WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

Review Article- Definitions (Glossary) used in Clinical Research

Dr. Vishal G. Jagtap[1], Jayesh Kakad[2]

[1]. Clinical research Executive, [2]. Clinical Quality Assurance

ABSTRACT

Clinical exploration assumes a huge part in the anticipation and fix of different wellbeing issues. Clinical examination includes the investigation of the clinical adequacy of materials and techniques that assume a critical part in the counteraction and fix of different wellbeing problems. So its important to know about the most widely recognized terms utilized when directing the clinical preliminaries. Thus, the point of the current paper is to introduce a far reaching glossary of the phrasing utilized in clinical preliminaries to help when planning, executing and reviewing clinical preliminaries.

Introduction-

Clinical preliminaries are research studies acted in individuals that are pointed toward assessing a clinical, careful, or social intercession. They are the essential way that scientists see whether another therapy, similar to another medication or diet or clinical gadget (for instance, a pacemaker) is protected and powerful in individuals.

A definitive objective of medication advancement is the formation of new, safe, and successful mixtures for treating human illness. Clinical preliminaries contain the piece of this undertaking including human subjects**.**

Definition / Glossary

1) **"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 Licensing Authority or regulatory authority of any country for marketing or commercial purpose;

2) **Act-**means the Drugs and Cosmetics Act, 1940 (23 of 1940);

3) **Active pharmaceutical ingredient** –means any substance which can be used in a pharmaceutical formulation with the intention to provide pharmacological activity; or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease; or to have direct effect in restoring, correcting or modifying physiological functions in human beings or animals;

4) **Adverse event** –means any untoward medical occurrence (including a symptom or disease or an abnormal laboratory finding) during treatment with an investigational drug or a pharmaceutical product in a patient or a trial subject that does not necessarily have a relationship with the treatment being given;

5) **Bioavailability study** –means a study to assess the rate and extent to which the drug is absorbed from a pharmaceutical formulation and becomes available in the systemic circulation or availability of the drug at the site of action;

6) **Bioequivalence study-**means a study to establish the absence of a statistically significant difference in the rate and extent of absorption of an active ingredient from a pharmaceutical formulation in comparison to the reference formulation having the same active ingredient when administered in the same molar dose under similar conditions;

7) **Bioavailability and bioequivalence study center** –means a center created or established to undertake bioavailability study or bioequivalence study of a drug for either clinical part or for both clinical and analytical part of such study;

8) "**Biomedical and health research"-** means research including studies on basic, applied and operational research or clinical research, designed primarily to increase scientific knowledge about diseases and conditions (physical or socio-behavioral); their detection and cause; and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation

9) "**Central Licensing Authority"-** means the Drugs Controller, India

10) **"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;

11) "**Clinical trial Protocol"-** means a document containing the background, objective, rationale, design, methodology including matters concerning performance, management, conduct, analysis, adverse event, withdrawal, statistical consideration and record keeping pertaining to clinical trial;

12) "**Clinical trial site**"- means any hospital or institute or any other clinical establishment having the required facilities to conduct a clinical trial;

13) "**Efficacy**"- in relation to a drug means its ability to achieve the desired effect in a controlled clinical setting;

14) **"Effectiveness**"- in relation to a drug means its ability to achieve the desired effect in a real world clinical situation after approval of the drug;

15) "**Good Clinical Practices Guidelines**"- means the Good Clinical Practices Guidelines for conduct of clinical studies in India, formulated by the Central Drugs Standard Control Organization and adopted by the Drugs Technical Advisory Board;

16) "**Global clinical trial"-** means any clinical trial which is conducted as part of a clinical development of a drug in more than one country;

17) "**Investigational new drug**"- means a new chemical or biological entity or substance that has not been approved for marketing as a drug in any country;

18) "**Investigational product"-** means the pharmaceutical formulation of an active ingredient or placebo being tested or used in a clinical trial;

19) "**Investigator**"- means a person who is responsible for conducting clinical trial at the clinical trial site;

