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Original Article

Clinical Trials Ecosystem in Ethiopia: A Qualitative Study of Stakeholder Views on Strength, Opportunities, Challenges and The Way Forward

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Abstract
Background: *Ethiopia's participation in clinical trials remains low. This study aimed to investigate the challenges and opportunities associated with conducting clinical trials in Ethiopia.*
Method: *This study employed a qualitative, exploratory design. Seventeen purposively selected clinical trial stakeholders participated: clinical trial investigators (n = 6), ethics review board members (n = 8), regulatory authority officials (n = 2), and an insurance company officer. Data were collected through in-depth interviews, which were audio recorded, transcribed, and analyzed thematically.*
Results: *Four themes were identified: (1) system of protocol approval, (2) investigator motivation, strengths, and opportunities, (3) challenges, and (4) recommendations on improving the clinical trial system. The potential impact and opportunities of clinical trials were the main motivating factors for investigators to engage in clinical trials. The availability of trial sites, patient recruitment potential, and recent interest of insurance companies were mentioned as the main opportunities. There was a bigger preoccupation with the challenges, and five groups of key challenges for conducting clinical trials were identified. These included the limited financial, infrastructural, and human resources, leading to a slow trial approval process. Investigator-related factors, including incomplete submissions, low protocol quality, delays in responding to reviewers' comments, and engagement in high-risk trials, were also identified.*
Conclusion: *Ethiopia offers promising foundations and opportunities for conducting clinical trials. However, many challenges prevail at every level. To harness the opportunities, stakeholders need to address the main challenges, namely addressing structural issues (resources, infrastructure, and harmonization) at both national and institutional levels, speeding up the approval process, and building broader clinical trials capacity.*

Keywords*: Clinical trial, Challenges, Opportunities, Clinical trial ecosystem, qualitative, Ethiopia*

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Introduction

Clinical trials are critical for establishing a high-quality evidence base for clinical practice, health system improvements, human and infrastructure development in healthcare, and rational allocation of resources (1). The global importance of expanded clinical trial capacity, as well as its challenges, was demonstrated during the recent COVID-19 pandemic. While the pandemic required large-scale trials and partnerships with new approaches, such as decentralized clinical trials (2), clinical trial quality and coordination were challenged (3). The pandemic also exposed the glaring inequity where the fragile healthcare system, poor infrastructure, and limited human capacity meant the limited participation of low-income countries in clinical trials (4). Participation of low-income countries in drug and vaccine trials, as well as compliance of studies from low-income countries with regulatory requirements, was significantly low (5). Despite such challenges, the pandemic has prompted countries and regions to prioritize ensuring sustainable access to healthcare, including improvements in clinical trial ecosystems. The relevance of regional entities, such as the African Medicines Regulatory Harmonization, has been enhanced. In individual countries such as Ethiopia, there have been attempts to expedite ethics and regulatory approvals in response to the pandemic.

Beyond the opportunity to close contextual evidence gaps often overlooked by international clinical trial undertakings (6), clinical trials provide opportunities to uncover the varying effects of interventions arising from genetic, environmental, nutritional, or biological strain variations (7, 8). The economic capacity of these countries demands robust evidence for affordable health services and interventions (9). Infrastructure and human capacity advancement prospects could also serve as a catalytic role in developing institutional research capacity (10). In addition, while not a priority, the growing expansion of international sponsors and the pharma industry has economic repercussions. The estimated median cost of trials in the United States generally ranges from $3.4 million (for Phase I) to $21.4 million (for Phase III) (11). The positive effect on human health expenditure savings on society will also be reflected in the national economy. In a study conducted in the United States, the projected net benefit to society from only 28 Phase III trials within a 10-year period was $15.2 billion (12).

