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

REPORT FOR EMERGING AND COMPLEX STUDY DESIGNS TRAINING, HELD FROM 10TH - 12TH JUNE AT KENYA MEDICAL RESEARCH INSTITUTE (KEMRI), NAIROBI, KENYA

SCALE-IT PROJECT

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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
UNCST	Uganda National Council of Technology

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. 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 reviewers in a wider range of research design and more diverse populations is required. Whilst much excellent training on ethical issues and regulatory requirements has

been undertaken in Uganda, the reviewers are often challenged with review of research proposals with complex and emerging study designs. 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 85 individuals from different RECS, NRRAs, and research institutions on emerging and complex study designs in Kenya.

1.02 General Objective

To strengthen capacity of Research Ethics Committees (RECs) in Kenya to carry out comprehensive and effective reviews of research protocols involving complex and emerging study designs in accordance with international ethical standards, in order to promptly and competently respond to researchers.

1.03 Specific Objectives

1. To provide REC members across Kenya with a comprehensive understanding of emerging and complex study designs, including their characteristics, implementation, and ethical considerations.
2. To identify key areas within emerging and complex study designs that require critical attention during the protocol review
3. To gather feedback from REC members across Kenya on the training content, structure, and effectiveness in enhancing their understanding and skills.
4. To assess the impact of the training on the knowledge and skills of REC members in Kenya regarding the review of protocols with emerging and complex study designs.

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 emerging and complex study designs was developed by carrying out a cross sectional survey where feedback on areas of greatest need were outlined. These areas

included; controlled human infection model, reverse pharmacology design, cluster randomized study design, implementation science research phase I-II clinical trials, step wedge design, adaptive design, case control in advanced epidemiology, evaluation of new technologies and digital health intervention and ecological studies. The participants 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.

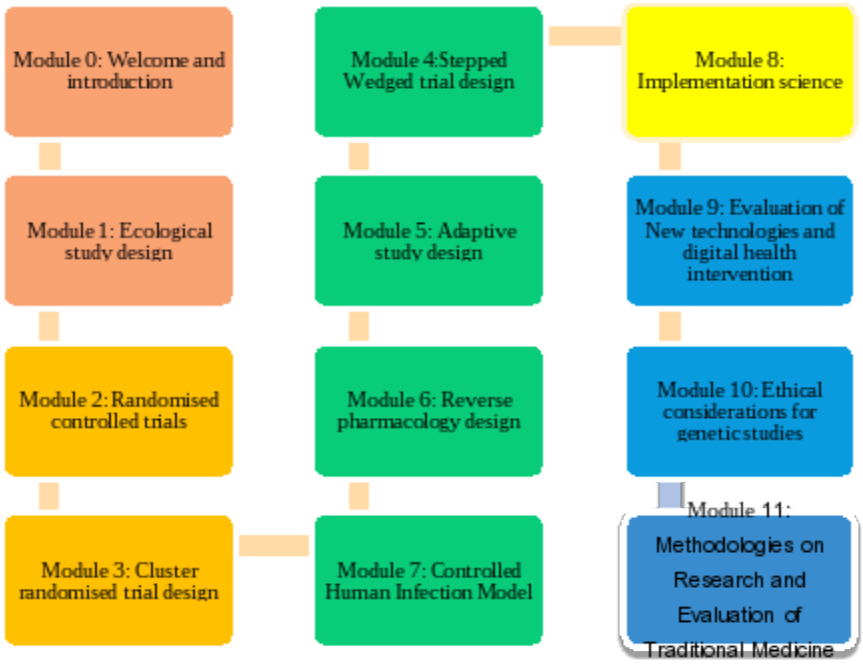
Through the SCALE-IT Project funded by Global Health EDCTP3, this curriculum training was scaled up to train REC and NRRA members, researchers and clinicians in Kenya on emerging and complex study designs. The curriculum developed under previous ethics project was reviewed and updated by competent consultants through conducting thorough literature review of physical and online documents, published papers and textbooks.

The content was organized by study design and structured as follows within each design; an introductory synopsis of the design, main components of the design, the areas for RECs to pay attention to, and a schedule of lectures/classes needed to cover the content with the recommended facilitators. Given that the randomized clinical trials (RCT) design is the conventional design for adducing evidence on the efficacy or effectiveness of an intervention, the designers of the curriculum deemed it fit to be the starting point and building block for other designs that follow.

