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

REPORT FOR CLINICAL TRIALS MONITORING TRAINING FOR TANZANIA COHORT HELD FROM OCTOBER TO NOVEMBER 2024 AT NATIONAL INSTITUTE OF MEDICAL RESEARCH (NIMR), TANZANIA

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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
NIMR	National Institute of Medical Research
KEMRI	Kenya Medical Research Institute
TAC	Training Advisory Committee

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 and Tanzania 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), National Institute of Medical Research (NIMR) Tanzania and other East African Community (EAC) partners are contributing towards strengthening scientific and ethics capacity in EAC for high quality research review, conduct and oversight, at international standards. Therefore, we trained 42 individuals from the different RECS, NRRAs, and research Institutions in Tanzania on clinical trials monitoring.

1.02 General Objective

To equip REC, and NRRA members, and monitoring officers in Tanzania 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.

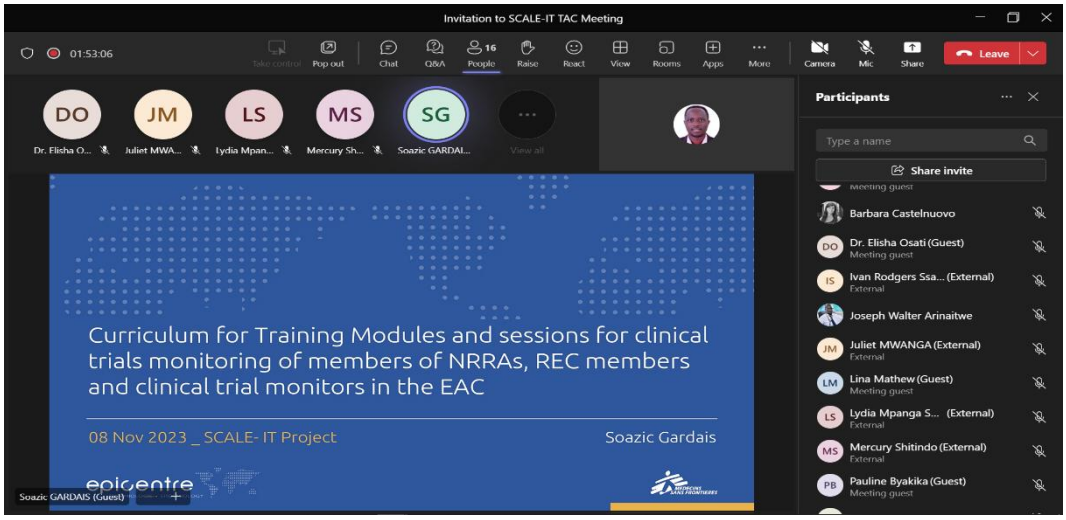
Through the Ethics project funded by National Institutes of Health (NIH) and coordinated by Infectious diseases Institute (IDI), a curriculum on clinical trials monitoring was developed. The participants who informed development of this curriculum came from research ethics committees at the Makerere 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 Tanzania, 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 interconnectedness of clinical trial monitoring and research design. The updated and revised curriculum has 6 modules that REC members and clinical trial monitors were trained on.

The updated curriculum was reviewed and approved by selected Training advisory committee (TAC) comprised of 8 experts across the East African community (EAC) partner states.

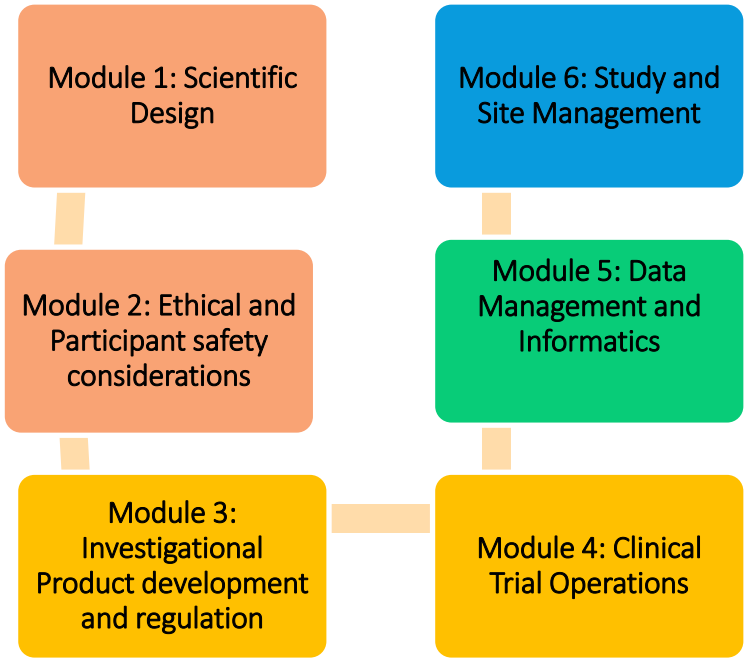
Figure 1: Presentation of the curriculum to the TAC members



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. During this time, trainee also engaged in discussions on difficult concepts via the e-learning platform and WhatsApp group. The course concluded with final two virtual days after the 4 weeks and certification of members that passed above the pass mark of 60%. The Trainees comprised of REC, and NRRA members and clinical trial monitors across Rwanda.

