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aadditive effect - The combined effect when two or more things are used together. adherence - Following the study directions and requirements. adverse event - Any health problem that happens during the study. adverse reaction - A health problem that happens during the study and is reported as possibly caused by the study treatment. analyze - To examine study data to answer a question and help reach conclusions. anonymize - Remove, change, or hide personal details to protect participant privacy. antibody - A protein made by the body to fight an illness or infection. antigen - A substance that causes the body's immune system to react. arm - A group of participants in a research study who all receive the same study treatment. assent - Willingness to take part in a research study by someone who is not able to give legal consent. assent form - A document used to explain the details of a research study to children or people who are unable to give legal consent. assessment - Information that is collected and analyzed from a study participant. bcdeffocus group - A group interview to learn what people think about a topic. frequency - How often something happens over a period of time. ggeneralizability - How research results can apply to people who were not part of the study. genetic testing - A medical test that could identify a health risk to a person or their biological family members by looking at their genes (DNA). hhazard ratio - A measure of risk that compares two treatments in the same study. healthy volunteer - A study participant who does not have a disease or condition, including the one being studied. hereditary - A parent's features and traits being passed to their biological children before birth. hypothesis - An idea that is tested in a research study. ilmMagnetic Resonance Imaging (MRI) - A way to take pictures of the inside of a person's body with a machine that uses strong magnets and radio waves. master protocol - An overall research plan that guides sub-studies that have their own research questions. maximum - The most or largest amount. mean - median - The middle number in a set of numbers when listed in order from lowest to highest. minimal - minimum - The smallest or least amount. minor - Someone considered too young to give legal consent. monitor - To observe, check, or evaluate something in a study over time. morbidity (rate) - The number of people who develop a disease or illness in a group over time. mortality (rate) - The number of deaths in a group of people over time. multicenter trial - A study that takes place at more than one research center. nnegative test result - A test result that shows a person does not have what was tested for. negligible - So small that it has little to no impact. non-compliance - Not following research requirements. non-inferiority trial - A study to test if a study treatment works about as well as another treatment for the same condition. opqrsttolerability - How much a participant or group of participants can accept a study treatment's unwanted effects so they can keep taking it. treatment effect - How much a study treatment changes a condition, symptom, or function. uumbrella trial - A research study that tests and compares two or more study treatments for one disease or condition. vwwash-out - A time before starting a study treatment when a person stops taking other medicines. withdraw - To stop being a participant in a study. xX-ray - A way of taking pictures of the inside of a person's body using X-ray radiation. Skip to content Sponsor Login Newsletter Sign-up Clinical Research Glossary The body's reaction to a substance, illness, or infection. An immune response is the body's way to fight something it thinks might be harmful. The immune response is how the body identifies and defends itself against germs like bacteria, viruses, and substances that seem to be harmful. An immune response helps the body stay safe. For example, a vaccine works by causing an immune response so that the body can fight off the germ, and remember to attack it if the germ ever comes back. You may see the term "immune response" used in a variety of ways in the research study context. For example, a study may be researching participants' immune responses to certain things or how different investigational products may affect a person's immune response. If you have questions about a study that is looking at immune response, be sure to ask your study team for more information. Version 2.0 September 2024 Skip to content Sponsor Login Newsletter Sign-up Clinical Research Glossary The use of medicine to treat a disease, condition, or symptom. Clinical trials are done to learn more about the risks and benefits of a drug therapy. There are many different types of drug therapy that can have multiples different purposes. A drug therapy could be used to: – make symptoms better, – treat a condition or disease, – lower the risk of getting a disease in the future, – or destroy harmful cells, like cancer cells. If a research study is testing a drug therapy it is important to understand the possible risks and benefits. You can ask questions during the consent process, but also anytime during the study if any new questions come up. The study team is there to make sure you stay safe while you are taking a drug therapy. Version 2.0 September 2024 Clinical Research Glossary We are eager for your feedback and ideas. Thank you in advance for sharing your perspective with us. Skip to content The Association of Clinical Research Professionals With terms frequently referenced in ACRP Educational Programs, this easy-to-use glossary is designed to enhance your knowledge base and provide a solid foundation in clinical research terminology. You can search by keyword or click the hyperlinked letters to jump directly to that section. However, it is important to note that the glossary is not exhaustive, as the field of clinical research is constantly evolving. New terms and concepts emerge regularly, so it's recommended to supplement this glossary with additional resources and stay updated with the latest developments. Please note, the terms are listed alphabetically in the glossary from left to right—not from top to down in the columns. Have feedback or want to suggest a new term? Contact Us > Sources Terms are sourced from the following resources: ICH E6(R3) – Good Clinical Practice MRCT – Clinical Research Glossary (The MRCT Center Clinical Research Glossary by the MRCT Center is licensed under CC BY-NC-SA 4.0) CDISC-GLOSS – Clinical Data Interchange Standards Consortium Clinical research is medical research that involves people to test new treatments and therapies. Clinical Trial A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Healthy Volunteer A Healthy volunteer is a person with no known significant health problems who participates in clinical research to test a new drug, device, or intervention. Inclusion/Exclusion Criteria Inclusion/Exclusion Criteria are factors that allow someone to participate in a clinical trial are inclusion criteria. Those that exclude or not allow participation are exclusion criteria. Informed Consent Informed consent explains risks and potential benefits about a clinical trial before someone decides whether to participate. Patient Volunteer A patient volunteer has a known health problem and participates in research to better understand, diagnose, treat, or cure that disease or condition. Phases of Clinical Trials Clinical trials are conducted in "phases." The trials at each phase have a different purpose and help researchers answer different questions. Phase I trials — An experimental drug or treatment in a small group of people (20–80) for the first time. The purpose is to evaluate its safety and identify side effects. Phase II trials — The experimental drug or treatment is administered to a larger group of people (100–300) to determine its effectiveness and to further evaluate its safety. Phase III trials — The experimental drug or treatment is administered to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard or equivalent treatments. Phase IV trials — After a drug is licensed and approved by the FDA researchers track its safety, seeking more information about its risks, benefits, and optimal use. Placebo A placebo is a pill or liquid that looks like the new treatment but does not have any treatment value from active ingredients. Protocol A Protocol is a carefully designed plan to safeguard the participants' health and answer specific research questions. Principal Investigator A Principal Investigator is a doctor who leads the clinical research team and, along with the other members of the research team, regularly monitors study participants' health to determine the study's safety and effectiveness. Randomization Randomization is the process by which two or more alternative treatments are assigned to volunteers by chance rather than by choice. Single- or Double-Blind Studies Single- or double-blind studies (also called single- or double-masked studies) are studies in which the participants do not know which medicine is being used, so they can describe what happens without bias. In single-blind ("single-masked") studies, you are not told what is being given, but the research team knows. In a double-blind study, neither you nor the research team are told what you are given; only the pharmacist knows. Members of the research team are not told which participants are receiving which treatment, in order to reduce bias. If medically necessary, however, it is always possible to find out which treatment you are receiving. Types of Clinical Trials Diagnostic trials determine better tests or procedures for diagnosing a particular disease or condition. Natural history studies provide valuable information about how disease and health progress. Prevention trials look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning. Quality of life trials (or supportive care trials) explore and measure ways to improve the comfort and quality of life of people with a chronic illness. Screening trials test the best way to detect certain diseases or health conditions. Treatment trials test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy. SOM Clinical Research