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Brief Communication

Streamlining Clinical Trial Approvals in Ethiopia: Recommendations of an Expert Workshop

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Abstract

Background: *Ethics approval of clinical trials in Ethiopia involves multiple institutions. Facilitated by the Advisory Committee on Clinical Trials (ACT) at CDT Africa of Addis Ababa University, we conducted national harmonization consultation workshop to evaluate ethics and regulatory review procedures, to understand challenges to trial approval and to propose solutions.*

Methods: *Two workshops brought together representatives from 12 organizations, including the Ethiopian Food and Drug Authority (EFDA), National Research Ethics Review Board (NRERB), Institutional Research Ethics Review Committees (IRERCs), investigators and research directors. The workshop was moderated by an experienced trialist and ethicist and participants discussed existing bottlenecks in the approval process and proposed recommendations for harmonized review procedures.*

Results: *Following an agreement that harmonization refers to the adoption of a uniform or standardized procedure to support the coordination of ethics and regulatory review procedures, four themes emerged from the discussions: (1) the current approval pathway, (2) opportunities, (3) challenges, and (4) proposed solutions.*

Current Approval Pathway*: Pathway follows sequential reviews by multiple institutions with inevitable delays in approval and trial activation.*

Challenges*: Capacity constraints faced by investigators, ethics committees and regulatory authority were considered barriers to timely approval. Policy-related issues were also raised, with particular concern regarding unqualified exclusion of children from clinical trials.*

Opportunities for improvement: *The acknowledgement of current problems and commitment to harmonizing approval procedures, and availability of multiple capacity building platforms were critical first steps. EFDA is making significant progress to attain WHO's Maturity Level 3.*

Proposed solutions: *Key recommendations included enhancement of NRERB's initiatives on registration and accreditation of IRERCs, synergizing capacity-strengthening initiatives, decentralization of review processes with proper oversight, and coordinating resources.*

Conclusion: *Harmonization with clear frameworks is an urgent priority. As a multi-institutional forum, the ACT should assist harmonization efforts; however, EFDA and NRERB should take the ultimate responsibility.*

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Introduction

The global share of clinical trials in Africa is negligible(1). Numerous factors account for this: shortage of expertise, limited infrastructure, an underdeveloped pharma industry, extremely few therapeutics in the product development pipeline for diseases of the region, and underdeveloped health system. Importantly, clinical trials may be sensitive, albeit less specific, indicators of the level of health system development and sophistication, which is sometimes referred to as 'Clinical Trials Index'(2). On the other hand, clinical trials may drive broader healthcare quality by way of human capital development, improvement in the standard of care and investment in infrastructure.

Slow regulatory approval due to poor coordination between the regulatory and ethics review processes is perhaps one of the most important reasons for the low participation of Africa in clinical trials. The typical CT protocol review and approval path in Ethiopia, as in many low and middle income countries (LMICs), is sequential(3), flowing from an initiating department or institution to a national ethics board, with the final trial approval mandate resting with the regulatory authority (Figure 1). The process inherently invites a protracted feedback and response loop at each stage of the approval process, with little (3). This prolonged TTA undermines the ability of clinical trial sites to participate in international clinical trials coordination between the various institutions and approval stages (4, 5).

Although more pronounced in Africa, the lack of coordination is a universal concern(6), and is associated with prolonged Time to Trial Activation (TTA), an important metric representing the time it takes from submission of a clinical trial protocol for approval to the enrolment of the first participant (3). This prolonged TTA undermines the ability of clinical trial sites to participate in international clinical trials.

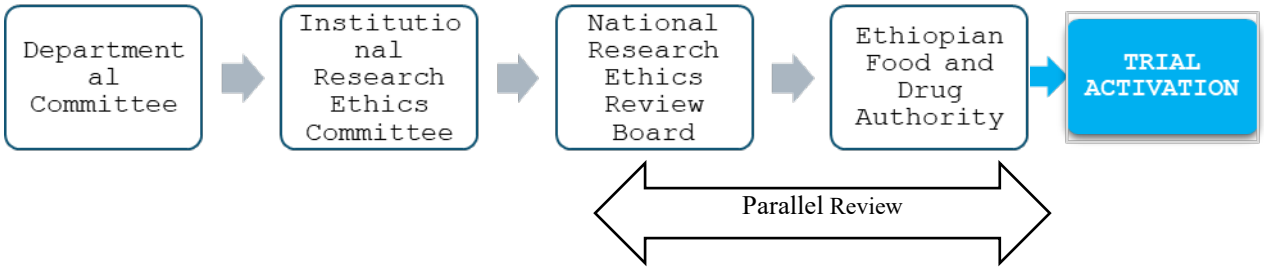

Figure 1: ***Sequential approval process of clinical trial protocols in Ethiopia***