Though the initial curriculum comprised of 10 modules, an additional module on methodologies of Research in Traditional Medicine was added after review of the curriculum by stakeholders prior to the training. The updated curriculum was then 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 comprised of 11 Modules



One week to the training, participants were enrolled on the IDI e-learning platform, and also underwent an online orientation where they were taken through how to navigate the online platform. Trainees via the online platform completed the pre-test which was mandatory prior to the Face to face training. From 10th – 12th June 2024, participants underwent a three days face to face (F2F) intensive training where they interfaced with the trainers in lively lectures. From 17th – 21st June 2024, trainees made self revision of the content via the online platform. The modules via the online platform were similar to the ones covered during the F2F training. However, this was met to give the trainees a better understanding through discussions, and research before they completed the post-test.

The Trainees comprised of REC members, National research regulatory personnel (NRRA) members and researchers across Kenya.

3.0 Training Delivery

Facilitators delivered sessions in lecture format using power point presentations. Some sessions included review of case scenarios, protocols, articles and feedback. The facilitators provided overview of the study designs and key areas REC members need to pay critical attention during the review of research protocols. Participants highly interacted with the facilitator during in-lecture discussions. Learning resources were

shared with participants at the beginning or end of each session for continuous learning and reference.

Figure 1: A trainer delivering a session at KEMRI

3.01 Trainees and training sites

The training took place at the KEMRI Graduate school training rooms. We received 85 trainees who included; REC, and NRRA members, researchers and clinicians in research. These members were nominated to attend the training by their supervisors based on their need to have deeper understanding of the concepts in emerging and complex study design.

4.0 Training Evaluation

Procedure

At the beginning of the training, participants completed a pre-training test (Appendix 2), and a post-training test at the end of the course via the IDI e-learning platform. In addition, participants completed training evaluation forms (Appendix 3) to assess each module and the training in general and. The filled forms were completed electronically with checks to ensure no missing fields

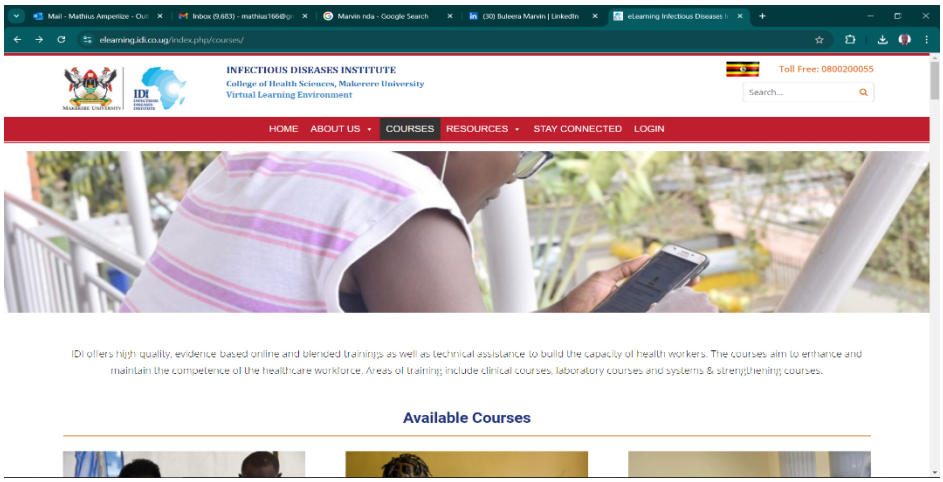


Figure 2: Interface of IDI e-learning platform

Pre and Post training assessment

The pre and post training assessment were comprised of the same questions assessing for knowledge on emerging and complex study designs that were covered during the training. They were composed of multiple answer questions, and short answer questions as shown in appendix 2. The completed assessment forms were automatically marked via the online system, and those who scored 70% 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 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 Emerging and Complex study designs, comment on how often they would you like to receive this training as a refresher, comment on any other study design or topic that they would recommend to be included in future trainings.