Glossary Clinical research has a highly specialized vocabulary with a vast number of acronyms and abbreviations that help facilitate scientific communication. Whether you are new to clinical research or an experienced member of the research team, understanding and remembering the nuances of clinical research vocabulary can be challenging. To ensure a consistent and clear clinical research communication, the CRSO has created the SOM Clinical Research Glossary, a comprehensive clinical research glossary in clear and plain language that aligns with industry and regulatory standards. As the glossary is intended to be broadly applicable to various types of research and audiences, its definitions provide nuances of usage. If there are variations in how key agencies are defining a term, each definition is provided. We need your feedback The SOM Clinical Research Glossary is intended to be a living resource that will be periodically updated with new terms and clarifications. Please let us know, if there is a word, acronym, or abbreviation you see regularly in clinical research that is not included in the glossary or if you want to propose an alternative definition. Skip to content Sponsor Login Newsletter Sign-up Clinical Research Glossary A protein made by the body to fight an illness or infection. Antibodies develop after an infection to help clear the infection and to prevent the infection from coming back. An antibody is a protein that is produced by the body's immune system and causes an immune response. Antibodies can be found in various areas of the body, including the blood, skin, lungs, tears, saliva, and even breast milk. Antibodies can be produced in response to viruses, bacteria, parasites and even medications. Antibodies can sometimes recognize someone's own body tissues and cause disease. In some cases, antibodies can also be used as a treatment/therapy. For example, antibodies are sometimes used to fight cancer cells. A research study may test whether a study treatment causes a person to develop antibodies to a disease. It may also test an antibody to see if it can treat a disease. If you have any questions about antibodies or immune reactions, you can ask the study team. Version 2.0 September 2024 Study record managers: refer to the Data Element Definitions if submitting registration or results information. Skip to content Sponsor Login Newsletter Sign-up Clinical Research Glossary A group of participants in a research study who all receive the same study treatment. If a study has two arms, one group will receive one study treatment while a second group will receive a different study treatment such as a placebo or the standard of care. Studies that compare two or more study treatments divide participants into separate arms to compare the effects of the different treatments. You may see the term "arm" in the consent form or when the study team is explaining the research study to you. They may mention that there will be different arms in the study you are joining. You may be randomized to one arm or another You can ask how many arms will be in a study. If there are arms, you can clarify how participants will be assigned to receive the different study treatments. Version 2.0 September 2024 Clinical Research Glossary Terms: Clinical research as field of study is complex and replete with specialised terminologies. If you are someone who works in the clinical research field, you could already be familiar with the terms. However, there's nothing to be ashamed about if you don't know one or two in the clinical research glossary, it happens – and that's okay! Why? Because we will help you out there with the essential clinical research terminology list you should be aware of! This LLRI blog comprises of all the important common clinical research terms, from A to Z – from the glossaries of NIA (Natural Institute of Aging), NIH (National Institutes of Health), MRCT (Multi-regional clinical trials), Novotech and other similar important portals. We have tried to converge all the important research terms in this glossary of clinical research here within this article on the common clinical research terms, hope this helps you guys understand essential clinical research terminology! Read on…. Glossary Of Clinical Research: A to Z of all the Common Clinical Research Terms A Adverse Event (AE): Any undesirable experience associated with the use of a medical product in a patient. This could be mild, moderate, or severe. Amendment: A formal change or addition made to the protocol of a clinical study. Assent: Agreement from a participant, often a minor, who is not legally able to give full consent but can understand the study and agree to participate. B Baseline: Initial set of measurements taken at the start of a study before the participant receives any treatment, used for comparison throughout the study. Basket Trial: A research study that tests one study treatment for different diseases and conditions. Bias: A systematic error or deviation from the truth, in results or inferences, in clinical research. Biomarker: Something in the body that is measured as an indicator of personal health or disease. Blinding (Masking): A method used to prevent study participants, healthcare providers, and/or researchers from knowing which intervention the participant is receiving to eliminate bias. Bioinformatics: The science of using computers, databases, and math to organize and analyze large amounts of biological, medical, and health information. Information may come from many sources, including patient statistics, tissue specimens, genetics research, and clinical trials. C Case Report Form (CRF): A document used to record data on each participant during a clinical trial. Clinical Endpoint: A primary outcome used to judge the effectiveness of a treatment. Clinical Trial: A research study conducted with human volunteers to evaluate the safety and efficacy of a medical treatment or intervention. Cohort: A group of individuals sharing a common characteristic, such as age or treatment, who are followed over a period of time. Keep reading the essential clinical research terminology below… D Data Monitoring Committee (DMC): An independent group of experts who monitor patient safety and treatment efficacy data while a clinical trial is ongoing. Data and Safety Monitoring Plan (DSMP): The DSMP deals with how the framework for safety and data monitoring of the clinical trials is laid out, and other factors such as how adverse events will be reported to the IRB and the NIH, and how the NIH Guidelines and FDA regulations for INDs and IDEs will be applied. Double-blind Study: A study in which neither the participants nor the investigators know who is receiving the experimental treatment and who is receiving a placebo. Dose-response Relationship: The relationship between the dose of a drug and the magnitude of its therapeutic or adverse effects. E Efficacy: The ability of a drug or treatment to produce the desired beneficial effect in controlled clinical trials. Endpoint: A primary or secondary outcome used to assess the effectiveness of a treatment in a clinical trial. Epoch: The planned stages of volunteer participation in a trial typically include assessing eligibility, a wash-out period to discontinue any previous treatments, administering the trial treatment, and conducting follow-up after the treatment has concluded. Ethics Committee: A group that reviews and monitors biomedical research involving humans, ensuring that the study is ethical, and the rights and welfare of participants are protected. Early Phase: Termed as Phase 0 previously, it defines the exploratory trials conducted before traditional phase 1 trials, which aims to explore/investigate how/whether a drug affects the body. Eligibility Criteria: These are the key requirements that individuals must meet to participate in a clinical study. Eligibility criteria include both inclusion criteria (which define who can join the study) and exclusion criteria (which specify who cannot participate). These criteria can be based on various factors such as health status, age, sex, or specific medical conditions. Enrolment: This refers to the number of participants in a clinical study. The "estimated" enrolment is the target number of participants that researchers aim to recruit for the study. Exclusion Criteria: These are specific factors that disqualify a person from participating in a clinical study. Exclusion criteria are a subset of eligibility criteria, ensuring that only suitable participants are included in the research. Emergency Use Authorization (EUA): It is the process that makes a vaccine or a treatment available during a public health emergency, for example, COVID-19 vaccines. Under EUA, the vaccine/treatment is made public before all the research is complete, and even before the full approval for its release. Here are few more essential clinical research terminology for your perusal. F FDA (Food and Drug Administration): The U.S. federal agency responsible for regulating food, drugs, medical devices, cosmetics, and more. Feasibility Study: A small-scale study conducted to determine whether a larger study is practical and what modifications may be needed. Formulation: The composition of a drug, including its active and inactive ingredients. G Good Clinical Practice (GCP): An international standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Gender-based Eligibility: A type of eligibility criteria that determines participation in a clinical study based on an individual's self-identified gender. Gender identity refers to a person's personal sense of gender, which may or may not align with their biological sex. Genotype: The genetic makeup of an individual, often studied to understand the impact on drug response. Guideline: A document providing principles or recommendations on how to carry out certain tasks or processes in clinical research. H Hypothesis: A proposed explanation made based on limited evidence as a starting point for further investigation in a study. Hazard Ratio: A measure used in survival analysis to compare the risk of an event happening in one group versus another. Human Subject: An individual who participates in research, either as a recipient of the test article or as a control. Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule: It is the first comprehensive Federal regulation safeguarding the privacy of personal health information. This rule governs how specific healthcare groups, organizations, or businesses, referred to as covered entities, manage individually identifiable health information, known as protected health information. I Institutional Review Board (IRB) / Independent Ethics Committee (IEC): An IRB or IEC is a group made up of medical experts, scientists, and non-scientists. Their job is to protect the rights and safety of people participating in clinical trials. They do this by reviewing and approving trial plans and changes and ensuring that the methods used to get and document participants' consent are appropriate. Intervention: An intervention is any procedure or treatment used in clinical research. This could include drugs, supplements, vaccines, behaviour changes, or device modifications. Investigational New Drug Application (IND): An IND is a request to the FDA for permission to test a new drug or biological product on humans. This approval is needed before shipping and administering any new drug or product that hasn't been officially approved yet. Inclusion Criteria: The characteristics that must be present for an individual to be eligible to participate in a clinical trial. Informed Consent: The process by which a participant voluntarily confirms their willingness to participate in a study after being informed of all aspects that are relevant to their decision to participate. Interim Analysis: An analysis of data conducted before the data collection has been completed to assess the safety, efficacy, or other important measures. Interventional Study: Also called a clinical trial, this type of study involves participants receiving specific interventions as outlined in the study protocol. Researchers use these interventions to assess their effects on a health condition. Investigational Drug: This refers to a drug being tested in a trial. It is also known as an "investigational new drug" or "investigational medicinal product." J Joint Monitoring: A collaborative effort between different stakeholders to monitor the conduct of a clinical trial, ensuring compliance with protocols and regulations. Justification: The reasoning behind certain decisions made during the design or conduct of a clinical trial. Journal Publication: The process of publishing the findings of a clinical trial in a scientific journal. K Kaplan-Meier Estimate: A statistical method used to estimate the survival function from lifetime data. Key Opinion Leader (KOL): An expert in a particular field whose opinion influences the decisions of others, often involved in clinical research design and analysis. Knowledge Transfer: The process of sharing or disseminating knowledge, skills, or technology from one organization or individual to another, especially in clinical research contexts. Read more on clinical research glossary here…….. L Legally Authorized Representative (LAR): A person authorized under applicable law to consent on behalf of a prospective participant to their participation in a clinical trial. Longitudinal Study: A study that follows participants over a long period of time to observe changes and long-term outcomes. Lost to Follow-Up: A term used when a participant in a clinical study cannot be contacted or does not return for follow-up assessments. M Monitoring: The ongoing oversight of a clinical trial, often involving data review, site visits, and ensuring adherence to the study protocol. Meta-Analysis: A statistical method that combines the results of multiple studies to arrive at a conclusion about the body of research. Multi-Center Trial: A clinical trial conducted at several different locations (hospitals, clinics, etc.) to increase the generalizability of the findings. Manual of Procedures (MOP): An MOP is a set of procedures describing study conduct and is developed to facilitate consistency in protocol implementation and data collection across study participants and clinical sites. N Non-Inferiority Trial: A type of clinical trial conducted to show that a new treatment is not worse than an existing treatment by more than a small, predefined amount. NDA (New Drug Application): The application submitted to the FDA for approval to market a new drug in the United States. Null Hypothesis: A hypothesis that there is no effect or no difference, often the starting point in statistical testing. NCT Number: This is a unique code assigned to each clinical study listed on ClinicalTrials.gov. It starts with "NCT" followed by an 8-digit number, such as NCT00000419. No Intervention Arm: This is a type of study group where participants do not receive any treatment or intervention during the clinical trial. Now, onto the next essential clinical research terminology list – O! O Open-Label Study: A type of study where both the researchers and participants know which treatment is being administered, with no blinding involved. Outcome Measure: A measure used to assess the effectiveness of a treatment or intervention in a clinical trial. Observational Study: A study in which participants are observed or certain outcomes are measured without treatment being applied by the researchers. Other Adverse Event: An adverse event that does not meet the criteria for a serious adverse event. It does not result in death, is not life-threatening, does not require hospitalization or extend an existing hospital stay, does not lead to significant disability or disrupt normal life functions, and does not cause a birth defect or congenital anomaly. It also does not put the participant in immediate danger or require medical or surgical intervention to prevent serious outcomes. Other Study IDs: These are identifiers or ID numbers, other than the NCT number, assigned to a clinical study by the sponsor, funders, or other entities. These may include unique identifiers from other trial registries or National Institutes of Health grant numbers. Other Terms: In the search feature, the "Other terms" field is used to refine a search. For example, entering the name of a drug or the NCT number of a clinical study can help narrow the search to records containing those specific terms. P Placebo: An inactive substance designed to resemble the drug being tested, used in clinical trials to test the efficacy of the active drug. Protocol: A document that describes the objectives, design, methodology, statistical considerations, and organization of a clinical trial. Principal Investigator (PI): The person responsible for the conduct of the clinical trial at a trial site, overseeing all aspects of the study. Phase: Categories defined by the Food and Drug Administration (FDA) to describe the stages of a drug's clinical trial. These categories are based on specific characteristics, such as the study's objective and the number of participants involved. The four phases are Phase 1, Phase 2, Phase 3, and Phase 4. Patient Registry: A type of observational study that gathers detailed information about patients' medical conditions and treatments. This data helps researchers understand how conditions or treatments impact patients in real-world settings. Q Quality Assurance (QA): Systematic activities implemented to ensure that the clinical trial is being conducted in accordance with regulatory requirements and good clinical practice (GCP). Query: A request for clarification on specific data points in a clinical trial, often raised during data monitoring or review. Quarantine: The isolation of participants or materials suspected of being exposed to or contaminated with infectious agents. R Randomization: The process of assigning trial participants to different treatment groups using random methods, ensuring that each participant has an equal chance of receiving any given treatment. Regulatory Authority: Government agencies responsible for overseeing and regulating clinical research, such as the FDA in the United States. Risk-Benefit Ratio: The comparison of the risk of harm to the potential benefits of a treatment or intervention in a clinical trial. Recruitment Plan: A strategy that details how participants will be selected for the study and the steps that will be taken to achieve the recruitment target. Retention Plan: A strategy that outlines the approaches and methods to be used to ensure participants remain engaged and continue their involvement throughout the clinical trial. Continue reading to learn about more common clinical research terms… S Screening: The process of evaluating potential participants to determine if they meet the eligibility criteria for a clinical trial. Serious Adverse Event (SAE): Any undesirable experience that results in death, is life-threatening, requires hospitalization, or causes significant disability/incapacity. Site Monitoring Visit: A visit conducted by a monitor to ensure that the study is being conducted properly at the clinical site, adhering to the protocol and regulatory requirements. Sham Comparator Arm: A study group where participants receive a procedure or device that mimics the actual treatment being tested but lacks any active components or processes. Statistical Analysis Plan (SAP): A detailed document outlining the statistical methods and considerations for analyzing the data gathered during a clinical study. Standard Operating Procedures (SOPs): Comprehensive written guidelines designed to ensure consistent execution of specific tasks across various studies and patients at a particular site. Stopping Rules: Predetermined safety guidelines that can temporarily suspend or permanently stop a study due to reasons such as futility or potential risks to participants. Stratification: The process of dividing a study population into distinct subgroups based on characteristics like age or gender to account for factors that could influence the study's outcomes. T Treatment Arm: A group or subgroup of participants in a clinical trial that receives a specific treatment or intervention. Translational Research: A type of research that aims to translate findings from basic science into practical applications that enhance human health and well-being. Trial Master File (TMF): A collection of essential documents that allow the