The implication of the low participation in international clinical trials is not fully appreciated by health system managers and policy makers. The most obvious is the lack of access to quality medicines for conditions with limited treatment availability, for example, cancer, antimicrobial-resistant infections, and inherited diseases. As a consequence, the opportunity to be part of the development of new therapeutics and contribute to global welfare is also lost. Less importantly, access to economic opportunities is also denied. However, a pattern of positive developments demonstrating national commitment to creating ethics and regulatory synergy and thereby improving the clinical trial ecosystem is emerging in Ethiopia. For instance, the Ethiopia Food and Drug Authority (EFDA) has established a dedicated executive office focused on clinical trials, is upgrading its infrastructure, including the introduction of product testing facilities, and is collaborating with the WHO to upgrade its maturity level. Similarly, the NRERB has engaged in extended capacity building work on IRERCs, and is introducing an accreditation system, which should assure acceptable quality standards of review and approval processes. New international mechanisms, for example, the "Global competency framework for regulators of medicines" is developed to harmonize "workforce development efforts for the regulation of medicines by establishing an internationally accepted set of best practice competencies"(7).

About four years ago, CDT-Africa, a medical discovery and development center of excellence of the Addis Ababa University, facilitated the establishment of the Advisory Committee on Clinical Trials (ACT), consisting of representatives from key clinical trial stakeholders including the IRERCs, NRERB, EFDA, and CDT-Africa(8). The main goal of ACT is to enhance the clinical trials ecosystem by offering a neutral space for open discussions

about necessary changes. This includes addressing key obstacles that hinder clinical trials and identifying effective strategies to overcome these challenges.

As part of its commitment to enhancing the clinical trials ecosystem in Ethiopia, ACT was tasked with convening a workshop to:

i) Review existing procedures of protocol review and oversight,
ii) Identify gaps and bottlenecks, and
Iii) Draw a set of harmonized solutions for improving the quality and efficiency of protocol review and oversight processes.

This convening of the workshop was preceded by studies to understand the barriers to timely initiation of clinical trials, which identified lack of coordination between ethics committees and regulatory bodies in protocol review and approval as a major factor contributing to initiation delays(4, 5).

In this brief communication, we describe the workshop discussion outputs and the recommendations for harmonized solutions to expedite the ethics and regulatory approval processes.

Methods

The report comes from two workshops, which followed a simple process of setting up a workshop: establishment of an Ad hoc committee, as well as conducting a preparatory consultative meeting and a harmonization workshop.

Ad hoc Committee: A three-member Ad hoc committee was established from members of ACT to help draft the agenda and set up the harmonization meetings.

Preparatory consultative workshop: Held on April 25, 2025. Seven of the nine ACT members met for a day to consolidate the workshop agenda and explore the parameters of harmonization. The meeting identified four key agenda points for the workshop: Clarification of what harmonization means within the context of clinical trials; determining the scope; identifying key areas that require harmonization; formulating recommendations to address the identified challenges.

Harmonization workshop: Held on June 4, 2025. The stakeholders selected were directly linked to clinical trial approval either as applicants or approvers. Thus, the invitees for the workshop were members of Level A IRERCs with experience in clinical trials protocol review. It was agreed to include two representatives of each institution; Chair or delegate of the IRERCs and the Research Director/Vice Executive Dean of the represented institutions; and leaders from relevant ministries and institutions (Ministry of Health, EFDA and Ministry of Education). Additionally, selected principal investigators were invited purposively. The institutional representation balanced the need for experiential discussion and higher leadership engagement. It was hoped that this selection would enable attendance of experienced stakeholders who can reflect on the challenges and solutions as well as decision making and execution capacity.

The workshop began with seven brief presentations designed to outline the current approval pathways, highlight the challenges faced, and describe the ongoing efforts to address these challenges. The presentations were followed by detailed discussions about the existing approval path as well as bottlenecks and proposing recommendations for harmonized ethics and regulatory review and approval procedures. The discussions were audio-recorded and subsequently transcribed. Based on the transcriptions and meeting notes, the discussions were summarized into major discussion themes.

