**STAR CRN Terminology List**

* **Administrative Review** – An initial review conducted by CRN staff to assess feasibility including budget, IRB approval, legal agreements, utilization needs.
* **Clinical Research** - Clinical research is medical research that involves people to test new treatments and therapies.
* **Clinical Research Network (CRN)** – A network comprised of many different health systems who collaborate to conduct research.
* **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.
* **Common Data Model** – Each site’s EHR data is housed in a data warehouse. The design of this warehouse and what it contains is the same at each site making it a common model among all sites for housing data. More succinctly, the CDM is a way of organizing data into a standard structure across sites.
* **Commons** – The Commons is a public website fostering connection, communication, learning, and engagement among people involved in clinical research. On the PCORnet Commons, you can share and access resources, engage in dialogue, and connect with colleagues.
* **Computable Phenotype** – Using EHR data to identify persons or populations with a condition or clinical profile.
* **Coordinating Center (CC)** – The CC leads the network’s data and engagement activities, connects with outside research partners, and supports the network infrastructure. The coordinating center for our CRN is Duke Clinical Research Institute (DCRI).
* **CRN Central Network Administration** – The VUMC administrative and faculty team (Network PI, Network Sr. Project Manager, Network Navigator, and Network Project Manager) that lead centralized operations on behalf of the CRN.
* **CRN Governance Structure** – A hybrid of administration and supervision via staff, faculty, and stakeholders that guides our policy-making, project engagement, and decision-making for the network via meetings and workgroups (Leadership Meeting, Operations Meeting, Oversight Council Meeting, Project Manager Meeting, Stakeholder Advisory Council Meeting) to assure responsible conduct of research.
* **Data Use Agreement** – An agreement between institutions for the sharing and use of research data.
* **De-Identified Data** – Data that has been stripped of information such as name and MRN.
* **De-Identified Queries** – Counts run on de-identified data to determine the number of patients in the CDM that fit a specific phenotype.
* **Engagement in Research** – Meaningful involvement of patients, caregivers, clinicians, and other healthcare stakeholders throughout the research process
* **Front Door** – The main access point for potential investigators, patient groups, health systems, and funders to reach the PCRF infrastructure.
* **Governance** – the system of administration and supervision through which the CRN is managed, participants and staff are protected, and accountability is assured. A multi-stakeholder process that involves all participants in the structure to strive for consensus-based decision-making and operating in an open, transparent, and accountable manner.
* **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.
* **Interventional Research** – A clinical study in which participants are assigned to receive one or more intervention (or no interventions) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes.
* **Leadership Meeting** – A weekly meeting consisting of CRN Central Administrative Staff, STAR Site Teams, and voting members of the STAR Leadership Team (10 voting members).
* **Observational Research** – A clinical study in which participants identified as belonging to study groups are assessed for biomedical or health outcomes.
* **Operations Meeting** – A quarterly meeting attended by STAR CRN Site Teams and past/present STAR CRN Project PIs. Provides an update on STAR CRN operations and metrics, while also providing a venue for STAR CRN Project PIs to present project results.
* **Oversight Council Meeting** – A twice yearly meeting designed to provide high-level STAR CRN information to executive leadership at STAR CRN Sites to encourage continued growth and discuss future direction.
* **Patient Partners** – Patients who are representatives of the population of interest in a particular study, as well as their family members, caregivers, and the organizations that represent them.
* **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.
* **PopMedNet** – A software application that provides users secure, customized, private protocols with file transfer capabilities. Users are able to query data held by partners in participating data networks or nodes via menu-driven analysis and distribution of complex analytics programs.
* **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.
* **Program Management Office (PMO)** – The PMO coordinates all internal and external communication platforms and provides leadership and infrastructure support and coordination and is housed at DCRI within the CC.
* **Project Manager Meeting** –A monthly meeting for STAR CRN Site Project Managers to discuss administrative and technical requirements and issues.
* **Protocol -** A Protocol is a carefully designed plan to safeguard the participants’ health and answer specific research questions.
* **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.
* **Stakeholders, Technology, and Research CRN (STAR)** – The CRN centered at Vanderbilt University Medical Center (VUMC) and comprised of VUMC, Vanderbilt Healthcare Affiliated Network (VHAN), Meharry Medical Center, Duke university, the University of North Carolina at Chapel Hill, Health Sciences South Carolina, Wake Forest, and the Mayo Clinic.
* **Stakeholder Advisory Council** – The SAC provides input to CRN Leadership and investigators to help generate research questions, review research proposals, assist in the conduct of research, monitor progress and help disseminate information. The primary purpose of the AV is to provide meaningful input from the patient and clinician stakeholder viewpoint to assure that the CRN’s activities are patient-centered and informed by practicing clinicians.

PCORI Terms <https://www.pcori.org/glossary>

* **Administrative Official (AO) –** The individual within the submitting organization/institution who is responsible for the proper administration of the contract, including, but not limited to, overseeing the submission of the contract activation, contract renewals, and additional materials required by the granting agency’s policies and procedures.
* **Allowable Costs –** A cost that is approved within the budget and is not otherwise unallowable under the Funded Research Policies. A direct cost is allocable to the project if the goods or services involved are chargeable or assignable to the project in accordance with relative benefits received or other equitable relationship. As a result, a cost is allocable to the funded project if (1) it is incurred solely to advance the work under the project, or (2) it benefits both the funded project and other work of the recipient organization, in proportions that can be approximated through use of reasonable methods.
* **Awardee –** An organization/institution that has received a grant award.
* **Biosketch –** A profile of the experience and accomplishments of the key personnel in an application.
* **Burden –** The frequency of the condition, the expected mortality and morbidity, and/or the degree of suffering associated with symptoms, complications, or other consequences of the condition. Additionally, it may include the costs to the US population of healthcare services used, the individual patient’s out-of-pocket expenses, as well as intangible costs to the patient, such as time away from paid or unpaid occupations.
* **Clinical Practice Guidelines –** Systematically developed statements or recommendations to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. They present indications for performing a test, procedure, or intervention, or the proper management for specific clinical problems. Guidelines may be developed by government agencies, institutions, organizations such as professional societies or governing boards, or by convening expert panels.
* **Care Transitions –** The movement patients make between different clinicians or settings—such as from a hospital to home or a nursing facility—during the course of their illness.
* **Co-Investigator (Co-I) –** An individual recognized by the prime institution and the principal investigator (PI) as someone making a significant contribution to a project. The Co-I is an individual who the PI relies on to assume responsibilities related to the execution of the project and to commit a specified percentage of time to the project. A Co-I is considered “key personnel” and may be employed by or formally affiliated (through written agreement) with the prime institution or a collaborating institution. The patient and/or stakeholder partner may be listed as a Co-I. The designation of a Co-I does not affect the PI’s roles and responsibilities nor does it imply a Dual PI Award.