conduct of a clinical trial to be understood and evaluated. U Unblinding: Revealing the treatment assignment to participants, investigators, or both in a clinical trial, usually after the study is completed or at a predetermined time point. Underpowered Study: A study with insufficient sample size to detect a statistically significant effect. Unanticipated Adverse Device Effects (UADEs): These refer to any unexpected serious adverse effect on health or safety, any life-threatening issue, or any death linked to a medical device. Urgent Safety Measure (USM): A measure taken to protect the participants in a clinical trial from an immediate hazard to their health or safety. V Vulnerable Population: Groups of individuals who may be at increased risk of coercion or undue influence in research settings, such as children, prisoners, or individuals with cognitive impairments. Voluntary Consent: Consent given freely and without coercion or undue influence, ensuring that participants are participating in a clinical trial of their own free will. Vaccine: A biological preparation that provides active acquired immunity to a particular infectious disease. W Washout Period: A period during which participants in a clinical trial do not receive any treatment, used to eliminate the effects of a previous treatment before starting a new one. Withdrawal: The removal of a participant from a clinical trial, either by the participant's choice or by the investigator, often due to safety concerns or non-compliance. On A Final Note… Clinical research is an important field that drives medical advancements and improves patient care worldwide. This clinical research glossary provides an overview of essential clinical research terminology key terms from A to Z, helping you navigate the complex landscape of clinical research as well as clinical trials with greater confidence. As the field of clinical research continues to evolve, staying informed about these common clinical research terms will not only improve your knowledge but also empower you to contribute meaningfully to this area of healthcare. If you wish to learn more on the same, the next step would be to join a clinical research course which can essentially help you learn in-depth about the common clinical research terms. Click here to know more. Skip to content Sponsor Login Newsletter Sign-up Clinical Research Glossary Someone considered too young to give legal consent. A minor is a person who is under the legal age of majority in a specific place. Studies that enroll children need to have processes in place to ensure a parent or a guardian gives consent. The minor, when appropriate, is asked for their agreement before they are enrolled in the study. This is called assent. "Minor" is another word for child or pediatric participant. If you are a parent or guardian with a child who may join a research study, you can ask any questions, such as whether there is a separate assent process for the child and whether there are additional protections for children. Version 2.0 September 2024 1572 aka Statement of Investigator Statement of the Investigator form that must be filed by an investigator running a clinical trial to study a new drug or agent. The investigator agrees to follow the U.S. Food and Drug Administration (FDA) Code of Federal Regulations for the clinical trial. The investigator verifies that he or she has the experience and background needed to conduct the trial and that it will be done in a way that is ethical and scientifically sound. 21CFR The portion of the Code of Federal Regulations that governs food and drugs within the United States for the Food and Drug Administration (FDA). 21CFR11 Electronic Records and Electronic Signatures-Provides guidance for companies using paperless record-keeping systems and ensures the use of electronic record-keeping systems are documented securely, authenticity, and are adequately maintained. 21CFR312 regulations pertaining to INDs 21CFR50 Protection of Human Subjects. Compliance with these parts is intended to protect the rights and safety of subjects involved in investigations filed with the Food and Drug Administration. 21CFR54 Financial Disclosure by Clinical Investigators.This section and conforming regulations require an applicant whose submission relies in part on clinical data to disclose certain financial arrangements between sponsor(s) of the covered studies and the clinical investigators and certain interests of the clinical investigators in the product under study or in the sponsor of the covered studies. 21CFR56 Institutional Review Boards. Ensures initial and continuing review of research. Regulates reportings, changes, approvals, and eliminates apparent immediate hazards to the human subjects. . 21CFR812 regulations pertaining to devices. Abnormal Values A value that is outside of the normal range value, both low or high. Accurate Error free data, any changes or amendments should be accompanied by documentation to support the changes. Additional Costs A list or disclosure of any known/potential costs that could accrue beyond the trial procedures Adverse Drug Reaction (ADR) An unintended reaction to a drug taken at a normal dose. Adverse Event (AE) any untoward medical occurrence in a study subject administered a pharmaceutical product; it does not necessarily have a causal relationship with the treatment. nih.gov Advertisement a notice or announcement in a public medium promoting clinical trial. ALCOA-C Principles by which Good Documentation of data: Attributable, Legible, Contemporaneous, Original, Accurate, and Complete Alternatives Other available treatments or no treatment at all. American Medical Association (AMA) A professional group that publishes research to advance public health and advocates for the interests of registered physician-members Assent Used to express willingness to participate in research by persons who are by definition too young to give informed consent but are old enough to understand the proposed research in general, its expected risks and possible benefits, and the activities expected of them as subjects. Association of Clinical Research Professionals (ACRP) credentialing organization recognizing professionals involved in all aspects of clinical studies/trials who have demonstrated the knowledge, skills, and abilities to perform ethical and responsible clinical research by passing proctored exams. Attributable This means that the evidence or data collected is attributable to the person collecting it. This ensures accountability. This contains a record of who performed an action and when. 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. nih.gov Benefits The potential positive outcomes that should be disclosed to the participants. 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. nih.gov Biospecimen Collection A sample of material, such as urine, blood, tissue, that may be used for a laboratory test or stored in a biorepository to be used for research. Budget The financial plan for clinical trials, including cost and expenses. Case Report Form (CRF) a record of the information collected from a subject during a trial. The information that is collected is based on what the protocol specifies. nih.gov Center for Drug Evaluation and Research (CDER) is a division of the U.S. Food and Drug Administration (FDA) that monitors drugs. Certified Clinical Research Coordinator (CCRC) or Certified Clinical Research Professional (CCRP) A credential award for those who has met eligibility requirements, demonstrated proficiency of specific knowledge and job-related skills, and passed the standardized certification exam. Clinically Significant (CS) An abnormal value with a result where a course of treatment has had genuine and quantifiable effects Clinical Research Clinical trials are a kind of clinical research designed to evaluate and test new interventions such as a device or medications. Clinical trials are often conducted in four phases. The trials at each phase have a different purpose and help scientists answer different questions. nih.gov Clinical Research Associate /Monitor (CRA) typically work for CROs. They are responsible for monitoring the study at study sites. They visit sites and look at the data collected and make sure the site is following the protocol. They work closely with the clinical research coordinators at the study sites. 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. nih.gov Clinical Trial NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Behavioral clinical trials involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fit this definition of a clinical trial. nih.gov Clinical Trial Agreement (CTA) CTA serve as a legally binding contract between a sponsor and site. It outlines each party's responsibilities and obligations for the clinical trial. umc.edu Clinical Trial Management System (CTMS) A software system used to manage clinical trials in clinical research. This CTMS will serve as a single, centralized, web-based enterprise resource to support clinical research studies conducted wikipedia.org Close Out Visit (COV) This is a visit in which the sponsor of the research study ensure that all of the necessary aspects of the study closure have been completed Code of Federal Regulations (CFR) The Code of Federal Regulations is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. Coercion an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance or consent Compensation Any form of reimbursement or monies for time/ or travel. This can be in many forms, checks, on a loaded payment card, gift card, or transportation card. Other compensations may include hotel, travel, and food. Complete Are there blank spaces in the data collection points? Even if there is an N/A you must write "N/A" in order to satisfy this element of ALCOA-C! 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_assignment. 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_assignment. nih.gov Confidentiality Ensurance of the participants' private information being in compliance with HIPAA and all privacy laws. 