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Original Article

Ethiopia's Clinical Trial Landscape: Analysis of International Registry Platforms

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Abstract

Introduction: *The number of clinical trials conducted globally is increasing over the past decade. However, engagement of low- and middle-income countries (LMICs) in clinical trials remains disproportionately low. This study aims to assess trends in clinical trials registered from Ethiopia in international trial registry platforms.*

Methods: *A systematic search was conducted across three major international clinical trial registries, i.e., International Clinical Trials Registry Platform (ICTRP), ClinicalTrials.gov, and the Pan-African Clinical Trials Registry (PACTR), to identify registered trials from Ethiopia. The search results were exported in XML format and analysed using STATA version 14.2.*

Results: *A total of 489 studies conducted in Ethiopia were identified across the three trial registry platforms. Over 80% of these trials were registered on ClinicalTrials.gov and the Pan-African Clinical Trials Registry. The predominant focus of the trials was on Infectious diseases, particularly NTDs, TB, HIV and malaria, which accounted for 54.4% of the total. Trials comprising behavioural interventions constituted about 40% of the total. Most of the registered clinical trials were sponsored by local academic institutions, and early-phase clinical trials constituted 9.8% of the total registered studies. The first clinical trial was registered in 1999. However, 85.0% of the trials were registered just in the past decade, since 2015, a year marking the celebration of the first International Clinical Trials Day.*

Conclusion: *Ethiopia has made significant strides in conducting clinical trials, especially in the past decade, reflecting a growing commitment to contributing to global clinical research. However, considerable work is still needed to enhance the role of clinical trials in therapeutic advancement. To sustain and accelerate the current momentum of clinical trials, ethics committees and regulatory authorities as well as academic and research institutes have to increase their effort in partnership with relevant national and international stakeholders, particularly the industry.*

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Introduction

Conducting clinical trials in developing nations, such as Ethiopia, presents a myriad of challenges (1). These obstacles can be categorized into systemic factors, including inadequacy of institutional infrastructure; organizational set up, such as insufficient funding; and individual level factors, notably deficit of experience (2-4).

Despite the high level of disease burden, diverse demographics, and competitive operational costs (5, 6), the number of clinical trials conducted in Africa remains disproportionately low (7). While there has been a global increase in the number of clinical trials over recent years, Africa's participation remains limited. The continent, which is home to over 18% of the world's population, hosts less than 3% of global clinical trials. Projections indicate that Africa's population may reach nearly 2.5 billion by 2050, accounting for over 25% of the global populace (6, 8). This demographic shift highlights the urgent necessity for enhanced investment in clinical trials within Africa to ensure that healthcare services are adequately tailored to meet the specific needs of its expanding and diverse population.

According to Global Data, between December 9, 2012, and March 8, 2023, only 2.2% of global clinical trials were conducted in Africa. During this timeframe, a total of 5,071 clinical trials were conducted, with Egypt accounting for the majority at 2,910 trials (9, 10).

Ethiopia is the second most populous country in Africa with huge potential to advance its health systems and health product development through clinical trials. In this study, we aimed to understand this potential by systematically analysing the evolution and volume of clinical trials conducted in Ethiopia, as evidenced by clinical trial registries. Unlike previous investigations that examined the status of clinical trials within registry platforms, this study specifically focuses on interventional clinical trials (11, 12).

Methods

Search strategy

The search was conducted in December 2024, with search completed on December 18th, 2024. The search focused on three international clinical trials registry platforms although other national registry platforms were also included.

1) The ClinicalTrials.gov: the American clinical trials registry system registers studies conducted in all 50 US states and over 200 countries. This platform is one of the oldest and most well-known clinical trial registry platforms and lists studies involving human participants, addressing health-related research questions, and adhering to ethics review and other health authority regulations and laws (clinicaltrials.gov) (7).
2) The International Clinical Trials Registry Platform (ICTRP): records clinical trial data from multiple registries through an accessible search portal. This platform is the largest clinical trials registry database aggregating data from more than 16 recognized clinical trial registries (13).

3) The Pan African Clinical Trials Registry (PACTR) Portal: includes studies being conducted across Africa (14).

All the databases were searched within the same day December 18th, 2024. The search term "Ethiopia" was entered into the advanced search toolbar, and the search extended from the date when the registry became operational ending on the final search date of December 18th, 2024. The resulting data were exported to XML format. After exporting the data, we verified the presence of all data items required for a clinical trial registration. All data were then exported into STATA version 14.2 for analysis.

Data Abstraction

Data abstraction followed three steps. First, registered studies were grouped into observational and interventional studies. Secondly, all observational studies were dropped as the aim of our study was to describe clinical trials conducted in Ethiopia. Finally, interventional studies were further scrutinized to investigate if the studies were clinical trials. Only studies that fulfilled our screening criteria were included into our synthesis. We extracted data on registration period (whether registered prospectively or retrospectively), conditions or diseases addressed, the type of intervention tested, study designs, purpose of the trial, primary sponsor, institutions responsible for leading the trials and phase of the trial.