Ethiopia is one of the most populous countries in the world, ranked 10th globally and 2nd in Africa, representing 1.62% of the global population and 8.6% of Africa's population (13), with an increasing burden of communicable and non-communicable diseases. However, engagement in clinical trials in Ethiopia remains very low (14, 15). Most clinical trials in Africa are conducted in Egypt and South Africa (16). The reasons for this low rate of clinical trials in Ethiopia have not been explored adequately. In recognition of this, the Advisory Committee on Clinical Trials (ACT) recommended a study to evaluate the existing clinical trials ecosystem, aiming to facilitate an informed discussion and recommendations that would accelerate improvement in the clinical trials ecosystem. ACT was established four years ago to identify the critical gaps and barriers for the conduct of clinical trials and explore ways to improve the clinical trials ecosystem in Ethiopia. The Centre for Innovative Drug Development and Clinical Trials for Africa (CDT-Africa), as a regional medical discovery centre and committed to clinical trials, has taken responsibility for facilitating the establishment and operation of the ACT. Thus, this study aimed to explore the systemic challenges and opportunities of conducting clinical trials in Ethiopia, with the goal of proposing practical solutions.

Materials and methods

Design

A qualitative study employing a phenomenological approach was conducted to explore the system, challenges, and opportunities of conducting clinical trials, examining the experiences of investigators, ethics committees, regulatory authorities, and the insurance industry.

Study settings

The study was conducted in Addis Ababa and regional states with major clinical trial activities (Gondar and Jimma University). Addis Ababa is the capital city of Ethiopia, where national clinical trial oversight bodies and accredited Institutional Research Ethics Review Committees (IRERCs), including the National Research Ethics Review Board (NRERB), are found. The study was conducted from December 2019 to January 2020.

Sampling technique and participants

Participants were purposively selected to include experts from the WHO/SIDCER recognized IRERCs (College of Health Sciences-Addis Ababa University (CHS-AAU), Armauer Hansen Research Ethics Committee (AHRI), and the Ethiopian Public Health Institute (EPHI)), National Research Ethics Review Board (NRERB), the Ethiopian Food and Drug Au-

thority (EFDA), clinical trial experts, and the insurance company. Two participants were included from each research ethics committee and regulatory body. Investigators who have been involved in at least three clinical trials and an insurance company that has recently initiated a pilot service provision were included. The number of participants was determined based on representation and the number needed to achieve theoretical saturation.

Data collection

Specific semi-structured topic guides were prepared for each group of participants. The topic guides explored key questions, including the clinical trial approval process, opportunities and challenges associated with conducting clinical trials, and potential solutions. In-depth interviews were conducted with each participant in Amharic, one of the official working languages of the country. Three experienced researchers (MM, MS, and MM) with backgrounds in clinical trials and qualitative research carried out the interviews. Interviews were audio-recorded and transcribed verbatim for analysis.

Data analysis

Thematic analysis of the data was employed. Initial codes were generated independently by two coders (MS and MM) using two selected transcripts. OpenCode software was used to assist in the analysis. Emerging codes were cross-compared for agreement and resolution of inter-coder disagreements. The codebook was then refined, and the two coders coded the remaining interviews. Themes were created from the final codes generated, and stepwise replication was carried out. Inconsistencies that arose from these separate analyses were addressed. Thematic categories were refined, and conceptual similarities and differences were explored and synthesized. Participant quotes were used to illustrate the themes.

Ethical considerations

Informed consent was obtained after participants were informed of the study aims, the purpose of the interviews, and other elements of consent. The protocol and interview guides have received approval from the Institutional Review Board (IRB) of the College of Health Sciences, AAU (Ref. No. 067/16/Psy). The audio recorded, as well as the transcribed interviews, were identified by codes instead of personal identifiers to maintain confidentiality.

Results

A total of 17 participants were included in the study (Table 1). Among these six were clinical trial researchers; eight were institutional and national ethics committee chairs, secretaries, and members; two were from the national regulatory authority, and one was from an insurance company. Under a third were women, while just over half were trained at PhD level. Among the clinical trial investigators, six were from higher education institutions: four from Addis Ababa and two from universities outside the city. Furthermore, two participants were from research institutes affiliated with ministries. Most participants were senior scientists with a minimum of 6 years of experience, extending to 40 years. All were involved as principal investigators. Regarding gender composition, only one of the trialists was female. The representative from the insurance industry was a department director at an insurance company that had begun providing coverage for a few clinical trials.

