Statistical Analysis Plan

Protocol Title:	A phase Ⅱ clinical trial of the recombinant novel coronavirus vaccine (adenovirus type 5 vector)
Protocol Number:	JSVCT089
Study Institutions:	Jiangsu Provincial Center for Disease Control and Prevention Hubei Provincial Center for Disease Control and Prevention Zhongnan Hospital of Wuhan University
Sponsors:	Beijing Institute of Biotechnology CanSino Biologics Inc.
Version:	Version 1.0
Version Date	May 18, 2020

1 Abbreviations

AE	Adverse Event
AR	Adverse Reaction
Ad5	Replication Defective Human Adenovirus Serotype 5
COVID-19	Corona Virus Disease 2019
CRF	Case Report Form
ELISA	Enzyme-linked Immunosorbent Assay
FAS	Full Analysis Set
GCP	Good Clinical Practice
GMI	Geometric Mean Fold Increase
GMP	Good Manufacturing Practice
GMT	Geometric Mean Titre
IEC	Independent Ethics Committee
ITT	Intent-to-treat
NIFDC	National Institute for Food and Drug Control
NMPA	National Medical Products Administration
PPS	Per Protocol Set
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOP	Standard Operation Procedure
SS	Safety Set
vp	Virus Particle

2 Introduction

In accordance with the relevant national guidelines and regulatory documents, this statistical analysis plan (SAP) gives a detailed description of the statistical analysis of the data collected in "A phase Ⅱ clinical trial of the recombinant novel coronavirus vaccine (adenovirus type 5 vector)" (sponsor/protocol number: Beijing Institute of Biotechnology, CanSino Biologics Inc./JSVCT089). The statistical analysis plan is made based on the protocol of the trial (version number/version date: V1.2/May 9, 2020).

This statistical analysis plan includes an overview of the trial design (related to statistics), definition and measurement of the endpoints, definition of data sets for analysis, definition of missing data and outliers, statistical analysis methods, chart templates, statistical software, references and so on.

3 Study summary

3.1 Objectives

To evaluate the immunogenicity and safety of the recombinant novel coronavirus vaccine (adenovirus type 5 vector) in healthy adults aged 18 years and above.

3.2 Trial design

This study is a randomized, double-blind, placebo-controlled phase Ⅱ clinical trial.

3.3 Sample size

This phase 2 trial is launched before we obtaining the immunogenicity data from the phase 1 trial. Therefore, the sample size of is not calculated, but determined based on expert experiences and the minimum sample size requirement in the technical guidelines for vaccine clinical trials issued by National Medical Products Administration, China. The final sample size is 250 in the middle dose group, 125 in

the low dose group and 125 in the placebo group, with a total sample size of 500.

The antibodies of all participants are measured by ELISA at day 0, day 14, day 28 and month 6, and the antibodies of participants are measured by live SARS-CoV-2 or pseudovirus neutralization test at day 0, day 28, and month 6.

3.4 Randomization and blinding

3.4.1 Randomization and grouping

In this study, randomization and blindness will be achieved by blinding the investigational vaccines. Qualified test vaccines and placebos will be provided by the sponsor, and then be blinded by a third party. SAS software is used to generate random codes by block randomization, and the test vaccine and placebo will be randomly assigned to serial numbers (the vaccine for each participant has a unique serial number). Participants will be randomly divided into the middle dose group, low dose group, and placebo group at a ratio of 2:1:1.

The investigator assigned the random numbers in order of the eligible participants arrived at the place where study number assigned, and filled the screening number and initials into the corresponding column of the random number assignment table, the corresponding number is the study number. In order to control the selection bias of age and gender, the age and gender distribution among the groups should be balanced as much as possible.

3.4.2 Blind code preservation

The statistical blinding staff will write the blinding procedure of randomization to make blind code. The blind code includes the first-level blind code and the second-level blind code. The first-level blind code is the group code, and each vaccine number, or study number, corresponding to each group (low dose group, middle dose group, placebo group) is represented by a different letter. The second-level blind code will reveal the final blind code, namely the name of the group (low dose group, middle dose group, placebo group). Two blind code copies will be put into envelopes, sealed and kept by

the investigator and the sponsor respectively. Emergency letters are also made independently by the blinding staff, sealed and handed over to the investigator for storage. Blinding staff shall not participate in the clinical trial work, and at the same time, they shall not disclose the contents of blinding to any person participating in the clinical trial work.

