



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
AUGUST TO SEPTEMBER 2024 IN KIGALI, RWANDA





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**SCALE-IT
PROJECT**

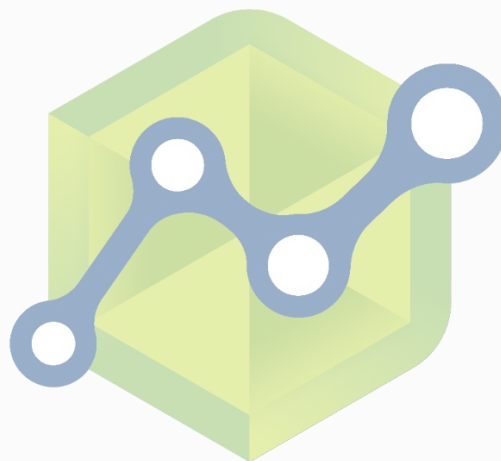




Table of Contents

1.0 Introduction	5
1.01 Background	5
1.02 General Objective	6
1.03 Specific Objectives	6
2.0 Training Design	6
2.01 Curriculum development, Rationale and Development	6
2.02 Training content, Schedule and Target Audience	8
3.0 Training Delivery	9
3.01 Trainees and training sites	9
4.0 Training Evaluation	10
5.0 Training Outcomes	11
5.01 Number of trainees	11
Post-test performance	12
Training Impact: Knowledge and Skills	12
Course training Evaluation	13
7.0 Challenges and Lessons Learned	15
8.0 Recommendations and conclusion	15
9.0 References	15
10.0 Appendices	16
Scaling Up Capacity to Support Conduct of Clinical Trials in East African Community (SCALE-IT)	20
Scaling Up Capacity to Support Conduct of Clinical Trials in East African Community (SCALE-IT)	28
Emerging and Complex Study Design Training for REC members	28
Training evaluation form	28





Table of Figures

Figure 1: Presentation of the curriculum to the TAC members
Figure 2: The Project officer, Mr Mathius delivering the introductory session at the beginning of the training
Figure 3: Interface of IDI e-learning platform
Figure 4: A pie chart showing Pre-test Performance
Figure 5: A pie chart showing post-test performance
Figure 6: A bar chart showing levels of satisfaction of participants with the overall training Venue
Figure 7: Best session preferred by the trainees
Figure 8: Frequency of the refresher Training

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
T	





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), Ministry of Health Rwanda and other East African Community (EAC) partners are strengthening scientific and ethics capacity in EAC for high quality research review, conduct and oversight, at international standards through the SCALE-IT project. We trained 25 individuals from different RECS, NRRAs, and research institutions on reviewing protocols with emerging and complex study designs in Rwanda

1.02 General training objective

To strengthen capacity of Research Ethics Committees (RECs) in Rwanda 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 Rwanda 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 Rwanda 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 Rwanda regarding the review of protocols with emerging and complex study designs.

2.0 Training Design

2.01 Curriculum development, 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-IV 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 EAC including Rwanda 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.



