ADDIS ABABA UNIVERSITY

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SETTING UP CONTRACT RESEARCH ORGANIZATIONS IN SUB-SAHARAN AFRICA: CHALLENGES, OPPORTUNITIES, AND PROSPECTS; A QUALITATIVE STUDY

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LIST OF ABBREVIATIONS AND ACRONYMS

AAU	Addis Ababa University
ACRO	Association of Clinical Research Organizations
AHRI	Armauer Hansen Research Institute
ANDA	Abbreviated New Drug Application
CAGR	Compound Annual Growth Rate
CDT	Center for Innovative Drug Development and Therapeutic Trials
CRO	Contract Research Organizations
EFDA	Ethiopian Food and Drug Authority
EPHI	Ethiopian Public Health Institute
ETB	Ethiopian Birr
GCP	Good Clinical Practice
HR	Human Resource
ICIPE	International Center of Insect Physiology & Etiology
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IT	Information Technology
IRB	Institutional Review Board
MoH	Ministry of Health
MSc	Master of Science
NAHDIC	National Animal Health Diagnostic and Investigation Center
NDA	New Drug Application
R&D	Research and Development
USA	United States of America
USD	United States Dollar

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ABSTRACT

Background: A Contract Research Organization (CRO) is a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions. Africa, emerging as a powerhouse of clinical research, presents significant opportunities for CROs. Despite the benefits of CROs, there is a lack of understanding of the challenges, opportunities and prospects of setting up CROs in sub-Saharan Africa.

Objective: To explore the setting up, challenges, opportunities and prospects of CROs in sub-Saharan Africa and to suggest the way forward for improved practice.

Methods: This qualitative research used a phenomenological study design. A semi-structured interview guide was used for the in-depth interviews with 13 CRO participants from nine sub-Saharan African countries, both face-to-face and virtually. Combination of purposive sampling procedure using criterion and snowball sampling were employed for study participant selection. Data collection took place from July 2023 to June 2024. Data was analyzed using thematic analysis, performed with ATLAS. ti version 8.4.24

Results: Five themes were identified: setting up of CROs, challenges of CROs, strategies used to overcome challenges, opportunities of CROs, and prospects of CROs in sub-Saharan Africa. To establish a CRO workforce and infrastructures are needed. Lack of regulations and bureaucratic challenges were the major identified challenge in homegrown CROs. Collaboration, partnerships, community engagement and creation of a strong networking platform were used to overcome their challenges. Opportunities like market potential and untapped industry were reported. Based on these findings, participants recommended that all regulatory bodies in their respective countries establish clear requirements and standards for setting up CROs.

Conclusion: Challenges faced by CROs reveals essential strategies that sponsors, regulatory bodies, and new CROs can adopt to understand how established CROs navigate and overcome operational difficulties. Countries should support emerging CROs due to the significant opportunities and needs in this field. Furthermore, collaboration among stakeholders is essential to leverage this opportunity and foster the expansion of the CRO sector in sub-Saharan Africa.

Key-words: Challenges, Opportunities, Prospects, CRO, sub-Saharan Africa

1. INTRODUCTION

A Contract Research Organization (CRO) is a company that provides clinical trial services for the pharmaceutical, biotechnology, and medical device industries(1). The United States Food and Drug Administration (US FDA) defines a CRO as a corporation that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor to design, select, monitor, evaluate, and/or prepare materials to be submitted to the FDA(2). The Ethiopian Food and Drug Authority adopted a similar definition from Good Clinical Practice (GCP) and defines CRO as "a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions"(3).

Historically, outsourcing in the pharmaceutical sector started in the 1980s concerning non-core activities like information technology, finance, human resource and payroll, sales etc. It only moved up to core functions like drug manufacturing and Research and Development (R&D) in the second half of the 1990s and the latter gave rise to a whole new contract research industry(4). Before CROs, academic institutions and laboratories handled drug development work(5). CROs have gradually taken over much of academia's traditional role in drug development over the past decades(6).

There are two basic types of sponsor-CRO outsourcing models used: functional outsourcing and full-service model. Functional outsourcing refers to the model in which individual clinical operation functions are outsourced to multiple firms, rather than outsourcing a complete trial to a single firm(7). Functions are outsourced to specialized vendors that are functional experts rather than drug development experts. The most common areas to be outsourced are study monitoring, data management, statistical programming, medical writing and statistics(8). In the full-service model, CROs function as a 'one-stop-shop' across the development cycle. In this model, a sponsor engages with global CROs to complete the services of a full clinical trial(9).

There are many advantages of outsourcing work to a CRO(10), including:

- Pharmaceutical companies can concentrate exclusively on developing the clinical trial itself, while the CRO manages all other aspects, encompassing every stage of the clinical trial process.

- CROs possess extensive experience and established systems for project management, data collection, and patient care, which enable them to complete work efficiently.
- Hiring a CRO can result in significant time and cost savings.
- CROs are prepared to commence work immediately upon contract signing.
- CROs have extensive experience and awareness of international medical and research markets, along with a thorough understanding of the various regulations in each country.
- Creating strategic collaborations with CROs promotes open communication about the specifics and priorities of clinical trials and aids in the development of trust. Research teams and pharmaceutical businesses can efficiently address any difficulties through this collaboration, which leverages the support of varied business cultures and operational systems.
- CROs can enroll a large number of participants since they have in-depth knowledge of the top clinical trial investigators and sites in particular areas.

As per ICH GCP E6R2, a sponsor can assign some or all of the trial-related tasks to a CRO, but the sponsor remains ultimately responsible for the quality and integrity of the trial data. The CRO should implement quality assurance and quality control measures. Any trial-related duties and functions not specifically transferred to and assumed by a CRO remain the responsibility of the sponsor. The sponsor must ensure oversight of all trial-related duties and functions carried out on its behalf, including those subcontracted to another party by the sponsor's contracted CROs(11).

As CROs perform only small pieces of a large puzzle(12), there are many different kinds of CROs, but in the medical field, typical services include data management, trial logistics management, biostatistics, medical writing, regulatory affairs, clinical trial planning, site selection and initiation, recruitment support, clinical monitoring, and project management(1). A large number of CROs exist, each with different specializations. These specializations vary in terms of fields of activity, ranging from the preclinical phases, such as toxicology, analytics, pharmacodynamics, and pharmacokinetics, to the various clinical phases, as well as in therapeutic areas(13).

Services such as biopharmaceutical development, biological assays, clinical trials, pharmacovigilance, outcomes research, and real estate can be provided by a CRO(14). Product development, formulation work, conducting phase I through IV clinical trials, facilitating IRB approval, performing statistical analysis of reports and plans, and other essential tasks related to

applying for a new drug application (NDA) or an abbreviated new drug application (ANDA) are examples of additional services that may be offered(2). In addition to the wide range of services mentioned above, CROs also actively engage in the following areas: site management, medical reporting and writing, chemistry and biological expertise, data entry and validation, data processing and management, clinical trial participant recruitment, medicine and disease coding, safety and efficiency reports, marketing support, study report review and submission, and database design and building(10).

The main roles found in a CRO include: project managers, research assistants, site contract managers, quality managers, clinical research associates, clinical trial assistants, regulatory affairs managers, heads of clinical operations, data managers, statistical programmers and biostatisticians(10).

The global CRO market was valued at USD 16.5 billion in 2007(15). The CRO market experienced an annual growth rate of 14-16%, reaching USD 24 billion by 2010. In that year, CROs represented around half of the research workforce involved in drug and medical product development(16). The CRO market was estimated to be worth USD 39.69 billion in 2021. It is anticipated to increase from USD 45.53 billion in 2022 to USD 115 billion by 2030, meaning that it will expand at a compound annual growth rate (CAGR) of 12.01% from 2022 to 2030(17). Currently, CROs in the USA revenue rose at a CAGR of 8.2% in the past five years (2018-2023), including 5.7% growth to reach USD 32.8 billion and a profit of 18.7% in 2023(18). As of 2022, there are approximately 4,250 CROs in the United States alone, posing a challenge for sponsors to select a CRO and for research sites to provide sufficient input for ideal partnerships(18). India is also a leading outsourcing destination for large pharmaceutical firms(19), with the Indian CRO industry reaching a market valuation of USD 1 billion in 2017 with a projected annual growth rate of 12% over the period running from 2017 to 2023(17). Due to the numerous new entrants, joint ventures, mergers, and acquisitions, it is challenging to pinpoint the exact number of CROs; estimates place the figure at approximately 150(20).

From 2022 to 2030, the CRO market is expected to grow rapidly. This growth is being driven by several key factors, including increased availability of research funding, government support for R&D, expansion of well-established healthcare sectors and healthcare expenditures, and a growing global patient population(17).

Although Africa has approximately 17.89% of the world's population(21), only an estimated 2% of global clinical trials are conducted in Africa(22), and no data shows the revenue capital in Africa.

As a result, this study investigated the current challenges and opportunities in setting up and, running of CROs in sub-Saharan Africa, as well as put the potential recommendations for future development of CRO system and structures in the region.

1.1 Statement of the problem

The growth in the CRO market is mainly attributed to the rising demand for pharmaceuticals, an increasing number of clinical trials, and growing government support for biopharmaceutical manufacturing. Moreover, opportunities from emerging markets, increasing demand for biosimilars and continuous advancements in bioprocessing techniques offer significant opportunities for players operating in the CROs market(23).

The various sets of data indicate that not only Ethiopia but also other sub-Saharan African countries lack centralized registration mechanisms and comprehensive data about CROs. For example, if we take Ethiopia, according to the Contract Research Map, there are only three registered CROs. These are Addis Ababa University (AAU), International Center of Insect Physiology & Etiology (ICIPE) and National Animal Health Diagnostic and Investigation Center (NAHDIC). The Contract Research Map is owned and maintained by Scientist.com. It was created to help researchers in the life sciences identify and connect with CROs based on geography(24).
Conversely, the Regional Bioequivalence Centre (RBEC) in Ethiopia is a public-private partnership (PPP) organization established in 2012. Its primary role is to function as a CRO serving East African pharmaceutical manufacturers registered at different locations(25).
AAU, CDT- Africa MSc in Clinical Trials curriculum, the first of its kind in Ethiopia and the African Region, is designed for the training of experts who are actively contributing to the clinical trials process in Africa. The program's overall aim is to prepare competent individuals who would work in pharmaceutical industries, regulatory agencies, CROs, academia and other research centers, with the primary objective of assisting with the designing, execution and reporting of clinical trials of drugs, diagnostics, behavioral interventions and medical devices commensurate with GCP, legal, ethical, and regulatory requirements(26).

AHRI clinical trial directorate has also been working in collaboration with sponsors to the design, protocol writing, conduct, management, monitoring and reporting of clinical trials for academic and regulatory purposes. It has a clinical trial site with phase I trial facilities including a study ward, safety clinical laboratory and acquired experience in setting up collaborating satellite trial sites in several healthcare facilities in Addis Ababa and beyond(27).

Although there are several ongoing efforts in the sub-Saharan African countries to improve the capacity of CROs and local manufacturing, the support provided so far is insufficient to establish capable CROs in compliance with the requirements for conducting a study of locally produced generic products. As a result, generic medicines produced locally in the region are allowed to be marketed without the required scientific evidence for their therapeutic equivalence with an innovator or comparator products. In addition, the effectiveness of imported generic products and the credibility of their study findings, which may have been conducted by CROs abroad with inadequate regulatory control, are other issues that are of growing concern. One of the challenges to most manufacturers in Africa is lack of accessible and affordable CROs, particularly concerning geographical and financial constraints(25).

Moreover, to our knowledge, there are not many previous studies that show the identified challenge and opportunities of setting up and running of CROs to the development of clinical trials in Africa. In the absence of official data, the importance of this segment of the industry is brought to light only by doing research.

1.2 Significance of the study

Conducting a study on setting up CROs in sub-Saharan Africa is of great significance. This study will provide valuable insights into the challenges, opportunities and prospects of setting up and running of such organizations in sub-Saharan Africa. It will help to identify the key factors that need to be taken into consideration when setting up such organizations, such as the availability of resources, the legal and regulatory framework, and the potential for collaboration with other organizations. Furthermore, it will provide a better understanding of the potential for success and the potential risks associated with setting up such organizations in the region.

The findings of this qualitative study will be of great value to policymakers, investors, researchers, academics, and other stakeholders in sub-Saharan Africa. It will provide them with a better

understanding of the potential for success and the potential risks associated with setting up such organizations in sub-Saharan Africa. This will enable them to make informed decisions about whether or not to invest in such organizations. Furthermore, the findings of this study will provide valuable insights into the potential for collaboration between different organizations and the potential for creating a supportive environment for such organizations in sub-Saharan Africa region.

The research will also explore the current regulatory environment in different countries of sub-Saharan Africa and the potential for growth in the CRO industry. It will also examine the challenges that must be addressed to create a successful CRO industry in the region. This includes understanding the current infrastructure, the availability of skilled personnel, and the investment potential. Additionally, the research will explore opportunities for growth in the CRO industry, such as the potential for collaboration with other countries and the potential for new technologies.

2 LITERATURE REVIEW

2.1 Introduction

A pragmatic approach was adopted for conducting the literature search. The strategy involved focusing on the most relevant key search terms to ensure comprehensive coverage of the topic. The search was centered around the following key terms: "challenges," "opportunities," "clinical trials," "CROs," and "Africa." This targeted approach was intended to identify pertinent research articles that discuss the various aspects of conducting clinical trials in Africa, as well as the specific roles and practices of CROs in this context.

The review present results from various research articles on the opportunities and challenges of conducting clinical trials in Africa. It examines the association between these challenges and opportunities and the practices of CROs as suggested by different authors.

The landscape of conducting clinical trials in Africa presents a range of perspectives, each with its own unique set of challenges and opportunities. As this landscape continues to evolve, CROs encounter a number of challenges that may impact their ability to conduct successful research(28).

Challenges encompass financial constraints, scarce human resources, infrastructure limitations, and navigating ethical and regulatory complexities. On the other hand, Africa's distinct characteristics have captured the attention of global enterprises. Opportunities arise from its large

and diverse population, genetic variations, prevalence of various diseases, cost-effectiveness in operations, promising economic prospects, and the growth of global health funding and research facilities. These challenges and opportunities are comparable to those encountered when practicing as CROs and hinder CROs ability to institutionalize their practice.

2.2 Challenges of clinical trial environment in Africa

a) Financial burden

The expenses involved in the entire process of developing a drug, from initial research to getting it to market, can differ, but reports have suggested that these costs could exceed USD 2.5 billion(24). In many low-income countries, conducting clinical trials may be considered a luxury. This is because the primary causes of death in these countries are diseases for which effective treatments exist but are not readily available due to insufficient funding(24). For instance, in Ethiopia, the health sector received only 8.8% of the total national government spending in 2017/18 and 3.9% in 2023, which is below the 15% target set by the Abuja Declaration(29,30). Developing countries get less than 10% of clinical trial funds even though they host 90% of the problems that affect the world's population(29-30). Funders and sponsors should understand that, with adequate funding, it is possible to conduct high-quality clinical trials in Africa(33). One common challenge faced by CROs in Africa is the lack of funding opportunities for the growing number of trainees as they advance in their careers, as well as insufficient financial support for research projects(34).

b) Limited human resource

Highly skilled personnel are essential for planning, initiating, and conducting clinical trials. Developing such human resources requires relatively stable, well-funded research and higher education institutions, as well as robust science governance systems, which are often lacking in developing countries(25). Graduates of medical schools and teaching hospitals in developing countries are often inadequately prepared to conduct clinical research(35). Additionally, the increasing internationalization of the labor market is causing a continuous brain drain, as highly qualified personnel seek opportunities abroad(25). Africa currently has 198 researchers per million people compared with 428 in Chile and loses some 20,000 professionals to high-income countries every year. Health professionals often struggle with understanding the importance of research

techniques such as randomization, blinding, and tools like the visual analogue scale(36). In some oncological conditions, clinical trials are not feasible due to limited human resources, including a lack of pathologists and trained cancer surgeons, which in turn impacts the ability to provide proper cancer care(30). All individuals involved in a clinical trial should receive proper training to ensure they comprehend the protocol and trial procedures. This is necessary for maintaining consistency, adhering to the protocol, and upholding high standards. Certain sponsors, CROs, and regulatory agencies may require specific training or accredited trainers(37). When sponsors want to outsource services depending on their needs, there should be enough trained people capable of investigating all services offered by CROs.

c) Infrastructure

In Africa, one of the challenges is the lack of a well-developed research infrastructure and a limited number of clinical trial units with administrative capacity(35). According to a study done to assess medical laboratories in sub-Saharan Africa there were only 380 laboratories qualified to meet international quality standards of which 91% were found in South Africa. Among 49 countries in the region, 37 countries did not have a single laboratory that meets international quality standards. Poor quality laboratory testing is a significant obstacle to providing quality health care in the region(31). For various trials, CROs should have a complete setting to attract sponsors and to generate more complete results that are relevant to clinical practice(38).

d) The Ethical and regulatory system

An underdeveloped regulatory framework may result in the approval of poorly designed trials, which could pose significant risks to participants and communities that would be unethical and costly. In developing countries where trust in health professionals and the healthcare system is already fragile, unethical clinical trials can worsen negative attitudes toward health professionals, reduce health-seeking behavior, and foster dangerous mistrust in public health systems. Therefore, it is essential to create opportunities for meaningful communication among patients, researchers, and community physicians regarding clinical trials(39). Developing opportunities for meaningful communication among patients, researchers, and community physicians about clinical trials is crucial(38). There should be an appealing environment for CROs to practice in, as well as smooth regulatory mechanisms.

