



COMMONLY USED ACRONYMS ASSOCIATED WITH CLINICAL TRIALS

AMC: Academic Medical Center

Academic medical center is a medical school and a hospital (university-based). Education, research, and clinical care are combined through the partnership between the University and the Hospital.

AE: Adverse Event

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

CA: Coverage Analysis (aka, PCA: Payor Coverage Analysis, MCA: Medicare Coverage Analysis)

A systematic review of all procedures listed in the study protocol's schedule of events to determine which ones are 'billable' and where these services should be billed.

CARM: Coverage Analysis Review Memo (University of Arizona Health Sciences (UAHS) term)

Principal Investigators (PI) attestation of review of the coverage analysis (CA) and agreement to accurately and properly document medical services performed in the medical record as outlined in the coverage analysis (CA).

CCTO: Centralized Clinical Trials Office (aka, CTO: Clinical Trials Office)

Provides infrastructure support for clinical trials, to include (but not limited to) billing compliance, grant submission, budgeting, and regulatory support.

CDA: Confidential Disclosure Agreement (aka, NDA: Non-Disclosure Agreement)

A legal agreement between a minimum of two parties, which outlines information the parties wish to share with one another for certain purposes but wish to restrict from wider use and dissemination. In clinical trial research, this agreement is required prior to receiving study information.

CI RB: Central Institutional Review Board (aka, IRB, sIRB: Single IRB)

The administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities. A central IRB is a single IRB that reviews research protocols. They monitor research for all sites involved in a research study and generally involve fewer regulatory submissions and a more streamlined, efficient review process.

CITI: Collaborative Institutional Training Initiative or CITI Program

CITI is dedicated to serving the training needs of colleges and universities, healthcare institutions, technology and research organizations, and governmental agencies, as they foster integrity and professional advancement of their learners.

CMS: Centers for Medicare & Medicaid Services

The federal agency within the United States Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid.



COI: Conflict of Interest

Occurs when an individual's personal interests – family, friendships, financial, or social factors – could compromise their judgment, decisions, or actions in the workplace.

Co-I: Co-Investigator

A senior or key investigator involved in a clinical study who does not have the overall responsibility and authority of the Principal Investigator (PI). A Co-I is expected to devote a specified amount of time to the project, make significant contributions, and may be involved in developing and/or carrying out the project.

CRC: Clinical Research Coordinator

Responsible for the coordination and administration of clinical trials under the direction of the Principal Investigator (PI).

CRF: Case Report Form (aka, eCRF: *electronic Case Report Form*)

A case report form is a paper or electronic questionnaire specifically used in clinical trial research. The case report form is the tool used by the sponsor of the clinical trial to collect data from each participating patient.

CRO: Contract Research Organization

A company hired by another company or research center to take over certain parts of running a clinical trial. The company may design, manage, monitor the trial, and/or analyze the results.

CTA: Clinical Trial Agreement

A legally binding agreement that manages the relationship between the sponsor that may be providing the study drug or device, the financial support and /or proprietary information and the institution that may be providing data and/or results, publication, input into further intellectual property.

CTMS: Clinical Trial Management System

A software system used to manage clinical trials in clinical research. The system maintains and manages planning, performing and reporting functions, along with participant contact information, tracking deadlines and milestones.

CTO: Clinical Trials Office (aka, CCTO: *Centralized Clinical Trials Office*)

Provides infrastructure support for clinical trials, to include (but not limited to) billing compliance, grant submission, budgeting, and regulatory support.

DMC: Data Monitoring Committee**DSMB: Data Safety Monitoring Board**

A group of independent scientists who monitor the safety and scientific integrity of a clinical trial. The DMC or DSMB can recommend to the sponsor that the trial be stopped if it is not effective, is harming participants, or is unlikely to serve its scientific purpose. Members are chosen based on the scientific skills and knowledge needed to monitor the particular trial.

DUA: Data Use Agreement

A contractual document used for the transfer of data that has been developed by nonprofit, government or private industry, where the data are nonpublic or is otherwise subject to some restrictions on its use.

eCRF: *electronic Case Report Form* (aka, CRF: *Case Report Form*)

An electronic case report form is an electronic questionnaire specifically used in clinical trial research. The case report form is the tool used by the sponsor of the clinical trial to collect data from each participating patient.



EHR: Electronic Health Record

An electronic version of a patient's medical history, that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that person's care under a particular provider, including demographics, progress notes, problems, medications.

EMR: Electronic Medical Record

The digital equivalent of paper records, or charts in a medical provider's facility. EMRs typically contain general information such as treatment and medical history about a patient as it is collected by the individual medical practice.

FDA: Food and Drug Administration

The agency that oversees the manufacturing and distribution of food, pharmaceuticals, medical devices, tobacco and other consumer products and veterinary medicine.

FDF: Financial Disclosure Form

Used to identify potential or actual conflicts of interest.

