# Quality Assurance and Quality Control (Part 10 of Phase 3 study of Vaccine Candidate for COVID-19)

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In 1 collection

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1 Works for me dx.doi.org/10.17504/protocols.io.bj57kq9n

Coronavirus Method Development Community PATH

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ABSTRACT

This is Part 10 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.bj57kq9n

PROTOCOL CITATION

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COLLECTIONS

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



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OWNERSHIP HISTORY

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

Guidance on internal and external processes to assure effective protocol implementation, quality of the research conducted, and compliance with **Sponsor** and applicable regulatory requirements.

### 10.1. General considerations

The study will be conducted in full compliance with the protocol and ICH GCP to provide public assurance the rights, safety, and well-being of trial participants are protected, and that clinical trial data are credible. To ensure quality and standardization, the site will develop SOPs for key protocol procedures and conduct the study as described in the protocol and further detailed in the study Manual of Procedures or other written guidelines. The site will also develop routine operational checks to verify critical protocol requirements and procedures are being executed correctly and completely at the time the work is being performed. Prior to study initiation, the CRO will train study staff on the protocol, including applicable SOPs.

The investigational site will provide direct access to all study related documents, source data/documents, and reports for the purpose of monitoring and auditing by **Sponsor**, and inspection by local and regulatory authorities.

### 10.2. Study monitoring

The CRO, on behalf of **Sponsor** of this study, is responsible for ensuring the study is conducted in accordance with ICH GCP and regulatory requirements. For this purpose, monitors will provide external monitoring for this study. A site initiation visit will be conducted prior to beginning the study, and monitoring will be conducted at initiation, during, and at closeout of the study. During the course of the study monitors will periodically visit (virtual visit permissible) the clinical site to verify protocol compliance; completeness, accuracy, and consistency of the data and study product accountability; and adherence to ICH GCP and applicable regulations. As needed and when appropriate, the monitors will also provide clarifications and additional training to help the site resolve issues identified during the monitoring visit. As appropriate and informed by risk assessment, remote centralized monitoring activities may be considered in place of or to supplement onsite monitoring. These may include analysis of data quality (e.g. missing or inconsistent data, outlier data) and identification of data trends not easily detected by onsite monitoring and performance metrics (e.g. screening or withdrawal rates, eligibility violations, timeliness and accuracy of data submission).

The extent and frequency of the monitoring visits will be described in a separate Clinical Monitoring Plan developed prior to study initiation. The investigator will be notified in advance of the scheduled monitoring visit. The monitor should have access to the trial site, participant medical records, study product accountability and other study-related records needed to conduct monitoring activities. The CRO will share monitoring visit findings, including any corrective actions, with the site PI. The site PI and the monitor must agree to cooperate to ensure any problems detected in the course of these monitoring visits are resolved in a predefined timeframe.

### 10.3. Independent auditing

**Sponsor** or its designee may audit the study to ensure that procedures and data collected comply with the protocol and applicable SOPs and that data are correct and complete. The PI will permit to verify source data



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validation of the regularly monitored clinical study. The auditors will compare the entries in the eCRFs with the source data and evaluate the study site for its adherence to the clinical study protocol and GCP guidelines and applicable regulatory requirements.

### 10.4. Regulatory agency auditing

The PI must be aware that regulatory authorities, including ERC/IRB may wish to inspect the site to verify the validity and integrity of the study data and protection of human research participants. The PI should notify the CRO within 24 hours of contact with a regulatory authority. The PI must make the relevant records available for inspection and be available to respond to reasonable requests and audit queries by authorized representatives of regulatory agencies.

### 10.5. Data and Safety Monitoring Board (DSMB) and Safety Monitoring Committee

A central DSMB and SPEAC safety monitoring committee composed of independent vaccine, infectious disease experts, and a biostatistician, will be established to periodically review cumulative data. DSMB responsibilities and procedures will be defined in the DSMB charter.

The DSMB will be responsible for safeguarding the interests of trial participants, assessing safety during the trial, and monitoring the overall conduct of the clinical trial. The DSMB will provide recommendations to the **Sponsor** about continuing, modifying, or stopping the trial. Items reviewed by the DSMB will include: study participant accrual and demographic information; interim/cumulative safety data; discontinuations of study injections; factors that might affect the study outcome or compromise the confidentiality of the trial data (such as treatment and endpoint unbinding); data quality, completeness, and timeliness; and factors external to the study, such as scientific or therapeutic developments that may impact participant safety or the ethics of the study, in addition to the interim efficacy/futility analysis.

The DSMB will convene prior to study initiation and then at least every **[time interval inserted here]**. In addition to routinely scheduled calls, if the protocol team has serious safety concerns the DSMB will convene by teleconference to jointly review the data. DSMB reviews will be summarized with recommendations to the study **Sponsor** as to whether there are safety concerns and whether the study should continue without change, be modified, or be terminated.

A Safety Monitoring Board will be chartered to assess safety outcomes with respect to vaccine AEs/SAEs and to monitor for the emergence of putative safety signals due to concern for VED (see section 1.6.2 for details). The composition of the Safety Monitoring Board as a subset of members from the DSMB or a stand-alone committee **is to be determined**.



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