visit. Changes from baseline will also be summarized. If only sparse data are available, the data may not be tabulated for single parameters, but listed only.

Peripheral blood mononuclear cell will not form part of this SAP and CSR analysis.

10.3.3 Cytokine assessment

Cytokine assessments will be summarized using descriptive statistics by parameter, vaccination group, and visit. Changes from baseline will also be summarized. If only sparse data are available, the data may not be tabulated for single parameters, but listed only.

10.3.4 Transcriptome Profiling

The results of transcriptome profiling will not be part of the trial database and are not subject to the statistical analysis.

10.3.5 Immune Receptor Sequencing

The results of immune receptor sequencing will not be part of the trial database and are not subject to the statistical analysis.

11. SAFETY ANALYSES

A description of the collection of safety assessments can be found in section 9.2 of the protocol.

11.1 Safety Endpoints and Variables

The analysis of the primary objective to assess the safety and reactogenicity profile will examine solicited and unsolicited adverse events.

The primary endpoints include the following:

- The percentages of subjects with, and the frequencies and intensities of solicited local AEs reported on the day of vaccination and the 7 subsequent days (Days 1-8).
- The percentages of subjects with, and the frequencies, intensities, and relationship to vaccination of solicited systemic AEs reported on the day of vaccination and the 7 subsequent days (Days 1-8).
- The duration (in days) of solicited local AEs, of solicited systemic AEs, and of the individual solicited AEs.
- The percentages of subjects with and frequencies and intensities of any unsolicited and related unsolicited AEs reported on the day of vaccination and the 28 subsequent days (Days 1-29).

- The percentages of subjects with and frequencies and relationship to vaccination of any serious AEs (SAEs) and any medically attended AEs (MAAEs) up to 12 months after the last dose.
- The percentages of subjects with and frequencies and relationship to vaccination of any AEs of special interest (AESIs) up to 12 months after the last dose.

Secondary safety endpoints are:

- The percentages of subjects with and frequencies of SAEs and MAAEs related to study vaccination from 12 months after the last dose up to 24 months after the last dose (trial end).
- The percentages of subjects with and frequencies and relationship to vaccination of any AESIs from 12 months after the last dose up to 24 months after the last dose (trial end).

Further safety variables include the following:

- Extent of exposure
- Physical examination, weight, BMI
- 12-Lead electrocardiogram
- Vital signs
- Safety laboratory - hematology, biochemistry, coagulation
- Laboratory - Urine dipstick pregnancy test, serum pregnancy test (human chorionic gonadotropin)

11.2 Adverse Events and Vaccination Site Reactogenicity Assessment

Definitions and procedures for recording, evaluating, follow-up, and reporting of AEs are provided in Appendix 11 of the protocol.

The intensity of AEs will be graded in the following manner:

Absent:	• Grade 0	• No AE
Mild:	• Grade 1	• An event that is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.
Moderate:	• Grade 2	• An event that causes sufficient discomfort to interfere with normal everyday activities.
Severe:	• Grade 3	• An event that prevents normal everyday activities. An AE that is assessed as severe should not be confused with a SAE. Severe is a category utilized for rating the intensity of an event; and both AEs and SAEs can be assessed as severe.

11.2.1 Solicited Adverse Events

Local (injection site pain, redness, swelling, and itching) and systemic (fever, nausea/vomiting, diarrhea, headache, fatigue, myalgia, and arthralgia) solicited AEs on the day of vaccination and the 7 subsequent days (Days 1 to 8, Day 8 to 15 [Rabipur Dose 2] and Days 29 to 36) will be collected on diary cards by the subjects.

By definition, all local solicited symptoms are considered related to vaccination.

AEs with individual AE term can be documented by the subject in the diary as other continuing general reaction with start and end date. If such an AE is documented in the diary, the investigator will also document it on the respective AE pages of the eCRF. It will then be analyzed within the unsolicited AEs documented there. The respective diary entries will only be listed.

Local and systemic solicited AEs will be assessed on an intensity scale of absent, mild, moderate, and severe. Direct data entries of mm for redness and swelling and °C for fever/temperature will be given. The following intensity grading for solicited AEs (day of vaccination and 7 subsequent days) will be applied:

Solicited AE	**Grade***	**Definition**
Local AEs (reported in the subject diary as Injection Site Reactions)		
Pain at injection site	0	Absent
	1	Does not interfere with activity
	2	Interferes with activity and/or repeated use of non-narcotic pain reliever >24 hours
	3	Prevents daily activity and/or repeated use of narcotic pain reliever
Redness	0	≤2.5 cm
	1	2.5 – 5 cm
	2	5.1 – 10 cm
	3	>10 cm
Swelling	0	≤2.5 cm
	1	2.5 – 5 cm and does not interfere with activity
	2	5.1 – 10 cm or interferes with activity
	3	>10 cm or prevents daily activity
Itching	0	Absent
	1	Mild, no interference with normal activity
	2	Moderate, some interference with normal activity
	3	Significant, prevents normal activity
Systemic AEs (reported in the subject diary as General Reactions)		
Body Temperature	0	<38°C
	1	≥38°C – 38.4°C
	2	≥38.5°C – 38.9°C
	3	≥39°C
Headache	0	Absent
	1	Mild, no interference with normal activity

Solicited AE	Grade*	Definition
	2	Moderate, some interference with normal activity and/or repeated use of non-narcotic pain reliever >24 hours
	3	Significant; any use of narcotic pain reliever and/or prevents daily activity
Fatigue	0	Absent
	1	Mild, no interference with normal activity
	2	Moderate, some interference with normal activity
	3	Significant, prevents normal activity
Chills	0	Absent
	1	Mild, no interference with normal activity
	2	Moderate, some interference with normal activity
	3	Severe, prevents normal activity
Myalgia	0	Absent
	1	Mild, no interference with normal activity
	2	Moderate, some interference with normal activity
	3	Significant, prevents normal activity
Arthralgia	0	Absent
	1	Mild, no interference with normal activity
	2	Moderate, some interference with normal activity
	3	Significant, prevents normal activity
Nausea/ Vomiting	0	Absent
	1	Mild, no interference with activity and/or 1 or 2 episodes/ 24 hours
	2	Moderate, some interference with activity and/or >2 episodes/ 24 hours
	3	Severe, prevents daily activity, requires outpatient i.v. hydration
Diarrhea	0	Absent
	1	2 or 3 loose stools or <400 g/24 hours
	2	4 or 5 stools or 400 – 800 g/24 hours
	3	6 or more watery stools or >800 g/24 hours or requires outpatient i.v. hydration

*United States Food and Drug Administration toxicity grading scale; i.v. = intravenous.

Solicited AEs are also documented as AEs on the respective eCRF pages by the investigator, if they are serious and/or are ongoing on Day 8.

For every solicited AE, the maximum over all grades documented in the diary on the day of vaccination and the 7 subsequent days will be defined as grade (intensity) of this solicited AE.

Frequencies and percentages of local and systemic solicited AEs reported on the day of vaccination and the 7 subsequent days will be displayed by vaccination group, by subject overall and vaccination dose (number).

An overall summary table will display frequencies and percentages by grade (intensity) including any grade of:

- Any solicited AEs
- Local solicited AEs

- Systemic solicited AEs
- Related systemic solicited AEs
- Any solicited AEs ongoing on Day 8

Frequencies and percentages by grade (intensity), including any grade, will also be displayed for the individual terms of solicited AEs. Gradings of zero (AE is absent) will not contribute to the numbers tabulated.

The duration in days of a solicited AE will be represented by the number of days with diary entries of Grade ≥1 (out of Days 1-8) reported by a subject per solicited AE term and diary (corresponding to vaccination dose). Thus, the duration in days can range from 1 to 8 per prespecified solicited event term and vaccination dose administered.

The duration of Grade 3 solicited AEs will be derived by counting only days with Grade 3 entries.

For subjects without a specified event term, no duration of this event will be calculated, ie, no zero durations are possible.

The number of days of solicited AEs, as well as the number of days of solicited Grade 3 AEs will be tabulated with basic statistics by vaccination group and vaccination dose (number) for any solicited AE, any local solicited AE, any systemic solicited AE, any related systemic solicited AE, and the individual terms of solicited AEs.

In addition, frequency tables displaying solicited AEs by diary day, grade, vaccination group, and vaccination dose (number) will be prepared as well for any solicited AE, any local solicited AE, any systemic solicited AE, any related systemic solicited AE, and the individual terms of solicited AEs. These tables will show grade (severity) as: None (Grade 0), Any (Grades 1 to 3), Grade 1, Grade 2, and Grade 3.

The days of onset of solicited AEs will be displayed by frequency counts for any solicited AE, any local solicited AE, any systemic solicited AE, any related systemic solicited AE, and the individual terms of solicited AEs.

11.2.2 Unsolicited Adverse Events

Serious AEs, intercurrent medical conditions, AEs leading to trial or vaccine withdrawal, AEs of special interest (AESIs) and MAAEs) will be collected by the investigator in the eCRF throughout the trial.

AEs with a suspected potential immune-mediated disease etiology will be considered AESIs. The investigator will assess if an AE is an AESI. A list of AESIs is provided in Appendix 10 of the protocol.

AEs that are reported as related to the test vaccine will be considered trial vaccine-related; missing classifications concerning trial vaccine relationship will also be considered trial vaccine-related.

Every unsolicited AE will be assigned to a vaccination dose (number) by consideration of the period of 28 days after vaccination administration. Unsolicited AEs can be assigned to either day 1 to 28 (dose 1 for any vaccination group), or day 29 to 57 (dose 2 for 2-dose regimens or dose 3 for the Rabipur group). For the Rabipur group, vaccination dose 2 is administered 8 days after vaccination dose 1, therefore no assignment of unsolicited AEs to vaccination dose 2 is done for the Rabipur group.

All AE summaries will be restricted to those AEs that occurred after the first administration of the trial product. Any other AE (ie, AE starting after trial entry and before the first vaccination) will be reflected only in the data listings. If it cannot be determined whether the AE occurred after the first administration of the trail product due to a partial onset date, then it will be counted as such. Verbatim terms in the eCRFs will be mapped to preferred terms (PTs) and system organ classes (SOCs) using the Medical Dictionary for Regulatory Activities (version 21.0 or higher).