Generally different perspectives should be well considered in conducting clinical trials in developing countries as CROs where easily preventable communicable diseases are of major concern and account for the highest death toll. The financial and human resources, infrastructure, ethical and regulatory contexts, cultural appropriateness and living conditions of host communities are triggering to ask if clinical trials and CROs are important in developing countries.

2.3 Opportunities of clinical trial environment in Africa

Low access to quality healthcare, epidemiological transition, a fast-growing population, a rising middle class, and rapid economic growth are some of the opportunities for conducting clinical trials in Africa.

1) Large number of populations

Africa is the second-largest and second-most populous continent on earth hosting 17.89% of the global population. In 2024 it's expected to be more than 1.4 billion(21). Despite the large number of population, the continent is underrepresented in clinical trial(40). Having this large number of populations has its special benefits for choosing Africa to conduct clinical trials. This large naïve population benefit CROs by having an opportunity to build many volunteer pools, which presents a significant opportunity for rapid, large-scale participant recruitment for sponsor-related activities.

2) Genetic Diversity

Africa hosts more than 3000 ethnic groups(41). For example, Ethiopia's population is also highly diverse, containing over 80 different ethnic groups(42). This incredible number of ethnic groups shows a diversified genetic makeup among the whole population. Genetic analyses shows that different ethnic groups show variable results to different treatments. For example, some interventions shown to be efficacious in high-income countries are not similarly effective when used in other contexts(48-49). This is a great opportunity for CROs to carry out clinical trials in Africa.

3) Diversity of disease

Most Africans are suffering from a double disease burden(45), comprising communicable and non-communicable diseases, which means that there is an abundance of the patient population

representing various disease areas, which further indicates an opportunity for rigorous scientific investigation and breakthroughs.

While infectious diseases may command the most attention, the continent also experiences a significant burden of non-communicable diseases. A World Bank report indicates that by 2030, non-communicable diseases are expected to cause more deaths in Africa than communicable diseases(46). This is largely due to the increasing number of deaths from cardiovascular disease among people under 70 years of age in sub-Saharan Africa(47). Cancer now kills more Africans than malaria, while conditions like type II diabetes and cardiovascular disease are on the rise. Gynecologic malignancies such as breast, cervical, and uterine cancers represent the first, third, and fifth most common cancers in women globally(48). According to a study conducted in sub-Saharan Africa, gynecological cancers account for approximately one-third of all female cancers. Among these, cervical cancer is the most prevalent, constituting 81.6% of all female cancers(49). Clinical trials play a crucial role globally in lessening the burden of diseases by contributing to the creation of safe and effective new treatments and vaccines(37). CROs can take advantage of these opportunities to alleviate such disease loads.

4) Lower operating cost

Compared to developed countries, the cost of running a trial is significantly cheaper in developing countries. This is largely due to lower salary and overhead costs, as well as shorter participant enrollment times(50).

According to reports from pharmaceutical sponsors, a second-tier center in the USA charges more than ten times the amount that a top-tier academic medical center in India charges per case report(51).

Other studies estimated that a trial in China or India could cost between a third to half of what it would cost in the USA(52). Recruitment of trial participants is easier than in the developed world; large outcome trials that require the enrolment of thousands of patients could make huge savings for the sponsor if the trial is conducted outside of developed countries(53). Subject recruitment alone accounts for approximately 23% of total trial costs, and 87% of US trials fail to meet their recruitment and enrollment milestones(54).

5) Positive economic outlook

The World Bank forecast notable economic growth in different sectors in sub-Saharan Africa. In 2024, the growth rate in sub-Saharan Africa is expected to increase to 3.5%, and then average around 3.9% in the years 2025-26. This is anticipated as inflation decreases, and there are improvements in private consumption and investment(55). Security threats have subsided in several countries and infrastructure investments to sustain growth are improving. A growing emphasis from both government and private sectors is being placed on luring biomedical research initiatives. This shift towards increased investment in science and technology in sub-Saharan Africa holds promise for the advancement of medical research in the region(56).

6) Increasing global health players

Africa has become a global health institution. Increasingly, there have been many clinical trial partnerships between Africa's academic research universities and those from the West. Expatriate biomedical scientists are welcomed to teaching hospitals and public research institutions in Africa to undertake research involving human subjects. Teaching and referral hospitals and African physicians are keen to participate in clinical trials and are hungry for research opportunities and grants for their institutions. Patient and researcher's priorities in Africa are often aligned to the needs of pharmaceutical sponsors. The abundance of well-trained English-speaking researchers and the availability of English source documents make Africa continent attractive for conducting clinical trials(56).

7) Research centers

These benefit in terms of staff gaining experience in conducting global standard research and getting trained in ICH/GCP, clinical, laboratory, data management procedures, use of new equipment and vaccine safety assessment.

The research teams gain national and international exposure and there are better opportunities for future research funding at the center(57).CROs brings these benefits to patients, health care workers, and the community before, during, and after a research.

As of June 26, 2024, ClinicalTrials.gov showed 55% of registered studies as having a "non-USA only" location. 30% were USA only registered studies and from these more than 65% of them were recruited participants outside of the USA(58). This shows that a growing number of registered studies in USA are physically conducted in countries like developing nations.

To attract clinical trials to sub-Saharan Africa, various strategies need to be implemented, especially in areas where research findings are currently unavailable. The existing literature has identified challenges related to conducting clinical trials in general, but not those specific to CROs. Therefore, this research aims to identify the opportunities and challenges faced by CROs in sub-Saharan Africa, as well as the strategies they use to navigate these issues. By focusing on the practices and experiences of CROs, this study seeks to provide a clearer understanding of how to effectively conduct clinical trials in the region and enhance the appeal of sub-Saharan Africa as a viable location for such research.

2.4 Conceptual framework

A conceptual framework based on the set up, opportunities, challenges faced, possible strategies, and prospects of CROs is depicted in Figure 1.

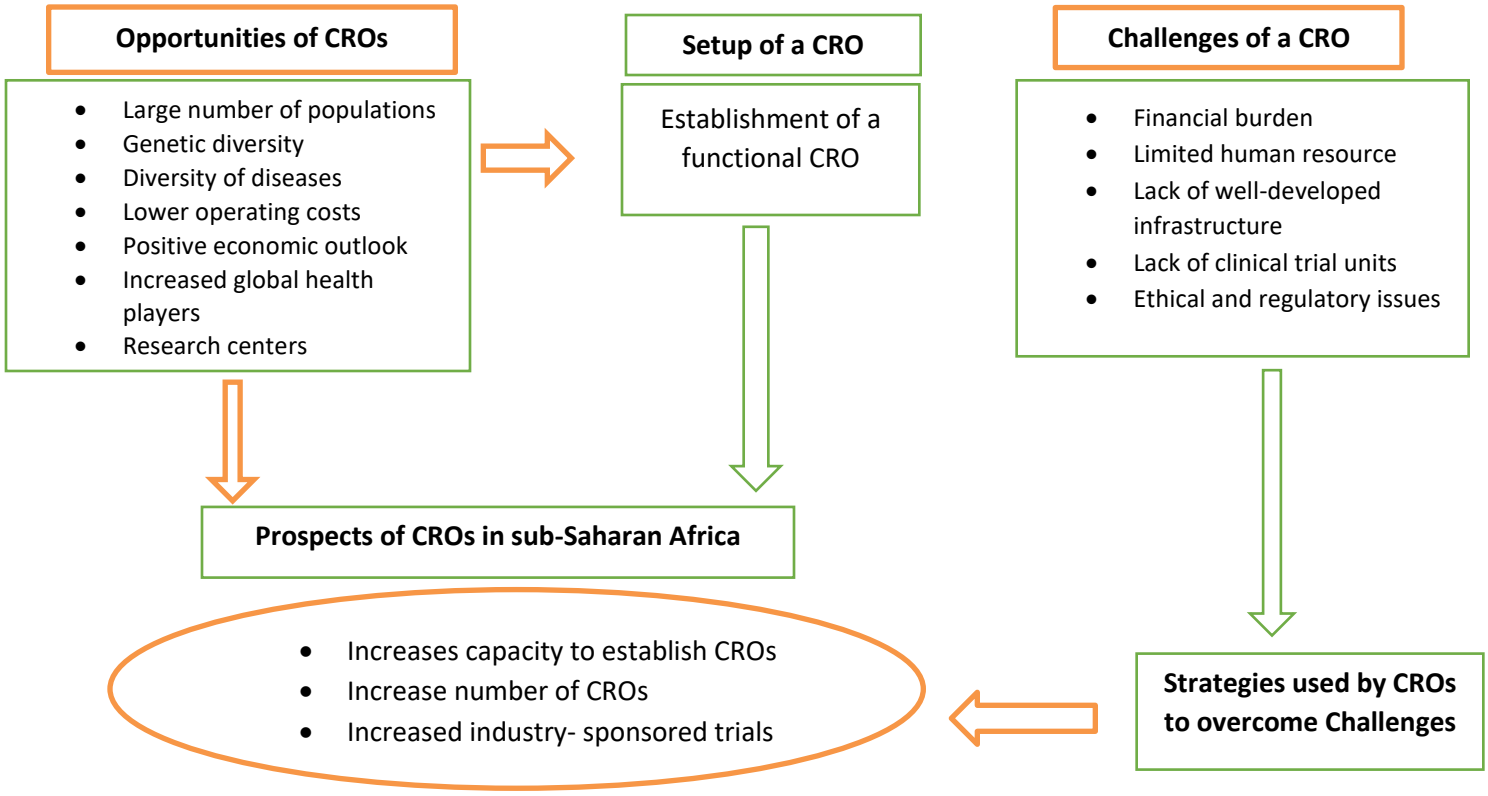

Figure 1: Conceptual framework the researcher developed from the literature, depicting the, opportunities, setup, challenges faced, strategies, and prospects of CROs.

This framework synthesizes existing literature to demonstrate the intricate interrelationships among these variables. It provides a comprehensive visual representation, showing how various opportunities have facilitated the establishment of CROs. Additionally, it highlights the challenges that CROs encounter, which may hinder progress if not addressed effectively. Crucially, the framework also outlines the strategic responses employed by CROs to overcome these challenges, ultimately contributing to the growth and development of the industry.

3 OBJECTIVES

3.1 General objective

To explore the challenges and opportunities in setting up and running CROs in sub–Saharan Africa and put a way forward for improved practice.

3.2 Specific objectives

1. To describe the requirements necessary for establishing CROs;
2. To identify the regulatory challenges faced by CROs in sub-Saharan Africa;
3. To explore the strategies employed by CROs to overcome challenges;
4. To identify potential opportunities for CROs in sub-Saharan Africa.

4 METHODS AND PARTICIPANTS

4.1 Study setting and period

The study was conducted in nine sub-Saharan African countries: Ethiopia, Gambia, Kenya, Malawi, Nigeria, Rwanda, Senegal, South Africa and Uganda. It focused on individuals who met the eligibility criteria. The study setting was purposively selected based on the availability of CROs to ensure relevant and insightful data. Data collection took place from July 2023 to June 2024.

4.2 Study design

Qualitative research employing the phenomenological approach was carried out.

4.3 Study participants

Participants who matched the eligibility criteria and could offer detailed information were chosen using a combination purposive sampling procedure. This study employed a combination of

criterion sampling and snowball sampling techniques to select participants. Initially, participants were selected based on specific eligibility criteria defined by the study, a process known as criterion sampling. Additionally, snowball sampling was utilized to further expand the participant pool. Initial participants were asked to refer other individuals who also met the study's eligibility criteria.

4.4 Sample size determination

The method used a phenomenological approach involving a total of 13 in-depth interviews who run a CRO and have a history of working in a CRO. After the 12th interview, data saturation was reached. Data collection was continued for one more interview to confirm that no new concepts were mentioned.

4.5 Eligibility criteria

To be eligible to participate in this study, the CRO must be located in the sub-Saharan African region and fulfill at least two of the following criteria:

1. A person who runs or works in a CRO, a person working in a CRO that has done at least one clinical trial in the past;
2. A person working in a CRO involved in an ongoing trial at the time of this study;
3. A person who runs clinical research consultancies involved in clinical research.

4.6 Participant recruitment

Combination purposive sampling technique was employed. Snowball/chain sampling and criterion sampling was used. The first 100 pages of google searched but there was no landscape analysis and no recorded data that lists the available CROs in Africa, so snowball/chain sampling was taken into account.

4.7 Data collection procedure

The researcher conducted all the in-depth interviews using Amharic for Ethiopian participants and English for participants from other sub-Saharan Africa countries. A semi-structured interview guide was in Amharic and English was employed (Annex2). The interview guide was piloted with two volunteers who matched the established qualifying requirements to ensure the clarity and understandability of the questions before the actual data collection. The pretest data was not

incorporated with the study results. Based on the findings of the pretest, necessary modifications were made to the questions.

Interviews were conducted face-to-face with the Ethiopian participants and virtually via Zoom for participants located outside Ethiopia.

An email and LinkedIn message outlining the purpose of the study was sent to potential candidates, along with, an informed consent, and ethics approval letter. Reminders were sent to non-responders. For participants expressing interest, they were invited to suggest an interview time, and a Zoom link was provided.

Subsequently, the researcher sent a Zoom meeting link and scheduled the interview. Interviews lasted an average of 34 minutes, and were audio recorded with permission.

4.8 Data processing and analysis

Data analysis was carried out alongside ongoing data collection and an interim analysis informed adaptation of the topic guide and ongoing sampling. Thematic analysis was used to analyze the data. The following technique of systematic and rigorous steps were used to analyze the information obtained in the in-depth interviews.

Step 1: The English transcripts were read repeatedly by researcher or Shiferaw Tesfaye (ST) to ensure familiarity with the data.

Step 2: The transcript data were then exported to ATLAS. ti version 8.4.24 where data were coded line by line including finding from notes taking, to aid the process of coding.

Step 3: ST and the main advisors tested the codes for clarity and consistency.

Step 4: ST coded the rest of the text and identified emerging themes as the data were still being collected.

Step 5: ST reassessed coding consistency.

Step 6: Identified codes, according to similarities and differences, were allocated into subthemes. Similar sub-themes were grouped into themes.

Finally, the sub-themes and codes were identified to capture the latent meaning of the text. The respondents' views were then used as quotes to support the points made in the study.

4.9 Ethical considerations

Ethical approval to conduct this research was granted by the Research and Ethical Review Committee of CDT-Africa, Addis Ababa University. Written consent was obtained via email and LinkedIn confirmation from each study participant after providing a clear explanation of the study's purpose. Participants' rights to refuse participation, answer only selected questions, or withdraw from the study at any time were respected. Confidentiality of participant information was maintained throughout the study and no formal monetary compensation was provided.

5 RESULTS

Two sections in these findings explore the setting up, challenges, opportunities, and prospects of CROs in eight participant countries. They are presented as follows: The first part describes the participant characteristics, and the second part describes the emerging themes and subthemes.

5.1 Participant Characteristics

From the 43 potential participants who were approached through email and LinkedIn, 25 did not respond to the invitation despite being contacted three times at different intervals. Five individuals initially responded but were unavailable for the scheduled interview. They were later contacted to see if they could reschedule for a more convenient time. Of those, three did not reply, while two did respond. However, despite these efforts, no one was available during the second or third attempts. The remaining five were interviewed. Nine were snowballed with eight participants interviewed.

