

Resource Summary Report

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Statistical Considerations (Part 9 of Phase 3 study of Vaccine Candidate for COVID-19)

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Protocol Information

URL: <https://dx.doi.org/10.17504/protocols.io.bj55kq86>

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Group: Coronavirus Method Development Community, PATH

Summary: This is Part 9 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.

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