The occurrence of unsolicited AEs reported on the day of vaccination and the 28 subsequent days will be presented. In addition selected AE summary tables will be repeated for unsolicited AEs occurring at any time after the first administration of the trial product.

Each AE summary will be displayed by vaccination group and dose regimen. Summaries by vaccination dose (number) will also be provided for all AEs. Summaries that are displayed by SOC and PT will be ordered by descending order of incidence of SOC and PT within each system organ class. Summaries will display number and percentage of subjects with at least 1 event and the number of events by vaccination group.

Summaries of the following types will be presented:

- Overall summary of unsolicited AEs that contain an overview of each item below
- All AEs
    - Mild (grade 1) AEs
    - Moderate (grade 2) AEs
    - Severe (grade 3) AEs
- Related AEs
    - Mild (grade 1) related AEs
    - Moderate (grade 2) related AEs
    - Severe (grade 3) related AEs
- SAEs
- Related SAEs
- MAAEs
- AEs leading to withdrawal from study
- AEs leading to discontinued vaccination

- AESIs

Laboratory data will be graded by the site in the AE form according to the United States Food and Drug Administration toxicity grading scale and the Common Terminology Criteria for Adverse Events Version 5.0.

11.2.3 Vaccination Site Reactogenicity Assessment

All subjects will undergo a vaccination site reactogenicity assessment (injection site pain, redness, swelling, and itching) at 1 hour after the vaccination on the day of vaccination (Day 1, Day 8 [Rabipur Dose 2], and Day 29 [Rabipur and Groups 3a and 4a]) and 1 or 2 days after each vaccination (Day 2 or 3, Day 10 [Rabipur], and Day 30 or 31 [Rabipur and Groups 3a and 4a]). Note that Days 3 and 31 were planned in the original protocol and only apply to subjects in Groups 1 and 2 who were already enrolled and vaccinated before the last protocol amendment was issued. Days 2 and 30 apply to all other subjects.

Local reactions will be assessed by the investigator on an intensity scale of absent, mild, moderate, and severe. Direct data entries of mm for redness and swelling and °C for fever/temperature will be given and mapped to intensity grading the same way as done for solicited local AEs.

The vaccination site reactogenicity assessment will be displayed for any symptom and for the individual terms by vaccination group for any vaccination dose and by vaccination dose (number).

Tabulations will also display frequencies and percentages by grade (intensity). Symptoms, that are documented on the day of vaccination and on 1 or 2 days after vaccination are counted only once per vaccination with highest grade.

11.3 Extent of Exposure

Subjects shall receive 1 or 2 vaccination doses of CV7202 or 3 vaccination doses of Rabipur. All data referring to the Vaccination section of the eCRF will be listed.

All visit dates will be listed. Time between visits as well as total trial duration will be derived and tabulated with descriptive statistics (duration of total trial [days] = date of trial completion or discontinuation – date of first informed consent + 1).

11.4 Physical Examination, Weight, BMI

Physical examination results will be included in data listings only. Weight and BMI will be summarized using descriptive statistics at baseline and at each postbaseline time point. BMI will be derived for post vaccination visits if not collected on the CRF and weight available at that visit. BMI will be derived as follows: weight (kg)/height $(m)^2$.

11.5 Vital Signs

Vital signs will be summarized using descriptive statistics at baseline and at each postbaseline visit.

11.6 Electrocardiogram

Overall interpretation of electrocardiogram results will be displayed in a listing.

11.7 Safety Laboratory Evaluation

Laboratory parameters (hematology, biochemistry, and coagulation) will be summarized using descriptive statistics at baseline and at each postbaseline time point. The categorization into low-normal-high (below lower reference range/ within reference range/ above upper reference range) will also be summarized. In summary tables, results below or above the detection limit are set to the detection limit.

11.8 Pregnancy Test Results

Results of serum pregnancy tests and urine dipstick pregnancy tests will be displayed in listings.

12. CHANGES TO PROTOCOL-SPECIFIED ANALYSES

The protocol defines 2 PP sets as subsets of the FA set. Due to the small number of subjects per treatment group, it was decided that no per-protocol sets will be defined and used for analysis.

13. REFERENCES

Not applicable

14. APPENDICES

Appendix A: Presentation of Data and Programming Specifications

General

- Specialized text styles, such as bold, italics, borders, shading, superscripted, and subscripted text will not be used in tables, figures, and data listings unless they add significant value to the table, figure, or data listing.
- Only standard keyboard characters are to be used in tables and data listings.
- Special characters, such as nonprintable control characters, printer specific, or font specific characters, will not be used on a table, figure, or data listing.
- Hexadecimal character representations are allowed (eg, μ, α, ß).
- All footnotes will be left justified and at the bottom of a page. Footnotes should be used sparingly and must add value to the table, figure, or data listing.

Tables

- Formal organization of tabulations may be changed during programming, if appropriate, eg, tables for the different variables may be combined into a single table, or tables with more than 1 variable may be split into several tables.
- Means and medians will be presented to 1 more decimal place than the raw data. Standard deviations will be presented to 2 more decimal places than the raw data. Minimums and maximums will be reported with the same number of decimal places as the raw data.
- Percentages will be presented to the tenth place.
- For frequency counts of categorical variables, categories whose counts are zero will be displayed for the sake of completeness. For example, if none of the subjects discontinue due to "lost to follow-up," this reason will be included in the table with a count of 0. Categories with zero counts will not have zero percentages displayed.
- The last footnotes will be
  - "PROGRAM SOURCE: ...\\xx.sas, DATA CUT OFF DATE: DDMMMYYYY, RUN DATE: DDMMYY hh:mm",
    where data cut-off date is the datestamp of the data snapshot used.

Figures

- Legends will be used for all figures with more than 1 variable or item displayed. Figures will be in black and white but can be in color to add value to the clarity and readability of a figure. Lines should be wide enough to see the line after being copied.
- The last footnotes will be
  - "PROGRAM SOURCE: ...\\xx.sas, DATA CUT OFF DATE: DDMMMYYYY, RUN DATE: DDMMYY hh:mm",
    where data cut-off date is the datestamp of the data snapshot used.

Listings

- Formal organization of the listings may be changed during programming, if appropriate, eg, additional variables may be included, change in the column order, or the listing may be split into multiple parts due to space constraints.
- If not otherwise specified, all data listings will be sorted by sequence/treatment, center, subject number, visit, and date/time, as appropriate.
- All date values will be presented in a SAS date (eg, 29AUG2001) format.
- All observed time values will be presented using a 24-hour clock HH:MM:SS format (eg, 01:35:45 or 11:26). Seconds will only be reported if they were measured as part of the study.
- The last footnote will be
  - "PROGRAM SOURCE: ...\\xx.sas, DATA CUT OFF DATE: DDMMMYYYY, RUN DATE: DDMMYY hh:mm",
    where data cut-off date is the datestamp of the data snapshot used.

Standard Calculations

Variables requiring calculation will be derived using the following formulas:

- **Days** – A duration expressed in days between 1 date (date1) and another later date (date2) is calculated using the formulas noted below:

  duration in days = date2 – date1 + 1

- **Change from baseline** – Change from baseline will be calculated as:
  Change = postbaseline value – baseline value.

Appendix B: SAS Programming QC requirements

All items must be completed to meet department programming validation standards as described in **WI-SOP-0205-003 QC Requirements**.

Appendix C: List of Tables, Figures, and Listings

The following proposal for sections 14 and 16.2 is completed according to ICH E3 guidelines. The ICH heading numbers and description are in **bold**.

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Table Number	Table Title	Analysis Set	Comment
14	**TABLES, FIGURES, AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT**		
14.1	**Demographic Data**		
14.1.1	Subject Disposition by Dosage/Vaccine	All Subjects	
14.1.2	Subject Disposition by Dosage/Vaccine and Treatment Group	All Subjects	
14.1.3	Subject Number by Country and Site	Safety Analysis Set	
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16.2.2	**Protocol Deviations**	
16.2.2.1	Protocol Deviations	All Subjects
16.2.2.2	Eligibility and Subjects not Fulfilling any Inclusion/Exclusion Criteria	All Subjects
16.2.3	**Subjects Excluded From the Efficacy/Immunogenicity Analysis**	
16.2.3.1	Subjects Excluded From Analysis	All Subjects
16.2.4	**Demographic data**	
16.2.4.1	Demographics and Baseline Characteristics	Safety Analysis Set
16.2.4.2	Medical History	Safety Analysis Set
16.2.4.3	Prior and Concomitant Medications/Vaccinations	Safety Analysis Set
16.2.5	**Vaccination Data**	
16.2.6	**Immunogenicity Data**	
16.2.6.1	VNTs	Full Analysis Set
16.2.6.2	RABV-G specific Immunoglobulin (ELISA)	Full Analysis Set
16.2.6.3	Cellular Immune Response and Leucocytes Phenotyping (PBMCs)	Full Analysis Set
16.2.6.4	Cytokine Assessment	Full Analysis Set
16.2.7	**Adverse Event and Vaccination Site Reactogenicity Assessment Listings**	
16.2.7.1	**Unsolicited Adverse Events**	
16.2.7.1.1	Unsolicited Adverse Events - CRF Entries	Safety Analysis Set
16.2.7.1.2	Unsolicited Adverse Events - MedDRA Coding	Safety Analysis Set
16.2.7.1.3	Serious Unsolicited Adverse Events	Safety Analysis Set
16.2.7.1.4	Unsolicited Adverse Events Leading to Trial or Vaccine Withdrawal	Safety Analysis Set
16.2.7.1.5	Deaths	Safety Analysis Set
16.2.7.2	**Solicited Adverse Events**	
16.2.7.2.1	Local Solicited Adverse Events	Safety Analysis Set

