Q&A: The COVID-19 Clinical Research Coalition

What is the COVID-19 Clinical Research Coalition and what is it aiming to do?
COVID-19 Clinical Research Coalition members are individuals and institutions working to fast-track research that will provide evidence on COVID-19 prevention, diagnosis, and case management in resource-limited settings. This is the evidence needed to guide policies and practices.

Coalition members will work together to map what they could contribute to the research agenda and to form the most effective partnerships.

The coalition will promote open sharing of research knowledge and data, and advocate for equitable and affordable access to these interventions.

Why is there a need for the COVID-19 Clinical Research Coalition?
The coalition was born out of concern that the needs of people and health systems in low-resource settings needed to be addressed in this COVID-19 pandemic. The adverse impact of COVID-19 on fragile health care systems could be devastating for all health care delivery.

The research response to the pandemic has been vigorous, and significant new funding is emerging almost daily. Resource-limited settings, and particularly vulnerable populations, must be part of global plans to evaluate the safety and effectiveness of new diagnostic tools, drugs, vaccines, and non-medical interventions, and specific research is needed to address their needs and priorities. Otherwise millions could be denied equitable access to proven and affordable interventions.

What does it mean to 'fast-track' COVID-19 research?
Conducting biomedical research involves many complex processes that normally take time, including clinical protocol development and approval by ethical review boards, engagement of regulatory agencies, approval and procurement of medications and materials for clinical sites, data management and analysis, and the sharing of data and outcomes. In the current context, all of these processes must be accelerated in an emergency context without compromising or absorbing healthcare capacity that is required to manage the pandemic.

By working together and with government agencies, coalition members can develop, share, or harmonize systems, processes, and standards to ensure that:

- research gets started quickly,
- clinical sites have the materials they need,
- key data are standardized,
- research results can be analysed and shared rapidly,
- research efforts can quickly change gears to evaluate other interventions if those tested do not have the expected efficacy.

This should help to ensure that any interventions proven to be effective are quickly scaled up or, where new health products are involved, approved to reach patients and health systems. Working in coalition will also provide greater leverage to ensure affordable pricing and equitable access.

Many coalition members already have active clinical trial sites that meet international standards, including Good Clinical and Laboratory Practices. Some coalition members are already planning or conducting clinical trials on COVID-19 prevention, diagnosis, and treatment. They may use the coalition to find partners to extend or adapt these trials to other countries in the same or other regions. Other coalition members can support by providing technical expertise, funding, materials, and other support to ensure that priority research supporting an effective response in low-resource settings is facilitated as quickly as possible.

What is the relationship of this coalition to the World Health Organization (WHO)?
The coalition is positioned in support of WHO and its Member States who are looking to WHO for evidence-based guidance on the response to COVID-19 in resource-limited settings. WHO has welcomed the launch of the coalition and its expertise in running clinical trials in resource-poor settings, calling it “an initiative that will help WHO in its coordinating role in the global response to COVID-19”.

Coalition member research results will, it is hoped, be able to identify interventions that are adapted and affordable for resource-limited settings. This research will inform WHO recommendations on managing COVID-19 in such contexts.

Why is this coalition needed, given that several LMICs have signed up to participate in WHO’s SOLIDARITY trial?
The SOLIDARITY clinical trial is an important study that will evaluate the effectiveness of four possible drugs or drug combinations to treat COVID-19 in thousands of patients around the world in comparison with the standard of care. However, many more research questions remain to be answered as quickly as possible. Coalition members may adapt open access research protocols already developed for COVID-19 studies, such as the SOLIDARITY trial or the COPCOV clinical trial (led by the Mahidol Oxford Tropical Medicine Research Unit) or other trials in development, or they may develop new protocols according to their research priorities.

Is there a risk that the coalition’s actions will interfere with countries’ priorities and healthcare needs?
Coalition members will work closely with their own and other governments to ensure research is adapted to national priorities. Research will also be adapted according to the epidemic situation in specific countries: for example, to standards of care, access to reverse transcription-polymerase chain reaction (RT-PCR) testing, and social distancing measures – all of which may vary, necessitating tailored diagnostic and treatment strategies.

The coalition is committed to ensuring research activities do not compromise or absorb healthcare capacity required to manage the pandemic. Also, as the prioritization of clinical studies versus issues of health commodity access (diagnostics, drugs, vaccines) change over time, coalition members will work together to leverage support according to evolving priorities.

How did the coalition get started, and who is in it?
The idea for the coalition came from Professor Nick White (Mahidol Oxford Tropical Medicine Research Unit [MORU], University of Oxford) Professor Philippe Guerin (Infectious Diseases Data Observatory [IDDO], University of Oxford), and Dr Nathalie Strub Wourgaft (Director of Neglected Tropical Diseases at the Drugs for Neglected Diseases *initiative* [DND*i*]) in mid-March. They recognized that there were many capable and willing organizations across the world and anticipated that many questions would quickly come, specific to COVID-19 prevention, diagnosis, and treatment in different settings, which would require rapid research.

The COVID-19 Clinical Research Coalition is now being formed with biomedical public and private research institutions, universities, non-profit organizations, regional research coalitions, health ministries, and funders from across Africa, Latin America, and South and South-East Asia, and their research allies and funders in Europe, Australia, East Asia, and North America. Among the participants of this coalition are many public-sector research institutes from LMICs. A full list of coalition members can be found at www.covid19crc.org.

The need for collaborative mechanisms to support global clinical research is clear. At its creation, more than 70 institutions had joined from over 30 countries.

Who leads the coalition?
There is no single organization leading the coalition. This is the beginning. The governance and facilitation/hosting mechanisms are now being established. Coalition members will use a web-based platform to share information and set up peer-to-peer collaborations to encourage quick action, avoid research duplication, solve problems, and partner to develop clinical studies that will serve public health in low-resource settings.

How can I or my organization become more involved?
Organizations or individuals ready to contribute existing capacity to facilitate clinical trials on COVID-19 in resource-limited settings are invited to join the coalition. More information can be found at www.covid19crc.org.