

Brief Communication

Ten Recommendations for Transforming the Clinical Trials Ecosystem in Ethiopia

Eyasu Makonnen^{1,2}, Yimtubezinash Woldeamanuel^{1,3}, Asrat Hailu^{1,3}, Asnakech Alemu,⁴ Telahun Teka⁵, Abebaw Fekadu^{1,6,7}

¹Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT Africa), Addis Ababa University, Addis Ababa, Ethiopia

²Department of Pharmacology and Clinical Pharmacy, College of Health Sciences, Addis Ababa University, Addis Ababa, Ethiopia

³Department of Microbiology, Immunology and Parasitology, College of Health Sciences, Addis Ababa University, Addis Ababa, Ethiopia

⁴Ethiopian Food and Drug Authority, Addis Ababa, Ethiopia

⁵Office of the National Research Ethics Review Board, Ministry of Education, Addis Ababa, Ethiopia

⁶Department of Psychiatry, College of Health Sciences, Addis Ababa University

⁷Department of Global Health and Infection, Brighton and Sussex Medical School, Brighton, UK

*Corresponding author: eyasumakonnen@yahoo.com

Abstract

As the number of clinical trials conducted in Ethiopia is too small compared to the population size, CDT Africa has established an advisory committee for clinical trials (ACT) composed of the regulatory body, the National Research Ethics Review Board, and the Institutional Research Ethics Review committees, which have received SIDCER recognition. ACT identified the key factors affecting conduct of clinical trials in the country, and recommended i) Reducing protocol approval time; ii) Facilitating trial authorization; iii) Providing training to insurance companies; iv) Establishing national clinical trials networking platform; v) Creating awareness of the public on clinical trials; vi) Providing training to health professionals; vii) Securing adequate financing; viii) Establishing/strengthening data management center; xi) Implementing the national clinical trials roadmap; and x) Establishing institutional capacity in clinical trials. If these recommendations are implemented, the number of clinical trials conducted in the country, no doubt, will increase.

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Though clinical trials are the primary tool through which new therapeutics are developed, these studies are rarely conducted in developing countries, including Ethiopia. For example, of the overall clinical studies registered worldwide from 2000 to May 2023 (n=454,000) (1), nearly 40% (n=168,520) were from the United States of America (2), while Africa, representing 18% of the world's population and a substantial disease burden, contributes only 2.5% of all clinical trials worldwide (3). To promote the conduct of clinical trials in Ethiopia, an Advisory Committee for Clinical Trials (ACT) has been established. This committee comprises the Ethiopian Food and Drug Authority (EFDA), the chairpersons of the National Research Ethics Review Board (NRERB) of Ethiopia,

and a nominated member from the Institutional Research Ethics Review Committees (IRERCs) of various institutes such as the Ethiopian Public Health Institute (EPHI), Armauer Hansen Research Institute (AHRI), Addis Ababa University's Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa), and College of Health Sciences (CHS) at Addis Ababa University. Upon the advice of the ACT, CDT-Africa conducted a mixed-methods study to identify factors contributing to the low number of clinical trials conducted in the country and to understand what may need to be done to address these challenges and improve the clinical trials ecosystem more broadly. Based on the identified factors, the

ACT has recommended the following to improve the clinical trials ecosystem in Ethiopia:

1. Reducing the lengthy clinical trial protocol approval

The lengthy trial approval process impacts clinical trial delivery in many ways. First, it discourages clinical researchers. Secondly, funders will lose interest and prioritize other countries to implement the study. The fund may also expire while the research team awaits approval. Most importantly, promising interventions will not be readily available to patients. To facilitate the ethical approval process, the following measures were proposed:

- Review of clinical trial protocols should be decentralized to Level A and ethics review committees recognized by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER). The NRERB should instead focus on developing guidelines and providing training to IRERCs and researchers. Similarly, the EFDA should also focus on regulatory issues.
- Ethics committee members should be well trained, and the committees should meet more frequently to review protocols.

