1. **What is Global Clinical Trial?**

   Global Clinical Trial means any clinical trial which is conducted as part of a clinical development of a drug in more than one country.

2. **What is Clinical Trial?**

   Clinical Trial in relation to a new drug or investigational new drug means any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its,- (i) clinical or; (ii) pharmacological including pharmacodynamics, pharmacokinetics or; (iii) adverse effects, with the objective of determining the safety, efficacy or tolerance of such new drug or investigational new drug;

3. **Are clinical trials regulated in India?**

   Yes, clinical trials are regulated in India under the provisions of the New Drugs and Clinical Trials Rules, 2019

4. **What are "phases" of clinical trial?**

   Phase I clinical trials -The objective of studies in this phase is the estimation of safety and tolerability with the initial administration of an investigational new drug into humans. Studies in this phase of development usually have non-therapeutic objectives and may be conducted in healthy subjects or certain types of patients. Drugs with significant potential toxicity e.g. cytotoxic drugs are usually studied in patients. Phase I trial should preferably be carried out by investigators trained in clinical pharmacology with access to the necessary facilities to closely observe and monitor the subjects.

   Phase II clinical trials- The primary objective of Phase II trials is to evaluate the effectiveness of a drug for a particular indication or indications in patients with the condition under study and to determine the common short-term side-effects and risks associated with the drug. Studies in Phase II should be conducted in a group of patients who are selected by relatively narrow criteria leading to a relatively homogeneous population. These studies should be closely monitored. An important goal for this phase is to determine the dose and regimen for Phase III trials. Doses used in Phase II are usually (but not always) less than the highest doses used in Phase I.

   Phase III studies have primary objective of demonstration or confirmation of therapeutic benefits. Studies in Phase III are designed to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication and recipient population. These studies should be intended to provide an adequate basis for marketing approval. Studies in Phase III may also further explore the dose-response relationships (relationships among dose, drug concentration in blood and clinical response), use of the drug in wider populations, in different stages of disease, or the safety and efficacy of the drug in combination with other drugs.

   Phase IV or post marketing trial of new drugs are performed after the approval of the drug and related to the approved indication. Such trials go beyond the prior demonstration of the drug's safety, efficacy and dose definition. Such trial might not have been considered essential at the time of new drug approval due to various reasons such as limitation in terms of patient exposure, duration of treatment during

clinical development of the drug, need for early introduction of the new drug in the interest of patients etc. Phase IV trials include additional drug-drug interaction, dose response or safety studies and trials design to support use under the approved indication e.g. mortality or morbidity studies, epidemiological studies, etc.

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 intended to be 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 New Drugs and Clinical Trials Rules, 2019 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 New Drugs and Clinical Trials Rules, 2019

.

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

Yes, applicants need to apply in Form CT-04 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 in Form CT-06.

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 CT-04 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	300000
Clinical Trial Phase-II	200000
Clinical Trial Phase-III	200000
Clinical Trial Phase-IV	200000
Academic Trial	Nil

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 CT-16 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. 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.

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

No original documents are not required to be submitted to DCGI office even after online application

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

As per rule SIXTH SCHEDULE of New Drugs and Clinical Trials Rules, 2019 applicant need to pay the fee of Rs 5000 per Drug Product.

25. How the fees shall be paid in India?

Requisite amount fee shall be paid by the applicant through Bharatkosh.

26. 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.

27. 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.

28. 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 New Drugs and Clinical Trials Rules, 2019 further approval of new drug and marketing authorization. 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.

32. 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."

33. 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 New Drugs and Clinical Trials Rules, 2019 further approval of new drug and marketing authorization.