Coding of disease conditions studied

Conditions extended from childhood states to infectious diseases and system problems. Studies focusing on conditions related to children including neonates and adolescents that did not involve nutritional disorders were categorized as "Child and Adolescent" conditions. Clinical trials focussing on maternal and reproductive health, excluding aspects related to nutrition, were classified as "Maternal and Reproductive Health". Studies focusing on Neglected Tropical Diseases (NTDs) and Non-Communicable Diseases (NCDs) were coded as NTD and NCD, respectively. Other studies investigating specific diseases such as cancer, malaria, tuberculosis (TB) and HIV were categorized according to their respective disease designations. Infectious diseases not covered by these categories were classified under "Other Infectious Diseases." Additionally, studies that focused on nutritional conditions or problems were coded as "Nutritional Disorders." Disorders that did not fit into any of the specified categories were classified as "Others."

Coding the type of intervention

Interventions involving drugs, vaccines, diagnostics, and devices were coded as "Drug," "Vaccine," "Diagnostic," and "Device interventions," respectively. Studies that provided nutritional supplements were classified as "Dietary Supplement," while those focusing on health systems were coded as "Service."

Studies that focused on surgical procedures were categorized as "Surgical Procedures." Additionally, education, psychosocial interventions, exercise and interventions related to behavioural change were coded as "Behavioural and Educational interventions." Studies that involved complex interventions were coded as “complex interventions”. Interventions that did not fit into any of the specified categories were classified as "Others."

Coding of institutes leading the trial

The study registries were reviewed and institutions that were primarily involved in the study were coded accordingly. If the primary institute was not clearly identified, then affiliation of the study contacts was reviewed, and their institute was considered the leading institute. If no institute was found, then the primary sponsor of the study was considered the leading institute of the study.

Coding of Sponsor type

Studies sponsored by Ethiopian higher education institutions were coded as “local academic institution” and those sponsored by academic institutes located outside Ethiopia were coded as “global academic institutes”. Those sponsored by research institutes were coded as “research institutes”. Industry sponsored trials were coded as “industry sponsored”. Studies sponsored by non-governmental organizations (NGOs) were coded as “NGO”. Those sponsored by the principal investigators, consultant offices and ministerial offices were coded as “other”.

Coding countries of study participant recruitment

The countries of recruitment were categorized as “Ethiopia” if conducted only in Ethiopia or “Multi-countries” if the trial included other countries.

Multiple registry

In cases where studies were registered across multiple registry sites, the registry platform that recorded the study first was used for analysis, while the subsequent registries were excluded from consideration.

Data were summarised through simple descriptive analysis, including descriptive graphs.

Results

Registry and selection

As of December 2024, a total of 1,001,794 studies are registered worldwide in the ICTRP. The search results for Ethiopia yielded a total of 1,102 studies: 259 from PACTR, 297 from ClinicalTrials.gov, and 646 from ICTRP. Of the studies identified, 560 duplicates were removed, and an additional 153 studies were excluded as they were registered in multiple sites or did not contain Ethiopia as a site or were not interventional but rather observational studies. (Figure 1).