2. Facilitating clinical trial authorization process

The efforts to modernize the regulatory authority and the authorization process are commendable. However, many researchers express frustration over the lengthy clinical trial authorization process. This similarly discourages researchers, funders, patients, and practitioners seeking improved treatment options. To facilitate the regulatory approval process, the following should be addressed:

- The regulatory body's capability needs to be further strengthened. Ensuring that all the staff involved in the clinical trial authorization process are trained and retained is critical.
- The infrastructure of the regulatory body, including appropriate offices, reliable internet access, and online submission and follow-up systems, should be improved.
- More work is needed to enhance the staff's attitude about the relevance of conducting clinical trials. Clear guidelines on clinical trial authorization are required, and awareness among all stakeholders should be ensured.

3. Providing training to insurance companies

Another factor contributing to the smaller number of clinical trials to be conducted in the country is the hesitancy of insurance companies to provide the relevant service for clinical trial participants. Even if they are willing to do so, the premium they give is unreasonably too high, sometimes even more than the budget of the clinical trial itself. This discourages researchers from being involved in clinical trial activities. To address this problem, the following actions

are recommended:

- Training should be given to insurance companies to create awareness of the relevance of clinical trials in coming up with better interventions for disease conditions
- Insurance companies should be encouraged to be involved in such exercises
- Experience sharing among insurance companies involved in clinical trial activities should be encouraged.
- Much more work has to be done on the wrong conception of staff working in insurance companies towards the exaggerated risks of participation in clinical trials

4. Establishing a national clinical trials networking platform

Only a few institutions are engaged vigorously in the conduct of clinical trials. Creating platforms for networking and experience sharing is likely to encourage other institutions to engage in clinical trials. It was suggested that, as a regional institution and given its experience in organizing the International Clinical Trials Day over the past 11 years, CDT-Africa may be better positioned to take the lead in engaging institutions. Networking, no doubt, plays a significant role in improving the ecosystem of clinical trials in the country.

5. Creating awareness among the public on clinical trials

Trial participants and public engagement (PPE) is a vital instrument for ensuring that clinical trials address the needs of the public (4). The active involvement of patients and the public in the planning, implementation, and dissemination of a clinical trial ensures that the study is aligned with the needs of the population, barriers to participation are addressed, and the benefits of the clinical research are equitably distributed. Methods for ensuring PPE should be developed or adapted as a priority.

6. Providing training in clinical trials to health professionals

Increasing the number of health professionals involved in clinical research increases the capacity for conducting clinical trials. Despite their interest, health professionals are reluctant because of a lack of expertise. Offering these health professionals skills-based short-term training in the operation of clinical trials, bioethics, and good clinical practice must also be a priority.

7. Securing adequate financing for clinical trials

Clinical trials are expensive ventures by their nature. Some researchers may be able and interested in conducting clinical trials, but they may not have the required finances. This may discourage them. Providing training on how they could secure grants and work with relevant industries will have paramount

importance in solving this problem.

8. Establishing/strengthening the data management center

Clinical trials require a strong data management center. Research institutes and universities involved in clinical trials must strengthen and/or establish a strong data management center. Collaboration in this area may also be needed.

9. Implementing the national clinical trials roadmap

The national clinical trial roadmap has been prepared by a think tank group established by the Ethiopian Federal Ministry of Health. While having the roadmap is important, it will remain a paper tiger unless implemented. Therefore, the Federal Ministry of Health has a responsibility to implement the roadmap as soon as possible.

10. Establishing institutional capacity in clinical trials

Broader institutional capacity to conduct clinical trials, including staff capacity, is crucial. Institutions should equip their staff with knowledge and skills in clinical trials. Advanced regional programs are available in Ethiopia, which should be utilized.

Furthermore, the Data Sharing Act and legal frameworks for clinical trials will also enhance the clinical trial ecosystem in Ethiopia.

If these recommendations are implemented, the number of clinical trials to be conducted is expected to increase substantially.

References

1. Matej Mikulic: Research expert covering health, pharma&medtech, Statista, 2023
2. WHO International Clinical Trials Registry, February 2023
3. Lucas Tina, Tariro Makadzange, Nsengi Ntamabyaliro: Increasing Clinical Research in Africa Presents An Opportunity To Address Global Health Challenges, FHI Clinical Africa, <http://www.fhiclinical.com>
4. The Lancet Healthy L: Increasing patient and public involvement in clinical research. The Lancet Healthy Longevity. 2024;5(2):e83.