Table 1: Characteristics of participants

Characteristics	Number	Percent
Sex		
Male	12	70.6
Female	5	29.4
Qualification		
MD	2	11.8
MSc	6	35.3
PhD	9	52.9
Years of Experience		
1-5	5	29.4
6-10	5	29.4
11-15	3	17.7
15+	4	23.5
Role		
Clinical Trial Researcher	6	35.3
Ethics Board Member	8	47.1
Regulatory Agency	2	11.8
Insurance Company	1	5.8

Four themes were identified: The overall clinical trial approval and regulatory system, Aspirations and opportunities, Challenges, and Recommendations on the way forward.

Theme I: The overall clinical trial approval and regulatory system

The overall clinical trial approval and regulatory system was related to the mandate of approval agencies, level of approval, and procedures (Figure 1). The approval process involves three layers: Institutional Review Boards (IRB)– often preceded by department-level approval and referral – the National Research Ethics Review Board (NRERB), and regulatory approval by the

Ethiopian Food and Drug Authority (EFDA). In terms of scope, while IRBs review all types of studies conducted in their respective institutions, the NRERB is mandated to review institutional or non-institutional studies involving multi-center collaborative studies, clinical trials, genetic research, and studies that require the transfer of biological material.

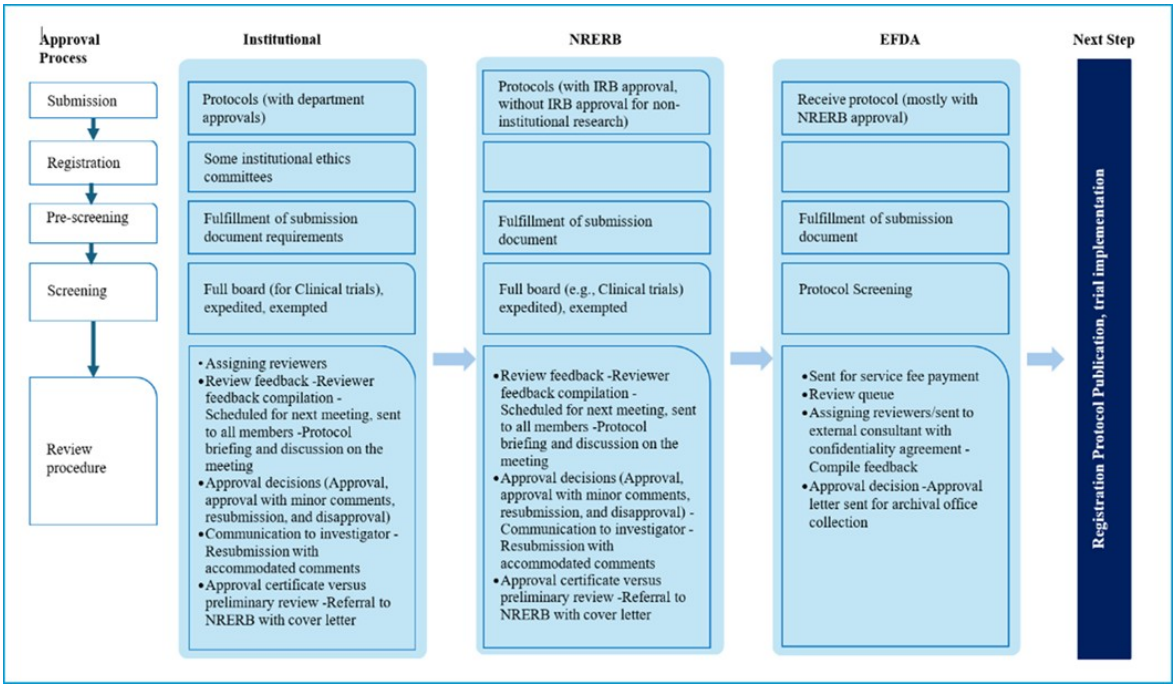

Figure 1: Clinical trial approval levels and processes in Ethiopia. NRERB = National Research Ethics Review Board; EFDA = Ethiopian Food and Drug Authority; CT = Clinical trial

The EFDA is legally mandated to provide oversight of all clinical trials involving investigational products. These include providing approval for trial protocols, monitoring/inspection of trial site, suspending or terminating trials which have safety concerns/violations, and requiring periodic/event-based/closeout reports for all. The IRERC is also mandated to conduct preliminary review, approve protocols, and follow up on adverse events. On top of these activities, EFDA is further mandated to approve investigational product (IP) importation, monitor IP disposal, and evaluate clinical trials result before dissemination, while NRERB is further mandated to approve the transfer of biological material.