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. nih.gov Consequences of Withdrawal Potential issues that could result from a subject withdrawing prior to completion date. Contacts Site information, including address, email address and phone numbers for study staff. Contacts may also include IRB and Sponsor information. Contemporaneous Is the documentation happening in real time vs. retroactively documenting an occurrence. Continuing Review this is when the IRB re-reviews the study to determine if it is appropriate for the study to continue, as is or with modifications. Contract This is the Clinical Trial Agreement (CTA) of Clinical Research Agreement (CRA). This is an agreement with a for-profit company providing funding or a drug/device for a Clinical Trial. This can be a Sponsor-initiated or Investigator-Initial-Clinical Trial Control Group The group of individuals in a clinical trial assigned to a comparison intervention. nih.gov Controlled The regimen is being compared to a control; the control being a placebo (medically ineffectual treatment) or a standard treatment. 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. nih.gov 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). nih.gov Corrective and Preventive Action (CAPA) A CAPA Plan is a series of actions taken to resolve a compliance issue, and most importantly, to prevent further recurrence. A CAPA plan will focus on the immediate noncompliance and the broader scope of the problem. Correspondence The communication between site and sponsor, CRO, or any other important person(s). CRO (Contract Research Organization) a company that provides clinical trial management services for the pharmaceutical, biotech, and medical device industries. Curriculum Vitae (CV) A curriculum vitae is a document that showcases a persons' academic and professional accomplishments. It is used to apply for positions within areas where a person's specific knowledge or expertise is required. Customer Relationship Management (CRM) A software system to manage relationships with customers Data and Safety Monitoring Board (DSMB) or Data and Safety Monitoring Committee (DSMC) a committe of experts reviewing clinical trial data on an ongoing basis to ensure the safety of study subjects and validity and integrity of the data. nih.gov Data 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. nih.gov Database lock (DBL) This is the process of locking a clinical trial database. This action is taken to prevent any further changes to the database. The database is locked after review, query resolution and determination that it is ready for analysis. 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. nih.gov 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. nih.gov Decentralized Clinical Trial (DCT) Trials executed through telemedicine and mobile/local healthcare providers, using processes and technologies that differ from the traditional clinical trial model advarra.com Decentralized clinical trials (DCT) studies executed virtually through telemedicine with our without a "site", using processes and technologies differing from the traditional clinical trial model. Declaration of Helsinki is a set of ethical principles regarding human experimentation developed originally in 1964 for the medical community by the World Medical Association (WMA). It is widely regarded as the cornerstone document on human research ethics Delegation of Authority (DOA) a list of who is authorized to do certain tasks on a trial. Diagnostic Trials refers to the practice of looking for better ways to identify a particular disorder or condition. Double Blind A trial design in which neither the investigator or the subject knows which treatment the subject is receiving. Efficacy Indication that the clinical trial intervention produces a desired therapeutic effect on the disease or condition under investigation. nih.gov Electrocardigram (ECG) A test used to check a heart's rhythm and electrical activity Electronic Case Report Form (eCRF) an electronic record of the information collected from a subject during a trial. The information that is collected is based on what the protocol specifies. Electronic Clinical Outcome Assessment (eCOA) A digital version of a COA (Clinical Outcome Assessment), which measures and records how a patient is feeling or functioning Electronic Data Capture (EDC) is a web-based software application used to collect, clean, transfer, and process data in clinical trials. Electronic Health Record (EHR)/Electronic Medical Record (EMR) is an electronic version of a patients medical history, that is maintained by the provider over time, including demographics, progress notes, problems, medications, ect. Electronic Informed Consent Form (eICF) an alternative to the conventional paper consent form, this must be desinged compliant with 21 CFR Part 11. Electronic Investigator Site File (eISF) An electronic investigator site file (eISF) is a technology solution designed to organize, collect, store, track, and archive required and essential study documents for an individual site involved in a particular research study Electronic Patient Reported Outcomes (ePRO) Electronic patient-reported outcomes (ePRO) are patient-provided information about symptoms, side effects, drug timing and other questions recorded on an electronic device during a clinical trial Electronic Trial Master File (eTMF) An electronic version of regulatory at the CRO and Sponsor level. Tells the story of how the trial ran across all sites told by the official documents maintained. Eligibility Criteria List of criteria guiding enrollment of participants into a study_assignment. The criteria describe both inclusionary and exclusionary factors, (e.g. inclusion criterion - participants must be between 55 and 85 years old; exclusion criterion nih.gov Enrollment The process of registering or entering a patient into a clinical trial. Once a patient has been enrolled, the participant would then follow the clinical trial protocol eRegulatory an electronic version of the story of how a trial ran, told by the official documents maintained. Referred to as a "reg binder" or "ISF" at the site level. Error Corrections When correcting data, it should meet the ALCOAC GDP with one line crossing out the error, then initial, date, and short explanation of the correction. Exclusion criteria A type of eligibility criteria. These are reasons that a person is not allowed to participate in a clinical study clinicaltrials.gov FDA Form 483 This is also known as the "Inspectional Observations". This is a list of conditions or practices that indicate the potential violation of the FDA's requirements. The observations on the FDA Form 483 are listed in descending order of importance. This is not an all inclusive list but more of a snapshot of possible issues noted at the site. This form is a public document that is available only by request. Feasibility Is the process of evaluating the particular site for the possibility of conducting the clinical trial or study. This process is to ensure that the site is able to to conduct the trial, within the budget and the timeline as well as maintain the integrity of the data and participant safety nih.gov Financial Disclosure Form (FDF) When a clinical investigator or staff member has disclosable financial interests and arrangements, the disclosure statement submitted to FDA is required to include a description of any steps taken to minimize the potential for bias resulting from any of the disclosed financial interests and arrangements. Food and Drug Administration (FDA) The United States Food and Drug Administration is a federal agency of the Department of Health and Human Services. The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. nih.gov 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 participants are protected. nih.gov Good Clinical Practice/ICH GCP E6(R2) (GCP) The guideline that outlines requirements for designing, conducting, recording and reporting trials that involve the participation of human subjects Good Documentation Practice (GDP) The term that describes the standard by which documents are created and maintained. Good Manufacturing Practice (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. Health and Human Services (HHS) A government agency that provide health services to Americans. Health Insurance Portability and Accountability Act (HIPAA) The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge. Health Insurance Portability and Accountability Act Privacy Rule (HIPAA) 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). nih.gov Human Subject A patient or healthy individual who is or becomes a participant in research, either as a recipient of the intervention or as a control. nih.gov Human Subjects Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) Identifiable private information Inclusion criteria A type of eligibility criteria. These are the reasons that a person is allowed to participate in a clinical study clinicaltrials.gov IN/EX(also referred to as I/E) The protocol will specify the inclusion/exclusion criteria for enrollment into a clinical trial. This is colloquially referred to as I/E ("I" "E") in the field. The inclusion criteria must be present and the exclusion criteria absent for a subject to be eligible for the trial. Informed Consent (IC/IFC) An informed consent document is typically used to provide subjects with the information they need to make a decision to volunteer for a research study. Federal regulations (45 CFR 46.116) provide the framework for the type of information that must be included as part of the consent process. nih.gov Informed Consent Form (ICF) An informed consent form is a document used in clinical research that outlines important information about the study to potential participants. It is a legal document that provides prospective participants with an explanation of the purpose, procedures, and risks associated with the research study, as well as the potential benefits and alternatives. The informed consent form also explains the participant's rights and obligations during the study, including their ability to withdraw at any time without penalty. The form is usually written in lay language and must be signed by the participant or their legally authorized representative before they can participate in the study. The informed consent process is an essential part of ethical research, ensuring that participants fully understand the risks and benefits of the study