Results

Participants

In the preparatory workshop, eight participants took part – seven of the nine members of ACT and one senior trial manager of CDT-Africa. These participants were all part of the main harmonization workshop in which 31 participants (11 female and 20 male) were involved representing 12 organizations, including one private research institute. These included research directors or vice executive deans for research (n=9), regulators (n=2), NRERB members (n=3), IRERC members (n=9), principal investigators (n=3), senior trial manager and coordinator (n=2) and representatives of the ACT (n=3).

Main discussion themes

Five main themes emerged from the discussions: i) the conceptualisation of harmonization, ii) current approval pathway, iii) regulatory challenges, iv) opportunities for improvement, and v) proposed solutions.

Theme 1: Conceptualization of harmonization

Participants emphasized the critical role of harmonization in enhancing Ethiopia's clinical trial ecosystem. They highlighted the necessity for a clear and shared understanding of harmonization, which would support consistency and quality across institutions involved in clinical trials.

The group agreed that harmonization entailed the adoption of standardized procedures. Harmonization was described as a system where ethical and regulatory standards for clinical trials are aligned and consistent across institutions with the authority to review and approve trial applications. It was noted that standardizing review procedures across institutions, defining consistent timelines, clarifying roles among the various parties (Ministry of

Education, the NRERB and IRERCs, etc.), and establishing joint protocol review mechanisms were critical priorities. The broad agreement was that harmonization should include joint monitoring, which may also serve as a capacity-building opportunity.

Theme 2: Current Approval Pathway

The existing approval process is sequential involving multiple institutions, and multiple reviews, wrought with back-and-forth feedback and responses (Figure 2).

The request for approval at some Academic Institutions often commences at the department level, with the Department Scientific Committee (DSC) tasked with the first review. The DSC refers the protocol to the IRERC, which in turn refers to the NRERB. The NRERB reviews the protocol afresh, and once all reviews are accommodated to its satisfaction, the NRERB forwards the protocol to the EFDA, which carries out both ethics and regulatory review and approves the application. But the process does not necessarily end once the EFDA approves. If other independent institutions, other than the primary applicant are involved, each institution's scientific or IRERC reviews the protocol again. Typically, all additional institutions do the same. If new changes to the protocol emerge in the new review process, additional amendment approvals would have to be sought. Often, it is more complicated when international trials are considered. Although the overall process is similar, approvals from international partner institutions must be submitted to the IRERC along with the application.

