

**EDITORIAL****CLARION CALL FOR MORE CLINICAL TRIALS: THE CASE OF ETHIOPIA**Sileshi Lulseged, MD, MMed,<sup>1</sup> Abraham Aseffa, MD, PhD<sup>2</sup>

Clinical trials are research studies performed on human participants to evaluate biomedical or behavioral interventions. They are designed to answer specific questions, providing either new solutions (such as novel medical devices, diagnostics, vaccines, drugs, dietary choices or behavioral changes) or known interventions that warrant further study. Randomized clinical trials are essential to generate data on safety and efficacy of new tools. When done properly the rigor of evidence they produce is unmatched by the results and evidence generated through any other study designs. Notwithstanding the advantages and clear benefits clinical trials offer, available data show that there is a paucity of clinical trials in Ethiopia (1). Indeed, all reports emphasize that clinical trials conducted in Ethiopia have been very much limited not only in quantity, but also in type and quality (2).

The report by Tefera B, et al. published in this Issue of the Ethiopian Medical Journal (EMJ) (3) shows that, by the end of 2016, only 145 clinical trials from Ethiopia were registered in the World Health Organization (WHO) Clinical Trial Registry Platform. The majority of these were on interventions against infectious diseases. Most of the trials were sponsored by international institutions. Other reports have also emphasized that health research in Ethiopia, especially in the form of clinical trials, is inadequate for the multitude health challenges in the country, with clinical trials comprising only a small proportion of this rather limited number (1,2). Until recently, only 1.5% of all registered clinical trials in Africa were conducted in Ethiopia most of which were on communicable diseases (3). Clinical trials on non-communicable diseases (NCDs) have been even more scarce. NCDs such as ischemic heart disease, cancer, cerebrovascular disease, and psychiatric disorders are on the rise, currently constituting a major public health threat in the country (4). Relatively little has been done on traditional medicine although the national health policy had for a long time identified it as one of the priority areas for research.

The variations in type and distribution of diseases, differences in demographics, changes in environment and lifestyle and socio-cultural factors in Ethiopia call for clinical trials targeting country-specific needs and conditions. Similarly, local investigators should be involved substantially in the design and conduct of clinical trials, as this approach is more likely to generate highly relevant data that could influence policy and guide proper allocation of scarce health-care resources, help in improving service delivery and bring about long lasting impact as well as better guarantee sustainability of relevant research (2,5). The trend to-date is that most of the clinical trials are sponsored, initiated and conducted by non-Ethiopian organizations, largely academic institutions. While this is important to ensure capacity strengthening, efforts should be made to benefit from the links to generate local leadership alongside. In-country funding should be made available to conduct clinical trials in health facilities such as in the postgraduate training hospitals of the country to help clinicians improve patient management based on their local experience. In Ethiopia, as in many developing countries, poverty, weak regulatory and administrative systems, limited skilled manpower and material resources, and fragmented healthcare delivery constitute key features, thwarting the conduct of clinical research (6,7). Nevertheless, there is sufficient critical mass of personnel and institutions now to venture into quality trials despite the overall weaknesses in the health research landscape.

Clinical trials need to meet even higher standards than other scientific studies and will thus require dedicated investigators who are happy to take the challenge and committed institutions ready to support them. Clinical trials involve rigorous approaches, as they are required to meet regulatory specifications, and thus require specialist expertise and intensive monitoring. Adherence to national and international guidelines on standards of Good Clinical Practice (GCP) in research, ensuring sound scientific and ethical standards, will in practice mean intensive attention to detail and strict discipline in documentation, sets of competencies that require intensive training, coaching, mentoring and monitoring of clinical trial staff. Institutions hosting trials are therefore expected to have developed critical core competencies including in administrative services. Clinical trial funding has to consider the additional cost required to ensure credibility and ethical standards. The higher cost of clinical trials is one of the reasons for the low numbers and external funding of those trials carried out in the country. Innovative cost-saving approaches and funding mechanisms should be able to resolve this.

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Fostering strong collaborations between local and international organizations will be useful to address the local challenges (5). Efforts to improve the conduct of clinical trials in Ethiopia will need to be shared by the government, industry, professional societies, patient advocacy groups, and other organizations. This not only helps improve the number, quality and acceptance of clinical trials, but will also provide opportunities for funding, technical support, experience and knowledge sharing and transfer of skills. Public, non-profit or private-for-profit Pharmaceutical and Biotechnology companies play a significant role in sponsoring clinical trials in general. Introduction of new tools (diagnostics, drugs, vaccines) into health care in the country is an area where clinical trials are required and benefiting from such a sponsorship. Collaboration with industry on clinical trials is an area that has yet to grow in Ethiopia.

As emphasized in a number of recent reports (2,3,7), there is a clear need for more clinical trials, which indeed are critically required to formulate evidence-based and sound health policies and improve on clinical practice in Ethiopia. In order to increase the volume and diversity of clinical trials and improve their quality, available evidence on gaps, key challenges, and potential enablers need to be critically appraised and systematically addressed. There is a need for a legal framework (10) in order to promote local registration of clinical trials as well as for mechanisms to incentivize and enforce registration. Local registration helps to easily identify published trials, guard against underreporting especially of negative results, and improve transparency and public confidence in data. It is time for Ethiopian health researchers to better contribute to clinical trial evidence building nationally and internationally, not only through consortium collaborations with advanced centers, but also within their own institutions through local networks addressing immediate practice challenges where they have ideas of possible solutions to test in a scientific way.

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