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# Strengthening capacity for clinical trial monitoring in the East African community: a multi-country training programme

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# Strengthening Capacity for Clinical Trial Monitoring in the East African Community: A Multi-Country Training Programme

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**Abstract**

**Background:** The expanding volume and increasing complexity of clinical research in East Africa, driven by emerging and re-emerging infectious diseases, has increased the need for strong regulatory monitoring systems. Clinical trials must be monitored to ensure regulatory compliance and participant safety. Despite strengthened regulatory and ethical frameworks in the region, gaps in trial monitoring persist due to a shortage of adequately trained monitors. This paper describes the design, implementation, and outcomes of a regional capacity-building initiative aimed at strengthening clinical trial monitoring capacity across six East African Community partner states.

**Methods:** We implemented a multi-country capacity-building project across six East African Community partner states: Burundi, Kenya, Rwanda, South Sudan, Tanzania, and Uganda. We conducted stakeholders' consultations to identify the training needs that informed development of a tailored curriculum on clinical trial monitoring comprised of six modules, and

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approved by the Training Advisory Committee (TAC). We trained National Research Regulatory Authority (NRRA) personnel, Research Ethics Committee (REC) members, clinical researchers, and clinical trial monitors. The programme was implemented between February 2024 and February 2025, with one group per partner state. Each cohort completed a five-week blended learning programme comprising a two-day in-person workshop, four weeks of self-paced online learning, and a two-day virtual wrap-up session. Pre- and post-training assessments were administered to measure knowledge gain. Data were downloaded as CSV files, cleaned in Microsoft Excel, and exported to STATA 15.0 for analysis. Descriptive analyses were conducted and data summarized.

**Results:** We trained 200 participants, majority 30.5% (n=61) of whom were from Uganda and 50.5% (n=101) were female. Overall, mean knowledge scores increased significantly from 61.8% at pre-test to 84.3% at post-test (22.5 percentage point improvement). The proportion of participants achieving the 60% pass mark increased from 37.5% (75/200) at pre-test to 95.6% (191/200) at post-test.

**Conclusion:** This capacity-building project showed a marked improvement in knowledge of clinical trial monitoring among NRRA personnel, REC members, clinical researchers, and clinical trial monitors across the EAC. Further studies should evaluate whether this knowledge gain translates into enhanced clinical trial monitoring and oversight practices.

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**Keywords:** Clinical trials; Clinical trial monitoring; Research ethics committees; Capacity building; Programme evaluation; East Africa

## Background

Over the past two decades, the East African Community (EAC) has experienced a marked increase in clinical trials evaluating the safety and efficacy of preventive and therapeutic interventions, largely in response to emerging and re-emerging infectious diseases such as HIV, Ebola, Marburg, Coronavirus disease 2019 (COVID-19) and mpox (1-4). This surge has heightened the need for rigorous monitoring of clinical trial conduct, particularly for studies involving novel vaccines, therapeutics (including traditional medicines), and next-generation therapies (5).

Clinical research must be conducted with strict adherence to scientific integrity and ethical standards to safeguard human participants. To this end, National Research Regulatory Authorities (NRRAs), Research Ethics Committees (RECs), and clinical trial monitors regulate and oversee clinical research conduct (6). In the EAC, the COVID-19 pandemic exposed critical gaps in clinical research oversight, primarily arising from the urgent need to deploy vaccines and therapeutic interventions (7). Although substantial progress has been made in strengthening regulatory and ethical frameworks across the region, persistent challenges remain in trial monitoring, largely due to limited availability of adequately trained monitors (8, 9).

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With support from the European & Developing Countries Clinical Trials Partnership 3 (EDCTP3), the Infectious Diseases Institute (IDI) in collaboration with Epicentre, France; the Kenya Medical Research Institute (KEMRI), the East African Health Research Commission (EAHRC), the National Institute of Medical Research (NIMR) Tanzania, the Ministry of Heath Rwanda, the University of Burundi, the Uganda National Council for Science and Technology (UNCST) and the University of Bahr El Ghazal South Sudan, implemented this training programme whose overall aim was to strengthen regional capacity for clinical trial monitoring among NRRA personnel, REC members, clinical researchers and trial monitors across six EAC partner states. This paper describes the design, implementation, and outcomes of this regional capacity-building initiative.

