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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 a "coalition of the willing", individuals and institutions working to fast-track research that will provide evidence for global guidance on COVID-19 prevention, diagnosis, and case management in resource-limited settings.

Members will work together to assess and map all institutions' potential contributions to the response. As clinical studies are being planned, this should help to rapidly connect potential partners in order to leverage capabilities and resources for maximum impact.

The coalition will also 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?
Equitable access to affordable healthcare and evidence-based health technologies is a fundamental right.

The coalition was borne out of concern in low- and middle-income countries (LMICs) that the specific needs of people and health systems in low-resource settings needed to be prioritized, particularly given the fragility of healthcare systems and the expected consequences of COVID-19 on public health in those settings.

The research response to the pandemic has been vigorous, and important new funding is emerging almost daily. That is encouraging. But if resource-limited settings and particularly vulnerable populations are not part of global plans to evaluate the safety and effectiveness of new diagnostic tools, drugs, vaccines, and non-medical interventions – with their needs and priorities in mind – millions could be denied access to proven interventions and guidance.

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 patient safety, research protocols, or ethics – and 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, that clinical sites have the materials they need, that key data are standardized, that research results are shared quickly, and that any interventions proven to be effective are quickly scaled up or, where health commodities 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 more rapidly extend 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.

Coalition member research results will, it is hoped, quickly identify interventions that are adapted and affordable for resource-limited settings. This research will guide WHO recommendations on managing COVID-19 in low-resource settings.

Why is this coalition needed, given that a number of LMICs have signed up to participate in WHO's SOLIDARITY trial?
The SOLIDARITY clinical trial is one 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. 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 University of Oxford/Mahidol Oxford Tropical Medicine Research Unit), 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 the national context and top priorities. As an example, the future availability of any tested medication must be assessed before engaging in research. 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) and Professor Philippe Guerin (Infectious Diseases Data Observatory [IDDO], University of Oxford) in mid-March, in

response to concerns being expressed by colleagues in low-resource settings when the pandemic was declared and the first cases were reported in sub-Saharan Africa. They reached out to the Drugs for Neglected Diseases *initiative* and partners around the world to develop the concept further.

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 public-sector research institutes from LMICs, including for example Fiocruz (Brazil), Institut National pour la Recherche Biomédicale (Democratic Republic of Congo), the Instituto Nacional de Salud de Colombia, the Ifakara Health Institute (Tanzania), and the Kenya Medical Research Institute (KEMRI).

The need for collaborative mechanisms to support global clinical research is clear. At its creation, more than 70 institutions had joined, representing 21 LMICs and 11 high-income countries.

Who leads the Coalition?
There is no single organization leading the coalition. 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 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.