3.4.3 Replacement vaccines

In order to prevent accidents such as damage to the blinded vaccine during the trial, additional replacement vaccines have been prepared for each group (8 boxes for the middle dose group, 4 boxes for the low dose group, and 4 boxes for the placebo group). The number of replacement vaccines is represented by four letters, each letter corresponding to 4 boxes of replacement vaccines. During the trial, when the replacement vaccine is needed, the vaccination staff will open the replacement vaccine letter corresponding to the participant's study number, and the participant will be vaccinated according to the replacement vaccine number recorded in the letter.

3.4.4 Unblinding

Unblinding time will be jointly decided by the sponsor and the investigator based on the progress of the study. The blinding documents will be jointly signed by the principal investigator, the sponsor and the statisticians.

After the last participant completed V2 (day 28), materials will be sorted out, the blind review being completed, and an independent third party conducted unblinding for the first analysis. Using the two-level unblinding method. The first unblinding is done after the blind review being completed and the data of the first analysis being locked, and then opened the first-level blind code, the group code corresponding to each participant is revealed, and the group is determined. The second unblinding will be carried out after the final statistical analysis report is finalized, and then open the second-level blind code to reveal the group corresponding to each group code.

3.4.5 Emergency unblinding regulations

If serious complications and adverse events occur during the trial, which affect the

choice of treatment measures, the investigators can break the blindness urgently if they think it is necessary to know the group of the participant. When it is necessary to break the blindness, the person in charge of the study center will open the emergency letter corresponding to the participant's study number and reveal their grouping information. The randomization letter should be signed by the person in charge of the study center after use and kept properly. After unblinding, the principal study institutions, the sponsor, the ethics committee and the CRA shall be notified in time.

3.4.6 Blind state maintenance

During the implementation of this clinical trial, the double-blind state should be maintained, that is, neither the investigator nor the participants know whether the participant receive the vaccine or placebo.

The first analysis will be completed by an independent statistician, the statistician un-blinded independently for statistical analysis, and submitted the first analysis report to the sponsor and the investigator. The grouping information of participants shall not be disclosed in the first analysis report. The study site will remain double-blind, and the blind code shall not be revealed during the entire clinical trial.

3.5 Inclusion and exclusion criteria

Inclusion criteria

- Aged 18 years and over.
- Able to understand the content of informed consent and willing to sign the informed consent.
- Able and willing to comply with the requirements of the clinical trial protocol and able to complete a 6-month study follow-up.
- Negative in HIV diagnostic blood test.
- Axillary temperature ≤37.0°C.
- Negative serum IgM and IgG to the SARS-CoV-2.
- A body mass index (BMI) are between 18.5 and 30.0.

- General good health as established by medical history and physical examination.

Exclusion criteria

- Family history of seizure, epilepsy, brain or mental disease
- Participant that has an allergic history to any ingredient of vaccines
- Woman who is pregnant, breast-feeding or positive in pregnancy test on day of enrollment, or is planning to be pregnant during the next 6 months
- Any acute fever disease or infections
- Have a medical history of SARS infection
- Have serious cardiovascular diseases, such as arrhythmia, conduction block, myocardial infarction, severe hypertension and not well-controlled
- Major chronic illness, such as asthma, diabetes, or thyroid disease, and not well-controlled
- Hereditary angioneurotic edema or acquired angioneurotic edema
- Urticaria in last one year
- Asplenia or functional asplenia
- Platelet disorder or other bleeding disorder may cause injection contraindication
- Faint at the sight of blood or needles.
- Prior administration of immunodepressant or corticosteroids, antianaphylaxis treatment, cytotoxic treatment in last 6 months
- Prior administration of blood products in last 4 months
- Prior administration of other research medicines in last 1 month
- Prior administration of attenuated vaccine in last 1 month
- Prior administration of subunit vaccine or inactivated vaccine in last 14 days
- Being treated for tuberculosis
- Any condition that in the opinion of the investigators may interfere with the evaluation of study objectives

4 Investigational vaccine and inoculation Method

4.1 Investigational vaccine

The recombinant novel coronavirus vaccine (adenovirus type 5 vector) and placebo are developed by the Beijing Institute of Biotechnology and CanSino Biologics Inc.

