



## 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 [CoVPN.SBS-CEU@fredhutch.org](mailto:CoVPN.SBS-CEU@fredhutch.org) 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?

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

| City /Town         | Clinical Research Site  | City /Town           | Clinical Research Site  |
|--------------------|---|----------------------|---|
| <b>Atlanta</b>     | <ul style="list-style-type: none"> <li>• Ponce de Leon Center</li> <li>• The Hope Clinic of the Emory Vaccine Center</li> </ul> | <b>New Orleans</b>   | <ul style="list-style-type: none"> <li>• Adolescent Trials Unit</li> </ul>  |
|                    |   | <b>Newark</b>        | <ul style="list-style-type: none"> <li>• New Jersey Medical School</li> </ul>                                     |
| <b>Baltimore</b>   | <ul style="list-style-type: none"> <li>• Johns Hopkins University</li> </ul>  | <b>New York</b>      | <ul style="list-style-type: none"> <li>• NY Blood Center</li> <li>• Columbia Physicians &amp; Surgeons</li> </ul> |
| <b>Boston</b>      | <ul style="list-style-type: none"> <li>• Brigham and Women's Hospital Vaccine</li> <li>• Fenway Health</li> </ul>               |                      | <b>Philadelphia</b>   |
| <b>Birmingham</b>  | <ul style="list-style-type: none"> <li>• University of Alabama - Birmingham</li> </ul>  | <b>San Francisco</b> | <ul style="list-style-type: none"> <li>• Bridge HIV</li> </ul>  |
| <b>Chapel Hill</b> | <ul style="list-style-type: none"> <li>• University of North Carolina -Chapel Hill</li> </ul>                                   | <b>Seattle</b>       | <ul style="list-style-type: none"> <li>• Seattle Vaccine Trials Unit</li> </ul>                                   |
| <b>Cleveland</b>   | <ul style="list-style-type: none"> <li>• Case Western Reserve/University Hospital</li> </ul>                                    | <b>St. Louis</b>     | <ul style="list-style-type: none"> <li>• St. Louis University</li> </ul>  |
| <b>Miami</b>       | <ul style="list-style-type: none"> <li>• University of Miami</li> </ul>   |                      |   |

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

| Country          | City / Town    | Clinical Research Site  |
|------------------|----------------|---|
| <b>Argentina</b> | Buenos Aires   | <ul style="list-style-type: none"> <li>• Balvanera, Ramos Mejia</li> <li>• Almagro</li> </ul>   |
|                  | Rosario        | <ul style="list-style-type: none"> <li>• Instituto CAICI</li> </ul>   |
| <b>Brazil</b>    | Belo Horizonte | <ul style="list-style-type: none"> <li>• FUMG</li> </ul>  |
|                  | Rio de Janeiro | <ul style="list-style-type: none"> <li>• IPEC-Fiocruz</li> </ul>  |
| <b>Mexico</b>    | Merida         | <ul style="list-style-type: none"> <li>• Unidad de Atención Medica e Investigacion en Salud (UNAMIS)</li> </ul>   |
|                  | Mexico City    | <ul style="list-style-type: none"> <li>• Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán /Clínica Especializada Condesa Iztapalapa</li> </ul> |
| <b>Peru</b>      | Iquitos        | <ul style="list-style-type: none"> <li>• Asociacion Civil Selva Amazonica</li> </ul>  |
|                  | Lima           | <ul style="list-style-type: none"> <li>• Impacta - Barranco</li> <li>• San Marcos</li> <li>• Impacta - San Miguel</li> <li>• Via Libre</li> </ul>                 |

**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   | <ul style="list-style-type: none"> <li>Groote Schuur Clinical Research Site</li> <li>Khayelitsha - eKhayaVac Clinic</li> <li>Masiphumelele Desmond Tutu HIV Foundation</li> </ul>   |
|              | Durban  | <ul style="list-style-type: none"> <li>Botha's Hill Clinical Research Site</li> <li>Chatsworth Clinical Research Site</li> <li>Isipingo Clinical Research Site</li> <li>CAPRISA</li> <li>Tongaat Clinical Research Site</li> <li>Verulam Clinical Research Site</li> <li>Vulindlela Clinical Research Site</li> </ul> |
|              | Elandsdoorn   | <ul style="list-style-type: none"> <li>Ndlovu Research Centre</li> </ul>  |
|              | Klerksdorp  | <ul style="list-style-type: none"> <li>The Aurum Institute Klerksdorp Clinical Research Site</li> </ul>   |
|              | Ladysmith   | <ul style="list-style-type: none"> <li>Qhakaza Mbokodo Research Clinic</li> </ul>   |
|              | Medunsa   | <ul style="list-style-type: none"> <li>MeCRU Medunsa</li> </ul>   |
|              | Mthatha   | <ul style="list-style-type: none"> <li>Nelson Mandela Academic Clinical Research Unit (NeMACRU)</li> </ul>  |
|              | Rustenburg  | <ul style="list-style-type: none"> <li>The Aurum Institute Rustenburg Clinical Research Center</li> </ul>   |
|              | Soweto  | <ul style="list-style-type: none"> <li>PHRU Soweto Bara</li> <li>PHRU-Kliptown</li> </ul>   |
|              | Soshanguve  | <ul style="list-style-type: none"> <li>Setshaba RC</li> </ul>   |
| Tembisa      | <ul style="list-style-type: none"> <li>Aurum, Tembisa Clinic 4</li> </ul> |   |
| Botswana     | Gabarone  | <ul style="list-style-type: none"> <li>Botswana Harvard AIDS Institute Partnership</li> </ul>   |
| Kenya        | Kisumu  | <ul style="list-style-type: none"> <li>KEMRI CGHR Clinical Research Centre</li> </ul>   |
| Mozambique   | Maputo  | <ul style="list-style-type: none"> <li>Polana Canico Health Research and Training Center Network</li> </ul>   |
| Malawi       | Lilongwe  | <ul style="list-style-type: none"> <li>Malawi</li> </ul>  |
| Tanzania     | Mbeya   | <ul style="list-style-type: none"> <li>National Institute for Medical Research Centre-Mbeya Medical Research Centre (NIMR-MMRC)</li> </ul>  |
| Zambia       | Lusaka  | <ul style="list-style-type: none"> <li>Matero</li> <li>ZEHRP Lusaka</li> </ul>  |
|              | Ndola   | <ul style="list-style-type: none"> <li>Ndola</li> </ul>   |
| Zimbabwe     | Harare  | <ul style="list-style-type: none"> <li>Milton Park</li> <li>Seke South</li> <li>St. Mary's</li> </ul>   |

### 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.

