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Original Article

Implementation of a Harmonized Ethical and Regulatory Review System for Clinical Trial Protocols in East Africa: Exploring Challenges and Opportunities

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Abstract

Background: *Medical products are regulated from premarket clinical trials (Phase I, II and III) to post marketing surveillance (phase IV clinical trials). Product development and research organizations have responsibilities to conduct clinical trials subject to ethical approval and clinical trial authorization prior to releasing products to the market. Harmonized approaches for ethical and regulatory approvals of clinical trials are practiced globally including in East African countries through regional economic communities. The aim of this study was to explore opportunities and challenges in the implementation of a harmonized ethical and regulatory review system for clinical trial protocols in East African Countries.*

Methods: *A qualitative study was conducted in five selected East African countries focusing on regional economic communities (RECs). Purposive sampling method was applied to select key informants from national health research ethics review committees, national medicine regulatory authorities, development partners, sponsors and research institutions. Data were collected through self-administered structured questionnaires shared through email. The data were analyzed using a thematic approach using QDA Miner Lite qualitative data analysis software.*

Results: *A total of 24 key informants (eight females) from five east African countries (Ethiopia, Kenya, Sudan, Uganda and Tanzania) were involved in this exploratory study. Strong desire to have strong ethics and regulatory review system, availability of established platforms and enabling opportunities were identified as opportunities for the implementation of a harmonized ethical review and trial authorization system in the region. On the other hand, weak capacity, lack of framework to support harmonization, difference in organizational structure and regulatory requirement, lack of procedural clarity, long incubation to establish harmonized system and lack of political commitment were some of the identified challenges.*

Conclusion: *The study highlights both the opportunities and challenges of implementing harmonized ethical review and regulatory authorization system for clinical trial protocols in East African countries. Given the importance of harmonized ethical review and regulatory authorization system in the region, actions need to be taken by all stakeholders of clinical trials to identify strategies in order to maximize the available opportunities and tackle the challenges in a sustainable way.*

Key words: *Harmonization, Clinical Trials Regulation, East Africa, ethical review system*
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Introduction

Medicinal products have to be regulated from premarket clinical trials (phases I, II and III) to post marketing surveillance (phase IV clinical trials) (1). Such medical products which require clinical trials include medicines, medical devices, biological/herbal medicines and other related products (2–5). Clinical trial is an experimental study conducted in humans to evaluate a new intervention or new way of using an existing treatment to develop better therapeutics (6, 7).

Competent and pragmatic regulatory process for authorization of trials and products is a critical step for

assuring safety and efficacy of specific medical products (8, 9). Medicines regulatory harmonization is taking place in various regions globally, including in the Asia-Pacific economic cooperation(APEC), East African Community (EAC) and the Pan American Network for Regulatory Harmonization(PANDRH) to reduce regulatory barriers, and standardize and expedite approvals (10,11). The EAC Medicines Regulatory Harmonization (EAC-MRH) initiative was launched in 2012 as a component of the broader African Medicines Regulatory Harmonization (AMRH) program, which aims to establish a more efficient regulatory landscape throughout the African continent. Clinical trial regulatory harmonization is a priority for the EAC (12). Such harmonization takes into account the minor cultural differences existing among countries of the regions (13). A harmonized ethical and regulatory review process for clinical trial protocols is believed to be among strategies for addressing various barriers and disparity in ethical and regulatory review process (14). Harmonization may also help address limitations in resources, technical competency, synergize support for regulatory bodies ensuring quality and sustainability of regulatory provisions for clinical trials (15). Regulatory harmonization may be of particular importance in multi-center and multi-country trials, which are enable recruitment of large number of participants in a short period of time and are useful for investigation of rarely occurring diseases (16). Regulatory harmonization is also important in outbreaks and public emergency conditions that require immediate responses at national, regional, and global levels (17–19). Therefore, collaborative procedures which facilitate the approval process, reduce cost and facilitate the shared use of regional findings for various regional and global problems could be relevant (20–22). The aim of the present study was to identify the opportunities and challenges of implementing a harmonized ethical and regulatory review system for clinical trial protocols in regional economic communities of the East African countries.