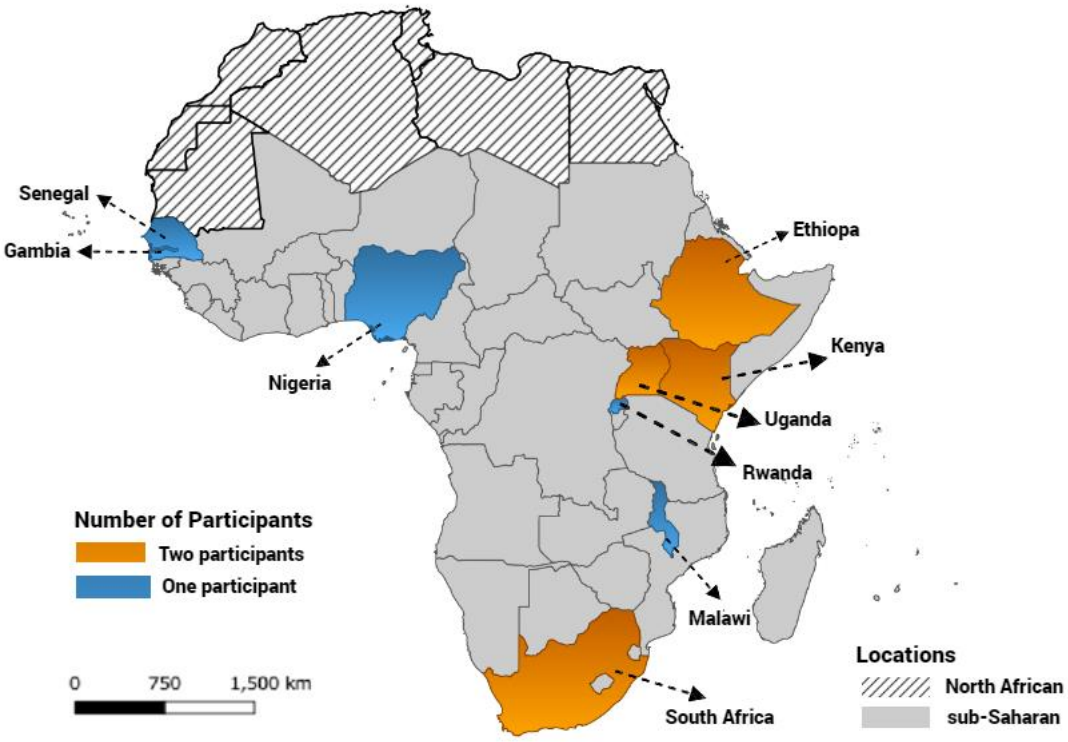

Figure 2: Map showing the country of residence of interview participants

Thirteen participants from nine sub-Saharan African countries were interviewed between July 2023 and June 2024. Participants were from Ethiopia, Gambia, Kenya, Malawi, Nigeria, Rwanda, Senegal, South Africa and Uganda. Two participants each were recruited from four of the countries (Ethiopia, Kenya, South Africa and Uganda) with the other countries contributing one participant each (Figure 2).

Participants were from nine different CROs. Participants working in Ethiopia and Uganda were working in the same CROs. Eight of the participants were male. Six of the participants were involved in the business with in the past five years. Eight of the participants were CEO or Founders of the CROs. Two participants were working as a clinical research coordinator (Table 1).

Table 1: Characteristics of study participants (N=13)

Characteristics	**Number**	**Percent**
Gender		
Male	8	61.5
Female	5	38.5

Level of education		
MSc	8	61.6
MD	3	23.0
PhD	2	15.4
Year of Experience in the CROs		
0-5 Years	6	46.1
5- 10 years	6	46.1
>10 years	1	7.7
Participant Profession		
Founder and CEO	8	61.5
Clinical research coordinator	2	15.4
Clinical research associate	1	7.7
Clinical research manager	1	7.7
Clinical researcher and data scientist	1	7.7
Type of CROs		
Partial Scale	13	100
Full Scale	0	0

5.2 Themes

Following the analysis of the data from the in-depth interviews, five main themes and 25 sub-themes emerged. The five themes were: setting up of CROs, challenges of CROs, strategies to overcome challenges, opportunities of CROs, and prospects of CROs (Figure 3).

Themes **Sub-themes**

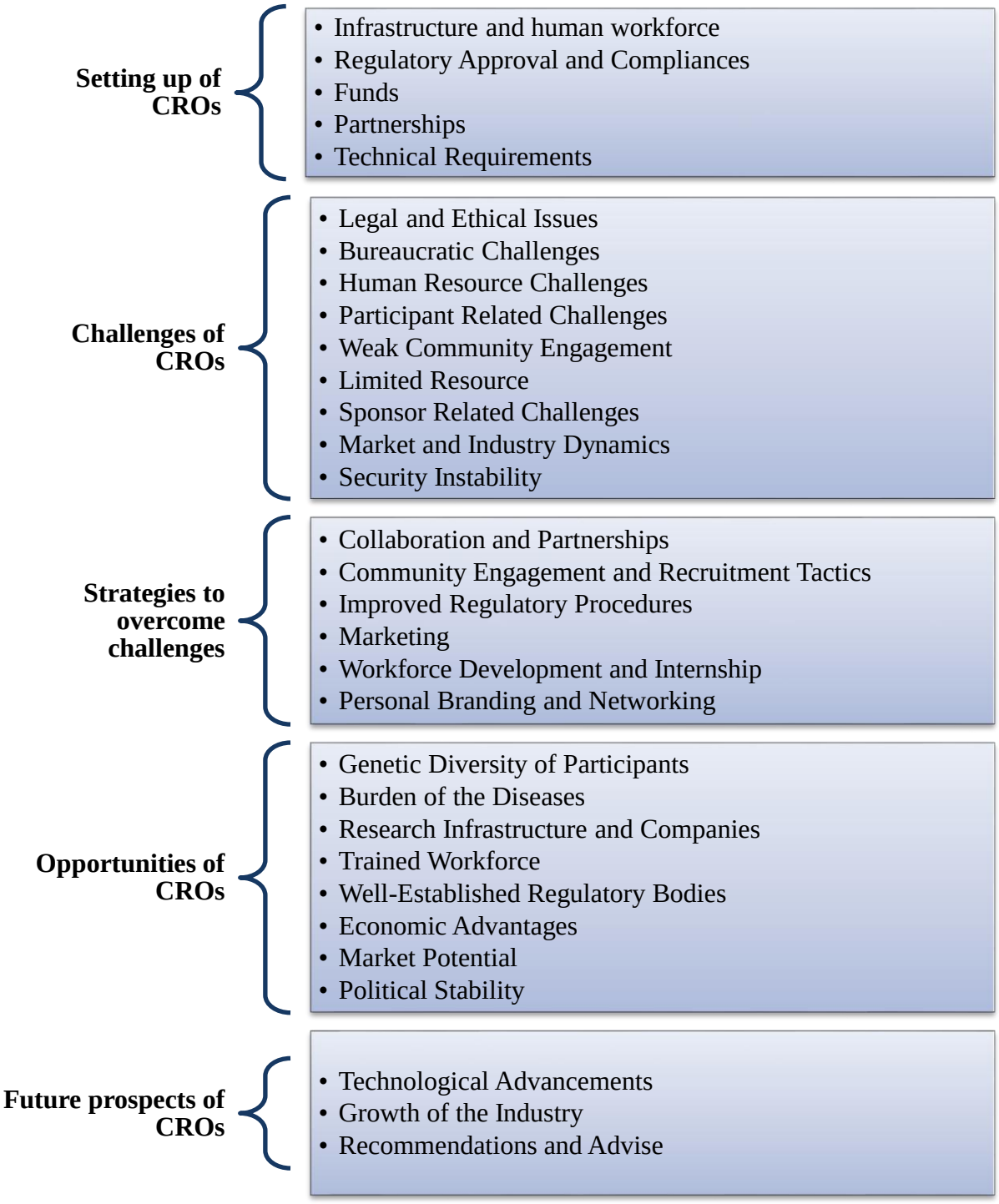

Figure 3: Schematic presentation of identified themes and subthemes

Theme 1: Setting up of CROs

The following section summarizes the themes and sub-themes that emerged from the interviews with corresponding quotes. This theme addressed many of the that participants raised as factors that we need whenever we set up a CRO.

The following five sub-themes emerged from this global theme, setting up of CROs: infrastructure and workforce, regulatory approvals and compliance, funds, partnerships and technical requirements.

Sub-theme 1: Infrastructure and human work force

The main infrastructures mentioned by participants were physical facilities and human resource components. The availability and quality of the CRO is determined by the infrastructure it has.

Physical facilities: All CROs highlighted the need for materials such as equipment, devices, and physical office space. However, a differing perspective was presented by one small CRO that primarily relies on paper-based projects. This viewpoint highlights the flexibility and adaptability of certain research processes, even in environments with limited physical infrastructure. This viewpoint highlights the flexibility and adaptability of certain research processes, even in environments with limited physical infrastructure.

> *"...Infrastructure-wise, having physical office space is important" (P05).*

> *"I think infrastructure is not as much because you can be home base…We can work because most of the work is either you can obviously need to have an internet, obviously, just have a laptop in terms of equipment, and internet connectivity. And you can work from your personal home" (P08).*

Trained and experienced manpower: All participants emphasized the critical importance of having qualified personnel when establishing a CRO. The Ethiopian CRO underscored the significance of having an MSc in clinical trials and other short-term training programs to develop a trained workforce. More than half of participants also mentioned the significance of having experience, motivation and expertise in the field.

> *"If you are going to establish a CRO in this part of the world, you need to have the right people at the company… People that are able to introduce the quality that is required. And*

when I say quality, I'm referring to issues like ICH-GCP, and the international standards. Like people that are able to understand what is expected of them and do it correctly. So that is one from the human perspective, getting people the right training, knowledge and experience "(P02).

"When my CRO was started, it has almost like less than 10 members who are willing. First, you have to get those people that are willing to sacrifice, because in the beginning, a lot of these big pharmaceutical companies, they are not aware of your potential or what you're capable of doing…" (P03).

"We need trained people, for example, in Ethiopia, we possess a well-trained workforce, including individuals with MSc qualifications in clinical trials and those who have undergone short-term trainings" (P05).

Sub-theme 2: Regulatory approval and compliances

Different participants noted several key requirements for establishing a CRO. Firstly, it's crucial to implement a strong quality management system with standard operating procedures (SOP) to regulate and demonstrate work processes. Additionally, the business must be registered with the relevant legal authority to understand all legal requirements. Even though it depends on the sort of CRO one is establishing, adequate infrastructure, particularly accredited laboratory facilities, is essential to meet regulatory obligations and support the conduct of trials. Lastly, organizations must ensure that they have essential facilities, which will be inspected to verify that they meet required standards before establishment.

SOPs: A CRO mentioned the importance of SOP to consider when establishing a CRO as described below,

"And then another aspect is your quality management system. Because starting up a CRO, you need to have like standard operating procedures to be able to present the work you do and how you do the work" (P02).

Licensing and registration: Participants emphasized the importance of obtaining licensing and registration as a business entity before establishing a CRO.

"You have to go to the Attorney General's chambers and record, I mean, register as a business entity with the name and everything. Then, from there, they will tell you the requirements" (P03).

"…you must be having an infrastructure where you are going to conduct your trials from. We should be accredited, especially of what you are going to do, especially the laboratory facilities, they must be in order in line with what you are going to do. And, you must be in position to meet the obligations of the regulatory bodies" (P04).

"I think you need to just have a legal entity in terms of a business, a legal business license is a basic start" (P08).

Inspection: Participants outlined that all necessary facilities need to meet the required standard and regulatory inspections are a standard part when we setting up a CRO.

"So, before an institution is being established or these organizations are established, they want to first of all ensure that you have the necessary facilities that are going to support you in doing the work that you set out to do… So, they'll have to do a tour of the facility to ensure that it meets the standards" (P07).

"They want to see that the infrastructure really supports. Then they want to see what are you basically going to do? Is it going to be your own initiative? Is it going to be research from a certain sponsor and you want to just execute it? They want to see; do you have collaborators? Do you have partners? Do you have people that you're working with? Do you have the necessary requirements that are going to be able to support you in doing all the work that you're going to do? So basically, it goes through a lot of reviews before it is being established" (P07).

Sub-theme 3: **Time and money investment**

For setting up a CRO it's important to have a fund with good amount as mentioned by the participants from three countries. CRO requires not only financial investment but also a significant investment of time.

"*One thing I know is you should have a bank statement that is very, very good, like a bank statement that spells out that you have money in your bank to run a project…. So, it's good to have a bank account that has a good standard, you know, financially" (P03).*

"…But for me, I wouldn't think, definitely you will need funding, but because of the nature of contracting for CROs, you may not need a lot of funding if you build it up step by step. It depends on how you build it" (P06).

"You need to invest. When I say invest, not just monetary-wise, not just investing your money. You need to invest your time" (P02).

On other hand, it is also mentioned that funding as a requirement is less important.

Sub-theme 4: Partnership

All CROs emphasized the importance of establishing partnerships with various stakeholders, including regulatory bodies, sponsors, monitors, pharmaceutical companies, community and

others. They highlighted that having a strong network is essential for securing projects related to clinical trials.

> *"You need a partnership with them so that when you send them a letter, they will understand the urgency of some of these things and they can process it really quickly and get back to you" (P03).*

> *"So, we need to connect with each other to actually understand what other people are doing that can help make our work better… I have seniors that I still learn from and I have other CROs that I'm familiar with. I try to learn from them to see how they make their work better, how they do things better than I'm already doing" (P02).*

> *"So, it's that, and you need to have what do they call this, established relationships with other people that may be able to grant you that opportunity" (P06).*

Community: The community is important when CROs are working. One of the participants from Uganda noted its importance by equating it to the other infrastructures.

> ***"**As long as the regulatory obligations are met and the infrastructure where you are going to have your clinical trial is of standard, you have well-trained staff, you have access to medical services and also the community, also to depend on the population…" (P04).*

Sub-theme 5: Technical requirements

Technical requirements include setting aside and giving time to comprehend the respective national context in the period needed to set up a CRO. These specifications are explained in more detail below.

Time investment: It is also noted that establishing a CRO requires not only financial investment but also a significant investment of time, as highlighted below.

> *"You need to invest. When I say invest, not just monetary-wise, not just investing your money. You need to invest your time" (P02).*

Time frame establishment of a CRO and getting approval of a project: Different participants found it challenging to estimate the exact time required for establishing a CRO, as various factors influence the timelines. Financial resources play a significant role, with ample funds expediting the process. Conversely, governmental support and regulatory clarity can also expedite the establishment process, potentially shortening the timeline to just a few weeks to a month.

> *"The National Regulatory Authority timeline is 60 working days. Within those 60 working days, you expect the feedback from them, depending on the level of feedback you get. If*

more work is needed from your end, then that might extend. But if everything is OK, within 60 working days, you will get your approval" (P02).

"...*It can even take a year. Actually, it depends on the funds. If someone has funds and you are able to construct or to work in hand with the hospital or any other facility, it can even take a short time. It depends on the funds" (P04).*

"If the government creates a legal framework and begins working on this, I believe it won't take much time to establish a CRO. Based on our experience and the processes involved, setting up everything could take a maximum of a few weeks, possibly less than a month. This timeline is feasible because we are focusing on a few specialized areas" (P05).

"Well, I do not have a specific timeframe, but actually it depends…Sometimes it will depend on the work that those volunteers really have. But also, it depends on how you are prepared … it can go on for like six months plus" (P07).

Start from consulting or small: All the CROs in the study said they started small, either by doing small studies or working as consultants, before becoming full CROs. Beginning with small projects was important for them to grow. They built their reputation step by step by doing smaller trials with limited resources. Starting as consultants helped them gain experience with different clients and improve their skills over time, leading to the creation of more structured CROs.

"A lot of people will not hire immediately. What they do is they will reach out to pharmaceutical companies, look out, look for trials, which will not need a lot of expenditure or a lot of manpower like small scale trials. And they start from there so that they can build up their reputation. So, it is when they get the reputation that they will start hiring the number of people that is required to reach or to address, to conduct certain types of studies" (P03).

"Firstly, before you actually can even call yourself a CRO, most people start as a consulting company more than a CRO. So, though a CRO is also sort of a consulting company, but a CRO is much more formalized structure. It's much bigger. When you get to a point where you call yourself a CRO, it means you have established yourself…But in most cases, even for myself, I wouldn't say that I'm a fully functional CRO, but you start as a consultant, firstly, in the area where you serve multiple clients, and then you build your profile" (P06).

Data: A participant from emphasized the importance of data. Data is crucial for marketing and presenting to sponsors to attract their support. It is one of the essential elements required when establishing a CRO.

