SCALING UP CAPACITY TO SUPPORT CONDUCT OF CLINICAL TRIALS IN EAST AFRICAN COMMUNITY (SCALE-IT)

REPORT FOR CLINICAL TRIALS MONITORING TRAINING FOR KENYA COHORT HELD FROM JUNE- JULY 2024 AT KENYA MEDICAL RESEARCH INSTITUTE, NAIROBI, KENYA

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Abbreviations and Acronyms

CPD	Continuous Professional Development
EDCTP	European and Developing Countries Clinical Trials Partnership
EAC	East African Community
HIV	Human Immunodeficiency Virus
IDI	Infectious Diseases Institute
NRRA	National Research Regulatory Authority
NDA	National Drug Authority
REC	Research Ethics Committee
KEMRI	Kenya Medical Research Institute
TAC	Training Advisory Committee
UNCS	Uganda National Council of Technology
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1.0 Introduction

1.01 Background

Clinical research remains cardinal in advancing knowledge on exposures and health outcomes including but not limited to diseases, and interventions including biomedical and socio-behavioural. The results of well conducted clinical research are vital to evidence based health care practice (1) Research Ethics Committees (RECs) and National Research Regulatory Agencies (NRRAs) oversee and regulate the conduct of clinical research with the aim of minimizing risk to human health and ensuring respect for the research participant's rights, values and interests, while advancing scientific knowledge(2). RECs are the doorways for research review and regulation and as such need to be well grounded and placed to conduct thorough and efficient reviews(2). Over

the past two decades, there has been an exponential rise in the clinical and health related research globally. This has been fuelled by the need for evidence-based decision-making in clinical practice as well as health and prevention care. Along this wave, Uganda has experienced a significant increase in clinical HIV research driven by the changing HIV epidemic, emerging and re-emerging other infectious diseases with or without epidemic/pandemic potential, and the increasing levels of non-communicable diseases and injuries(3-6). In addition to the increased capacity of local researchers, the volume of research studies as well as the complexity of research designs have not only expanded but also continue to increase. This has created a multiplicity of problems namely; 1) broadening the volume, spectrum and complexity of research protocol to be evaluated by RECs; 2) increasing workload for RECs and the pressure to provide useful comments in an efficient manner, and 3) increasing the requirement of technical expertise on RECs to handle the complex designs. Among roles of REC involves onsite monitoring of clinical trials to ensure compliance with regulatory requirements. Clinical trial monitoring is key in ensuring participants' well-being is protected, trial data are accurate and complete, and the conduct of the trial complies with the protocol, regulatory requirements and Good Clinical Practice (GCP) guidelines (7). It is therefore imperative to carry out continuous capacity building and enhancement for research review and human participants protection to suit the ever-changing research agenda and methodological advancement. Across Sub Saharan Africa, there is an increasing focus on novel HIV preventative research, the next generation of HIV therapies and research towards a cure, as well as treatment of co-morbidities(3). This research is driving new, advanced innovative study design. Urgent training of REC members and clinical research monitors in clinical trial monitoring in paramount to ensure regulatory compliance with good clinical practices and human subjects protection. With support from the EDCTP3, the Infectious Diseases Institute

(IDI) in collaboration with EPICENTER, Kenya Medical Research Institute (KEMRI), East African Health Research Commission (EAHRC), and other East African Community (EAC) partners would like to contribute towards strengthening scientific and ethics capacity in EAC for high quality research review, conduct and oversight, at international standards. Therefore, we trained 30 individuals from the different RECS, NRRAs, and research Institutions in Kenya on clinical trials monitoring.

1.02 General Objective

To equip REC, and NRRA members, and monitoring officers with the necessary technical competencies in research scientific designs, ethical considerations, product development regulations, clinical trial operations, site management, and data informatics, enabling them to work more efficiently and improve research ethics applications.

1.03 Specific Objectives

1. Understand the scientific concepts underlying research and research operations, enabling them to make informed decisions during research monitoring activities.
2. Elaborate on the ethical and participant safety considerations in planning, regulating, and implementing research studies, ensuring adherence to national and international research ethics standards.
3. Explain the regulatory processes involved in investigational product (drug or device) development and approval, facilitating efficient regulatory compliance.
4. Develop skills in preparing tools and documents necessary for regulatory and monitoring activities, such as REC submissions, SOPs, visit reports, and logs, enhancing documentation

and compliance practices.

2.0 Training Design

2.01 Curriculum development

2.02 Rationale and Development.

Through the Ethics project funded by National Institutes of Health (NIH) and coordinated by Infectious diseases Institute (IDI), a curriculum on clinical trials monitoring was developed. The participants who informed development of this curriculum came from research ethics committees at the Makerere University College of Health Sciences (School of Health Science, School of Medicine, School of Biomedical Sciences, and School of Public Health), Mulago Hospital, and Uganda Cancer Institute.

Through the SCALE-IT project funded by Global Health EDCTP3, this curriculum training is being scaled up to train all the REC members in EAC. In Kenya, members from different accredited RECS, and NRRAs, and Clinical trials monitors were trained. The curriculum developed under previous ethics project was reviewed and updated by competent consultants through conducting thorough literature review of physical and online documents, published papers and textbooks.