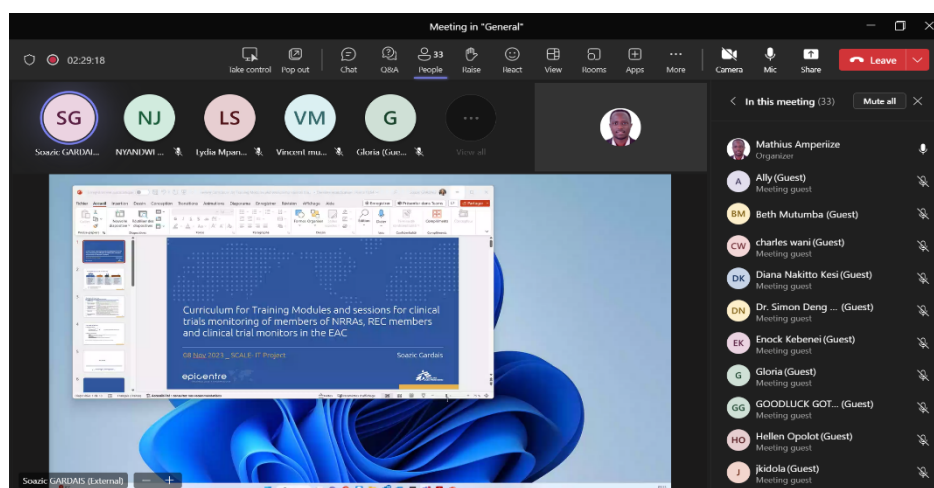
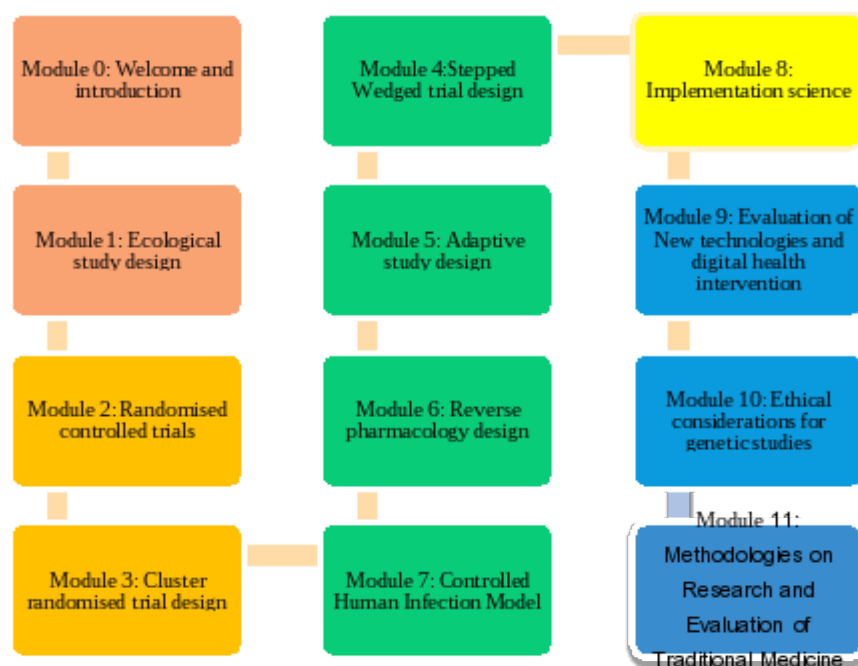


Figure 1: Presentation of the curriculum to the TAC members

2.02 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 19th – 21st August 2024, participants underwent a three days face to face (F2F) intensive training where they interfaced with the trainers in lively lectures.





From 22nd August – 6th September 2024, trainees made self-revision of the content via the online platform and consequently completed the post-test. 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 and NRRRA members, researchers and clinicians in research across Rwanda

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 facilitators during in-lecture discussions. Learning resources were shared with participants at the beginning or end of each sessions for continuous learning and reference.



Figure 2: The Project officer, Mr Mathius delivering the introductory session at the beginning of the training

3.01 Trainees and training sites

The training took Place at Sainte Famille Hotel, Kigali Rwanda. We received 25 trainees who





included; REC, and NRRRA 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. The filled forms were completed electronically with checks to ensure no missing fields

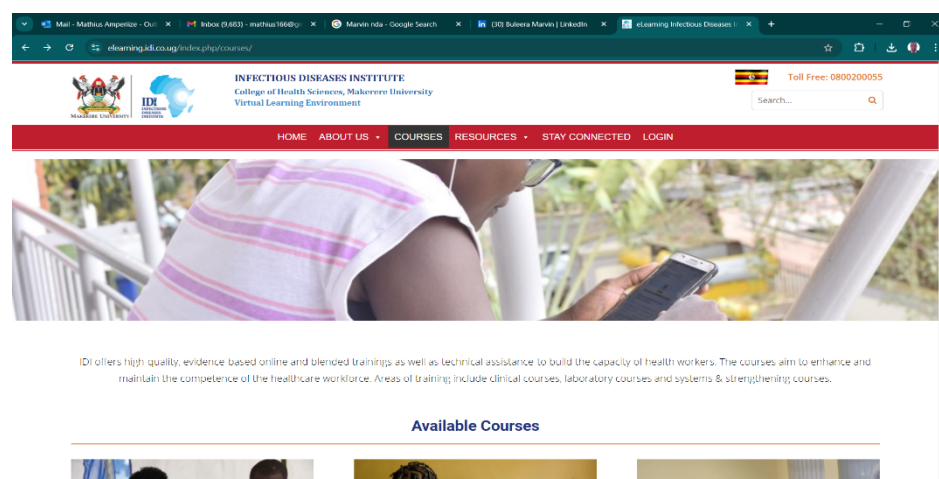


Figure 3: Interface of IDI e-learning platform
Pre and Post training assessment

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 60% and above were categorized as passed thus qualified for certification while those who scored below 59% were categorized as failed hence didn't qualify for certification.

