MASTERING CLINICAL RESEARCH

A Comprehensive Online Course for Clinical Research Coordinators

COMMON ACRONYMS & ABBREVIATIONS

Navigating clinical research requires fluency in a broad vocabulary of acronyms and abbreviations — from regulatory frameworks and electronic systems to safety reporting and data management. This expanded reference provides context-rich definitions for the acronyms you will encounter most frequently as a Clinical Research Coordinator. This is not an exhaustive list, and some acronyms carry multiple meanings. Always defer to your protocol, SOPs, and sponsor guidance.

Acronym	Full Name	Context & Notes
AAHRPP	**Association for the Accreditation of Human Research Protection Programs**	Independent accreditor of human research protection programs at universities, hospitals, and research institutions.
ACRP	**Association of Clinical Research Professionals**	Leading professional organization offering CCRC and CCRA certification, education, and career resources for clinical research professionals.
ADR	**Adverse Drug Reaction**	An unintended, harmful response to a medication at normal doses. Unlike an AE, causality to the drug has been established.
AE	**Adverse Event**	Any untoward medical occurrence in a study participant, not necessarily related to the investigational product. All AEs must be documented per protocol.
ALCOA	**Attributable, Legible, Contemporaneous, Original, Accurate**	The foundational GCP data integrity principles. Extended to ALCOA+ (adding Complete, Consistent, Enduring, Available) by many sponsors.
ALCOA+	**Attributable, Legible, Contemporaneous, Original, Accurate + Complete, Consistent, Enduring, Available**	Expanded data quality framework used by FDA and ICH to ensure research data integrity throughout the trial lifecycle.
BA/BE	**Bioavailability / Bioequivalence**	BA measures the rate/extent a drug reaches systemic circulation; BE compares BA between two formulations. Critical in generic drug development.
BLA	**Biological Licensing Application**	FDA submission requesting permission to market a biologic product (vaccines, blood products, gene therapies). The biologics equivalent of an NDA.
CAPA	**Corrective and Preventive Action**	Quality system process to identify root causes of deviations, implement fixes, and prevent recurrence. Often triggered by audit findings or protocol deviations.
CDM	**Clinical Data Management**	End-to-end process of collecting, cleaning, and managing trial data to ensure accuracy, completeness, and GCP compliance.
CDP	**Clinical Development Plan**	Strategic document outlining the overall development strategy for an investigational product from Phase I through approval.

CFR	**Code of Federal Regulations**	Codification of U.S. federal regulations. Key CRs for clinical research: 21 CFR Parts 11, 50, 54, 56, 312, and 314.
COA	**Clinical Outcome Assessment**	Measure of how a patient feels, functions, or survives. Includes PROs, ClinROs, ObsROs, and PerFOs.
CPM	**Clinical Project Manager**	Oversees the planning, execution, and delivery of clinical trials across multiple functions and sites.
CRA	**Clinical Research Associate**	Also called a monitor. Responsible for site qualification, initiation, monitoring visits, and closeout per ICH-GCP.
CRC	**Clinical Research Coordinator**	The site-level professional responsible for day-to-day trial operations, participant management, data collection, and regulatory compliance.
CRF	**Case Report Form**	Paper or electronic instrument used to record protocol-required data for each study participant. Must reflect source documentation.
CRMS	**Clinical Research Management System**	Software platform used to manage clinical trial operations including tracking, reporting, and compliance activities.
CRO	**Contract Research Organization**	Company providing outsourced research services to sponsors including study management, monitoring, data management, and regulatory affairs.
CSM	**Clinical Study Manager / Clinical Site Manager**	Manages operational aspects of a clinical study or serves as the sponsor's representative managing investigative sites.
CSR	**Clinical Study Report**	Comprehensive document summarizing the methodology, results, and analysis of a completed clinical trial. Required for regulatory submissions.
CTA	**Clinical Trial Authorization**	Regulatory approval (EU and other regions) required before a clinical trial can begin. U.S. equivalent is the IND.
CTCAE	**Common Terminology Criteria for Adverse Events**	NCI-developed standardized grading system (Grades 1–5) for classifying severity of adverse events. Standard in oncology and many other trials.
CTM	**Clinical Trial Manager**	Manages the operational execution of one or more clinical trials, often overseeing CRAs and site management activities.
CTMS	**Clinical Trial Management System**	Software platform for planning, tracking, and managing trials. Manages site info, monitoring visits, enrollment, budgets, and milestones.
DHHS	**Department of Health and Human Services**	U.S. federal department overseeing public health, including the FDA, NIH, and OHRP — all key regulatory bodies in clinical research.
DM	**Data Manager**	Responsible for clinical database design, data entry review, query management, and data lock activities within the CDM function.
DMC	**Data Monitoring Committee**	Independent group of experts reviewing accumulating safety and efficacy data during a trial to protect participant welfare and trial integrity.
DSMB	**Data and Safety Monitoring Board**	Often used interchangeably with DMC. Reviews unblinded interim data and can recommend trial modification or early termination.

