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Publication and Data Sharing Policy (Part 13 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.bj6akrae

Coronavirus Method Development Community PATH

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ABSTRACT

This is Part 13 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

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 information generated in this study will be used by the **Sponsor** in connection with the development of the product and therefore may be disclosed to government regulatory agencies in various countries, as well as global public health organizations, such as the WHO. Study results will be made publicly available in compliance with the WHO mandated timeframe for public disclosure of results from clinical trials. The International Committee of Medical Journal Editors member journals have adopted a clinical trials registration policy as a condition for publication. The description of this study and the summary of results will be available on http://www.ClinicalTrials.gov. **Sponsor** or its designees will prepare a clinical study report according to ICH-E3 guidelines.

Sponsor/manufacturer recognizes the importance of communicating study findings and will therefore encourage publication in reputable scientific journals and presentation at seminars or conferences, while protecting the integrity of the ongoing trial. Any publication, lecture, or manuscripts of study findings by any individual involved with the study will be governed by the procedure outlined in the Clinical Trial Agreements by the relevant Parties. Within any presentation or publication, confidentiality of individual participants will be maintained, with identification by participant code number and initials, if applicable.

Any new information from this study or other studies that may affect the participant's health, welfare, or willingness to continue with the study will be given to the participant. The results of the study will be shared with the participants at their request. This will be through a letter, approved by the IRBs, detailing the information.

Additional Considerations:

Depending on the stage of development of the vaccine candidate, the existence of promising data from other COVID-19 vaccines, or the availability of an already licensed COVID-19 vaccine **Sponsor** may consider the use of a positive control (another COVID-19 vaccine) as a comparator for all three primary objectives of the Phase 3 trial, namely efficacy, safety, and immunogenicity. This would significantly impact the design of the study; for instance, if a correlate of protection has been identified for a licensed vaccine based on the same platform, there might not be a need to prove vaccine efficacy as a clinical endpoint if the immunogenicity of the unlicensed vaccine is qualitatively and quantitatively similar to that of the licensed vaccine.

It would be feasible and convenient to augment the current Phase 3 trial design to test, when applicable, the clinical consistency of the vaccine across three different lots, a requirement by many international regulatory agencies and the WHO PQ process. In that case, equal numbers of each of the three lots of vaccines will be randomly provided to sufficient recipients of each product to ensure statistical consistency in the immunogenicity outcome of the validated assay identified.

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