

## **Start of the Largest Clinical Trial in Africa on the Treatment of Mild Cases of COVID-19**

*ISGlobal is participating in the ANTICOV clinical trials in Mozambique and assumes co-leadership of the immunological study*

**Barcelona, 24 November, 2020** – Thirteen African countries and an international network of research centres have joined forces to launch the **largest clinical trial in Africa** on the treatment of **patients with mild to moderate forms of COVID-19**. The aim of the ANTICOV clinical trial is to respond to the urgent need to identify treatments that can be used in the **early treatment** of these more moderate cases to prevent hospitalisation surges that could overwhelm fragile and overburdened health systems.

The clinical trial will be carried out at 19 sites in **13 countries** by the [ANTICOV consortium](#), which includes 26 African organisations and well-known international research and development institutions, including the [Barcelona Institute for Global Health \(ISGlobal\)](#), a centre supported by the "la Caixa" Foundation. The project is being coordinated by the [Drugs for Neglected Diseases initiative](#).

"Large clinical trials on COVID-19 in Africa are needed **to answer research questions specific to the African context**", explains **John Nkengasong**, Director of the Africa Centres for Disease Control and Prevention ([Africa CDC](#)). "The pandemic is spreading throughout our continent so we welcome the ANTICOV trial **led by African doctors**. It will help answer one of our most pressing questions: With limited intensive care facilities in Africa, can we treat people for COVID-19 earlier and stop our hospitals from being overwhelmed?"

ANTICOV will assess the safety and efficacy of **different treatments in 2000 to 3000 patients with mild to moderate disease who have not been hospitalised**. Trials will take place in Burkina Faso, Cameroon, Côte d'Ivoire, Ethiopia, Ghana, Guinea, Equatorial Guinea, Kenya, Mali, Mozambique, the Democratic Republic of Congo (DRC), Sudan and Uganda. The aim is to ascertain whether early treatment can prevent progression of COVID-19 to severe disease and potentially limit transmission.

"It is heartening to see so many African countries collaborate to get much-needed answers about our particular needs for patients with COVID-19", said **Borna Nyaoke-Anoke**, Senior Clinical Project Manager at DNDi, which is also sponsoring the clinical trials in the DRC, Kenya and Sudan. "**Africa has for the most part avoided the large-scale mortality** seen in other countries; however, with the end of the lockdown and reopening of borders **we need to be prepared**. We need research here in Africa that will inform policies and test-and-treat strategies, so that as health professionals we can offer the best options to people with COVID-19."

### **The Role of ISGlobal**

**ISGlobal's** role in the ANTICOV project is twofold. First, the Institute will work together with two of the hospitals where clinical trials are being carried out, both located in **Mozambique**:

the [Manhiça Health Research Centre \(CISM\)](#) and the Centro de Investigação e Treino em Saúde da Polana Caniço (CISPOC), which forms part of the country's [National Institute of Health](#).

In addition, ISGlobal is co-leader, together with the Institute of Tropical Medicine (ITM) in Antwerp (Belgium), of one of the project's two ancillary studies. This is an immunology study that will be carried out in 7 countries to analyse whether the treatments tested in the clinical trial in patients with mild to moderate COVID-19 alter the strength or duration of immune responses to SARS-CoV-2. The researchers will study antibodies and T-lymphocytes and compare the immune responses of symptomatic and asymptomatic patients. In the words of [Gemma Moncunill](#), an immunologist at ISGlobal and the study's scientific coordinator, "This is an important study because we have no data on the immune response to COVID-19 in Africa, and the possible impact of effective treatments is, as yet, unknown". The fact that **other infections, such as malaria, tuberculosis and HIV**, are prevalent on the continent will also "provide data on how these other infections may affect the immune response to SARS-CoV-2". The study will include samples from around 1000 participants collected over a one-year period from patients with mild to moderate symptoms of COVID-19 participating in the ANTICOV clinical trial and some of their asymptomatic contacts who test positive for infection and are recruited to an epidemiological study that will also be carried out within the framework of the project.

**CISPOC, an affiliate of the Mozambican National Institute of Health**, is taking part in both the immunological study and the epidemiological study (the other ancillary study, which is being coordinated by ITM) in close collaboration with ISGlobal. **Isabel Remane** will be the principal investigator at CISPOC for both the ANTICOV clinical trial and the ancillary trials.

"COVID-19 has overwhelmed well-structured health systems in many countries around the world. The non-robust health system in Mozambique, which is already under pressure from other infectious diseases, would be unable to withstand the overload that can result from the spread of COVID-19 and particularly from the severe forms and unfavourable outcomes caused by this disease. This is why we are working to find the scientific evidence that can prevent or minimise deaths from COVID-19 and, at the same time, reduce the burden of this disease on the economy in both our country and across Africa."