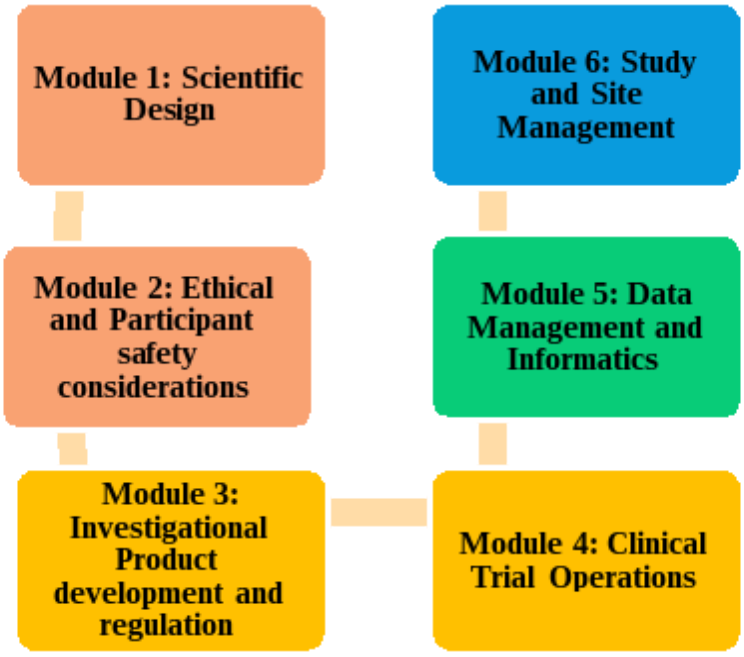
The content was organized in module format with each module having different sessions. The first module was Scientific design and research concept so that trainees would appreciate the relevance of monitoring in research. The updated and revised curriculum has 6 modules that REC members were trained on.

The updated curriculum was reviewed and approved by selected Training advisory committee (TAC) comprised of experts across the East African community (EAC) partner states.

2.03 Training content, Schedule and Target Audience

The Training curriculum is comprised of six Modules

Figure 1: Clinical Trials Monitoring Training Modules and Sessions



The trainees attended an online orientation one week prior to the training so as to receive an overview about the training as well as being guided on how to navigate the online IDI e-learning platform where they were enrolled to complete the pre-test that is mandatory prior to the F2F sessions. The trainees later underwent a two days face to face (F2F) intensive training where they interfaced with the trainers in lively lectures. Subsequently, trainees proceeded with 4 weeks of self-paced online learning under the e-learning platform. The course concluded with final virtual

days after the 4 weeks and certification of members that passed above the pass mark.

The Trainees comprised of REC, and NRRA members and clinical trial monitors across Kenya.

3.0 Training Delivery

Facilitators delivered sessions in lecture format using power point presentations. Prior to the physical sessions, trainees shared their expectations which mostly included their desire to understand the relevance of monitoring of clinical trials and the importance. Some sessions included review of case scenarios, protocols, articles and feedback. The facilitators provided overview of scientific design, and research concept as the preliminary module to ensure trainees appreciate the relevance of monitoring in clinical trials research. The delivery also included discussions on the WhatsApp group during the four weeks of online self-paced learning. This ensured that trainees got a deeper understanding of different concepts that were hard for them. The course was blended with final two virtual sessions to mark completion. During the final virtual sessions, the trainees were taken through the sessions that weren't covered in the two virtual days but were available on the online course during self paced learning. The trainers also were able to answer any necessary questions from trainees to ensure explicit comprehension.

3.01 Trainees and training sites

The training took place at the Kenya Medical Research Institute (KEMRI) graduate school training rooms. Trainees were the REC, and NRRA Members, clinical trial monitors and researchers. These members were nominated to attend the training by their institutional heads based on their need to have deeper understanding of the concepts in clinical trials monitoring. The trainees were from over different RECs, NRRAs, and research Institutions across the country.

4.0 Training Evaluation

Procedure

Prior to the physical training, participants completed a pre-training test (Appendix 2) and post-training test at the end of the course. In addition, participants completed a training evaluation form (Appendix 3) assessing the training in general, and each of the sessions conducted. The forms were completed electronically.

Pre and Post training assessment

The pre and post training assessment were comprised of the same questions assessing for knowledge on clinical trials monitoring modules that were covered during the training. They were composed of multiple answer questions, and short answer questions as shown in appendix 2. The filled assessment forms were completed electronically under the IDI e-learning platform with marks awarded automatically by the system. Trainees that scored 70% and above were categorized as passed, and those who scored 69%, and below were categorized as failed.

Training evaluation form

The form (Appendix 3) had both closed and open-ended questions. The form assessed how participants felt about the course overall and each day's sessions covered during the training. The questions asked about training venue, content and trainers; This was assessed using a rating scale ranging from 1-5 with 1= very poor, 2=poor, 3= Fair, 4=good and 5=very good.

The last part of the evaluation form comprised of open-ended questions. It required trainees to; note down their best session, comment on how to improve future training on clinical trials monitoring, comment on how often they would to receive this training as a refresher, comment on

any other topic that they would recommend to be included in future trainings.

Data management

Data from the assessment and evaluation forms was downloaded as a CSV file and cleaned in Excel, and were then exported to STATA 15.0 for analysis. Descriptive analysis was done, and data summarised using frequencies, percentages, means, ranges and figures.