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 interconnectedness of clinical trial monitoring and research design. 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 course completion. During the two 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 were also able to answer any necessary questions from trainees to ensure explicit comprehension of the modules.

3.01 Trainees and training sites

The training was held at the National Institute of Medical Research (NIMR) in Dar Es Salaam, Tanzania. Participants included members of the REC, and NRRA , clinical trial monitors and

researchers. These participants were nominated by their institutional heads based on the need to have deeper understanding of the concepts in clinical trials monitoring. Attendees represented various RECs, NRRAs, and research Institutions from across the country.

4.0 Training Evaluation

Procedure

Prior to the physical training, participants completed a pre-training test (Appendix 2) and post-training assessment 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 through Microsoft forms

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 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 60% and above were categorized as passed, and those who scored 59%, 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 overall course 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 want to receive this training as a refresher, comment on any other topic that they would recommend to be included in future training.

Data management

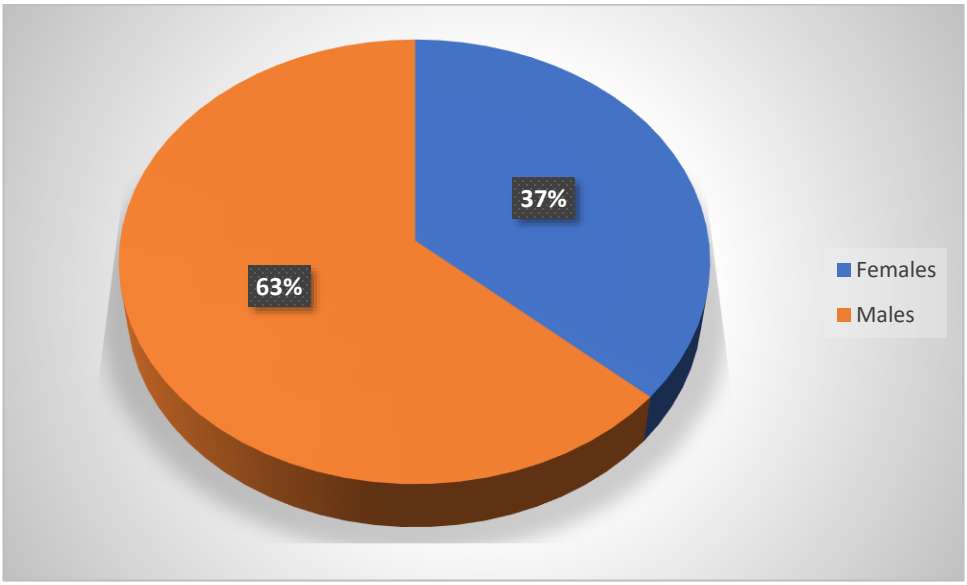
Data from the assessment and evaluation forms was downloaded as a CSV file and cleaned in excel, and then exported to STATA 15.0 for analysis. Descriptive analysis was done, and data summarised using frequencies, percentages, means, ranges and figures.

5.0 Training Outcomes

5.01 Number of trainees

In total, 42/42 invited REC, and NRRA members, and clinical trial monitors were trained on clinical trials monitoring, and majority,63% (26/42) were males as shown in figure 2 below. 42 trainees completed pre-test, while 37 completed post-test.