Data management

Data from the assessment was exported to STATA 15.0 for cleaning and analysis. Data from the training evaluation forms was cleaned in the Microsoft excel. Descriptive analysis was done and data summarised using frequencies, percentages, means, ranges and figures.

5.0 Training Outcomes

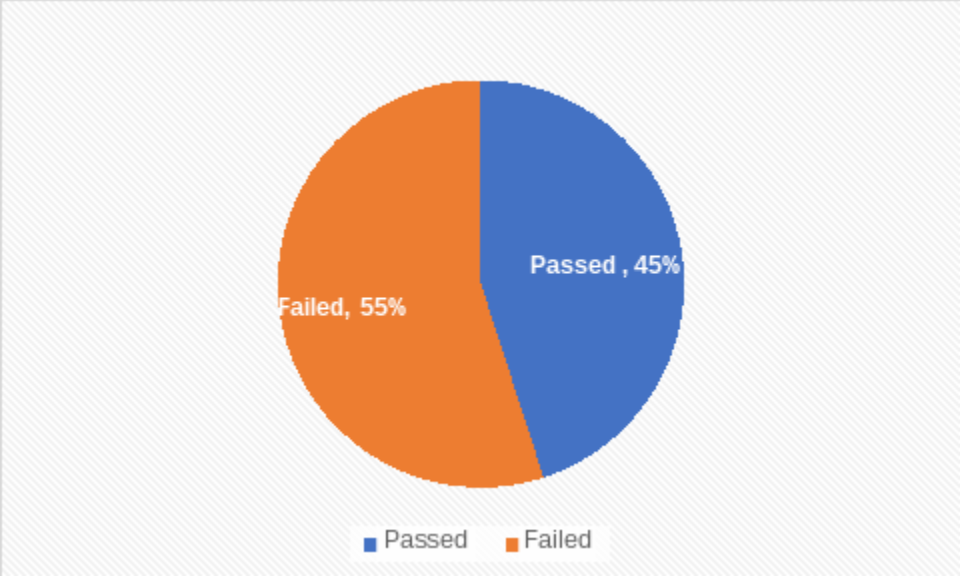
5.01 Number of trainees

In total, 31/31 of the invited REC, and NRRA members, researchers and clinicians were trained on emerging and complex study design. All participants completed pre-test, and post-test. Majority, 58% of the participants were females while 42% were males.

5.02 Pre-test performance

Of those that sat the pre-test training assessment, majority 55% failed by scoring below 70% pass mark while 45% passed. The minimum mark in pre-test was 40.5%, maximum mark was 98.8%, and the average mark was 66.7.

Figure 3: A pie chart showing Pre-test Performance



Post-test performance

All, 100% of the trainees passed post-test training assessment by scoring above the 70% pass mark. The

minimum mark was 73.4%, maximum mark was 100%, and the average mark was 93.7.

Training Impact: Knowledge and Skills

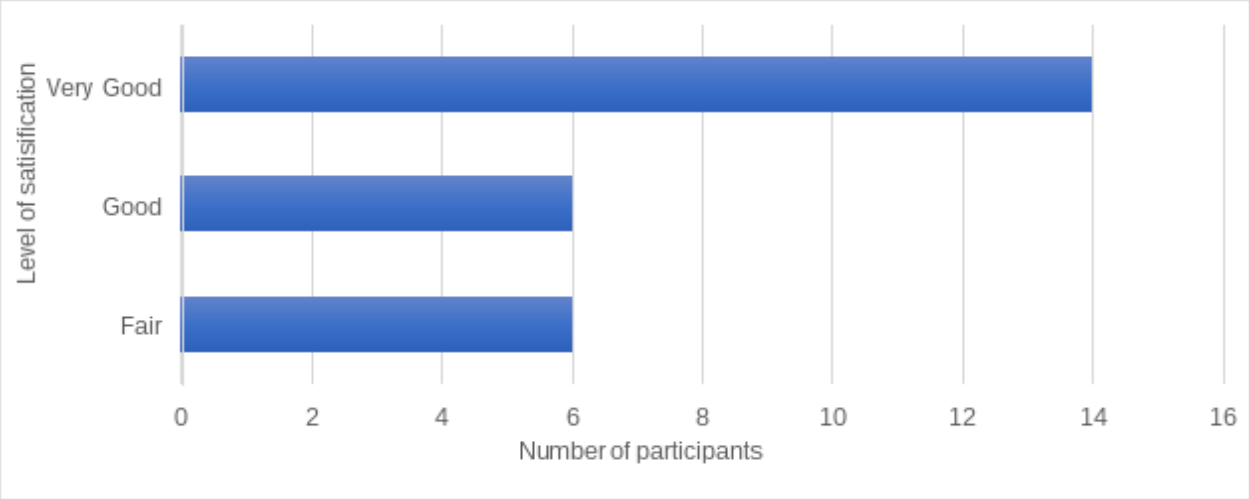
There was increase in the average score in new and complex study design from 66.7% in a pre-training assessment to 93.7% in post training assessment. The lowest score in the pre-test was 40.5% while it increased to 73.4% in the post test. The highest score in the pre-test was 98.8% while it increased to 100% in the post-test. There was also increase in the proportion of people who passed from 45% at pre-test to 100% in post-test. There was an average knowledge shift of 27.3

