

CoVPN 5001 Study fact sheet

What is the CoVPN 5001 study about?

CoVPN 5001 will help researchers understand early SARS-CoV-2 infection and the body's early immune responses to the virus that causes COVID-19 illness. The data obtained through this study will describe viral progression and the immunological characteristics of early infection with SARS-CoV-2. Information about the clinical course of SARS-CoV-2 infection, especially during its early stage, is needed to close knowledge gaps and will potentially suggest markers of protection that could be used in evaluating the efficacy of future COVID-19 vaccine candidates.

Where will the study take place?

Study teams seek to enroll approximately 800 study participants at more than 58 participating trial sites in the United States, South America, and sub-Saharan Africa.

Who can enroll in the study?

Study participants aged 18 years and older who have tested positive for SARS-CoV-2 infection will be enrolled. Study participants will be enrolled into one of three groups: those showing no symptoms, those showing mild symptoms, and those showing severe symptoms that require hospitalization.

How will study participants contribute to CoVPN 5001?

- Samples to be collected from participants include blood samples, nasal samples, saliva samples, and urine samples. The collection of stool samples will be optional.
- These sample collections may be done either by clinic staff or the study participant themselves. Blood samples will only be collected by clinic staff.
- Six study visits spread over one month will be conducted at either a participating trial site, hospital, or at the place where the study participant resides.
- A final study visit, to check on the health of study participants, will be conducted approximately two months after enrollment.
- Interested individuals can email <u>CoVPN.SBS-CEU@fredhutch.org</u> for more information.

Why is it important to conduct CoVPN 5001?

- CoVPN 5001 is designed to develop the clinical and laboratory pipelines for the rapid implementation of COVID vaccine efficacy trials while conducting groundbreaking scientific investigations.
- The data obtained through this study will describe viral progression and immunological characteristics of early infection with SARS-CoV-2.
- Information about the clinical course of SARS-CoV-2 infection, especially during its early stage, is needed to close knowledge gaps and will potentially suggest markers of protection that could be used in evaluating the efficacy of future COVID-19 vaccine candidates.
- A safe and effective vaccine is necessary to reduce morbidity and mortality and aid the global community to return to a thriving social and economic global infrastructure.

Which clinical trial sites will participate in CoVPN 5001?

City /Town	Clinical Research Site	City /Town	Clinical Research Site
	Ponce de Leon Center	New Orleans	Adolescent Trials Unit
Atlanta	 The Hope Clinic of the Emory Vaccine Center 	Newark	New Jersey Medical School
Baltimore	 Johns Hopkins University 		NY Blood Center
D (Brigham and Women's Hospital Vaccine	New York	 Columbia Physicians & Surgeons
Boston	Fenway Health	Philadelphia	University of Pennsylvania
Birmingham	University of Alabama - Birmingham	San Francisco	 San Francisco Department of Public Health
Chapel Hill	University of North Carolina -Chapel Hill	Seattle	Seattle Vaccine Trials Unit
Cleveland	Case Western Reserve/University Hospital	St. Louis	St. Louis University
Miami	University of Miami		

Table 1: List of clinical trial sites (17) in the US participating in CoVPN 5001

Table 2: List of clinical trial sites (12) in South America participating in CoVPN 5001

Country	City / Town	Clinical Research Site	
Argentina	Buenos Aires	Balvanera, Ramos MejiaFundacion Huesped	
	Rosario	Instituto CAICI	
Brazil	Belo Horizonte	• FUMG	
	Rio de Janeiro	IPEC-Fiocruz	
Mexico	Merida	Unidad de Atención Medica e Investigacion en Salud (UNAMIS)	
	Mexico City	 Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán /Clínica Especializada Condesa Iztapalapa 	
Peru	Iquitos	Asociacion Civil Selva Amazonica	
	Lima	 Impacta - Barranco San Marcos Impacta - San Miguel Via Libre 	



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Table 3: List of clinical trial sites (31) in sub-Saharan Africa participating in CoVPN 5001

Country	City / Town	Clinical Research Site	
South Africa	Cape Town	Groote Schuur Clinical Research Site Khayelitsha - eKhayaVac Clinic Masiphumelele Desmond Tutu HIV Foundation	
	Durban	 Botha's Hill Clinical Research Site Chatsworth Clinical Research Site Isipingo Clinical Research Site CAPRISA Tongaat Clinical Research Site Verulam Clinical Research Site Vulindlela Clinical Research Site 	
	Elandsdoorn	Ndlovu Research Centre	
	Klerksdorp	The Aurum Institute Klerksdorp Clinical Research Site	
	Ladysmith	Qhakaza Mbokodo Research Clinic	
	Medunsa	MeCRU Medunsa	
	Mthatha	Nelson Mandela Academic Clinical Research Unit (NeMACRU)	
	Rustenburg	The Aurum Institute Rustenburg Clinical Research Center	
	Soweto	PHRU Soweto BaraPHRU-Kliptown	
	Soshanguve	Setshaba RC	
	Tembisa	Aurum, Tembisa Clinic 4	
Botswana	Gaborone	Botswana Harvard AIDS Institute Partnership	
Kenya	Kisumu	KEMRI CGHR Clinical Research Centre	
Mozambique	Maputo	Polana Canico Health Research and Training Center Network	
Malawi	Lilongwe	UNC Project Lilongwe	
Tanzania	Mbeya	National Institute for Medical Research Centre-Mbeya Medical Research Centre (NIMR-MMRC)	
Zambia	Lusaka	MateroZEHRP Lusaka	
	Ndola	ZEHRP Ndola	
Zimbabwe	Harare	 Milton Park Seke South St. Mary's 	

Description of the COVID-19 Prevention Network (CoVPN)

The COVID-19 Prevention Network (CoVPN) was formed by the National Institute of Allergy and Infectious Diseases (NIAID) at the US National Institutes of Health to respond to the global pandemic. Through the CoVPN, NIAID is leveraging the infectious disease expertise of its existing research networks and global partners to address the pressing need for vaccines and antibodies against SARS-CoV-2. CoVPN will work to develop and conduct studies to ensure rapid and thorough evaluation of vaccines and antibodies for the prevention of COVID-19. The CoVPN is headquartered at the Fred Hutchinson Cancer Research Center.