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

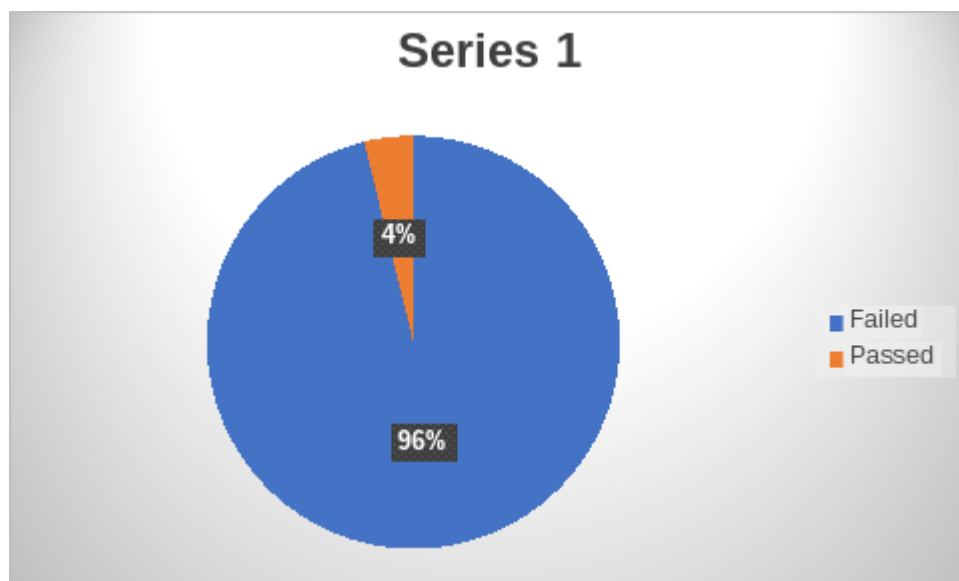
In total, 26/26 of the invited REC, and NRRA members, researchers and clinicians were trained on emerging and complex study design. All participants completed pre-test, and post-test. Majority, 58% of the participants were females while 42% were males.

5.02 Pre-test performance

Of those that sat the pre-test training assessment, majority 96% (25/26) failed by scoring below the 60% pass mark while 4.0 % (1/26) passed. The minimum mark in pre-test was 30.0%, maximum mark was 90.0%, and the average mark was 57.0%.