* **Co-Principal Investigator (Co-PI) –** An individual recognized by the prime institution and the principal investigator (PI) as someone who shares scientific and administrative leadership responsibilities for a project with the PI. The Co-PI is an individual who the PI relies on to contribute substantively to the scientific development and direction of the project in addition to the execution of the project. The Co-PI shares responsibility with the PI for ensuring that milestones are achieved and contracted deliverables are completed on time. The Co-PI is considered “key personnel” and may be employed by or formally affiliated (through a written agreement) with the prime institution or a collaborating institution. The patient and/or stakeholder partner may be listed as a Co-PI. The designation of a Co-PI does not affect the PI’s roles and responsibilities nor does it imply a Dual PI Award.
* **Collaborative Research Groups (CRGs) –** These groups are composed of content experts from within PCORnet focused on generating high-priority, engaging research questions to leverage PCORnet’s unique infrastructure. The CRGs collaborate with stakeholders including patients, caregivers, advocacy groups, providers, and funders early on to move research forward more quickly and more efficiently.
* **Comparators –** Two or more options for diagnosis, prevention, treatment, or healthcare delivery that would be available to the patients, caregivers, providers, and/or health systems facing the actual healthcare decision. For PCORI studies, usual care should not be used as a comparator unless it represents a legitimate and coherent clinical option (e.g., a clinical alternative based on guidelines).
* **Conflict of Interest –** Conflict of Interest is any association, including a financial or personal association, that has the potential to bias or has the appearance of biasing an individual’s decisions in matters related to the Institute or the conduct of activities.
* **Consultant –** Typically an individual who is not involved with the management of the project, but instead provides general services or subject matter expertise for an hourly fee.
* **Data and Safety Monitoring Board (DSMB) –** An independent committee of experts responsible for reviewing research study data on an ongoing basis to ensure the safety of study subjects and validity and integrity of the data.
* **Data Universal Numbering System (DUNS) –** A unique identifier assigned to a single business entity.
* **Decisional Dilemma –** Challenging clinical choices faced by patients, caregivers, clinicians, or health systems about what works best for whom, and under what circumstances. PCORI studies should be designed to support better-informed decisions by generating evidence that improves understanding of the risks and benefits of the available options.
* **Dissemination (active) –** The intentional, active process of identifying target audiences and tailoring communication strategies to increase awareness and understanding of evidence, and to motivate its use in policy, practice, and individual choices. The purpose of dissemination is to spread and sustain knowledge and the associated evidence-based interventions.
* **Dissemination (passive) –** Sometimes called research diffusion, is an untargeted dissemination process whereby new evidence is absorbed and acted upon by a small body of highly motivated recipients.
* **Electronic Health Record (EHR)/Electronic Medical Record (EMR) –** An electronic health record is a repository of electronic information about an individual’s health status and health care. EHRs contain much of the same information that is found in a patient’s (paper) medical chart, but because the records are digitized, the data can be viewed, and providers (eg, primary care physicians and specialists) can capture far more extensive information. EHRs may contain administrative and billing data, patient demographics, progress notes, vital signs, medical histories, diagnoses, medications, immunization records, allergies, radiology images, laboratory and other test results, and much more.
* **Employer Identification Number (EIN) –** The Federal Tax Identification Number used to identify a business entity.
* **Engagement in Research –** The meaningful involvement of patients, caregivers, clinicians, and other healthcare stakeholders throughout the research process—from topic selection through design and conduct of research to dissemination of results.
* **Engagement Rubric –** A resource intended to provide guidance regarding engagement in the conduct of research to those planning or conducting research, merit reviewers, awardees, engagement/program officers (for creating milestones and monitoring projects), and interested patients, caregivers, patient/caregiver organizations, and other stakeholders.
* **Evidence for Engagement –** Manuscripts that include a formal evaluation of engagement within the context of a health research study, or a study with the primary objective to evaluate or synthesize engagement methods/impacts in health research.
* **Evidence Updates –** These materials present information from recent PCORI studies or from systematic reviews that summarize evidence.  Created in collaboration with patient organizations, clinicians, and others with an interest in the findings, these materials bring timely and relevant information to audiences who can benefit from knowing and using the information.
* **Example of Engagement in Health Research –** Manuscripts with a primary objective of reporting on a health research study that engaged partners in at least one phase of the research and describe at least one impact of engagement on their work.
* **Final Research Report –** The Final Research Report is a comprehensive account of all the work done in this study and has been peer reviewed by research experts and patients with lived experience. It includes details on the investigators' work with patients and other stakeholders throughout the study process. It also includes important information about what did not work in the planned research and lessons investigators learned that will inform future research.
* **Financial Official (FO) –** The individual designated by the recipient organization who is responsible for the proper accounting of contract funds and the submission of payment details. The FO is responsible for completing and certifying the required yearly expenditure reports.
* **Fringe Benefits –** A form of pay for the performance of services. Fringe benefits commonly include health insurance, group term life coverage, and nonwage compensation.
* **Greater-Than Request –** A request for budget and/or time that exceeds the total award amount and/or maximum project period specified in the funding announcement.
* **Implementation –** The deliberate, iterative process of integrating evidence into policy and practice through adapting evidence to different contexts and facilitating behavior change and decision making based on evidence across individuals, communities, and healthcare systems.
* **Indirect Costs –** Costs not directly accountable to the project. Indirect costs include taxes, administration, personnel (not directly related to the project), and security costs.
* **Inpatient Costs –** Costs incurred for patient study participants who are formally admitted to a hospital on doctor’s orders.
* **Institutional Review Board (IRB) –** A group that follows federal regulations, state laws, and institutional policy to review, monitor, and approve research in order to protect the ethical rights and privacy of the subjects involved.
* **Key Personnel –** Individuals who contribute to the scientific development or execution of the project in a substantive and measurable way. The contribution is independent of financial compensation.
* **Letter of Intent (LOI) or Letter of Inquiry –** A letter notifying an agency that an organization/institution intends to submit an application for a funding announcement.
* **Letters of Collaboration –** Signed letters from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. Letters of support from patient and stakeholder partners should clearly describe the origin of the study topic and the role of the patient partners in defining the question, outcomes, comparators, goals and outcomes, etc. Letters from the partners or partnering organizations affirming support to disseminate and implement research findings that are germane and warranted for implementation are also highly encouraged.