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## Methods

### Study Design

We conducted a before-and-after intervention study to evaluate the effectiveness of a multi-country training program targeting NRRA personnel, REC members, clinical researchers and clinical trial monitors. The evaluation employed pre- and post-training knowledge assessments to measure learning outcomes.

### Curriculum Design

We conducted stakeholder meetings to identify priority needs among 40 key clinical research oversight actors. The insights from these engagements

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informed the development of a tailored clinical trial monitoring curriculum for NRRA personnel, REC members, clinical researchers, and trial monitors. This team of consultants reviewed relevant online resources, regulatory guidelines, and published literature to develop the curriculum and training materials.

The curriculum was reviewed and approved by a Training Advisory Committee (TAC) comprising eight experts drawn from the six partner states of the EAC, one member from each of the six partner states and two international members. The final curriculum consisted of six modules delivered sequentially as detailed in ***Table 1.***

The first module focused on scientific research design and core clinical research concepts enabling participants to understand the interconnection between study design and effective clinical trial monitoring. Overall, the curriculum aimed to strengthen technical competencies and enhance the quality and efficiency of clinical trial oversight and regulatory monitoring practices.

***Table 1: Clinical Trial Monitoring Training sessions by module***

| **Module Number** | **Module name** | **Sessions** |
|---|---|---|
| 1. | Scientific Design | Protocol interpretation, Research study designs, Clinical trial phases including |

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| | | |
|---|---|---|
| | | adaptive platform trials, Eligibility criteria and Basic Statistical principles |
| 2. | Ethical and participant safety considerations | Principles of Research Ethics, Informed Consent, Vulnerable populations, Risk management strategies and principles, Study safety, Regulatory bodies, Participant welfare, re-imbursement and compensation |
| 3. | Investigational product development and regulation | Investigational new drug application and Investigational Device exemption, Classification of Investigational drug product and Medical device, Investigational Product (IP) Management |
| 4. | Clinical Trial Operations | Standard Operating Procedures, Roles in the conduct of research study, Delegation of responsibilities, Essential Documents, Quality Assurance and Quality Control, Digitalization of clinical trial operations |
| 5. | Study and Site Management | Site selection activities, including site initiation and closure, Protocol deviations and violations, Participant's recruitment and retention strategies, Study monitoring visits, Study Audits and Inspections, Study staff |

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| | | |
|---|---|---|
| | | trainings, Termination or suspension of a study |
| 6. | Data Management and Informatics | Documentation, Case Report Forms and data validation, Data privacy, Source Data Verification, Record retention requirements for research |

**Participants**

The training program comprised members of RECs, NRRA personnel, clinical trial monitors, and clinical researchers from the six EAC partner states; Republic of Burundi, Republic of Kenya, Republic of Rwanda, Republic of South Sudan, Republic of Tanzania, and Republic of Uganda.

Members from the other two EAC partner states; Democratic Republic of the Congo (DRC) and the Republic of Somalia, were not included in the training program. This is because these countries hadn’t joined the EAC at the time of the grant application. The Democratic Republic of the Congo (DRC) joined the EAC on Tuesday, 29th March, 2022 (10), while the Republic of Somalia joined the EAC on 4th March 2024 (11).

The training programme was implemented between February 2024 and February 2025 across the participating partner states, with one cohort trained in each partner state. Each cohort completed a structured training programme lasting approximately five weeks. Participant selection involved the official dissemination of training invitations to RECs, NRRAs, and

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research institutions, followed by the receipt of applications from interested candidates who submitted applications through their institutions. Eligibility was limited to REC members, NRRA personnel, clinical trial monitors and clinical researchers actively involved in clinical research review, oversight, and implementation. Final selection was done by the co-investigators from each partner state based on identified needs for enhanced competencies in clinical trial monitoring.

Contact information for NRRA personnel was obtained through the EAHRC, for REC members through the NRRAs and for clinical trial monitors through collaborating research institutions. Eligible participants were invited via email to attend the training. We used purposive selection to ensure balance in gender, age and professional experience. Due to limited clinical trial activity in Burundi, Rwanda, and South Sudan, clinical trial monitors from these countries were not represented.

