1. **What is Global Clinical Trial?**
   Global Clinical Trial means any clinical trial which is conducted as part of multi-national (more than one country) clinical development for designed and development for approval of a new drug worldwide. .
2. **What is Clinical Trial?**
   Clinical Trial means a systematic study of any new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic), and/or adverse effects with the objective of determining safety and/or efficacy of the new drug.
3. **Are clinical trials regulated in India?**
   Yes, clinical trials are regulated in India under the provisions of the Drugs & Cosmetic Act, 1940 & Rules, 1945
4. **What are "phases" of clinical trial?**
   Phase I clinical trials, researchers test a new drug or treatment for the first time in a small group of normal, healthy volunteers (about 20 to 80) to evaluate its safety, determine a safe dosage range, and identify side effects.
   Phase II clinical trials, the study drug or treatment is given to a larger group of people (about 100 to 300), including patients with the particular disease, to see if the drug or treatment is effective, and to further evaluate its safety.
   Phase III clinical trials, the study drug or treatment is given to large groups of people (from 1,000 to 3,000), including patients, to confirm its effectiveness, monitor side effects, compare it to other commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
   Phase IV clinical trials are done after the drug or treatment has been approved by the DCGI and marketed for public use. These studies continue testing the drug or treatment to collect information about its effect in various populations and gather data on any side effects associated with long-term use.
5. **What is academic trial?**
   "Academic clinical trial" means a clinical trial of a drug already approved for a certain claim and initiated by any investigator, academic or research institution for a new indication or new route of administration or new dose or new dosage form, where the results of such a trial are used only for academic or research purposes and not for seeking approval of the Central Licencing Authority or regulatory authority of any country for marketing or commercial purpose.
6. **What is a randomized trial?**
   Randomized is used to describe a research study that hopes to compare two or more different treatments or procedures. Randomized means that you will be assigned to a study group by chance, like flipping a coin.
7. **If subject withdraw from a randomized trial, will they be told if they received the placebo (an inactive, dummy pill) or the active drug?**
   Most randomized trials will only disclose this kind of information when the study has been completely finalized; this is done to protect the integrity of the research data and results. If the trial is a "double-blind" trial, the doctor will not even know which substance is received. Most protocols will have information with respect to when a

study will be unblended (during emergency situation/sever adverse reaction and its management).

8. **What are "blind" or "masked" studies?**
   In a "blinded" or "masked" study, participants do not know whether they are getting the drug being tested, or whether they are in the control group. The goal is to prevent the so-called "placebo effect" from influencing the results of the experiment. The placebo effect is the phenomenon of patients feeling better simply because they think they are receiving a helpful drug or treatment.
9. **What are "double blind" or "double masked" studies?**
   The "double-blind" or "double-masked" means that neither the participants, nor the study staff members, know who is receiving the experimental drug and who is in the control group. Studies are performed in this way so that neither the patients' nor the doctors' expectations about the experimental drug can influence the observations and results.
10. **What is Informed consent?**
    Informed consent is a process by which a subject voluntary confirms his/her willingness to participate in one or another clinical trial. And only after having been informed of all aspects of the study Informed consent should be documented by means of a written, signed and dated Informed Consent Form (ICF).In all trials, a freely given, informed, written consent is required to be obtained from each study subject. The Investigator must provide information about the study verbally as well as using a patient information sheet, in a language that is non- technical and understandable by the study subject.
11. **Is there any specific form/document for Informed consent?**
    Yes, Informed Consent Form (ICF) and its elements are prescribed in Schedule Y (Appendix-V) under the provisions of the Drugs and Cosmetic Rules, 1945. The subject's consent must be obtained in writing using an 'Informed Consent Form'. Both the patient information sheet as well as the informed consent form should have been approved by the ethics committee and furnished to the Central Licencing Authority. Any changes in the informed consent documents should be approved by the ethics committee and submitted to the Central Licencing Authority before such changes are implemented.
12. **What is procedure to obtaining Informed consent person whose is unable to give his own consent?**
    Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative (a legally acceptable representative is a person who is able to give consent for or authorize and intervention in the patient as provided by the law of India).
13. **What is an impartial witness?**
    If the trial subject or his/her legally acceptable representative is unable to read/write an impartial witness should be present during the entire informed consent process who must append his/her signature to the consent form.

14. What is Audio-Video consent?

An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record.

15. Weather Audio-Video consent is required for anti-HIV and anti-leprosy trial?

Only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

16. What is Clinical study protocol?

Every clinical investigation begins with the development of a clinical trial protocol. The protocol is a document that describes how a clinical trial will be conducted (the objective(s), design, methodology, statistical considerations and organization of a clinical trial,) and ensures the safety of the trial subjects and integrity of the data collected. The contents of clinical trial protocol should be complied with Schedule Y of Appendix X in Drugs and Cosmetics Rules, 1945.

