GHTC Statement on the WHO Clinical Trials Resolution

Last year's clinical trial resolution was a major milestone for building greater clinical trial capacity in low- and middle-income countries. However, creating a framework for standardization and implementation is still slow and ongoing. There are numerous areas where the current framework could be improved.

Member states have highlighted that there continues to be inadequate reporting of data disaggregated by sex and gender relating to the World Health Organization's (WHO's) priority pathogens, such as those for neglected tropical diseases and in WHO's R&D Blueprint, as well as for new antibiotics for highly-resistant pathogens. Actions are needed to fill these gaps in the global evidence base, as well as for strengthening inclusiveness.

Greater coordination is also needed to ensure efficacy and alignment with other clinical trial capacity-strengthening mechanisms, including the Global Health Security Agenda, and investments driven through international financial institutions, including the new Pandemic Fund. There is also a need for domestic resource mobilization, and other sustainable financing mechanisms should also support capacity-building initiatives.

We, therefore, urge members and WHO to consider the following recommendations to build upon the work started last year:

1. Improve international collaboration and coordination among member states on key research priorities and multiregional clinical trials, where appropriate. At present, effective coordination mechanisms are lacking for clinical trials, and funding for clinical trials across all WHO regions and disease areas is insufficient. Furthermore, improved coordination around global research agendas could enable more timely capacity-building of clinical trial sites.

2. Support new trial modalities such as decentralized and paperless clinical trials that incorporate patient perspectives, mobile technologies and telemedicine, and increased use of adaptive, multicountry platform trials.

3. Invest in building regulatory capacity in low- and middle-income countries (LMICs), including further building off of progress to date across the African Medicines Regulatory Harmonization programme and supporting the launch of the African Medicines Agency. Continued investment in regulatory strengthening will be critical to expanding clinical trial capacity in LMICs.

4. Increase investment in workforce capacity and research institute infrastructure in LMICs. Additional investment is critical to sustainably build the capacity of LMICs to execute their own research agendas.

5. Address gaps in data on specific population groups and disease targets and gender biases in data. Biases may result in these groups being precluded from the development of, and access to, needed interventions. This includes, but is not restricted to, pediatric data and data from pregnant and breastfeeding people.

6. Support the Global Accelerator for Paediatric Formulations and the WHO International Clinical Trial Registry Platform through data sharing and technical support, as these platforms will be crucial for providing and streamlining the clinical evidence base necessary for policymakers to understand the current clinical trial landscape and its current gaps. There is also an urgent need to overcome the challenges in clinical trials for children and support platforms such as the Global Accelerator for Paediatric Formulations to strengthen partnerships to overcome these barriers.