The most extended time period indicated in the guidelines for obtaining clinical trial approval is 60 days for most IRERCs and NRERB, and 90 days for EFDA. However, from their experience, investigators noted that the minimum approval duration was six months.

Investigators described the approval process as follows.

> "*The ethical approval works at different levels. As to my experience, the process begins at the institute level then to science and technology, and finally to EFDA ...the process almost took six months...it is all about identifying the requirements and fulfilling what is needed but there are some challenges.*" CTI 002

> "*...the whole process... [the] hierarchical nature or the steps of the approval process is cumbersome; parallel submission is not allowed as you know. Getting institutional support as well as approval is mandatory and not encouraging.*" CTI 001

Theme II: Aspirations, strengths, and opportunities

Clinical trial investigators have indicated that, although they are sometimes frustrated by the challenges they face, most aspire to continue conducting clinical trials. Factors cited to inspire them or keep them motivated were the trial process and the impact, as well as potential opportunities arising from clinical trials. These included the challenging and problem-solving nature of clinical trials; the potential to address treatment gaps; the fact that it is an intersection between research and patient care; the opportunity it presents to build capacity and to the acquisition of wholistic administrative knowledge;

the gratifying result; generation of country-specific and locally relevant evidence and its high impact in changing policy (Box 1).

''In the process of conducting clinical trials, how meticulous you should be and how every detail requires carefulness made me appreciate it. I have seen that it is different from what I have assumed at first and from other customary research'' CTI002.

a. Clinical trials' impact in changing policy
b. Clinical trials offer an opportunity to build human capital
c. The challenging nature of clinical trials, i.e., the need to be resourceful
d. The problem-solving nature of clinical trials and the potential for addressing critical treatment needs
e. The end result of clinical trials, which is the best scientific evidence ("your ability to get high-level/valuable results is gratifying")
f. An intersection between research and patient care – unlike other research methods, it provides the opportunity for clinicians to combine both clinical and research practices.
g. Opportunity for producing country-specific/locally relevant evidence
h. Exposes the researcher to multidisciplinary knowledge and holistic roles, e.g., finance, patient management, and administration.

Box 1: Factors motivating health professionals to be involved in clinical trials

The IRERCs acknowledged that securing international recognition (WHO SIDCER recognition) was an important milestone and a strength. The availability of ethics and regulatory submission guidelines, checklists, and standard operating procedures (SOPs) was also valuable support for the submission process. The motivated and committed members serving on the review process, without financial compensation, were also cited as critical inputs. Regarding their structure and functioning, most have noted that the composition and representation of board members meet international standards. One of the IRERCs has alternative committee members so that scheduled meetings will not be canceled in the absence of regular members. Some, especially IRERCs in research institutes, have strong institutional support and a well-trained secretariat. Government recognition and legal mandate of NRERB and EFDA, respectively, are cited as additional strengths of the national oversight bodies. Participants from EFDA stated that they have created the opportunity to discuss with investigators for further clarification of the protocol.

Members of the IRERCs pointed out opportunities to strengthen their capabilities. They indicated that some have secured grants for capacity building, established connections, or collaborated with IRERCs in other countries. EFDA has already established a separate directorate for clinical trials and pharmacovigilance, consisting of two distinct units for each. The initiation of training on clinical trials at the master's level by AAU was also mentioned as an opportunity. The investigators noted that they had no trouble finding trial sites or facing issues related to patient recruitment. The insurance company representative mentioned that the insurance industry has only recently recognized the business opportunity for providing insurance coverage for clinical trials. However, one reason for the delay in protocol approval is the lack of insurance coverage. Researchers typically purchased insurance coverage from outside Ethiopia. Following recent engagement with insurance companies, researchers have begun to procure coverage within the country.

