BACKGROUND DOCUMENT

ANTICOV is the largest study in Africa testing multiple early treatment options for COVID-19

3,000 patients to be enrolled across 19 sites in 13 African countries

Bringing African scientific leaders and global partners together

The ANTICOV trial was designed by a consortium bringing together African researchers and scientists involved in the COVID-19 response and other research institutions with strong networks on the African continent.

The consortium is coordinated by the Drugs for Neglected Diseases initiative (DNDi), an experienced non-profit drug research and development (R&D) group with extensive partnerships in Africa.

ANTICOV mobilizes African and global science and public health leaders to respond to an urgent unmet medical need and will provide much-needed answers to enable countries in Africa and beyond to adopt effective therapeutic strategies adapted to resource-constrained settings.
Identifying treatments that prevent severe complications of COVID-19

Treating people with mild-to-moderate forms of COVID-19 – before they develop more severe disease and require hospitalization and specialized care – is an important challenge around the world.

Health systems in high-income countries have at times been overwhelmed by COVID-19. Preventing hospitalization is therefore all the more important in countries where healthcare infrastructure and staffing are fragile. Resource-limited settings in Africa have considerably fewer intensive care beds and limited access to oxygen and ventilators – as well as fewer staff to operate them and monitor their use.

Committing to open science and equitable access

By identifying treatments for mild-to-moderate cases that are adapted to resource-limited settings, ANTICOV will enable early treatment and alleviate pressure on fragile hospital systems in Africa.

All clinical trial data generated by ANTICOV will be integrated and shared openly and transparently. In addition, 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.

ANTICOV partners will work with the Unitaid-led Access to COVID-19 Tools Accelerator (ACT-A) market dynamics group on availability, supply, and procurement.
Generating evidence for decision-making, fast

To generate evidence, COVID-19 trials need to be well-designed. The ‘adaptive platform trial’ design means ANTICOV can simultaneously test several different treatments. The design also enables decisions to be made rapidly based on an ongoing analysis of study results:

- Any treatment seen to be underperforming can be dropped;
- New treatments can be added as evidence of their potential emerges; and
- If data supports it, one or more treatment arms can rapidly be declared superior.

Adaptive platform trial designs generate results faster, which reduces costs, ensures more prompt access to decisive evidence for policymakers, and ultimately more rapid access to safe and effective treatments for clinicians and patients.

ANTICOV is designed to ensure that research yields prompt and decisive results. By informing practice and regulatory decisions in Africa, the aim is to provide clinicians and patients with the treatments they need, fast.

Providing decisive answers to pressing research questions

ANTICOV will aim to provide decisive answers to research questions that are yet to be addressed, notably on hydroxychloroquine (HCQ) and lopinavir/ritonavir (LPV/r). While recent data show HCQ is not effective in severe, hospitalized cases, there is no global consensus on mild and moderate cases backed by sufficiently large clinical trials. There is a need to provide a definitive answer and guidance for countries that are still using HCQ as a standard of care. Indeed today, at least 16 African countries are recommending the use of chloroquine (CQ) or HCQ alone or in combination as a treatment for COVID-19, including seven of the 13 countries in ANTICOV.

Studies have also looked at LPV/r as a treatment for COVID-19, but the ANTICOV trial adopts a different approach and aims to assess its potential impact on mild and moderate cases, and whether using a stronger initial ‘loading’ dose, to reach higher therapeutic concentrations earlier, could be beneficial.

Testing the most promising therapeutic options by building on the latest evidence

Beyond these first two treatment arms, additional arms will soon be added, selected from among repurposed drugs under review, such as alisporivir, amodiaquine, atazanavir/ritonavir, colchicine, daclatasvir, imatinib, type-one interferons, ivermectin, nitazoxanide, pyronaridine, and sofosbuvir. One strong contender for inclusion (although this remains to be confirmed) is the oral combination of atazanavir/ritonavir plus nitazoxanide, two drugs with different mechanisms of action, which could answer to the need to ensure rapid exposure to drug concentrations associated with antiviral efficacy.
In a second stage, ANTICOV may serve as the platform to assess innovative approaches targeting SARS-CoV-2 based on regimens composed of new drugs or regimens, including non-registered antivirals, monoclonal antibodies, and immunomodulators.

With expert guidance, ANTICOV will select the most promising treatments from ongoing global scientific efforts with solid proof of safety and efficacy, and include them as additional treatment arms in the ANTICOV trial within weeks.

Complementing the global and regional COVID-19 response

The ANTICOV trial is aligned with the WHO R&D Blueprint, as well as other clinical trials looking at treatment or prevention for COVID-19. SOLIDARITY, launched by WHO in March 2020, focuses on moderate to severe hospitalized cases. ANTICOV is tackling the problem earlier, by looking at solutions that would prevent mild and moderate cases from becoming severe.

The ANTICOV study was developed with African lead researchers. It is aligned with the strategy of the Africa CDC, and is securing regulatory and ethics approval in 13 African countries. It leveraged the support of the COVID-19 Clinical Research Coalition, a coalition of institutions aiming to accelerate COVID-19 research in resource-limited settings. The coalition includes more than 100 researchers from Africa, including leading regional institutions.

The ANTICOV study works in close collaboration with ACT-A and its Therapeutics Partnership. The ACT-A Therapeutics Partnership is co-convened by Wellcome, on behalf of the COVID-19 Therapeutics Accelerator, and Unitaid, one of the principal funders of ANTICOV. The ANTICOV consortium’s selection of trial drugs is informed by reviews conducted by the ACT-A Therapeutics Partnership expert working group identifying new treatment candidates, with leadership from Wellcome and the Bill & Melinda Gates Foundation.

ANTICOV consortium members

- Alliance for International Medical Action (ALIMA), France / Senegal
- Agence Nationale de Recherche sur le Sida et les Hépatites Virales (ANRS), France
- Bahir Dar University, Ethiopia
- Barcelona Institute for Global Health (ISGlobal), Spain
- Bernhard-Nocht-Institut für Tropenmedizin (BNITM), Germany
- Centre Muraz, Institut National de Santé Publique, Burkina Faso
- Centre for Research in Therapeutic Sciences, Kenya
- Centro de Investigação em Saúde de Manhiça, 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 - (coordinating partner)
- Epicentre, France
- Foundation for Innovative New Diagnostics (FIND), Switzerland
- Ifakara Health Institute, Tanzania
- Infectious Diseases Data Observatory (IDDO), United Kingdom
- Institute of Endemic Diseases, University of Khartoum, Sudan
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