ICH Listing Number	Listing Title	Analysis Set
16.2.7.2.2	Systemic Solicited Adverse Events	Safety Analysis Set
16.2.7.3	Vaccination Site Reactogenicity Assessment (by Investigator)	Safety Analysis Set
16.2.8	**Listing of Individual Laboratory Measurements by Subject**	
16.2.8.1	Hematology	Safety Analysis Set
16.2.8.2	Biochemistry	Safety Analysis Set
16.2.8.3	Coagulation	Safety Analysis Set
16.2.8.4	Pregnancy Test Results	Safety Analysis Set
16.2.9	**Other Data**	
16.2.9.1	Physical Examination, Weight, BMI	Safety Analysis Set
16.2.9.2	Vital Signs	Safety Analysis Set
16.2.9.3	Electrocardiogram	Safety Analysis Set
16.2.10	Visit and Diary Information	Safety Analysis Set

Appendix D: Table, Figure, Listing Layouts

Appendix D1: Study-Specific Shells for Section 14

14.1.1 Subject Disposition by Dosage/Vaccine, All Subjects

		CV7202 1 µg	CV7202 2 µg	CV7202 5 µg	Rabipur	Total
Subjects screened						N
Subjects enrolled						x
Subjects vaccinated		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects ongoing		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects completed		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects withdrawn		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Safety Analysis Set [a]		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Full analysis (FA) set [b]		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Main reason for termination	Consent withdrawn	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Violation of in/ex criteria	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Continuation jeopardizes subject	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Adverse event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Non-compliance	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Lost to follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Study terminated by sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Received at least 1 dose of CV7202 or Rabipur.
[b] All subjects of the Safety Analysis Set with baseline and at least 1 postbaseline VNT sample.
Percentages are based on the number of vaccinated subjects in each column.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Subjects ongoing will only be displayed, if table is generated before end of the trial.

14.1.2 Subject Disposition by Dosage/Vaccine and Treatment Group, All Subjects

		CV7202 1x1 µg	CV7202 2x1 µg	CV7202 1x2 µg	CV7202 2x2 µg
Subjects screened					
Subjects enrolled					
Subjects vaccinated		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects ongoing		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects completed		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects withdrawn		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Safety Analysis Set [a]		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Full analysis (FA) set [b]		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Main reason for termination	Consent withdrawn	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Violation of in/ex criteria	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Continuation jeopardizes subject	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Adverse event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Non-compliance	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Lost to follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Study terminated by sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Received at least 1 dose of CV7202 or Rabpur.
[b] All subjects of the Safety Analysis Set with baseline and at least 1 postbaseline VNT sample.
Percentages are based on the number of vaccinated subjects in each column.

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Programming note:
Subjects ongoing will only be displayed, if table is generated before end of the trial.

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14.1.3 Subject Number by Country and Site
Safety Analysis Set

	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)	Total (N = xx)
Germany Site 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Belgium Site 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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14.1.4.1 Demographic Characteristics by Dosage/Vaccine, Safety Analysis Set

	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)	Total (N = xx)
Age (years)					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Gender					
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	x	x	x	x	x
Childbearing potential					
Childbearing potential	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Postmenopausal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Surgically sterile	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not applicable (male subject)	x	x	x	x	x
Ethnic origin					
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	x	x	x	x	x

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14.1.4.2 Demographic Characteristics by Dosage/Vaccine and Treatment Group, Safety Analysis Set

	CV7202 1x1 µg (N=xx)	CV7202 2x1 µg (N=xx)	CV7202 1x2 µg (N=xx)	CV7202 2x2 µg (N=xx)
Age (years)				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Gender				
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	x	x	x	x
Childbearing potential				
Childbearing potential	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Postmenopausal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Surgically sterile	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not applicable (male subject)	x	x	x	x
Ethnic origin				
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	x	x	x	x

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14.1.4.3 Demographic Characteristics by Dosage/Vaccine, Full Analysis Set

Programming note:
Repeat table 14.1.4.1 for 14.1.4.3

14.1.4.4 Demographic Characteristics by Dosage/Vaccine and Treatment Group, Full Analysis Set

Programming note:
Repeat table 14.1.4.2 for 14.1.4.4

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14.1.5.1 Baseline Characteristics by Dosage/Vaccine, Safety Analysis Set

	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)	Total (N = xx)
Height (cm)					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Weight (kg)					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
BMI (kg/m^2)					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

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14.1.5.2 Baseline Characteristics by Dosage/Vaccine and Treatment Group, Safety Analysis Set

	CV7202 1x1 µg (N=xx)	CV7202 2x1 µg (N=xx)	CV7202 1x2 µg (N=xx)	CV7202 2x2 µg (N=xx)
Height (cm)				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Weight (kg)				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
BMI (kg/m^2)				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

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14.1.5.3 Baseline Characteristics by Dosage/Vaccine, Full Analysis Set

Programming note:
Repeat table 14.1.5.1 for 14.1.5.3

14.1.5.4 Baseline Characteristics by Dosage/Vaccine and Treatment Group, Full Analysis Set

Programming note:
Repeat table 14.1.5.2 for 14.1.5.4

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14.1.6 Concomitant Medications/Vaccinations by Dosage/Vaccine, Safety Analysis Set

ATC class Preferred Name [n (%)]	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)	Total (N = xx)
Subjects receiving any ongoing or concomitant medications/vaccinations	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC Class 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
.					
.					
ATC Class 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Name 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
.					
.					

Note: At each level of summation (overall, ATC class, preferred name), subjects reporting more than 1 medication / vaccination are counted only once.
Table is sorted by descending total subject count on the ATC level.
Percentages are based on total no. of subjects in each treatment group.
Terms were coded using WHODrug Global B3 format, Sep2021 release.

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14.2.1.1 Rabies Specific VNTs >= 0.5 IU/ml by Dosage/Vaccine, Full Analysis Set

		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
VNTs >= 0.5 IU/ml					
V3 (Day 1)	n	xx	xx	xx	xx
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
V5 (Day 8)	n	xx	xx	xx	xx
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
V7 (Day 15)	..				
V8 (Day 29)					
V10 (Day 36)					
V11 (Day 43)					
V12 (Day 57)					
V13 (Day 91)					
V14 (Month 6)					
V15 (Month 12)					
V16 (Month 18)					
V17 (Trial End/Month 24)					

CI = Confidence interval (exact Clopper-Pearson confidence interval) for category yes.
VNT >= 0.5 IU/mL = virus neutralization titer threshold according to WHO guideline.

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14.2.1.2 Rabies Specific VNTs >= 0.5 IU/ml by Dosage/Vaccine and Treatment Group, Full Analysis Set

		CV7202 1x1 µg (N = xx)	CV7202 2x1 µg (N = xx)	CV7202 1x2 µg (N = xx)	CV7202 2x2 µg (N = xx)
VNTs >= 0.5 IU/ml					
V3 (Day 1)	n	xx	xx	xx	xx
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
V5 (Day 8)	n	xx	xx	xx	xx
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
V7 (Day 15)					
V8 (Day 29)					
V10 (Day 36)					
V11 (Day 43)					
V12 (Day 57)					
V13 (Day 91)					
V14 (Month 6)					
V15 (Month 12)					
V16 (Month 18)					
V17 (Trial End/Month 24)					

CI = Confidence interval (exact Clopper-Pearson confidence interval) for category yes.
VNT >= 0.5 IU/mL = virus neutralization titer threshold according to WHO guideline.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

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14.2.1.3 Rabies Specific VNTs (IU/mL) by Dosage/Vaccine, Full Analysis Set

		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
V3 (Day 1)	n	xx	xx	xx	xx
	GMT (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	95% CL	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
V5 (Day 8)	n	xx	xx	xx	xx
	GMT (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	95% CL	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
V7 (Day 15)	..				
V8 (Day 29)					
V10 (Day 36)					
V11 (Day 43)					
V12 (Day 57)					
V13 (Day 91)					
V14 (Month 6)					
V15 (Month 12)					
V16 (Month 18)					
V17 (Trial End/Month 24)					

GMT = Geometric mean titer, CL = Confidence limit.
Data are log-transformed, mean, SD and 95% CLs calculated and antilog of mean, SD and 95% CLs tabulated.
Titers marked as below lower limit of quantification (LLOQ=0.1 IU/mL) are set to 0.5*LLOQ.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

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14.2.1.4 Rabies Specific VNTs (IU/mL) by Dosage/Vaccine and Treatment Group, Full Analysis Set

		CV7202 1x1 µg (N = xx)	CV7202 2x1 µg (N = xx)	CV7202 1x2 µg (N = xx)	CV7202 2x2 µg (N = xx)
V3 (Day 1)	n	xx	xx	xx	xx
	GMT (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	95% CL	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
V5 (Day 8)	n	xx	xx	xx	xx
	GMT (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	95% CL	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
V7 (Day 15)	..				
V8 (Day 29)					
V10 (Day 36)					
V11 (Day 43)					
V12 (Day 57)					
V13 (Day 91)					
V14 (Month 6)					
V15 (Month 12)					
V16 (Month 18)					
V17 (Month 24)					

GMT = Geometric mean titer, CL = Confidence limit.
Data are log-transformed, mean, SD and 95% CLs calculated and antilog of mean, SD and 95% CLs tabulated.
Titers marked as below lower limit of quantification (LLOQ=0.1 IU/mL) are set to 0.5*LLOQ.

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14.2.2.1.1 RABV-G Specific Levels of IgM >= 780 U/ml by Dosage/Vaccine, Full Analysis Set

		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
IgM >= 780 U/ml					
V3 (Day 1)	n	xx	xx	xx	xx
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
V5 (Day 8)	n	xx	xx	xx	xx
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
V7 (Day 15)	..				
V8 (Day 29)					
V10 (Day 36)					
V11 (Day 43)					
V12 (Day 57)					
V13 (Day 91)					
V14 (Month 6)					
V15 (Month 12)					

CI = Confidence interval (exact Clopper-Pearson confidence interval) for category yes.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

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14.2.2.1.2 RABV-G Specific Levels of IgM >= 780 U/ml by Dosage/Vaccine and Treatment Group, Full Analysis Set

		CV7202 1x1 µg (N = xx)	CV7202 2x1 µg (N = xx)	CV7202 1x2 µg (N = xx)	CV7202 2x2 µg (N = xx)
IgM >= 780 U/ml					
V3 (Day 1)	n	xx	xx	xx	xx
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
V5 (Day 8)	n	xx	xx	xx	xx
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
V7 (Day 15)	..				
V8 (Day 29)					
V10 (Day 36)					
V11 (Day 43)					
V12 (Day 57)					
V13 (Day 91)					
V14 (Month 6)					
V15 (Month 12)					

CI = Confidence interval (exact Clopper-Pearson confidence interval) for category yes.