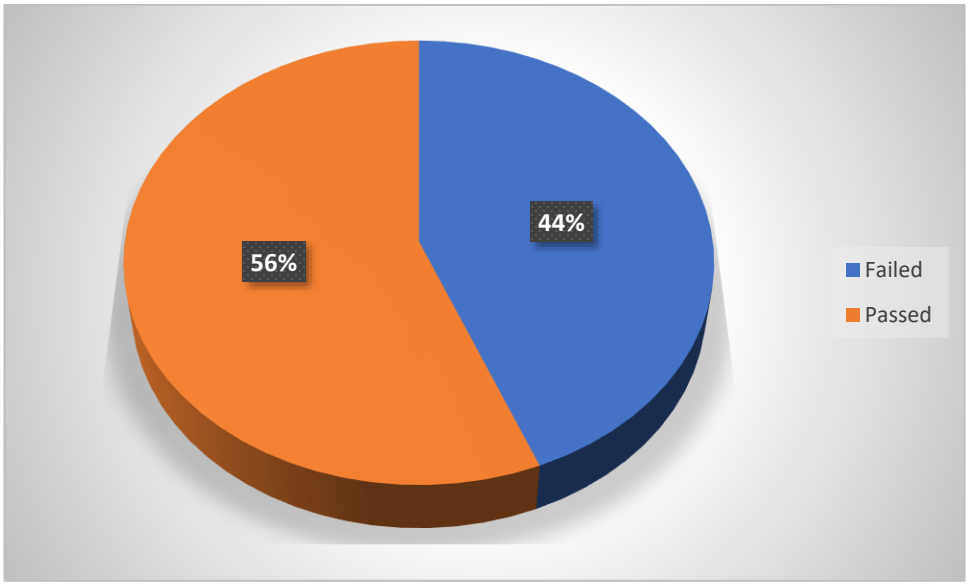
Figure 2: Percentage of males and females that attended the training



5.02 Pre-test performance

Of those that completed the pre-test-test training assessment, majority 56.0 % passed by scoring above the 60% pass mark. The minimum mark was 46.8%, maximum mark was 86.2%, and the average percentage mark was 68.8.

Figure 3: A pie chart showing pre-test performance



5.05 Posttest performance of participants

Among those that sat the post-test training assessment, 97% (36/37) passed by scoring above the 60% pass mark. The minimum mark was 66 %, while maximum mark was 100 %, and the average mark was 89.4. Results are summarised in figure 2 below.