Course training Evaluation

Training Venue

Overall, majority of the participants were satisfied with the training venue as shown in the bar chart below.

Figure 4: A bar chart showing levels of satisfaction of participants with the overall training Venue



Assessment of different modules.

We assessed different aspects for each module including; teaching quality, relevance of the module to the trainee's roles, organization of the training content, effectiveness of the trainers. Overall, trainees highly rated the different variables. This was evident in the pass mark where most participants scored above the pass mark in the post test assessment.

Randomized controlled Trial.

Majority of the participants were very satisfied with the quality of how RCTs module was delivered.

Figure 5: Assessment of the Quality of teaching for the RCTS course

Majority, 74% of the trainees also agreed that the module was relevant to their roles that they do.

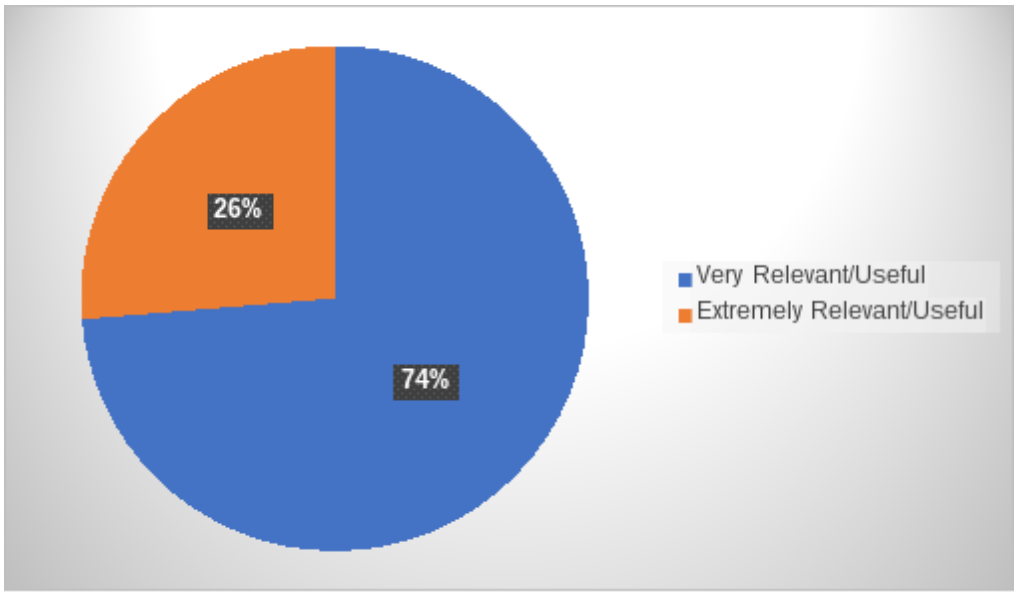


Figure 6: Relevance of the module content to the trainee's job

Assessment of Cluster Randomized Controlled Trial.

Most trainees were more satisfied with the quality of teaching for the cluster randomized module.