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14.2.2.1.3 RABV-G Specific Levels of IgM (U/mL) by Dosage/Vaccine, Full Analysis Set

		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
V3 (Day 1)	n	xx	xx	xx	xx
	GMT (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	95% CL	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
V5 (Day 8)	n	xx	xx	xx	xx
	GMT (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	95% CL	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
V7 (Day 15)	..				
V8 (Day 29)					
V10 (Day 36)					
V11 (Day 43)					
V12 (Day 57)					
V13 (Day 91)					
V14 (Month 6)					
V15 (Month 12)					

GMT = Geometric mean titer, CL = Confidence limit.
Data are log-transformed, mean, SD and 95% CLs calculated and antilog of mean, SD and 95% CLs tabulated.
Titers marked as below lower limit of quantification (LLOQ=780 U/mL) are set to 0.5*LLOQ.

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Programming note:
Number of decimals will vary by lab parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.

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14.2.2.1.4 RABV-G Specific Levels of IgM (U/mL) by Dosage/Vaccine and Treatment Group, Full Analysis Set

		CV7202 1x1 µg (N = xx)	CV7202 2x1 µg (N = xx)	CV7202 1x2 µg (N = xx)	CV7202 2x2 µg (N = xx)
V3 (Day 1)	n	xx	xx	xx	xx
	GMT (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	95% CL	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
V5 (Day 8)	n	xx	xx	xx	xx
	GMT (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	95% CL	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
V7 (Day 15)	..				
V8 (Day 29)					
V10 (Day 36)					
V11 (Day 43)					
V12 (Day 57)					
V13 (Day 91)					
V14 (Month 6)					
V15 (Month 12)					

GMT = Geometric mean titer, CL = Confidence limit.
Data are log-transformed, mean, SD and 95% CLs calculated and antilog of mean, SD and 95% CLs tabulated.
Titers marked as below lower limit of quantification (LLOQ=780 U/mL) are set to 0.5*LLOQ.

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Programming note:
Number of decimals will vary by lab parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.

14.2.2.2.1 RABV-G Specific Levels of IgA >=195.5 U/ml by Dosage/Vaccine, Full Analysis Set

Programming note:
Repeat table 14.2.2.1.1 for 14.2.2.2.1

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14.2.2.2.2 RABV-G Specific Levels of IgA >= 195.5 U/ml by Dosage/Vaccine and Treatment Group, Full Analysis Set

Programming note:
Repeat table 14.2.2.1.2 for 14.2.2.2.2

14.2.2.2.3 RABV-G Specific Levels of IgA (U/mL) by Dosage/VaccineVisit, Full Analysis Set

Programming note:
Repeat table 14.2.2.1.3 for 14.2.2.2.3
Number of decimals will vary by lab parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.

14.2.2.2.4 RABV-G Specific Levels of IgA (U/mL) by Dosage/Vaccine and Treatment Group, Full Analysis Set

Programming note:
Repeat table 14.2.2.1.4 for 14.2.2.2.4
Number of decimals will vary by lab parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.

14.2.2.3.1 RABV-G Specific Levels of IgG >=780 U/ml by Dosage/Vaccine, Full Analysis Set

Programming note:
Repeat table 14.2.2.1.1 for 14.2.2.3.1 IgG, including V16 (Month 18) and V17 (Month 24) data of subjects with detectable RABV-G specific IgG at 6 months after the last vaccination.

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14.2.2.3.2 RABV-G Specific Levels of IgG >=780 U/ml by Dosage/Vaccine and Treatment Group, Full Analysis Set

Programming note:
Repeat table 14.2.2.1.2 for 14.2.2.3.2 IgG, including V16 (Month 18) and V17 (Month 24) data of subjects with detectable RABV-G specific IgG at 6 months after the last vaccination.

14.2.2.3.3 RABV-G Specific Levels of IgG (U/mL) by Dosage/Vaccine, Full Analysis Set

Programming note:
Repeat table 14.2.2.1.3 for 14.2.2.3.3 IgG, ***including V16 (Month 18) and V17 (Month 24) data of subjects with detectable RABV-G specific IgG at 6 months after the last vaccination.***
Number of decimals will vary by lab parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.

14.2.2.3.4 RABV-G Specific Levels of IgG (U/mL) by Dosage/Vaccine and Treatment Group, Full Analysis Set

Programming note:
Repeat table 14.2.2.1.4 for 14.2.2.3.4 ***IgG, including V16 (Month 18) and V17 (Month 24) data of subjects with detectable RABV-G specific IgG at 6 months after the last vaccination.***
Number of decimals will vary by lab parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.

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14.2.3.1 Cellular Immune Response by Dosage/Vaccine, Full Analysis Set

		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Parameter (unit)	Baseline				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	Actual result (Visit xx)				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	Change from baseline (Visit xx)				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

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Programming note:
Display for available parameters with sufficient data and visits with scheduled sampling.
Number of decimals will vary by lab parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.

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14.2.3.2 Cellular Immune Response by Dosage/Vaccine and Treatment Group, Full Analysis Set

		CV7202 1x1 µg (N = xx)	CV7202 2x1 µg (N = xx)	CV7202 1x2 µg (N = xx)	CV7202 2x2 µg (N = xx)
Parameter (unit)	Baseline				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	Actual result (Visit xx)				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	Change from baseline (Visit xx)				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Display for available parameters with sufficient data and visits with scheduled sampling.
Number of decimals will vary by lab parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.

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14.2.3.3 Cytokine Assessment by Dosage/Vaccine, Full Analysis Set

		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Parameter (unit)	Baseline				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	Actual result (Visit xx)				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	Change from baseline (Visit xx)				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Display for available parameters with sufficient data and visits with scheduled sampling.
Number of decimals will vary by lab parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.

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14.2.3.4 Cytokine Assessment by Dosage/Vaccine and Treatment Group, Full Analysis Set

		CV7202 1x1 µg (N = xx)	CV7202 2x1 µg (N = xx)	CV7202 1x2 µg (N = xx)	CV7202 2x2 µg (N = xx)
Parameter (unit)	Baseline				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	Actual result (Visit xx)				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	Change from baseline (Visit xx)				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Display for available parameters with sufficient data and visits with scheduled sampling.
Number of decimals will vary by lab parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.

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14.3.1.1.1.1 Summary of Solicited Adverse Events Within 7 Days After any Dose, Safety Analysis Set

Category [n (%)]		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Any solicited adverse event	AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1 (mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2 (moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3 (severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Any local solicited adverse event	AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	..	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Any systemic solicited adverse event					
Any related systemic solicited adverse event					
Any solicited adverse event ongoing on day 8					
Any local solicited adverse event ongoing on day 8					
Any systemic solicited adverse event ongoing on day 8					

n = Number of subjects
Subjects are counted once based on highest severity.
Percentages are based on total no. of subjects in each vaccination group.

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14.3.1.1.1.2 Summary of Solicited Adverse Events Within 7 Days Post Dose 1, Safety Analysis Set

Category [n (%)]		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Any solicited adverse event	AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1 (mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2 (moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3 (severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Any local solicited adverse event	AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	..	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Any systemic solicited adverse event					
Any related systemic solicited adverse event					
Any solicited adverse event ongoing on day 8					
Any local solicited adverse event ongoing on day 8					
Any systemic solicited adverse event ongoing on day 8					

n = Number of subjects
Subjects are counted once based on highest severity.
Percentages are based on total no. of subjects in each vaccination group.

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14.3.1.1.1.3 Summary of Solicited Adverse Events Within 7 Days Post Dose 2, Safety Analysis Set

Category [n (%)]		CV7202 2x1 µg (N = xx)	CV7202 2x2 µg (N = xx)	Rabipur (N = xx)
Any solicited adverse event	AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1 (mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2 (moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3 (severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Any local solicited adverse event	AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	..	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Any systemic solicited adverse event				
Any related systemic solicited adverse event				
Any solicited adverse event ongoing on day 8				
Any local solicited adverse event ongoing on day 8				
Any systemic solicited adverse event ongoing on day 8				

n = Number of subjects
Subjects are counted once based on highest severity.
Percentages are based on total no. of subjects in each vaccination group.

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14.3.1.1.1.4 Summary of Solicited Adverse Events Within 7 Days Post Dose 3, Safety Analysis Set

Category [n (%)]		Rabipur (N = xx)
Any solicited adverse event	AE (Grade 1,2,3)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)
	Grade 1 (mild)	xx (xx.x%)
	Grade 2 (moderate)	xx (xx.x%)
	Grade 3 (severe)	xx (xx.x%)
	Not assessed	xx (xx.x%)
Any local solicited adverse event	..	
Any systemic solicited adverse event		
Any related systemic solicited adverse event		
Any solicited adverse event ongoing on day 8		
Any local solicited adverse event ongoing on day 8		
Any systemic solicited adverse event ongoing on day 8		

n = Number of subjects
Subjects are counted once based on highest severity.
Percentages are based on total no. of subjects in each vaccination group.

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14.3.1.1.1.5 Local Solicited Adverse Events Within 7 Days After any Dose, Safety Analysis Set

Category [n (%)]		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Pain	AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1 (mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2 (moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3 (severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Redness	AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade xx (xx)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	..				
Swelling	..				
Itching	..				

n = Number of subjects
Subjects are counted once based on highest severity.
Percentages are based on total no. of subjects in each vaccination group.
Redness is graded to <2.5 cm as grade 0, 2.5-5cm as grade 1, 5.1-10cm as grade 2, >10cm as grade 3.
Swelling is graded to <2.5 cm as grade 0, 2.5-5cm and does not interfere with activity as grade 1, 5.1-10cm or interferes with activity as grade 2, >10cm or prevents daily activity as grade 3.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
If different gradings per symptom can be included in table columns directly, the respective footnotes can be removed.