This view was echoed by **Edson Bernardo**, principal investigator on this project in CISM, "Mozambique is a developing country where physical isolation is almost impossible. This is the reason we are concerned about a high rate of transmission and an accelerated increase in cases, which could Remine ruin the country's economy. Finding rapid solutions that can prevent disease progression and the more severe forms would help prevent the collapse not just of our health system but also of our economy."

The coordination of the ISGlobal centers in Mozambique, as well as the coordination with DNDi, is led by **Elisa López Varela**, co-principal investigator (PI) of the project, together with **Denise Nanche**, scientific director of ISGlobal.

### **A Flexible and Adaptive Study**

ANTICOV is an adaptive platform trial, an innovative type of clinical trial that allows researchers **to test several treatments simultaneously. allows the researchers to test several treatments simultaneously.** The model was pioneered in drugs designed to combat cancer. Treatments can be eliminated from the study depending on the results obtained and

new treatments can be introduced as data and studies become available on their efficacy in mild to moderate cases of the disease. The ANTICOV treatments are being selected in collaboration with the ACT-A Therapeutics Partnership. Candidates include drugs used to treat malaria, HIV, hepatitis C, parasitic infections and certain cancers.

Initially, ANTICOV will focus on drugs for which large-scale randomised clinical trials could provide missing efficacy data in mild-to-moderate patients. The trial will begin by testing the HIV antiretroviral combination lopinavir/ritonavir and the malaria drug hydroxychloroquine, which is still the standard of care for COVID-19 today in many African countries.

“The ANTICOV consortium is a broad partnership bringing together African scientific leaders and global organisations to respond to an urgent unmet medical need. Collaboration is the only way to provide robust scientific responses to these research questions,” explains **Nathalie Strub-Wourgaft**, Director of the COVID-19 response at DNDi. “The trial was designed in a way that enables rapid and flexible decisions as we gather knowledge.”

All the clinical trial data generated by ANTICOV will be integrated and shared openly and transparently to inform public health policy. Every effort will be made to work with all relevant partners to ensure that **treatments that prove safe and effective will be affordable, available, and accessible for all.**

The trial was reviewed with support from the [African Vaccine Regulatory Forum \(AVAREF\)](#), a platform set up by the World Health Organisation comprising representatives from national ethical and regulatory review bodies. AVAREF has simplified and helped to expedite approval in each country.

ANTICOV is aligned with the WHO [R&D Blueprint](#), which aims to improve coordination between scientists and global health professionals, accelerate the research and development process, and develop new norms and standards to learn from and improve upon the global COVID-19 response. The study was designed in close collaboration with the [Access to COVID-19 Tools Accelerator \(ACT-A\)](#) and its Therapeutics Partnership.

The Consortium is funded by the **German Federal Ministry of Education and Research (BMBF)** through a credit for reconstruction (KfW) and the global health agency Unitaid, as part of ACT-A.

\* The ANTICOV consortium is mobilising a network of partners with recognised experience in clinical research. The 26 members of the consortium are:

- Alliance for International Medical Action (ALIMA), France
- Bahir Dar University, Ethiopia
- Bernhard-Nocht-Institut für Tropenmedizin, Germany
- Centre Muraz, Institut National de Santé Publique, Burkina Faso
- Centre for Research in Therapeutic Sciences (CREATES), Kenya
- Centro de Investigação em Saúde de Manhiça (CISM), Mozambique

- Centro de Investigação e Treino em Saúde da Polana Caniço (CISPOC), Instituto Nacional de Saúde, Mozambique
- Centre Pasteur du Cameroun (CPC), Cameroon
- Centre pour le Développement des Vaccins, Ministry of Health, Mali
- Centre Suisse de Recherches Scientifiques (CSRS), Côte d'Ivoire
- Drugs for Neglected Diseases *initiative* (DNDi), Switzerland
- Epicentre, France
- Foundation for Innovative New Diagnostics (FIND), Switzerland
- Ifakara Health Institute (IHI), Tanzania
- Infectious Diseases Data Observatory (IDDO), United Kingdom
- Institute of Endemic Diseases (IEND) – University of Khartoum, Sudan
- Institute of Tropical Medicine (ITM), Antwerp , Belgium
- Institut National de Recherche Biomédicale (INRB), Democratic Republic of Congo
- Institut National de la Santé et de la Recherche Médicale (INSERM) / Agence Nationale de Recherche sur le Sida et les Hépatites Virales (ANRS), France
- ISGlobal – Barcelona Institute for Global Health, Spain
- The Kenya Medical Research Institute (KEMRI), Kenya
- Kumasi Centre for Collaborative Research in Tropical Medicine (KCCR), Ghana
- Medicines for Malaria Venture (MMV), Switzerland
- Swiss Tropical and Public Health Institute (Swiss TPH), Switzerland
- Université de Bordeaux, France
- Universidad de Gondar, Ethiopia

**Photos/videos for media:**

<https://dndi.widencollective.com/c/o78q8o6a>