5.0 Training Outcomes

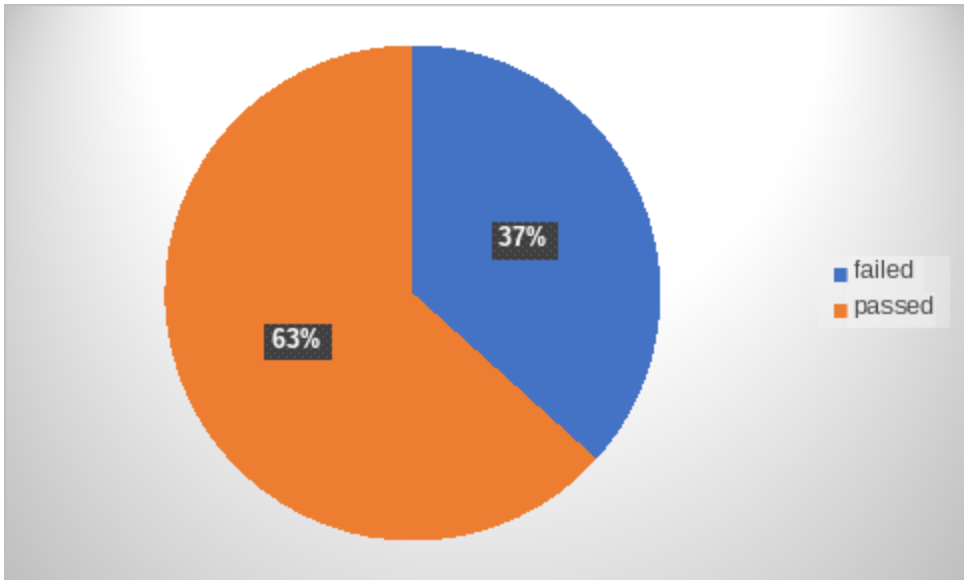
5.01 Number of trainees

In total, 30/30 invited REC, and NRRA members, and clinical trial monitors were trained on clinical trials monitoring. All participants completed pre-test, sessions quizzes, and the post-test.

5.02 Pre-test performance

Of those that sat the pretest-test training assessment, majority 63% passed by scoring above the 70% pass mark while 37% failed. The minimum mark was 20%, maximum mark was 97.9%, and the average mark was 69.7

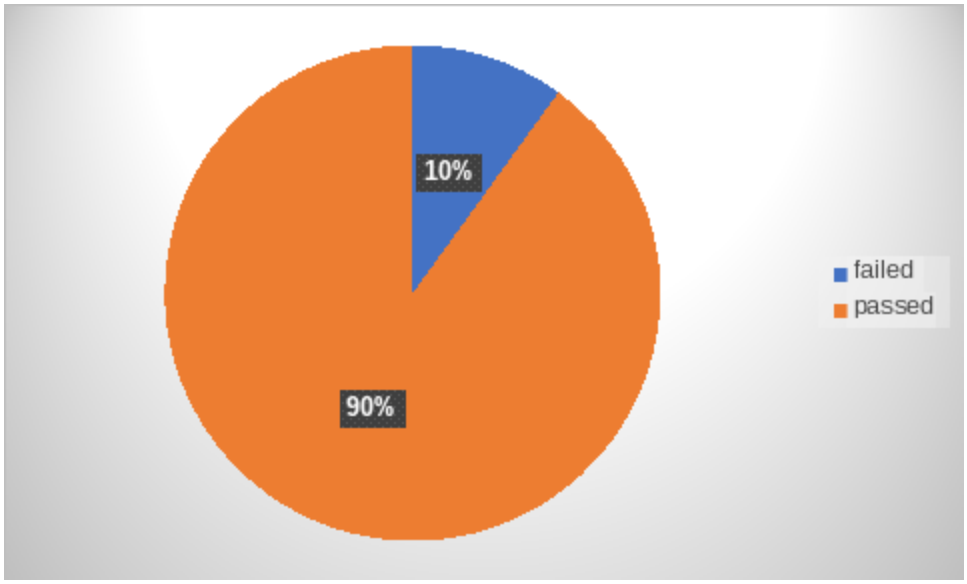
Figure 1: A pie chart showing Pre-test Performance



5.05 Posttest performance of participants

Of those that sat the post-test training assessment, majority 90 % passed by scoring above the 70% pass mark while 10% failed. The minimum mark was 61.2%, maximum mark was 100 %, and the average mark was 91.3. Results are summarised in figure 2 below.

Figure 2: Trainees' post-test performance



6.0 Training Impact: Knowledge and Skills

There was increase in the average score in clinical trials monitoring course from 69.7 in a pre-training assessment to 91.3 in post training assessment. The lowest score in the pre-test was 20% while it increased to 62.1 % in the post test. The highest score in the pre-test was 97.9% % while it increased to 100 % in the post-test. There was also increase in the proportion of participants who passed from (n=19/30, 63%) at pre-test to (n=27/30, 90%) in post-test. There was an average knowledge shift of 21.6