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14.3.1.1.1.6 Local Solicited Adverse Events Within 7 Days Post Dose 1, Safety Analysis Set

Category [n (%)]		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Pain	AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1 (mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2 (moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3 (severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Redness	AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1 (mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	..	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Swelling	..				
Itching	..				

n = Number of subjects
Subjects are counted once based on highest severity.
Percentages are based on total no. of subjects in each vaccination group.
Redness is graded to <2.5 cm as grade 0, 2.5-5cm as grade 1, 5.1-10cm as grade 2, >10cm as grade 3.
Swelling is graded to <2.5 cm as grade 0, 2.5-5cm and does not interfere with activity as grade 1, 5.1-10cm or interferes with activity as grade 2, >10cm or prevents daily activity as grade 3.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
If different gradings per symptom can be included in table columns directly, the respective footnotes can be removed.

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14.3.1.1.1.7 Local Solicited Adverse Events within 7 Days Post Dose 2, Safety Analysis Set

Category [n (%)]		CV7202 2x1 µg (N = xx)	CV7202 2x2 µg (N = xx)	Rabipur (N = xx)
Pain	AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 1 (mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 2 (moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade 3 (severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Redness	AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Grade x (xx)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Swelling	..			
Itching	..			

n = Number of subjects
Subjects are counted once based on highest severity.
Percentages are based on total no. of subjects in each vaccination group.
Redness is graded to <2.5 cm as grade 0, 2.5-5cm as grade 1, 5.1-10cm as grade 2, >10cm as grade 3.
Swelling is graded to <2.5 cm as grade 0, 2.5-5cm and does not interfere with activity as grade 1, 5.1-10cm or interferes with activity as grade 2, >10cm or prevents daily activity as grade 3.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
If different gradings per symptom can be included in table columns directly, the respective footnotes can be removed.

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14.3.1.1.1.8 Local Solicited Adverse Events Within 7 Days Post Dose 3, Safety Analysis Set

Category [n (%)]		Rabipur (N = xx)
Pain	AE (Grade 1,2,3)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)
	Grade 1 (mild)	xx (xx.x%)
	Grade 2 (moderate)	xx (xx.x%)
	Grade 3 (severe)	xx (xx.x%)
	Not assessed	xx (xx.x%)
Redness	AE (Grade 1,2,3)	xx (xx.x%)
	No AE (Grade 0)	xx (xx.x%)
	Grade x (xx)	xx (xx.x%)
Swelling	..	
Itching	..	

n = Number of subjects
Subjects are counted once based on highest severity.
Percentages are based on total no. of subjects in each vaccination group.
Redness is graded to <2.5 cm as grade 0, 2.5-5cm as grade 1, 5.1-10cm as grade 2, >10cm as grade 3.
Swelling is graded to <2.5 cm as grade 0, 2.5-5cm and does not interfere with activity as grade 1, 5.1-10cm or interferes with activity as grade 2, >10cm or prevents daily activity as grade 3.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
If different gradings per symptom can be included in table columns directly, the respective footnotes can be removed.

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14.3.1.1.1.9 Systemic Solicited Adverse Events Within 7 Days After any Dose, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.1.5 for systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea. Replace footnote on grading of redness and swelling by Temperature is graded to < 38°C as grade 0, ≥38°C-38.4°C as grade 1, ≥38.5°C-38.9°C to grade 2 and ≥39°C to grade 3

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14.3.1.1.1.10 Systemic Solicited Adverse Events Within 7 Days Post Dose 1, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.1.6 for systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea. Replace footnote on grading of redness and swelling by Temperature is graded to < 38°C as grade 0, ≥38°C-38.4°C as grade 1, ≥38.5°C-38.9°C to grade 2 and ≥39°C to grade 3

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14.3.1.1.1.11 Systemic Solicited Adverse Events Within 7 Days Post Dose 2, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.1.7 for systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea. Replace footnote on grading of redness and swelling by Temperature is graded to < 38°C as grade 0, ≥38°C-38.4°C as grade 1, ≥38.5°C-38.9°C to grade 2 and ≥39°C to grade 3

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14.3.1.1.1.12 Systemic Solicited Adverse Events Within 7 Days Post Dose 3, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.1.8 for systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea. Replace footnote on grading of redness and swelling by Temperature is graded to < 38°C as grade 0, ≥38°C-38.4°C as grade 1, ≥38.5°C-38.9°C to grade 2 and ≥39°C to grade 3

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14.3.1.1.1.13 Related Systemic Solicited Adverse Events Within 7 Days After any Dose, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.1.9 for related systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.1.14 Related Systemic Solicited Adverse Events Within 7 Days Post Dose 1, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.1.10 for related systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.1.15 Related Systemic Solicited Adverse Events Within 7 Days Post Dose 2, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.1.11 for related systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.1.16 Related Systemic Solicited Adverse Events Within 7 Days Post Dose 3, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.1.12 for related systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.2.1 Number of Days of Local Solicited Adverse Events Post Dose 1, Safety Analysis Set

		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Pain	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Redness	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Swelling	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Itching	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

Table counts solicited adverse events with grade > 0 only.
Duration is calculated as the sum of days with local systemic adverse event (days 1 to 8).

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14.3.1.1.2.2 Number of Days of Local Solicited Adverse Events Post Dose 2, Safety Analysis Set

		CV7202 2x1 µg (N = xx)	CV7202 2x2 µg (N = xx)	Rabipur (N = xx)
Pain	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Redness	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Swelling	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Itching	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx

Table counts solicited adverse events with grade > 0 only.
Duration is calculated as the sum of days with local systemic adverse event (days 1 to 8).

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14.3.1.1.2.3 Number of Days of Local Solicited Adverse Events Post Dose 3, Safety Analysis Set

		Rabipur (N = xx)
Pain	n	xx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Redness	n	xx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Swelling	n	xx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx
Itching	n	xx
	Mean (SD)	xx.x (xx.xx)
	Median	xx.x
	Min, Max	xx, xx

Table counts solicited adverse events with grade > 0 only.
Duration is calculated as the sum of days with local systemic adverse event (days 1 to 8).

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14.3.1.1.2.4 Number of Days of Grade 3 Local Solicited Adverse Events Post Dose 1, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.2.1 for grade 3 local solicited adverse events.

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14.3.1.1.2.5 Number of Days of Grade 3 Local Solicited Adverse Events Post Dose 2, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.2.2 for grade 3 local solicited adverse events.

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14.3.1.1.2.6 Number of Days of Grade 3 Local Solicited Adverse Events Post Dose 3, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.2.3 for grade 3 local solicited adverse events.

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14.3.1.1.2.7 Number of Days of Systemic Solicited Adverse Events Post Dose 1, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.2.1 for systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.2.8 Number of Days of Systemic Solicited Adverse Events Post Dose 2, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.2.2 for systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.2.9 Number of Days of Systemic Solicited Adverse Events Post Dose 3, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.2.3 for systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.2.10 Number of Days of Grade 3 Systemic Solicited Adverse Events Post Dose 1, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.2.7 for grade 3 systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.2.11 Number of Days of Grade 3 Systemic Solicited Adverse Events Post Dose 2, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.2.8 for grade 3 systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.2.12 Number of Days of Grade 3 Systemic Solicited Adverse Events Post Dose 3, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.2.9 for grade 3 systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.3.1 Daily Summary of Local Solicited Adverse Events Post Dose 1, Safety Analysis Set

	CV7202 1 µg (N = xx)							
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8
Pain								
AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1 (mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2 (moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3 (severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Redness								
AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1 (mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2 (moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3 (severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Swelling								
..								
Itching								
..								

Percentages are based on total no. of subjects in each vaccination group.
Redness is graded to <2.5 cm as grade 0, 2.5-5cm as grade 1, 5.1-10cm as grade 2, >10cm as grade 3.
Swelling is graded to <2.5 cm as grade 0, 2.5-5cm and does not interfere with activity as grade 1, 5.1-10cm or interferes with activity as grade 2, >10cm or prevents daily activity as grade 3.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Display also for CV7202 2 µg group, CV7202 5 µg group, and Rabipur group.

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14.3.1.1.3.2 Daily Summary of Local Solicited Adverse Events Post Dose 2, Safety Analysis Set

	CV7202 2x1 µg (N = xx)							
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8
Pain								
AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1 (mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2 (moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3 (severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Redness								
AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1 (mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2 (moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3 (severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Swelling								
..								
Itching								
..								

Percentages are based on total no. of subjects in each vaccination group.
Redness is graded to <2.5 cm as grade 0, 2.5-5cm as grade 1, 5.1-10cm as grade 2, >10cm as grade 3.
Swelling is graded to <2.5 cm as grade 0, 2.5-5cm and does not interfere with activity as grade 1, 5.1-10cm or interferes with activity as grade 2, >10cm or prevents daily activity as grade 3.

Source: xxx
PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Display also for CV7202 2x2 µg group and Rabipur group.

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14.3.1.1.3.3 Daily Summary of Local Solicited Adverse Events Post Dose 3, Safety Analysis Set

	Rabipur (N = xx)							
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8
Pain								
AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1 (mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2 (moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3 (severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Redness								
AE (Grade 1,2,3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No AE (Grade 0)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 1 (mild)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 2 (moderate)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade 3 (severe)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Swelling								
..								
Itching								
..								