"When I was doing my feasibility, let's say assessments, I realized that we are not keeping data of what we're doing. Basically, if you come and ask to a clinician or a researcher, how many patients suffering from sickle cell anemia…whatever, they will not be able to

answer because they don't have the data readily available. So, which makes it very difficult to actually produce something that can convince sponsors to invest and do studies in the country" (P09).

Citizenship: In order to set up a CRO and operate as a business entity in a specific country, it is a requirement to be a citizen of that country. It is described as:

"…for you to set up a CRO, I think the only thing that you need to do is you must be a citizen"(P08).

Theme 2: Challenges of CROs

This theme addresses many of the challenges faced by CROs. The participants mentioned various challenges and it is categorized into nine sub-themes. These sub-themes encompass legal and ethical issues, bureaucratic hurdles, human resources, participant-related challenges, inadequate community engagement, resource limitations, sponsor-related issues, market and industry dynamics, as well as security challenges.

Sub-theme 1: Legal and ethical issues

CROs frequently cite legal hurdles as significant challenges. Concerns about potential government shutdowns due to inadequate legislation, ethical issues, and export permit restrictions are among the obstacles explained by industry participants.

Lack of laws for CROs establishment: All participants noted specific regulations and standards governing the establishment of CROs are not available in their respective countries. This lack of clear guidelines poses a significant challenge. Without precise directives, initiating a CRO becomes complex and uncertain, making it difficult to ensure compliance and proper procedures. Consequently, the absence of clear legal frameworks hampers the smooth and effective operation of CROs.

"…. We do not have specific laws that indicate how you actually open a CROs…. this is both an advantage and a disadvantage. It's an advantage to any external CRO, but it's a disadvantage to those within the country who want to build something local. It becomes a challenge because the laws have been there for more than 30 years" (P03).

"The main challenge is the absence of directives and legislation governing CROs in the country. Unlike opening a hospital, clinic, or pharmacy where you can easily find the necessary requirements from books or websites, establishing a CRO is uncharted territory… Even if you were to request licensing from EFDA as a CRO, they would likely

decline and withhold the license. In fact, I doubt they are familiar with the term "CRO" at all" (P05).

"…there are no standard regulated requirements that states that this is what you require to be a CRO" (P06).

"…there's no firm structure that anybody tells you in terms of what needs to be done. So, for inside Africa, there's no firm structure to say like, this is the requirements of the CRO" (P08).

Fear of closure of CRO by government: A CRO expressed concerns about the lack of regulatory framework in the country. They fear that without proper laws in place, their office could be at risk of closure in the future. It described it as

"We are concerned that EFDA might intervene one day and demand cessation of our consultancy services, especially given the absence of clear legislation on the matter" (P05).

Government misconceptions: Misconceptions within government bodies hinder effective collaboration with CROs, as they often perceive private operations as solely profit-oriented, overlooking the valuable expertise and contributions offered by private entities for the country's benefit as described below.

"Another challenge arises when working with government bodies from a private sector perspective. There is a misconception within the government that our operations are solely profit-driven. They fail to consider our experience, the expertise of our team, and the benefits our services bring to the country" (P05).

Lack of government support: A participant highlighted the lack of government support as a significant challenge, noting that most resources are allocated to research and development (R&D) rather than to clinical research.

"There is, I think R&D's infrastructure in Africa from the government's perspective to settle for, I don't even think they support clinical trials. I think R&D mainly in terms of maybe like other types of research, but not clinical research. So, majority of the funding is unfortunately international sponsors like your biotechs and pharmaceutical companies" (P08).

Delayed export permits: A CRO also highlighted another challenge related to delays in obtaining export permits. The approval process for these permits by regulatory bodies is expected to take more than four weeks, which could potentially impact their timeline for export.

" …And the other thing that my country experience, it's the requirement for export permits. And the requirements for the export permits needs to be secured, especially when you ship

biological samples out of a country. So, you have to, and you can only apply for the export permit after you have secured your regulatory approval, which means it can extend your startup timelines…" (P06).

Ethical issues: It's described as there are some biases in the internal ethical committees of internal CROs. It's described as

"So basically, the current ethics committee that is used for studies is based in their campus. So, you can see that there will be a little bit of bias with regards to other competing CRO when they come to work, because at MRC, they have their internal CRO. Internally. Well, many of the sponsors, they don't want to use anything internal because it will be biased. So, they would rather hire an external CRO. So, these are the challenges you will face" (P03).

Lack of awareness: It was noted by CROs that there is a significant lack of awareness about CRO operations among regulatory bodies. It's explained as

"…they have never heard of a CRO. Like, if you can tell them, contract research organization, they would come back to you, what's that? And yet, these people are working in the research institutions''(P10).

Sub-theme 2: Bureaucratic challenges

CROs highlighted numerous bureaucratic hurdles, such as extended delays in obtaining licenses and registrations, challenges with regulatory approvals, and the centralization of services under a single provider.

Delayed registration and licensing: According to a CRO, the licensing process can be lengthy when registering as a business entity. It's described as

"Like any business who is going to be registered especially when starting start-up, it was very lengthy, Tiresome" (P01).

Delayed regulatory approvals: Participants noted that while regulatory approval processes have improved in recent years, challenges remain. It used to be more difficult to get timely reviews and approvals from regulatory authorities, but progress has been made, and efforts continue to shorten these timelines despite limited resources and staffing issues. Delays in approval still occur, often taking two to three months or even longer. In some countries, the back-and-forth communication can extend the approval process to over six months.

"Let's say five years ago, seven years ago, it was a bit more difficult to get the regulatory authorities to review your study faster and give you approval. But now things have improved. We are still pushing for shorter timelines. We still feel like they need to do more

because they themselves, their resources are limited. Sometimes they will tell you, oh, we don't have enough staff to conduct some of these reviews or we need more time, things like that" (P02).

"We also face challenges of delay of approvals when we make submissions. Some approvals might be delayed, can take like two months to three months, something like that…" (P04).

Because there will be that back and forth, back and forth trying to see which time a year plus, depending on what is really available… Because even approving certain trials to happen, it can go on for like six months plus" (P07).

Centralization of process: A CRO mentioned that the registration for setting up of a CRO is centralized and solely under one organization. It's described that;

"…But it's so unfortunate that in my country, we have everything centralized…. just recently, they have approved a policy regarding research. …The Ministry of Higher Education, Research, Science and Technology is responsible for research in this country" (P04).

Sub-theme 3: Human resource

Three CROs have highlighted specific challenges related to limited workforce and high turnover, which are important to consider.

Limited workforce: CROs described the difficulties associated with finding individuals with sufficient expertise in clinical research as;

"Another challenge we are also having is getting the right people to do the work…. We have a lot of healthcare workers existing on the continent, but many of them don't actually know how researches like clinical trials are being conducted. So, we have a limited workforce" (P02).

"Some skills like, for example, for public health or medical monitoring and safety, we don't have qualified people. Now, that one puts us in a very difficult situation sometimes" (P12).

High staff turnover: Each participant noted that the high turnover rate in CROs is connected to various factors, including employees looking for opportunities elsewhere and challenges arising from ineffective leadership. This scenario could significantly impact the progress and outcomes of clinical trials. Additionally, the prevalence of contract-based employment exacerbates the issue, as workers seek more stable jobs elsewhere, resulting in continual staff turnover and potential disruptions to research efforts.

"Sometimes you find the management in the CRO is not really good. And this makes the work in the environment not conducive for staffs. And the staffs end up moving from CRO to CRO and not retaining your staff can also have an impact on the conduct of the clinical trials" (P04).

"Staff turnover is a problem. I think that's common across the globe, because the majority of the people that do the work, which is the monitoring work, the site management work, they don't usually stay for long in one company" (P06).

"Maybe sometimes the research organizations will face staff turnovers, for example. They work on contract basis… sometimes we're not assured. Today, this is an employee of this organization. But the next day, they are looking for somewhere else. So, you find before they maybe do the work to maximum, they will have moved to another organization where they think they have some job securities. So, we have staff that keep on moving from one job to another because of such challenges" (P07).

Limitation in trainings: Participants addressed the lack of training as a challenge. There is a lack of universities or training avenues for CRO professionals, and establishing a local CRO focused on training would significantly help address this gap. While staffing itself is not a problem, hiring less experienced staff requires substantial effort and financial investment in their development, which can be challenging for smaller CROs.

''… we do not have universities or avenues to train a lot of CRO…. Maybe someday if we have a local CRO that we can focus on training a lot of CROs in this country, that would really help" (P03).

"So staffing is not an issue, but then I think for me, as small as I am, I would tend to want to get less experienced staff. Obviously, with less experienced staff, I will really have to involve and put a lot of energy into development, which sometimes it's more financial impact to be able to do that" (P08).

"The lack of training is the major challenge that we have, both from the regulatory and also from the sites" (P09).

Sub-theme 4: Participant related challenges

Recruitment and participant retention are common challenges encountered by approximately half of the participating CROs.

Recruitment: Participants underscored the importance of participant recruitment and involvement of the community, especially when conducting disease specific research. They noted that the type of disease being studied directly impacts participant recruitment. It's also noted that participant recruitment is not an issue for smaller CROs since their work is mainly from office.

"In terms of getting trial participants, it depends on the disease area that you are working on. Yes, there are some trials that it might be hard for you to get participants because you have tight inclusion and exclusion criteria… Yeah, simple trials are easy" (P02).

"*We have challenges in regard to recruitment. Sensitization actually takes more time when you are beginning a clinical trial. So, you need to invest a lot in recruitment, in community engagement activities to make the community aware about the importance and the benefits of having clinical trials in our countries" (P04).*

"When it comes to recruitment, it may also depend on the kind of studies that you're recruiting for. Let's say you get a vaccine study, it's very easy to recruit for a vaccine study in South Africa, but if you may, to find maybe rare diseases, you know, so it depends on the condition that you're recruiting for" (P06).

"In terms of patient recruitment, not as much. It would be more like a site facing issue than from my end as a CRO facing issue" (P08).

Participant Retention: It is also noted that CROs face problems with participant retention while conducting trials. For example, a CRO highlighted the challenge of retaining study participants due to various factors. Some participants leave the country for better opportunities, affecting retention rates. Additionally, working with mobile communities, such as fishing communities poses difficulties since individuals frequently move in search of livelihood.

"…And also, for lack of participants, sometimes you recruit participants and they leave the country, they go for green pastures in the Arab countries So, sometimes also affects your retention" (P04).

"You know, we have different communities. Now, if I give an example, where I think we basically work in fishing communities. And one of the challenges that we face is the retention of those people. Remember, these people are going to the islands to look for survival, do something. So, they tend to be mobile, right? They move from one area to another looking for survival…they will move to far distant areas. So, if your work does not cater for maybe transportation from where they are going to come back at the research center, you may end up losing them" (P07).

Sub-theme 5: Poor community engagement

It's also noted that community involvement is crucial not only during recruitment but throughout the entire trial process. Major challenges faced within the community include lack of awareness, myths and misconceptions, and violence against participants.

Lack of awareness: As mentioned by participants, lack of awareness about clinical trials is a major challenge among the people. It's described by the participants as

"So, it's a bit difficult for us to actually convince people why they should do their trials in the first place, because they have doubts about people having the right knowledge or having the right skill to actually generate quality data for them or actually following the

ethical practices, the correct ethical practices when it comes to dealing with participants" (P02).

"We know some communities are not aware whether that is what happens with clinical trials" (P04).

"…people not knowing what clinical trials is" (09).

Myths, misconceptions and violence on participants: This is noted as the most common challenge faced by CROs as participants from two countries explained.

"…They will have these ideas that people are taking their blood samples for something else, you know, that kind of spiritual or ritualistic mind" (P03).

"But basically, the one which is most worrying is the myth and misconceptions in communities about clinical trials, especially when you are conducting prep trials, something that maybe you are injecting them with HIV, a lot" (P04).

"You get misconceptions and myths about clinical trials, participants being enrolled, even end up getting even gender-based violence depending on the participants" (P04).

Sub-theme 6: Limited resources

Challenges related to resources include no CROs, inadequate infrastructure, limited training opportunities, a scarcity of universities or training institutions, and financial constraints.

Absence of local CROs: It's noted that in many of the countries there is a limited number of research facilities and CROs. Lack of CROs or a single CRO in the country leads to lack of competition in the area. Participant described it as

"So, in my country, one of the biggest challenges is having only one research facility, which is MRC, MRC Gambia. They are affiliated with London School of Health, London School of Tropical Medicine… we do not have any CRO in the country, no CRO, only the one, the internal one at MRC, which they are trying to upgrade to make it to make it an international CRO…. We do not have anyone competing them." (P03).

Infrastructure: A participant noted that delays in infrastructure impede research advancement, CROs lack services especially in carrying out laboratory tasks and managing data, resulting in constraints in adhering to study protocols.

"Then another delay is the infrastructure. Of course, you may be interested in conducting certain research that has laboratory work into it and also maybe data management. But sometimes you find yourself short of what to use. Let me say you cannot run a certain test as per the protocol" (P07).

Sub-theme 7: Sponsor related challenges

Challenges are not only limited to issues with the government, staff, or participants, but also extend to challenges from sponsors. These challenges may include a lack of trust, the specific nature of the project, and issues related to project finances.

Lack of trust by sponsors: CROs mentioned that sponsors lack confidence in African CROs due to doubts about the expertise and capabilities of the individuals responsible for conducting clinical trials in the region. It is explained as

> *"I feel my biggest challenge is that when you get a contract, it's almost like they want to know who's your backup. And so, what we've done in the past is having like different contractors' kind of collaborating, but then that didn't work as such. They want you when you present your profile to them, you need to tell them your employee structure, how long they've been working with you. And so that seems to be a challenge. It's almost like you need to be in order before they will provide you a contract" (P08).*

Nature of the project undertaken: Some of the sponsors ask CROs to do only one type of job which required or might be done by only one person as mentioned by a Nigerian CRO.

> *"…some people will say, oh, please, I need you to assist me with this. Then it might be a kind of job that only one person would do. So, I can just take care of it for them as their consultant… the kind of projects we are getting is just projects that require just one person to do" (P02).*

Financial problems: A CRO emphasized the significance of funding for starting and sustaining the business, highlighting the challenge of sponsors not releasing the entire amount.

> *"I think one of the major challenges as to why we do not have CROs in the country is finance …. Most of these pharmaceutical companies, how they tend to work with some of the CROs that are emerging in Africa, they don't give them, they don't pay up 100 percent. They pay 15 percent or 25 percent and to see how it goes about so that they can easily just call it quits at a stage when the money is still with them" (P03).*

Sub-theme 8: Market and industry dynamics

Various participants highlighted challenges in market and industry dynamics, including the limited number of trials coming to Africa, changes affecting market sustainability, and the high costs of conducting trials.

Limited number of clinical trials in Africa: There are a lot of clinical trials currently conducted particularly in Africa. But the number of trials conducted in other countries are limited. A CRO describe the challenge as

"So right now we are seeing that South Africa seems to be doing better than Egypt. But other countries that are in the continent are still struggling to bring in trials here…It's not just, it's an African issue because we don't really get a lot of clinical trials coming into Africa compared to other continents… that challenge of we don't have a lot of clinical trials happening in Africa" (P02).

Sustainability issues for new CROs: A participant noted that new and small CROs struggle to sustain themselves in the business environment. It explained as

"It's sustainability, first of all, because the workload or the work that may come, it's variable. You don't control what will come. Okay. It depends on the work that comes, and if you secure that work, you understand what I mean. So, it's not like you are certain, even if you can plan and you go out there and market, there's no guarantee that you'll find that job, especially being a small CRO, unlike the established CRO, because the established CRO, they probably have established lines, which they plan their pipeline with" (P06).

High cost of conducting studies: One of the most significant obstacles for CROs is the high cost associated with conducting clinical trials. This issue presents a major challenge for researchers and organizations looking to advance medical knowledge and develop new treatments within the country.

"What I've also learned is that South Africa is becoming more expensive with regard to the cost of conduct of studies. So, what I've seen is that most of the sponsor companies that, or maybe most of the biotech companies that consider the small CROs, are not as rich as the big biotech's or the big pharma's… But sometimes South Africa can be expensive for smaller companies" (P06).

Competition with larger CROs: A CRO noted that larger CROs might impede the entry of new competitors by utilizing their established relationships and resources, thereby fostering a competitive landscape for smaller or emerging CROs seeking business opportunities.

"What I feel maybe it might fit into your challenges that the existing biggest CROs, once they have established people, they're almost like gatekeeping for the next one, which I understand is obviously competitive if they want the business" (P08).