Figure 4: A pie chart showing Pre-test Performance

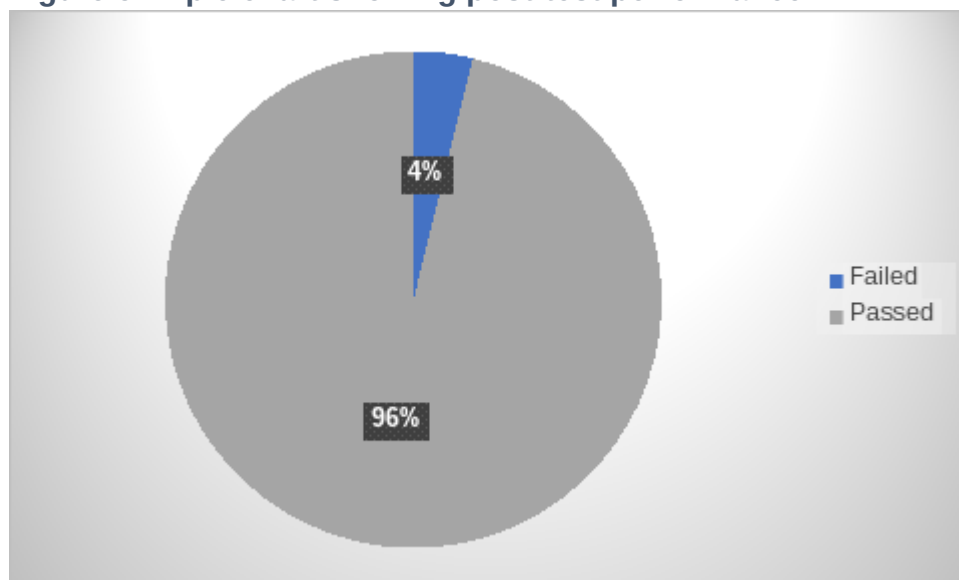




Post-test performance

Among those that sat post-test assessment, 96% (25/26) scored above the pass mark by scoring above the 60% pass mark. The minimum mark was 32.5%, maximum mark was 100%, and the average percentage mark was 88.8.

Figure 5: A pie chart showing post-test performance



Training Impact: Knowledge and Skills

There was increase in the average score in new and complex study design from 57.0 % in a





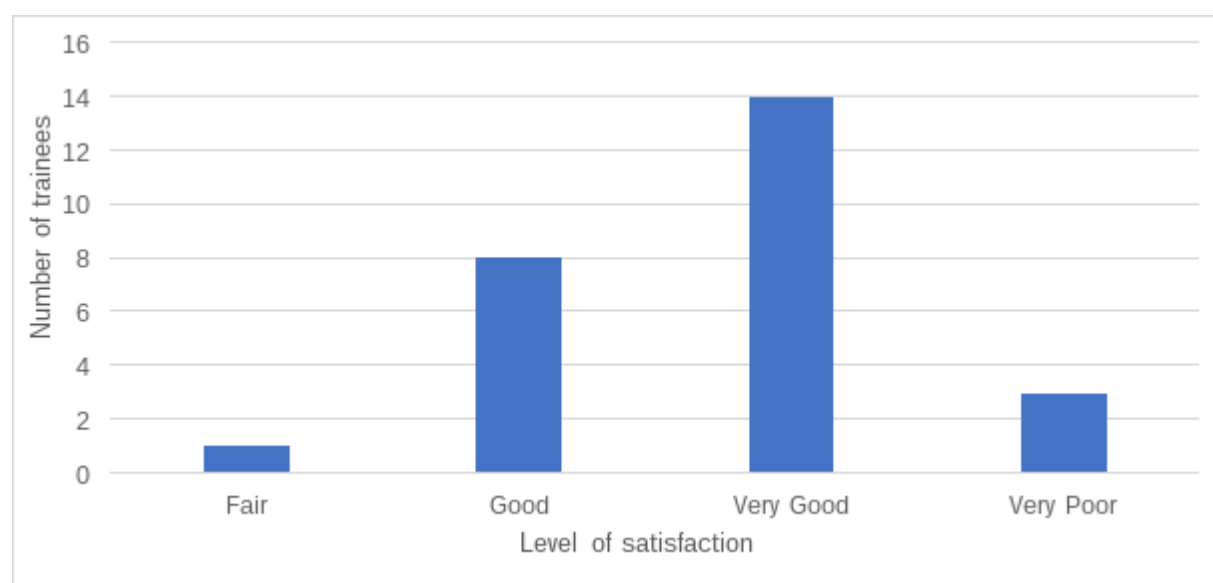
pre-training assessment to 88.8 % in post training assessment. The lowest score in the pre-test was 30.0% while it increased to 32.5 % in the post test. The highest score in the pre-test was 90.0% while it increased to 100% in the post-test. There was also increase in the proportion of people who passed from 4% at pre-test to 96% in post-test. There was an average knowledge shift of 31.8. There was no statistical significance between the performance at post-test and sex of the trainees (P-value =0.31)

Course training Evaluation

Training Venue

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

Figure 6: A bar chart showing levels of satisfaction of participants with the overall training Venue