* **Letters of Organizational Support –** Letters of support signed by the Department Chair or appropriate organizational official, confirming the institutional support of the proposed project, space to conduct the research, equipment, and other resources available for the project, including staff. A letter from the leadership of your department or organization affirming support to disseminate research findings that are appropriate and warranted for implementation may also be included.
* **Limited Competition –** The process by which only certain groups may apply for an award, such as only networks or teams that have a completed a project previously for that funding agency.
* **Merit Review –** A review of the scientific and technical merit of applications for funding. Merit review consists of both online and in-person reviews by qualified reviewers who read, score, and provide feedback on the applications.
* **Merit Review Officer –** A scientist who presides over a merit review panel and is responsible for coordinating and reporting the discussion of each application assigned to it. The MRO serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications reviewed.
* **Outpatient Costs –** Costs incurred for patient care when the patient is not formally admitted to a hospital.
* **Patient Engagement –** Involvement of patients and other stakeholders throughout the planning, conduct, and dissemination of the proposed projects.
* **Patient Investigator –** Patients or other stakeholders involved in the investigation of research who have a role in guiding the aims of the study.
* **Patient Partners –** Patients who are representative of the population of interest in a study, as well as their family members, caregivers, and the organizations that represent them. Patient partners are not to be confused with patient subjects; patient partners are members of the research team and involved in the planning, conduct, and dissemination of the research, whereas patient subjects are those individuals enrolled in the study as participants.
* **Patient-Centered Outcomes Research –** Research that helps people and their caregivers communicate and make informed healthcare decisions, while allowing their voices to be heard in assessing the value of healthcare options. This research answers patient-centered questions.
* **Patient-Powered Research Networks (PPRNs) –** PPRNs are operated and governed by patient groups and their partners, and are focused on particular conditions or populations.
* **Patients –** Individuals who have or have had the condition under study; it may include patient surrogates or caregivers as well. It does not necessarily mean, but does not exclude, patient advocates or patient navigators.
* **Patients and Public Stakeholders –** The patient and public stakeholders involved as the intended user of the tool and/or resource, as applicable.
* **Payers –** Those who function as financial intermediaries in the health system, including private insurers and public insurers, and organizations representing insurers, such as America’s Health Insurance Plans.
* **PCORnet –** PCORnet is a network of networks that brings together patients, clinicians, researchers, and healthcare systems to share information and participate in research.
* **Principal Investigator –** The lead researcher and primary contact for the study.
* **Programmatic Review –** A review of the scientific portion(s) of the application to ensure that it meets programmatic requirements. These may include but are not limited to: presence of a CER question; absence of a cost effectiveness question; and, when applicable, addressing the specific research question in a targeted funding announcement.
* **Project Type – Research projects** are designed for two purposes: to improve patient outcomes by comparing two or more care approaches and to enhance the methods and infrastructure needed to support such research. **Engagement in research projects** are designed to encourage better integration of patients and other stakeholders into the research process, and they are not research studies. **Research infrastructure projects** are designed to either (1) enhance and optimize network infrastructure and promote sustainability goals, or (2) develop the role of patient- or participant-driven organizations to advance health outcomes improvement and guide the clinical and care-delivery research enterprise. **Dissemination and implementation projects** either (1) support the uptake of findings from funded research in real-world practice to improve health care and health outcomes, or (2) promote the use of effective shared decision making approaches in healthcare settings to help patients and their clinicians make choices that are best for them. Projects marked as **Other Evidence Products** fall within our broader research synthesis efforts, which take advantage of a wide variety of tools to pull together and analyze results for public use.
* **Public Abstract –** A summary of the research plan or research findings that is written for, and accessible to, a general lay audience.
* **Purchasers –** Those who purchase health benefits for employees and their dependents, including individual businesses as well as local, state, regional, and national business groups, coalitions that represent businesses, and health coalitions.
* **Randomized Controlled Trial (RCT) –** An experiment in which participants are randomly allocated to receive one of two (or more) diagnostic, preventive, therapeutic, or palliative interventions and are then followed to determine the effects of the intervention.
* **Reasonable Costs –** A cost may be considered reasonable if the nature of the goods or services acquired or applied is appropriate and justifiable. The amount involved reflects the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made.
* **Renewed Support –** Approval of an additional funding period for the same project within the approved project period. The original agreement will remain in place and additional funds obligated near the end of each funding period. Any funds remaining on the contract prior to the new obligation will remain available for the recipient’s use.
* **Research Team –** A group of people organized to function cooperatively to design and conduct research.
* **Resource Focus –** These help to identify how the tool or resource can be used to support engagement efforts in patient-centered outcomes research.
* **Resubmission –** An application that was submitted and received a summary statement, but was not funded and is being resubmitted to the same funding agency for new consideration.
* **Shared Decision Making –** An intervention or approach that draws on and presents available evidence to inform patients of available treatment options and their risks and benefits, and either engages patients in a decision-making process with their clinician or promotes their ability to engage in such a process.
* **Stakeholder Partner –** Members of constituencies based on professional, rather than personal, experience. These can include clinicians, healthcare purchasers, payers, industry, hospitals and other health systems, policy makers, training institutions, and researchers. Some individuals may fit into several categories.
* **Stakeholders –** Stakeholder partners may include members of constituencies based on professional, rather than personal, experience. For example, these constituencies can include: clinicians, purchasers, payers, industry, hospitals and health systems, policy makers, and training institutions. Some individuals may fit into several categories.
* **Study Registration –** PCORI-funded studies are required to register in ClinicalTrials.gov (NCT) or the National Library of Medicine’s Health Services Research Projects in Progress (HSRP) database. Study registration information includes study aims, patient population eligibility, interventions and comparators, outcomes measures, and, as required, participant recruitment status.
* **Subcontractor –** An individual or group who takes a portion of a contract from the prime contractor (awardee) or from another subcontractor.
* **Systematic Review –** A synthesis and critique of existing literature, which can identify evidence gaps and inform decisions regarding how to address these gaps.
* **Technical Abstract –** A summary of the research plan that is written for scientists and researchers.
* **Transitional Care –** A range of services designed to ensure continuity and promote safe and coordinated transitions between settings and clinicians.

FDA Terms <https://www.fda.gov/patients/clinical-trials-what-patients-need-know/glossary-terms>

* **Adverse Event –** drug reaction is also known as a side effect, is any undesirable experience associated with the use of a medicine in a patient. Adverse events can range from mild to severe. Serious adverse events are those that can cause disability, are life-threatening, result in hospitalization or death, or are birth defects.
* **Boxed Warning –** This type of warning is also commonly referred to as a “black box warning.” It appears on a prescription drug’s label and is designed to call attention to serious or life-threatening risks.