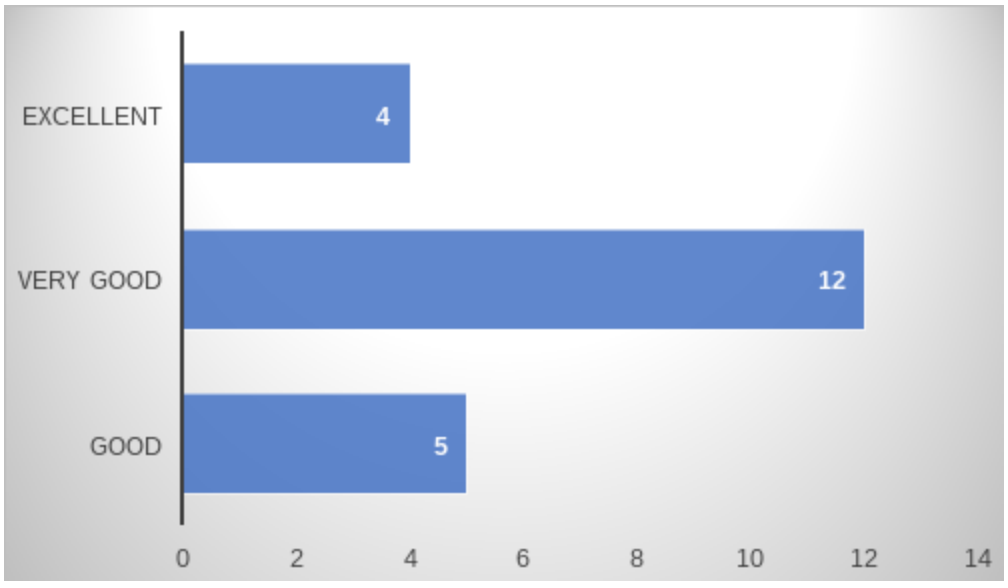


Figure 7: Quality of training of the cluster randomized controlled trial module

Assessment of Ecological Study Design Training

Under this module most trainees highly rated the trainers to be extremely knowledgeable and effective while delivering the sessions.

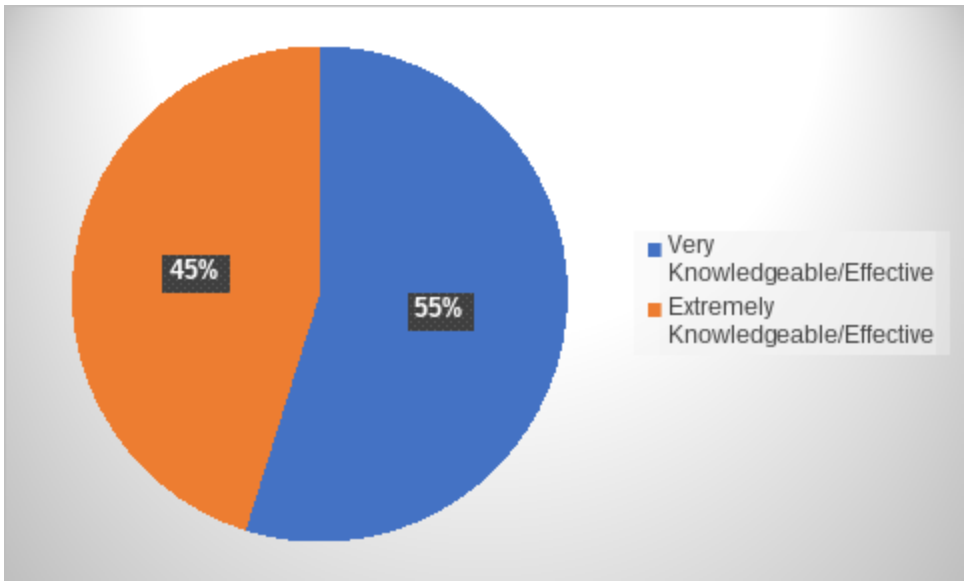


Figure 8: Rating effectiveness of the trainers for the ecological study design training module

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

- **Training Logistics**: Emphasize better planning, venue selection, time management, and early communication.
- **Training Duration**: Extend training sessions to cover more complex topics; several respondents suggested a week-long format.
- **Content & Interaction**: Include practical exercises, audience interaction, specialized topics like machine learning, and more hands-on scenarios.

7.0 Challenges and Lessons Learned

- The three days schedule wasn't enough for all ten modules 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.