EC	**Ethics Committee**	Independent body (similar to IRB) reviewing and approving clinical trial protocols to protect participants' rights and welfare. Common outside the U.S.
eCOA	**Electronic Clinical Outcome Assessment**	Digital platforms used to capture patient-reported, clinician-reported, or observer-reported outcome data directly from participants or clinicians.
eCRF	**Electronic Case Report Form**	Electronic version of the CRF, typically entered in an EDC system. Must be completed per GCP with a full audit trail.
EDC	**Electronic Data Capture**	Web-based systems for collecting and managing clinical trial data electronically (e.g., Medidata Rave, Oracle InForm). Must comply with 21 CFR Part 11.
EHR	**Electronic Health Record**	Digital version of a patient's medical history maintained by a healthcare provider. Frequently serves as source documentation in clinical trials.
EMR	**Electronic Medical Record**	Similar to EHR; typically refers to records within a single practice. Often used as source data in clinical trials.
ePRO	**Electronic Patient-Reported Outcomes**	Digital tools (apps, tablets, wearables) used to collect participant-reported data directly, reducing site burden and improving data timeliness.
eTMF	**Electronic Trial Master File**	Digital system for organizing, storing, and managing all essential trial documents throughout the study lifecycle per ICH E6(R2).
FDA	**Food and Drug Administration**	U.S. federal agency regulating drugs, biologics, devices, and food safety. Oversees clinical trial regulations under 21 CFR.
FIH	**First in Human**	Initial phase of a clinical trial where an investigational product is administered to human subjects for the first time (Phase 1).
GCP	**Good Clinical Practice**	International ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials (ICH E6). Core to all CRC work.
GDP	**Good Documentation Practice**	Standards ensuring all trial data and records are attributable, legible, contemporaneous, original, and accurate (ALCOA). Core to GCP compliance.
GLP	**Good Laboratory Practice**	Quality system for non-clinical laboratory (preclinical safety) studies. Regulated by the FDA and OECD.
GMP	**Good Manufacturing Practice**	Regulations ensuring drugs and investigational products are consistently produced to quality standards. Relevant to IP handling at sites.
HIPAA	**Health Insurance Portability and Accountability Act**	U.S. law protecting the privacy and security of individually identifiable health information (PHI). Clinical trials must comply with the HIPAA Privacy Rule.
HRPP	**Human Research Protection Program**	Institutional program providing oversight of all human subjects research, ensuring compliance with federal regulations and ethical standards.
IBC	**Institutional Biosafety Committee**	Committee required by NIH reviewing research involving recombinant DNA, biological agents, and certain biohazards.

ICF	**Informed Consent Form**	Document describing the study to potential participants in understandable language so they can make a voluntary, informed decision to participate.
ICH	**International Council for Harmonisation**	International body developing harmonized technical guidelines for pharmaceutical development. ICH E6(R2) GCP guideline is foundational for all CRCs.
IDE	**Investigational Device Exemption**	FDA approval allowing an unapproved medical device to be used in a clinical study to collect safety and effectiveness data.
IEC	**Independent Ethics Committee**	Independent group reviewing the ethics of research protocols. Functions similarly to an IRB; often used in international contexts.
IHCRA	**In-House Clinical Research Associate**	CRA who works primarily at a sponsor or CRO headquarters rather than traveling to sites. Also called a remote or desk monitor.
IIT	**Investigator-Initiated Trial**	Clinical trial sponsored and managed by an investigator (not a pharma company) using their own IND/IDE. Common in academic medical centers.
IMP	**Investigational Medicinal Product**	EU/ICH term for a drug or biologic being tested in a clinical trial. Equivalent to IP in U.S. terminology.
IND	**Investigational New Drug Application**	Application submitted to the FDA before a new drug can be tested in humans in the U.S. Contains preclinical data, manufacturing info, and clinical protocols.
IP	**Investigational Product**	The drug, biologic, or device being studied in a clinical trial, including comparators and placebos. Proper handling, storage, and accountability are critical GCP requirements.
IRB	**Institutional Review Board**	Formally designated committee reviewing and monitoring research involving human subjects to protect their rights and welfare (21 CFR Part 56).
ISF	**Investigator Site File**	Site's collection of essential documents required by GCP (ICH E6). Also called Regulatory Binder. Mirrors the sponsor's TMF.
IxRS	**Interactive Response Technology System**	Modern umbrella term for IVRS/IWRS systems used for randomization and drug supply management across clinical trials.
IVRS	**Interactive Voice Response System**	Telephone-based system used to randomize participants and manage IP dispensing. Largely replaced by IWRS/IxRS.
IWRS	**Interactive Web Response System**	Web-based system for randomization and trial supply management (RTSM). Also called IxRS.
LTFU	**Long-Term Follow-Up**	Monitoring of participants after the primary study period ends. Required for gene therapies, cellular therapies, and products with potential long-term effects.
MAD	**Multiple Ascending Dose**	Phase 1 study design where a drug is administered in multiple doses to evaluate safety, tolerability, and PK/PD for dose regimen selection.
MOP	**Manual of Procedures**	Comprehensive document describing operational procedures for conducting a trial at the site level. More operationally focused than the protocol.