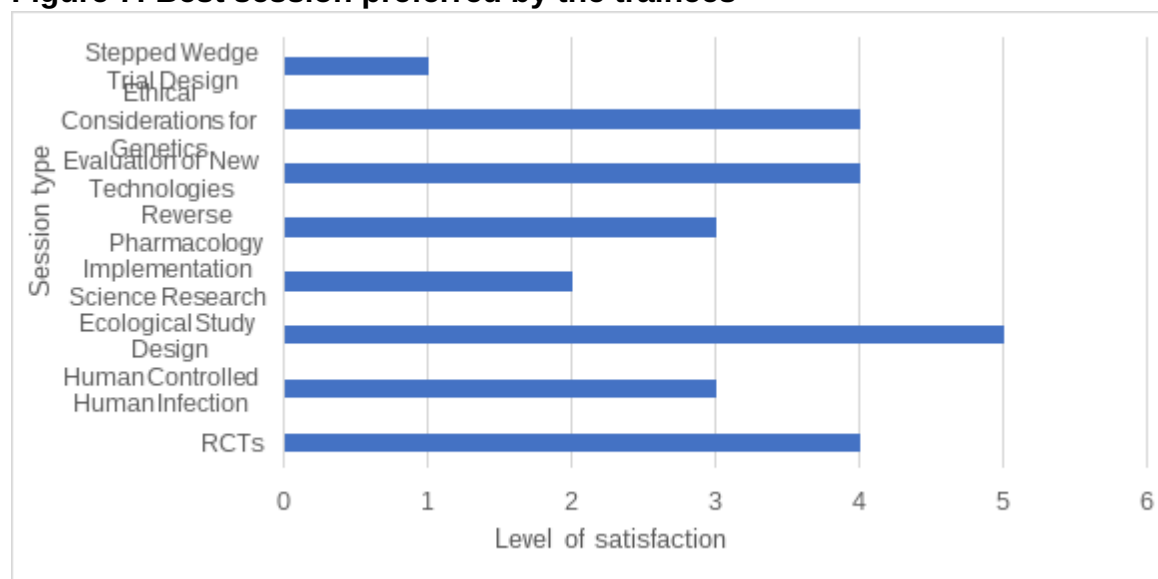
Best module for the participants

From the evaluation, more participants preferred Ecological study designs as their best session





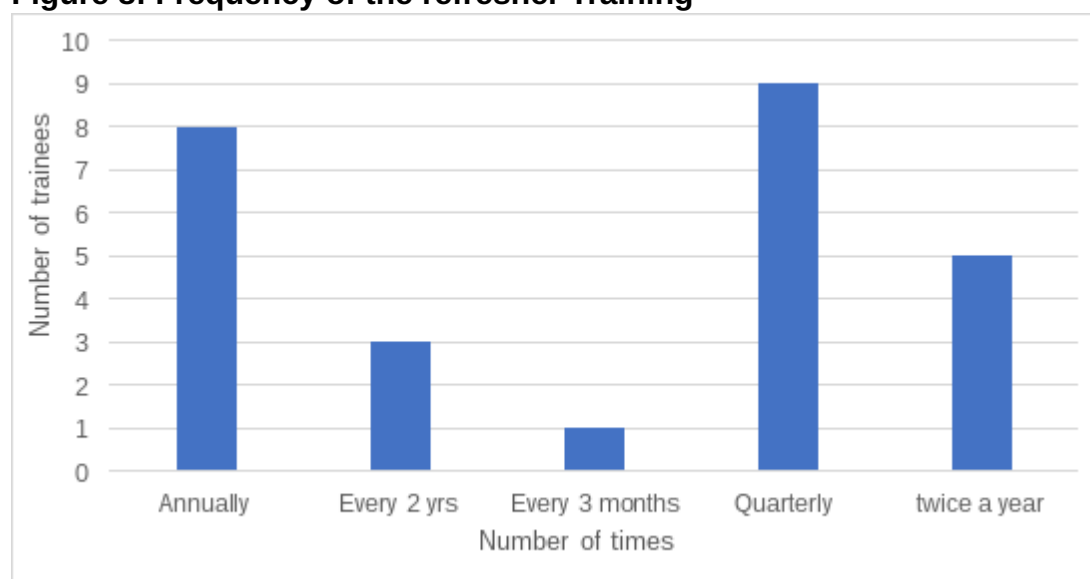
Figure 7: Best session preferred by the trainees



Number of times for the refresher training

Overall, majority of the participants 34.6% preferred quarterly as the frequency of how often the trainings should be carried out.

Figure 8: Frequency of the refresher Training



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

Extend Training Duration – Increase the number of days (e.g., from 3 to 5 or a full week)





and allow more hours for in-depth learning.

Increase Participation – Invite more members in health research and expand face-to-face training opportunities.