* **Cardiovascular Disease –** also called heart disease is a class of diseases that involve the heart, the blood vessels (arteries, capillaries, and veins) or both.
* **Center for Devices and Radiological Health (CDRH) –** assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products.
* **ClinicalTrials.gov –** is an online registry of clinical trials that are being conducted around the world.  ClinicalTrials.gov is operated by the National Library of Medicine at the National Institutes of Health and can be accessed by anyone who has access to the internet.
* **Comparison –** To learn more, researchers compare results from patients in the experimental groups with results from patients in the control groups.
* **Compassionate Use –** Expanded access, also called “compassionate use,” provides a pathway for patients to gain access to investigational drugs, biologics and medical devices for serious diseases or conditions. Investigational drugs and devices have not yet been approved by the FDA and they have not been proven to be safe and effective. Therefore, they may be effective in the treatment of a condition, or they may not. It is important to remember that the drug/biologic/medical device may have unexpected serious side effects and that patients need to consider all the possible risks when seeking access to an investigational medical product.
* **Confidentiality regarding participants –** This refers to the practice of maintaining as private all information related to clinical trial participants, including their personal identity and all personal medical information. Results from the study will usually be presented in terms of trends or overall findings and will not mention any specific participants.
* **Consumer Medication Information (CMI) –** Compared to a Medication Guide,  a Consumer Medication Information sheet  gives broader  information on how to use a medicine. CMI sheets are not developed or regulated by FDA. These information sheets are prepared by pharmacies and given out with prescription drugs. CMI sheets are not available on the FDA Web site.
* **Control group –** The group of participants that receives standard treatment or a placebo. The control group may also be made up of healthy volunteers. Researchers compare results from the control group with results from the experimental group to find and learn from any differences.
* **DailyMed –** Developed with the National Library of Medicine, [DailyMed](https://dailymed.nlm.nih.gov/dailymed/%22%20%5Ct%20%22_blank) is a Web site that gives physicians and patients electronic access to FDA-approved drug labels.
* **Diabetes –** is a disease in which blood glucose levels are above normal. Most of the food we eat is turned into glucose, or sugar, for our bodies to use for energy.
* **Double-Blind Research Design –** A study in which neither the participant nor the researcher knows whether the participant is in the treatment or control group.
* **Double-Blind, Randomized, Controlled Clinical Trial –** This is a clinical trial in which the researchers evenly divide study participants into a group receiving the experimental intervention and a group receiving standard or no treatment. Neither group knows how it has been assigned. This practice reduces the chance for a “placebo effect,” in which a treatment with no active ingredient produces results expected from a treatment with an active ingredient.
* **Drugs@FDA –** is a resource allows  you  to  search for information about  FDA approved brand  name  and  generic  drugs  and therapeutic  biological products . These are proteins derived from living material (such as cells or tissues) used to treat or cure disease. You can search in many ways, including by drug name and active ingredient.
* **Drug Product Recalls –** FDA provides information on drug products that have been recalled due to manufacturing problems and/or safety concerns.  In addition to information released to the public by a manufacturer using the normal media channels.
* **Drug Recall –** A drug recall is an action taken by a firm to remove a product from the market that FDA considers to be in violation of the law. Recalls are classified as Class I, Class II, or Class III. Class I recalls are the most serious and involve situations where there is a reasonable probability that the use of or exposure to a volatile product, will cause serious adverse health consequences or death. A drug may be recalled due to factors such as problems with packaging, manufacturing, or contamination.
* **Drug Withdrawal –** In rare cases, FDA may need to reassess and change its approval decision on a drug. A conclusion that a drug should no longer be marketed is based on the nature and frequency of the adverse events and how the drug’s benefit and risk balance compares with treatment alternatives. When FDA believes that a drug’s benefits no longer outweigh its risks, the agency will ask the manufacturer to withdraw the drug.
* **Durable Power of Attorney –** The authority to act for another person in specified or all legal or financial matters.
* **Early Communication about an ongoing safety review –** This type of communication is part of FDA’s effort to communicate early with the public when the agency is still evaluating data and has not reached a conclusion. FDA shares information in the interest of informing doctors and patients about the issues that are under review and when FDA experts anticipate completing their review.
* **Experiment –** A study done to answer a question. Other words to describe an experiment are “research,” “study,” and “protocol.”
* **Expanded Access –** also called “compassionate use,” provides a pathway for patients to gain access to investigational drugs, biologics and medical devices for serious diseases or conditions. Investigational drugs and devices have not yet been approved by the FDA and they have not been proven to be safe and effective. Therefore, they may be effective in the treatment of a condition, or they may not. It is important to remember that the drug/biologic/medical device may have unexpected serious side effects and that patients need to consider all the possible risks when seeking access to an investigational medical product.
* **Experimental Group –** The group of participants in a study that receive the experimental or study intervention (such as medication or psychotherapy).
* **FDA Adverse Reporting System –** is a computerized database containing reports of adverse events. It supports FDA’s post-market safety surveillance program for all approved drugs and therapeutic biologics.
* **FDASIA Section 907 –** directed FDA to report on the extent to which demographic subgroups (sex, age, race and ethnicity) participate in clinical trials in marketing applications for drugs, biologics, and devices. This report provided an important opportunity to take a closer look at the inclusion and analysis of demographic subgroups.
* **Federal Register –** abbreviated FR or sometimes Fed. Reg., is the official journal of the federal government of the United States that contains most routine publications and public notices of government agencies. It is a daily (except federal holidays) publication. The Federal Register is compiled by the Office of the Federal Register (within the National Archives and Records Administration) and is printed by the Government Printing Office. The final rules promulgated by a federal agency and published in the Federal Register are ultimately reorganized by topic or subject matter and codified in the Code of Federal Regulations (CFR), which is updated annually. There are no copyright restrictions on the Federal Register; as a work of the U.S. government, it is in the public domain.[1] Citations from the Federal Register are [volume] FR [page number] ([date]), e.g., 65 FR 741 (Jan. 6, 2000).
* **Form FDA 3926 –** Used by physicians when submitting requests for expanded access to investigational drugs, including emergency requests. This form is designed specifically for [single patient requests](https://www.fda.gov/news-events/expanded-access/expanded-access-categories-drugs-including-biologics) only.
* **Healthy volunteer –** In a clinical study, a person who does not have the disorder or disease being studied. Results from healthy controls are compared to results from the group being studied.
* **In vitro –** In glass, as in a test tube. An in vitro test is one that is done in glass or plastic vessels in the laboratory. In vitro is the opposite of in vivo.
* **In vivo –** In the living organism. For example, an experiment that is done in vivo is done in the body of a living organism. In vivo is the opposite of in vitro.