Pricing issues: CROs should establish standardized fee structures with a minimum and average rate to remain competitive. A CRO explained it as

"CROs, we need to have like minimum fee to be charged for clients and an average fee. For example, if I bid for a project and I request for, let's say, $50 an hour and someone else requests for $75 in an hour. So, in a way, we may be too expensive in a region and then that's why you find a lot of international organizations, they go to India. They like India and CROs because they are very competitive in terms of pricing" (P11).

Sub-theme 9: Security challenges

A CRO has reported that security issues in the country have become one of the current challenges they are facing.

> *"For example, in this year starting from last year like there were many challenges. you can't travel safely. I mean it's hard, its challenging" (P01).*

Theme 3: Strategies to Overcome Challenges

CROs have been working to overcome those challenges with different mechanisms. Participants from different countries have been implementing various strategies to their respective problems. These strategies can be categorized into six sub-themes, including collaboration and partnerships, community engagement, improved regulatory procedures, marketing, internships, and networking.

Sub-theme 1: Collaboration and partnerships

CROs are employing strategies such as signing Memorandums of Understanding (MoUs) with various stakeholders and outsourcing services they do not provide themselves to address challenges associated with limited resources.

Signing of MoU: Two participants addressed the value of partnerships with other institutions. Through signing and utilizing MoU, they gained access to clinical trial sites and laboratories, which helped address equipment availability issues effectively.

> *"We have MoU with AHRI, allowing us to use their clinical trial sites when needed… Although we haven't conducted onsite clinical trials yet, we can leverage AHRI's facilities based on the MoU." (P05).*

> *"Most of the time, it's being solved through the collaborations that we have two laboratories. We work with certain organizations that do have that equipment that can run those tests. So, you will have an MoU with them, send the samples, they process them and send back the results. But that one also limits, like sometimes the results take a long time. They create a delay" (P07).*

Outsourcing services: You don't have to provide all services at once when taking a trial. It is important to establish strong partnerships, which allows you to delegate some services to your partners. This approach helps in managing workload effectively and saving time for other important tasks as described by the CROs.

> *"And you don't have to offer all services. You can outsource the services as well, which can be paid for by the sponsoring company. Let's say, for example, they want data*

management, but you're not able to provide data management services. You partner with other organizations that have data management services, and the pharmaceutical companies can pay for that. And I mean, so you're just the middleman, basically, as a CRO. You don't necessarily have to own everything" (P06).

Sub-theme 2: Community engagement and recruitment tactics

CROs overcame community challenges by actively engaging with the community through sensitization workshops. Additionally, they facilitated recruitment by establishing awareness creation with in the community.

Myth and misconceptions: Workshop for the community members about the myths and misconceptions are important and used by CROs. They described it as

"*We conduct sensitization of members in the communities about research and conducting workshops with the community team, the community leaders, the Village Health Teams (VHTs) to address any misconception that is brought in the country within the community members" (P04).*

"…But now they know that, actually, these tests that are done or some of the samples that are used, it's made clear to them. Yeah, so basically, I don't think it's an issue now for you to have the number of people that you need for particular research" (P03).

"Train people and make them aware, to raise awareness around clinical research and especially what CROs are doing" (09).

Recruitment tactics: Expanding research locations and engaging the community more actively are essential tactics for increasing participant numbers, as noted by two participants. Overcoming recruitment challenges effectively requires these strategies. To address misconceptions and other obstacles, establishing a robust community team that collaborates closely with community members, leaders, and Village Health Teams (VHTs) is crucial. This collaborative effort fosters awareness and engagement, ultimately easing the recruitment process.

"So, you need to do more work in expanding your sites and maybe more community engagement to get more people to come and become part of it" (P02).

"For challenges of recruitment, that one, we have set up a strong community team that collaborates with the community members, the community leaders, the VHTs that help them in sensitization. I've said that in order to have the challenge of myth and misconception, we have a community engagement team that helps in recruitment" (P04).

Sub-theme 3: Improved regulatory procedures

Regulatory procedures have seen advancements, particularly with the digitalization of submission, registration, and approval processes. Additionally, the government's development of new policies is contributing to these improvements.

New policy development: In some countries its stated that the development of new policies will play many roles for CROs to make the ethical committee independent. It is described as

> *" ...But I believe with the policy coming forward, it will really help us to at least address some of these issues" (P03).*

Digitalization: CROs marked the significance of routine monitoring of regulatory activities to tackle challenges associated with delays in submissions and approvals. Additionally, they noted that advancements in digital systems have greatly streamlined the submission process, enabling real-time tracking and monitoring of progress.

> *"It is about having an active regulatory team at your site that is in a position to always follow up with the regulatory authorities about their submissions. And also, the site to always give feedback on what has been found out in what you are submitting, to always respond to the queries that have been raised by the regulatory authorities in time" (P04).*

> *"In terms of delays, we can first of all manage it by submitting. Not submitting very late…when you keep on following, asking for update, this time it has been improved. Back in the days, we used to submit paperwork manually, physically. But now they have created systems where you upload and you can see the progress of the things that you submitted" (P07).*

Sub-theme 4: Marketing

There are efforts to market Africa as a destination for clinical trials and attract sponsors. Showing the potential and adaptability to the business environment is among the mechanisms.

Showing the potential: A participant described the mechanism they used to attract sponsors is showing the potential they have. It explained as

> *"So, we are investing a lot of our time in actually marketing the continent to the world, like making people know the potential of running clinical trials here, making people understand that we have clinical sites that can actually do the work and do it correctly" (P02).*

Building a personal reputation in the industry: In addition to showcasing the potential of the CRO, it is equally important to cultivate a personal reputation within the industry, thereby increasing awareness of the services offered, as explained by a participant.

"So, what I really do is like, I've really kind of grown my name personally, especially in the investigator-initiated space, those protocols where I've grown my name to make people aware that this is who I am and this is the services I'm providing" (P08).

Adaptability: It's important to stay in the business as a marketing strategy, especially for small CROs. As we mentioned above sustainability is a challenge as mentioned by the CRO.

"With the sustainability as the first thing. Yeah. It's the matter of just to continue and staying out there and just continue consulting, doing work. You may not get opportunity where you own the study, but then you get a chance to do part of the work within the CRO space" (P06).

Sub-theme 5: Workforce development and internship

Participants shared how training and internship opportunities helped them overcome the challenge of the lack of a trained workforce.

"We support training. So, one of the things I do personally is I help train the younger generation and healthcare workers that are interested in learning about clinical research. Because the more you have trained people, the more the work quality gets better and the more the trust in working with Africans increases… I told you we are investing a lot in training" (P02).

"Train young people on clinical research and everything around clinical research, and afterwards offer them internships and offer them contracts so that they can gain experience and work for us. So, this is one, for instance, challenge that we have and how we overcome it" (P09).

Sub-theme 6: Personal branding and networking

Participants stress the importance of networking on social media platforms and attending conferences to increase visibility and attract work opportunities. Moreover, they highlight the significance of collaborations among CROs, both locally and internationally through various associations, as it allows for shared expertise and resources, leading to collective achievements and synergy.

Social media: Two participants described the main social media platform used by CROs as LinkedIn. They use it to promote their work, build connections, and showcase their professional profiles. It described as

"You need to connect with people via LinkedIn. You need to put yourself out there so the people will even know you in the first place. Because the more they know you, the more they want to maybe give you work. And then by the time they see the quality of work from your end, then they want to come back to you" (P02).

"I'm also very active on LinkedIn and being clear on LinkedIn in terms of who I am and what I actually provide…people either contact me on LinkedIn for new work or it will be previously because people I have used before, it will come back and use my services" (P08).

Attending conferences: Two people said that going to conferences is really important. It helps you learn about new things happening in the industry and talk with other people doing similar work. Also, different groups are talking about how to make things better in the industry, showing that everyone is working together to improve things.

"*And then you have to attend conferences because when you attend these conferences, we tend to talk a lot about advancements in the industry… The idea is learning and learning. Learn the new advancements in the industry" (P02).*

"I've attended a couple of conferences organized by different stakeholders. I've noticed they are actively discussing these matters, and I believe they are taking steps to address them" (P05).

Memberships: It is mentioned that membership in professional associations and community of contractors is important in order to update to the latest information and tackle the challenges that are being faced when working as a CRO.

"There's also a local South African Clinical Research Association (SACRA), which is a non-profit organization. So, I'm a member of that. So, they have from time-to-time meetings and obviously in those meetings you connect with other people and colleagues in the industry. And oftentimes they have like presentations about what's happening, where we are, like that. I also have a community of contractors where we have like a personal group just for contractors" (P08).

"We have the Clinical Research Society of Kenya, where we also engage the regulators and ethical people to understand the impact of delays on our projects" (P11).

Theme 4: Opportunities of CROs

There are many opportunities for CROs working in the African Region. Some of the opportunities are categorized in-to seven sub-themes. These include genetic diversity, the prevalence and impact of various diseases, the state of infrastructure, availability of a skilled workforce, robust regulatory frameworks, economic advantages, market potential, and political stability.

Sub-theme 1: Genetic diversity of participants

Genetic diversity presents a significant opportunity due to the distinct genetic makeup of individuals from different regions. For instance, the genetic composition of individuals in Africa differs from those of individuals in the USA or Europe. Furthermore, the presence of various racial groups in South Africa further highlights the importance of conducting clinical research in Africa. It is described by participants as

> *"The pharmacokinetics and pharmacodynamics of drugs differ when it comes to different races. So, there are some drugs that are working for white people that are not working for black people… And then there are some adverse events that are causing in clinical trials now that we missed in earlier clinical trials because they were not around here. So, there are lots of opportunities." (P02).*

> *"There is a diversity of participants, because in South Africa, you have all, you don't just get African people, you get Caucasians, you get Chinese, you get Indians, you understand what I mean? So, there's diversity. And in every, in most cases, places where the majority of the big research sites are located, you're able to get diverse data" (P06).*

> *"It's just the diverse genetic makeup of our population that I believe is unparalleled anywhere else in Africa" (P08).*

Another CRO also mentioned that

> *"We have so many patients who have never been, by spending nightly on trials, so we have like kind of clean patients. Who have not been exposed to any investigational products" (P11).*

Sub-theme 2: Burden of diseases

There are many diseases affecting the region. It's also sometimes referred to as like double burden of diseases. It is also described as an opportunity.

> *"Uganda is also among the undeveloped countries where we have challenges of illnesses, different kinds of illnesses of which the researchers would wish to really conduct clinical trials in Uganda" (P04).*

Sub-theme 3: Research infrastructure and companies

Participants highlighted the advantageous presence of robust infrastructure in certain countries, which offers a conducive environment for CRO operations. Specifically, they noted that the existence of well-established pharmaceutical companies and extensive infrastructure, including numerous research sites, serves as a significant opportunity for CROs to thrive.

> *"We have very good labs, standard labs. We also have a biobank of which the power is really stable, both primary and secondary power supplies. They are all stable. They have built-in system in their freezers where if there is any excursion, you will know… There are*

primary and secondary power supply. So, when this one is gone, when this one goes, the other one will be there. And also, they have automated temperature detectors. So, like they are called data loggers." (P03).

"Uganda is somehow well-established. We have hospitals and also, we have health facilities" (P04).

"The presence of multinational and local pharmaceutical companies operating in our country presents opportunities for CROs to thrive." (P05).

"South Africa has a lot of infrastructure. I think that we have about 1,800 research sites and expertise." (P06).

"I think South Africa clinical research work will always come to South Africa. Number one, it's one of, in Africa… it's one of the most developed countries in terms of resourcing and infrastructure" (P08).

Sub-theme 4: **Trained workforce**

Five participants highlighted the availability of trained workers as a positive aspect. They mentioned that there are many skilled people, some with research experience, which makes the workforce strong. Also, the presence of many Master's and PhD projects adds to the talent pool for research. These workers have expertise in different areas and committed, which helps maintain high-quality work in various tasks of CROs.

"The people are friendly. And you have a lot of people who are educated and sitting here and they have no jobs. So, it's easy to get demand power…Almost all the staffs are well acquainted and experienced when it comes to research" (P03).

"Regarding working manpower, we have well-trained health workers and also even the staffs who have worked on research experience are now very many" (P04).

"Additionally, the abundance of Master's in clinical trial and PhD projects serves as another opportunity" (P05).

"…we have people that are committed, by the way, to work… we have very many people now that are trained in good clinical practice and human subjects protection. So, you are assured that your work is done for the good clinical practice" (P07).

Sub-theme 5: Well-established regulatory bodies

In Gambia, the presence of a flexible ethical committee offers a significant advantage, allowing CROs to navigate potential challenges with greater ease. Meanwhile, five African countries including South Africa and Nigeria, stand out for their well-established level-three regulatory bodies, which instill confidence in sponsors seeking to engage with CROs. South Africa's

regulatory infrastructure underscores the diverse opportunities available across the African continent for CROs. Its described as

> *"…it's obviously the established regulatory body with a maturity level three, which is covered by WHO. And the regulator in South Africa is well-established, the ethics committees are well-established" (P06).*

Sub-theme 6: Economic advantages

CROs working in sub-Saharan African countries benefit from several economic advantages. These include reduced costs, governmental support, and strategies for optimizing taxes.

Low expenditure and high profit: As explained by a participant, there are low expenditure and high profits opportunities. Its described as

> *"You don't need much expenditure when it comes to research here in this country, even though at MRC they will charge you because their standard is based on the affiliation they have with London School in the UK. But I think you will spend less here than in other countries…. So, you will always make profits at the end of the day" (P03).*

Government support: Participants also noted that government support, particularly from entities like the Ministry of Health, provides opportunities for assistance and faster processes.

> *"…and also, the government is also open for collaboration so you can collaborate. The Ministry of Health and other ministries, depending on what research you're going to do. So, when you collaborate, you are assured of getting certain support and having some negotiations done and certain things done faster" (P07).*

Tax optimization techniques: CROs sometimes establish a main office elsewhere and hire consultants in various locations to evade tax responsibilities, placing the tax burden on the employees instead. It is also mentioned that there is lack of government support for clinical trials.

> *"What companies are doing, especially some of these CROs, is that they will have their offices elsewhere, just one central office somewhere, and then they will hire people as consultants. So, this allows them not to pay tax. And it moves the tax to the responsibility of those staff. So, any staff, if you're in Gambia, Gabon, Nigeria, whatever, you will be the one paying your own tax, whereas the company will only pay tax where the headquarters is" (P03).*

Sub-theme 7: Market potential

The African market remains largely untapped, making the continent highly favorable for the CRO industry. Its naïve population presents a valuable opportunity for sponsors, attracting them to invest in clinical research and development.

Naive Population: A CRO has noted that there is a growing openness to clinical research within the population, particularly following the COVID-19 pandemic.

> *"It's a new thing. We have a naive population, if I must say, which are not very conversant with clinical research, which makes the market like, you know, open for everyone who wants to profit" (P09).*

Untapped industry: A participant explained that the CRO business in Africa remains largely untapped compared to other continents, presenting significant opportunities for growth and development. It is described as

> *"I feel like we haven't even explored 1% of our ability in Africa. Remember I told you America has all they have, yet they're still running nucleic trials every day" (P02).*

English Speaking Countries: Language was identified as a potential opportunity for CROs to attract sponsors. For instance, a CRO highlighted how linguistic capabilities could be leveraged to appeal to international clients and enhance their competitive edge.

> *"My country, also, being an English-speaking country, and GCP being an English kind of regulations, it becomes more easier to run studies here" (P11).*

Sub-theme 8: Political Stability

A CRO described how the long-standing political stability make it an appealing and secure destination for potential sponsors.

> *"We are politically stable. We never had any coup; we never had any instability. So, this attracts business and also our well-known university and our researchers because they are everywhere" (P09).*

Theme 5: Prospects of CROs

All of the participants think that the business will grow in the future in their own respective countries. The theme is categorized into three sub-themes, namely technological advancement, industry growth, and strategic recommendations such as integrating with health systems and developing networking mechanisms.

Sub-theme 1: Technological advancements

Technology is really important for CROs. They need to keep up with new ideas to keep going strong now and in the future. Virtual trials are a big change in the industry. This shows how much using technology matters to stay ahead and be important. Using new tech doesn't just make things work better; it also lets us try new ways of doing research and talking to people involved.

"Our CROs in my country is doing enough. But will grow if it advances with the use of technology" (P04).
"Let's say, for example, changes in virtual trials, you know. What are the new systems that are being used in order to enable virtual trials? And what are the setups that will be needed if those kinds of systems are to be implemented in Africa or in South Africa? So, you have to be there as part of those networks" (P06).