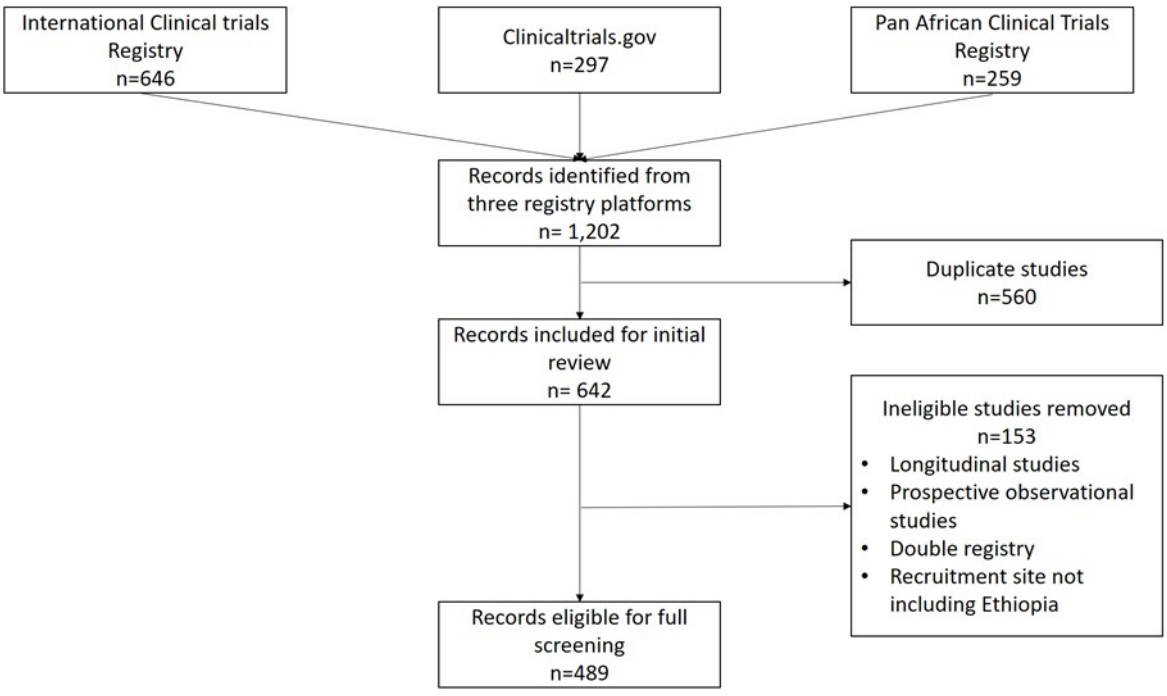

Figure 1 : Study selection flow diagram, Dec 2024

In addition to the three main registry platforms, eight additional registries were identified. However, all these studies were mostly registered on Clinicaltrials.gov and PACTR (Table 1).

Table 1: Clinical trials registering platforms, Dec 2024

S. No	Registering platform	Number of Trials Registered
1	Clinicaltrials.gov (USA)	230
2	Pan African Clinical Trial Registry (PACTR) South Africa	201
3	ICTRP	68
	Specific Registry platforms on ICTRP	
1	United Kingdom's Clinical Trials registry platform ISRCTN	34
2	Australian New Zealand Clinical Trials Registry (ANZCTR), Australia	9
3	Clinical Trials Registry – India (CTRI), India	7
4	Others	8

Others: Chinese Clinical Trial Registry (ChiCTR), China, EU Clinical Trials Register of European Union Countries, German Clinical Trials Register, Germany, Iranian Registry of Clinical Trials (IRCT), Iran, Brazilian Clinical Trials Registry (REBEC), Brazil, Thai Clinical Trials Registry (TCTR), Thailand

The first clinical trial conducted in Ethiopia was registered in 1999 (5), and since that time, the number of registered clinical trials has steadily increased (Figure 2). Between 2009 and 2014, the number of registered clinical trials remained stable, exhibiting consistent growth.

There was a notable rise in the number of clinical trials in 2014, of which 85% were registered since 2015. There was further surge, albeit modest, following the COVID-19 pandemic although this falls to pre-2020 level in 2024.

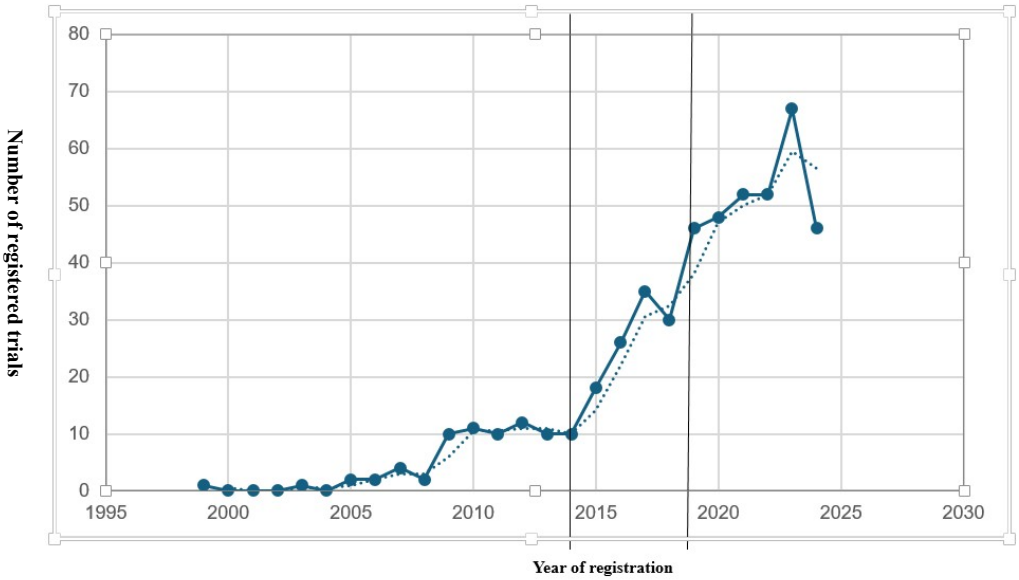

Figure 2: Number of clinical trials registered in the three registry databases by year of registration (with trend line), Dec 2024.