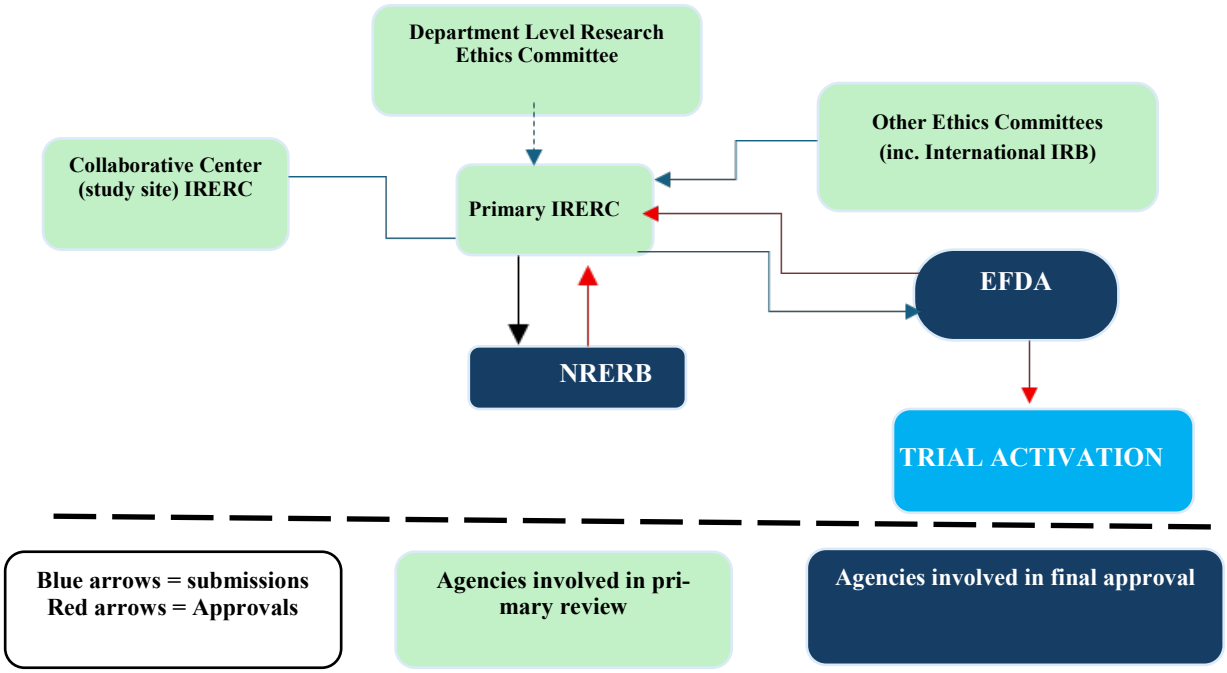

Figure 2 Approval process of clinical trials when multiple independent institutions, including international partners, are involved.

Theme 3: Challenges to harmonization

These include capacity constraints faced by investigators, ethics review bodies and regulatory authority. The lack of operational guidance was also an important challenge. Policy-related issues were also discussed, with particular concern regarding the blanket exclusion of certain vulnerable populations, such as children, from clinical trials. It was clarified that 'appropriate justification' was needed to include children in clinical trials.

The issue of capacity was mentioned as particularly important in the context of the seriousness of clinical trial approval. It was considered important that all the IRERCs be competent in evaluating clinical trials so that the delegation of responsibility considers the due diligence required. A strong accreditation and registration system, already proposed by NRERB, was considered critical. It was also suggested to assess a random sample of protocols and evaluations from different institutions in order to understand the needs and establish informed basis

for interventions. Some IRERCs do not follow the national guidelines consistently causing harmonization challenges. Lack of predictable financial support mechanisms with current arrangements relying on external funding limits oversight and support engagements as well as capacity building. The lack of operational guidance, specifically on how harmonization may be initiated, for example, who should start it and lead it, is unclear. Criteria for harmonized consideration, e.g., for which types of clinical trials it will be applicable, are not outlined.

The exclusion of children and pregnant women was considered an important policy challenge, at least from the perspective of investigators. However, this was clarified by EFDA that the existing policy does not exclude vulnerable populations per se. Similarly, the approval processing fee by EFDA was considered a barrier for locally initiated clinical trials. Although this was a legally mandated provision, it was mentioned that a provision for waiver of fee was in place, as has been the approach during the reviews of COVID-19 trial protocols. Whether this waiver could be applied to locally initiated trials was raised.

Theme 4: Opportunities for Improvement

There was a clear recognition of the challenges and determination to introduce changes across all stakeholders, especially institutions tasked with leading and implementing improvement efforts. There was already an experience sharing opportunity of the Ethiopian regulatory team with the Ugandan counterpart, which has already developed a system, including a joint review guideline. This was considered an important resource and can help shape or support the development of Ethiopia's joint review and harmonization guideline. Significant progress has already been made to upgrade the regulatory maturity of EFDA, with the expectation that it will reach Maturity Level 3 soon[1]. EFDA has increased the number of its staff with relevant professional mix and is also working with AVAREF to advance its systems, including opportunities for joint reviews. Many opportunities for capacity building also exist. For example, NRERB has received external funding to support regulatory and ethics review capacity. CDT-Africa has advanced training programmes, including accredited MSc in Clinical Trials and an advanced short course for the clinical trial operation (ClinOps) program. Other institutions also have various capacity-building platforms, which need to be mapped and made available for all.

Furthermore, there are advanced efforts by NRERB to digitize the protocol submission and approval process. NRERB has also formed technical committees and a manual for accreditation of IRERCs. It also plans to transition its focus from review to monitoring and capacity building of IRERCs. For the transition period, NRERB's subcommittees such as the CT Expert Review Panel (CTERP) and Research Ethics Review and Oversight (RERO) will assist the review.

Theme 5: Strategic Recommendations for Harmonization and Strengthening Ethics and Regulatory Approval Procedures

Key recommendations to support regulatory and harmonization procedures, and strengthening the broader ethics and regulatory ecosystem included offering clear role delineation for the various approval agencies, accreditation and registration of ethics committees, integrated capacity-strengthening initiatives, decentralization of approval processes with proper oversight, and pooling of resources for shared achievement of goals. Interagency and interdisciplinary entities such as the ACT may play an important facilitative role. Details of the recommendations are summarized in Box 1.