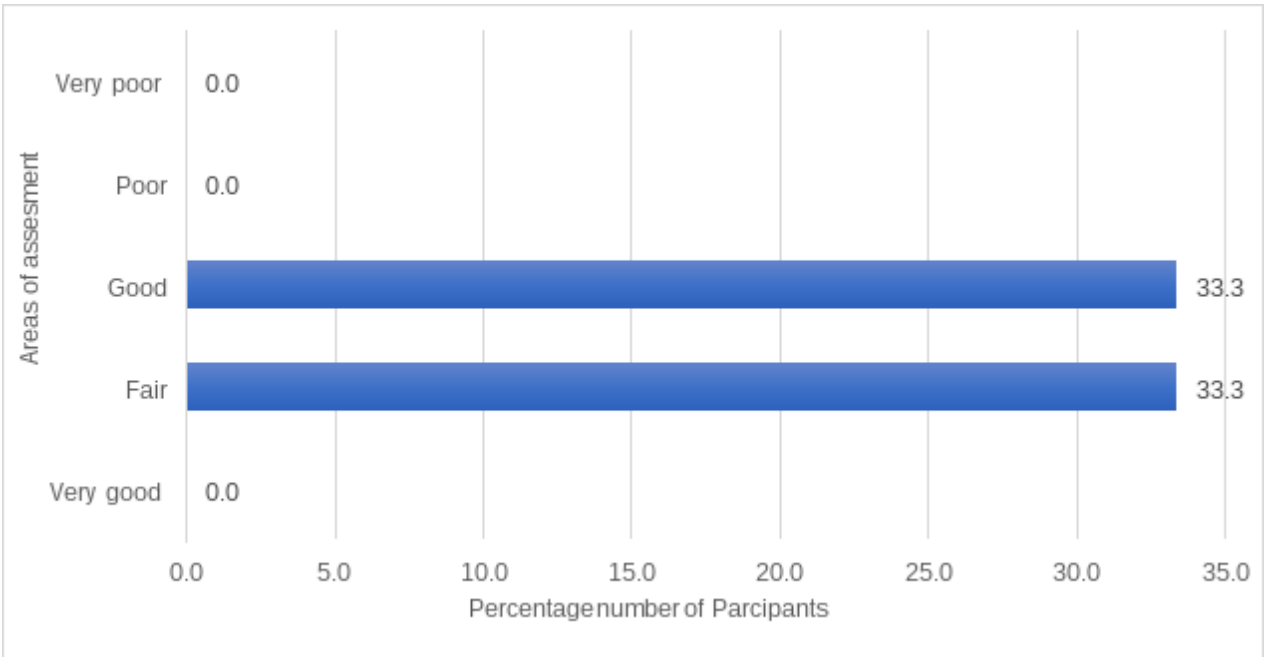
6.01 Course training Evaluation

Training Venue

Overall, majority of the participants fairly satisfied wit the training venue. Most participants noted

that the training venue wasn't spacious for the big number of participants. Data is summarised in figure 3 below.

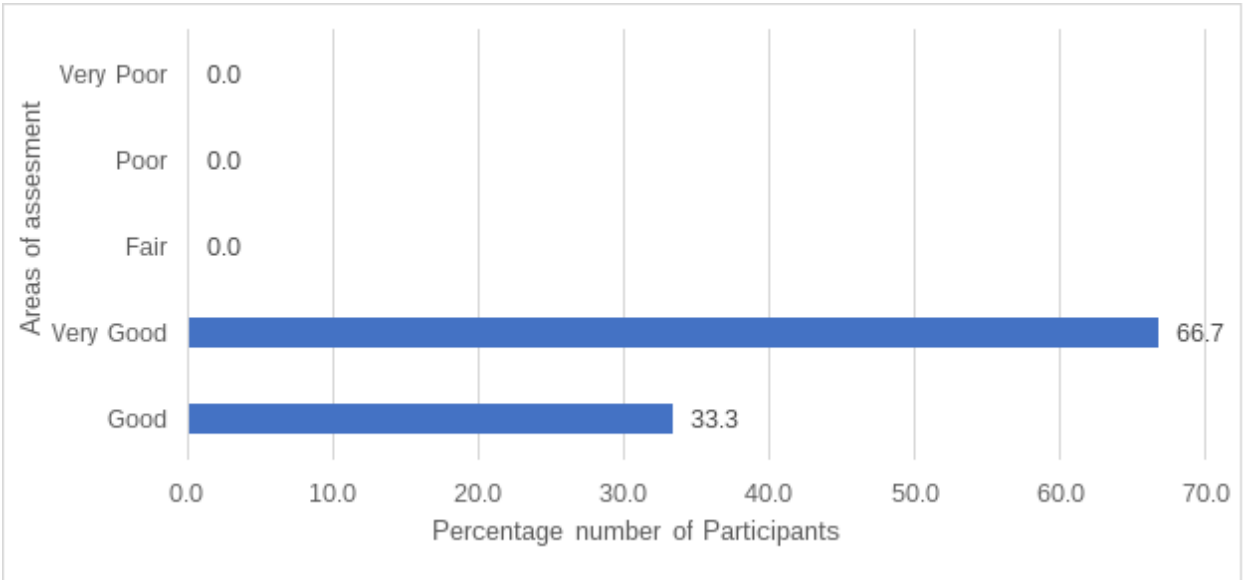
Figure 3: levels of satisfaction of participants with the overall training Venue



Training Content

Overall, participants were very satisfied with training content. Data is summarised in figure 4 below.

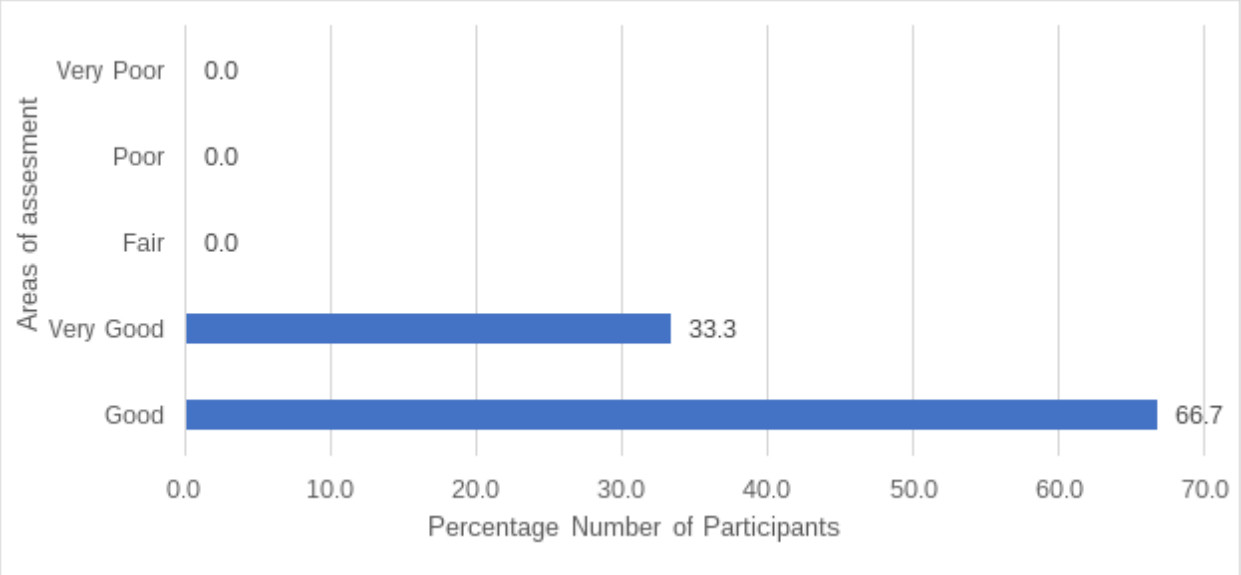
Figure 4:levels of satisfaction of participants with the overall training Content



