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Study Vaccine (Part 5 of Phase 3 study of Vaccine Candidate for COVID-19)

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Coronavirus Method De...

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We use this protocol and it's working

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Abstract

This is Part 5 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 Prot...

560KB

Guidelines

	Vaccine/product name	Formulation	Presentation	Volume to be administered
	< Vaccine Candidate >	< Sponsor to enter >	< Sponsor to enter >	< X mL >
	Control (Placebo or relevant licensed vaccine)	< Sponsor to enter >	< Sponsor to enter >	< X mL >

5.1. Acquisition

IPs will be provided by **Sponsor** and sent directly to the study site(s) in validated shipping containers for distribution to the investigational sites under refrigerated conditions.

5.2. Formulation, appearance, packaging, and labeling

See IB and package inserts for details. The investigational product will be labeled with the following information: manufacturer's name and address, product name, manufacture date, expiration date, storage requirements (**XX°C**), directions for use, and any other investigational product labeling appropriate to the jurisdiction in which the trial is conducted. To protect the study blind, **Vaccine Candidate** and the placebo should preferably be identical in appearance, including details regarding vial/syringe and vaccine appearance (i.e., clear, colorless, opaque, etc.). Otherwise consider masking the syringe.

Product Storage and Handling:

Vaccine Candidate and placebo will be stored at **+2°C to +8°C** in a temperature monitored cold room. Access will be limited to designated site personnel. All vaccine/adjuvant/water for injection vials will be stored in a safe and locked place with no unauthorized access. The storage conditions will be assessed during pre-study activities under the responsibility of **Sponsor** study contact. The storage temperature should be continuously monitored with calibrated (if not validated) temperature monitoring device(s) and recorded according to standard operating procedures (SOPs) at the investigator's site. An alarm system and a back-up refrigerator will be available in case of power failure/breakdown. Whether it occurs prior to receipt of IP at the site or after, **Sponsor** and the study monitor must be contacted if the cold chain is broken (e.g. vaccines become frozen or refrigeration fails).

Sponsor will manage temperature deviations during the primary shipment until reception at the clinical trial site. Temperature excursions become the responsibility of the site upon receipt of study product. Data will be provided to **Sponsor** that will allow **Sponsor** to decide whether the IP can still be administered or should be destroyed following a temperature excursion.

5.3. Preparation

TO BE FILLED IN BY SPONSOR.

Dose preparation will be carried out by a qualified unblinded research pharmacist and witnessed by another unblinded study staff member. Masking of the syringe will occur at the time the unblinded pharmacist dispenses the product for administration.

Provide description of how treatments will be blinded to both administrator and subject. Refer to a Pharmacy Manual or Manual of Procedures where detailed product formulation, administration, and accountability procedures will be further described. An unblinded team member who is not participating in other study activities will be administering the vaccine.

5.4. Route of administration

The route of administration for vaccines will be **IM to the deltoid of the arm**. The study injection (**XX mL**) will be administered into the deltoid region by inserting the needle (**XX gauge, 25 mm**), drawing back to ensure the needle is not in a blood vessel, and slowly depressing the plunger. The needle will be removed, and the injection site gently rubbed with cotton wool.

5.5. Vaccination schedule

Refer to Appendix A for vaccination schedule.

5.6. Tracking of dose

Adherence to and tracking doses of vaccines will be documented in the CRF for each participant.

5.7. Study vaccine accountability and disposal procedures

The study vaccines will be distributed to and maintained by the site pharmacy. Vaccine accountability will include the amount of product shipped, documentation of adequate and safe handling and use, a temperature log for the vaccine product, and plans for returning or destroying of unused product.

The unblinded pharmacist will dispense IP in a masked syringe (with needle for administration), labeled with the participant's identification number (PTID), randomization number, the date and time prepared, and the preparer's initials. The vaccination will be administered by a blinded clinic staff as detailed in the Pharmacy Manual.

The site pharmacist is required to maintain complete records of all study products received from the **Sponsor** and will be responsible for maintaining an accurate record of the randomization codes and inventory, and an accountability record of vaccines for this study. The site pharmacist will also be responsible for ensuring the security of these documents. Partially used vials will not be used for human administration or *in vitro* experimental studies. At the end of the study, the site will receive instructions from **Sponsor** regarding the final disposition of

any remaining study products after all IP monitoring is completed. The investigator, in accordance with **Sponsor's** specifications, will document the destruction of any IP.

