



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