Methods

Study setting

The study was conducted in five East African countries focusing on regional economic communities, specifically the EAC and the Inter-Governmental Authority on Development (IGAD) including, Ethiopia, Kenya, Sudan, Tanzania and Uganda. The selected countries were chosen based on the relative experience of conducting clinical trials, evolving drug discovery initiatives, increasing demographic changes along with demand and accessibility of key informants. The study was conducted between March and September, 2020.

Study design and participants

The study employed a descriptive qualitative study design. Stakeholders of clinical trials including National Ethics Committee members, investigators, sponsors, and regulatory experts from various National Medicine Regulatory Authorities (NMRAs) were included in the study. The NMRAs were the National Medicine and Poison Board (NMPB) of Sudan, Ethiopian Food and Drug Authority (EFDA), Kenyan Pharmacy and Poison Board (KPPB), Tanzania Medicine and Medical Devices Authority (TMDA), and National Drug Authority (NDA) of Uganda). In addition experts who are involved in other core regulatory functions, such as Pharmacovigilance, medicine registration and harmonization were involved in the study. In addition, due to their important role in capacity building activities, experts from Armauer Hansen Research Institute (AHRI) and the development partners such as IGAD, Drugs for Neglected Disease initiative (DNDi), United States Pharmacopeia (USP), and Kenya Medical Research Institute (KMRI) were also involved.

Eligibility criteria

Those who met the following criteria were involved in the study:

- National Research Ethics Review Board (NRERBs) members
- NMRAs staff involved in harmonization activities of East African countries having experience of regulation of clinical trials, Pharmacovigilance or medicine registration
- Sponsors involved in at least one clinical trial in the region
- Research institutions having experience of conducting clinical trials in the region
- Development partners which participate in facilitation and capacity building activities in the region

Sampling procedure

Key informants were purposively selected using criterion-based and maximum variation sampling to capture a wide range of perspectives and experiences. This included individuals involved in capacity building, ethical and regulatory reviews, clinical trials, and coordination of regional harmonization initiatives, ensuring diverse perspectives aligned with the nature of research questions. A total of 24 participants participated in this study. Among selected countries in East Africa, one EAC member country, two both EAC and IGAD member countries and two IGAD member countries were involved in the study. The sampling procedure is schematically presented (Fig. 1).

Figure 1: Schematic Presentation of sampling procedure

Data collection
Data were collected using a self-completed structured questionnaires. Specific questionnaires were developed for each stakeholder group i) national health research ethics review boards, ii) regulators, iii) sponsors, iv) development partners and v) investigators in selected research institutions. The questions asked key informants opinion on the opportunities and challenges of implementing harmonized ethical and regulatory review system on clinical trial protocols. The data collection tool was prepared considering the general harmonization approach of core regulatory functions. Additionally, guidelines of international organizations, such as the Africa Vaccine Regulatory Forum (AVAREF) tools and WHO's Global bench marking tool were also used. Then questionnaires were delivered to participants through email using facilitators assigned in each country. The questionnaires were piloted before administering to all participants to identify and fix any issues before full-scale administration.

Data analysis
Participant responses were exported to QDA Miner Lite software and analyzed using a thematic analysis approach. First, the first author read and reread the responses given by the key informants and familiarized himself with the responses. Then, initial codes were generated by two persons independently using the QDA Miner Lite software. The codes were reviewed and refined. Then, themes and subthemes were developed by grouping codes with similar ideas and patterns of meaning. Themes and sub themes were presented in tables.

Trustworthiness
Ensuring rigor of the research included, re-administering the analyzed part of the research for some of the selected study participants, re-reading and iterative processes were followed during coding and thematic analysis. Two researchers other than the principal investigator were involved independently in the coding of qualitative data to avoid researcher bias.

Ethical Considerations
The protocol was approved by the Scientific and Ethics committee of CDT Africa, College of Health Sciences, Addis Ababa University (Ref No: CDT/540/20). Informed consent was obtained from each study participant after providing relevant information about the study. Confidentiality and anonymity were maintained.