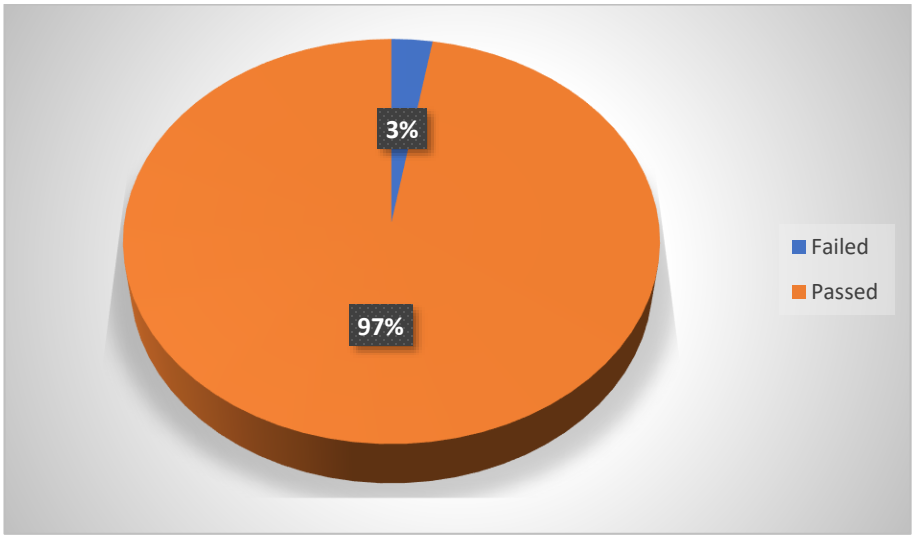


Figure 4: Performance of the trainees at post-test

6.0 Training Impact: Knowledge and Skills

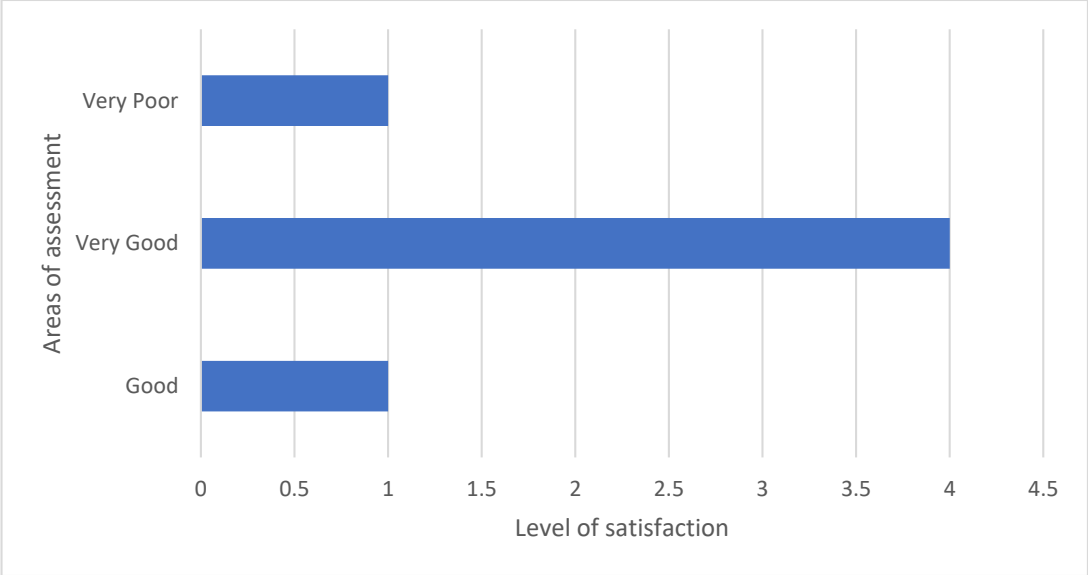
There was increase in the average score in clinical trials monitoring course from 68.8% in a pre-training assessment to 89.4% in post training assessment. The lowest score in the pre-test was 46.8 % while it increased to 66.0 % in the post test. The highest score in the pre-test was 86.2 while it increased to 100 % in the post-test. There was also increase in the proportion of participants who passed from 56. 0 % at pre-test to 97.0 % in post-test. There was a percentage average knowledge shift of 20.6

6.01 Course training Evaluation

Training Venue

Overall, majority of the participants very satisfied with the training venue. Data is summarised in figure 4 below.

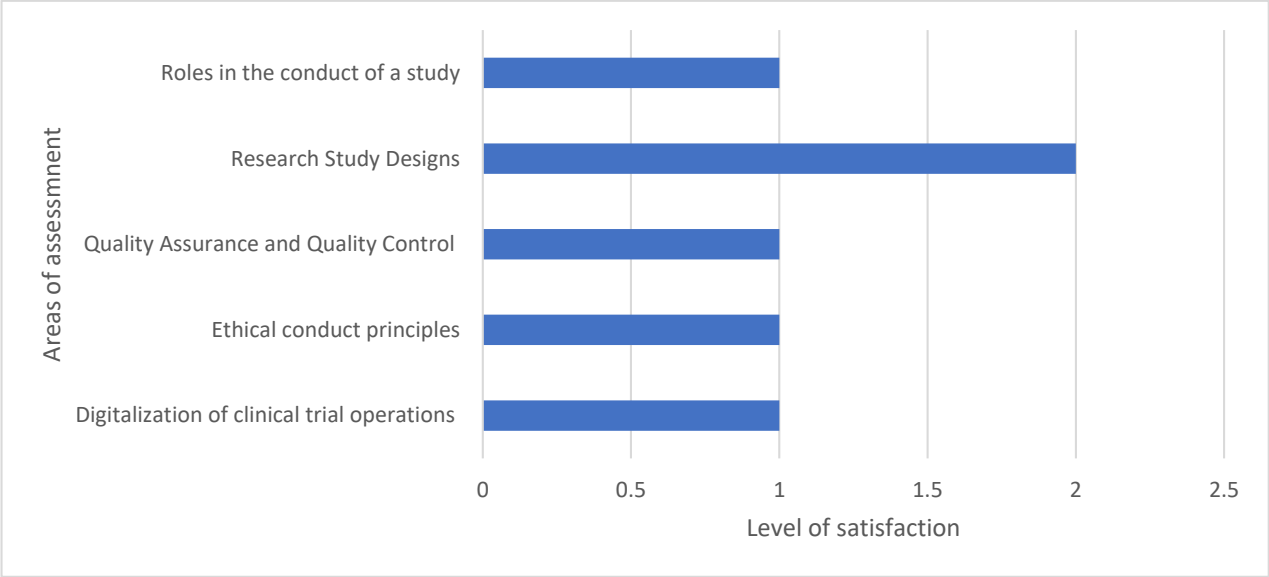
Figure 5: levels of satisfaction of participants with the overall training Venue



Training Content

Overall, participants' best session was research study designs in clinical trial monitoring. Data is summarised in figure 5 below.