MRN	**Medical Record Number**	Unique identifier assigned to a patient within a healthcare system. Links study records to source documentation; must be kept confidential.
NDA	**New Drug Application**	Submission to the FDA requesting approval to market a new drug in the U.S. Includes all clinical, preclinical, manufacturing, and labeling data.
NIH	**National Institutes of Health**	Primary U.S. federal agency for conducting and supporting biomedical research. Sponsors many IITs and sets standards for human subjects protection.
OHRP	**Office for Human Research Protections**	Division of DHHS providing guidance on ethical research conduct and overseeing compliance with 45 CFR Part 46 (the Common Rule).
PHI	**Protected Health Information**	Individually identifiable health information protected under HIPAA. Must be de-identified or have proper authorization before use in research.
PI	**Principal Investigator**	Physician or qualified individual responsible for the conduct of a clinical trial at a site. Ultimately accountable for protocol and GCP compliance.
PK/PD	**Pharmacokinetics / Pharmacodynamics**	PK studies how the body processes a drug (ADME); PD studies the drug's biological effects. Together they inform dosing strategy.
PRO	**Patient-Reported Outcome**	Measurement based on a direct patient report about their health status, without clinician interpretation. Central to COA strategies.
QC	**Quality Control**	Operational techniques used to fulfill quality requirements: reviewing data entries, verifying consent forms, checking source documentation.
QMS	**Quality Management System**	Formalized system documenting processes, procedures, and responsibilities for achieving quality in clinical research. Includes SOPs, CAPAs, and audits.
RBM	**Risk-Based Monitoring**	Monitoring approach using risk assessment and data analytics to focus monitoring on the most critical data and processes, per ICH E6(R2).
SAD	**Single Ascending Dose**	Phase 1 study design where single escalating doses are administered to assess safety, tolerability, and PK before proceeding to MAD.
SAE	**Serious Adverse Event**	AE resulting in death, life-threatening risk, hospitalization, disability, congenital anomaly, or requiring medical intervention. Subject to expedited reporting.
SC	**Study Coordinator**	Used interchangeably with CRC. Site staff member managing day-to-day trial operations, participant interactions, and data collection.
SDR	**Source Document Review / Source Data Review**	Process of reviewing source documents to verify accuracy and completeness of study data. Typically performed during monitoring visits.
SDV	**Source Document Verification**	Process of comparing eCRF/CRF entries against source documents to confirm accuracy and consistency. A core monitoring activity.

SF	**Screen Fail**	A participant who was consented and screened but did not meet eligibility criteria or withdrew before enrollment. Must be tracked per protocol.
SI	**Sub-Investigator**	Team member supervised by the PI who performs trial-related procedures or makes important trial decisions. Must be listed on FDA Form 1572.
SIF	**Site Information Form**	Sponsor- or CRO-provided form capturing key site and personnel information. Often used alongside or in lieu of Form FDA 1572 updates.
SMO	**Site Management Organization**	Company providing operational and administrative support to investigative sites, including staff, infrastructure, and regulatory expertise.
SOC	**Standard of Care**	Accepted, evidence-based medical treatment for a specific condition. Clinical trials often compare investigational products to the current SOC.
SOE	**Schedule of Events**	Protocol table listing all study visits, assessments, and procedures at each time point. An essential CRC reference for managing participant visits.
SOP	**Standard Operating Procedure**	Detailed written instruction for routine operations ensuring consistent GCP and regulatory compliance. Sites and sponsors must maintain current SOPs.
SPOREs	**Specialized Programs of Research Excellence**	NCI-funded translational research programs accelerating movement of basic research findings into clinical settings for specific cancer types.
SRB	**Scientific Review Board**	Internal or external committee evaluating the scientific merit, feasibility, and design of proposed research studies.
SRC	**Scientific Review Committee**	Similar to SRB. Reviews protocols for scientific rigor and resource utilization, especially at academic medical centers.
SUSAR	**Suspected Unexpected Serious Adverse Reaction**	SAE that is both unexpected (not in IB) and reasonably related to the investigational product. Subject to expedited reporting to regulatory authorities.
SVT	**Subject Visit Template**	Tool used by CRCs to prepare for and document study visits, ensuring all protocol-required procedures and assessments are completed.
TMF	**Trial Master File**	Collection of all essential documents required by ICH E6 GCP for a clinical trial. Maintained by the sponsor. Site equivalent is the ISF.
UADE	**Unanticipated Adverse Device Effect**	Serious adverse effect caused by a device not anticipated in the investigational plan. Must be reported to the IRB and FDA.
UADR	**Unexpected Adverse Drug Reaction**	ADR not consistent with applicable product information (e.g., Investigator's Brochure). Key trigger for expedited safety reporting.
UAP	**Unanticipated Problem**	Incident or outcome that is unexpected, related to the research, and suggests greater risk of harm than anticipated. Must be reported to the IRB.

Note: *This list is not exhaustive and acronyms may carry different meanings depending on context, sponsor, or institution. Always refer to your study protocol, Investigator's Brochure, and applicable SOPs for study-specific definitions.*