The recombinant novel coronavirus vaccine (adenovirus type 5 vector) is a liquid formulation, using replication-defective human adenovirus type 5 as a vector, and express the specific S protein of the SARS-CoV-2. The quality of the test vaccine is in line with the "recombinant novel coronavirus vaccine (adenovirus type 5 vector) manufacturing and verification regulations (draft)" formulated by the sponsor. The recombinant novel coronavirus vaccine (adenovirus type 5 vector) has got the certification from National Institutes for Food and Drug Control.

The placebos contain no replication-defective human type 5 adenovirus that expressed the S protein of SARS-CoV-2, and the other ingredients are consistent with the test vaccine and are approved by National Institutes for Food and Drug Control.

In addition to providing adequate quantities of investigational vaccines, the sponsor shall provide replacement vaccines at 5 percent of the number of vaccines required for each group. If the investigational vaccine is damaged or otherwise unavailable, it should be discarded. Although in such cases (with the exception of cold-chain incidents) the sponsor need not be notified immediately, the investigator should keep a detailed record of the damage to the investigational vaccine.

4.2 Immunization procedure and immunization pathway

All investigational vaccines will be immunized by single dose, and the immunization pathway is intramuscular injection of the lateral deltoid muscle of the upper arm.

Middle-dose group: 2 vials of investigational vaccine will be extracted with a syringe, the total volume is 1ml, and the total dosage is 1×10^{11}vp.

Low-dose group: 1 vial of investigational vaccine and 1 vial of placebo will be extracted with a syringe, the total volume is 1ml, and the total dosage is 5×10^{10}vp.

Placebo control group: 2 vials of placebos will be extracted with a syringe, the total

volume is 1ml, and the total dosage is 0vp.

Before injection, 75% alcohol is used for disinfection at the injection site and then intramuscular vaccination will be administrated. Shaking the vaccine before use. No intravascular, intradermal or subcutaneous injection is allowed with the investigational vaccine. Participants should be carefully observed for at least 30 minutes after vaccination and appropriate emergency medical treatment should be in place to prevent possible allergic reactions after vaccination.

5 Study endpoints

5.1 Primary endpoint

5.1.1 Safety endpoint

- Occurrence of adverse reactions (AR) within 14 days after vaccination.

5.1.2 Immunogenicity endpoint

- Geometric mean titer (GMT) of antigen-specific antibody at day 28 after vaccination measured by ELISA.
- Geometric mean titer (GMT) of specific neutralizing antibody against SARS-CoV-2 at day 28 after immunization measured by live SARS-CoV-2 and pseudovirus neutralization test.

5.2 Secondary endpoint

5.2.1 Safety endpoint

- Occurrence of adverse events (AE) within 14 days after vaccination.
- Occurrence of adverse events (AE) within 28 days after vaccination.
- Occurrence of serious adverse events (SAE) within 28 days after vaccination.
- Occurrence of serious adverse events during the whole follow-up period (6 months).

5.2.2 Immunogenicity endpoint

- Geometric mean titer (GMT) of antigen-specific antibody at day 14, and month 6 measured by ELISA.

- Geometric mean titer (GMT) of specific neutralizing antibody against SARS-CoV-2 at month 6 after immunization measured by live SARS-CoV-2 and pseudovirus neutralization test.
- Seroconversion rate of antigen-specific antibody at day 14, day 28, and month 6 measured by ELISA.
- Geometric mean fold increase (GMI) of antigen-specific antibody at day 14, day 28, and month 6 measured by ELISA.
- Seroconversion rate of specific neutralizing antibody against SARS-CoV-2 at day 28, and month 6 measured by live SARS-CoV-2 and pseudovirus neutralization test.
- Geometric mean fold increase (GMI) of specific neutralizing antibody against SARS-CoV-2 at day 28, and month 6 measured by live SARS-CoV-2 and pseudovirus neutralization test.
- Geometric mean titer (GMT) of neutralizing antibody against Ad5 at day 28, and month 6.
- Geometric mean fold increase (GMI) of neutralizing antibody against Ad5 at day 28, and month 6
- The positive rate and level of IFN- γ stimulated by S protein overlapping peptide library at day 28 measured by ELISpot.

For uncertain values: when calculating GMT, GMI and seroconversion of antibodies, if the antibody level is below the initial detection limit, half of the initial value will be used; if the antibody level is greater than the detection limit, the maximum dilution will be used.