GCP: Good Clinical Practice

An international set of guidelines that helps make sure that the results of a clinical trial are reliable and that the patients are protected. Good Clinical Practice covers the way a clinical trial is designed, conducted, performed, monitored, audited, recorded, analyzed, and reported.

HIPAA: Health Insurance Portability and Accountability Act

A US law designed to provide privacy standards to protect patients' medical records and other health information.

IATA Certification: International Air Transport Association

Shipping and transport of regulated biological materials is designed as initial training and periodic retraining for employees who package or ship diagnostic and clinical human or animal specimens, human or animal pathogens, and other regulated biohazards.

IB: Investigator Brochure

A comprehensive document summarizing the body of information about an investigational product (IP or study drug) obtained during a drug trial. The IB is a document of critical importance throughout the drug development process and is updated with new information as it becomes available. The purpose of the IB is to compile data relevant to studies of the IP in human subjects gathered during preclinical and other clinical trials.

ICF: Informed Consent Form

Provides the patient with information regarding the purpose, benefits, risks, costs, and expectations of participation in the study. A voluntary agreement to participate in research.

IDE: Investigational Device Exemptions

An investigational device exemption (IDE) allows an investigational device (e.g., a device that is the subject of a clinical study) to be used in order to collect safety and effectiveness data.

IIR: Investigator Initiated Research (aka, IST: Investigator-Sponsored Study)**IIS: Investigator Initiated Study (aka, IST: Investigator-Sponsored Study)****IIT: Investigator Initiated Trial (aka, IST: Investigator-Sponsored Study)**

Clinical trials / studies proposed and developed directly by an Investigator for which the investigator will act as the sponsor. IIR/IIS/IIT/ISTs may be industry funded, grant funded or self-funded.



IND: Investigational New Drug (Application)

An Investigational New Drug Application (IND) is a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans.

INV: Invoice /Invoiceable

A statement of sum due for items / services of value. Also referred to as a bill. Clinical trial budgets will use an INV to bill the study's funding source for money owed as outlined in the agreed budget.

IP #: Institutional Proposal Number (*University of Arizona term*)

Sponsored Projects Services (SPS) reviews the research proposal and submission package, coordinates any changes or corrections, submits the proposal, and finalizes the UAccess Research (UAR) proposal in the system (converting it to an IP and assigning a system number).

IP: Intellectual Property

Clinical trial results may be protected and commercialized under the following types of intellectual property: Patents (and utility models) – patents are granted for an invention in any technological field if it is new, based on an inventive step and industrially applicable.

IP: Investigational Product

A preventative (vaccine), a therapeutic (drug or biologic), device, diagnostic, or palliative used in a clinical trial.

IRB: Institutional Review Board (*aka, cIRB: Central IRB, sIRB: Single IRB*)

The administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities.

IST: Investigator-Sponsored Study (*aka, IIR: Investigator Initiated Research, IIS: Investigator Initiated Study, IIT: Investigator Initiated Trial*)

Clinical trials / studies proposed and developed directly by an Investigator for which the investigator will act as the sponsor. IIR/IIS/IIT/ISTs may be industry funded, grant funded or self-funded.

LAR: Legally Authorized Representative

An individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in a research study.

LCD: Local Coverage Determination

Policies to limit or guide appropriate billing for Medicare coverage of specific items. LCDs are determined and implemented by the provider's regional Medicare contract administrator.

MAC: Medicare Administrative Contractor

A private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B medical claims.

MCA: Medicare Coverage Analysis (*aka, CA: Coverage Analysis, PCA: Payer Coverage Analysis*)

A systematic review of all procedures listed in the study protocol's schedule of events to determine which ones are 'billable' and where these services should be billed.

MCTA: Master Clinical Trial Agreement

Provides agreed-upon terms and conditions establishing the basic relationship between the University and a sponsor that typically covers all clinical trials with the sponsor in a specified time period.



MRN: Medical Record Number

A standard unique identifier, assigned by a licensed health care institution or a health care provider, for documentation concerning the diagnosis or treatment of a patient.

MTA: Material Transfer Agreement

A contract that governs the transfer of tangible research materials between two organizations when the recipient intends to use it for his or her own research purposes.

NCD: National Coverage Determination

Policies to limit or guide appropriate billing for Medicare coverage of specific items. NCDs are issued by CMS.

NCI: National Cancer Institute

One of the National Institutes of Health (NIH) in the U.S., whose mission is to "lead a national effort to reduce the burden of cancer morbidity and mortality and ultimately to prevent the disease."

NCT: National Clinical Trial

ClinicalTrials.gov identifier (NCT number). A unique identification code is given to each clinical study upon registration at ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (e.g., NCT00000419)

NDA: Non-Disclosure Agreement (aka, CDA: Confidential Disclosure Agreement)

A legal agreement between a minimum of two parties, which outlines information the parties wish to share with one another for certain purposes but wish to restrict from wider use and dissemination. In clinical trial research, this agreement is required prior to receiving study information.