20) "**Medical management**"- means treatment and other necessary activities for providing the medical care to complement the treatment;

21) "**New chemical entity**"- means any substance that has not been approved for marketing as a drug by a drug regulatory authority of any country including the authorities specified under these rules and is proposed to be developed as a new drug for the first time by establishing its safety and efficacy;

22) "**New drug**" means,**—**

(i) a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent, except in accordance with the provisions of the Act and the rules made thereunder, as per conditions specified in the labelling thereof and has not been approved as safe and efficacious by the Central Licensing Authority with respect to its claims; or

(ii) a drug approved by the Central Licensing Authority for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or

(iii) a fixed dose combination of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or

(iv) a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licensing Authority; or

(v) a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug;

Explanation.**—** The drugs, other than drugs referred to in sub-clauses (iv) and (v), shall continue to be new drugs for a period of four years from the date of their permission granted by the Central Licensing Authority and the drugs referred to in sub-clauses

(iv) and (v) shall always be deemed to be new drugs

23) "**Orphan drug**"- means a drug intended to treat a condition which affects not more than five lakh persons in India;

24) "**Pharmaceutical formulation**"- means any preparation for human or veterinary use containing one or more active pharmaceutical ingredients, with or without pharmaceutical excipients or additives, that is formulated to produce a specific physical form, such as, tablet, capsule or solution, suitable for administration to human or animals;

25) "**Pharmacovigilance**"- means the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug- related problem;

26) "**Phytopharmaceutical drug**" - means a drug of purified and standardized fraction, assessed qualitatively and quantitatively with defined minimum four bio- active or phytochemical compounds of an extract of a medicinal plant or its part, for internal or external use on human beings or animals, for diagnosis, treatment, mitigation or prevention of any disease or disorder but does not include drug administered through parenteral route;

27) "**Placebo**" - means an inactive substance visually identical in appearance to a drug being tested in a clinical trial;

28) "**Post-trial access**" - means making a new drug or investigational new drug available to a trial subject after completion of clinical trial through which the said drug has been found beneficial to a trial subject during clinical trial, for such period as considered necessary by the investigator and the Ethics Committee;

29) "**Registered pharmacist**"- shall have the meaning as assigned to it in clause(i) of section 2 of the Pharmacy Act, 1948 (8 of 1948);

30) "**Serious adverse event**"- means an untoward medical occurrence during clinical trial resulting in death or permanent disability, or hospitalization of the trial subject where the trial subject is an outdoor patient or a healthy person, prolongation of hospitalization where the trial subject is an indoor-patient, persistent or significant disability or incapacity, congenital anomaly, birth defect or life threatening event;

31) "**Similar biologic**"- means a biological product which is similar in terms of quality, safety and efficacy to reference biological product licensed or approved in India, or any innovator product approved in International Council of Harmonization (ICH)member countries;

32) "**Sponsor**"- includes a person, a company or an institution or an organization responsible for initiation and management of a clinical trial;

33) "**State Licensing Authority**"- means Licensing Authority appointed by a State Government having qualifications specified in rule 49A of the Drugs and Cosmetics Rules, 1945;

34) "**Trial subject**"- means a person who is either a patient or a healthy person to whom investigational product is administered for the purposes of a clinical trial.

35) **Adverse Drug Reaction (ADR)**- In the preapproval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

36) **Adverse Event (AE)**- Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.

37) **Audit** -A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s).

38) **Audit Certificate**- A declaration of confirmation by the auditor that an audit has taken place.

39) **Audit Report**- A written evaluation by the sponsor's auditor of the results of the audit.

40) **Audit Trail**- Documentation that allows reconstruction of the course of events.

41) **Blinding/Masking**- A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

42) Case Report Form (CRF)- A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

43) Clinical Trial/Study- Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

44) Clinical Trial/Study Report -A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report (see the ICH Guidance for Structure and Content of Clinical Study Reports).