"…basically, in technology, I would want to see a lot of change and improvement. Because when you look at how organizations were 10 years back, it's not the same as they are right now" (P07).

Sub-theme 2: **Growth in the industry**

All participants share the belief that the business of CROs will experience significant growth in the near future due to numerous opportunities on the horizon. Specifically, in South Africa, there exists a regulation mandating foreign partners to collaborate with local CROs whenever conducting trials. This requirement not only fosters partnerships between international and domestic entities but also promotes knowledge exchange and capacity building within the local research community.

"Health is wealth. People always want the best for this, best for that. So, research is never ending. So, we haven't even done anything at all. We haven't even started as Africans. So, there is a huge prospect in the industry" (P02).

"I think it will grow. I think it will get to that point where the regulators within the African context, they can even say, if you are due to do trials also in Africa, you must also equip and partner with local CROs" (P06).

Sub-theme 3: Recommendations and advise

All participants have offered various recommendations on how CROs should operate, despite facing numerous challenges. Key suggestions revolve around regulatory enhancements and the establishment of effective networking mechanisms.

Creation of a centralized ecosystem: A participant emphasized the importance of regulatory bodies establishing a centralized ecosystem to monitor the activities and functioning of CROs.

"It's almost like everybody does everything, like you just need to register a business and maybe also if they can be maybe a hub where all the CROs can register themselves and maybe just create an ecosystem just to know who, how many are we" (P08).

Integration with health system: As recommended by a CRO, integrating clinical research into the existing health system is recommended for the industry's growth. Additionally, increasing research efforts is crucial for advancing the health system within clinical research.

> *"One of the ways we can also help develop our health care system, one of the main ways, is clinical trials… If you're talking about advancing our health care system, definitely we need to do more research" (P02).*

Delivering quality service: For CROs, ensuring the delivery of high-quality services to sponsors is paramount for maintaining strong working relationships and securing future collaborations. Moreover, delivering quality service enhances the reputation of the CRO within the industry, attracting new sponsors and opportunities for future work.

> *"They have to deliver quality. I think all the other things may matter, but quality matters more. So, we have to be known for something that differentiates ourselves" (P06).*

Importance of patience: Patience is essential for achieving long-term success in the CRO industry. A CRO recommends that business owners remain patient, as they may feel frustrated by a lack of projects and experience moments of doubt. Maintaining patience is crucial in overcoming these challenges and avoiding the feeling of failure.

> *"Yeah, so for someone that wants to get into the CRO business, my first advice is patience. That person needs to be very patient. Because I've seen a lot of people that see the clinical research industry now in Africa as a new money-making machine, where they can go in and start making money because it's new. But that's not the case. There is a lot of work involved. You have to put in the work and then be patient because things will not be turning as fast as you think" (P02).*

Leadership development: According to a participant, an effective leadership mechanism is essential to address the problems faced by CROs.

> *"All CROs I know they have management teams and they have leaders. So really, leadership skills should be emphasized in the conduct of clinical trials" (P04).*

Networking mechanisms: All participants suggested utilizing networking and partnership mechanisms to facilitate knowledge exchange, offer support, and promote collaboration within the industry. Such mechanisms may encompass mentorship programs, participation in professional associations, and engagement in discussions with stakeholders.

> *"Stakeholders need to engage in discussions about the setup and licensing of CROs and propose a suitable format. Currently, there is some awareness, but more discussions are needed" (P05).*

"But I would love to see maybe one of the bigger companies with maybe at least every now and then, even once every five years, just choose a company with potential and maybe kind of take them in in the mentorship ability and just develop them and grow from there" (P08).

"Organizing summits between CROs or trying to have a kind of association where all CROs can meet, let's say once a year or twice a year in a particular place to share experiences, you know, try to understand what their challenges are in their different areas. And then, you know, share insights in order to make sure that we would be up to par in whatever is coming" (P09).

6 DISCUSSION

In this study, participants from nine sub-Saharan African countries recognize both the challenges and opportunities associated with CROs in their specific setting. Challenges that arise in one country may not be relevant in another; on the other hand, opportunities in one country may be the challenge for the other one. In sub-Saharan Africa, challenges often outweigh opportunities, yet participants remain optimistic about the industry's future growth. Challenges such as inadequate regulatory frameworks, inconsistent legal and ethical standards, and bureaucratic obstacles are significant issues faced by CROs. Various strategies have been implemented to address these significant challenges, including fostering collaborations and forming strategic partnerships. Therefore, promoting the opportunities available in sub-Saharan Africa holds great potential for the industry's growth. It is crucial for different stakeholders to collaborate in order to enhance practices and establish CROs in the region since recent times have seen Africa gaining recognition as a key player in the clinical trials arena(59).

6.1 Comparison among the participated countries

The participating countries come from diverse socio-economic backgrounds, even though they are all located in sub-Saharan Africa. Given the importance of diversifying African economies, it is crucial to understand how different aspects of diversification can influence the range of available policy options(60). According to the IMF's 2024 forecast, South Africa is Africa's largest economy(61). In contrast, Gambia, Uganda, and Ethiopia are ranked among the poorest countries globally, at 20th, 24th, and 33rd, respectively(62). This economic disparity significantly influences the findings related to the setting up, challenges, and opportunities of CROs in each country.

Registration: Because of concern about CRO registration, some seem to have resorted to carry out a CRO function through consultancy. While this is acceptable if the functions are defined

within the consultancy services the organization offers, the entity will not be visible to industry requiring a CRO service.

Regulatory: Flexible and well-established regulatory registration, submission, and approval processes are cited as significant opportunities in South Africa and Gambia, facilitating smoother and more efficient operations for CROs and sponsors. These streamlined processes can accelerate the initiation and conduct of clinical trials, making the region attractive for investment and collaboration. On the other hand, the other sub-Saharan African countries face challenges with delayed regulatory registration, submissions, and approvals which is also the a finding in other researches(39). These delays create substantial bottlenecks, slowing down the progress of clinical trials and discouraging potential sponsors and CROs from engaging in these markets. A recent study has also indicated that the rising regulatory demands pose a significant challenge for CROs. As regulations for clinical research become increasingly strict, CROs may face difficulties in complying with the expectations set by regulatory bodies. This entails the responsibility of ensuring that clinical trials are conducted with the highest ethical standards and in alignment with GCP guidelines. To address this, CROs will be required to make substantial investments in training and resources to ensure full compliance with these requirements and to avoid costly delays or regulatory obstacles(28).

Infrastructure: According to participants from Ethiopia and Uganda, their operations are severely hampered by delays in infrastructure development. The region faces significant limitations due to inadequate laboratory facilities and other essential infrastructure, a challenge that is also highlighted in other studies(31). Some of the strategies they use were signing MoU and outsourcing some services. The Ethiopian based CRO signed MoU with AHRI to get some laboratory services. Working with contact diagnostic organizations (CDOs) enhances the scientific community as a whole, helps the laboratories they service, and promotes a culture of cooperation and knowledge sharing amongst industry specialists(63).

On the other hand, participants from South Africa, Ethiopia, and the Gambia highlighted the availability of big infrastructure, which includes lots of research locations, as a big chance for CROs to succeed. This contrast draws attention to how different regions have distinct infrastructure and how it affects CROs' capacities and growth prospects.

The need for physical infrastructure while starting a CRO has also been brought up by other CROs. It is notable, though, that South African CROs have chosen a different strategy, choosing to work

remotely and from home. A CRO offering regulatory services from conception to approval without the need for in-house staff was identified by a previous study(64). They successfully offer sponsors document-related services in spite of this atypical configuration. This example shows how the CRO sector is flexible and adaptable, offering several ways of operating that can still provide clients with high-quality services.

Workforce: CROs from Ethiopia, Gambia, Senegal, South Africa, and Uganda have mentioned the availability of trained workers in their countries as a significant opportunity. In contrast, Nigerian-based CROs, along with the rest, have reported challenges in finding individuals with sufficient expertise in clinical research which is evidenced by other researches(25,30,35).

A South African participant highlighted that her CRO is small, and she works alone to deliver services to sponsors. This observation aligns with findings from a previous study, which emphasized the importance of this model. To maximize profit, it is common for a typical CRO to have a single person, regardless of their role, involved in multiple studies. This approach allows for greater flexibility and efficiency in managing various projects(65).

CROs are adopting a novel strategy in which they are increasingly incorporating technology into clinical trials. Recent research has indicated that machine learning and artificial intelligence (AI) will play a significant role in reshaping the landscape of clinical trials. As a result, CROs are expected to rely less on manual labor due to these advancements(66).

Prior experience: It is mentioned by all participants about the need of training and experience when setting up of a CRO. The advantages of prior experience, personnel training, and background is in line with previous research(67).

Finance: South African CROs specifically highlighted that one of the most significant obstacles they encounter is the high cost associated with conducting clinical trials. This issue is compounded by findings from other research, which also points to the financial burden as a critical challenge for CROs operating in the region(24,34). On the other hand, economic opportunities have been explained by CROs in various regions. For instance, Gambian CROs noted reduced costs, Ugandan CROs pointed out governmental support, and South African CROs identified strategies for optimizing taxes.

Data quality: A recommendation from a CRO based in South Africa suggested and prioritized data quality. This suggestion aligned with a report indicate that CROs often encounter compliance issues. Despite being expected to deliver high-quality services, CROs may face challenges such as poor data quality, inadequate site oversight, and insufficient staff training(68,69). Improvements in data quality are essential steps for CROs to meet compliance standards and enhance credibility of their services.

Government support: According to participants from Ethiopia there is a notable lack of government support and prevalent misconceptions about clinical research consultancies. These consultancies are often mistakenly viewed solely as business entities, rather than as contributors to scientific and medical advancements. Additionally, there is a pervasive fear among these consultancies that their offices could be shut down unexpectedly. A participant from South Africa has also mentioned the focus of the government is to R&D rather than of clinical researches. In contrast, participants from other African countries reported receiving government support and assistance, and did not mention facing similar issues. This finding is consistence with other study (23).

High population and genetic diversity: All participants noted that their countries' high populations with significant genetic diversity and various ethnicities present a unique opportunity for CROs in the region. This finding is supported by other research, which underscores the potential for diverse genetic and ethnic backgrounds to enhance the scope and impact of clinical trials conducted by CROs in sub-Saharan Africa(40,44).

7 STRENGTHS AND LIMITATIONS

One of the strengths of this study is its qualitative research approach, which enabled the uncovering and delineation of the diverse experiences of interviewees with CROs. Notably, this study is the first of its kind in the African region, shedding light on a previously unexplored area and providing valuable insights into the operations and dynamics of CROs. This cross-country comparison highlighted unique challenges and strategies, offering a richer, divergent views and more detailed understanding of the landscape in which CROs operate in Sub-Saharan Africa.

However, it's important to acknowledge the limitations of this study. Notably, there is a lack of representation from regulatory, pharmaceutical CROs and academia, which may have resulted in

a partial view of the landscape. The study also involved participants only from sub-Saharan Africa doesn't explore from northern Africa region.

Further analysis reveals that the participants lack the necessary knowledge required for establishing a CRO, as evidenced by their stated requirements. Efforts were made to conduct Focus Group Discussions (FGDs); however, the challenge of coordinating participants simultaneously posed difficulties in execution.

8 CONCLUSIONS

In conclusion, the insights gained from this research provide a strategic foundation for clinical research experts to understand the process of establishing CROs and the potential challenges they may encounter. Exploration of these challenges reveals several strategies that are essential for new CROs, providing insight into how established CROs navigate and overcome operational difficulties.

Regulatory bodies should focus on developing a CRO specific standard and regulations. Furthermore, stakeholders including policymakers and sponsors can create a more supportive environment for clinical research, which will ultimately contribute to the expansion and success of CROs industry in sub-Saharan Africa.

9 RECOMMENDATION

CROs in sub- Saharan Africa region should give emphasis towards addressing at least the following issues;

- All regulatory bodies in the participating countries need to establish clear requirements and standards for setting up CROs. This will ensure consistency, quality, and compliance across the region.
- There should be strong networking platforms that connect new CROs with the established ones as well as CROs with stakeholders like sponsors. Establishment of local and regional associations is important for CROs to work collaboratively and assess the challenges and solve their problems together. Additionally, creating mentorship and internship opportunities for new CROs can significantly enhance practices and expertise within the region.

- Sponsors should actively support the growth of new CROs by fostering and facilitating capacity-building activities.
- Further research at the African level is advised to gain detailed insights and contribute to progress in this field. Subsequent studies should also engage representatives from regulatory bodies, pharmaceutical CROs, academic institutions, and other stakeholders.

By addressing these recommendations, the effectiveness and sustainability of CROs in sub-Saharan Africa can be significantly improved, fostering a more conducive environment for clinical research and development.

10 REFERENCES

1. Brooke Corcoran. What is a contract research organization (CRO)? – MED Institute [Internet]. 2022 [cited 2023 Aug 14]. Available from: https://medinstitute.com/blog/what-is-a-contract-research-organization-cro/

2. BCC Research. BCC Research. 2021 [cited 2023 Aug 14]. Global Market for Contract Research Organization (CRO) Services. Available from: https://www.reportlinker.com/p05647308/Global-Market-for-Contract-Research-Organization-CRO-Services.html

3. Food E, Authority D, Trial C, Guideline A. CLINICAL TRIAL AUTHORIZATION GUIDELINE EFDA / GDL / 005 Third Edition Addis Ababa , Ethiopia. 2023;(April). Available from: http://www.efda.gov.et/wp-content/uploads/2023/06/CTA-Guideline-3rd-edition.pdf

4. Terwindt C. Health rights litigation pushes for accountability in clinical trials in India. Health Hum Rights [Internet]. 2014;16(2):84–95. Available from: https://www.hsph.harvard.edu/wp-content/uploads/sites/2469/2014/12/Terwindt-final.pdf

5. Arora Nageen AN. CONTRACT RESEARCH ORGANIZATION AND ITS GROWTH CRITERIA. IOSR J Pharm [Internet]. 2012 Jan;2(2):182–3. Available from: http://www.iosrphr.org/papers/v2i2/K022182183.pdf

6. Engla NEW, Journal ND. New engla nd journal. 2007;1365–8. Available from: https://www.nejm.org/doi/pdf/10.1056/NEJMp078176?articleTools=true

7. van Huijstee M, Homedes N. Putting contract research organisations on the radar. Vol. 9, International Psychiatry. 2012. 32–34 p.

8. kim Oliver. Contract Pharma. 2005 [cited 2023 Aug 14]. Functional Outsourcing | Contract Pharma. Available from: https://www.contractpharma.com/issues/2005-05/view_features/functional-outsourcing/

9. Ide U. Rediscovering the Role of Regulatory Scientists The ABCs of SOP Best Practices.

Appl Clin Trials [Internet]. 2010; Available from: https://cdn.sanity.io/files/0vv8moc6/act/7034a95a074493149de442d7baf30617896dbe35.pdf/article-821341.pdf

10. Cros S, Data M, Medical PB. Contract Research Organisations and the Different Roles They Play | Novotech CRO. NOVOTECH [Internet]. 2022; Available from: https://novotech-cro.com/faq/contract-research-organisations-and-different-roles-they-play

11. TECHNICAL ICFHO, (ICH) RFPFHU. ICH E6(R2): Guideline for Good Clinical Practice [Internet]. Vol. 13. 2016. 225–232 p. Available from: https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

12. Alvesson M. Management of Knowledge - Intensive Companies. De Gruyter [Internet]. 1995;61:61. Available from: https://doi.org/10.1515/9783110900569

13. Balconi M, Lorenz V. The increasing role of contract research organizations in the evolution of the biopharmaceutical industry. Dep Econ Manag Univ Pavia, Italy [Internet]. 2017;(February). Available from: https://www.lem.sssup.it/WPLem/files/2017-10.pdf

14. Lucas N. Contract Research Organizations: Key Partners In The Drug Development Journey. Forbes [Internet]. 2021;2021. Available from: https://www.forbes.com/sites/forbestechcouncil/2021/04/09/contract-research-organizations-key-partners-in-the-drug-development-journey/?sh=174a7e0b7a58

15. Milne CP. Tufts Center for the Study of Drug Development. 2001 Jan 1; Available from: https://www.crainsnewyork.com/assets/pdf/CN1022081027.PDF

16. Brooks K. CRO industry update. Contract Pharma [Internet]. 2009;(5):29. Available from: https://www.contractpharma.com/issues/2011-05/view_features/cro-industry-update-2011-04-29-10-53-51/

17. Dey K. Contract Research Organizations (CRO) Market Research Report Information. Mark Res Rep [Internet]. 2021;3322. Available from: https://www.marketresearchfuture.com/reports/contract-research-organization-market-

3322

18. INDUSTRY RESEARCH REPORTS. Construction Industry in the US - Market Research Report. IbisworldCom [Internet]. 2021; Available from: https://www.ibisworld.com/united-states/market-research-reports/construction-sector/

19. Kamat VR. Fast, cheap, and out of control? Speculations and ethical concerns in the conduct of outsourced clinical trials in India. Soc Sci Med [Internet]. 2014;104(March):48–55. Available from: https://pubmed.ncbi.nlm.nih.gov/24581061/

20. Balganesh T, Kundu TK, Chakraborty TK, Roy S. Drug discovery research in India: Current state and future prospects. ACS Med Chem Lett. 2014;5(7):724–6.