Origin and type of registered studies
Over three quarters of the studies (n=399, 81.6%) were carried out exclusively in Ethiopia, while the remaining 90 studies (18.4%) involved other African countries or other regions as well.

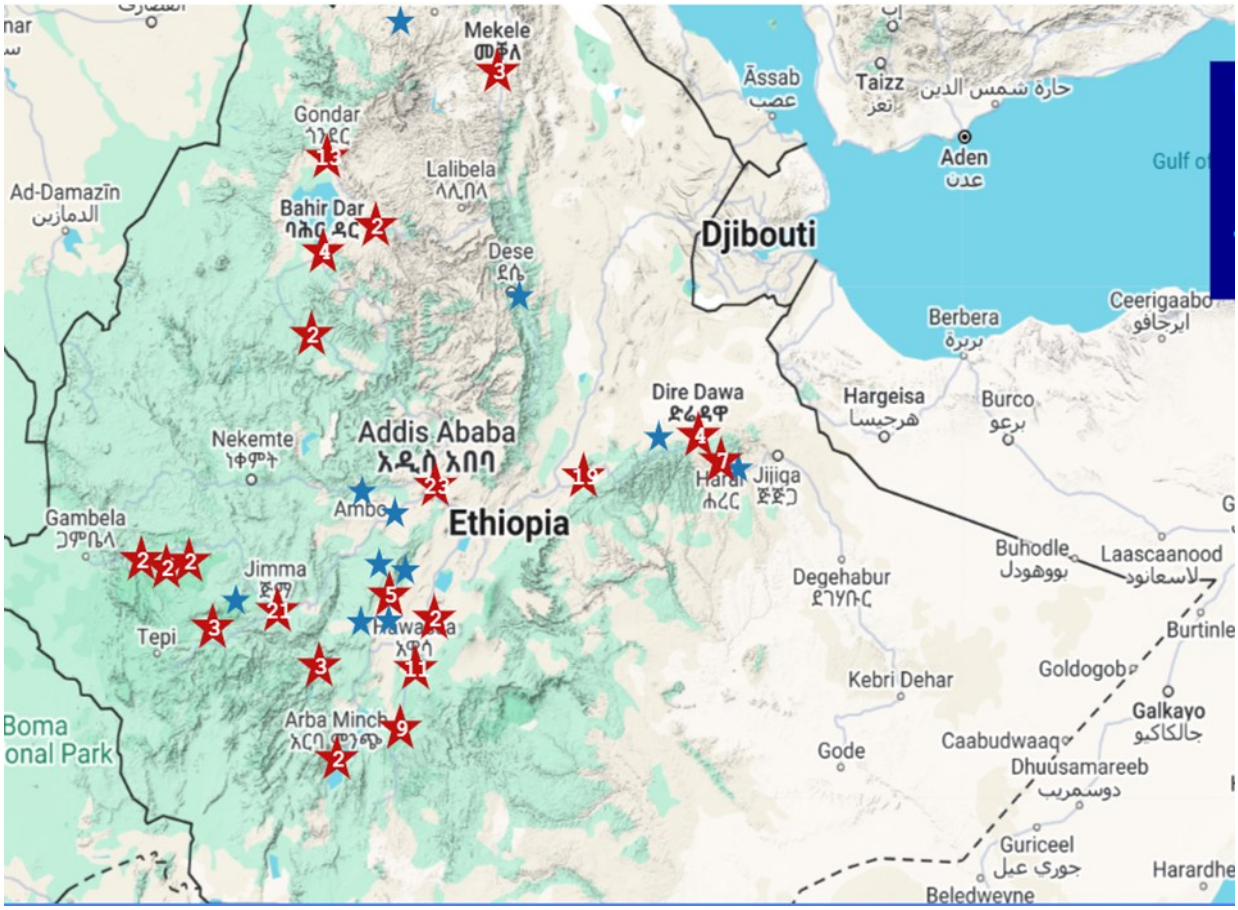

Figure 3: trial sites in Ethiopia (Source Pan African Clinica trials Registry platform https://pactr.samrc.ac.za/Search.aspx).

: Single recruitment centre,

Multiple recruitment centre

Within Ethiopia, there were over 500 recruitment sites across the country (Figure 3), with Addis Ababa University, Jimma University, the University of Gondar, Hawassa University, the Armauer Hansen Research Institute (AHRI) and the Ethiopian Public Health Institute, being the leading institutions conducting and/or sponsoring the trials.

More than 57% of the trials were registered retrospectively, and over a quarter of the trials (27.4%) included more than 1,000 participants (Table 2). The clinical trials employed a diverse range of designs, with the majority employing parallel randomized trials (n=338, 69.13%), while stepped wedge design representing under 1% of the trials (n=2).