Results
Participants Characteristics
A total of 24 participants were involved in the study, of whom 3 were from NRERBs, 9 from NMRAs, 5 from development partners, 3 from sponsors and 4 from research institutions. A third of the participants were female (n = 8/24) with diverse professional mix: pharmacists (n = 12), physicians (n = 5) and other disciplines (n = 7) (Table 1). Most had a MSc qualification.(Table 2)

Opportunities for Implementation of Harmonization at regional level
Three main themes were identified as opportunities for implementation of harmonization at regional level (Table 3).

Opportunities for implementation of a harmonized ethical and regulatory review system for clinical trial protocols included (1) the strong desire to have strong ethics and regulatory review system, (2) ongoing initiatives and platforms and (3) availability of enabling situations.

1. Strong desire to have strong ethics and regulatory review system
Strong regulatory and ethical review system was characterized by robust approval system with clear legal framework, harmonized standards and procedures which facilitate the approval processes and promotes efficiency of ethics committees and regulatory authorities.

Table 1: Participants Characteristics

Characteristics		Number (%)
Age Group	18-29	1(4.16%)
	30-39	12(50%)
	40-49	10(41.6%)
	>50	1(4.16%)
Sex	Male	16(66.7%)
	Female	8(33.3%)
Highest Level of Education	First Degree	7(29.17%)
	MSc	16(66.7%)
	PhD	1(4.16%)
Year of Experience In Years	1-10	15(62.5%)
	11-20	6(25%)
	21-30	2(8.33%)
Profession	Pharmacist	12(50%)
	Physicians	5(20.83%)
	Pharmacologist	2(8.33)
	Bioethicist	1(4.16%)
	Immunologist	1(4.16%)
	Medical Manager	1(4.16%)
	Clinical Trials	1(4.16%)
	Chemist(environmentalist)	1(4.16%)

Table 2: Study Participants by Country and Organization

S.no.	Country	Organization
1	Kenya	Kenya Pharmacy and Poison Board(KPPB), Neglected Tropical
2	Tanzania	Tanzania Medicine and Medical device Authority
3	Sudan	National Medicine and Poison Board
4	Ethiopia	IGAD MHR Program, Research Institutions, NRERB, EFDA
5	Uganda	National Drug Authority of Uganda

The desire to have such a system was described by most of the participants as the primary push factor and a prime opportunity for harmonization, which attracts trial sponsors.

> *I think we need a strong ethical review and regulatory system that can address the challenges of providing the timely and quality of services for approval process with the goal of creating opportunities of access to quality, safe and effective medical products to the people. Therefore, harmonization of the ethics review and regulation guidelines in EAC is a great initiative."* ID 10

> *"…we need to review the clinical trial in harmonized ways because it [is] important to reduce the time required to approve protocols, attract funding by researchers from funding agencies; provide stakeholders with timely information about the status and progress of the various research projects, enhance sharing of experiences and gain knowledge "* ID 4

> ***"…****[Harmonization] will increase the interest of sponsors, pharmaceutical* manufactures *toward Africa, and [even more so] if the regional BE [bioequivalence] center [is] accredited by WHO*." ID 21

Some participants mentioned the need for harmonization related to the desire to promote efficiency of clinical trial approvals

> *"Harmonization speeds up the review process, which eventually ensures increased accessibility of medicines to the public, reduction of cost for manufacturers as it reduces the need of compiling different applications and sometimes in different languages to suit individual countries". ID 19*

Desire to share data and information easily, which speeds up the review process and avoids duplication, was also another opportunity

> *"The harmonized approach will give member countries the opportunity to share data and information system and pooling of their resources that could speed up the review and regulatory processes. It will also greatly help the regulatory bodies to save time, resources, avoid duplications and prioritize regulatory activities."* ID 10

2. Ongoing initiatives and platforms

Encouraging initiatives that support and promote harmonization procedures mentioned were efforts of harmonization at regional economic centers, including the AVAREF platform for joint and harmonized clinical trial regulatory activities, and availability of global tools to follow and evaluate system.

For example, two participants mentioned such opportunities*: "...Different regional Initiatives for economic integration could be an entry point for harmonization"* ID 07

"...the existence of common WHO/GBT/ tools for [national regulatory authority (NRA)] functions, which address different regulatory functions of a variety of countries, is an opportunity..." ID 19

3. Availability of enabling opportunities

Availability of enabling opportunities, such as the large population size in the region, regular occurrence of public health emergencies and the increase in local pharmaceuticals were mentioned as opportunities. Participants indicated that the regions' larger number of population with diverse genetic makeup as an enabling factor to support researchers conduct clinical trials and call upon regional collaboration.

