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Schedule of Study Visits and Evaluations (Appendix A 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 Appendix A 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...

557KB

Guidelines

APPENDIX A: SCHEDULE OF STUDY VISITS AND EVALUATIONS -EXAMPLE PROVIDED; VACCINE DEPENDENT

Study Day	-7 to 1	1	15 (+7 days)	29 (+5 days)	57 (+5 days)	57 to study end	180	365/ 730
Visit #	1	2	3	4	5	6	7	8
Clinic visits	X	X	X	X	X		X	X
Phone call, SMS text, email (approximately every two weeks)						X		
Informed consent form signed	X							
Initial screening	X							
Inclusion and exclusion criteria	X	X	X					
Demographic data	X							
Medical history screening	X							
Height/weight measurements	X							
Vital signs/physical examination screening	X							
Blood collection for safety: hematology (CBC), ALT, AST, Bilirubin, creatinine	X							
Nasopharyngeal swab for SARS-CoV-2 RT-PCR		X						
Blood collection for serology (X mL)		X	X	X			X	X
Randomization		X						
Concomitant medication	X	X	X	X	X	X		
Pregnancy test (urine or blood)	X	X	X					
Study vaccination		X	X					
Interim medical history		X	X	X	X			X



	Review of diary/memory aid			X	X	X			
	Vital signs/targeted physical examination		X	X					
	COVID-19 case capture		X	X	X	X	X	X	X
	Total blood volume (mL)	X	X	X	X	X		X	X
	Study end								X