NIH: National Institutes of Health

The principal federal agency for health research in the United States. The NIH is part of the Department of Health and Human Services.

NTF: Note to File

Written to identify and record: a discrepancy or problem in the conduct of the clinical research study; the root cause of the identified problem; the corrective action taken to prevent recurrence of the problem; and the corrective action that has resolved the problem. Filed in the site's regulatory binder.

OHRP: Office of Human Research Protections

Provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS).

PA: Protocol Amendment

PAs occur when there are changes in the existing protocol that significantly affect safety of subjects, scope of the investigation, or scientific quality of the study. Such amendment should contain a brief description of the change(s) and reference (date and number) to the submission that contained the original protocol.

PCA: Payor Coverage Analysis (aka, CA: Coverage Analysis, MCA: Medicare Coverage Analysis)

A systematic review of all procedures listed in the study protocol's schedule of events to determine which ones are 'billable' and where these services should be billed.

PHI: Protected Health Information

Any information about health status, provision of health care, or payment for health care that is created or collected by a Covered Entity and can be linked to a specific individual.



PI: Principal Investigator

In clinical research, the individual responsible for the oversight and conduct of a research protocol at the research site.

PSP: Protocol Signature Page

Records that contain the agreements and signatures to a clinical study protocol made and signed by investigators and sponsors in a clinical trial.

PSSV: Pre-Study Site Visit (aka, SSV: Site Selection Visit, SQV: Site Qualification Visit)

conducted to determine if the investigator and clinical site have the capability to conduct the study. During this visit, both an investigator and a study coordinator must be available.

RDC: Research Data Coordinator

Primary duties include conducting, coordinating and auditing medical record abstraction, as well as identifying data entry, data quality and integrity problems that are relevant to the research study, and working with staff to resolve these issues.

RIA: Research Intake Application (University of Arizona Health Sciences (UAHS) term)

All UAHS submissions involving patients, facilities, services, health records, and/or resources of a clinical provider (e.g., Banner Health) must be submitted to the RIA prior to submission to the University of Arizona Institutional Review Board (IRB). For new studies, the RIA initiates multiple processes including Banner feasibility review, coverage analysis development, budget & contract negotiations, financial review of ICF, and entering the study into the OnCore clinical trial management system (CTMS), as applicable. Studies with amendments (e.g., protocol, budget/contract, ICF) or PI changes also must be submitted through the RIA process.

SAE: Serious Adverse Event

Any untoward medical occurrence that at any dose results in death, is life threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization, results in persistent or significant disability/incapacity, causes a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment of damage.

SEV: Site Evaluation Visit

A visit to confirm the accuracy of the site's capabilities to satisfy the sponsors' goals. Usually performed after the CDA (confidential disclosure agreement) and site has expressed interest in performing the study.

sIRB: Single Institutional Review Board (aka, IRB, cIRB: Central IRB)

The administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities. A single IRB (sIRB) is the IRB of record that oversees all clinical trial sites participating in a multi-site study.

SIV: Site Initiation Visit

To prepare and set up a research site to conduct a study and must occur prior to patient recruitment. The principal investigator (PI) must attend this visit together with as many members of the research team as possible. Usually takes place after the contract (CTA) inclusive of budget have been completed and the study has IRB approval.

SOE: Schedule of Events

A plan of care that the study subject will receive during their participation in the research protocol.



SOP: Standard Operating Procedure

Documented processes put in place to ensure services and/or products are delivered consistently every time.

SQV: Site Qualification Visit (aka, PSSV: Pre-Study Site Visit, SSV: Site Selection Visit)

conducted to determine if the investigator and clinical site have the capability to conduct the study. During this visit, both an investigator and a study coordinator must be available.

SRC: Scientific Review Committee

A group of doctors, scientists, and other experts that reviews the detailed plan of a clinical trial for scientific quality and correct study design. The scientific review committee reviews most clinical trials before they go to the facility's Institutional Review Board (IRB) for approval.

SSV: Site Selection Visit (aka, PSSV: Pre-Study Site Visit, SQV: Site Qualification Visit)

conducted to determine if the investigator and clinical site have the capability to conduct the study. During this visit, both an investigator and a study coordinator must be available.

SUB-I: Sub-Investigator

Includes any other individual member of that team (e.g., research fellows, residents) who will be assisting the principal investigator in the conduct of the research study.

SUSAR: Suspected Unexpected Serious Adverse Reaction

An adverse event that occurs in a clinical trial subject, which is assessed by the sponsor and or study investigator as being unexpected, serious, and as having a reasonable possibility of a causal relationship with the study drug. Reports of these reactions are subject to expedited submission to health authorities.

Additional clinical trial terms can be found at ClinicalTrials.gov:

(<https://clinicaltrials.gov/ct2/about-studies/glossary>)