Other study designs or topics that trainees recommended to be included in future trainings

- Statistical Analysis including quantitative and qualitative Analysis
- Cross-Sectional Studies
- Research Methodology
- Effect of Research on Global Health
- Mixed-Methods Research
- Big Data and AI in Research
- Community-Based Research

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 26 members from different institutions in Rwanda. 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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6. Fhogartaigh CN, Aarons E. Viral haemorrhagic fever. Clin Med (Lond). 2015;15(1):61-

10.0 Appendices

Appendix 1: Emerging and Complex study designs Training Schedule

SCHEDULE FOR EMERGING AND COMPLEX STUDY DESIGNS TRAINING (19th – 21st AUG 2024)



VENUE: SAINTE FAMILLE HOTEL, KIGALI, RWANDA





Emerging and Complex Study Designs Curriculum Training: Friday 16th Aug 2024; Day 0

Time (EAT)	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 19th Aug 2024; Day 1

Time	Module /Activity	Facilitator (s)	Venue
08:00 - 08:10	Registration	Mathius Amperiize	Sainte Famille Hotel
08:10 - 08:30	Welcome Remarks	Dr Vincent Mutabazi	Sainte Famille Hotel
08:30 - 08:50	Remarks from IDI	Mathius Amperiize	Sainte Famille Hotel
08:50 - 09:00	Training Launch	MOH	Sainte Famille Hotel
09:00 - 09:30	Introduction & Expectations	Dr. Vincent Mutabazi /Mathius Amperiize	Sainte Famille Hotel
09:30 - 10:00	Introduction to SCALE-IT & course	Mathius Amperiize	Sainte Famille Hotel
09:40 - 11:00	Randomized Controlled Trials (RCTS)	Dr Vincent Mutabazi	Sainte Famille Hotel
11:00 - 11:20	BREAKFAST		Sainte Famille Hotel
11:20 - 13:00	Ecological study design	Dr. Hategekimana Jean Paul	Sainte Famille Hotel
13:00 - 14:00	LUNCH TIME	Mathius Amperiize	Sainte Famille Hotel
14:00	Stepped Wedge trial design	Dr. Vincent Mutabazi	Sainte



15:30			Famille Hotel
15:30 - 16:00	Completion of Online knowledge checks and Modules' Evaluation	Mathius Amperiize	Sainte Famille Hotel
Emerging and Complex Study Designs Curriculum Training: Tuesday 20th Aug 2024; Day 2			
08:00- 08:10	Registration	Mathius Amperiize	Sainte Famille Hotel
08:10 - 10:30	Adaptive study design	Dr. Uwanyirigira Donatha	Sainte Famille Hotel
10:30 - 11:00	BREAK FAST	Mathius Amperiize	Sainte Famille Hotel
11:00 - 13:00	Cluster Randomized Trials	Dr. Hategekimana Jean Paul	Sainte Famille Hotel
13:00- 13:30	LUNCH TIME	Mathius Amperiize	Sainte Famille Hotel
13:30 - 15:00	Reverse Pharmacology.	Dr. Hategekimana Jean Paul	Sainte Famille Hotel
15:00 - 16:30	Methodologies on Research and Evaluation of Traditional Medicine	Dr Vincent Mutabazi	Sainte Famille Hotel
16:30 - 17:00	Completion of Online knowledge checks and Modules' Evaluation	Mathius Amperiize	Sainte Famille Hotel
Emerging and Complex Study Designs Curriculum Training: Wednesday 21st Aug 2024: Day 3			
08:00 - 08:10	Registration	Mathius Amperiize	Sainte Famille Hotel
08:10 -	Controlled Human Infection	Dr. Hategekimana Jean Paul	Sainte



10:30		Model		Famille Hotel
10:30 - 11:00		BREAK FAST	Mathius Amperiize	Sainte Famille Hotel
11:00 - 13:00	-	Implementation Science Research	Dr. Uwanyirigira Donatha	Sainte Famille Hotel
13:00 - 13:30	-	LUNCH TIME	Mathius Amperiize	Sainte Famille Hotel
13:30 - 15:00	-	Ethical considerations for Genetics Research	Dr Vincent Mutabazi	Sainte Famille Hotel
15:00 - 16:30	-	Evaluation of New technologies and Digital Interventions	Dr. Hategekimana Jean Paul	Sainte Famille Hotel
16:30 - 17:00	-	Completion of Online knowledge checks and Modules' Evaluation	Mathius Amperiize	Sainte Famille Hotel
17:00 - 17:05	-	Closing Remarks	Dr Vincent Mutabazi	Sainte Famille Hotel
		Group photo and Departure	Mathius Amperiize	Sainte Famille Hotel
POST TEST COMPLETION				
26 th – 30 th Aug		Completion of Post-test by Trainees		Trainees
2 nd to 6 th Sep		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

Initials

How many years of experience in Clinical Trials related work do you have?