> *"...[The large] number of people within the member state countries supports researchers and Contract Research Organizations and enables new drug and vaccine development during the COVID-19 pandemic" ID 28*

> *"...[The large] number of people within the member state countries supports researchers and Contract Research Organizations and enables new drug and vaccine development during the COVID-19 pandemic" ID 28*

Public health emergencies (outbreaks) which demands the preparedness and regional collaboration were mentioned as opportunity;

> *"...outbreak of certain epidemics such as EBOLA, and the COVID-19 Pandemic, support from development partners, the eagerness to accelerate access to new vaccines, etc. are pushing for harmonization of national ethics review and regulation of clinical trial with consideration of conflict of interest".* ID 25

The growth of local pharmaceuticals in the region was also mentioned as an opportunity.

> *"...The growing of local pharmaceutical industry that will surely [be] seeking for regional marketing may be an immediate pressing demand for harmonization" ID 07*

Table 3: Opportunities by themes

Themes	Specific opportunities
Strong desire to have strong ethics and regulatory review system	Desire to promote efficiency of protocol review, desire to strengthen system through the process, desire to share information and experience easily, desire to have harmonized guidelines and procedures
Ongoing initiatives and Platforms	availability of global tools to follow and evaluate system, presence of regional economic centers (REC)
Availability of enabling opportunities	population size in the region, regular occurrence of public health emergencies, increase in local pharmaceutical manufacturers

Challenges to Implementing Harmonized Ethical review

Challenges identified for implementing harmonized clinical trials regulatory and ethics review system were (1) Weak capacity, (2) Attitude towards harmonization and (3) weak framework (Table 4).

1. Weak Capacity

Weak capacity including shortage of competent staffs, inadequate budget, and inadequate infrastructure were identified as challenges for implementing a harmonized system. Most informants mentioned shortage of competent staffs in the ethics committees and regulatory authorities. There is also difference among the member states in the levels of expertise and experience. This affects ability to share same standards and maintain consistency for harmonization.

> *"Most of the [national regulatory authorities (NRAs)] in the region have a shortage of staff, and even the existing ones are not competent to carry [out]the assessment and inspections of clinical trial applications in the region."* ID 17
>
> *"Different levels of expertise and experience among ethics committee and IRB members in member states are a challenge."* ID 16

Inadequate budget allocated to most of the regulatory and ethics bodies' is also a challenge as it hampers capacity to conduct joint reviews or implement harmonized systems. Some informants noted that most of the east African countries face budget shortages to execute their function smoothly.

> "*Most East African countries are facing an inadequate budget, which is allocated in the [national regulatory authority (NRA)] which hampers the smooth execution of the regulatory functions."* ID 17

Another informant added that *"..[There is] lack of sufficient budget for different activities to be performed in harmonization review*"

Poor infrastructure, in particular limited internet connection and access to virtual platforms along with poor familiarity with virtual platforms constrain the ability to engage in coordinated reviews.

> *"…lack of complete infrastructure for reviewing virtually, poor internet infrastructure and knowledge gap how to use technology during virtual meeting is a challenge" ID 01*

2. Attitude towards harmonization

Attitudes towards harmonization including readiness in attitude, political will and commitment, interest, fear of loss of earnings, mistrust of quality standards and low awareness were mentioned as challenges. Readiness in attitude to implement harmonization among member states was one of the challenges mentioned. Informants noted that implementing harmonization requires readiness to adopt best practices and there is a difference in the readiness of the different member states which could hamper the implementation of the harmonization process.

> *"This [Harmonization] requires the good will from all involved countries to be ready to take on best practices from each other and drop practices that hinder the efficiency and quality of the review process." ID 12*
>
> *"The fact is all countries are not at the same level of preparedness for implementation of the clinical trials regulatory and national ethics review harmonization." ID 14*

Another informant added that difference in attitude about the importance and urgency of implementing the harmonization among the countries could hamper the implementation.