before they decide to participate. It is also a legal requirement in most countries and is necessary to protect both the participants and the researchers. Informed Consent Form A document that describes the rights of a study participant and provides details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. nih.gov Institutional Review Board (IRB) In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects. Sometimes called an Independent Ethics Committee(IEC) Institutional Review Board/Independent Ethics Committee (IRB/IEC) An independent body constituted of medical, scientific, and nonscientific members whose responsibility it 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 trials, protocols and amendments, and of the methods and material to be used to obtaining and documenting informed consent of the trial participant. nih.gov Interactive Response Technology (IRT) Helps clinical trial sponsors and sites manage the patient and drug supply logistics throughout a clinical trial. Interactive Voice and Web Response System (IXRS) are the technologies that research sites use to enroll patients into clinical trials, randomize patients, and manage study drug supplies. Othernames: Interactive Web Response System (IWRS)/Interactive Voice Response System (IVRS) Interim Monitoring Visit (IMV) This visit is conducted by the CRA to review source documents and study related materials to ensure protocol and regulatory compliance. This visit is completed during the conduct of the study International Air Transport Association (IATA) supports aviation with global standards for airline safety, security, efficiency and sustainability. International Council for Harmonisation (ICH) an organization that brings together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. Intervention A procedure or treatment such as a drug, nutritional supplement, gene transfer, vaccine, behavior or device modification that is performed for clinical research purposes. nih.gov Investigational New Drug Application (IND) a request from a study sponsor to obtain FDA approval to administer investigational drug to humans. nih.gov Investigational Product (IP) The IP may be a drug, biologic, medical device, or combination product that has not received a marketing approval. nih.gov Investigator (PI) (sometimes called Clinical Investigator or more often Principal Investigator (PI)) is an individual responsible for the preparation, conduct, and administration of a clinical trial. Investigator Meeting (IM) This is a meeting where everyone involved with the new clinical trial to meet and become familiar with the study, including learning about the roles of the study Investigator's Brochure (IB) The Investigator's Brochure is a comprehensive compilation of clinical and nonclinical data on the investigational product (drug, supplement, device or other product) maintained by a drug developer or investigator that contains the body of information about the investigational product obtained before and during a drug trial. IRB Approval This is the process in accordance with FDA regulations, to which the IRB must review and approve all research involving humans prior to any research activities may begin. The IRB has the authority to approve, require modification in or disapprove the research. Late Entry Documentation after it has happened and notating it as "late entry". Legible Is the documentation able to be read easily and clearly. Long Form The long form embodies all the elements of informed consent as required under 21 CFR 50.25. When the long form is used, a copy must be provided to the person signing the form, that is, the subject or the subject's legally authorized representative. 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. nih.gov Masking/Blinding A procedure in which the investigator administering the assessments and intervention as well as the participants in a clinical trial are kept unaware of the treatment assignment(s). Single blinding usually refers to the study participant(s) being unaware, and double blinding usually refers to the study participant(s) and any of the following being unaware of the treatment assignment(s): investigator(s), monitor, and data analyst(s). nih.gov National Institutes of Health (NIH) The primary Federal agency for conducting and supporting medical research. NCT Number (NCT) A unique identification code given to each clinical study record registered on ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419). Also called the ClinicalTrials.gov identifier clinicaltrials.gov 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. nih.gov Non-disclosure agreement (NDA) Also know as a confidently agreement. This is a contract that establishes a confidential relationship. The party or parties signing the agreement agree that sensitive information they may obtain will not be made available to any others. Not Clinically Significant (NCS) A abnormal value that does not have a genuine effect. Number of Subjects in Study The total amount of subjects the sponsor wants to enroll into participation in the study. Nuremberg Code A ten point code that describes the basic principles of ethical behavior in the conduct of human experimentation. Observational Study Monitoring Board (OSMB) The safety and data monitoring body for observational studies with large or vulnerable populations or risks associated with tests or standard of care. nih.gov Office for Human Research Protection (OHRP) A federal government agency within the Department of Health and Human Services (DHHS) charged with the protection of human subjects participating in government funded research. It issues assurances and oversees compliance of regulatory guidelines by research institutions. nih.gov Office for Human Research Protections (OHRP) Provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services. Open-Label A study in which the subjects and the investigator are aware of the drug and/or dose that is being administered. Open-Label Trial A clinical trial in which investigators and participants know which intervention is being administered. nih.gov Original Is the documentation the first pen to paper? Fun fact- if you take your measurements down on a napkin- that napkin is now SOURCE! Original records should be preserved, meaning the material used should be durable, in the case of duplicates, the creator of the original records should confirm the authenticity of the copies. Over-the-counter (OTC) Refers to a medicine that can be bought without a prescription. Participant Termination Subject, Sponsor, and/or Site has the right to terminate their participation at any point during the trial. Parts of a Protocol not inclusive ● Study Title- This is meant to explain the key features of the study purpose, design, population , procedures, timeline, and participant safety. ● Study Name ● Title Page ● Summary ● Flow Chart/Study Schema/Schedule of Events ● Baseline -An initial measurement that is taken at an early time point and used for comparison over time to look for changes. ● Introduction ● Study Objectives ● Study Design ○ Is it controlled? If so, what is the control? ○ Is it randomized? ○ Is it blinded? ● Randomization procedures ● Blinding ● Unblinding (breaking the blind) procedures ● IP ○ Name ○ Storage ○ Dosage ○ Formulation ○ Route of administration ○ Regimen ● Subject Selection ● I/E ● Enrollment Procedures ● Pre-Screening ● Screening ● Concomitant Medications ("Conmeds") ○ Prescription ○ OTC ○ Herbal Supplements ○ Vitamins ● Exclusionary Medications ● AEs ● SAEs ● Data Recording ● Data Quality Assurance ● Data Analysis/Statistics 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 clinicaltrials.gov Pharmacokinetics The process (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine. nih.gov Phase I Researchers test an experimental drug or treatment in a small group of people for the first time. The researchers evaluate the treatment's safety, determine a safe dosage range, and identify side effects. nih.gov Phase II The experimental drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety. nih.gov Phase III The experimental study drug or treatment is given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely. nih.gov Phase IV Post-marketing studies, which are conducted after a treatment is approved for use by the FDA, provide additional information including the treatment or drug's risks, benefits, and best use. nih.gov Placebo A placebo is an inactive treatment. In fact, a placebo may be in a pill or tablet form, or it may be an injection or a medical device. Whatever the form, placebos often look like the real medical treatment that is being studied except they do not contain the active medication. nih.gov Placebo Controlled Study A method of investigation in which an inactive substance/treatment (the placebo) is given to one group of participants, while the test article is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective in treating the condition. nih.gov Pre-Clinical Research The aim of a preclinical study is to collect data in support of the safety of the new treatment. Preclinical studies are required before clinical trials in humans can be started. Pre-Screening Activities before obtaining informed consent to determine initial eligibility for and interest in a study. Pre-screening may be performed over the telephone, in-person or on-line and may not include any research procedures Pre-selection visit (PSV) A visit to ensure pre-qualification of a site and eliminate sites that do not possess adequate qualities to conduct the trial. Pre-Site Selection Visit (PSV/PSSV) This is to ensure pre qualification of the site and eliminates sites that do not meet the qualifications to conduct the clinical trial or study. This visit must take place to determine if additional resources should be used in order to perform a Site initiation Visit Prevention Trials Looks for better ways to prevent disorders from developing or returning. Different kinds of prevention research may study medicines, vitamins, vaccines, minerals, or lifestyle changes. Principal Investigator (PI) The person in charge and responsible for a clinical trial. cancer.gov 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. nih.gov Protected Health Information (PHI) A person's health