

## Editorial

### Strengthening Ethiopia's Clinical Trial Ecosystem: Challenges, Opportunities, and the Way Forward

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A clinical trial is a study conducted with human volunteers in clinical settings to develop new therapeutic interventions for future generations. Although Africa hosts 19% of the world's population and bears 25% of the global disease burden, only 2.5% of all global clinical trials are conducted in Africa (1). This contrasts with the number of trials registered in Europe, America, and the Western Pacific, which has increased at a much higher rate. For example, the number of trials registered in the Western Pacific was about 14 times higher than that in Africa (2). Nevertheless, Africa has tremendous potential for developing new interventions due to its large biodiversity, disease epidemiology, pathogenic profile, and populations with diverse genetic makeups (3).

Ethiopia is the 2<sup>nd</sup> most populous country in Africa with about 127 million people (3, 5) and 10<sup>th</sup> in the world (6, 7). Unfortunately, the number of clinical trials conducted in Ethiopia is tiny compared to its large population. For example, just 145 clinical trials were registered from Ethiopia until November 2016 compared to the enormous number of clinical trials registered in Egypt and South Africa (8). Although the registered trials have tripled since then (9), the number remains relatively small. This low rate of clinical trials is attributed to the unfavorable clinical trial ecosystem, which has not provided a fertile ground for conducting clinical trials in the country. However, there is considerable potential for the conduct of clinical trials in the country. In addition to the population size and disease profiles, there is an increasing number of trained and qualified personnel in the various health disciplines, including in clinical trials, who can be engaged in clinical trials. Moreover, different stakeholders of clinical trials, including academic and research institutes, trained clinical monitors, experts who can be employed as members of the data safety monitoring board, accredited research ethics review committees, a strong National Medicine Regulatory Authority, and insurance companies that have adequate awareness of clinical trials, are available. There are a large number of potential traditional medicinal remedies that could be subject to clinical trials in the country. These tremendous opportunities have not been tapped sufficiently due to the weak clinical trial ecosystem.

A lot of effort has been made to promote clinical trials in Ethiopia in the past few years. The Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa), Addis Ababa University, has developed a Master's program in Clinical Trials, which has received international accreditation since 2023. Several cohorts of professionals from Africa, including Ethiopia, have been trained in this program. This program has, no doubt, addressed a vital bottleneck, human capital, for the conduct of clinical trials. The center has also developed an internationally accredited ten-week online course in clinical trials, which is expanding capability in clinical trials across Africa (10). CDT Africa also took the initiative to establish an advisory committee on clinical trials (ACT) involving the Ethiopian Food and Drug Authority (EFDA), National Research Ethics Review Board (NRERB), and Institutional Research Ethics Review Committees (IRERCs) of the College of Health Sciences (CHS), Addis Ababa University, Armauer Hansen Research Institute (AHRI), and the Ethiopian Public Health Institute (EPHI). An effort is being made to expand the committee's membership to institutions active in clinical trials across Ethiopia. This committee has terms of reference (ToR) and meets regularly to discuss issues related to improving the ecosystem for conducting clinical trials.

As part of its advocacy work, the ACT has celebrated International Clinical Trials Day (ICTD) every year since its establishment to enhance awareness regarding clinical trials. The financial support obtained from several funding

organizations such as drugs for Neglected Diseases initiative (DNDi), European and Developing Countries Partnership (EDCP), Wellcome Trust, US National Institute of Health (NIH), the Bill & Melinda Gates Foundation and UK National Institute of Health Research NIHR) have helped improve the clinical trial ecosystem in Ethiopia. The recently approved Clinical Trial Roadmap by the Ministry of Health has also contributed. All these efforts are beginning to show promising results in improving the clinical trial ecosystem in the country.

As part of its broader effort to improve the clinical trials ecosystem, the ACT conducted a study of the country's clinical trials ecosystem. The study identifies many opportunities and challenges for conducting clinical trials. This supplement presents the findings from this study in the hope that more stakeholders will be aware of them and join hands to improve the clinical trials ecosystem.

There is much to be done to meet the demand for access to therapeutics for the Ethiopian population by promoting clinical trials systematically, including facilitating the safe use of untapped resources and traditional medical knowledge. This requires the collaborative efforts of all concerned parties. The Ethiopian government has made clear commitments to improve the clinical trials ecosystem. One important step in this regard is the establishment of a dedicated new executive office, equivalent to a directorate, responsible for clinical trials and pharmacovigilance (11). These initiatives should be encouraged. Timely revisions and implementations of clinical trial policies are also important. This editorial highlights the active initiatives for enhancing the clinical trials ecosystem of Ethiopia and encourages wider and stronger engagement and commitment from more stakeholders. In this regard, partnerships with industry will play a critical role in improving the clinical trials ecosystem and enhancing clinical trial standards. The series of papers published in this special issue further highlight the opportunities, challenges, and remedies for strengthening the clinical trials ecosystem of Ethiopia.

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