Session Trainers.

Majority of the participants were very satisfied with the session trainers as shown in figure 5 below.

Figure 5: Levels of satisfaction with session trainers



Best sessions by the participants

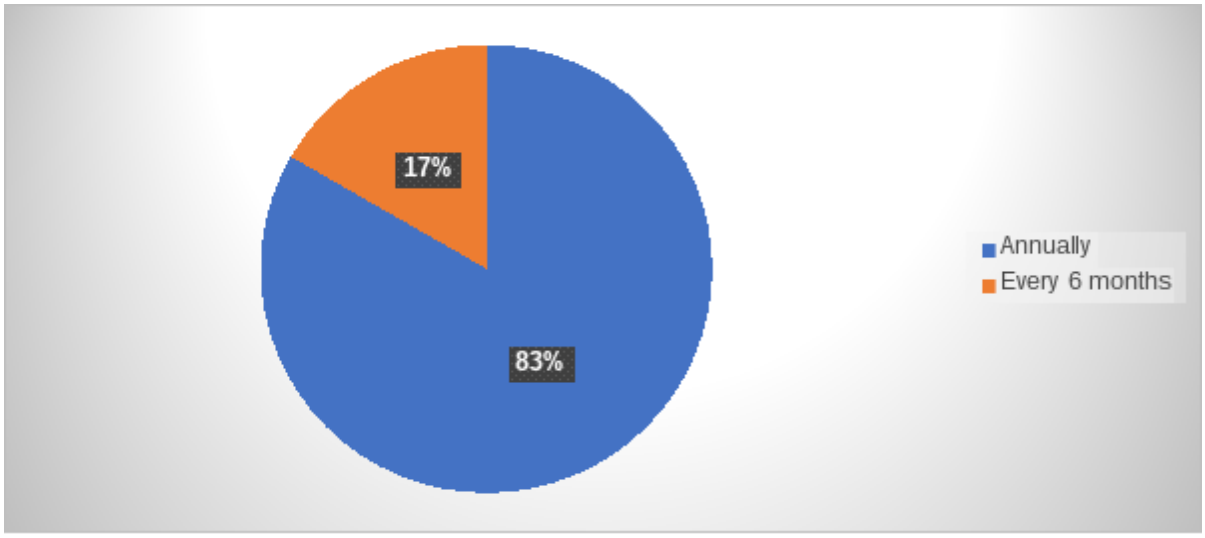
The best sessions for the participants included; Protocol deviations, Informed Consent Clinical trial operations, ethical and participant safety, and protocol Investigational drugs

Frequency Preference for Emerging and Complex Study designs Refresher training

Majority of the participants 83%, preferred to receive this training annually while 17% preferred to receive this training every after six months.

Figure 6: Frequency Preference for Emerging and Complex Study designs Refresher

training



Participant' suggestions on how to improve future training on Emerging and Complex study designs

- Use a bigger training room to accommodate all participants comfortably.
- Conduct refresher training sessions for monitors to keep their skills up to date.
- Provide yearly inputs and consider a more spacious venue for future training sessions.

7.0 Challenges and Lessons Learned

- The two days of F2F weren't enough for all sessions to be explored extensively. However, participants were enrolled to the online version of the course so that they can undertake an online self-paced version of the course to enrich their knowledge, and final two virtual sessions.

- The budget wasn't sufficient to offer accommodation for all participants. Only upcountry trainers were provided with accommodation.

8.0 Recommendations and conclusion

We trained 30 REC, and NRRA members, and clinical research monitors from different institutions in Uganda. The RECs were spanning from those that handle clinical trials research, social sciences research, and animal research. The trainees were from all fields of research. Overall, there was an average knowledge shift in the pre-test and post test results. We recommend assessment of long-term impact of the training on the competencies in clinical trial monitoring.