5.3 Exploratory endpoint

- The correlation between antigen-specific antibody measured by ELISA and neutralizing antibody against SARS-CoV-2.
- The persistence of the antigen-specific antibody measured by ELISA at month 6.

6 Statistical analysis population

6.1 Data set for safety evaluation

All participants who received vaccination after randomization should be included in the safety evaluation. Data of the participants who violate the protocol should not be excluded.

6.2 Data set for immunogenicity evaluation

Full analysis set (FAS): FAS is based on ITT (intention to treat analysis) principle to determine the participants. All of the participants that meet the inclusion/exclusion criteria, receiving randomization and vaccination, and have at least one blood testing result after vaccination, should be included in the FAS for immunogenicity.

Per-protocol set (PPS): It is a subset of FAS. The participants in this data set will be more compliant to the protocol, with no significant deviation or violation of protocol, all meet the selection/exclusion criteria and completed vaccination within the vaccination time window according to the requirements of the protocol, and the participants who being collected blood at day 0, day14, day 28, and month 6 will be included in the PPS. This method of analysis does not include participants who violate the protocol, and confirmed COVID-19 cases during the study.

In this trial, the FAS is the primary analysis set for immunogenicity evaluation, but the PPS will also be analyzed. Any difference of analysis results between PPS and FAS will be discussed in the report.

7 Data processing specifications

7.1 Treatment of missing values and outliers

The missing values will not be filled. The handling of outliers will be discussed and decided at the data review meeting.

7.2 Processing of data rounding

Minimum, maximum, mean, median, quartile, standard deviation, confidence interval reserve at least four significant digits or two decimals; percentages reserve two decimals. In the process of calculation, the original data is used to calculate, and only when the final data is presented, it is rounded.

7.3 Handling of other abnormal data

If the format of the security data is inconsistent (such as date/time, etc.), it is uniformly intercepted upward to the same format during processing, and downward filling is not considered.

If there is no clinical judgment of the safety index, the statistician shall not evaluate the data during the analysis, and compare it with the normal range and classify it into low, medium and high levels.

If there is a vacancy, according to the statistical table specification, the cross table or the change table before and after medication should be indicated by "missing" or "N/A". However, in the schedule, the data shown are all raw data, and no other processing of the data is considered.

The statistical time of adverse events and combined use of drugs will be from entering the group to the end of the trial. Adverse events and combined use of drugs during the screening period and at other times will not be reflected in the report and will only be listed in the attached table.

8 Statistical methods

8.1 General principles

In this study, the statistical analysis will be completed by SAS 9.4 ®software, and part of the statistical charts will be completed by SPICE 6. The related database is exported and saved in SAS XPORT format.

The statistical analysis plan is formulated by biostatisticians and the principal

investigator according to the protocol, and the final document is refined and formed before the data is locked.

- Continuous variables will be described by mean, standard deviation, median, quartile, minimum, maximum, and coefficient of variation.
- The categorical and ranked data will be described by frequency and percentage.
- The continuous variables will be analyzed by analysis of variance. When the test level is $\alpha=0.05$ and $P\leq0.05$, the difference will be considered to be statistically significant, and the pairwise comparison will be made by SNK method.
- Chi-square test will be used to classify the categorical variables, and the difference is considered to be statistically significant when the test level is $\alpha=0.05$ and $P\leq0.05$. the chi-square partition method will be used for pairwise comparison, and the Bonferroni method will be used to correct α, $\alpha'= \alpha$/comparison times.
- The rank sum test will be used for the data of unknown or non-normal distribution, and the difference is considered to be statistically significant when the test level is $\alpha=0.05$ ($P\leq0.05$). Pairwise comparison using Bonferroni method to correct α, $\alpha'= \alpha$/comparison times

8.2 Analysis of participants' enrollment

- Statistics on the number of selected, completed and uncompleted participants.
- Statistics on the number of participants included in each dataset and a detailed list of datasets.
- Statistics on the number of participants who deviate/violate the protocol and the reasons.
- Draw the flow chart of participant distribution.
- The list shows the participants who did not complete the trial and the reasons for dropout.

8.3 Demographic data and Baseline analysis

Descriptive statistical demographic data and other baseline values:

- The participants' age, sex, height, weight and BMI are statistically described.
- To make a statistical description of the combined diseases of the participants.
- Descriptive statistics of participants' baseline vital signs, pregnancy test, etc.
- The measurement data calculates the number, mean, standard deviation, median, quartile, minimum and maximum values.
- The frequency and constituent ratio of counting data are calculated.