45) Comparator (Product) -An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.

46) Compliance (in relation to trials)- Adherence to all the trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory requirements.

47) Confidentiality- Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

48) Contract -A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

49) Coordinating Committee- A committee that a sponsor may organize to coordinate the conduct of a multicenter trial.

50) Coordinating Investigator -An investigator assigned the responsibility for the coordination of investigators at different centers participating in a multicenter trial.

51) Contract Research Organization (CRO) -A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

52) Direct Access- Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsor's monitors, and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

53) Documentation -All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

54) Essential Documents-Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced (see section 8. "Essential Documents for the Conduct of a Clinical Trial").

55) Good Clinical Practice (GCP)- A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

56) Impartial Witness- A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

57) Independent Ethics Committee (IEC) -An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose Contains Nonbinding Recommendations 6 responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. The legal status, composition, function, operations and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP as described in this guidance.

58) Informed Consent- A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

59) Inspection- The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CROs) facilities, or at other establishments deemed appropriate by the regulatory authority(ies).

60) Institution (medical)- Any public or private entity or agency or medical or dental facility where clinical trials are conducted.

61) Institutional Review Board (IRB) -An independent body constituted of medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocols and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

62) Interim Clinical Trial/Study Report- A report of intermediate results and their evaluation based on analyses performed during the course of a trial.

63) Investigational Product- A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

64) Investigator- A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. (See also Sub investigator.)

65) Investigator/Institution- An expression meaning "the investigator and/or institution, where required by the applicable regulatory requirements."

66) Investigator's Brochure - A compilation of the clinical and nonclinical data on the investigational product(s) that is relevant to the study of the investigational product(s) in human subjects (see section 7. "Investigator's Brochure").

67) Legally Acceptable Representative -An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

68) Monitoring -The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), GCP, and the applicable regulatory requirement(s).

69) Monitoring Report- A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOPs.

70) Multicenter Trial- A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

71) Nonclinical Study- Biomedical studies not performed on human subjects.

72) Opinion (in relation to Independent Ethics Committee)- The judgment and/or the advice provided by an Independent Ethics Committee (IEC).

73) Protocol - A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guidance, the term protocol refers to protocol and protocol amendments.

74) Protocol Amendment -A written description of a change(s) to or formal clarification of a protocol

75) Quality Assurance (QA) -All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).

76) Quality Control (QC)- The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.

77) Randomization -The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

78) Regulatory Authorities - Bodies having the power to regulate. In the ICH GCP guidance, the expression "Regulatory Authorities" includes the authorities that review submitted clinical data and those that conduct inspections . These bodies are sometimes referred to as competent authorities.

79) Source Data- All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

80) Source Document- Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

81) Sponsor - An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

82) Sponsor Investigator-An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

83) Standard Operating Procedures (SOPs)- Detailed, written instructions to achieve uniformity of the performance of a specific function.

84) Sub investigator- Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). See also Investigator.

85) Subject/Trial Subject - An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

86) Subject Identification Code -A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial-related data.

87) Trial Site The location(s)- where trial-related activities are actually conducted.

88) Unexpected Adverse Drug Reaction- An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product). (See the ICH Guidance for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.)

89) Vulnerable Subjects- Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

90) Well-being (of the trial subjects)- The physical and mental integrity of the subjects participating in a clinical trial.

91) Certified Copy- A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.

92) Monitoring Plan- A document that describes the strategy, methods, responsibilities, and requirements for monitoring the trial.

93) Validation of Computerized Systems-A process of establishing and documenting that the specified requirements of a computerized system can be consistently fulfilled from design until decommissioning of the system or transition to a new system. The approach to validation should be based on a risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human subject protection and reliability of trial results.

94) Stakeholders/Consumers-Stakeholders/Consumers include health insurers, managed care organizations, health care systems, organized medicine, voluntary health agencies, patient advocacy groups, purchasers of health care, and providers of health care, public health systems, and individual consumers.