8.0 Recommendations and conclusion

We trained 31 members from different institutions in Kenya. 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 new and complex study designs.

9.0 References

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10.0 Appendices

Appendix 1: Emerging and Complex study designs Training Schedule

SCHEDULE FOR EMERGING AND COMPLEX STUDY DESIGNS TRAINING (10th - 12th June 2024)

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

Emerging and Complex Study Designs Curriculum Training: Friday 7th Jun 2024; Day 0			
Time	**Module /Activity**	**Facilitator (s)**	**Venue**
14:00 -15:00	Course Orientation and Pre-test Completion	Training Team	Online
Emerging and Complex Study Designs Curriculum Training: Monday 10th Jun 2024; Day 1			
Time	**Module /Activity**	**Facilitator (s)**	**Venue**
08:00 - 08: 10	Registration	Mathius Amperiize	KEMRI HQ CBRD

08:10 - 08:30	Welcome Remarks	Dr Steve Wandiga	KEMRI HQ CBRD
08:30 -08:50	Remarks from IDI	Mathius Amperiize	KEMRI HQ CBRD
08:50 - 09:00	Training Launch	KEMRI	KEMRI HQ CBRD
09:00 - 09:30	Introduction & Expectations	Dr. Steve Wandiga / Mathius Amperiize	KEMRI HQ CBRD
09:30 - 10:00	Introduction to the course	Dr Steve Wandiga	KEMRI HQ CBRD
09: 40 - 11:00	Randomized Controlled Trials (RCTS)	Dr. Rose Bosire	KEMRI HQ CBRD
11:00 - 11:20	**BREAKFAST**		KEMRI HQ CBRD
11:20 - 13:00	Ecological study design	Dr. Vincent Were	KEMRI HQ CBRD
13:00 - 14:00	**LUNCH TIME**	**Mathius Amperiize**	KEMRI HQ CBRD
14:00 -15:30	Stepped Wedge trial design	Prof Noah Kiwanuka	KEMRI HQ CBRD
15:30 - 16:00	Completion of Online knowledge checks and Modules' Evaluation	Mathius Amperiize	KEMRI HQ CBRD
Emerging and Complex Study Designs Curriculum Training: Tuesday 11th Jun 2024; Day 2			
08:00- 08: 10	Registration	Mathius Amperiize	KEMRI HQ CBRD
08:10 - 10:30	Adaptive study design	Prof Noah Kiwanuka	KEMRI HQ CBRD
10:30 - 11:00	**BREAK FAST**	**Mathius Amperiize**	KEMRI HQ CBRD
11:00 -13:00	Cluster Randomized Trials	Dr. Rose Bosire	KEMRI HQ CBRD
13:00– 13:30	***LUNCH TIME***	***Mathius Amperiize***	KEMRI HQ CBRD
13:30 - 15:00	Reverse Pharmacology.	Dr. Ruth Nyangacha	KEMRI HQ CBRD
15:00 - 16:30	Evaluation of New technologies	Dr. Vincent Were	KEMRI HQ

	and Digital Interventions		CBRD
16:30 – 17:00	Completion of Online knowledge checks and Modules' Evaluation	Mathius Amperiize	KEMRI HQ CBRD
Emerging and Complex Study Designs Curriculum Training: Wednesday 12th Jun 2024: Day 3			
08:00 – 08:10	Registration	Mathius Amperiize	KEMRI HQ CBRD
08:10 -10:30	Human Controlled Human Infection Model	Prof Noah Kiwanuka	KEMRI HQ CBRD
10:30 - 11:00	**BREAK FAST**	**Mathius Amperiize**	KEMRI HQ CBRD
11:00 -13:00	Implementation Science Research	Dr. Jane On'gang'o	KEMRI HQ CBRD
13:00 - 13:30	**LUNCH TIME**	**Mathius Amperiize**	KEMRI HQ CBRD
13:30 - 15:00	Ethical considerations for Genetics Research	Dr. Jane On'gang'o	KEMRI HQ CBRD
15:00 – 16:30	Methodologies on Research and Evaluation of Traditional Medicine	Dr. Festus Tolo	KEMRI HQ CBRD
16:30 - 17:00	Completion of Online knowledge checks and Modules' Evaluation	Mathius Amperiize	KEMRI HQ CBRD
17:00 - 17:05	Closing Remarks	Dr Steve Wandiga	KEMRI HQ CBRD
17:05 –	Group photo and Departure	Mathius Amperiize	KEMRI HQ CBRD
POST TEST COMPLETION			
14th -21st Jun 2	**Completion of Post-test by Trainees**		Trainees
24th -28th Jun	**Compiling Marks & Emailing Certificates to Participants**		Training Team

Appendix 2: Emerging and Complex study designs Pre and Post-Test

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

Pre and Post training assessment

Emerging and Complex Study Design Training for REC members.

