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Data Handling and Recordkeeping (Part 8 of Phase 3 study of Vaccine Candidate for COVID-19)

In 1 collection

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1 Works for me dx.doi.org/10.17504/protocols.io.bj53kq8n

Coronavirus Method Development Community PATH

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ABSTRACT

This is Part 8 of "Phase 3 randomized, double-blinded, placebo-controlled trial to evaluate the safety, immunogenicity, and efficacy of **Vaccine Candidate** against COVID-19 in adults > 18 years of age"

This generic Phase 3 protocol was developed by the PATH team with support of the Bill and Melinda Gates Foundation. The aim of the collection is to share recommended best practices in designing and implementing a Phase 3 study of a COVID-19 vaccine candidate. As Phase 3 trials of different Vaccine Candidates proceed around the world, following the same protocols will ensure consistency and comparability of the Phase 3 trial results.

Please note that this is an evolving document, to be versioned and updated, based on community feedback and new data.

ATTACHMENTS

Generic Phase 3 Protocol COVID-19 Vaccine - 25AUG2020-version 1.docx

DOI

dx.doi.org/10.17504/protocols.io.bj53kq8n

PROTOCOL CITATION

Chris Ockenhouse, Chris Gast, Renee Holt, Jorge Flores 2020. Data Handling and Recordkeeping (Part 8 of Phase 3 study of Vaccine Candidate for COVID-19). **protocols.io** https://dx.doi.org/10.17504/protocols.io.bj53kq8n

COLLECTIONS

Collection of Protocols and Guidelines for Phase 3 study of Vaccine Candidate for COVID-19

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Aug 22, 2020 Lenny Teytelman protocols.io

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PARENT PROTOCOLS

Part of collection

Collection of Protocols and Guidelines for Phase 3 study of Vaccine Candidate for COVID-19

GUIDELINES

The investigator is responsible for ensuring the data collected are complete, legible, attributable, accurate, and recorded in a timely manner. Data collection is the responsibility of the site clinical trial staff under the supervision of the site PI. All source documents and laboratory reports must be reviewed by the clinical team and data entry staff, who will ensure they are accurate and complete. AEs must be graded, assessed for severity and causality, and reviewed by the site investigators.

The CRO is responsible for data management activities, including quality review, analysis, and study data reporting according to SOPs.

8.1. Details of data management

A thorough Data Management Plan and corresponding database compliant with International Conference on Harmonization (ICH) guidelines and US FDA 21 CFR Part 11 requirements will be developed by the SDMC of the CRO contracted by **Sponsor**. The SDMC will build, validate, and maintain a GCP compliant EDC system. The eCRF for the EDC system will be developed by the SDMC with input and approval from the study staff and **Sponsor**. The data system will include password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Write access to the system will be limited to authorized investigators and study staff, and the system will automatically keep an audit trail of all entries and corrections in the eCRF.

The SDMC will perform all activities as per their SOPs. The eCRFs and any supporting documentation should be available for retrieval or review at any time.

8.1.1 Coding

Coding of medical history and adverse events will be performed using the latest version of Medical Dictionary for Regulatory Activities (MedDRA). Medications will be coded using the latest WHO Drug Dictionary. The CRO Medical Monitor will review and approve coding listings.

8.1.2 Data validation

The CRO will inspect the data entered into the database for completeness and consistency, including generating, tracking, and resolving queries and discrepancies from automatic and manual reviews.

8.1.3 Source and data verification

For source data verification (SDV), the monitor (on behalf of **Sponsor**) must have direct access to source documents that support the data recorded, e.g., medical records, original laboratory records, and informed consent forms (ICFs). If source data are electronic, these data must be printed, signed, and dated by the PI and stored in the participant's study file. Clinical laboratory data will remain in study participant's records. Essential documents, including ICFs, must be filed and kept in the study files on an ongoing basis.

8.1.4 Definitions

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Source data
Source data includes all information in original records and certified copies of original records or clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies; ICH E6[R2] section 1.51).

Source documents
Source documents are original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, participants' diaries of evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, participant files, and records kept at the pharmacy, laboratories, and at medico-technical departments involved in the clinical trial)(ICH E6[R2] section 1.52).

8.2. Data capture methods (case report from development and completion)

The clinical data in source documents will be entered directly into an EDC system by trained and qualified study staff. The data management system will include password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data for each participant will be entered directly into the eCRF from the source documents.

It is the site PIs' responsibility to ensure the accuracy, completeness, and timeliness of the data reported in the participant's eCRF and any supporting documentation. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. Source documentation supporting the eCRF data should document the dates and details of study procedures, AEs, and participant status. The site PI/institution will maintain all information in the eCRFs and all source documents that support participant data in a secure area. Data and documents will be treated as confidential material.

8.3. Data storage

All study documentation containing participants' personal information (consent forms and other documents that might link subject ID with other subject personal details) will be kept in a secure locked area with limited access. Such documentation will only be made available to authorized personnel including investigators and clinical personnel, who might require this information to treat the participants or for auditing reasons. In addition, access to participants' medical records will be granted to representatives of **Sponsor**, regulatory agencies, ethics committees for the purpose of validating data.

8.4. Database locking procedures

A final database lock will occur after all participants have completed all follow-up visits, a case-by-case review of the severity of any AEs has been performed and finalized, all data anomalies and queries have been resolved, and monitoring is complete.

8.5. Retention of study records

The PI is responsible for retaining study records for a period of at least X years following the date that a prequalification application is approved or rejected by the WHO. Or, if no application is to be filed, until **X** years after the trial clinical study report is completed.

These records are also to be maintained in compliance with local ERC and local authority medical records retention requirements—whichever is longest. Storage of all trial-related documents will be such that confidentiality will be strictly maintained to the extent provided by local law.

8.6. Protocol deviations

A protocol deviation is any noncompliance with the clinical trial protocol, or GCP requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions should be developed by the site and implemented promptly. It is the responsibility of the site to

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use continuous vigilance to identify and report deviations and address them according to Corrective and Preventive Actions (CAPAs).

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