95) Accepts healthy volunteers-A type of eligibility criteria that indicates whether people who do not have the condition/disease being studied can participate in that clinical study.

96) Active comparator arm-An arm type in which a group of participants receives an intervention/treatment considered to be effective (or active) by health care providers.

97) Protocol Deviations – Failure to conduct a study as described in the protocol. The failure may be accidental or due to negligence and in either case, the protocol deviation should be documented. This also includes failure to comply with federal laws and regulations, the institution's commitments and policies, and standards of professional conduct and practice. Examples of noncompliance include:

- failure to obtain/maintain approval for research,
- failure to obtain informed consent when required,
- failure to file adverse event reports,
- performance of an unapproved study procedure,
- performance of research at an unapproved site,
- failure to file protocol modifications and
- failure to adhere to an approved protocol.

98) Baseline – The initial time point in a clinical trial that provides a basis for assessing changes in subsequent assessments or observations. At this reference point, measurable values such as physical exam, laboratory tests, and outcome assessments are recorded.

99) Protocol Deviations Report – Internal document created as part of the ongoing quality control process summarizing compliance with the protocol and listing protocol deviations and/or violations.

100) Prospectively Assigned – A pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo or other control) of the clinical trial.

101) *Recruitment Plan* – The plan that outlines how individuals will be recruited for the study and how the study will reach the recruitment goal.

102) *Retention Plan* – The plan that details the methods in which the study will use in order to retain study participation in the clinical trial.

103) *Safety Monitoring Plan* – A plan that outlines the oversight of a clinical trial.

104) Screening Log – An essential document that records all individuals who entered the screening process. The screening log demonstrates the investigator's attempt to enroll a representative sample of participants.

105) Screening Process – A process designed to determine individual's eligibility for participation in a clinical research study.

106) *Stopping Rules* –Established safety criteria that would either pause or halt a study due to reasons including but not limited to futility or risk(s) to the participants.

107) Stratification – Separation of a study cohort into subgroups or strata according to specific characteristics such as age, gender, etc., so that factors which might affect the outcome of the study, can be taken into account.

108) Bias – A point of view or preference which prevents impartial judgment in the way in which a measurement, assessment, procedure, or analysis is carried out or reported.

109) Coordinating Center (CC) – A group organized to coordinate the planning and operational aspects of a multi-center clinical trial. CCs may also be referred to as Data Coordinating Centers (DCCs) or Data Management Centers (DMCs).

110) Clinical Research or Study Coordinator (CRC) – An individual that handles the administrative and day-to-day responsibilities of a clinical trial and acts as a liaison for the clinical site. This person may collect the data or review it before it is entered into a study database.

111) Concomitant Medication – Prescription and over-the-counter drugs and supplements a study participant has taken along with the study intervention. This information may be collected as a history item as well as during the study. Some studies may collect only those medications that may interact with the study or intervention or that may exclude an individual from participating in a study.

112) Conflict of Interest – A conflict of interest occurs when individuals involved with the conduct, reporting, oversight, or review of research

also have financial or other interests, from which they can benefit, depending on the results of the research.

113) Control Group – The group of individuals in a clinical trial assigned to a comparison intervention.

114) Controlled Clinical Trial – A clinical trial in which at least one group of participants is given a test intervention, while at least one other group concurrently receives a control intervention.

115) Data Management – The processes of handling the data collected during a clinical trial from development of the study forms/CRFs through the database locking process and transmission to statistician for final analysis.

116) Data Management Plan (DMP) – A plan that documents the processes for handling the flow of data from collection through analysis. Software and hardware systems along with quality control and validation of these systems, as relevant are described.

117) Data and Safety Monitoring Board (DSMB) –A group of individuals independent of the study investigators that is appointed by the NIA to monitor participant safety, data quality and to assess clinical trial progress.

118) ata and Safety Monitoring Plan (DSMP) – Plan included with the grant application for clinical trials which establishes the overall framework for data and safety monitoring, how adverse events will be reported to the IRB and the NIH and, when appropriate, how the NIH Guidelines and FDA regulations for INDs and IDEs will be satisfied.

