Financing and Insurance (Part 12 of Phase 3 study of Vaccine Candidate for COVID-19)

In 1 collection

Chris Ockenhouse, Chris Gast, Renee Holt, Flores

1Center for Vaccine Innovation and Access, PATH (Washington D.C. and Seattle, Washington)

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Protocol status: Working
We use this protocol and it's working

Created: Aug 22, 2020
ABSTRACT

This is Part 12 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

GUIDELINES

The trial is supported by funding from Sponsor and XXX. Funding of the site and CRO activities will also be covered by XXX. Pharmaceutical support is provided by Sponsor. Sponsor will secure insurance that complies with the regulatory and legal requirements.