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**Description of the Intervention**

The training programme was implemented between February 2024 and February 2025 across the participating partner states, with one training delivered per country in the following sequence: Uganda, Kenya, Burundi, Rwanda, Tanzania, and South Sudan (six sessions in total), in line with country-specific scheduling considerations and project implementation timelines. Each group completed a structured training programme lasting approximately five weeks.

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Participants first attended an orientation session to familiarize themselves with the e-learning platform and programme structure, followed by completion of a pre-training assessment. This was followed by a two-day in-person workshop covering modules one to four to facilitate interactive learning, case-based discussion, and real-time clarification of foundational concepts, then four weeks of self-paced online learning delivered through the Infectious Diseases Institute virtual learning platform (VLE) (12). During the online learning phase, participants engaged in discussions on challenging concepts through the e-learning platform and WhatsApp discussion groups. The programme concluded with a two-day virtual session via Microsoft Teams to review and consolidate modules five and six, address questions arising from the online learning phase, and reinforce key concepts after which the post-test was. The modules were split (1-4) and (5-6) to ensure full curriculum coverage while maintaining effective use of the limited in-person training period and avoiding participant overload. Pre- and post-training assessments were administered via the VLE, with participants allowed one attempt and a maximum completion time of one hour, to measure knowledge gain.

On average, four country-specific clinical trial monitoring subject matter experts facilitated the different modules during the training, adapting materials to local context by incorporating relevant context specific case scenarios. Although the training was delivered in English and all materials were developed in English, facilitators occasionally used local languages (Kirundi in Burundi, Kinyarwanda in Rwanda, and Kiswahili in Kenya and

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Tanzania) to clarify concepts and enhance understanding. In South Sudan, where local content experts were unavailable, facilitators from Uganda conducted the sessions.

The training programme was implemented using a blended learning approach. The blended learning approach integrated face-to-face instruction with interactive online learning. E-learning materials for each module were made available as open-access resources through the IDI VLE: https://elearning.idi.co.ug/index.php/clinical-trials-monitoring/ enabling participants to engage with content beyond what was covered during classroom sessions. Participants achieving a post-test score above the pass mark received certificates of completion.

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**Evaluation of the intervention**

Knowledge acquisition was assessed using pre- and post-training self-administered questionnaires comprising identical multiple-choice questions **(*Appendix 1*).** Assessments were completed electronically through the IDI VLE platform with automated scoring. A pass mark of 60% was considered based on a previous similar training program (9). Baseline demographic characteristics, including sex, country of affiliation, professional role, level of education, years of clinical trial monitoring experience and frequency of refresher trainings, were collected through a structured self-administered questionnaire.

**Data management and analysis**

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Assessment data were downloaded as CSV files, cleaned in Microsoft Excel, and exported to STATA 15.0 for analysis. Descriptive analyses were conducted, summarizing data using frequencies, percentages, means, and ranges. Pre- and post-training knowledge scores were compared using descriptive statistics, with changes presented as mean differences and percentage point improvements. Results are presented in tables and figures to illustrate changes in knowledge before and after training.

Data from participants with incomplete demographic questionnaires were excluded from the demographic analysis. However, all participants completed both pre- and post-training assessments, and these were included in the final analysis of knowledge outcomes.

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**Results**

A total of 200 participants attended the training comprising of NRRA personnel, REC members, clinical researchers, and clinical trial monitors **(*Table* 2)**. Participation varied across countries, with the highest participation from Uganda at 30.5% (61/200), followed by Tanzania at 21% (42/200), Kenya at 15% (30/200), and South Sudan at 11.5% (23/200). Rwanda and Burundi each had the lowest participation at 11% (22/200 each). Overall, half of participants 50.5%, (n=101) were female.