119) Food and Drug Administration (FDA) – An agency within the U.S. Department of Health and Human Services (DHHS) responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, nation's food supply, cosmetics, and products that emit radiation.

120) Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule – The first comprehensive Federal protection for the privacy of personal health information. The Privacy Rule regulates the way certain health care groups, organizations, or businesses, called covered entities under the Rule, handle the individually identifiable health information known as protected health information (PHI).

121) *Manual of Procedures (MOP)* – A set of procedures describing study conduct. A MOP is developed to facilitate consistency in protocol implementation and data collection across study participants and clinical sites.

122) New Drug Application (NDA) – An application submitted by the manufacturer of a drug to the FDA, after the clinical trial has been completed, for a license to market the drug for a specified indication.

123) Open-Label Trial – A clinical trial in which investigators and participants know which intervention is being administered.

124) Pharmacokinetics – The process (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine.

125) Clinical phases

Phase I – clinical trials to test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., to determine a safe dosage range and to identify side effects). It can include healthy participants or patients.
Phase II – clinical trials to study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety. It is conducted in participants with the condition or disease under study and will determine common short-term side effects and risks.
Phase III – studies to investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.
Phase IV – studies conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

126) Age or age group-A type of eligibility criteria that indicates the age a person must be to participate in a clinical study.

127) Protocol Amendments – A written description of a change(s) to or formal clarification of a protocol.

128) All-cause mortality-A measure of all deaths, due to any cause, that occur during a clinical study.

129) Allocation-A method used to assign participants to an arm of a clinical study. The types of allocation are randomized allocation and nonrandomized.

130) Arm-A group or subgroup of participants in a clinical trial that receives a specific intervention/treatment, or no intervention, according to the trial's protocol.

131) Baseline characteristics-Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. These data include demographics, such as age, sex/gender, race and ethnicity, and study-specific measures (for example, systolic blood pressure, prior antidepressant treatment).

132) Collaborator-An organization other than the sponsor that provides support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting.

133) Cross-over assignment-A type of intervention model describing a clinical trial in which groups of participants receive two or more interventions in a specific order. For example, two-by-two cross-over assignment involves two groups of participants. One group receives

drug A during the initial phase of the trial, followed by drug B during a later phase. The other group receives drug B during the initial phase, followed by drug A. So during the trial, participants "cross over" to the other drug. All participants receive drug A and drug B at some point during the trial but in a different order, depending on the group to which they are assigned.

134) **Data Monitoring Committee (DMC)-**A group of independent scientists who monitor the safety and scientific integrity of a clinical trial. The DMC can recommend to the sponsor that the trial be stopped if it is not effective, is harming participants, or is unlikely to serve its scientific purpose. Members are chosen based on the scientific skills and knowledge needed to monitor the particular trial. Also called a data safety and monitoring board, or DSMB.

135) **Eligibility criteria-**The key requirements that people who want to participate in a clinical study must meet or the characteristics they must have. Eligibility criteria consist of both inclusion criteria (which are required for a person to participate in the study) and exclusion criteria (which prevent a person from participating). Types of eligibility criteria include whether a study accepts healthy volunteers, has age or age group requirements, or is limited by sex.

136) **Enrollment-**The number of participants in a clinical study. The "estimated" enrollment is the target number of participants that the researchers need for the study.

137) **Exclusion criteria-**A type of eligibility criteria. These are reasons that a person is not allowed to participate in a clinical study.

138) **Factorial assignment-**A type of intervention model describing a clinical trial in which groups of participants receive one of several combinations of interventions. For example, two-by-two factorial assignment involves four groups of participants. Each group receives one of the following pairs of interventions: (1) drug A and drug B, (2) drug A and a placebo, (3) a placebo and drug B, or (4) a placebo and a placebo. So during the trial, all possible combinations of the two drugs (A and B) and the placebos are given to different groups of participants.