Theme III: The challenges

Regardless of the investigators' motivation for involvement, the process of conducting clinical trials was regarded as very challenging. There was considerable agreement among investigators on the types of challenges described. The ethics committees, as well as the regulatory authority, described challenges encountered in protocol review and oversight from their end. These challenges are related to human resources, financial resources, infrastructure, institutional/administrative factors, and researcher factors.

Human Resources: From the perspectives of the

ethics committees and the regulatory body, one of the main challenges raised was the shortage of human resources, particularly in terms of reviewers for protocol reviews and conducting regular monitoring and inspections. Occasionally, an expert might be requested to review the same protocol at different tiers of the ethics approval process. The number of secretariat staff was also noted to be not proportional to the workload. For example, one of the IRERCs is staffed by one full-time secretariat personnel. A shortage of human resources was also stated to be a significant challenge for EFDA, the department responsible for authorizing clinical trials, with limited number of professionals assigned to two major case teams (pharmaco-vigilance and clinical trials). Time was cited as the most significant factor contributing to the shortage of reviewers.

> "*Reviewing takes a lot of time and so we take our spare time...for me, I always need extra time to read or review a protocol. Since I don't have a dedicated time for my* IRERCs *related duties I am always obliged to use after hour ... that is the same for all reviewers*." ECC001

Generally, inadequate capability for reviewing clinical trials was an overarching challenge. Participants also noted the high demand for reviewers in some specialties leading to a higher workload on reviewers working in these specialties. Participants also expressed the difficulty of finding chairpersons for review boards due to the demanding nature of the position.

The absence of a dedicated secretariat team was a common issue at the national level. Consequently, a clinical trial is just one of the many competing tasks the team must manage. Although one of the institutional review boards noted that they have a dedicated secretariat, the individual is employed by a capacity-building project, raising questions about sustainability. They also struggle to hire experienced and competent individuals for the demands of the ethics review process, leading to inadequate decision consolidation, insufficient follow-up from reviewers, and widespread delays in convening meetings.

> "IRERC *without a good secretariat is weak and inefficient in a sense that you know as an investigator when you visit the office there should be somebody to discuss to and give appropriate information when you submit your protocol ....in addition, someone who is capable of communicating reviewers' feedback"* ECC01

Frequent staff/secretariat turnover and the inability to build the capacity responsive to the frequency of staff replacement is a shared challenge both from the oversight bodies as well as the investigators.

> "*There is a very high staff turnover in our* IRERC *staff, when we go to the* IRERC *office to check the progress of our protocol review, we will not find them...most of the time we will get their telephone number from the former staff...and you are supposed to explain your case many times*" CTI005

A substantial staff turnover in site clinicians is also reported by the investigators. Due to this challenge, most are obliged to hire their site clinician for the clinical trial period. The turnover necessitates training in Good Clinical Practice (GCP) multiple times during the clinical trial period.

Financial Resources: Typically, the budget is allocated by the government; however, there are IRERCs without institutional funding, and in some cases, the allocated budget is inadequate. This results in a lack of capacity to run the IRERC smoothly, including the inability to conduct site visit monitoring. There are also cases in which the allocated budget is not utilized. In the case of the EFDA, evaluation fees are collected, which were deemed necessary for contracting external consultants.

Infrastructural: Almost all have reported inadequate working space or archival space. The trial site challenge is also shared by most, particularly the space in health facilities. Occasionally, the distance of the field study site from a general hospital was mentioned as a challenge to handling adverse events. All use private laboratories for most of their tests due to noncompliance and the low interest of governmental institutional laboratories in carrying out GCLP-compliant tests.

Institutional and administrative: Participants described limitations related to an underestimation of the role of ethics committees as well as demands of trial-related tasks by leaders of institutions and higher officials, which leads to poor attention to tasks related to clinical trials. The issue associated with incomplete structural transitions during restructuring was also raised. This resulted in the sharing of resources, the loss of experienced staff and accumulated expertise, and an incomplete transfer of databases, such as identifying suitable reviewers for a particular protocol. The latter resulted in overburdening of chairpersons with consultation for many cases. Inefficiencies of the administrative procedures were cited by almost all respondents. From the insurance industry perspective, the insurance company representative stated that clinical trial has yet to be identified as an industry track, although there is a lot that the industry could benefit from.