**Table 2: Participant composition by country**

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| Composition | Uganda n=61(%) | Kenya n=30(%) | Tanzania n=42(%) | South Sudan n=23(%) | Burundi n=22(%) | Rwanda n=22(%) |
|---|---|---|---|---|---|---|
| NRRA | 6 (9.8) | 5 (16.7) | 4 (9.5) | 3 (13) | 5 (22.7) | 0 (0) |
| Clinical Researchers | 2 (3.3) | 7 (23.3) | 11 (26.2) | 9 (39.1) | 8 (36.4) | 13 (59.1) |
| Clinical Trial Monitors | 11 (18) | 8 (26.7) | 11 (26.2) | 3 (13) | 2 (9.1) | 2 (9.1) |
| REC Members | 42 (68.9) | 10 (33) | 1638.1) | 8 (34.9) | 7 (31.8) | 7 (31.8) |

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Detailed demographic data were available for 127 of 200 participants (63.5%) due to incomplete questionnaire responses. Within this subsample, the majority (56.7%, n=72) held master's degrees, and approximately half (51.9%, n=66) had less than one year of experience in clinical trial monitoring. In addition, two-thirds (66.9%, n=85) indicated they had never received refresher training related to clinical trial monitoring ***(Table 3)***.

**Table 3: Demographic characteristics of participants**

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| Characteristic | n=127(%) |
|---|---|
| **Highest Educational Level** | |
| Bachelor's degree | 38 (29.9) |
| Master's degree | 72 (56.7) |
| Doctoral degree | 17 (13.4) |
| **Years of Clinical Trial Monitoring Experience** | |
| <1 year | 66 (51.9) |
| 1-3 years | 35 (27.6) |
| 3-5 years | 16 (12.6) |
| >5 years | 10 (7.9) |
| **Previous Refresher Training** | |
| Yes | 42 (33.1) |
| No | 85 (66.9) |

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**Knowledge Improvement Following Training**

The proportion of participants achieving the pass threshold (≥60%) increased from 37.5% (75/200) at pre-test to 95.6% (191/200) at post-test, representing a 58.1 percentage point improvement. Overall, mean knowledge scores increased significantly from 61.8% (SD=15.4) at pre-test to 84.3% (SD=10.2)

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at post-test (22.5 percentage point improvement) following training ***(Table 4)***.

**Table 4: Pre- and Post-Training Knowledge Scores**

| Assessment | Mean Score (%) | SD | Pass Rate (≥60%) | Range (%) |
|---|---|---|---|---|
| Pre-test | 61.8 | 15.4 | 37.5% (75/200) | 25-95 |
| Post-test | 84.3 | 10.2 | 95.6% (191/200) | 45-100 |
| **Difference** | **+22.5*** | - | **+58.1 pp** | - |

*pp = percentage points

Knowledge improvement was observed across all six countries following the training. The greatest gains were seen in Burundi (mean improvement: 32.5%) and South Sudan (25.6%), while the smallest gains were observed in Uganda (10.8%) and Tanzania (20.6%) ***(Figure 1)***.

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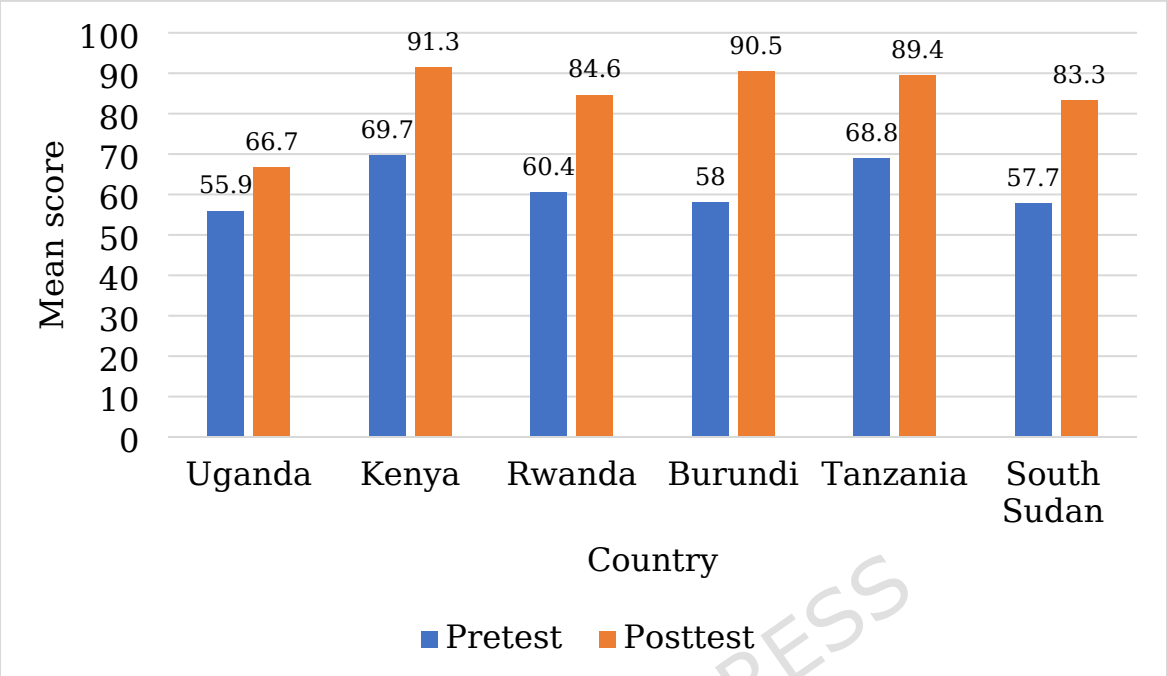
**Figure 1: Pre- and Post-Training Mean Knowledge Scores by country**