9.0 References

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10.0 Appendices

Appendix 1: Clinical Trials Monitoring Training Schedule

SCALING UP CAPACITY TO SUPPORT CONDUCT OF CLINICAL TRIALS IN EAST AFRICAN COMMUNITY (SCALE-IT)

SCHEDULE FOR CLINICAL TRIALS MONITORING TRAINING (13th – 14th June 2024)

VENUE: KENYA MEDICAL RESEARCH INSTITUTE (KEMRI), CBRD CONFERENCE ROOM, KEMRI HQ

Clinical Trials Monitoring Training: Thursday 13th June 2024: Day 1			
Time	**Module /Activity**	**Facilitator (s)**	**Venue**
08:00 - 08: 10	Registration	Mathius Amperiize	**KEMRI HQ CBRD**
08:10 - 08:15	Welcome Remarks	Dr. Steve Wandiga	**KEMRI HQ**

			CBRD
08:15 - 08:20	Remarks from IDI	Mathius Amperiize	**KEMRI HQ CBRD**
08:20 – 08:30	Training Launch	KEMRI	**KEMRI HQ CBRD**
08:30 - 08:40	Introduction & Expectations	Mathius Amperiize/Dr Steve Wandiga	**KEMRI HQ CBRD**
08:40 – 09: 00	Introduction to SCALE-IT Project	Dr Steve Wandiga	**KEMRI HQ CBRD**
09:00 – 09:20	Introduction to Clinical Trials Monitoring Curriculum	Dr. Steve Wandiga	**KEMRI HQ CBRD**
09: 20 - 11:00	**Scientific design and research concepts** · Protocol interpretation	Dr. Gloria Omosa	**KEMRI HQ CBRD**
11:00 - 11:20	**BREAKFAST**		**KEMRI HQ CBRD**
11:20 - 13:30	**Scientific design and research concepts** · Research study designs · Eligibility critkeria	Dr. Gloria Omosa	**KEMRI HQ CBRD**
13:30 - 14:00	**LUNCH TIME**		**KEMRI HQ CBRD**
			KEMRI HQ CBRD
14:00 -16:00	**Ethical and participant safety considerations** · Ethical conduct principals · Informed consent	Enock Kibienei	**KEMRI HQ CBRD**
16:00 - 17:00	**Ethical and participant safety considerations**	Enock Kibienei	**KEMRI**

	· Regulatory bodies		**HQ CBRD**
Clinical Trials Monitoring Training: Thursday 14th June 2024: Day 2			
08:00 – 08: 10	Registration	Mathius Amperiize	**KEMRI HQ CBRD**
08:10 - 10:10	**Clinical Trial Operations** · Standard Operating Procedures (SOPs) · Roles in the conduct of the study · Delegation of responsibilities	· Dr. Vera Manduku · Nick Kisengese · Nick Kisengese	**KEMRI HQ CBRD**
10:10 - 10:30	**BREAK FAST**	**Mathius Amperiize**	**KEMRI HQ CBRD**
10:30 -13:30	**Investigational Product development and regulation** · Investigational new drug application and Investigational Device Exemption · Classification of Investigational drug product and Medical device	· Nick Kisengese	**KEMRI HQ CBRD**
13:30 – 14:00	**LUNCH TIME**	**Mathius Amperiize**	
14:00 - 15:30	**Clinical Trial Operations** · Essential Documents · Quality Assurance and Quality Control	· Dr. Vera Manduku · Nick Kisengese	**KEMRI HQ CBRD**
15:30 - 17:00	**Clinical Trial Operations** · Digitalization of clinical trial operations **Scientific design and research concepts** · Statistical principles	· Nick Kisengese · Dr Steve Wandiga	**KEMRI HQ CBRD**
Six-Weeks	**INTERSESSION: 1**		
Final Virtual Sessions			
Clinical Trials Monitoring Training: Virtual session Day 1			
08:00 – 08:10	Registration	Mathius Amperiize	
08:10 -10:00	**Study and Site Management** · Site selection activities	· Nick Kisengese · Nick Kisengese	**Online**

	· Protocol deviations and violations · Participant's recruitment and retention strategies	· Dr. Vera Manduku	
10:00 - 10:30	**BREAK FAST**	**Mathius Amperiize**	
10:30 -12:00	Study and Site Management · Study monitoring visits · Study Audits and Inspections	· Nick Kisengese · Dr Steve Wandiga	**Online**
12:00 – 13:30	Study and Site Management · Trainings · Termination or suspension of a study	· Dr. Vera Manduku · Dr. Vera Manduku	**Online**
13:00 - 13:30	**LUNCH TIME**	**Mathius Amperiize**	**Online**
13:30 - 15:00	Data management and informatics · Case report forms and data validation · Data privacy · Fraud and Misconduct	· Dr Steve Wandiga · Dr Steve Wandiga · Nick Kisengese	**Online**
Clinical Trials Monitoring Training: Final Virtual session Day 2			
08:00 – 08: 10	Registration	Mathius Amperiize	**Online**
08:10 – 09:00	Clinical trial design	Dr. Gloria Omosa	**Online**
09:00 – 10:00	Study safety & Vulnerable populations	Enock Kibienei	**Online**
10:00 – 11:00	Participant re-imbursement and compensation	Enock Kibienei	**Online**
11:00 – 12:00	Investigational Product (IP) Management	Nick Kisengese	**Online**
12:00 – 13:30	· Source Data Verification · Record Retention requirements for Research	Nick Kisengese Dr Steve Wandiga	**Online**
13:30 -14:00	Closing Remarks & Closure	Prof Pauline	**Online**
7th week	**Trainees Complete Post-test**		Trainees
8th week	**Trainees receive Certificates**		Training Team

Appendix 2: Clinical Trial Monitoring Pre and Post-Test

Scaling Up Capacity to Support Conduct of Clinical Trials in East African Community (SCALE-IT)

Pre and Post training assessment

Clinical Trial Monitoring for REC members.