> *"I was very much surprised when the doctor said they are buying insurance coverage from foreign countries...when they asked other insurance companies, they have not even heard the name [clinical trial]…. We are losing a big opportunity, and this is embarrassing as a country."* INS001

Researcher factors: Several factors related to researchers were identified as contributing to the delay in protocol approval. These included: incomplete submission, i.e., failure to comply with submission guidelines which relate to experience in submitting protocols; substandard protocol quality; mistimed protocol submission as the review process is highly dependent on regular meetings; the late response of researchers to feedback; and uninformed expectations from the investigator's side i.e., researcher's underestimation of time required for ethics approval. Some researchers are also involved in sponsor-driven trials designed without consideration of the risk-benefit ratio. In multi-country or multi-institutional research, slow approval from partner institutions can also delay approval.

Theme IV: Recommendations for the way forward
Several recommendations addressing factors that delay approval, related to IRERC/regulatory authorities, investigators, and resources, were suggested (Box 2).

Further specific recommendations were made to strengthen the structure of the NRERB by establishing a council or national task force backed by legal frameworks that enhance accountability at a higher level. A revision of NRERB guidelines to address emerging areas of research was also recommended. Regarding the EFDA, specific recommendations included adjusting the regulatory service fee, particularly for nationally initiated studies. An additional suggestion was to establish a senior independent advisory committee or consultants, whose technical expertise can be utilized for certain research areas beyond the capacity of regulatory experts. Recognizing it could be a significant service area with great potential, involving the insurance industry as a stakeholder and enhancing its capacity regarding clinical trials and risk assessments were recommended.

Box 2: Recommendations for improving the clinical trial ecosystem, focused on ethics and regulatory approval processes

- Strengthen ownership: Better sense of ownership by institutional leaders, including providing for a dedicated secretariat; improving physical and IT infrastructure; ensuring adequate institutional budget allocation for review committee functions.
- Establish Registry System: Setting up a web-based national clinical trial registry system.
- Implement Interventions: Conduct gap analysis and implement specific interventions with each stakeholder.
- Build Reviewer Capacity, Particularly in Emergent Areas of Clinical Research and Ethics.
- Incentivize Reviewers: Time compensations, considering review as teaching load, certification, training
- Harmonize approvals: Harmonize ethics and regulatory approvals to eliminate redundant approval processes—Capacitate IRERC to complete ethical approvals, with NRERB assuming an oversight role. As an independent entity, the Advisory Committee on Clinical Trials (ACT) can facilitate such harmonization.
- Conduct Self-Audits: Practice of regular internal self-auditing
- Enhance Communication: Improve communication and information exchange among various stakeholders. Advocacy and awareness creation among institutional leaders and the government. Platforms, such as the ACT, and regular celebrations of International Clinical Trials Day, as well as AHRI's Clinical Trials Net-

Discussion

The ground for conducting clinical trials in Ethiopia appears to be fertile, as indicated by the enthusiasm and aspirations of investigators and representatives from the IRERC and regulatory authorities. The major stakeholders of clinical trials have also identified many strengths and opportunities in the clinical trial system. Strong IRERCs with international recognition is encouraging. Dependable IRERC also eases the burden at higher levels and shortens the overall approval time. Investigators appreciated opportunities for patient recruitment and retention. Although the system was overall considered well-established, it has many challenges and would benefit from improvements. Marked challenges related to human, financial, and infrastructural resources were noted. Institutional factors and those related to researchers were also pronounced.

Challenges related to funding constraints, insufficient incentives, limited capacity-building opportunities, deficiencies in human resources, materials, and infrastructure, along with weak regulatory and administrative systems, have resulted in delayed approvals, complex oversight, and administrative inefficiencies (17, 18). Recommendations made were mainly capacity building, knowledge sharing, experience exchange, networking, collaboration, and prioritizing research systems (17). As the sample of investigators enrolled in our study consisted of investigators, reviewers, and regulators with vast experience in clinical trials, a lack of awareness, confidence, and motivation didn't arise in our study. However, considering the time gap between our study and these two previous studies (17, 18), the similarity of challenges identified signifies unresolved long-standing issues.