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**Discussion**

This capacity building programme was designed to strengthen technical competencies in clinical trial monitoring among REC members, NRRA personnel, clinical researchers and clinical trial monitors with the overarching aim of safeguarding participant welfare, ensuring data integrity, and promoting compliance with regulatory requirements and Good Clinical Practice (GCP) guidelines. The findings demonstrate the effectiveness of the programme with marked improvements in post-training knowledge scored across all modules, reflecting substantial knowledge gain.

Across the six partner states, Uganda and Tanzania had the highest participation. This likely reflects the higher volume of clinical research

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activity in these countries, as well as the larger number of accredited RECs. According to the EAHRC, Uganda and Tanzania host the highest numbers of accredited RECs within the EAC (13). In addition, both countries have experienced steady growth in clinical trials, particularly in response to emerging and re-emerging infectious diseases (14). This highlights the central role of RECs in strengthening ethical oversight and clinical trial monitoring to uphold ethical standards, protect participants, and ensure research credibility.

In addition, the small knowledge gains in Uganda and Tanzania may be partly explained by variations in group size and baseline exposure to clinical research. In Uganda, participants were trained in a single relatively large group, which may have limited opportunities for individualized interaction and engagement compared to smaller groups implemented in other partner states. This reduced trainer–participant interaction intensity could have influenced the extent of knowledge gain observed. In addition, Uganda and Tanzania generally have more established clinical research ecosystems and higher baseline exposure to clinical research activities compared to some of the other partner states (15). Consequently, participants from these settings may have started with comparatively higher baseline knowledge, potentially resulting in smaller relative improvements due to a ceiling effect. These contextual and structural differences across sites may help explain the observed variation in post-training knowledge gains.

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Conversely, Rwanda, Burundi and South Sudan had the lowest participation. This limited participation likely reflects the early stage of clinical research development in these countries. In South Sudan, the prolonged conflict has weakened health systems, limited institutional infrastructure and constrained clinical research capacity development (16). In Rwanda, although clinical trial activity is increasing, much of the focus remains on building technical capacity to support emerging health innovation initiatives (17, 18). Limited prior exposure to clinical trials in such contexts often restricts experience in ethical review and monitoring, underscoring the need for context-sensitive strategies to strengthen clinical trial monitoring in emerging research environments.

Overall, the observed knowledge gains can be attributed to several key elements of the training design. First, engaging country-based facilitators ensured delivery of contextually relevant content tailored to local regulatory environments, ethical norms and country-specific challenges, likely enhanced both comprehension and participant engagement. Second, the interactive, face-to-face sessions facilitated active learning and real-time discussion, enabling participants to clarify complex concepts and share experiences with peers. Third, the blended learning model allowed participants to revisit materials at their own pace through the online platform, reinforcing learning and supporting knowledge retention beyond classroom sessions. These elements collectively created a dynamic and inclusive learning environment that likely contributed to the marked knowledge improvements.