139) **Group/cohort-**A group or subgroup of participants in an observational study that is assessed for biomedical or health outcomes.

140) **Inclusion criteria-**A type of eligibility criteria. These are the reasons that a person is allowed to participate in a clinical study.

141) **Informed consent form (ICF)-**The document used in the informed consent or process.

142) **Intervention model-**The general design of the strategy for assigning interventions to participants in a clinical study. Types of intervention models include: single group assignment, parallel assignment, cross-over assignment, and factorial assignment.

143) **Intervention/treatment-**A process or action that is the focus of a clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include noninvasive approaches, such as education or modifying diet and exercise.

144) **Observational study-**A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to a specific interventions/treatment.
A patient registry is a type of observational study.

145) **Observational study model-**The general design of the strategy for identifying and following up with participants during an observational study. Types of observational study models include cohort, case-control, case-only, case-cross-over, ecologic or community studies, family-based, and other.

146) **Other adverse event-**An adverse event that is not a serious adverse event, meaning that it does not result in death, is not life-threatening, does not require inpatient hospitalization or extend a current hospital stay, does not result in an ongoing or significant incapacity or interfere substantially with normal life functions, and does not cause a congenital anomaly or birth defect; it also does not put the participant in danger and does not require medical or surgical intervention to prevent one of the results listed above.

147) **Parallel assignment-**A type of intervention model describing a clinical trial in which two or more groups of participants receive different interventions. For example, a two-arm parallel assignment involves two groups of participants. One group receives drug A, and the other group receives drug B. So during the trial, participants in one group receive drug A "in parallel" to participants in the other group, who receive drug B.

148) **Participant flow-**A summary of the progress of participants through each stage of a clinical study, by study arm or group/cohort. This includes the number of participants who started, completed, and dropped out of the study.

149) **Patient registry-**A type of observational study that collects information about patients' medical conditions and/or treatments to better understand how a condition or treatment affects patients in the real world

150) **Placebo-**An inactive substance or treatment that looks the same as, and is given in the same way as, an active drug or intervention/treatment being studied.

151) **Recruitment status**

Not yet recruiting: The study has not started recruiting participants.

Recruiting: The study is currently recruiting participants.

Enrolling by invitation: The study is selecting its participants from a population, or group of people, decided on by the researchers in advance. These studies are not open to everyone who meets the eligibility criteria but only to people in that particular population, who are

specifically invited to participate.

Active, not recruiting: The study is ongoing, and participants are receiving an intervention or being examined, but potential participants are not currently being recruited or enrolled.

Suspended: The study has stopped early but may start again.

Terminated: The study has stopped early and will not start again. Participants are no longer being examined or treated.

Completed: The study has ended normally, and participants are no longer being examined or treated (that is, the last participant's last visit has occurred).

Withdrawn: The study stopped early, before enrolling its first participant.

Unknown: A study on ClinicalTrials.gov whose last known status was recruiting; not yet recruiting; or active, not recruiting but that has passed its completion date, and the status has not been last verified within the past 2 years.

152) Registration-The process of submitting and updating summary information about a clinical study and its protocol, from its beginning to end, to a structured, public Web-based study registry that is accessible to the public, such as ClinicalTrials.gov.

153) Statistical analysis plan (SAP)-The written description of the statistical considerations and methods for analyzing the data collected in the clinical study.

154) Status-Indicates the current recruitment status or the expanded access status.

155) Study design-The investigative methods and strategies used in the clinical study.

Conclusion

This article gives a total glossary containing definitions and clarifications for the most normally utilized terms when leading clinical preliminaries. It is trusted that characterizing these terms will help scientists during the plan and revealing phases of a preliminary in and different disciplines. Moreover, fostering a comprehension of the phrasing and plans provisions of clinical preliminaries ought to at last work on the nature of exploration around here and ultimately the nature of proof supporting clinical choices practically speaking.

Conflict of interest

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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