There is also a similarity in some of the significant identified barriers and facilitators of clinical trials in Ethiopia such as underdeveloped research infrastructure, workforce capacity, low prioritization, limited funding, and staff turnover, with other study reports (19). Experience of challenges related to recruitment and consent has also been reported. Nonetheless, none of the investigators in our study identified this as a challenge. Availability of patient pool and ease of recruitment were, in fact, identified as an opportunity for conducting clinical trials in Ethiopia, similar to other studies conducted in other developing countries (20). There is also a clear need for building the capacity of investigators. One of the challenges identified in the quantitative research (21), is the low intensity of engagement of clinical trial investigators. Having highly qualified investigators, who are intensely engaged in clinical trials, may have a transformative impact on the national clinical trial landscape.

Due to these many challenges, the progress of clinical trials in Ethiopia has been slow. In a study conducted in 2016, the number of registered studies from Ethiopia was 145 (22).

The number has increased since, though the growth is well below the potential of the opportunities available for Ethiopia. Despite some African countries showing higher participation in clinical trials, the challenges faced by trialists across Africa are shared and reflected in the findings of this study (23-26). However, continental initiatives such as Africa's commitment to local manufacturing of essential health products (27), regional harmonization (24, 28, 29), and efforts to enhance regulatory systems (30, 31) should improve the clinical trials ecosystem. Moreover, the potential benefits offered by clinical trials for improving the standard of clinical care, attracting investment, and contributing to economic growth should not be overlooked by government officials.

Several limitations must be considered when reading this report. First, the number of participants, given the diversity of stakeholders, is limited. For instance, pharmaceutical companies or stakeholders from the private health sector were not involved. This may have restricted the range of opinions and recommendations. The team coordinating the study is working diligently to improve the clinical trial ecosystem. This goal may also have introduced biases. The differing motivations of respondents, such as ethics board members, researchers, and regulators, were not explored adequately.

Conclusion

Clinical trials, corresponding to the complexity and the strength of evidence they provide, rely on interconnected processes, systems, and stakeholders. This study has explored the ecosystem of clinical trials, examining the overall system's strengths, opportunities, challenges, and recommendations for the way forward, based on the experiences of key clinical trial stakeholders. The insights can be beneficial for building on existing strengths and opportunities. One of the critical issues that needs to be tackled as a priority is the lack of overall leadership in the field. While some institutions have attempted to fill the gap, this has not been a mandated responsibility. For instance, as a multi-institutional entity focused on enhancing the clinical trials ecosystem, restructuring the ACT to have a delegated responsibility to coordinate the national clinical trials system will make a significant contribution to national clinical trial leadership. Building broad clinical trials capacity, speeding up the ethics and regulatory approval processes, engaging the pharmaceutical industry and Contract Research Organizations, leveraging digital technologies, and encouraging regionalization are critical ingredients for expanding clinical trial opportunities. In the context of the huge unmet health need, the rapidly growing population, and the drive for local biomanufacturing, Ethiopia can be one of the major clinical trial destinations in the world if a

holistic national engagement is assured.

Abbreviations
AAU: Addis Ababa University; AHRI: Armauer Hansen Research Institute; CHS: College of Health Sciences; EFDA: Ethiopian Food and Drug Authority; EPHI: Ethiopian Public Health Institute; GCP: Good Clinical Practice; IP: Investigational Product; IRERC: Institutional Research Ethics Review Committees; NRERB: National Research Ethics Review Board; TASH: Tikur Anbessa Specialized Hospital

Declarations
Ethics approval and consent to participate: The study was approved by the Institutional Review Board of the College of Health Sciences, Addis Ababa University (Ref No. 067/16/Psy). Prior written informed consent was obtained from the participants. Only codes were used to secure the anonymity of participants and ensure confidentiality.

Consent for publication: Not applicable

Availability of data and material: Data will be made up on a reasonable request to the corresponding author, AF.

Competing interests: The authors declare that they have no competing interests.
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Author's contribution: AF, EM, AH, YW, SMA, TT, AA, AA, and HG conceptualized the study. MM, MS, and MM contributed to the data collection and analysis. MM wrote the first draft of the manuscript under close supervision of AF. All authors reviewed the manuscript and approved the final version.

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