Percentages are based on total no. of subjects in each vaccination group.
Redness is graded to <2.5 cm as grade 0, 2.5-5cm as grade 1, 5.1-10cm as grade 2, >10cm as grade 3.
Swelling is graded to <2.5 cm as grade 0, 2.5-5cm and does not interfere with activity as grade 1, 5.1-10cm or interferes with activity as grade 2, >10cm or prevents daily activity as grade 3.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

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14.3.1.1.3.4 Daily Summary of Systemic Solicited Adverse Events Post Dose 1, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.3.1 for systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.3.5 Daily Summary of Systemic Solicited Adverse Events Post Dose 2, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.3.2 for systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.3.6 Daily Summary of Systemic Solicited Adverse Events Post Dose 3, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.3.3 for systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.4.1 Day of First Onset of Solicited Adverse Events Post Dose 1, Safety Analysis Set

Category [n (%)]	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Any solicited adverse event				
No AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 6	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 7	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 8	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Any local solicited adverse event				
No AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
..				
Any systemic solicited adverse event				
Any related systemic solicited adverse event				

n = Number of subjects
Subjects are counted once based the first occurrence of an event per the category.
Percentages are based on total no. of subjects in each vaccination group.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

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14.3.1.1.4.2 Day of First Onset of Solicited Adverse Events Post Dose 2, Safety Analysis Set

Category [n (%)]	CV7202 2x1 µg (N = xx)	CV7202 2x2 µg (N = xx)	Rabipur (N = xx)
Any solicited adverse event			
No AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 6	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 7	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 8	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Any local solicited adverse event			
No AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
..			
Any systemic solicited adverse event			
Any related systemic solicited adverse event			

n = Number of subjects
Subjects are counted once based the first occurrence of an event per category.
Percentages are based on total no. of subjects in each vaccination group.

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14.3.1.1.4.3 Day of First Onset of Solicited Adverse Events Post Dose 3, Safety Analysis Set

Category [n (%)]	Rabipur (N = xx)
Any solicited adverse event	
No AE	xx (xx.x%)
Day 1	xx (xx.x%)
Day 2	xx (xx.x%)
Day 3	xx (xx.x%)
Day 4	xx (xx.x%)
Day 5	xx (xx.x%)
Day 6	xx (xx.x%)
Day 7	xx (xx.x%)
Day 8	xx (xx.x%)
Not assessed	xx (xx.x%)
Any local solicited adverse event	
No AE	xx (xx.x%)
Day 1	xx (xx.x%)
Day 2	xx (xx.x%)
..	
Any systemic solicited adverse event	
Any related systemic solicited adverse event	

n = Number of subjects
Subjects are counted once based the first occurrence of an event per category.
Percentages are based on total no. of subjects in each vaccination group.

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14.3.1.1.4.4 Day of First Onset of Local Solicited Adverse Events Post Dose 1, Safety Analysis Set

Category [n (%)]	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Pain				
No AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 6	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 7	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 8	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Redness				
No AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
..				
Swelling				
Itching				

n = Number of subjects
Subjects are counted once based the first occurrence of an event per the category.
Percentages are based on total no. of subjects in each vaccination group.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

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14.3.1.1.4.5 Day of First Onset of Local Solicited Adverse Events Post Dose 2, Safety Analysis Set

Category [n (%)]	CV7202 2x1 µg (N = xx)	CV7202 2x2 µg (N = xx)	Rabipur (N = xx)
Pain			
No AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 5	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 6	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 7	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 8	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not assessed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Redness			
No AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
..			
Swelling			
Itching			

n = Number of subjects
Subjects are counted once based the first occurrence of an event per category.
Percentages are based on total no. of subjects in each vaccination group.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

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14.3.1.1.4.6 Day of First Onset of Local Solicited Adverse Events Post Dose 3, Safety Analysis Set

Category [n (%)]	Rabipur (N = xx)
Pain	
No AE	xx (xx.x%)
Day 1	xx (xx.x%)
Day 2	xx (xx.x%)
Day 3	xx (xx.x%)
Day 4	xx (xx.x%)
Day 5	xx (xx.x%)
Day 6	xx (xx.x%)
Day 7	xx (xx.x%)
Day 8	xx (xx.x%)
Not assessed	xx (xx.x%)
Redness	
No AE	xx (xx.x%)
Day 1	xx (xx.x%)
Day 2	xx (xx.x%)
..	
Swelling	
Itching	

n = Number of subjects
Subjects are counted once based the first occurrence of an event per category.
Percentages are based on total no. of subjects in each vaccination group.

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14.3.1.1.4.7 Day of First Onset of Systemic Solicited Adverse Events Post Dose 1, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.4.4 for systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.4.8 Day of First Onset of Systemic Solicited Adverse Events Post Dose 2, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.4.5 for systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.4.9 Day of First Onset of Systemic Solicited Adverse Events Post Dose 3, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.4.6 for systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.4.10 Day of First Onset of Related Systemic Solicited Adverse Events Post Dose 1, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.4.4 for related systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.4.11 Day of First Onset of Related Systemic Solicited Adverse Events Post Dose 2, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.4.5 for related systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.1.4.12 Day of First Onset of Related Systemic Solicited Adverse Events Post Dose 3, Safety Analysis Set

Programming note:
Repeat table 14.3.1.1.4.6 for related systemic solicited adverse events, categories: Temperature, Headache, Fatigue, Chills, Myalgia, Arthralgia, Nausea/ Vomiting and Diarrhea.

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14.3.1.2.1 Overall Summary of Unsolicited Adverse Events Within 28 Days After any Dose, Safety Analysis Set

Adverse Event Category [n (%) m]	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
All unsolicited adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Related unsolicited adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Serious adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Relatedserious adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Medically attended adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Adverse events leading to withdrawal from study	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Adverse events leading to discontinued vaccination	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Adverse events of special interest	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx

n = Number of subjects; m = Number of events; AEs on the day of vaccination and 28 subsequent days
Subjects reporting more than 1 event are counted only once for the subject count.
Percentages are based on total no. of subjects in each vaccination group.
Related: Adverse events which were assessed by the investigator as related to trial vaccine or study procedure.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
According to the SAP all unsolicited AE tables will be restricted to adverse events that occurred AFTER the first administration of the trial vaccine. If adverse events BEFORE are documented, these will be flagged and listed only.

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14.3.1.2.2 Overall Summary of Unsolicited Adverse Events Within 28 Days Post Dose 1, Safety Analysis Set

Adverse Event Category [n (%) m]	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
All unsolicited adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Related unsolicited adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Serious adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Relatedserious adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Medically attended adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Adverse events leading to withdrawal from study	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Adverse events leading to discontinued vaccination	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Adverse events of special interest	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx

n = Number of subjects; m = Number of events;
AEs on the day of vaccination and 28 subsequent days, but before dose 2 CV7202 or dose 3 of Rabipur.
Subjects reporting more than 1 event are counted only once for the subject count.
Percentages are based on total no. of subjects in each vaccination group.
Related: Adverse events which were assessed by the investigator as related to trial vaccine or study procedure.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
According to the SAP all unsolicited AE tables will be restricted to adverse events that occurred AFTER the first administration of the trial vaccine. If adverse events BEFORE are documented, these will be flagged and listed only. AEs on the day of vaccination and 28 subsequent days, but before dose 2 CV7202 or dose 3 of Rabipur.

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14.3.1.2.3 Overall Summary of Unsolicited Adverse Events Within 28 Days Post Dose 2 CV7202 or Dose 3 Rabipur, Safety Analysis Set

Adverse Event Category [n (%) m]	CV7202 2x1 µg (N = xx)	CV7202 2x2 µg (N = xx)	Rabipur (N = xx)
All unsolicited adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Related unsolicited adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Serious adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Relatedserious adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Medically attended adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Adverse events leading to withdrawal from study	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Adverse events leading to discontinued vaccination	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Adverse events of special interest	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx

n = Number of subjects; m = Number of events;
AEs on the day of vaccination and 28 subsequent days
Subjects reporting more than 1 event are counted only once for the subject count.
Percentages are based on total no. of subjects in each vaccination group.
Related: Adverse events which were assessed by the investigator as related to trial vaccine or study procedure.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
According to the SAP all unsolicited AE tables will be restricted to adverse events that occurred AFTER the first administration of the trial vaccine. If adverse events BEFORE are documented, these will be flagged and listed only.

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14.3.1.2.4 Summary of Unsolicited Adverse Events Within 28 Days by Maximum Intensity (Grade) After any Dose, Safety Analysis Set

Adverse Event Category [n (%)]		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
All unsolicited adverse events	Mild (grade 1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate (grade 2)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe (grade 3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related unsolicited adverse events	Mild (grade 1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate (grade 2)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe (grade 3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

n = Number of subjects; AEs on the day of vaccination and 28 subsequent days
Subjects reporting more than 1 event are counted only once for the subject count with highest intensity (grade).
Percentages are based on total no. of subjects in each vaccination group.
Related: Adverse events which were assessed by the investigator as related to trial vaccine or study procedure.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
According to the SAP all unsolicited AE tables will be restricted to adverse events that occurred AFTER the first administration of the trial vaccine. If adverse events BEFORE are documented, these will be flagged and listed only.

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14.3.1.2.5 Unsolicited Adverse Events Within 28 Days After any Dose, Safety Analysis Set

System organ class Preferred term [n (%) m]	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)	Total (N = xx)
Any adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
System organ class 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 3	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 4	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
...	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
System organ class 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 3	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
...	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx

n = Number of subjects; m = Number of events; AEs on the day of vaccination and 28 subsequent days
Adverse events were coded using MedDRA version 24.1. At each level of summation (system organs class, preferred term) subjects reporting more than 1 event are included only once.
Table is sorted by descending subject count in the total column by system organ class and preferred term.
Percentages are based on total number of subjects in each vaccination group

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Sort by decreasing frequency of the total column by SOC and preferred term.
According to the SAP all unsolicited AE tables will be restricted to adverse events that occurred AFTER the first administration of the trial vaccine (post vaccination). If adverse events BEFORE are documented, they will be flagged and listed only.

