

Therapeutics Working Group – Terms of Reference

The COVID-19 Clinical Research Coalition was launched in April 2020, with a mission to advocate and collaborate for the advancement of COVID-19 research driven by the needs of resource-limited settings, and to strive for equitable access to solutions in the global response to the pandemic. Since the coalition's creation, topic-specific working groups have been convened to tackle a broad spectrum of pandemic-related issues as they emerge and have identified focused priorities. The call for a Therapeutics Working Group has come from coalition members, including those involved in other working groups and serving on the Steering Committee.

Rationale

Vaccines are the main component of COVID-19 prevention and control, but therapeutics are also important. Immune modulating drugs (notably corticosteroids) reduce mortality in hospitalized COVID-19 patients, and there is increasing evidence for the benefits of some antivirals (monoclonal antibodies and small molecule drugs), particularly in earlier disease.

In low-resource settings (LRS), prevention of hospitalization is the therapeutic priority, but there is little therapeutics research occurring in these settings, and there is uncertainty on the future affordability and availability of proven therapeutics in LRS, including those being prioritized by the Therapeutics Partnership of the Access to COVID-19 Tools Accelerator, a multilateral effort hosted by the World Health Organization to support the rapid identification, development and production of effective COVID-19 therapeutics. A platform to discuss COVID-19 therapeutics in LRS and promote relevant research and priorities would be beneficial, and the working group would aim to fill this gap.

Working Group Objectives

The Therapeutics Working Group will provide:

1. An **advisory role** for the coalition and its extended networks, providing a platform for relevant COVID-19 therapeutics discussions;
2. An **advocacy role**, focusing on promoting the therapeutics research that will generate the most relevant evidence for LRS; and
3. COVID-19 therapeutics **knowledge/evidence generation and synthesis** for LRS.

Activities will include (but not be limited to):

1. Discussing and disseminating current knowledge of the COVID-19 therapeutics landscape, including:
 - a. Trials in COVID-19 therapeutics
 - b. Emerging therapies
 - c. Evolving global treatment guidelines for COVID-19
2. Assessing available COVID-19 therapeutic recommendations in LRS
3. Identifying and reviewing new and emerging COVID-19 therapeutics in LMICs
4. Knowledge and expert-opinion sharing through webinars, workshops, communications, viewpoints, commentaries, joint recommendations, etc.
5. Identifying and fostering partnerships among key stakeholders in therapeutics research and development.

Structure of the Working Group

Overall governance

Adheres to governance and any guidance provided by the Coalition's Steering Committee.

Working group members

Working group members will be identified via an open call for members issued to the coalition membership, who may share the call outside of the coalition, nominate themselves or others, or propose names for follow-up. Membership is individual and not institutional. Members should have therapeutics expertise and acute awareness of the treatment needs and priorities of low-resource settings.

The coalition's secretariat will screen applications for membership and share a long list with instigating coalition members and the Steering Committee for discussion and decision, including on an ongoing basis as any ad hoc applications are received.

Two co-chairs will be proposed by the Steering Committee, at least one of whom from a low-resource setting, to act as chief liaisons between the working group and the coalition's Steering Committee. They will provide oversight and leadership of the group of experts striving for an effective contribution in the field of therapeutics for COVID-19 in low-resource settings; foster collaboration, dynamic interaction and amplify the collective voice of the group.

Coordination & administration

A working group coordinator with some knowledge of the topic will be provided for up to several hours each week to manage communication with working group members, organize working group meetings and agendas in collaboration with the co-chairs, take and distribute meeting notes, follow up on action points, organize any events with the support of the coalition's secretariat, and provide support as needed to the co-chairs.