Circle the answers

0. Initials ……

1. How many years of experience in Clinical Trial Monitoring related work do you have?
   a. < 1 yr.
   b. 1-3 yrs.
   c. 3-5 yrs.
   d. 5-10 yrs.
   e. >10yrs

2. How often do you attend refresher training on Clinical trial Monitoring?
   a. None
   b. Annually

c. Every two years
d. Every three years
e. Every five years

3. What is your highest level of Education?
a. Diploma
b. Bachelors
c. Masters
d. PhD
e. Others; Specify ……

4. Which of the following documents outlines the objectives, design, methodology, statistical considerations and organization of a clinical trial?

a) Informed Consent Form

b) Case Report Form

c) Protocol

d) Investigator's Brochure

5. In the context of clinical trials, what is a placebo?

a) An unapproved drug

b) A fake or inactive treatment

c) A substitute for the control group

d) A substitute for the experimental group

6. In a clinical trial, what is a protocol amendment?

a) A change to the trial's objectives after trial completion

b) A change to the trial's design, methodology or procedures after approval

c) A change in the primary endpoint after data analysis

d) A change to the trial's duration after trial completion

c) All the above

7. Corrective Action Preventive Action involves?

a) Identify the problem

b) Categorizing the problem

c) Root cause analysis

d) All the above

8. During site selection activities, the following are usually assessed

a) Adequacy of facilities

b) Availability of Equipment

c) Ability to recruit participants

d) All the above

9. Which of the following clinical trial monitoring aspects requires access to information on treatment comparison?

a) Trial data quality review by the trial monitors during site visits
b) At interim analysis of the trial data
c) Both of the above
d) None of the above

10. Which of the following is done at interim analysis of clinical trial data?

a) Unblinded access to group assignments and comparative treatment group summary information
b) Protocol should have a statistical analysis plan for interim analysis to prevent certain types of bias
c) Interim analysis involves accruing of comparative results
d) All the above

11. The informed Consent process encompasses the following except (select one answer).

a) Reading and signing an informed consent form
b) Documenting discussions with participants
c) Discussing participant reimbursement
d) Storage of the signed informed consent form
e) Analysis of study risks by participants

12. The principles for conducting ethical research include;

a) Beneficence
b) Obtaining informed consent
c) Autonomy
d) Non-maleficence
e) Justice

13. Select vulnerable participants in research from the list;
    a) Pregnant women
    b) Ordinary level school boys
    c) Drowsy patients attending a clinic
    d) Comatose patients
    e) Beggars enrolled in a study distributing food to participants

14. Landmark events that informed the development of ethical principles in research are (tick all that apply);
    a) Tuskegee syphilis study
    b) Patients at the Jewish Chronic Disease hospital
    c) Nuremberg war crimes
    d) Vietnam war
    e) The Willowbrook study

15. According to UNCST guidelines, archival of data collected from research participants should be maintained;

a) Until the last clinic visit of the last participant
b) < 2 years
c) ≥ 2 years
d) ≥ 5 years
e) Indefinitely

16. Which of these are elements of the informed consent?
a) A statement that data about the participant will be stored
b) Projected duration of the study
c) Details of sites participating in the study
d) Explanation of the purpose of the study
e) A statement that withdrawing consent to the study is not permitted

17. What is the role of Regulatory bodies in Clinical Research?
a) To review, approve and inspect research.
b) To supervise researchers and study participants
c) To support Government activities
d) Creation of employment opportunities and revenue collection

18. What does IEC stand for?
a) Investigational Ethics Committee
b) International Ethics Committee
c) Independent Ethics Committee

19. What is the definition of Participation compensation?

a) Any monetary, cash equivalent and nonmonetary items offered to research participant in exchange for their participation in a human subject's research study.
b) Laboratory tests, treatment, mosquito nets given to a participant in exchange for their participation.
c) Money given to participants to cater for their transport to return to study visits and
d) to cater for time spent on study procedures which they would have gained elsewhere if they were working.
e) Monetary Incentives to attract participants to join the study.

20. In which kinds of research should Participants be reimbursed and compensated
    a) Clinical Trials
    b) Qualitative Studies
    c) Observational Studies
    d) All kinds of Research

21. Where are essential document stored / filed at the site?
    a) Investigator Site File (ISF)
    b) Trial Master File (TMF)
    c) Open shelf
    d) Accessible area accessed by everyone.

22. What is Quality Assurance in research?
    a) A planned and systematic actions that are established to ensure that the trial is

performed and the data are generated, documented (recorded) and reported in compliance with Good Clinical Practice (GCP) and the applicable requirements.

b) The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial related activities have been fulfilled.

c) All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.

23. What is Quality Control in Research?

a) A planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded) and reported in compliance with Good Clinical Practice (GCP) and the applicable requirements.

b) The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial related activities have been fulfilled.

c) All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.

24. What is Monitoring in research?

a) A planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded) and reported in compliance with Good Clinical Practice (GCP) and the applicable requirements.

b) The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial related activities have been fulfilled.

c) The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures, Good Clinical Practice and applicable regulatory requirements.

25. How many types of monitoring are there in clinical trials? Check all that apply.
    a) Pre-Study (Feasibility Assessment) Visits
    b) Site Initiation Visits
    c) Routine periodic Monitoring Visits
    d) Close Out Visits
    e) Inspection Visits
    f) Audit Visits
    g) Root Cause Analysis Visits

26. What is the difference between Audit and Monitoring in Clinical research? Check one of the following.
    a) Monitoring is an ongoing activity throughout the conduct of a trial, while auditing is an assessment of compliance with defined standards at a given movement in the clinical trial.
    b) The act of overseeing the progress of a clinical trial, ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, the Principles of GCP,

and the Medicines for Human Use (Clinical Trails) Regulations - where applicable.

c) Monitoring is “an act by a competent authority of conducting an official review of documents, facilities, records and other resources that are deemed by the competent authority to be related to the clinical trial and that may be located at the trial site, at the sponsor and/or contract research organization.