Circle the answers

0. Initials ……

1. How many years of experience in Clinical Trials 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 Emerging and Complex study designs?

a. None
b. Annually
c. Every two years
d. Every three years
e. Every five years

3. What is your higher level of Education?

a. Diploma
b. Bachelors
c. Masters
d. PhD
e. Others; Specify ……

4. Reported cases of COVID-19 are higher in Masaka than Kampala. Vaccination rates for COVID-19 are lower in Masaka than Kampala. Which of the following are reasons why it would be incorrect to simply assume that higher vaccination in Kampala is what is causing the fewer reported cases of the flu? ***Choose all that apply.***

a. Masaka and Kampala may have different strains of the flu

b. Masaka and Kampala may have different proportions of people in their populations who are especially vulnerable to the flu (e.g. the elderly)
c. Masaka and Kampala may have differences in health care accessibility, leading to differences in testing and diagnosis of the flu
d. Don't know

5. Researchers study the community of one town in Eastern Uganda over a 10-year period. They conduct an ecological study and collect data on the prevalence of HIV each year and the percentage of adults in the town who get married. Based on their data, the researchers conclude that those who get married are more likely to get HIV. Which of the following are true about the researchers' conclusion? ***Choose all that apply.***
   a. The researchers' conclusion is valid
   b. The researchers have correctly used group-level data to draw conclusions about individual adults
   c. The researchers do not know if the adults that are getting married are the same that get infected with HIV, therefore, their conclusion is not valid
   d. Don't know

6. By nature, a randomized controlled trial is; **only one choice possible**

a. Prospective
b. Retrospective
c. Don't know

7. The following are the goals of randomisation ***(check all that applies)***

a. Get groups that are comparable with regard to known and unknown factors
b. Avoid subjective selection and predictability in assigning participants to groups
c. Achieve balance in numbers of participants assigned to different groups
d. Don't know

8. The following are characteristics of phase I clinical trial except ***(only one option possible)***

a. Phase I studies' purpose is to find the highest dose of the new treatment that can be given safely without serious side effects (Maximum tolerated dose).
b. The focus in phase I is looking at what the drug does to the body (Pharmacodynamics) and what the body does with the drug (pharmacokinetics).
c. Placebos (sham or inactive treatments) are not part of these trials.
d. These studies usually include a small number of people (typically up to a few dozen).
e. These studies are designed to find out if the new treatment works
f. Don't know

9. What is the unit of randomization in a cluster randomized trial? **(only one option possible)**

a. Individuals
b. Groups
c. Don't know

10. Cluster RCTs involve two levels of consent: for the involvement of the group and the individual, and Group consent is not a substitute for individual consent **(only one option possible)**

a. True
b. False
c. Don't know

11. Stepped wedged trial is ***(check all that applies)***

a. An experimental design
b. Randomised controlled trial
c. Cluster randomised trial

d. An observational study designs.
e. Don't know

12. What type of study design which, includes prospectively planned opportunity for modification of one or more specific aspects of the original design and hypothesis after initiation without undermining its validity and integrity?
(Only one option possible)

a. Adoption trial design
b. Step wedged design
c. Adaptive study design
d. Don't know

13. The following applies to reverse pharmacology study design except **(Only one option possible)**

a. Integrates documentation of clinical experiences and experiential observations into leads, by interdisciplinary exploratory studies and further developing them into drug candidates and formulations through robust preclinical and clinical research
b. Is used to discover new drugs from natural products already in use by humans
c. The reverse pharmacology design makes the drug development process much longer than the classical approach
d. Don't know