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14.3.1.2.6 Unsolicited Adverse Events Within 28 Days Post Dose 1, Safety Analysis Set

System organ class Preferred term [n (%) m]	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)	Total (N = xx)
Any adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
System organ class 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 3	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 4	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
...	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
System organ class 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 3	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
...	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx

n = Number of subjects; m = Number of events;
AEs on the day of vaccination and 28 subsequent days, but before 2nd CV7202 or 3rd Rabipur vaccination.
Adverse events were coded using MedDRA version 24.1. At each level of summation (system organs class, preferred term) subjects reporting more than 1 event are included only once.
Table is sorted by descending subject count in the total column by system organ class and preferred term.
Percentages are based on total number of subjects in each vaccination group

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Sort by decreasing frequency of the total column by SOC and preferred term.
According to the SAP all unsolicited AE tables will be restricted to adverse events that occurred AFTER the first administration of the trial vaccine (post vaccination). If adverse events BEFORE are documented, they will be flagged and listed only.

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14.3.1.2.7 Unsolicited Adverse Events Within 28 Days Post Dose 2 CV7202 or Dose 3 Rabipur, Safety Analysis Set

System organ class Preferred term [n (%) m]	CV7202 2x1 µg (N = xx)	CV7202 2x2 µg (N = xx)	Rabipur (N = xx)	Total (N = xx)
Any adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
System organ class 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 3	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 4	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
...	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
System organ class 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 3	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
...	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx

n = Number of subjects; m = Number of events;
AEs on the day of vaccination and 28 subsequent days.
Adverse events were coded using MedDRA version 24.1. At each level of summation (system organs class, preferred term) subjects reporting more than 1 event are included only once.
Table is sorted by descending subject count in the total column by system organ class and preferred term.
Percentages are based on total number of subjects in each vaccination group

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Sort by decreasing frequency of the total column by SOC and preferred term.
According to the SAP all unsolicited AE tables will be restricted to adverse events that occurred AFTER the first administration of the trial vaccine (post vaccination). If adverse events BEFORE are documented, they will be flagged and listed only.

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14.3.1.3.1 Overall Summary of Unsolicited Adverse Events for the Duration of the Trial After any Dose, Safety Analysis Set

Adverse Event Category [n (%) m]	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
All unsolicited adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Related unsolicited adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Serious adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Related serious adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Medically attended adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Adverse events leading to withdrawal from study	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Adverse events leading to discontinued vaccination	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Adverse events of special interest	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx

n = Number of subjects; m = Number of events; AEs on the day of vaccination and all subsequent days
Subjects reporting more than 1 event are counted only once for the subject count.
Percentages are based on total no. of subjects in each vaccination group.
Related: Adverse events which were assessed by the investigator as related to trial vaccine or study procedure.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
According to the SAP all unsolicited AE tables will be restricted to adverse events that occurred AFTER the first administration of the trial vaccine. If adverse events BEFORE are documented, these will be flagged and listed only.

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14.3.1.3.2 Summary of Unsolicited Adverse Events for the Duration of the Trial by Maximum Intensity (Grade) After any Dose, Safety Analysis Set

Adverse Event Category [n (%)]		CV7202 1x1 µg (N = xx)	CV7202 2x1 µg (N = xx)	CV7202 1x2 µg (N = xx)	CV7202 2x2 µg (N = xx)
All unsolicited adverse events	Mild (grade 1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate (grade 2)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe (grade 3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related unsolicited adverse events	Mild (grade 1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate (grade 2)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe (grade 3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

n = Number of subjects; AEs on the day of vaccination and all subsequent days
Subjects reporting more than 1 event are counted only once for the subject count with highest intensity (grade).
Percentages are based on total no. of subjects in each vaccination group.
Related: Adverse events which were assessed by the investigator as related to trial vaccine or study procedure.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
According to the SAP all unsolicited AE tables will be restricted to adverse events that occurred AFTER the first administration of the trial vaccine. If adverse events BEFORE are documented, these will be flagged and listed only.

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14.3.1.3.3 Unsolicited Adverse Events for the Duration of the Trial After any Dose, Safety Analysis Set

System organ class Preferred term [n (%) m]	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)	Total (N = xx)
Any adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
System organ class 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 3	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 4	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
...	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
System organ class 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 3	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
...	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx

n = Number of subjects; m = Number of events; AEs on the day of vaccination and all subsequent days
Adverse events were coded using MedDRA version 24.1. At each level of summation (system organs class, preferred term) subjects reporting more than 1 event are included only once.
Table is sorted by descending subject count in the total column by system organ class and preferred term.
Percentages are based on total number of subjects in each vaccination group

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Sort by decreasing frequency of the total column by SOC and preferred term.
According to the SAP all unsolicited AE tables will be restricted to adverse events that occurred AFTER the first administration of the trial vaccine (post vaccination). If adverse events BEFORE are documented, they will be flagged and listed only.

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14.3.1.3.4 Unsolicited Adverse Events for the Duration of the Trial Post Dose 1, Safety Analysis Set

System organ class Preferred term [n (%) m]	CV7202 1x1 µg (N = xx)	CV7202 1x2 µg (N = xx)	CV7202 5 µg (N = xx)	Total (N = xx)
Any adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
System organ class 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 3	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 4	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
...	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
System organ class 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 3	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
...	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx

n = Number of subjects; m = Number of events;
AEs on the day of vaccination and all subsequent days.
Adverse events were coded using MedDRA version 24.1. At each level of summation (system organs class, preferred term) subjects reporting more than 1 event are included only once.
Table is sorted by descending subject count in the total column by system organ class and preferred term.
Percentages are based on total number of subjects in each vaccination group

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Sort by decreasing frequency of the total column by SOC and preferred term.
According to the SAP all unsolicited AE tables will be restricted to adverse events that occurred AFTER the first administration of the trial vaccine (post vaccination). If adverse events BEFORE are documented, they will be flagged and listed only.

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14.3.1.3.5 Unsolicited Adverse Events for the Duration of the Trial Post Dose 2 CV7202 or Dose 3 Rabipur, Safety Analysis Set

System organ class Preferred term [n (%) m]	CV7202 2x1 µg (N = xx)	CV7202 2x2 µg (N = xx)	Rabipur (N = xx)	Total (N = xx)
Any adverse events	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
System organ class 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 3	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 4	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
...	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
System organ class 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 1	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 2	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
Preferred term 3	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx
...	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx	xx (xx.x%) xxx

n = Number of subjects; m = Number of events; AEs on the day of vaccination and all subsequent days
Adverse events were coded using MedDRA version 24.1. At each level of summation (system organs class, preferred term) subjects reporting more than 1 event are included only once.
Table is sorted by descending subject count in the total column by system organ class and preferred term.
Percentages are based on total number of subjects in each vaccination group

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Sort by decreasing frequency of the total column by SOC and preferred term.
According to the SAP all unsolicited AE tables will be restricted to adverse events that occurred AFTER the first administration of the trial vaccine (post vaccination). If adverse events BEFORE are documented, they will be flagged and listed only.

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14.3.2 Listing of Deaths, Other Serious and Significant Adverse Events. Safety Analysis Set

Programming note:
Create an empty table with the following reference message: "Please refer to listing 16.2.7.1.3"

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14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events, Safety Analysis Set

Programming note:
This is a cross-reference to section 12.3.2 of the CSR

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14.3.4 Abnormal Laboratory Value Listing (Each Subject), Safety Analysis Set

Programming note:
Layout analogous to section 16.2 lab listings

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14.3.5.1 Vaccination Site Reactogenicity Investigator Assessment Overview, Safety Analysis Set

Category [n (%)]		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Any symptom with grade > 0	V3 (Day 1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	V4 (Day 2/3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	V5 (Day 8)				xx (xx.x%)
	V6 (Day 10)				xx (xx.x%)
	V8 (Day 29)	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
	V9 (Day 30)	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

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14.3.5.2 Vaccination Site Reactogenicity Investigator Assessment Overview by Treatment Group, Safety Analysis Set

Category [n (%)]		CV7202 1x1 µg (N = xx)	CV7202 2x1 µg (N = xx)	CV7202 1x2 µg (N = xx)	CV7202 2x2 µg (N = xx)
Any symptoms with grade > 0	V3 (Day 1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	V4 (Day 2/3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	V8 (Day 29)			xx (xx.x%)	xx (xx.x%)
	V9 (Day 30)			xx (xx.x%)	xx (xx.x%)

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14.3.5.3 Vaccination Site Reactogenicity Investigator Assessment, Safety Analysis Set

Category [n (%)]			CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Injection pain	V3 (Day 1)	Grade 0	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	V4 (Day 2/3)	Grade 0	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	V5 (Day 8)	Grade 0				xx (xx.x%)
		Grade 1				xx (xx.x%)
		Grade 2				xx (xx.x%)
		Grade 3				xx (xx.x%)
	V6 (Day 10)	Grade 0				xx (xx.x%)
		Grade 1				xx (xx.x%)
		Grade 2				xx (xx.x%)
		Grade 3				xx (xx.x%)
	V8 (Day 29)	Grade 0	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
		Grade 1	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
		Grade 2	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
		Grade 3	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
	V9 (Day 30)	Grade 0	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
		Grade 1	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
		Grade 2	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
		Grade 3	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:

Repeat for redness, swelling, itching.

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14.3.5.4 Vaccination Site Reactogenicity Investigator Assessment by Treatment Group, Safety Analysis Set

Category [n (%)]			CV7202 1x1 µg (N = xx)	CV7202 2x1 µg (N = xx)	CV7202 1x2 µg (N = xx)	CV7202 2x2 µg (N = xx)
Injection pain	V3 (Day 1)	Grade 0	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	V4 (Day 2/3)	Grade 0	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Grade 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Grade 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Grade 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	V8 (Day 29)	Grade 0			xx (xx.x%)	xx (xx.x%)
		Grade 1			xx (xx.x%)	xx (xx.x%)
		Grade 2			xx (xx.x%)	xx (xx.x%)
		Grade 3			xx (xx.x%)	xx (xx.x%)
	V9 (Day 30)	Grade 0			xx (xx.x%)	xx (xx.x%)
		Grade 1			xx (xx.x%)	xx (xx.x%)
		Grade 2			xx (xx.x%)	xx (xx.x%)
		Grade 3			xx (xx.x%)	xx (xx.x%)

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Repeat for redness, swelling, itching.