Table 2: Characteristics of studies by registration period, study design and sample size, Dec 2024

	Number	Percent
Registration period		
Prospectively registered	207	42.3
Retrospectively registered	282	57.7
Sample size		
0-100	89	18.2
101-200	64	13.1
201-500	119	24.3
501- 1000	83	17.0
More than 1000	134	27.4
Study Design		
Parallel, randomized	338	69.1
Parallel, non-randomized	34	7.0
Factorial	53	10.8
Single Group Assignment	32	6.5
Cross-over	18	3.7
Sequential Assignment	12	2.5
Stepped wedge	2	0.4

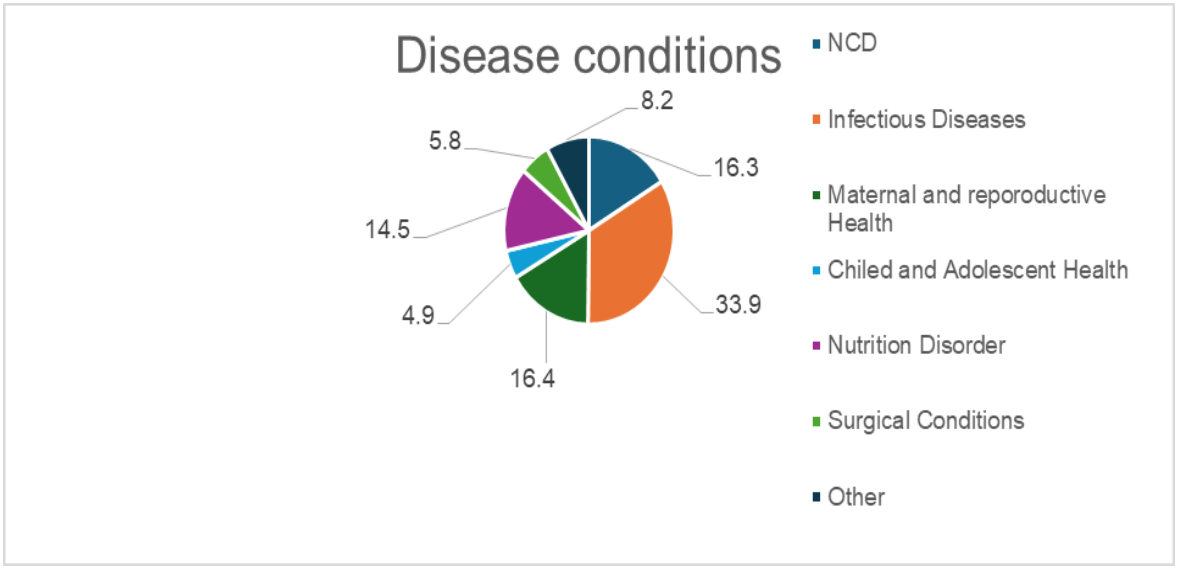

Figure 4: Summary of conditions addressed in the clinical trials, Dec 2024.

Disease Conditions

Most of the trials focussed on Infectious conditions, particularly NTDs, HIV and malaria. However, non-infectious diseases, including diabetes mellitus, and hypertension are also receiving more attention (Figure 4 and Figure 5).