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Notably, the majority of participants reported having never received refresher training in clinical trial monitoring. Continuous professional development is essential for keeping REC and NRRA personnel, clinical researchers and clinical trial monitors abreast of advances in science and ethics. Some partner states mandate regular refresher training; for example, UNCST requires REC members to undertake research ethics training biennially (6). This programme provided an opportunity to strengthen scientific and ethics capacity in the EAC for high-quality research review conduct, and oversight of clinical trials at international standards. To support ongoing professional development, self-paced training modules remain accessible via the IDI eLearning platform.

The substantial knowledge gains observed are consistent with findings from other capacity-building initiatives in low- and middle-income countries (LMICs) which demonstrate that targeted training programmes can significantly strengthen ethical and regulatory competencies (13, 19). Similar outcomes have been reported by initiatives such as the Vanderbilt Institute for Research Development and Ethics (VIRDE) programme, which documented improvements in research capacity among biomedical investigators in resource-limited settings (19). Together, these findings reinforce the value of structured, contextually adapted training models in strengthening clinical research oversight systems.

**Strengths and Limitations**

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Key strengths of this capacity-building programme include: the use of pre- and post-test assessment design, which enabled direct measurement of participants' knowledge gain attributable to the intervention. The multi-country implementation across diverse regulatory context enhanced regional relevance, while the blended learning model, and engagement of country-based facilitators promoted contextual adaptation, participant engagement and programme acceptability. In addition, sustained access to training materials through an open-access platform supports ongoing learning and long-term capacity strengthening.

Some limitations should be considered when interpreting these findings. The evaluation assessed, only short-term knowledge gain and did not evaluate long-term retention, changes in attitudes, or translation of knowledge into practice, including actual improvements in clinical trial monitoring and ethical review processes. The absence of a control group limits our ability to attribute knowledge gains solely to the training programme. Furthermore, demographic data were not available for some of participants due to incomplete questionnaire responses, limiting our ability to conduct subgroup analyses. Changes in knowledge were assessed using descriptive comparisons (mean differences and percentage point changes) rather than inferential statistical tests. As a result, statistical significance of the observed changes could not be determined. The assessment relied on self-administered tests, which may be subject to social desirability bias. Finally, participation varied considerably across countries, potentially reflecting differences in

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research infrastructure and capacity that may limit generalizability across the broader region.

Future studies should incorporate longitudinal follow-up to assess sustained knowledge retention, direct observation studies of monitoring practices, and evaluation of impacts on clinical trial quality indicators such as protocol deviations, adverse event reporting, and data quality. Cost-effectiveness analyses would also inform scalability and sustainability planning of similar capacity-building interventions.

## Conclusion

This capacity-building project substantially enhanced knowledge of clinical trial monitoring among NRRA personnel, REC members, clinical researchers, and clinical trial monitors across the EAC. Sustained investment in capacity building, coupled with regular refresher training and supportive supervision, will be essential to strengthen clinical trial monitoring systems across the region and ensure ethical, high-quality research across the region.

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## Declarations

### Ethical Considerations

The study protocol was approved by Makerere University, School of Medicine Research Ethics Committee, (SOMREC; REF: 2020–024), and the Uganda National Council for Science and Technology (UNCST; HS542ES). School of Medicine Research Ethics Committee is a REC under the Makerere

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University School of Medicine and is accredited by the Uganda National Council for Science and Technology. Administrative approval to conduct the trainings was obtained from the respective partner institutions across the six EAC partner states. Co-investigators and focal persons in each country informed all relevant stakeholders about the training program and associated assessments. Participation in the training and associated assessments was entirely voluntary, and all participants provided their informed consent to take part. All assessment activities were conducted in compliance with the principles of the Declaration of Helsinki.

**Consent for Publication**

Not applicable

**Availability of data and materials**

The datasets used and analyzed during this study are available from the corresponding author upon reasonable request.

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**Competing interests**

The authors declare that they have no competing interests.

**Clinical trial number**

Not applicable

**Funding**

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**Author's contributions**

BT, MA, PA and PBK conceptualized the study. BT reviewed and analyzed the data and wrote the first draft of the manuscript. BM, HO, SG, SW, HN, KJ, VM, RN, LSMA, NT, DNK, SO, BC contributed to editing the manuscript and provided contextual insights from their respective countries. PA, SW and PBK reviewed and edited the manuscript for substantial intellectual content. All authors reviewed and approved the final manuscript for submission.

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