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14.3.6 Exposure, Safety Analysis Set

		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Vaccination doses	1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	2	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
	3				xx (xx.x%)

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14.3.7.1 Weight and BMI, Safety Analysis Set

Parameter (unit)	Visit	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Parameter (unit)	Baseline				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	Actual result (Visit xx)				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	...				

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Display for parameters Weight and BMI and all visits with data collected for these parameters.
Number of decimals will vary by parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.

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14.3.7.2 Vital Signs, Safety Analysis Set

Parameter (unit)	Visit	CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Parameter (unit)	Baseline				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	Actual result (Visit xx)				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	...				

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Display for parameters systolic blood pressure, diastolic blood pressure, pulse and body temperature and all visits and timepoints with data collected for these parameters.
Number of decimals will vary by parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.

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14.3.7.3.1 Hematology, Safety Analysis Set

Parameter (unit) Visit		CV7202 1 µg (N = xx)	CV7202 2 µg (N = xx)	CV7202 5 µg (N = xx)	Rabipur (N = xx)
Parameter (unit)	Visit xx				
	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Visit xx	…			

Values are categorized into low-normal-high (below lower reference range/ within reference range/ above upper reference range).In the occurrence of a repeat, only the last valid result is considered.
Unscheduled visits are not presented for this summary. Results reported as below or above the detection limit are set to the detection limit.

PROGRAM SOURCE: tlf-###, DATA CUT OFF DATE: DDMMMYYYY RUN DATE: DDMMYYYY hh:mm

Programming note:
Display for all hematology parameters and all visits and timepoints with data collected for these parameters. Number of decimals will vary by parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.

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14.3.7.3.2 Biochemistry, Safety Analysis Set

Programming note:
Repeat table 14.3.7.3.1 for all biochemistry parameters.
Number of decimals will vary by parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.
Check whether footnote "Results reported as below or above the detection limit are set to the detection limit." Is applicable for this lab group and delete if not applicable.

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14.3.7.3.3 Coagulation, Safety Analysis Set

Programming note:
Repeat table 14.3.7.3.1 for all coagulation parameters.
Number of decimals will vary by parameter – in general present mean, median to 1 decimal more than individual data, SD to 2 decimals more than individual data. Refer to SAP.
Check whether footnote "Results reported as below or above the detection limit are set to the detection limit." Is applicable for this lab group and delete if not applicable.

Appendix D2: Study-Specific Shells for Section 16.2

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16.2.1.1 Subject Disposition
All Subjects

Group	Subject number	Complete subject code	Safety set [a]	FAS set [b]	Informed consent obtained on	(First) Vaccination on

[a] Received at least 1 administration of the trial product.
[b] Reveived at least 1 administration of the trial product and has baseline and at least 1 additional blood sample available for VNT analysis.

PROGRAM SOURCE: tlf-###, DATA CUT-OFF DATE: DDMMMYYYY

RUN DATE: DDMMYYYY hh:mm

16.2.1.2 Discontinued Subjects
All Subjects

Group	Subject number	Complete subject code	Did the subject complete the study?	Date of completion or early termination	Main reason for study termination (Specification of other reason)	Comment

16.2.2.1 Protocol Deviations
All Subjects

Group	Subject number	Complete subject code	Deviation Type	Protocol Deviation Category	Description of Protocol Deviation

16.2.2.2 Eligibility and Subjects Not Fulfilling any Inclusion/Exclusion Criteria
All Subjects

Group	Subject number	Complete subject code	Enrolled/Screened under protocol version	Criterion NOT Met	Criterion No.

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16.2.3.1 Subjects Excluded from Analysis
All Subjects

Group	Subject number	Complete subject code	Excluded from FA set	Reason for exclusion

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Programming Note:
Subjects can have multiple reasons for being excluded from the analysis set (ie, not having postbaseline data by definition of the population or from having a major protocol deviation).

16.2.4.1 Demographics and Baseline Characteristics
Safety Analysis Set

Group	Complete subject code	Age (years)	Gender	Childbearing potential	Ethnic origin	Height (cm)	Weight (kg)	BMI (kg/m²)

Programming Note:
Please display Gender as Female/Male, i.e. do not present the abbreviation F/M.

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16.2.4.2 Medical History
Safety Analysis Set

Group	Complete subject code	Diagnosis	Start date	Ongoing	End date

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Programming note:
Sort by start date within each subject.

16.2.4.3 Prior and Concomitant Medications/Vaccinations
Safety Analysis Set

Group	Complete subject code	*	Medication/Vaccination (PT)	Total daily dose	Unit/ Route/ Frequency	Indication	Start date/ Stop Date

* P: prior, O: ongoing (starting pre-vaccination), C: concomitant (starting post-vaccination), PT: preferred term

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Programming note:
Sort by start date and stop date within each subject.

16.2.5 Vaccination Data
Safety Anaysis Set

Group	Complete subject code	Injection no.	Visit	Visit date	Has vaccine been administered?	Time of injection	Injection site	Description of site and reason	Comment

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16.2.6.1 VNTs
Full Analysis Set

Group	Complete subject code	Visit	Visit date	Blood sample taken and shipped?	Parameter (unit)	Result	>= 0.5 IU/ml?	Comment

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16.2.6.2 Immunoglobulin (ELISA)
Full Analysis Set

Group	Complete subject code	Visit	Visit date	Blood sample taken and shipped?	Parameter (unit)	Result	Comment

LLOQ = Lower limit of quantification.
IgA LLOQ = 195.5 U/mL; IgG LLOQ = 780 U/mL; IgM LLOQ = 780 U/mL.

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16.2.6.3 Cellular Immune Response and Leucocytes Phenotyping (PBMCs)
Full Analysis Set

Group	Complete subject code	Visit	Visit date	Blood sample taken and shipped?	Parameter (unit)	Result	Comment

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16.2.6.4 Cytokine Assessment
Full Analysis Set

Group	Complete subject code	Visit	Visit date	Blood sample taken and shipped?	Parameter (unit)	Result	Comment

BLQ = Below limit of quantification

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16.2.7.1.1 Unsolicited Adverse Events – CRF Entries
Safety Analysis Set

Group: xxxxx

Complete subject code	Medical term of AE/ PT	Start date/ time End date	Injection site/ systemic reaction	Outcome	AESI/ MAAE/ IC[a]	Intensity	Relationship	Action taken	Serious	Comment
&										

$ Post-vaccination adverse event
AESI = AE of special interest, MAAE = medically attended AE
[a] IC = Intercurrent

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Programming note:
Sort by start date and stop date within each subject.

16.2.7.1.2 Unsolicited Adverse Events – MedDRA Coding
Safety Analysis Set

Group	Complete subject code ID	Description	Low level term	Preferred term	High level term	High level group term	System organ class

Adverse events were coded using MedDRA version 24.1.

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Programming note: sort by ID within each subject.

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16.2.7.1.3 Serious Unsolicited Adverse Events
Safety Analysis Set

Programming note:
Repeat listing 16.2.7.1.1 for serious AEs. Include applicable SAE criteria data.

16.2.7.1.4 Unsolicited Adverse Events Leading to Trial or Vaccine Withdrawal
Safety Analysis Set

Programming note:
Repeat listing 16.2.7.1.1 for AEs with taken = withdrawn from study or vaccination discontinued

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16.2.7.1.5 Deaths
Safety Analysis Set

Programming note:
Repeat listing 16.2.7.1.1 for serious AEs leading to death.

16.2.7.2.1 Local Solicited Adverse Events
Safety Analysis Set

Group: xxxxx

Complete subject code	Date of day 1	Injection site reaction	Diary – Day	Measurement – Result	Grade	Ongoing after day 8	Reaction serious	Medically attended	Comment	Related

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Programming note: sort by symptom and diary day within each subject.

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16.2.7.2.2 Systemic Solicited Adverse Events
Safety Analysis Set

Group: xxxxx

Complete subject code	Date of day 1	General reaction	Diary – Day	Measurement – Result	Grade	Ongoing after day 8	Reaction serious	Medically attended	Comment	Related

PROGRAM SOURCE: tlf-###, DATA CUT-OFF DATE: DDMMMYYYY

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Programming note:
Sort by symptom and diary day within each subject.

16.2.7.3 Vaccination Site Reactogenicity Assessment (Investigator)
Safety Analysis Set

Group	Complete subject code	Visit	Visit Date	Time of assessment	Symptom / reaction	Measurement	Grade

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Programming note:
Sort by visit and symptom within each subject.

16.2.8.1 Hematology
Safety Analysis Set

Group	Parameter (unit)	Complete subject code	Visit	Date of sample	Value	Comment	Lower limit	Upper limit	High/ low	Inv. assessment	Specification of CS

The laboratory results were converted from the original units given in the eCRF to international standard units according to SI.
L: Low, H: High, NCS: not clinically significant, CS: clinically significant

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Programming note:
Sort by group, parameter, subject and visit.

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16.2.8.2 Biochemistry
Safety Analysis Set

Programming note:
Repeat listing 16.2.8.1 for biochemistry parameters

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16.2.8.3 Coagulation
Safety Analysis Set

Programming note:
Repeat listing 16.2.8.1 for coagulation parameters

16.2.8.4 Pregnancy Test Results
Safety Analysis Set

Group	Parameter (unit)	Complete subject code	Visit	Date of test performed	Completion status	Result

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16.2.9.1 Physical Examination, Weight, BMI
Safety Analysis Set

Group	Complete subject code	Visit	Weight (kg)	BMI (kg/m²)	Physical examination performed	Result	Body system	Specification of abnormality

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Programming note:
Sort by parameter, subject and visit.

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16.2.9.2 Vital Signs
Safety Analysis Set

Group	Parameter (unit)	Complete subject code	Visit	Date of visit	Time post dose [h]	Value	Change

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Programming note:
Sort by parameter, subject and visit.

16.2.9.3 Electrocardiogram
Safety Analysis Set

Group	Complete subject code	Visit	ECG performed	Result	Investigator interpretation	Specification of abnormality

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Programming note:
Sort by parameter, subject and visit.

16.2.10 Visit and Diary Information
Safety Analysis Set

Group	Complete subject code	Visit	Date of visit	Question	Answer

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Programming note:
Sort by parameter, subject and visit.