Figure 6: Best session preferred by the participants



Frequency of conducting the training

Majority, 90% of the participants preferred to receive this training quarterly followed by annually, 10%

Participant' suggestions on how to improve future training

- Extend training duration: Increase the number of days (e.g., to at least 5) for deeper learning.
- Enhance engagement: Make sessions more participatory for better interaction.
- Improve logistics: Streamline payment processes to accommodate international payment processes

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 were held

- 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 42 REC, and NRRA members, and clinical research monitors from different institutions in Tanzania. 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 (CTM) TRAINING (24th – 25th October 2024)

VENUE: National Institute of Medical Research (NIMR) Tanzania

Clinical Trials Monitoring Training (CTM): Friday 18th October 2024: Day 0			
Time	**Module /Activity**	**Facilitator (s)**	**Venue**
15:00 -16:00	Course Orientation and Pre-test Completion	Training Team	Online
Clinical Trials Monitoring Training (CTM): Thursday 24nd October 2024: Day 1			
Time	**Module /Activity**	**Facilitator (s)**	**Venue**
08:00 - 08: 10	Registration	Belinda Twesigye	CEEMI Training Room
08:10 - 08:15	Welcome Remarks	Dr Jeremiah Kidola	CEEMI Training Room
08:15 - 08:20	Remarks from IDI	Mathius Amperiize	CEEMI Training Room
08:20 – 08:30	Training Launch	NIMRI Representative	CEEMI Training Room
08:30 - 08:40	Introduction & Expectations	Mathius Amperiize	CEEMI Training Room

08:40 – 09: 00	Introduction to SCALE-IT Project		CEEMI Training Room
09:00 – 09:20	Introduction to Clinical Trials Monitoring Curriculum	Mathius Amperiize	CEEMI Training Room
09: 20 - 11:00	**Scientific design and research concepts** • Protocol interpretation		CEEMI Training Room
11:00 - 11:20	**BREAKFAST**		CEEMI Training Room
11:20 - 13:30	**Scientific design and research concepts** • Research study designs • Eligibility criteria		CEEMI Training Room
13:30 - 14:00	**LUNCH TIME**		CEEMI Training Room
			CEEMI Training Room
14:00 -16:00	**Ethical and participant safety considerations** • Ethical conduct principals • Informed consent	• Dr. Apolo Balyesigawa •	CEEMI Training Room
16:00 - 17:00	**Ethical and participant safety considerations** • Regulatory bodies	• Dr. Apolo Balyesigawa	CEEMI Training Room
Clinical Trials Monitoring Training: Friday 25th October 2024: Day 2			
08:00 – 08: 10	Registration	Belinda Twesigye	CEEMI Training Room
08:10 - 10:10	**Clinical Trial Operations** • Standard Operating Procedures (SOPs) • Roles in the conduct of the study • Delegation of responsibilities	Dr. Apolo Balyesigawa	CEEMI Training Room

10:10 - 10:30	**BREAK FAST**	**Mathius Amperiize**	CEEMI Training Room
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		CEEMI Training Room
13:30 – 14:00	• **LUNCH TIME**	**Mathius Amperiize**	CEEMI Training Room
14:00 - 15:30	**Clinical Trial Operations** • Essential Documents • Quality Assurance and Quality Control		CEEMI Training Room
15:30 - 17:00	**Clinical Trial Operations** • Digitalization of clinical trial operations **Scientific design and research concepts** • Statistical principles	• Dr. Apolo Balyesigawa •	CEEMI Training Room
Six-Weeks	**INTERSESSION: 1**		
Final Virtual Sessions			
Clinical Trials Monitoring Training: Virtual session Day 1			
08:00 – 08:10	Registration	Belinda Twesigye	
08:10 -10:00	**Study and Site Management** • Site selection activities • Protocol deviations and violations • Participant's recruitment and retention strategies	• Dr. Apolo Balyesigawa • Dr. Apolo Balyesigawa • Dr. Apolo Balyesigawa	**Online**
10:00 - 10:30	**BREAK FAST**	**Mathius Amperiize**	
10:30 -12:00	**Study and Site Management** • Study monitoring visits • Study Audits and Inspections	•	**Online**

12:00 – 13:30	**Study and Site Management** • Trainings • Termination or suspension of a study	•	**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		**Online**
Clinical Trials Monitoring Training: Final Virtual session Day 2			
08:00 – 08: 10	Registration	Balinda Twesigye	**Online**
08:10 – 09:00	Clinical trial design		**Online**
09:00 – 10:00	Study safety & Vulnerable populations	Dr. Apolo Balyesigawa	**Online**
10:00 – 11:00	Participant re-imbursement and compensation	Dr. Apolo Balyesigawa	**Online**
11:00 – 12:00	Investigational Product (IP) Management		**Online**
12:00 – 13:30	• Source Data Verification • Record Retention requirements for Research	Dr. Apolo Balyesigawa	**Online**
13:30 -14:00	Closing Remarks & Closure		**Online**
5th week	**Trainees Complete Post-test**		Trainees
6th 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

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?
    a) Unauthorized access
    b) Plagiarism
    c) Fabrication
    d) Falsification

Appendix 4: Photos from the training