Aug 25, 2020

Ethical Considerations and Informed Consent (Part 11 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.bj58kq9w

Coronavirus Method Development Community PATH

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ABSTRACT

This is Part 11 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

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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

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PARENT PROTOCOLS

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

GUIDELINES

11.1. Ethical standards

This study will be conducted in accordance and in conformity with ICH GCP, the Declaration of Helsinki, and all applicable regulations. The study protocol, site-specific ICFs, participant education and recruitment materials, and other requested documents—including any subsequent modifications—will be reviewed and approved by the ERC/IRB responsible for oversight of research conducted at the study sites. Subsequent to initial review and approval, the ERC/IRB-of-record will review the study at least annually.

11.2. Ethical review

The site PI will be responsible for assuring this protocol, the ICFs, and other study-related documents are reviewed and approved by the applicable local ERC/IRB prior to implementation of the protocol. Any amendments to the protocol, ICFs, or other study-related documents must be approved by the ERC/IRB prior to implementation. A copy of the protocol, proposed ICF or other written participant information, and any proposed recruitment material should be submitted to the site's ERC/IRB for written approval. The investigator must submit and obtain, as necessary, approval from the ERC/IRB for all subsequent protocol amendments and changes to the ICF form. The investigator will notify the ERC/IRB of SAEs as noted in the protocol and of protocol deviations according to local regulatory authority and ERC/IRB requirements. The study will be conducted in full compliance with the protocol.

The protocol will not be amended without prior written approval by **Sponsor**. All protocol amendments must be submitted to and approved by relevant ERC/IRB(s) prior to implementing the amendment at each site.

11.3. Informed consent process

The principles of informed consent in the current edition of the Declaration of Helsinki will be implemented in each clinical study before any protocol-specified procedures or interventions are carried out. Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continuing throughout the individual's study participation. Before any study-related activities and in agreement with applicable regulatory requirements, the investigator(s) must ensure the participant is fully informed about the aims, procedures, potential risks, and potential benefits of the study. The participant will be given the written, local ERC/IRB approved ICF and given ample time to read the form. Participants will be encouraged to ask questions about the study, will have their questions answered, and then be given time to decide if they would like to participate in the study. The voluntary nature of participation will be emphasized, along with the participant's right to decline to participate or to subsequently withdraw from the study at any time without prejudice.

The investigator(s) must obtain the participant's voluntary consent, evidenced by a signed and dated ICF, before any study-related procedures can be performed. Study staff must document the informed consent process. The original, signed ICF must be kept in the site study file. A copy of the ICF from will be given to participants for their records. This fact will be documented in the participant's record.

11.4. Participant confidentiality

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The investigators and **Sponsor** and all staff from organizations involved in the implementation of the trial must ensure participant confidentiality is maintained. Personal identifiers will not be included in any study report. All study records will be kept confidential to the extent provided by national and local laws. Medical records containing identifying information may be made available for review by representatives of the **Sponsor** as part of their responsibilities for ensuring the protection of research participants. In addition, the regulatory authority may request permission to review study records as part of its responsibility in licensing the vaccine. Direct access may include examining, analyzing, verifying, and reproducing any records and reports important to the evaluation of the study.The results of the study may be published in a medical book or journal, or presented at meetings for educational purposes. If the study results are published, the participant's identity will be kept confidential.

When appropriate and to the extent possible, study procedures will be conducted to protect participant privacy and confidentiality.

All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with access limited to study staff. Data collection, process, administrative forms, laboratory specimens, and other reports will be identified by a coded number only to maintain participant confidentiality. All records that contain names or other personal identifiers, such as locator forms and ICFs forms, will be stored separately from study records identified by code number. All local databases will be secured with password-protected access systems. Forms, lists, logbooks, appointment books, and any other listings that link participant ID numbers with other identifying information will be stored in a separate, locked file in an area with limited access. Participants' study information will not be released without their written permission, except as necessary for monitoring.

11.5. Reimbursement

In general, barring country-specific guidance, participants **will not** be compensated for their time, lost wages, or any inconvenience experienced during scheduled study visits. The trial team **will not** pay for long term treatment of unrelated conditions diagnosed during the trial.

11.6. Risk and Benefits

Participants will potentially receive a protective benefit from **Vaccine Candidate**. However, it is also possible the candidate vaccine may harm participants or cause enhancement of disease with COVID-19, if they are subsequently infected. Participation in this study will hopefully contribute to more widespread availability of a COVID-19 vaccine to address a global public health concern.

Hypersensitivity reactions may occur following the administration of any vaccine, including licensed vaccines. In rare circumstances these reactions may be life-threatening. The protocol and Investigator Brochure (IB) will inform investigators of this possibility. The ICF will inform all participants of this possibility and participants will be and observed for a minimum of 30 minutes following study vaccine administration. As with all immunizations, appropriate emergency medical treatment will be made available in case of severe immediate reactions, such as anaphylaxis. Participants with a known hypersensitivity to any component of the study vaccine will be excluded from the study.

Blood drawing and venipuncture associated risks may include minor bleeding or bruising at the venous access site, mild discomfort, upset stomach, dizziness, light-headedness, syncope, or very rarely infection. Blood samples will only be drawn by trained staff members using aseptic technique. Medical assistance will be available in case of any complications. Participants will be informed of risks in the ICF and will be in a seated or supine position during blood draws.

VED is a theoretical risk (described in Section 1.5.2). The ICF must include language to alert the participant of the possibility the vaccine could induce a higher than expected enhancement of respiratory disease from infection with SARS-CoV-2.

11.6.1 Risk to study personnel

The principal risk to study personnel is through the handling of needles that may be contaminated with blood or body fluids and the associated risk of acquiring a blood-borne pathogen (including hepatitis B and C viruses and

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human immunodeficiency virus [HIV]) during phlebotomy. Adherence to SOPs for working with infectious agents and universal precautions will reduce the risk of exposure.

Study personnel may come into contact with participants who are infected with COVID-19. As described in section 4.8, study personnel will have specialized training and PPE to adequately manage the risk of COVID-19 infection. Study staff will be routinely tested for SARS-COV-2 virus to monitor their health and prevent transmission to others.

11.7. Reporting of communicable disease

To be completed in compliance with requirements for the site.

11.8. Policy regarding study-related injury care and compensation

Participants who experience AEs during the study will be evaluated and managed by study clinicians at study facilities, whenever possible. When appropriate assessment and care cannot be provided by study physicians, participants will be referred to an alternative facility, according to the nature of the complaint. Any costs associated with such care in line with good medical practice in **Country Awill/will not** be covered by the **investigator team/study sponsor**.

Clinical trial insurance to cover the costs of care for study-related injury—including, when necessary, the costs of evacuation for treatment outside the country—will be purchased as required by local authorities. In addition, there are limited study funds available for care of study-related injury. Both **Sponsor**, and **Vaccine Manufacturer** will have liability insurance coverage for the trial. Participants will be insured against injury caused by the study according to legal requirements, which will provide compensation for research related injury (to include costs of long-term and future medical care needs), should it occur. The costs of the treatment will be paid with the clinical trials insurance policy. The participant will be informed this is not a waiver or release of their legal rights.

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