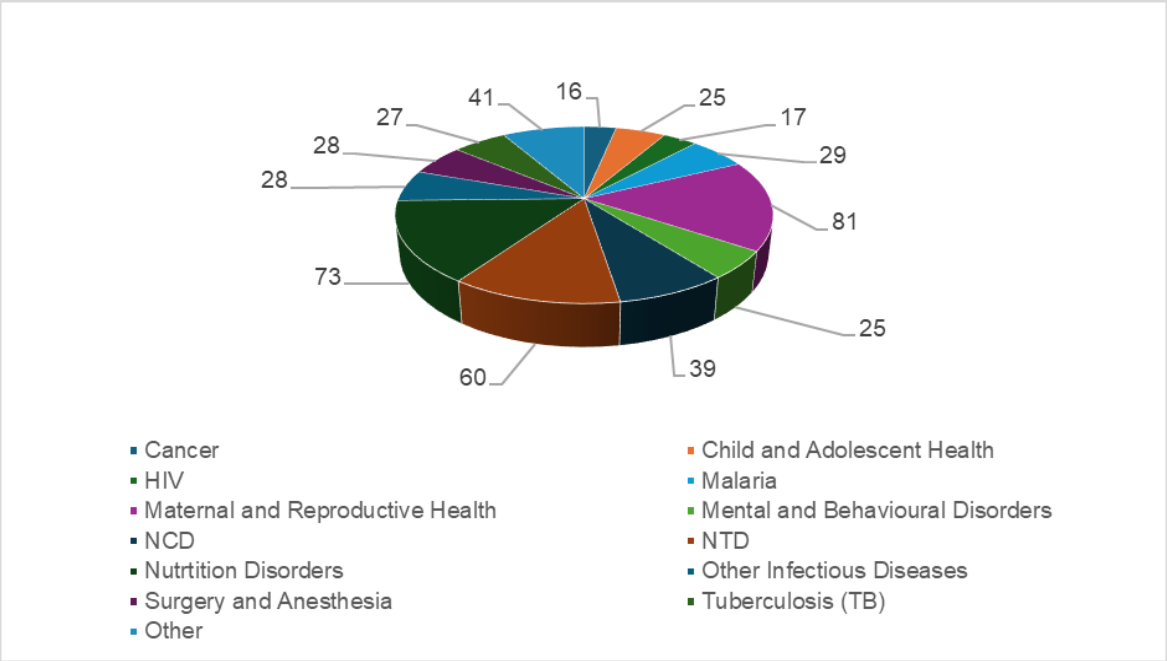

Figure 5: Extended list of disease conditions. Other=Old people, Anaemia, healthy people, No disease condition, Dec 2024

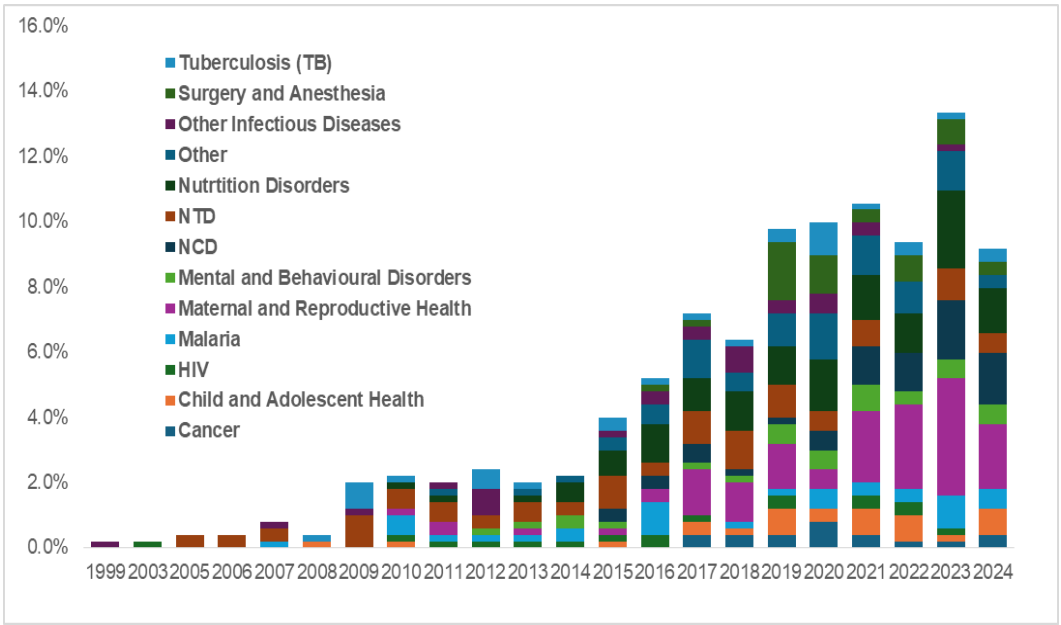

Figure 6 : Conditions registered by year of registration, Dec 2024

Clinical trials focusing on conditions such as cancer emerged in 2017, and since then, their numbers have shown a consistent increase until 2024, when there was a general decline in the registration of clinical trials. In contrast, clinical trials related to NCDs have been steadily increasing since 2019 (Figure 6).

Intervention type

Behavioral and educational interventions were the most prevalent types of interventions, followed by drug trials (Figure 7). A substantial proportion of clinical trials were designed with two primary objectives: prevention (35%) and treatment (33%). The number of vaccine trials, and diagnostic trials represented a small fraction of the total number of clinical trials: about a quarter of the trials (26.1%, n=120) were related to drugs, with 0.6% (n=3) for vaccines and 2.6% (n=13) for diagnostics. Behavioral and educational interventions focussed on nutrition-related research addressing nutritional health outcomes.