information including but not limited to demographics, medical history, test/lab results, insurance information, ect. Protocol Directions for how to run a particular trial. nih.gov Protocol Amendments A written description of a change(s) to or formal clarification of a protocol. nih.gov 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: nih.gov 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. nih.gov Purpose The reasoning behind a trial being conducted- what is the end goal? What is the desired outcome? Quality Assurance (QA)/Quality Control (QC) 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 requirements. nih.gov Quality Control (QC) The internal operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of trial related activities have been fulfilled (e.g., data and form checks, monitoring by study staff, routine reports, correction actions, etc.). nih.gov Quality of Life Trials explores ways to improve comfort and the quality of life for individuals with a chronic illness. Randomization The process of assigning clinical trial participants to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. nih.gov Randomized The patient population is randomly allocated to treatment groups. This helps reduce bias by ensuring there isn’t a pattern in assigning treatment to the subjects. Recruitment The act of trying to find the right patients for a clinical trial. Recruitment Goal The targeted number of patients to screen or enroll in a clinical trial. Recruitment Materials Advertisements and other items used to help find participants in the study. Recruitment Plan The plan that outlines how individuals will be recruited for the study and how the study will reach the recruitment goal. nih.gov Regulatory The story of how a trial ran is told by the essential documents maintained. Referred to as “reg binder” or “ISF” at the site level. Research A systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Retainment the process of keeping patients/subjects in the study or engaged to participate in the study. Retention The strategy and tactics designed to keep patients enrolled in clinical trials, and from discontinuing participation and “dropping out.” Retention Goal the targeted number of patients to keep in the tria after enrollment. Should be as close to 100% as possible. Retention Plan The site’s plan to keep patients in the study long-term. nih.gov Risk The potential negative outcomes that need to be disclosed to the participants. Risk based monitoring (RBM) an adaptive approach that directs monitoring focus and activities to the evolving areas of greatest need which have the most potential to impact patient safety and data quality. Safety Monitoring Plan A plan that outlines the oversight of a clinical trial. nih.gov Safety Officer (SO) An independent individual, often a clinician who is appointed by the NIA and performs data and safety monitoring activities in low-risk, single site clinical studies. The SO advises the NIA regarding participant safety, scientific integrity, and ethical conduct of a study_assignment. The SO is advisory to the Institute Director. nih.gov Screening the process by which activities are evaluated to determine whether they are eligible for enrollment in a clinical trial. 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. nih.gov Screening Process A process designed to determine individual’s eligibility for participation in a clinical research study_assignment. nih.gov Screening Trials aims to find the best ways to detect certain disorders or health conditions Serious Adverse Event (SAE) This is any untoward medical occurrence at any dose that results in death, is life-threatening, requires hospitalization (or prolongation of hospitalization), results in persistent or significant disability, or is a birth defect. nih.gov Short Form An IRB approved short form may be used in appropriate situations where the elements of the consent form are presented to the subject or subject’s legal authorized representative. It is a written summary of the information to be presented orally which is signed by the subject or subject’s LAR. Single Blind A study that is set up so that participants do not know which study treatment they are getting. Site Evaluation Visit (SEV) This is a visit conducted to evaluate the sites and it’s investigators, resources and the sites capabilities to conduct study terms. Infrastructure, adequacy and availability of the site facilities Site initiation visit (SIV) The site initiation visit is a required visit to prepare and set up a research site to conduct a study and must occur prior to patient recruitment. Site Initiation Visit (SIV) This is a critical visit that’s completed by the Sponsor prior to the start of the study. During this visit the Sponsor ensures that the investigators team has all of the necessary resources and is ready to conduct the human subjects research conducted under the Investigational New Drug (IND) or Investigational Device Exemption Application (IDE). The SIV ensures that the Investigator and team is aware of the responsibilities with the Study Protocol and are familiar with the study documentation, investigational product management and administrative procedures. Site Qualification Visit (SQV) This is a meeting with a sponsor representative in order to ensure that the institution is fully capable and equipped to run the clinical study or trial. This visit may also be referred to as the Site Selection Visit (SSV) or Pre Study Qualification Visit (PSQV) Site Visit Log Record of the monitor (CRA) visiting the site. They are required to sign in and sign out. Society for Clinical Research Sites (SCRS) an organization established to support global clinical research communities Society of Clinical Research Associates (SoCRA) credentialing organization recognizing professionals involved in all aspects of clinical studies/trials who have demonstrated the knowledge, skills, and abilities to perform ethical and responsible clinical research by passing proctored exams. Source Document Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, participant diaries, recorded data from automated instruments, x-rays, etc.) that are used in a clinical trial. nih.gov Source documents documents in which data collected for a clinical trial is first recorded. The data is usually later entered in an electronic data capturing system (EDC). Source Document Verification (SDV) This is the process by which the data within the CRF or other data that has been collected is compared against the original source of information Sponsor The company, institution or organization that takes on legal responsibility for the initiation, management and/or financing of the research. clinicaltrials.gov Standard of Care (SOC) Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Standard Operating Procedure (SOP) Detailed written instructions to achieve uniformity of the performance of a specific function across studies and patients at an individual site. nih.gov 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. nih.gov 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. nih.gov Study Award This is also known as the Feasibility Award, when a site is chosen by the sponsor to conduct a trial based on their feasibility. Study Population in a clinical trial, the participants make up the study population. Sub-Investigator (Sub-I) A delegated member of the research tream that helps back up the PI and preform study related procedures. Suspected unexpected serious adverse reaction (SUSAR) Any unfavourable occurrence in a trial participant that is judged to have a major impact on their health and was not anticipated and could potentially be due to the intervention under investigation. The Belmont Report The Belmont Report summarizes ethical principles and guidelines for research involving human subjects. Three core principles are identified: respect for persons, beneficence, and justice. TMF (Trial Master File) Regulatory at the CRO and Sponsor level. Tells the story of how the trial ran across all sites told by the official documents maintained. Training Log a list of who is trained to do what on a trial. Treatment Trials looks for better ways to treat disorders from developing or returning. Different kinds of prevention research may study medicines, vitamins, vaccines, minerals, or lifestyle changes. Trial master file (TMF) The trial master file (TMF) is the collection of essential documents which allows the conduct of a clinical trial to be reconstructed and evaluated wikipedia.org Unanticipated Adverse Device Effects (UADE) Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in a nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application) or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects. nih.gov Unanticipated Problems (UAP) Unanticipated problems involving risks to subjects or others, which meet all of the following criteria: nih.gov Unforeseeable Risks Any problem or event that in the opinion of the local investigator meets all three of these criteria: Serious, Unanticipated (Not already described as a potential risk in the approved materials), and Related. Unmasking/Unblinding A procedure in which one or more parties to the trial are made aware of the treatment assignment(s). nih.gov US National Research Act A response to the Tuskegee Syphilis Study. Signed into law in 1974 and created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Identifies the basic principles of research conduct and oversees human experimentation in medicine Vendor Third party companies to help with services and ancillary procedures of the clinical trial. Some examples may be payment services, central readers for procedures or imaging, and/or recruitment companies. Voluntary Participation Ensuring patients agree completely unforced or uncoerced to be a subject in the study trial. Giving the patient alternatives, risk/benefits, and ample time to consent. Vulnerable Populations Includes children, pregnant women, prisoners, handicapped persons, the mentally disabled, people with acute or chronic severe mental illness, economically disadvantaged, and educationally disadvantaged. When some or all of the subjects are likely to be vulnerable to coercion or undue influence additional safeguards should be included in the study to protect the rights and welfare of these subjects. The .gov means it’s official. Federal government websites often end in .gov or .mil. Before sharing sensitive information, make sure you’re on a federal government site. The site is secure. The https:// ensures that you are connecting to the official website and that any information you provide is encrypted and transmitted securely. Explore easy-to-understand definitions for terms commonly used in aging and geriatric research. This list also includes acronyms and other abbreviations used at NIA and NIH.A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | ZAdverse Event (AE) – Any untoward or unfavorable medical occurrence in a clinical research study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants’ involvement in the research, whether or not considered related to participation in the research.