Discussion and Conclusion

Clinical trials are not a luxury – they improve the quality of patient care, enhance the skills of practitioners, offer opportunities for the introduction of new and improved therapeutics and may also lead to system and infrastructure improvements. For Ethiopia to actively contribute and benefit from clinical trials, a broader effort to improve the clinical trials ecosystem is underway. Perhaps, the most important is the concerted engagement to harmonize the ethics review and regulatory processes. Harmonization of ethics and regulatory procedures with clear frameworks is an urgent priority to ensure timely implementation of clinical trials in Ethiopia. Coherence is required within the national system and with regional initiatives. The African Vaccine Regulatory Forum (AVAREF) supports regulatory harmonization by providing standardized tools for assessment, joint reviews and inspection. The African Medicines Regulatory Harmonization Initiative is another important undertaking that supports regional harmonization. Important regional harmonization challenges also need to be considered as highlighted in this special issue (9).

Strengthening the regulatory and ethics approval systems does not respond to all the gaps in the clinical trials ecosystem but is a rate limiting step in trial implementation and quality. In the context of the growing national and regional opportunities, the time to implement harmonized solutions is now. As a multi-disciplinary and multi-institutional forum, the ACT offers a neutral platform for facilitating discussions and expedited follow-ups although the ultimate responsibility rests with the national regulatory authority (EFDA) and the national ethics review board (NRERB). Although the necessary precautions must be implemented, the tendency to apply overly restrictive standards among special populations (10, 11) needs addressing through legislative clarifications and trainings.

1Since the workshop, Ethiopia has achieved Maturity Level 3 in its medicine regulatory functions (Ethiopia achieves major milestone in medicines regulation reaching WHO Maturity Level 3

Box 1: Summary of recommendations

- Standardize review procedures across IRERCs and institutions.
- Establish a joint protocol review mechanism (currently EFDA is finalizing reliance and Joint Review Guidelines which will include provision for establishing procedure with NRERB, other NRAs and other regional bodies.)
- Clarify roles and harmonize activities between EFDA, NRERB, IRERCs and trial site ethics entities.
- Set consistent timelines for protocol approval – this should not exceed 60 days.
- All IRERCs that review clinical trials should be accredited.
- Multicenter trials should be submitted directly to the national board for approval. If role of NRERB changes, a primary accredited IRERC should be delegated to provide the review. Alternatively, there should be a reliance mechanism between IRERCs where the approval/decision of one IRERC is accepted by other IRERC.
- Establish a monitoring and feedback mechanism for IRERCs and Investigators.
- Ensure consistent implementation of the national guideline for ethical review of research protocols.
- Standardize protocol submission forms, review fees and standard operating procedures, based on national guidelines.
- Provide standardized training for all IRERCs involved in clinical trial review and oversight.
- Pre-submission engagement with relevant IRERCs and other relevant agencies.
- Leverage and harmonize capacity building platforms.
- Revise and standardize review and oversight fee based on the nature of the study, for example associated risks and oversight needs.
- Organize annual meetings of key stakeholders of clinical trials.
- Organize follow up meetings through a common platform, such as the ACT, to facilitate the process.

International clinical trials present particular challenges. Specific recommendations have been put forward to facilitate such trials(12). These include the single research ethics committee (REC) model, which advocates for a single REC per country that streamlines decisions for multi-country trials. A pre-submission engagement is also recommended. This calls for early involvement and joint meetings with regulators to resolve any ethics concerns upfront. It also calls for well-funded capacity strengthening by employing full-time or adjunct REC staff in LMICs to support timely and quality reviews.

The paper should be read within the context of important limitations. First it is based on two workshops. Secondly, the views expressed may have institutional biases, such that some of the recommendation may reflect such biases. Thirdly, clinical trial participants and industry were not included. However, the harmonization workshop marks a significant milestone. Prompt follow-up and implementation of the recommendations (Box 1) should be prioritized. Leveraging the commitments and achievements of the regulatory authority and national research ethics review board, pulling together resources, adapting tools, and strengthening accountability mechanisms will enhance the advancement of both clinical trials and the broader health system opportunities.

Author's contributions

AH and AF drafted the manuscript. AH, EM, YW, SM, KH, RB, MD, AE, AT and AF contributed to the conceptualization and reviewed the final version of the manuscript. All workshop participants contributed to the discussions.

Appendix 1: Workshop participants

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