* **Inclusion/Exclusion Criteria –** are the factors that allow someone to participate in a clinical trial. Exclusion criteria are the factors that prevent someone from participating in the trial. These factors may include a person’s illness, health history, past treatment, age, sex, or where he or she lives.
* **Informed Consent –** When a participant provides informed consent, it means that he or she has learned the key facts about a research study and agrees to take part in it.
* **Inpatient –** A person who is hospitalized for at least one night to receive treatment or participate in a study.
* **Institutional Review Board –** As defined in the [Code of Federal Regulations Title 21 Part 56](https://www.ecfr.gov/cgi-bin/text-idx?SID=85bb9f5921a9354a3164a72f956a09a1&mc=true&node=pt21.1.56&rgn=div5) means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.
* **Medication Guides –** are paper hand-outs/pamphlets that are required to be given to patients with certain medications by the pharmacist. Medication Guides communicate risk information that is specific to particular drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events.
* **MedWatch –** [MedWatch](https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program) is FDA’s safety information and adverse event reporting program. It provides important and timely medical product information to healthcare professionals, including information on prescription and over- the-counter drugs, biologics, medical devices, and special nutritional products. Healthcare professionals and consumers can also report serious problems they suspect are related to certain FDA-regulated products.
* **Minimal Risk –** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
* **National Cancer Institute (NCI) –** (NCI) is part of the National Institutes of Health (NIH), which is one of 11 agencies that compose the Department of Health and Human Services (HHS). The NCI coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.
* **National Institutes of Health (NIH) –** Part of the U.S. Department of Health and Human Services, NIH is the primary Federal agency for conducting and supporting medical research. NIH scientists investigate ways to prevent disease as well as the causes, treatments, and even cures for common and rare diseases. Composed of 27 Institutes and Centers, NIH provides leadership and financial support to researchers in every state and throughout the world.
* **National Library of Medicine (NLM) –** The world’s largest biomedical library, the National Library of Medicine (NLM) maintains and makes available a vast print collection and produces electronic information resources on a wide range of topics that are searched billions of times each year by millions of people around the globe. It also supports and conducts research, development, and training in biomedical informatics and health information technology. In addition, the Library coordinates a 6,000-member National Network of Libraries of Medicine that promotes and provides access to health information in communities across the United States.
* **New Drug Approval Process –** After the animal testing stage, FDA decides whether it is reasonably safe for the company to move forward with clinical trials—studies that evaluate the safety and effectiveness of a drug in healthy people and in patients. The drug company submits the results of such studies to FDA for review. The agency conducts a thorough review of the safety and effectiveness data, and considers how the benefits compare to the risks when making a decision of whether or not to approve a drug.
* **Nonprescription Drug Label (“Drug Facts”) –** For an over-the-counter (OTC), or nonprescription medicine, information printed on the medication bottle or package under the heading Drug Facts is important for taking care of yourself and your family. The Drug Facts tell you what a medicine is supposed to do, who should or should not take it, and how to use it. Safety information and instructions for use are displayed in a uniform and easy- to-read format.
* **Off Label Use –** also called [unapproved use of an approved product](https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label), is when your healthcare provider uses an FDA-approved medical product for a use that has not been studied yet.
* **Office of Minority Health (FDA) –** was established in 2010. OMH serves as the principal advisor to the Commissioner on minority health and health disparities. The Office provides leadership and direction in identifying agency actions that can help reduce health disparities, including the coordination of efforts across the Agency.
* **Outpatient –** A person who receives treatment or participates in a study but is not hospitalized overnight.
* **Patient Network News –** This bi-weekly newsletter provided by the Office of Health and Constituent Affairs is intended to inform you of current FDA-related information on medical product: \*approvals \*labeling changes \*safety warnings \*ways to participate on upcoming public meetings \*ways to comment on proposed regulatory guidances \*other information of interest to patients and patient advocates.
* **Placebo –** An inactive pill. This is sometimes called a “sugar pill.” In some studies, participants may be assigned to take a placebo rather than the study medication.
* **Placebo effect –** Sometimes people taking a study medication receive benefits that are not from the chemicals in the medicine. This is called a “placebo effect.” For example, if a participant feels hopeful about a treatment, he or she may be more likely to notice positive changes than negatives ones. A researcher’s hope may also sway a participant’s response. Double-blind research design helps minimize the placebo effect.
* **Post-Market Surveillance –** is the process by which a drug’s safety is monitored on an ongoing basis after a drug is approved by FDA. Post-market surveillance looks to identify problems that were not observed or recognized before approval and any problems that may arise because a drug may not be used as described in the drug labeling, or because a drug is being manufactured incorrectly.
* **Pre-Clinical Data –** Before a drug can be tested in people in the United States; sponsors (drug manufacturers, research institutions, and other organizations that develop drugs) must show FDA results of testing they have done in laboratory animals and what they propose to do for human testing.
* **Prediabetes –** means the amount of glucose, also called sugar, in your blood is higher than normal but not high enough to be called diabetes. Glucose is a form of sugar your body uses for energy. Too much glucose in your blood can damage your body over time. If you have prediabetes, also called impaired fasting glucose (IFG) or impaired glucose tolerance (IGT), you are more likely to develop type 2 diabetes, heart disease, and stroke.
* **Protocol –** A study done to answer a question. Other words to describe a protocol are “research,” “study,” and “experiment.” “Protocol” also refers to the plan that details what researchers will do during the study.
* **Randomization/Random Assignment –** This is the process in which researchers evenly assign study participants into a group receiving the experimental treatment being studied, and others into a group receiving standard or no treatment. Participants are assigned to a group based on chance, not choice. You have the same chance to be placed in any of the test groups.
* **Regulatory Agency –** is a public authority or government agency responsible for exercising autonomous authority over some area of human activity in a regulatory or supervisory capacity. An independent regulatory agency is a regulatory agency that is independent from other branches or arms of the government. Regulatory agencies deal in the area of administrative law—regulation or rulemaking (codifying and enforcing rules and regulations and imposing supervision or oversight for the benefit of the public at large).
* **Research –** A study done to answer a question. Scientists do research when they’re not sure what will work best to help people with an illness. Other words to describe clinical research are “clinical trial,” “protocol,” “study,” and “experiment.”
* **Single-Blind Research Design –** A study in which one party, either the investigator or participant, is unaware of what medication or intervention the participant is taking; also called single-masked study.
* **Sponsors –** Clinical trials are sponsored or funded by various organizations or individuals, including physicians, foundations, medical institutions, voluntary groups, and pharmaceutical companies, as well as Federal agencies such as NIH, FDA, the Department of Defense, and the Department of Veterans Affairs.