21. Worldometer. Population of Africa (2024) - Worldometer [Internet]. 2024 [cited 2024 Jun 27]. Available from: https://www.worldometers.info/world-population/africa-population/

22. Bairu M, Chin R. Global Clinical Trials Playbook. Glob Clin Trials Playb [Internet]. 2012;2012. Available from: https://shop.elsevier.com/books/global-clinical-trials-playbook/bairu/978-0-12-415787-3

23. Woods L. Globe News Wire. 2021 [cited 2023 Aug 15]. The Worldwide Contract Research Organizations (CRO). Available from: https://www.globenewswire.com/en/news-release/2021/01/08/2155430/28124/en/The-Worldwide-Contract-Research-Organizations-CRO-Industry-is-Expected-to-Grow-to-64-4-Billion-by-2027.html

24. Contract research map. Ethiopia CROs - Contract Research Map [Internet]. 2023 [cited 2023 Aug 15]. Available from: https://www.contractresearchmap.com/places/ethiopia

25. Cevent. Workshop on CRO summary. 2022;6887.

26. AAU. Center for Innovative Drug Development and Therapeutic Trials for Africa [Internet]. 2018. Available from: https://ace2.iucea.org/CDT-Africa-Advert_MSc Clinical-Trial.pdf

27. AHRI. AHRI. 2023. p. 2023 Clinical Trials Directorate AHRI. Available from:

https://ahri.gov.et/clinical-trial/

28. Leshchenko A. Farmovs. 2023 [cited 2024 Jun 28]. Challenges to watch in 2023 for CROs. | LinkedIn. Available from: https://www.linkedin.com/pulse/challenges-watch-2023-cros-anton-leshchenko/

29. Advances D. Ethiopia ' s 2023-24 Budget. 2023;1–15.

30. UNICEF. 2016/17 Malawi Health Budget Brief. 2016;(March):1–9. Available from: http://apps.who.int/nha/database/ViewData/

31. Røttingen JA, Chamas C, Goyal LC, Harb H, Lagradae L, Mayosi BM. Securing the public good of health research and development for developing countries. Bull World Health Organ [Internet]. 2012 May 5 [cited 2023 Aug 15];90(5):398. Available from: /pmc/articles/PMC3341704/

32. Governance GF. The 10 / 90 Report on Health Research. Health (San Francisco). 2002.

33. Medical Device Network. Could Africa become a clinical trial powerhouse? - Medical Device Network [Internet]. 2021 [cited 2023 Aug 15]. Available from: https://www.medicaldevice-network.com/features/could-africa-become-a-clinical-trial-powerhouse/

34. Kasprowicz VO, Chopera D, Waddilove KD, Brockman MA, Gilmour J, Hunter E, et al. African-led health research and capacity building- is it working? BMC Public Health. 2020;20(1):1–10.

35. Wouters OJ, McKee M, Luyten J. Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. JAMA - J Am Med Assoc. 2020;323(9):844–53.

36. Harris E. Building scientific capacity in developing countries. EMBO Rep. 2004;5(1):7–11.

37. Lang T, Siribaddana S. Clinical trials have gone global: is this a good thing? PLoS Med [Internet]. 2012 [cited 2023 Aug 15];9(6):6. Available from:

https://pubmed.ncbi.nlm.nih.gov/22719228/

38. Neil Weisfeld, Rebecca A. English, and Anne B. Claiborne R. Envisioning a Transformed Clinical Trials Enterprise in the United States [Internet]. Envisioning a Transformed Clinical Trials Enterprise in the United States. 2012. Available from: https://nap.nationalacademies.org/download/13345

39. Kochhar S. Challenges and impact of conducting vaccine trials in Asia and Africa: New Technologies in Emerging Markets, October 16th-18th 2012; World Vaccine Congress, Lyon. Hum Vaccin Immunother [Internet]. 2013 Apr [cited 2023 Aug 15];9(4):924–7. Available from: https://pubmed.ncbi.nlm.nih.gov/23321645/

40. Clinicaltrials.gov. National Library of Medicine. 2023 [cited 2023 Aug 15]. Trends, Charts, and Maps - ClinicalTrials.gov. Available from: https://classic.clinicaltrials.gov/ct2/resources/trends

41. Study.com. Ethnic Groups in Africa - Video & Lesson Transcript | Study.com [Internet]. 2023 [cited 2023 Aug 15]. Available from: https://study.com/academy/lesson/ethnic-groups-in-africa.html

42. Wikipedia. List of ethnic groups in Ethiopia - Wikipedia [Internet]. 2023 [cited 2023 Aug 15]. Available from: https://en.wikipedia.org/wiki/List_of_ethnic_groups_in_Ethiopia

43. Buekens P, Keusch G, Belizan J, Bhutta ZA. Evidence-based global health. JAMA [Internet]. 2004 Jun 2 [cited 2023 Aug 15];291(21):2639–41. Available from: https://www.researchgate.net/publication/8533953_Evidence-Based_Global_Health

44. Siegfried N, van der Merwe L, Brocklehurst P, Sint TT. Antiretrovirals for reducing the risk of mother-to-child transmission of HIV infection. Cochrane database Syst Rev [Internet]. 2011 Jul 6 [cited 2023 Aug 15];(7). Available from: https://pubmed.ncbi.nlm.nih.gov/21735394/

45. World Health Organization. Global status report on noncommunicable diseases. World Heal Organ. 2010;53(9):1689–99.

46. Marquez P. The Challenge of Non-Communicable diseases and Road Traffic Injuries.

World Bank Rep. 2013;(July).

47. Dean T Jamison, Richard G Feachem, Malegapuru W Makgoba, Eduard R Bos, Florence K Baingana, Karen J Hofman KOR. Pubmed. 2006 [cited 2023 Aug 15]. Disease and Mortality in Sub-Saharan Africa - PubMed. Available from: https://pubmed.ncbi.nlm.nih.gov/21290641/

48. Ferlay J, Soerjomataram I, Dikshit R, Eser S, Mathers C, Rebelo M, et al. Cancer incidence and mortality worldwide: Sources, methods and major patterns in GLOBOCAN 2012. Int J Cancer. 2015;136(5):E359–86.

49. Rebbeck TR. Cancer in sub-Saharan Africa. Science (80-) [Internet]. 2020 Jan 3 [cited 2024 Jun 17];367(6473):27–8. Available from: https://www.science.org/doi/10.1126/science.aay4743

50. Mbuagbaw L, Thabane L, Ongolo-Zogo P, Lang T. The challenges and opportunities of conducting a clinical trial in a low resource setting: The case of the Cameroon mobile phone SMS (CAMPS) trial, an investigator initiated trial. Trials. 2011;12:1–7.

51. Glickman SW, McHutchison JG, Peterson ED, Cairns CB, Harrington RA, Califf RM, et al. Ethical and Scientific Implications of the Globalization of Clinical Research. N Engl J Med. 2009;360(8):816–23.

52. Hayasaka E. Approaches vary for clinical trials in developing countries. J Natl Cancer Inst. 2005;97(19):1401–3.

53. Malakoff D. Clinical trials and tribulations. Spiraling costs threaten gridlock. Science [Internet]. 2008 Oct 10 [cited 2023 Aug 15];322(5899):210–3. Available from: https://pubmed.ncbi.nlm.nih.gov/18845742/

54. Bansal N. The opportunities and challenges in conducting clinical trials globally. Clin Res Regul Aff. 2012 Mar;29(1):9–14.

55. World Bank. Recent developments. World Bank Rep. 2024;

56. NDhere A. Benefits of Conducting Clinical Trials in Europe. ACE Res [Internet]. 2023;

Available from: https://www.atlantclinical.com/benefits-of-conducting-clinical-trials-in-europe

57. Dal-Ré R, Ndebele P, Higgs E, Sewankambo N, Wendler D. Protections for clinical trials in low and middle income countries need strengthening not weakening. BMJ [Internet]. 2014 Jul 4 [cited 2023 Aug 15];349. Available from: https://pubmed.ncbi.nlm.nih.gov/24996885/

58. ClinicalTrials.gov. ClinicalTrials.gov. 2024 [cited 2024 Jun 27]. Trends and Charts on Registered Studies | ClinicalTrials.gov. Available from: https://clinicaltrials.gov/about-site/trends-charts

59. Philpott J. Clinical Trials Arena. 2024 [cited 2024 May 23]. Clinical trials in Africa: Where there is a challenge, there is an opportunity - Clinical Trials Arena. Available from: https://www.clinicaltrialsarena.com/news/clinical-trials-in-africa-where-there-is-a-challenge-there-is-an-opportunity/

60. Zainab Usman and David Landry. Carnegie. 2021 [cited 2024 May 23]. Economic Diversification in Africa: How and Why It Matters - Carnegie Endowment for International Peace. Available from: https://carnegieendowment.org/research/2021/04/economic-diversification-in-africa-how-and-why-it-matters?lang=en

61. Africa IBS. Sovereign. 2024 [cited 2024 May 23]. IMF Forecasts SA To Have Africa's Largest Economy In 2024. Available from: https://www.sovereigngroup.com/news/news-and-views/imf-forecasts-south-africa-to-have-africas-largest-economy-in-2024/

62. Luca Ventura. Global Finance. 2024 [cited 2024 May 23]. Poorest Countries in the World 2024 | Global Finance Magazine. Available from: https://gfmag.com/data/economic-data/poorest-country-in-the-world/

63. Berries Health & Genetics. Barriers and Health genetics. 2023 [cited 2024 May 23]. Bridging the Resource and Infrastructure Gaps: The Vital Role of Contr – Berries Health & Genetics. Available from: https://berrieshealthinc.com/blogs/news/bridging-the-resource-and-infrastructure-gaps-the-vital-role-of-contract-research-and-diagnostics-

organizations

64. Mew A, Smith DA, Cole J, Sadow C, Tirumani SH, Ramaiya NH. Role of Radiologists in Contract Research Organizations (CROs). Curr Probl Diagn Radiol. 2023 Mar 1;52(2):77–83.

65. Salminen WF, Greenhaw J, Fowler JM. Introduction. Nonclinical Study Contract Monit. 2013;1–17.

66. Novotech. The Future of Contract Research Organisations | Novotech CRO [Internet]. 2024 [cited 2024 Jun 28]. Available from: https://novotech-cro.com/faq/future-contract-research-organisations

67. Messersmith E. How to Select and Oversee Contract Research Organizations. Glob Clin Trials Playb Capacit Capab Build. 2012 Jan 1;39–55.

68. Kumar TS, Kamaraj R. Compliance challenges in clinical research organizations: A USFDA inspection retrospective. J Pharm Pharmacogn Res. 2024 Jan 1;12(1):91–8.

69. Guest Column. C;linical Leader. 2023 [cited 2024 May 23]. Key Considerations For Working With CROs. Available from: https://www.clinicalleader.com/doc/key-considerations-for-working-with-cros-0001

ANNEX 1: INFORMATION SHEET AND CONSENT FORM

This informed consent form is for key informants and who we are inviting to participate in this research, titled "Setting up contract research organizations (CROs) in Sub-Saharan Africa: Challenges, Opportunities, and future prospects; a qualitative study"

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction

I am Shiferaw Tesfaye, a prospective Masters Student in Clinical Trial at CDT-Africa, Addis Ababa University. I am doing research on CROs which is a growing market area in research industry in African region and in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

Purpose of the research

According to the Ethiopian Food and Drug Authority adopted a similar definition from GCP and define CRO as "a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions"

The aim of this research is to collect information and to identify the challenges, opportunities, setting up and running of CROs practice in Sub-Saharan Africa and to put way forward for improved practices.

This Interview also help to explore the regulatory, technical challenges of CROs practice and services that CROs should focus on in the region.

Type of Research Intervention

This research will involve your participation in an individual discussion that will take about 30-50 minutes.

Participant Selection

You are being invited to take part in this research because we feel that your experience as a clinical researcher (or as CEOs or as senior scientists,) can contribute much to our understanding and knowledge of local health practices.

Voluntary Participation

Your participation in this research is entirely voluntary. The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.

Procedures

During the interview, I or another interviewer will sit down with you in a comfortable place at the Centre. If it is better for you, the interview can take place in your office. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential, and no one else except PI will access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The information recorded is confidential, and no one else except Shiferaw Tesfaye will have access to the tapes. The tapes will be destroyed after 4 weeks.

Risks

There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.)

Benefits

There will be no direct benefit to you, but your participation is likely to help us find out more about the setting up, challenges and opportunities of CROs in Sub-Saharan Africa.

Reimbursements

You will not receive any incentives for participating in the research. However, your name will be acknowledged in the journal publication of this paper.

Confidentiality

We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key.

Sharing the Results

Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you before it is made widely available to the public. Each participant will receive a summary of the results. Following the meetings, we will publish the results so that other interested people may learn from the research.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the interview at any time that you wish without your job being affected. I will give you an opportunity at the end of the interview to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.

Who to Contact

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following:

Investigator`s Name: Shiferaw Tesfaye

Email: sheftilahun@gmail.com

Phone: +251913539111

Advisor`s Name: Abebaw Fekadu (Professor)

Email:abebaw.fekadu@aau.edu.et

Anteneh Belete (PhD)

Email: anteneh.belete@aau.edu.et

This proposal has been reviewed and approved by IRBof CDT Africa, Addis Ababa University, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact

Dr Tsegahun Manyazewal

Email- tsegahunm@gmail.com

Part II: Certificate of Consent

I have been invited to participate in research about Setting up contract research organizations (CRO) in Sub-Saharan Africa: challenges, opportunities, and future prospects; a Qualitative Study

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

አባሪ

የመረጃ ሉህ እና የፍቃድ ቅፅ

ይህ በመረጃ የተደገፈ የስምምነት ፎርም ለቁልፍ መረጃ ሰጭዎች እና በዚህ ጥናት ላይ እንዲሳተፉ የምንጋብዛቸው፣ ሰዎች ሲሆን የጥናቱ ርእስ የኮንትራት ምርምር ድርጅቶችን ከሰሃራ በታች ያሉ የአፍሪካ አገሮች፡ ተግዳሮት፣ እድሎች፣ አቋቋም እና የወደፊት ተስፋዎች፡አይነታዊ ጥናት የሚል ይሆናል።

ይህ በመረጃ የተደገፈ የስምምነት ቅጽ ሁለት ክፍሎች አሉት፡-

- **የመረጃ ሉህ (ስለ ጥናቱ መረጃ ለእርስዎ ለመጋራት)**
- **የፍቃድ የምስክር ወረቀት (ለመሳተፍ ከመረጡ ፊርማዎች ጋር)**

ሙሉ መረጃ ያለው የስምምነት ቅጽ ቅጂ ይሰጥዎታል

<u>ክፍል አንድ፡ የመረጃ ሉህ</u>

<u>መግቢያ</u>

እኔ ሽፈራው ተስፋዬ ነኝ፣ በአዲስ አበባ ዩኒቨርሲቲ በCDT-አፍሪካ ክሊኒካል ሙከራ የማስተርስ ተማሪ ነኝ። በአፍሪካ ክልል እና በዚህ ሀገር ውስጥ በምርምር ኢንዱስትሪ ውስጥ እያደገ በመጣው የ CROs ኢንዱስትሪ ላይ ምርምር እያደረግሁ ነው። ለእርስዎ መረጃ በመስጠት የዚህ ጥናት አካል እንዲሆኑ እጋብዛለሁ። በጥናቱ ውስጥ መሳተፍ ወይም አለመሳተፍ ዛሬ መወሰን የለብዎትም. ከመወሰንዎ በፊት, ስለ ጥናቱ ምኞት የሚሰማዎትን ማንኛውንም ሰው ማነጋገር ይችላሉ። ይህ የፈቃድ ቅጽ እርስዎ የማይረዱዋቸውን ቃላት ሊይዝ ይችላል። እባክዎን መረጃውን እንደምናልፍ እንዲያቆም ጠይቁኝ እና ለማብራራት ጊዜ እወስዳለሁ። በኋላ ላይ ጥያቄዎች ካሉዎት ከእኔ ወይም ከሌላ ተመራማሪ መጠየቅ ይችላሉ።