> *"It is not a question of are countries ready to implement the CT regulatory and ethics review harmonization; it is a question of how important is it and when is it needed? I believe not all countries are capable of implementing the harmonized requirements."* ID 15

Lack of political commitment and interest among countries was also mentioned as a challenge.

> *"There is a lack of strong will politically to pursue this and minus political good will this effort will not succeed." ID 11*
>
> *"….all member countries might not have equal interest due to their political situation" ID 13*

Fear of loss of earnings, including fees charged for services, has led to some countries resisting mutual recognition of regulatory decisions and harmonization.

> *"There is a lack of mutual recognition of regulatory decisions. A lot of this is tied to finances. Each country wants to do their own thing as thing is also a way for the regulators to earn money for activities through charging fees."* ID 11

Mistrust of quality standards due to a difference in capacity of the authorities in different countries is another challenge

> *"Different capacity in different county is a barrier as it is a cause of mistrust in each other's capacity."* ID 11

Few informants also mentioned the lack of awareness among researchers about regulation of clinical trials in the region as a challenge

> *"..the researchers have low awareness on the laws and rules on regulations of clinical trials in the region"* ID 17

3. Lack frameworks

Lack of frameworks including lack of framework to support harmonization, difference in organizational structure, difference in regulatory requirement, lack of procedural clarity, lack of common vision and clear goal and long incubation to establish harmonized system was identified as a challenge to implement harmonized system. Most informants mentioned that there is difference in the organizational structure, and mandates of the regulatory authorities among different countries, which in turn could hamper implementation of harmonized systems.

> *"Organizational structure of member states at the country level (Ministry of Health) that oversee the activities of local IRBs and National Ethics Committee differ between member states…" ID 16*

> *"Different levels of regulatory activities among the countries obstruct the smooth execution of harmonized activities..." ID 14*

The requirements for clinical trial applications are also inconsistent and there is a *difference in capacity of member states authorities.*

> *"Differences in regulatory requirements for CT applications in the different member states is a challenge" ID 15*

> *"Other countries have advanced in term of regulatory function and other they don't have even regulatory framework such as laws and regulation of clinical trials"* ID 17

Some informants also noted lack of mutual endorsement of approvals by different countries as a challenge for implementing a harmonization. Lack of clarity of process between review boards and regulatory authorities was also mentioned.

> *"….lack of clarity of process between review boards and regulatory authorities. There is no mutual recognition of CTA approval from other countries"* ID 02

Lack of frameworks that support harmonization such as guidelines, procedures, databases, data sharing systems and monitoring and evaluation tools was mentioned by most participants as a challenge.

> *" As a region we are not prepared. Most review board and regulatory authority do not have clear harmonized technical guidelines available to stakeholders. "ID 02*

One informant suggested the following to make countries ready

> *"Feasibility study and putting place necessary legal frameworks (MOU/TOR, shared database or data management system, a monitoring and evaluation system and so on) is required to make the countries ready."* ID 13

Longer incubation period was another challenge. Informants noted that developing the frameworks required to support harmonization and implementing it requires longer period.

> "*Implementation and acceptance of the harmonized method will take long, including developing governing guidelines…*" ID 09

Discussion

To our knowledge, this study is the first study to assess the potential challenges and opportunities of implementing regulatory harmonization in the East Africa region. Strong desire to have strong ethics and regulatory review system, ongoing initiatives and platforms and availability of enabling opportunities were identified as an opportunity for implementing a harmonized system in the present study. The perceived benefits of harmonized systems were the main push factor for harmonization. Expediting the drug development process, guaranteeing safety and consistency, and promoting international cooperation requires harmonized clinical trial regulation. Harmonization of clinical trial procedures reduces delays in approval, enhances cost effectiveness, and accelerates access of medical products by fostering innovations (31). Regulatory harmonization is likely to have more benefits in low resource regions given its potential for efficiently utilizing resources while assuring better standards and quality (12). There is even a greater need for harmonization in the context of the need for multi-center and multi-country trials (25).