17. Is there any permission required to conduct Global Clinical Trial?

Yes, applicants need to apply in Form 44 for permission to conduct Global Clinical Trial through applicant dashboard of online SUGUM portal for Global Clinical Trial. The Licensing Authority on being satisfied that the data submitted along with the application in support of the proposed clinical trial is adequate in all respects, issue permission for conduct of Global Clinical Trial.

18. Where to apply for permission of Global Clinical Trial (GCT)?

Application for Global Clinical Trial shall be accepted only through Sugam online portal mode and no offline applications will be accepted.

19. Is there any Form available for application for permission to conduct Global Clinical Trial?

Yes, application for Global clinical Trial needs to be done in Form 44 and copy of same along with copy of Fee Challan needs to be uploaded in designated section of Checklist available on online Sugam portal.

20. What are the fees for clinical trials?

Permission for CT-NOC	Applicable Fee
Clinical Trial Phase-I	50,000
Clinical Trial Phase-II	25,000
Clinical Trial Phase-III	25,000

21. Is there any Form available for application for import of drugs for Global Clinical Trial?

Yes, application for import of drug for Global Clinical Trial needs to be done in Form 12 and copy of same along with copy of Fee Challan needs to be uploaded in designated section of Checklist available on online Sugam portal.

22. Why, sometimes it's observed that Form-12 is not linked with form -44?

First of all applicant need to fill Form-12, save and submit then applicant receive a reference number on their dashboard and then applicant has mention the same reference number to proceed further filling Form-44 save and submit.

23. How to apply for permission of Global Clinical Trial?

Applicant need to register in online SUGAM portal with all applicable documents posted on Global Clinical Trial dash board through IT help desk.

24. Are there any original documents required to be submitted to DCGI office even after online application?

All originals of legal documents like Form 44, Form 12, Fee Challans, undertakings and affidavit's hard copy (in original) needs to be submitted to concerned department through CRU division of CDSCO HQ, FDA Bhawan, Kotla Road, New Delhi-110002.

25. What are the fees to be paid for import of Trial drug in India?

As per rule 33 of Drugs and Cosmetic Act, 1940 applicant need to pay the fees.

T.R 6 Challan of Rs 100/- for 1st drug and Rs 50/- for each additional Product is required.

26. How the fees shall be paid in India?

Preferably the requisite amount fee shall be paid by the applicant through Bharatkosh

Or

Through a Challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch or branches of Bank of Baroda, or any other bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines"

27. Can I give reference of IB for preclinical and clinical studies in the checklist of Sugam portal?

No, specific information regarding relevant section of checklist needs to be given in respective section so that processing of application can be hasten.

28. Can I mark any irrelevant section of checklist as "Not Applicable"?

Yes, you can mark irrelevant section of checklist as Not Applicable, but there needs to be given proper justification (supporting documents) why that section is irrelevant/Not applicable with respect to your application.

29. Who can participate in clinical trial?

All clinical trials have guidelines about who can participate, called inclusion and exclusion criteria. Both sets of criteria are based on factors such as age, gender, the type and stage of a disease, previous treatment history and other medical conditions.

Before joining a clinical trial, a participant must qualify for the study. Some studies look for participants with illnesses or conditions to be studied in the clinical trial, while others need healthy volunteers. Some studies need both types of volunteers.

Inclusion and exclusion criteria are not used to reject people personally; rather, the criteria are used to see if the study is a good fit for participants, keep them safe and help ensure scientists can find the information they need.

Next steps vary from study to study. You might be allowed to continue taking the study medication if you had a good response to it during the study, or you might be

given a chance to take the study medication if you didn't receive it. Most often, participation ends when the study ends because full safety information is not yet known.

30. **If subject withdraw from a randomized trial, will they be told if they received the placebo (an inactive, dummy pill) or the active drug?**

    Most randomized trials will only disclose this kind of information when the study has been completely finalized; this is done to protect the integrity of the research data and results. If the trial is a "double-blind" trial, the doctor will not even know which substance is received. Most protocols will have information with respect to when a study will be "unblinded."

31. **What happens during & after the study is over?**

    Depending on the results, Sponsor and the Data Safety Monitoring Board (DSMB) then decide whether to stop or continue testing the new drug or treatment.

    After a clinical trial is over, Sponsor carefully looks at the information collected during the study to determine the drug's effectiveness, if it is safe and if there are any side effects. Clinical Study Report should be submitted to DCGI in prescribed manner as per Schedule Y of Appendix II in Drugs and Cosmetics Rules, 1945 further approval of new drug and marketing authorization.