FAQs for SEM 2023

1. What is a clinical trial?
2. What documents should I submit as part of my clinical trial?
3. How do I determine if my research is a clinical trial that requires FDA approval?
4. Can I submit my application electronically?
5. What is the timeline to expect a response from the FDA after submission of an application?
6. Does the FDA have fast track application process?
7. Is there a standard application fee for conducting clinical trials in Ghana?
8. Are the application fees refundable if the trial is not approved?
9. Apart from application fees, are there any other fees I need to pay for the trial?
10. Is it mandatory for the principal investigator to be a Medical Doctor?
11. What action can I take if I do not agree with FDAs decision on my trial?
12. Why do deferred applicants have to appeal with the Ministry of Health instead of FDA?
13. Where can I find information regarding conducting clinical trials in Ghana?
14. Once my clinical trial is approved, what next?
15. What happens if I do not comply with regulatory requirements?
16. Does the FDA offer scientific advice or regulatory guidance prior to submission?
17. Is insurance a requirement for the participants and the study team?
18. Is it the sponsor's responsibility to provide insurance for the study team?
19. Is it necessary to have a local DSMB?
20. Can we know the number of trials that have been approved, deferred or cancelled?
21. Does the FDA organize training programs for researchers?
22. What is the full meaning of FAPAR?
23. Why should the applicant or study team have to review the FAPAR?
24. How can a Phase 1 trial provide data on efficacy for the FAPAR?
25. Where will FAPAR be published?