8.4 Compliance Analysis

- The compliance of blood collection of participants will be counted.
- List the detail of the vaccination, safety observation and blood collection of the participants.

8.5 Analysis of combined drugs/combined vaccines

- Describe the occurrence of combined drug use and calculate the percentage of participants with combined drug use.
- The combined drugs are classified by WHO ATC code, the number, episode and percentage of combined drug use are described according to the coded system and standard name.
- Describe the occurrence of the combined vaccine and calculate the percentage of participants receiving combined vaccine.
- The drugs list describes in detail the usage, dosage, using time, etc., of the combined drug/combined vaccine.

8.6 Safety Analysis

- Adverse reactions for 0-14 days after vaccination.
    - Statistics on the number of participants, episode and percentage of participants of vaccine-related adverse events occurred 0-14 days after vaccination.
    - Statistics on the number of participants, episode and percentage of participants of vaccine-related adverse events occurred 0-14 days after vaccination according to the severity,

symptoms and time of occurrence (within 30min after vaccination).

- Chi-square test or Fisher's exact test is used for comparison between groups.

- Adverse events for 0-14 days after vaccination
  - Statistics on the number of participants, episode and percentage of participants of adverse events occurred 0-14 days after vaccination.
  - Statistics on the number of participants, episode and percentage of participants of adverse events occurred 0-14 days after vaccination according to severity, correlation and symptoms.
  - Chi-square test or Fisher's exact test is used for comparison between groups.
- Adverse events for 0-28 days after vaccination
  - Statistics on the number of participants, episode and percentage of participants of adverse events occurred 0-28 days after vaccination.
  - Statistics on the number of participants, episode and percentage of participants of adverse events occurred 0-28 days after vaccination according to severity, correlation and symptoms.
  - Chi-square test or Fisher's exact test is used for comparison between groups.
- Serious adverse events for 0-28 days after vaccination.
  - Statistics on the number of participants, episode and percentage of participants of serious adverse events occurred 0-28 days after vaccination.
  - Statistics on the number of participants, episode and percentage of participants of adverse events occurred 0-28 days after vaccination according to severity, correlation and symptoms.
  - Chi-square test or Fisher's exact test is used for comparison between groups.
- Serious adverse events within 6 months after vaccination.
  - Statistics on the number of participants, episode and percentage of participants of serious adverse events occurred within 6 months after vaccination.
  - Statistics on the number of participants, episode and percentage of participants of adverse events occurred within 6 months after vaccination according to severity, correlation and symptoms.
  - Chi-square test or Fisher's exact test is used for comparison between groups.

8.7 Immunogenicity Analysis

- Specific antibody against S protein of SARS-CoV-2 (ELISA method) (day 0, day14, day 28, and month 6).
  - The geometric mean titer (GMT) of each visit in each group is described by numbers, geometric mean, standard deviation, median, quartile, maximum and minimum, etc.
  - Count the conversion rate of each group, expressed by the number and percentage, and calculate the 95%CI of the conversion rate.
  - The geometric mean fold increase (GMI) of each visit in each group is described by effective numbers, geometric mean, standard deviation, median, quartile, maximum and minimum, etc.
  - Stratification analysis is carried out according to the level of Ad5 antibody before immunization (Ad5>200, Ad5≤200).
  - The continuous index is compared by analysis of variance between groups, and the pairwise comparison between groups is carried out by SNK method.
  - Chi-square test or Fisher's exact test is used to compare the classification index between groups, and chi-square segmentation/Fisher's exact test is used for pairwise comparison between groups.
  - Draw a reverse cumulative distribution map

- Specific neutralizing antibody against SARS-CoV-2 (neutralization test with live SARS-CoV-2 and its pseudovirus) (day 0, day 28, and month 6).
  - The geometric mean titer (GMT) of each visit in each group is described by numbers, geometric mean, standard deviation, median, quartile, maximum and minimum, etc.
  - Count the conversion rate of each group, expressed by the number and percentage, and calculate the 95%CI of the conversion rate.
  - The geometric mean fold increase (GMI) of each visit in each group is described by effective numbers, geometric mean, standard deviation, median, quartile, maximum and minimum, etc.
  - Stratification analysis is carried out according to the level of Ad5 antibody

before immunization (Ad5>200, Ad5≤200).