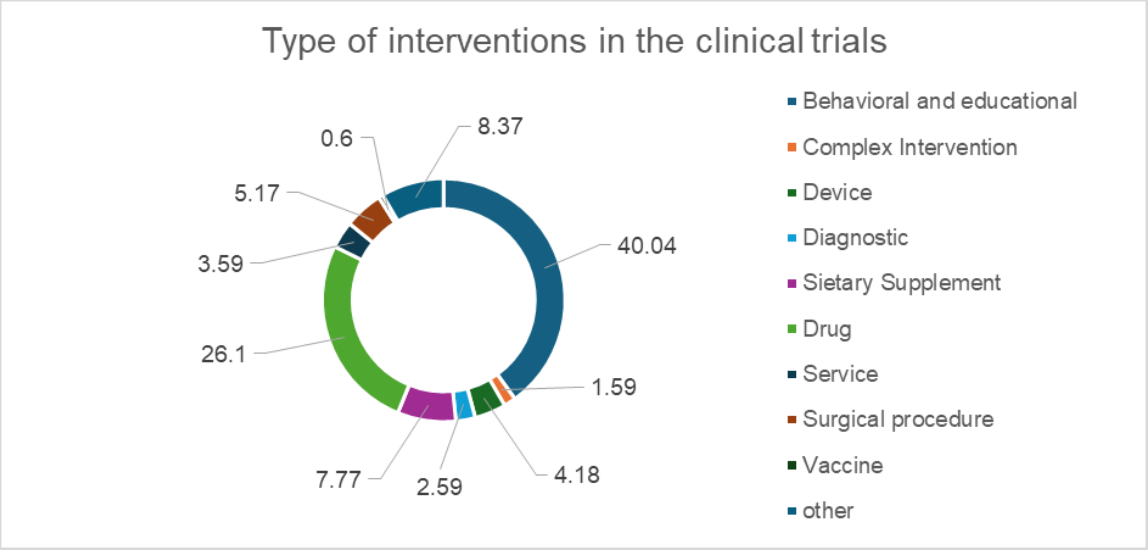

Figure 7: Type of interventions in the clinical trials presented as percentages, Dec 2024.

Other: community based TPT initiation, program evaluation, community-based demonstration, Application of mother milk on umbilical cord, Solar Water Disinfection, changing stove, wash infrastructure and education, weekly questionnaire administration

Although the majority of the trials were Phase III, 9.8% of the trials fall within the early phases (Phase 0-II). These early-phase studies included bioequivalence, safety trials, and novel entity trials among patients with cancer.

Sponsor type

Local academic institutes were the primary bodies for conducting clinical trials, accounting for more than 68% of the registered trials (Figure 3). Clinical trials sponsored by pharmaceutical companies remain limited in number. Most of the studies were sponsored by local academic institutions such as Addis Ababa University, Jimma University, the University of Gondar, Arba Mich university, Hawassa University and research institutions such as the Armauer Hansen Research Institute (AHRI) and the Ethiopian Public Health Institute.

Discussion

A total of 503 trials were identified across various registry platforms, employing diverse designs. Over 9% of these studies were early-phase investigations, with an increasing trend observed over the years. The studies were conducted at numerous recruiting centres. Trials in infectious diseases were predominant, followed by maternal and reproductive health; however, a shift overtime towards NCDs is being noted.

Most trials were registered in the PACTR and ClinicalTrials.gov, accounting for over 87% of registered trials. According to the ICTRP, Ethiopia is ranked 78th in the world and 9th in Africa in the number of clinical trials conducted, following Egypt, South Africa, Kenya, Nigeria, Tunisia, the United Republic of Tanzania, Uganda and Ghana (13).

Prior to 2014, Ethiopia had registered a total of 145 clinical trials (11). A remarkable shift occurred in 2015, with steep increase in the number of clinical trials. Although many factors are likely to have operated, it is worth noting that the first International Clinical Trials Day (ICTD) was celebrated in May 2014 (1). Despite this encouraging trend in the number of trials being conducted, Ethiopia's overall contribution to the African clinical trials landscape has shown only a marginal increase. Specifically, the country's share rose from 1.5% (1) to 1.68%, reflecting a mere 0.18% growth. This statistic suggests that while local research activities are indeed on the rise, they may not be keeping pace with the broader expansion of clinical research across the African continent. Given that Ethiopia is the second most populous country in Africa, the per capita distribution of clinical trials remains quite low. This situation highlights a pressing need for strategic interventions aimed at bolstering Ethiopia's contribution to the global clinical trial.

Ethiopia, with rich heritage of traditional medicine resources and knowledge and recognized as one of the African countries to adopt modern medical practices early (15), has paradoxically made only modest strides in the field of clinical trials over the years. With a population exceeding 130 million and making 1.7 % of the world's population (16), contributes less than 0.1% of the global clinical trials. This underwhelming figure may be attributed to a multitude of factors that impede the advancement of clinical trial within the country such as poor linkage between institutes, limited research capacity and underdeveloped research infrastructure (1, 12).

Early-phase clinical trials in Ethiopia are considerably fewer in number compared to those conducted in other African countries, such as Egypt, Kenya, Nigeria, and South Africa (12, 17, 18). Building the necessary expertise to design and conduct early phase trials effectively and strengthening infrastructure needed to conduct Phase I clinical trials is important to increase opportunities for early phase studies and health product development.

Additionally, the current landscape of clinical trials in Ethiopia reveals a notable disparity in the number of bioequivalence studies compared to other types of clinical research. However, this trend is anticipated to shift soon due to recent regulatory developments in which the Ethiopian Food and Drug Authority (19) has started pushing pharmaceutical companies to conduct bioequivalence studies prior to market entry of their products.