14. Which of the following research projects are examples of implementation research (IR)
(Up to two choices possible)

a. Study of the health impact of an intervention strategy
b. Community trial to assess the effectiveness of a drug in real-life settings
c. Study to improve priority setting and budget allocation at health district level
d. Study to develop a strategy to overcome multi-sectoral obstacles to scale up of mechanical ploughing for control of cutaneous leishmaniasis
e. Clinical trial to investigate the efficacy of a new drug

f. Study to improve distribution and utilization of insecticide treated bed nets
g. Don't know

15. A very basic question that distinguishes IR questions from questions for other types of research is… ***(only one possible option)***

a. What proteins should be targeted for a more effective vaccine?
b. What are the knowledge and attitudes of the service beneficiaries?
c. What are possible interventions that could be tested to address the implementation gaps?
d. Which medicine is more efficacious for the controlling of an infectious disease of poverty?
e. Don't know

16. The following applies to Controlled Human Infection model (CHIMs) **Check all that applies**

a. They are commonly applied in vaccine research
b. Carefully selected human participants are purposely infected with infectious agents/germs in order to better understand how diseases are established in the human body, how the body responds, they germs spread, and how they can be treated and prevented
c. Absence of appropriate animal models can justify the conduct of CHIMs
d. Study participants are first given the experimental vaccine and afterwards get exposed to a germ.
e. Don't know

17. Which of the following constitutes digital health intervention research? **Check all that applies**

a) Digital health tools for patient care
b) mHealth evidence reporting and assessment (MERA) guidelines
c) Artificial Intelligence

d) Machine Learning Block chain

e) Don't know

18. Name any two pathogen that have been used in conducted controlled human infection studies

_____

_____

19. The following are the risks that are related to genetic research. **Check all that applies**

a. Family members who did not participate in the genetic research may face similar risks of harm.

b. It can produce discoveries about entire subpopulations, which may correspond to racial or ethnic groups.

c. It could potentially lead to family breakages and domestic violence especially if it results in paternity disputes

d. Testing itself could cause anxiety

e. Don't know

20. Name any two countries in Africa that have conducted controlled human infection studies

_____

_____

21. Is it ethically justified to conduct controlled human infection studies in LMICs?

a. Yes

b. No

c. Don't know

22. In adaptive study design, ***check all that applies***

a) Not all adaptations may be appropriate for every trial. The researcher should carefully consider which aspects to make "adaptive".
b) The purpose of adaptation is to remedy inadequacies in planning.
c) The adaptations must be scientifically justifiable and as much as possible prospectively planned and based on analysis of unblinded data.
d) The indicators of adaptation and the areas of the trial design to adapt should be clearly stated, including their implications on the trial outcomes/endpoints in the protocol.
e) Don't know

23. The following are challenges to ensuring a valid consent in genetic research

a) Ensuring participants understanding of genetic research complexities and potential risks of harm
b) Discussing how the genetic information collected might affect entire families, including members who do not know or participate in the research being conducted
c) Fair benefit sharing and data ownership
d) Explaining whether the research will (if known) or might include whole genome sequencing
e) Don't Know

25. In evaluating herbal medicines with a well-documented history, what sources of information are considered? ***(Only one choice possible)***

a) Clinical studies

b) In vitro data

c) Database searches

d) Animal studies

e) I don't know

26. What challenges might arise when adapting clinical trial design principles for herbal medicines? ***(Up to two choices possible)***

a) Strong or prominent smells

b) Use of placebos in all cases

c) Randomization of patients with prior herbal medicine treatment

d) Application of conventional drug principles

e) I don't know

Appendix 3: Emerging and Complex study designs Training Photos

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

Emerging and Complex Study Design Training for REC members.

Training evaluation form

Emerging and Complex study Design Training for REC members Training evaluation form

Please Evaluate: Honestly (Anonymous)

	Very Good	Good	Fair	Poor	Very Poor	Comments
How do you rate the training venue?						
How do you rate the training content?						
How do you rate the trainers?						

Which was your best session and why?	
How can we improve future training on Emerging and Complex study designs?	
How often would you like to receive this training as a refresher|?	
Do you have any other comments?	
Is there any other study design or topic that you recommend to be included in future trainings?	

Appendix 4: Emerging and Complex study designs Training Photos Figure

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