- The continuous index is compared by analysis of variance between groups, and the pairwise comparison between groups is carried out by SNK method.
- Chi-square test or Fisher's exact test is used to compare the classification index between groups, and chi-square segmentation/Fisher's exact test is used for pairwise comparison between groups.
- Draw a reverse cumulative distribution map

■ Specific neutralizing antibody of Ad5 (day 0, day 28, and month 6).

- The geometric mean titer (GMT) of each visit in each group is described by numbers, geometric mean, standard deviation, median, quartile, maximum and minimum, etc.
- Count the positive rate of Ad5 in each group, expressed by the number and percentage, and calculate the 95%CI of the positive rate.
- The geometric mean fold increase (GMI) of each visit in each group is described by effective numbers, geometric mean, standard deviation, median, quartile, maximum and minimum, etc.
- Stratification analysis is carried out according to the level of Ad5 antibody before immunization (Ad5>200, Ad5≤200).
- The continuous index is compared by analysis of variance between groups, and the pairwise comparison between groups is carried out by SNK method.
- Chi-square test or Fisher's exact test is used to compare the classification index between groups, and chi-square segmentation/Fisher's exact test is used for pairwise comparison between groups.
- Draw a reverse cumulative distribution map

■ Detection of IFN- γ stimulated by S protein overlapping peptide library by ELISpot (day 28).

- The ELISpot of each group and each visit is used to detect the level of IFN- γ

stimulated by S protein overlapping peptide library, which is described by numbers, mean, standard deviation, median, quartile, maximum, minimum, and 95%CI, etc.

- Count the positive rate of ELISpot of each group and each visit, expressed by the number and percentage, and calculate the 95%CI of the positive rate.
- Stratification analysis is carried out according to the level of Ad5 antibody before immunization (Ad5>200, Ad5≤200).
- Rank sum test is used for comparison of IFN- γ levels among groups, Wilcoxon rank sum test is used for pair comparison between groups adjusted by Bonferroni method.
- Chi-square test or Fisher's exact test is used to compare the positive rate between groups, and chi-square segmentation/Fisher's exact test is used for pairwise comparison between groups.
- Draw a bar chart of the level and positive rate of cellular response.
- Make statistics according to the positive and negative test results provided by the testing organization

8.8 Exploratory Aanalysts

■ Analysis of the consistency of humoral immunity.

- Linear regression is used to evaluate the consistency of specific antibodies against S protein of SARS-CoV-2 (ELISA method) and specific neutralizing antibodies (neutralization test with live SARS-CoV-2 and its pseudovirus). 95% confidence interval for calculating intercept and slope.
- Taking the results of ELISA method as dependent variables and the values of neutralization test with live SARS-CoV-2 and its pseudovirus as independent variables, the scatter plot is drawn and the pearson correlation coefficient is marked.

■ Analysis of persistence of humoral immunity.

- The geometric mean titer (GMT) of each group at month 6 is described by effective numbers, geometric mean, standard deviation, median, quartile, maximum and minimum.
- Count the conversion rate of each group at month 6, expressed as the number and percentage, and calculate the 95%CI of the conversion rate.
- The geometric mean fold increase (GMI) of each group at month 6 is described by effective number, geometric mean, standard deviation, median, quartile, maximum and minimum, etc. The detection value is described by the number of effective numbers, geometric mean, standard deviation, median, quartile, maximum, minimum and so on.
- The continuous index is compared by analysis of variance between groups, and the pairwise comparison between groups is carried out by SNK method.
- Chi-square test or Fisher's exact test is used to compare the classification index between groups, and chi-square segmentation/Fisher's exact test is used for pairwise comparison between groups.

8.9 Analysis Plan

8.9.1 First analysis

After the last participant completes visit 2 (28 days after immunization), and the study database is entered, reviewed and locked, it can be handed over to the independent statistical party for the first analysis. The first statistical analysis report must be reviewed by the DSMB to determined that the report is carried out in strict accordance with the first statistical analysis plan before it can be submitted to the investigators and sponsors.

8.9.2 Final analysis

After the last participant completes visit 3 (month 6), collect the data of serious adverse events, humoral immunity and cellular immunity from visit 2 (day 28) to visit 3 (month 6), and carry out final statistical analysis and summary.

9 Statistical tables

See CM20200407 a phase Ⅱ clinical trial of the recombinant novel coronavirus vaccine_tableshell_V1.0_20200518.