It is also noteworthy that more than two-thirds of the clinical trials conducted in Ethiopia are sponsored by local academic institutes. This statistic highlights a high reliance on domestic resources for clinical research and underscores the urgent need for capacity development within the country. While local institutes play a critical role in advancing clinical trials, there is an urgent necessity for increased engagement of industry and product development partners to enable genuine therapeutic advancement in the country.

In line with the evidence from this registry study, previous studies have highlighted the shift in the focus of clinical trials in Ethiopia towards NCDs (11). The surge in research related to NCDs can be largely attributed to the rising prevalence of these diseases within the country, which mirrors broader global health trends (20)

While it is encouraging to note the increase in clinical trials specifically addressing cancer, it is important to recognize that the number of these trials remains significantly lower than the actual burden of cancer in Ethiopia. This discrepancy is unlikely to be merely due to capacity or infrastructure issues, especially considering the higher the volume of cancer-related clinical trials conducted in other African nations (18, 21). Further action, including enhancing partnerships with industry, is required.
The current landscape of clinical trials in Ethiopia also reveals a somewhat worrisome trend: the number of trials focused on drug, diagnostic, and vaccine remains relatively low. Furthermore, the drug trials that do exist predominantly involve non-novel products. Integrating traditional medicine with modern therapeutic approaches may be needed.

Behavioural and nutritional interventions are commonly reported. Whether these were driven by external donor interests or prompted by national priorities is unclear.

While there is compelling evidence suggesting that Ethiopia possesses the capacity and potential for growth in the realm of clinical trials—evidenced by the increasing number of ongoing trials, recruitment sites and a few number of early phase clinical trials—the engagement of pharmaceutical companies and Contract Research Organizations (CROs) remains conspicuously limited in comparison to other African nations such as South Africa and Egypt. In these countries, a significant proportion of clinical trials—approximately 40% in South Africa (19) and between 38% to 43% in Egypt (18) -- are primarily sponsored by industry. Pharmaceutical companies heavily invest in research and development, contributing substantially to the world economy and created numerous jobs (22). Thus, this apparent disparity highlights a critical gap in Ethiopia's clinical trials landscape.

Despite having established a robust ethical and regulatory framework (1), Ethiopia faces challenges in attracting the involvement of pharmaceutical companies and CROs. These organizations play a pivotal role in the global clinical research ecosystem, not only by providing financial resources but also by fostering innovation and facilitating access to cutting -edge therapies (23). The absence of substantial sponsorship from these entities limits the scope and scale of clinical trials in Ethiopia, thereby hindering the country's ability to contribute significantly to global health advancements. To enhance the clinical research landscape in Ethiopia, targeted efforts must be exerted to engage pharmaceutical companies and CROs. This can be achieved through the development of strategic partnerships, and initiatives aimed at showcasing the country's unique potentials and disease profiles that are of interest to global researchers. It is also important to improve the clinical trials ecosystem more broadly.

The strength of our study lies in the comprehensiveness of the information gathered. We meticulously collected and verified data from each study, ensuring that all relevant details were included and accurately represented. This thorough approach not only enhances the reliability of our findings, but also provides a solid foundation for drawing meaningful conclusions.

One limitation of our study was the inability to clearly delineate the study phases due to inconsistencies across the various platforms used for data collection. Each platform has unique format, structure, and comprehensiveness. This lack of standardization made it challenging to synthesize data effectively, as specific details that were available on one platform were often missing or presented differently on another.
Additionally, we encountered difficulties with the PACTR. Navigating this registry proved cumbersome, as the interface was not intuitive, and retrieving relevant information required considerable time and effort (16).

Conclusion
Ethiopia has made commendable progress in enhancing its engagement in clinical trials; however, there remains considerable work to be done to fully realize its potential as a significant contributor to global clinical trials. To build on this progress, it is imperative to address the barriers that hinder engagement of pharmaceutical companies and CROs. Furthermore, the government should provide targeted support and incentives for academic institutes to cultivate innovation and enhance research-related activities, including training programs for researchers and streamlined processes for trial approvals. By fostering a collaborative ecosystem that prioritizes research and development, Ethiopia can improve its clinical trial landscape, but also position itself as a key player in the global clinical trials arena, ultimately benefiting public health both locally and internationally.

Abbreviations
CRO: Contract Research Organizations, ICTD: International Clinical Trials Day, ICTRP: International Clinical Trials Registry Platform, NCD: Non Communicable Disease, NGO: Non-Governmental Organizations, NTD: Neglected Tropical Disease, PACTR: Pan African Clinical Trials Registry,

Declarations
Ethics approval and consent to participate: Not applicable

Consent for publication: Not applicable

Availability of data and material: De-identified participant 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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