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.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.Case Report Form (CRF) – A printed, optical, or electronic (eCRF) document designed to capture all protocol-required information for a study.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).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.Clinical Research – NIH defines clinical research as:Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.Epidemiologic and behavioral studies.Outcomes research and health services research.Clinical Trial – NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Behavioral clinical trials involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fit this definition of a clinical trial.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.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.Control Group – The group of individuals in a clinical trial assigned to a comparison intervention.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.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.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.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.Data 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. Efficacy – Indication that the clinical trial intervention produces a desired therapeutic effect on the disease or condition under investigation.Eligibility Criteria – List of criteria guiding enrollment of participants into a study. The criteria describe both inclusionary and exclusionary factors, (e.g. inclusion criterion - participants must be between 55 and 85 years old; exclusion criterion – must not take drug X three month prior to the study).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.Good Clinical Practice – 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 participants are protected.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).Human Subject – A patient or healthy individual who is or becomes a participant in research, either as a recipient of the intervention or as a control.Informed Consent – A process by which a participant or legal guardian 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 participant’s decision to take part in the clinical trial. Informed consent is usually documented by means of a written, signed, and dated informed consent form, which has been approved by an IRB/IEC.Informed Consent Form – A document that describes the rights of a study participant and provides details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document.Institutional Review Board (IRB)/Independent Ethics Committee (IEC) – An independent body constituted of medical, scientific, and nonscientific members whose responsibility it 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 trials, protocols and amendments, and of the methods and material to be used to obtaining and documenting informed consent of the trial participant.Intervention – A procedure or treatment such as a drug, nutritional supplement, gene transfer, vaccine, behavior or device modification that is performed for clinical research purposes.Investigational New Drug Application (IND) – An IND is a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved New Drug Application or Biologics/Product License Application (21 CFR 312).Masking/Blinding – A procedure in which the investigator administering the assessments and intervention as well as the participants in a clinical trial are kept unaware of the treatment assignment(s). Single blinding usually refers to the study participant(s) being unaware, and double blinding usually refers to the study participant(s) and any of the following being unaware of the treatment assignment(s): investigator(s), monitor, and data analyst(s).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.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.Observational Study Monitoring Board (OSMB) – The safety and data monitoring body for observational studies with large or vulnerable populations or risks associated with tests or standard of care. Office for Human Research Protection (OHRP) – A federal government agency within the Department of Health and Human Services (DHHS) charged with the protection of human subjects participating in government funded research. It issues assurances and oversees compliance of regulatory guidelines by research institutions.Open-Label Trial – A clinical trial in which investigators and participants know which intervention is being administered.Pharmacokinetics – The process (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine.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.An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.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.Placebo – A placebo is an inactive pill, liquid, powder, or other intervention that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness.Placebo Controlled Study – A method of investigation in which an inactive substance/treatment (the placebo) is given to one group of participants, while the test article is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective in treating the condition.Protocol – A document that describes the objective(s), design, methodology, statistical consideration, and organization of a trial.Protocol Amendments – A written description of a change(s) to or formal clarification of a protocol.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 andfailure to adhere to an approved protocol.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.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.Quality Assurance (QA) – Systematic approach to ensure that the data are generated, documented (recorded), and reported in compliance with the protocol and good clinical practice (GCP) standards.Quality Control (QC) – The internal operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of trial related activities have been fulfilled (e.g., data and form checks, monitoring by study staff, routine reports, correction actions, etc.).Randomization – The process of assigning clinical trial participants to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.Recruitment Plan – The plan that outlines how individuals will be recruited for the study and how the study will reach the recruitment goal.Retention Plan – The plan that details the methods in which the study will use in order to retain study participation in the clinical trial.Safety Monitoring Plan – A plan that outlines the oversight of a clinical trial.Safety Officer (SO)– An independent individual, often a clinician who is appointed by the NIA and performs data and safety monitoring activities in low-risk, single site clinical studies. The SO advises the NIA regarding participant safety, scientific integrity, and ethical conduct of a study. The SO is advisory to the Institute Director.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.Screening Process – A process designed to determine individual’s eligibility for participation in a clinical research study.Serious Adverse Event (SAE) – Any adverse event that:Results in deathIs life threatening, or places the participant at immediate risk of death from the event as it occurredRequires or prolongs hospitalizationCauses persistent or significant disability or incapacityResults in congenital anomalies or birth defectsIs another condition which investigators judge to represent significant hazardsSource Document – Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, participant diaries, recorded data from automated instruments, x-rays, etc.) that are used in a clinical trial.Standard Operating Procedure (SOPs) – Detailed written instructions to achieve uniformity of the performance of a specific function across studies and patients at an individual site.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.Stratification – Separation of a study cohort into subgroups or strata according to specific characteristics such as age, sex, etc., so that factors which might affect the outcome of the study, can be taken into account.Unanticipated Problems (UAPs) – Unanticipated problems involving risks to subjects or others, which meet all of the following criteria:Unexpected in terms of nature, severity, or frequency;Related or possibly related to participation in the research, and;Suggests that the research placces subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.Unmasking/Unblinding – A procedure in which one or more parties to the trial are made aware of the treatment assignment(s).Unanticipated Adverse Device Effects (UADEs) – Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in a nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application) or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.Glossary SourcesClinical Trials.govNINDS Glossary of Clinical Research TermsCenterWatch, Inc. Patient Resources: Glossary.OHRP WebsiteNIH DefinitionsFriedman LM, Furberg CD, DeMets DL. Fundamentals of Clinical Trials (3 ed.). Missouri: Mosby-Year Book Inc., 1996.Meinert CL. Clinical Trials: Design, Conduct, and Analysis. New York: Oxford University Press, Inc., 1986.Return to the NIA Clinical Research Investigator's Toolbox. Last updated: January 30, 2025 Get a sneak peek of concepts approved by the National Advisory Council on Aging. Learn about grants and funding opportunities from NIA. Find resources and data for researchers from NIA. nia.nih.gov An official website of the National Institutes of Health