< 1 yr.

1-3 yrs.

3-5 yrs.

5-10 yrs.





>10yrs

How often do you attend refresher training on Emerging and Complex study designs?

None

Annually

Every two years

Every three years

Every five years

What is your higher level of Education?

Diploma

Bachelors

Masters

PhD

Others; Specify

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.*

Masaka and Kampala may have different strains of the flu

Masaka and Kampala may have different proportions of people in their populations who are especially vulnerable to the flu (e.g. the elderly)

Masaka and Kampala may have differences in health care accessibility, leading to differences in testing and diagnosis of the flu

Don't know

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.*

The researchers' conclusion is valid

The researchers have correctly used group-level data to draw conclusions about individual adults

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

Don't know

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

Prospective

Retrospective

Don't know

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

Get groups that are comparable with regard to known and unknown factors

Avoid subjective selection and predictability in assigning participants to groups

Achieve balance in numbers of participants assigned to different groups

Don't know

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

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).

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).

Placebos (sham or inactive treatments) are not part of these trials.





These studies usually include a small number of people (typically up to a few dozen).

These studies are designed to find out if the new treatment works

Don't know

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

Individuals

Groups

Don't know

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)

True

False

Don't know

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

An experimental design

Randomised controlled trial

Cluster randomised trial

An observational study designs.

Don't know

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)

Adoption trial design





Step wedged design

Adaptive study design

Don't know

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

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

Is used to discover new drugs from natural products already in use by humans

The reverse pharmacology design makes the drug development process much longer than the classical approach

Don't know

Which of the following research projects are examples of implementation research (IR)

(Up to two choices possible)

Study of the health impact of an intervention strategy

Community trial to assess the effectiveness of a drug in real-life settings

Study to improve priority setting and budget allocation at health district level

Study to develop a strategy to overcome multi-sectoral obstacles to scale up of mechanical ploughing for control of cutaneous leishmaniasis

Clinical trial to investigate the efficacy of a new drug

Study to improve distribution and utilization of insecticide treated bed nets

Don't know

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

What proteins should be targeted for a more effective vaccine?

What are the knowledge and attitudes of the service beneficiaries?





What are possible interventions that could be tested to address the implementation gaps?

Which medicine is more efficacious for the controlling of an infectious disease of poverty?

Don't know

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

They are commonly applied in vaccine research

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

Absence of appropriate animal models can justify the conduct of CHIMs

Study participants are first given the experimental vaccine and afterwards get exposed to a germ.

Don't know

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

Digital health tools for patient care

mHealth evidence reporting and assessment (MERA) guidelines

Artificial Intelligence

Machine Learning Block chain

Don't know

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





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

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

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

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

Testing itself could cause anxiety

Don't know

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

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

Yes

No

Don't know

In adaptive study design, *check all that applies*

Not all adaptations may be appropriate for every trial. The researcher should carefully consider which aspects to make “adaptive”.

The purpose of adaptation is to remedy inadequacies in planning.

The adaptations must be scientifically justifiable and as much as possible prospectively planned and based on analysis of unblinded data.

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.





Don't know

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

Ensuring participants understanding of genetic research complexities and potential risks of harm

Discussing how the genetic information collected might affect entire families, including members who do not know or participate in the research being conducted

Fair benefit sharing and data ownership

Explaining whether the research will (if known) or might include whole genome sequencing

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





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



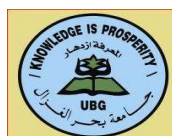


Please Evaluate: Honestly (Anonymous)

	Very Good	Good	Fair	Poor	Very Poor	Comments
How do you rate the training venue?						
How do you rate the training						
How do you rate the trainers?						
Which was your best session and why?						
How can we improve future training on Emerging and Complex study						
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





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