የጥናቱ ዓላማ

የኢትዮጵያ ምግብና መድኃኒት ባለሥልጣን እንደገለጸው ከጂሲፒ ተመሳሳይ ትርጉም ወስዶ CROን በዚህ መልኩ ያስርዳል “አንድ ወይም ከዚያ በላይ የስፖንሰር አድራጊ ከሙከራ ጋር የተያያዙ ተግባራትን እና ተግባራትን ለማከናወን በስፖንሰሩ የተዋዋለው ሰው ወይም ድርጅት (ንግድ፣ አካዳሚክ ወይም ሌላ) ነው። ” የዚህ ጥናት አላማ መረጃን መሰብሰብ እና ተግዳሮቶችን፣ እድሎችን፣ የCROs ልምምድን በከሰሃራ በታች ያሉ የአፍሪካ አገሮች ውስጥ ማዋቀር እና ማስኬድ እና የተሻሻሉ አሰራሮችን ማስቀጠል ነው። ይህ ቃለ ምልልስ በኢትዮጵያ ውስጥ CROs ሊያተኩሩባቸው የሚገቡ የቁጥጥር፣ የቴክኒክ ተግዳሮቶችን እና አገልግሎቶችን ለመዳሰስ ይሞክራል።

የምርምር ጣልቃ ገብነት አይነት

ይህ ጥናት ከ30-50 ደቂቃ በሚወስድ የግለሰብ ውይይት ላይ ተሳትፎዎን ይጠይቃል።

የተሳታፊ ምርጫ

በዚህ ጥናት ላይ እንድትሳተፉ ተጋብዘዋል ምክንያቱም እንደ ክሊኒካል ተመራማሪ (ወይም እንደ ዋና ሥራ አስፈፃሚ ወይም እንደ ከፍተኛ ሳይንቲስቶች) ያለዎት ልምድ በአካባቢያዊ የጤና አሠራሮች ላይ ግንዛቤ እና እውቀት ላይ ከፍተኛ አስተዋጽኦ እንደሚያበረክት ስለምንናምን ነው።

በፈቃደኝነት ተሳትፎ

በዚህ ጥናት ውስጥ ያለዎት ተሳትፎ ሙሉ በሙሉ በፈቃደኝነት ነው። የመረጡት ምርጫ በስራዎ ላይ ወይም በማንኛውም ከስራ ጋር በተያያዙ ግምገማዎች ወይም ዘገባዎች ላይ ምንም ተጽእኖ አይኖረውም. በኋላ ላይ ሃሳብዎን መቀየር እና ቀደም ብለው የተስማሙ ቢሆንም መሳተፍዎን ሊያቆሙ ይችላሉ።

ሂደቶች

በቃለ መጠይቁ ወቅት እኔ ወይም ሌላ ቃለ መጠይቅ አድራጊ በማእከሉ ውስጥ ምቹ ቦታ ላይ ከእርስዎ ጋር እንቀመጣለን። ለእርስዎ የተሻለ ከሆነ, ቃለ-መጠይቁ በቢሮዎ ውስጥ ሊከናወን ይችላል. በቃለ መጠይቁ ወቅት ማንኛቸውንም ጥያቄዎች መመለስ ካልፈለጉ፣ እንዲህ ማለት ይችላሉ እና ጠያቂው ወደሚቀጥለው ጥያቄ ይሸጋገራል። ሌላ ሰው እንዲገኝ ካልፈለጉ በስተቀር ከጠያቂው በስተቀር ሌላ ማንም አይኖርም። የተመዘገበው መረጃ ሚስጥራዊ ነው፣ እና ከ PI በስተቀር ማንም በቃለ መጠይቅዎ ወቅት የተመዘገበውን መረጃ አያገኝም። ሙሉ ቃለ መጠይቁ በቴፕ ይቀረጻል፣ ነገር ግን ማንም በቴፕ ላይ በስም አይታወቅም። የተቀረፀው መረጃ ሚስጥራዊ ነው እና ከአቶ ሽፈራው ተስፋዬ በስተቀር ሌላ ማንም ሰው ካሴቶቹን ማግኘት አይችልም። ካሴቶቹ ከ 4 ሳምንታት በኋላ ይደመሰሳሉ።

አደጋዎች

አንዳንድ ግላዊ ወይም ሚስጥራዊ መረጃዎችን በአጋጣሚ ማጋራት ወይም ስለ አንዳንድ ርእሶች ማውራት አለመመቸት ሊሰማህ ይችላል። ሆኖም ይህ እንዲሆን አንፈልግም። ጥያቄዎቹ በጣም የግል እንደሆኑ ከተሰማዎት ወይም ስለእነሱ ማውራት የማይመቸዎ ከሆነ ማንኛውንም ጥያቄ መመለስ ወይም በውይይቱ/ቃለ መጠይቁ/ዳሰሳ ላይ መሳተፍ የለብዎትም።

ጥቅሞች

ለእርስዎ ምንም አይነት ቀጥተኛ ጥቅም አይኖርዎትም, ነገር ግን የእርስዎ ተሳትፎ በኢትዮጵያ ውስጥ ስለ CROዎች አደረጃጀት, ተግዳሮቶች እና እድሎች የበለጠ እንድናውቅ ሊረዳን ይችላል.

ማካካሻዎች

በጥናቱ ላይ ለመሳተፍ ምንም አይነት ማበረታቻ አይሰጥዎትም። ሆኖም ለጊዜዎ የ200 ብር የሞባይል ካርድ እንሰጥዎታለን።

ሚስጥራዊነት

ስለእርስዎ መረጃ ከተመራማሪው ቡድን ውጭ ለማንም አናጋራም። ከዚህ የምርምር ፕሮጀክት የምንሰበስበው መረጃ በሚስጥር ይጠበቃል። ስለእርስዎ ያለ ማንኛውም መረጃ ከእርስዎ ስም ይልቅ በእሱ ላይ ቁጥር ይኖረዋል። ቁጥርዎ ምን እንደሆነ ተመራማሪዎቹ ብቻ ያውቃሉ እና ያንን መረጃ በመቆለፊያ ቁልፍ እንቆልፋለን።

ውጤቶቹን በማጋራት ላይ

ዛሬ እርስዎ የሚነግሩን ምንም ነገር ከተመራማሪው ቡድን ውጭ ለማንም አይጋራም፣ እና ምንም ነገር በስምዎ አይቆጠርም። ከዚህ ጥናት የምናገኘው እውቀት ለህዝብ በስፋት ከመቅረቡ በፊት እናካፍላችኋለን። እያንዳንዱ ተሳታፊ የውጤቶቹን ማጠቃለያ ይቀበላል. ከስብሰባዎቹ በኋላ ሌሎች ፍላጎት ያላቸው ሰዎች ከጥናቱ እንዲማሩ ውጤቱን እናተምታለን።

እምቢ የማለት ወይም የመውጣት መብት

ይህንን ለማድረግ ካልፈለጉ በዚህ ጥናት ውስጥ መሳተፍ የለብዎትም እና ለመሳተፍ መምረጥ በምንም መልኩ ከስራዎ ወይም ከስራዎ ጋር በተያያዙ ግምገማዎች ላይ ተጽእኖ አይኖረውም. ስራዎ ሳይነካ በፈለጉት ጊዜ በቃለ መጠይቁ ላይ መሳተፍ ማቆም ይችላሉ። በቃለ መጠይቁ መጨረሻ ላይ አስተያየትዎን እንዲገመግሙ እድል እሰጣችኋለሁ፣ እና በማስታወሻዎቼ ካልተስማሙ ወይም በትክክል ካልተረዳሁ የእነዚያን ክፍል እንዲያሻሽሉ ወይም እንዲያነሱት መጠየቅ ይችላሉ።

ማንን ማነጋገር እንዳለበት

ማንኛቸውም ጥያቄዎች ካሉዎት አሁን ወይም በኋላ ሊጠይቋቸው ይችላሉ። በኋላ ላይ ጥያቄዎችን መጠየቅ ከፈለጉ ከሚከተሉት አንዱን ማነጋገር ይችላሉ።

የተመራማሪው ስም፡ ሽፈራው ተስፋዬ

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ይህ ፕሮፖዛል በ IRB of ሲዲቲ አፍሪካ, አዲስ አበባ ዩኒቨርሲቲ, ታይቶ ጸድቋል, ይህም የምርምር ተሳታፊዎች ከጉዳት እንዲጠበቁ የማጣራት ስራው የሆነበት ኮሚቴ ነው. ስለ IRB የበለጠ ለማወቅ ከፈለጉ የሚከተለውን ያነጋግሩ

ዶ/ር ፀጋሁን ማንያዘዋል

ኢሜል -tsegahunm@gmail.com

ክፍል II፡ የፍቃድ የምስክር ወረቀት

ከሰሃራ በታች ያሉ የአፍሪካ አገሮች የኮንትራት ምርምር ድርጅቶችን ማቋቋም (CRO) በሚመለከት ጥናት ላይ እንድሳተፍ ተጋብዣለሁ፡ ተግዳሮቶች፣ እድሎች እና የወደፊት ተስፋዎች

ከላይ ያለውን መረጃ አንብቤዋለሁ ወይም ተነቦልኛል። ስለሱ ጥያቄዎችን ለመጠየቅ እናም ማንኛውንም የጠየኩትን ጥያቄዎች መልስ አግኝቻለሁ። በዚህ ጥናት ውስጥ ተሳታፊ ለመሆን በፈቃደኝነት ተስማምቻለሁ።

የተሳታፊው ስም _____

ፊርማ _____

ቀን _____

በተመራማሪው/በፍቃደኝነት የሚወስደው ሰው የተሰጠ መግለጫ

ተሳታፊው ስለ ጥናቱ ጥያቄዎችን ለመጠየቅ እድል እንደተሰጠው አረጋግጣለሁ, እና በአሳታፊው የተጠየቁት ሁሉም ጥያቄዎች በትክክል እና በተቻለኝ መጠን ምላሽ አግኝተዋል። ግለሰቡ ፈቃድ እንዲሰጥ እንዳልተገደደ፣ እና ፈቃዱ በነጻ እና በፈቃደኝነት መሰጠቱን አረጋግጣለሁ።

የዚህ አይሲኤፍ ቅጂ ለተሳታፊው ተሰጥቷል።

ፈቃዱን የወሰደ የተመራማሪው ስም _____

ፊርማ _____

ቀን _____

ANNEX 2: INTERVIEW GUIDE

Title of the Study: Setting up contract research organizations (CRO) in sub-Saharan Africa: challenges, opportunities, and future prospects; a Qualitative Study

GENERAL INTRODUCTION

I am **Shiferaw Tesfaye**, a master's student at CDT-Africa, College of Health Sciences, Addis Ababa University. I am going to facilitate our discussion today. Our discussion will be on your personal views and experiences about setting up contract research organizations (CRO's) in sub-Saharan Africa: challenges, opportunities, and future prospects.

Identifications	
Name of the CRO:	
Country:	
Position:	
Educational background:	
Years of experience:	
Age of the participant:	
Sex of the participant:	
Interviewers (data collectors)	
Date of visit	

No	Questions
1	What is/was the role of your CRO?
2	What was/is your role in the CRO?
3	What is your experience as CROs in your country? Explain
4	How do you describe your commitment to staying updated with industry advancements and their approach to fostering innovation within a CRO?
5	What challenges have you faced in working as a CROs in your country? Explain
6	What is your understanding of the key components required to establish a successful CRO.
7	How do you see your familiarity with regulatory requirements and quality assurance standards for CROs.
8	What strategies have you used to overcome the challenges of working as CROs in your country?
9	What opportunities have you seen in working as CROs in your country?
10	What do you think are the most important benefits of working as CROs in your country?
11	What advice would you give to other researchers working as CROs in your country?
12	What changes would you like to see in the way CROs operate in your country?
13	What do you think are the most important factors for successful collaboration between researchers and CROs in your country?
14	Do you have any recommendations for improved practice in your country? Explain.

Table 2: Interview guide

ቃለ መጠይቅ መመሪያ

የጥናቱ ርዕስ፡ የኮንትራት ምርምር ድርጅቶችን ከሰሃራ በታች ያሉ የአፍሪካ አገሮች: ተግዳሮት፣ እድሎች፣ አቋቋም እና የወደፊት ተስፋዎች፡አይነታዊ ጥናት

አጠቃላይ መግቢያ

እኔ ሽፈራው ተስፋዬ በአዲስ አበባ ዩኒቨርሲቲ የጤና ሳይንስ ኮሌጅ በሲዲቲ-አፍሪካ የማስተርስ ተማሪ

ስሆን ውይይታችንን ለመምራት እድሉን ስላገኘው ምስጋናዬን እያቀረብኩ ለመመረቂያ ጥናት ግብዓት ይሆን ዘንድ ለምናረገው ውይይት ፈቃደኛ ስለሆኑ ልባዊ አክብሮቴ የላቀ ነው ። ጥያቄዎቼም የኮንትራት ምርምር ድርጅቶች ከሰሃራ በታች ያሉ የአፍሪካ አገሮች፡ ተግዳሮት፣ እድሎች፣ አቋቋም እና የወደፊት ተስፋዎች ላይ ያተኮሩ ሲሆን የእርስዎ የግል እይታ እና ተሞክሮ ምን ይመስላል የሚሉትን ለመዳሰስ ይሞክራል ።

ሰንጠረዥ 5፤ የቃለ መጠይቅ ጥያቄ መመሪያ የኮንትራት ምርምር ድርጅቶች

መለያዎች	
የ ሲ አር ኦ ስም፡	
ሀገር፡	
ስልጣን፡	
የትምህርት ዳራ፡	
የዓመታት ልምድ፡	
የተሳታፊው ዕድሜ፡	
የተሳታፊው ጾታ፡	
ጠያቂዎች (መረጃ ሰብሳቢዎች)፡	
የጉብኝት ቀን፡	

ተ.ቁ	ጥያቄዎች
1	የእርስዎ የሲ አር ኦ ሚና ምንድን ነው/ነበር?
2	በ ሲ አር ኦ ውስጥ የእርስዎ ሚና ምን ነበር?
3	እንደ ሲ አር ኦ በኢትዮጵያ ያላችሁ ልምድ ምን ይመስላል? አብራራ/ሪ
4	በኢንዱስትሪ እድገቶች እና በሲ አር ኦ ውስጥ ፈጠራን ለማጎልበት ያላቸውን ቁርጠኝነት እንዴት ይገልፁታል??
5	ኢትዮጵያ ውስጥ እንደ ሲ አር ኦ ስትስሩ ምን ተግዳሮቶች አጋጥሞት ነበር? አብራራ/ሪ
6	የተሳካ ሲ አር ኦን ለመመስረት ስለሚያስፈልጋቸው ቁልፍ አካላት ያለዎት ግንዛቤ ምንድነው?
7	ከቁጥጥር መስፈርቶች እና ሲ አር ኦን የጥራት ማረጋገጫ ደረጃዎች ጋር ያለዎትን ትውውቅ እንዴት ያዩታል።
8	በኢትዮጵያ እንደ ሲ አር ኦ የመስራት ፈተናዎችን ለማሸነፍ ምን ስልቶችን ተጠቅማችኋል?
9	በኢትዮጵያ እንደ ሲ አር ኦ ለመስራት ምን እድሎች አይተዋል?
10	በኢትዮጵያ እንደ ሲ አር ኦ በመስራት የሚገኝ ትልቅ ጥቅሞች ምንድ ናቸው ብለው ያስባሉ?
11	በኢትዮጵያ እንደ ሲ አር ኦ ለሚሰሩ ሌሎች ተመራማሪዎች ምን ምክር ይሰጣሉ?
12	ሲ አር ኦ በኢትዮጵያ ውስጥ በሚሰሩበት መንገድ ላይ ምን አይነት ለውጦችን ማየት ይፈልጋሉ ?
13	በኢትዮጵያ በተመራማሪዎች እና በሲ አር ኦ መካከል ስኬታማ ትብብር እንዲኖር በጣም አስፈላጊዎቹ ነገሮች ምን ይመስላችኋል?
14	በኢትዮጵያ ለወደፊት የተሻለ አሰራር ምክሮች አሎት? አብራራ/ሪ።

ሠንጠረዥ 3: የቃለ መጠይቅ መመሪያ