* **Standard Treatment –** The treatment that medical professionals consider at the time of the study to be the most prevalent and best available treatment.
* **Standardized Procedures –** These are study rules that researchers must follow exactly for every participant, regardless of what each participant is used to. For example, if you normally take a medicine by injection but the experiment is testing the same medicine in pill form, the researcher must prescribe pills to you. The researcher cannot use a different method for you.
* **Study –** Conducted by a principal investigator who is often a doctor. Members of the research team regularly monitor the participant’s health to determine the study’s safety and effectiveness. Other words to describe a study are “clinical trial,” “protocol,” “experiment,” and “research.”
* **Type 1 Diabetes –** Diabetes mellitus type 1 (also known as type 1 diabetes, or T1DM; formerly insulin dependent diabetes or juvenile diabetes) is a form of diabetes mellitus that results from the autoimmune destruction of the insulin-producing beta cells in the pancreas. The subsequent lack of insulin leads to increased blood and urine glucose.
* **Type 2 Diabetes –** Type 2 diabetes, once called non-insulin-dependent diabetes, is the most common form of diabetes, affecting 90% to 95% of the 26 million Americans with diabetes. Unlike people with type 1 diabetes, the bodies of people with type 2 diabetes make insulin. But either their pancreas does not make enough insulin or the body cannot use the insulin well enough. This is called insulin resistance. When there isn't enough insulin or the insulin is not used as it should be, glucose (sugar) can't get into the body's cells. When glucose builds up in the blood instead of going into cells, the body's cells are not able to function properly.

MDIC Terms [file:///C:/Users/cookmm3/Desktop/A-Framework-for-Incorporating-Information-on-Patient-Preferences-Regarding-Benefit-and-Risk-into-Regulatory-Assessments-of-New-Medical-Technology.pdf](file:///C%3A%5CUsers%5Ccookmm3%5CDesktop%5CA-Framework-for-Incorporating-Information-on-Patient-Preferences-Regarding-Benefit-and-Risk-into-Regulatory-Assessments-of-New-Medical-Technology.pdf)

* **Benefit, Harm, and Risk –**
	+ **Benefit –** is a favorable effect or desirable outcome of a diagnostic or therapeutic strategy.
	+ **Harm –** is an unfavorable effect or desirable outcome of a diagnostic or therapeutic strategy.
	+ **Risk –** is defined as the qualitative notion of the probability and/or severity of a particular harm. This definition accommodates how the term “risk” is used in much of the benefit‐risk literature and prior FDA CDRH guidance.
* **Preferences –** The concept of “preferences” may be defined differently by different stakeholders. The definition of preference may also differ depending on the method by which preferences are elicited. Preferences are defined as “qualitative or quantitative statements of the relative desirability or acceptability of attributes that differ among alternative health interventions”, a definition consistent with the use of the term in patient preference literature.
* **Attributes –** Attributes of a medical device are features such as effectiveness, safety, tolerability, means of implantation/use, duration of the effect, duration of use, frequency of use, lifestyle aspects of use, and other device characteristics that impact benefit-risk considerations.
* **Patient Preferences –** are those expressed by patients with regards to decisions concerning their health care.
* **Risk Tolerance –** refers to the impact of uncertainty on decisions and applies to both benefits and harms. A notion reflecting the degree to which a patient would accept greater probability or severity of a harm in exchange for a given benefit, while maximum acceptable risk and minimum required benefit are quantitative measures of this notion.
* **Maximum Acceptable Risk –** is the greatest increase in probability or magnitude of a harm that a patient would accept for a given benefit.
* **Minimum Required Benefit –** is the smallest increase in probability or magnitude of a benefit that a patient would require to offset a given risk.
* **Uncertainty Attitude –** is a reflection of the degree to which uncertainty in the attributes of a treatment alters one’s decisions about use of the treatment. Highly relevant to medical decision-making.
* **Uncertainty Averse –** Patients who are uncertainty averse react to uncertainty by decreasing their maximum acceptable risk for a given benefit, or by increasing their minimum required benefit for a given risk.
* **Uncertainty Tolerant –** Patients who are uncertainty tolerant react to uncertainty by increasing their maximum acceptable risk for a given benefit, or by decreasing their minimum required benefit for a given risk.
* **Uncertainty Neutral –** Patients whose maximum acceptable risk is not impacted by uncertainty are referred to as uncertainty neutral.
* **Preference Sensitive Decisions –** are those in which there are multiple diagnostic or treatment options, and the decision about which option to pursue depends upon the particular preferences of the decision maker. This concept has an important role in assessing when patient preferences information is of value.

CDC Terms <https://www.cdc.gov/eval/guide/glossary/>

* **Accountability –** The responsibility of program managers and staff to provide evidence to stakeholders and funding agencies that a program is effective and in conformance with its coverage, service, legal, and fiscal requirements.
* **Accuracy –** The extent to which an evaluation is truthful or valid in what it says about a program, project, or material.
* **Activities –** The actual events or actions that take place as a part of the program.
* **Attribution –** The estimation of the extent to which any results observed are caused by a program, meaning that the program has produced incremental effects.
* **Breadth –** The scope of the measurement’s coverage.
* **Case Study –** A data collection method that involves in‑depth studies of specific cases or projects within a program. The method itself is made up of one or more data collection methods (such as interviews and file review).
* **Causal Inference –** The logical process used to draw conclusions from evidence concerning what has been produced or “caused” by a program. To say that a program produced or caused a certain result means that, if the program had not been there (or if it had been there in a different form or degree), then the observed result (or level of result) would not have occurred.
* **Comparison Group –** A group not exposed to a program or treatment. Also referred to as a control group.
* **Comprehensiveness –** Full breadth and depth of coverage on the evaluation issues of interest.
* **Conclusion Validity –** The ability to generalize the conclusions about an existing program to other places, times, or situations. Both internal and external validity issues must be addressed if such conclusions are to be reached.
* **Confidence Level –** A statement that the true value of a parameter for a population lays within a specified range of values with a certain level of probability.
* **Control Group –** In quasi-experimental designs, a group of subjects who receive all influences except the program in exactly the same fashion as the treatment group (the latter called, in some circumstances, the experimental or program group). Also referred to as a non-program group.
* **Cost-Benefit Analysis –** An analysis that combines the benefits of a program with the costs of the program. The benefits and costs are transformed into monetary terms.
* **Cost-Effectiveness Analysis –** An analysis that combines program costs and effects (impacts). However, the impacts do not have to be transformed into monetary benefits or costs.
* **Cross-Sectional Data –** Data collected at one point in time from various entities.