Existence of WHO bench marking tools to follow and evaluate system and the presence of REC as entry points were noted as important initiatives and platforms to facilitate the regional regulatory and ethical review system harmonization for clinical trials (27). At global level, regulatory harmonization is a continuing process aimed at standardizing laws and procedures to increase efficiency and access to medical products globally (23). With key role of the International Council for Harmonization guidelines and technical requirements are developed and adopted and implemented by regulatory authorities. The large population size in the region, regular occurrence of public health emergencies and increase in local pharmaceutical were reported in our study as opportunities. In the context of the large population size, multi-country studies, facilitated by a harmonized regulatory system, are also important for generating generalizable data (28). With the increasing burden of non-communicable diseases in these regions, research and development on therapeutics will accelerate access to medicines (29) Harmonized clinical trial approval processes are also nec-

Table 4: Themes and specific challenges

Themes	Specific challenges
Weak Capacity	Inadequate budget, shortage of competent staffs, difference in experience and expertise, inadequate infrastructure
Attitude towards harmonization	Readiness in attitude political will and commitment, interest, fear of loss of earnings, mistrust of quality standards, low awareness
Weak framework	Lack of framework to support harmonization, difference in organizational structure, difference in regulatory requirement, lack of procedural clarity, long incubation to establish harmonized system

essary for rapid access to vaccines as part of an emergency preparedness package, as was shown during the worldwide COVID-19 pandemic (30).

Despite the ongoing efforts at different regions such as regional economic communities, to ensure the harmonized regulatory and ethical procedures (32), success has been slow. Weak capacity, attitude towards harmonization and weak framework were the main challenges reported by the informants in this study. Our findings align with other studies, highlighting the challenges such as shortage of competent staff, inadequate budget, poor infrastructure, and, lack of political commitment, (10, 11, 33, 34, 35). Similarly, a study conducted to assess the potential barriers to medicines regulatory harmonization in the Southern African Development Community region (34), also found difference in the capacity, experience, mandate and structure among member states as a challenge. Lack of legal frameworks along with attitude towards harmonization were challenges reported in the present study, consistent with the findings of previous studies (33, 34).

Limitation

This study was one of the first to be conducted across five countries that serve as important regional platforms. It was not possible to conduct face-to-face interviews for the data collection due to travel restrictions during global COVID 19 pandemic. Thus, the questionnaires were administered though emails which didn't allow us to probe and ask follow up questions and get depth information from the informants. Additionally, some potential partners for the initiative were not included in the study. This may have limited the breadth of the perspectives.

Conclusions

The opportunities for harmonization of the clinical trial ethics and regulatory systems in the East Africa region is substantial. Although the challenges are formidable, they are tractable. Considering the critical importance of a harmonized regulatory systems in East Africa, strategies to address the challenges and leverage the opportunities should be identified and implemented.

Abbreviations

AHRI: Armauer Hansen Research Institute; AMRH: African Medicines Regulatory Harmonization; APEC: Asia-Pacific economic cooperation; AVAREF: Africa Vaccine Regulatory Forum; DNDi: Drugs for Neglected Disease initiative; EAC: East African Community; EAC-MRH: East African Community Medicines Regulatory Harmonization; EFDA: Ethiopian Food and Drug Authority; IGAD: Inter-Governmental Authority on Development; KMRI: Kenya Medical Research Institute; KPPB: Kenyan Pharmacy and Poison Board; NDA: National Drug Authority ; NMPB: National Medicine and Poison Board; NMRA: National Medicine Regulatory Authorities; NRA: National Regulatory Authorities; NRERB: National Research Ethics Review Board; PANDRH: Pan American Network for Regulatory Harmonization ; RECs: Regional Economic communities; TMDA: Tanzania Medicine and Medical Devices Authority; USP: United States Pharmacopeia

Declarations

Ethics approval and consent to participate: The study was approved by the Scientific and Ethics committee of CDT Africa, College of Health Sciences, Addis Ababa University (Ref No: CDT/540/20). Informed consent was obtained from each study participant after providing relevant information about the study. Confidentiality and anonymity were maintained.

Consent for publication: Not applicable

Availability of data and material: De-identified participant data will be made up on a reasonable request to the corresponding author.

Competing interests: The authors declare that they have no competing interests.

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Author's contribution: AE and EM conceptualized the study. AE contributed to data collection and anal-

ysis. AE drafted the initial manuscript under the close supervision of EM. All authors reviewed and approved the final version of the manuscript.

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