27. What is the purpose of conducting an audit in a clinical trial? Check one of the following.

a) FDA Requirement
b) Government Requirement
c) Evaluate the trial is conducted in compliance with the protocol, SOPs, GCP and the applicable regulatory requirements and it is a quality assurance tool.
d) All the above
e) None of the above

28. What are the types of audits in a Clinical trial? Check all that apply.

a) Routine Audits
b) For -cause Audits
c) Police Audits
d) Government Audits

29. The investigator running a study should be qualified by; a) Training, b) Education, c) Experience, d) Adhere to Regulatory & Ethical Bodies.

a) A
b) B

c) A, B, C

d) D

e) A, B, D

30. Research teams should be trained on the following documents before they start on any study procedure. Check all that apply.

a) Protocol

b) Standard Operating Procedures

c) Informed Consent Forms

d) Case Report Forms

e) Trial Master File

f) Agreements between the Sponsor and the Investigator

31. As representatives from the Research Ethics Committee or Study Monitor, how can you verify the Research team was trained before conducting study procedures during your site monitoring visit? Check all that apply!

a) Dated and signed training logs.

b) Training materials

c) Training Agenda

d) Study timelines and budget.

e) Test of Understanding Checklist

32. Who has the authority to terminate or suspend a study? Check all that apply.

a) IRB

b) Sponsor
c) Regulatory body
d) Principal Investigator
e) Participant
f) Research staff.
g) World Health Organization
h) None of the above
i) All the above

33. When should an IRB suspend or terminate approval of a research? Check all that apply.
a) Low recruitment
b) No payment of salaries
c) Events identified represent serious risks to participants.
d) Continuous noncompliance or unanticipated problems involving risks to
e) Participants.
f) Protocol Violations
g) The study has many Serious Adverse Events of grade 4.
h) None of the above
i) All the above

34. Who should the Principal Investigator notify if the study has been terminated or suspended by the Research Ethics Committee? Check all that apply.
a) Sponsor

b) Regulatory Bodies
c) Research Team
d) Participants
e) All the above
f) None of the above

35. What is the primary purpose of Standard Operating Procedures (SOPs)?
a) To ensure regulatory compliance
b) To maximize profits for pharmaceutical companies
c) To expedite the trial process
d) To minimize patient enrollment

36. Who is responsible for developing and maintaining Standard Operating Procedures (SOPs) in a clinical trial setting?
a) Clinical trial participants
b) B) Regulatory agencies
c) C) Principal Investigators
d) D) Patients' families

37. What action should be taken if a deviation from a Standard Operating Procedure (SOP) occurs during a clinical trial?
a) Nothing, as deviations are common and not significant.
b) Document the deviation and its rationale.
c) Ignore the deviation and continue as usual.

d) Inform the regulatory authorities immediately.

38. What is the primary responsibility of a Principal Investigator (PI) in a clinical trial?

a) Conducting data analysis

b) Recruiting study participants

c) Overseeing the entire trial

d) Administering study medication

39. Who is typically responsible for ensuring that the trial protocol is followed and that the study is conducted in compliance with regulatory requirements?

a) Clinical Research Coordinator (CRC)

b) Data Manager

c) Biostatistician

d) Clinical Monitor

40. Which team member is responsible for ensuring that informed consent is obtained from each study participant before any trial-related procedures are conducted?

a) Clinical Research Coordinator (CRC)

b) Principal Investigator (PI)

c) Institutional Review Board (IRB)

d) Study Sponsor

41. Who is primarily responsible for ensuring that all aspects of a clinical trial are conducted in

compliance with regulatory requirements and protocols?

a) Principal Investigator

b) Clinical Research Coordinator

c) Sponsor

d) Institutional Review Board (IRB)

42. Which of the following tasks is typically delegated to a Clinical Research Coordinator (CRC) in a clinical trial?

a) Overseeing the financial aspects of the trial

b) Administering investigational drugs to participants

c) Approving the study protocol

d) Reviewing adverse event reports

43. What is the primary purpose of study monitoring in clinical trials?

a) To ensure participants are compensated adequately

b) To assess the efficacy of the investigational product

c) To detect and prevent deviations from the protocol

d) To expedite the approval process with regulatory agencies

44. During a routine study monitoring visit, the monitor discovers a serious deviation from the protocol that may jeopardize participant safety. What is the appropriate course of action?

a) Ignore the deviation if it's not directly related to the primary endpoint

b) Document the deviation in the monitoring report and inform the study sponsor

immediately

c) Wait until the next monitoring visit to report the deviation

d) Discuss the deviation with the principal investigator and resolve it internally

45. “Notice of Inspection” is to be report on:

a) Form 482

b) Form 483

c) Form 1571

d) Form 1572

46. What are primary ethical, human subjects, and legal concerns related to the use of digital tools in clinical research.

a) Ensuring proper informed consent procedures with electronic materials

b) For proper accountability

c) Protecting participant privacy/confidentiality when using digital technology

d) For proper drug development

47. What is appropriate period for designing a case report form in a clinical trial.

a) At the initiation of the clinical trial

b) During the conduct of clinical trail

c) After database design

48. Data validation should be carried.
    a) Prior study commencement.
    b) During the running of the study
    c) Before data is analysed
    d) None of the above

49. Once the participant has signed consent the investigator can freely share their research data with any other person.
    a) True
    b) False

    a) Unauthorized access

    b) Plagiarism

    c) Fabrication

    d) Falsification

50. Which type of research misconduct most likely occurred if someone intentionally removes data points from the data set in order to generate a deceptive conclusion?

Appendix 4: Photos from the training

SCALE-IT PROJECT