* **Data Collection Method –** The way facts about a program and its outcomes are amassed. Data collection methods often used in program evaluations include literature search, file review, natural observations, surveys, expert opinion, and case studies.
* **Depth –** A measurement’s degree of accuracy and detail.
* **Descriptive Statistical Analysis –** Numbers and tabulations used to summarize and present quantitative information concisely.
* **Diffusion or Imitation of Treatment –** Respondents in one group get the effect intended for the treatment (program) group. This is a threat to internal validity.
* **Direct Analytic Methods –** Methods used to process data to provide evidence on the direct impacts or outcomes of a program.
* **Evaluation Design –** The logical model or conceptual framework used to arrive at conclusions about outcomes.
* **Evaluation Plan –** A written document describing the overall approach or design that will be used to guide an evaluation. It includes what will be done, how it will be done, who will do it, when it will be done, why the evaluation is being conducted, and how the findings will likely be used.
* **Evaluation Strategy –** The method used to gather evidence about one or more outcomes of a program. An evaluation strategy is made up of an evaluation design, a data collection method, and an analysis technique.
* **Ex Ante Cost-Benefit or Cost-Effectiveness Analysis -** A cost-benefit or cost-effectiveness analysis that does not estimate the actual benefits and costs of a program but that uses hypothesized before-the-fact costs and benefits. This type of analysis is used for planning purposes rather than for evaluation.
* **Ex Post Cost-Benefit or Cost-Effectiveness Analysis –** A cost-benefit or cost-effectiveness analysis that takes place after a program has been in operation for some time and that is used to assess actual costs and actual benefits.
* **Executive Summary –** A nontechnical summary statement designed to provide a quick overview of the full-length report on which it is based.
* **Experimental (or randomized) Designs –** Designs that try to ensure the initial equivalence of one or more control groups to a treatment group by administratively creating the groups through random assignment, thereby ensuring their mathematical equivalence. Examples of experimental or randomized designs are randomized block designs, Latin square designs, fractional designs, and the Solomon four-group.
* **Expert Opinion –** A data collection method that involves using the perceptions and knowledge of experts in functional areas as indicators of program outcome.
* **External Validity –** The ability to generalize conclusions about a program to future or different conditions. Threats to external validity include selection and program interaction, setting and program interaction, and history and program interaction.
* **File Review –** A data collection method involving a review of program files. There are usually two types of program files: general program files and files on individual projects, clients, or participants.
* **Focus Group –** A group of people selected for their relevance to an evaluation that is engaged by a trained facilitator in a series of discussions designed for sharing insights, ideas, and observations on a topic of concern.
* **History –** Events outside the program that affect the responses of those involved in the program.
* **History and Program Interaction –** The conditions under which the program took place are not representative of future conditions. This is a threat to external validity.
* **Ideal Evaluation Design –** The conceptual comparison of two or more situations that are identical except that in one case the program is operational. Only one group (the treatment group) receives the program; the other groups (the control groups) are subject to all pertinent influences except for the operation of the program, in exactly the same fashion as the treatment group. Outcomes are measured in exactly the same way for both groups and any differences can be attributed to the program.
* **Implicit Design –** A design with no formal control group and where measurement is made after exposure to the program.
* **Indicator –** A specific, observable, and measurable characteristic or change that shows the progress a program is making toward achieving a specified outcome.
* **Inferential Statistical Analysis –** Statistical analysis using models to confirm relationships among variables of interest or to generalize findings to an overall population.
* **Informal Conversational Interview –** An interviewing technique that relies on the natural flow of a conversation to generate spontaneous questions, often as part of an ongoing observation of the activities of a program.
* **Inputs –** Resources that go into a program in order to mount the activities successfully.
* **Instrumentation –** The effect of changing measuring instruments from one measurement to another, as when different interviewers are used. This is a threat to internal validity.
* **Interaction Effect –** The joint net effect of two (or more) variables affecting the outcome of a quasi-experiment.
* **Internal Validity –** The ability to assert that a program has caused measured results (to a certain degree), in the face of plausible potential alternative explanations. The most common threats to internal validity are history, maturation, mortality, selection bias, regression artifacts, diffusion, and imitation of treatment and testing.
* **Interview Guide –** A list of issues or questions to be raised in the course of an interview.
* **Interviewer Bias –** The influence of the interviewer on the interviewee. This may result from several factors, including the physical and psychological characteristics of the interviewer, which may affect the interviewees and cause differential responses among them.
* **List Sampling –** Usually in reference to telephone interviewing, a technique used to select a sample. The interviewer starts with a sampling frame containing telephone numbers, selects a unit from the frame, and conducts an interview over the telephone either with a specific person at the number or with anyone at the number.
* **Literature Search –** A data collection method that involves an identification and examination of research reports, published papers, and books.
* **Logic Model –** A systematic and visual way to present the perceived relationships among the resources you have to operate the program, the activities you plan to do, and the changes or results you hope to achieve.
* **Longitudinal Data –** Data collected over a period of time, sometimes involving a stream of data for particular persons or entities over time.
* **Macro-Economic Model –** A model of the interactions between the goods, labor, and assets markets of an economy. The model is concerned with the level of outputs and prices based on the interactions between aggregate demand and supply.
* **Main Effects –** The separate independent effects of each experimental variable.
* **Matching –** Dividing the population into “blocks” in terms of one or more variables (other than the program) that are expected to have an influence on the impact of the program.
* **Maturation –** Changes in the outcomes that are a consequence of time rather than of the program, such as participant aging. This is a threat to internal validity.
* **Measurement Validity –** A measurement is valid to the extent that it represents what it is intended and presumed to represent. Valid measures have no systematic bias.
* **Measuring Devices or Instruments –** Devices that are used to collect data (such as questionnaires, interview guidelines, and observation record forms).
* **Micro-Economic Model –** A model of the economic behavior of individual buyers and sellers, in a specific market and set of circumstances.
* **Monetary Policy –** Government action that influences the money supply and interest rates. May also take the form of a program.
* **Mortality –** Treatment (or control) group participants dropping out of the program. It can undermine the comparability of the treatment and control groups and is a threat to internal validity.
* **Multiples Lines of Evidence –** The use of several independent evaluation strategies to address the same evaluation issue, relying on different data sources, on different analytical methods, or on both.
* **Natural Observation –** A data collection method that involves on‑site visits to locations where a program is operating. It directly assesses the setting of a program, its activities, and individuals who participate in the activities.
* **Non-Probability Sampling –** When the units of a sample are chosen so that each unit in the population does not have a calculable non-zero probability of being selected in the sample.
* **Non-Response –** A situation in which information from sampling units is unavailable.
* **Non-Response Bias –** Potential skewing because of non-response. The answers from sampling units that do produce information may differ on items of interest from the answers from the sampling units that do not reply.
* **Non-Sampling Error –** The errors, other than those attributable to sampling, that arise during the course of almost all survey activities (even a complete census), such as respondents’ different interpretation of questions, mistakes in processing results, or errors in the sampling frame.
* **Objective Data –** Observations that do not involve personal feelings and are based on observable facts. Objective data can be measured quantitatively or qualitatively.
* **Objectivity –** Evidence and conclusions that can be verified by someone other than the original authors.
* **Order Bias –** A skewing of results caused by the order in which questions are placed in a survey.
* **Outcome Effectiveness Issues –** A class of evaluation issues concerned with the achievement of a program’s objectives and the other impacts and effects of the program, intended or unintended.
* **Outcome Evaluation –** The systematic collection of information to assess the impact of a program, present conclusions about the merit or worth of a program, and make recommendations about future program direction or improvement.
* **Outcomes –** The results of program operations or activities; the effects triggered by the program. (For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced TB morbidity and mortality.)
* **Outputs –** The direct products of program activities; immediate measures of what the program did.
* **Plausible Hypotheses –** Likely alternative explanations or ways of accounting for program results, meaning those involving influences other than the program.
* **Population –** The set of units to which the results of a survey apply.
* **Primary Data –** Data collected by an evaluation team specifically for the evaluation study.
* **Probability Sampling –** The selection of units from a population based on the principle of randomization. Every unit of the population has a calculable (non-zero) probability of being selected.
* **Process Evaluation –** The systematic collection of information to document and assess how a program was implemented and operates.
* **Program Evaluation –** The systematic collection of information about the activities, characteristics, and outcomes of programs to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development.
* **Program Goal –** A statement of the overall mission or purpose(s) of the program.
* **Propriety –** The extent to which the evaluation has been conducted in a manner that evidences uncompromising adherence to the highest principles and ideals (including professional ethics, civil law, moral code, and contractual agreements).
* **Qualitative Data –** Observations that are categorical rather than numerical, and often involve knowledge, attitudes, perceptions, and intentions.
* **Quantitative Data –** Observations that are numerical.
* **Quasi-Experimental Design –** Study structures that use comparison groups to draw causal inferences but do not use randomization to create the treatment and control groups. The treatment group is usually given. The control group is selected to match the treatment group as closely as possible so that inferences on the incremental impacts of the program can be made.
* **Random Digit Dialing –** In telephone interviewing, a technique used to select a sample. A computer, using a probability‑based dialing system, selects and dials a number for the interviewer.
* **Randomization –** Use of a probability scheme for choosing a sample. This can be done using random number tables, computers, dice, cards, and so forth.
* **Regression Artifacts –** Pseudo-changes in program results occurring when persons or treatment units have been selected for the program on the basis of their extreme scores. Regression artifacts are a threat to internal validity.
* **Reliability –** The extent to which a measurement, when repeatedly applied to a given situation consistently produces the same results if the situation does not change between the applications. Reliability can refer to the stability of the measurement over time or to the consistency of the measurement from place to place.
* **Replicate Sampling –** A probability sampling technique that involves the selection of a number of independent samples from a population rather than one single sample. Each of the smaller samples is termed a replicate and is independently selected on the basis of the same sample design.
* **Resources –** Assets available and anticipated for operations. They include people, equipment, facilities, and other things used to plan, implement, and evaluate programs.
* **Sample Size –** The number of units to be sampled.
* **Sample Size Formula –** An equation that varies with the type of estimate to be made, the desired precision of the sample and the sampling method, and which is used to determine the required minimum sample size.
* **Sampling Error –** The error attributed to sampling and measuring a portion of the population rather than carrying out a census under the same general conditions.
* **Sampling Frame –** Complete list of all people or households in the target population.
* **Sampling Method –** The method by which the sampling units are selected (such as systematic or stratified sampling).
* **Sampling Unit –** The unit used for sampling. The population should be divisible into a finite number of distinct, non‑overlapping units, so that each member of the population belongs to only one sampling unit.
* **Secondary Data –** Data collected and recorded by another (usually earlier) person or organization, usually for different purposes than the current evaluation.
* **Selection and Program Interaction –** The uncharacteristic responsiveness of program participants because they are aware of being in the program or being part of a survey. This interaction is a threat to internal and external validity.
* **Selection Bias –** When the treatment and control groups involved in the program are initially statistically unequal in terms of one or more of the factors of interest. This is a threat to internal validity.
* **Setting and Program Interaction –** When the setting of the experimental or pilot project is not typical of the setting envisioned for the full-scale program. This interaction is a threat to external validity.
* **Stakeholders –** People or organizations that are invested in the program or that are interested in the results of the evaluation or what will be done with results of the evaluation.
* **Standard –** A principle commonly agreed to by experts in the conduct and use of an evaluation for the measure of the value or quality of an evaluation (e.g., accuracy, feasibility, propriety, utility).
* **Standard Deviation –** The standard deviation of a set of numerical measurements (on an “interval scale”). It indicates how closely individual measurements cluster around the mean.
* **Standardized Format Interview –** An interviewing technique that uses open-ended and closed‑ended interview questions written out before the interview in exactly the way they are asked later.
* **Statistical Analysis –** The manipulation of numerical or categorical data to predict phenomena, to draw conclusions about relationships among variables or to generalize results.
* **Statistical Model –** A model that is normally based on previous research and permits transformation of a specific impact measure into another specific impact measure, one specific impact measure into a range of other impact measures, or a range of impact measures into a range of other impact measures.
* **Statistically Significant Effects –** Effects that are observed and are unlikely to result solely from chance variation. These can be assessed through the use of statistical tests.
* **Stratified Sampling –** A probability sampling technique that divides a population into relatively homogeneous layers called strata, and selects appropriate samples independently in each of those layers.
* **Subjective Data –** Observations that involve personal feelings, attitudes, and perceptions. Subjective data can be measured quantitatively or qualitatively.
* **Surveys –** A data collection method that involves a planned effort to collect needed data from a sample (or a complete census) of the relevant population. The relevant population consists of people or entities affected by the program (or of similar people or entities).
* **Testing Bias –** Changes observed in a quasi-experiment that may be the result of excessive familiarity with the measuring instrument. This is a potential threat to internal validity.
* **Treatment Group –** In research design, the group of subjects that receives the program. Also referred to as the experimental or program group.
* **Utility -** The extent to which an evaluation produces and disseminates reports that inform relevant audiences and have beneficial impact on their work.