Shortcuts: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

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Adverse Drug Reaction (ADR)	Refer to ICH E6 R2 1.1.
Adverse Event (AE)	Refer to 21 CFR 312.32(a).
Adverse Events of Special Interest (AESI)	Refer to FDA Guidance E2F Development Safety Update Report, Appendix A – Glossary
Adjudication Committee	Refer to https://globalclinicaltrialpartners.com/adjudication-clinical-trials-primer/
Applicable Regulatory Requirement(s)	Refer to ICH E6 R2 1.4.
Assent	Refer to 45 CFR 46.402(b).
Associate Investigator	See Investigator.
Audit	Refer to ICH E6 R2 1.6.
Audit Certificate	Refer to ICH E6 R2 1.7.
Audit Trail	Refer to ICH E6 R2 1.9.

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Baseline	Refer to CDISC Glossary.
Blinding/Masking	Refer to ICH E6 R2 1.10.
Biologic License Application (BLA)	Refer to 21 CFR 601.2(a).
Biologic Product	Refer to 21 CFR 600.3(h).

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Case Report Form (CRF)	Refer to ICH E6 R2 1.11.
Centralized Monitoring	Refer to FDA Guidance for Industry: Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring, III.A.2.
Certified Copy	Refer to ICH E6 R2 1.63.
Chemical, Manufacturing and Control (CMC)	Refer to 21 CFR 312.23(a)(7)
Clinical Hold	Refer to 21 CFR 312.42(a).
Clinical Investigator	See Investigator.
Clinical Laboratory	Refer to 42 CFR 493.2 (definition of "laboratory")
Clinical Monitoring Plan (CMP)	See Monitoring Plan.
Clinical Research	Refer to NIH Glossary.
Clinical Research Associate	See Monitor.
Clinical Study	See Clinical Trial.
Clinical Study Report (CSR)	Refer to ICH E6 R2 1.13.

Clinical Trial	Refer to ICH E6 R2 1.12.
Closeout Visit	A final site visit by a monitor that must be conducted after a study has been completed, suspended or terminated for any reason.
Code of Federal Regulations (CFR)	The codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government.
Comparator (Product)	Refer to ICH E6 R2 1.14.
Compliance (in relation to trials)	Refer to ICH E6 R2 1.15.
Confidentiality	Refer to ICH E6 R2 1.16.
Contract	Refer to ICH E6 R2 1.17.
Contract Research Organization (CRO)	Refer to ICH E6 R2 1.20.
Controlled Document	A document that goes through a structured review process, formal approval, controlled distribution, controlled modification, controlled storage and access; and to which a sequential version number and associated version date are applied and tracked.
Coordinating Committee	Refer to ICH E6 R2 1.18.
Coordinating Investigator	Refer to ICH E6 R2 1.19.
Corrective Action	Refer to ICH Q10.
Council for International Organizations of Medical Sciences (CIOMS)	Refer to CIOMS website.

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Data Analysis Plan	Refer to ICH E9.
Data Management Plan (DMP)	Refer to FDA Patient Focused Drug Development Glossary and FDA Guidance – Computerized Systems Used in Clinical Investigations, the Appendix A – Standard Operating Procedures
Data Monitoring Committee (DMC)	Refer to ICH E6 (R2) 1.25.
Data Originator	Refer to FDA Guidance – Electronic Source Data in Clinical Investigations.
Data Safety Monitoring Board (DSMB)	See Data Monitoring Committee.
Deviation (from the Protocol)	Refer to Protocol Non-Adherence
Device	Refer to Food, Drug and Cosmetic Act, section 201(h)
Diary	See Patient-Reported Outcome (PRO).
Digital Signature	Refer to 21 CFR 11.3.
Direct Access	Refer to ICH E6 R2 1.21.
Direct Data Entry	Refer to FDA Guidance – Electronic Source Data in Clinical Investigations.
Documentation	Refer to ICH E6 R2 1.22.
Drug Master File (DMF)	Refer to FDA Guidance – Drug Master Files: Guidelines.

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Electronic Case Report Form (eCRF)	Refer to FDA Guidance – Electronic Source Data in Clinical Investigations, Glossary of Terms.
Electronic Record	Refer to 21 CFR 11.3.
Electronic Signature	Refer to 21 CFR 11.3.
Eligibility	The determination that a potential participant satisfies or meets the enrollment criteria for inclusion into a clinical study.
Endpoint	Refer to FDA Clinical Trial Glossary.
Enrollment Criteria	The medical or other guidelines that determines whether a person may or may not be allowed to enter a clinical trial.
Essential Documents	Refer to ICH E6 (R2) Section 8.

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Finished Device	Refer to 21 CFR 820.3(l).
First-in-human (FIH)	Refer to FDA Guidance: Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics Guidance for Industry.

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Good Clinical Practice (GCP)	Refer to ICH E6 R2.
Good Laboratory Practice (GLP)	Refer to 21 CFR 58.
Good Manufacturing Practice (GMP)	Refer to 21 CFR 210 and 21 CFR 211.

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Human Subject	Refer to 21 CFR 50.3.

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Independent Data-Monitoring Committee (IDMC)	Refer to ICH E6 R2 1.25.
Impartial Witness	Refer to ICH E6 R2 1.26.
Independent Ethics Committee (IEC)	Refer to ICH E6 R2 1.27.
Instruction for Use (IFU)	Refer to FDA Guidance – Instruction for Use – Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products – Content and Format and FDA Guidance – Medical Device Patient Labeling
Individually Identifiable Health Information	Refer to 45 CFR 160.103.

Informed Consent	Refer to 21 CFR 50.20.
Informed Consent Form (ICF)	Refer to 21 CFR 50.25 and ICH E6 R2 4.8.
Initiation Visit	A meeting between a sponsor representative(s) and investigators (and other key personnel), at which the objectives and the methodology of the clinical study are defined, regulatory requirements are reviewed, and appropriate training of the site's key personnel is conducted.
Inspection	Refer to ICH E6 R2 1.29.
Institutional Review Board (IRB)	Refer to 21 CFR 56.102(g) and ICH E6 R2 1.27.
Interim Study Report	Refer to ICH E6 R2 1.32.
International Council for Harmonization (ICH)	Refer to Overview of ICH.
Intervention	Refer to FDA Clinical Trial Glossary
Investigational Device	Refer to 21 CFR 812.
Investigational Device Exemption (IDE)	Refer to 21 CFR 812.
Investigational Drug Product	Refer to 21 CFR 312.3(b).
Investigational New Drug Application (IND)	Refer to 21 CFR 312.3(b).
Investigational Product (IP)	Refer to ICH E6 R2 1.33.
Investigator	Refer to ICH E6 R2 1.34.
Investigator's Brochure (IB)	Refer to ICH E6 R2 1.36.

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Label	Refer to 21 CFR 1.3(b).
Labeling	Refer to 21 CFR 1.3(a).
Legally Acceptable Representative (LAR)	Refer to ICH E6 R2 1.37.

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Medical Device	Refer to Food, Drug and Cosmetic Act, section 201(h)
Medical Device Report (MDR)	Refer to 21 CFR 803
Memory Aid	See Patient-Reported Outcome (PRO)
Monitor or Monitoring (verb)	Refer to ICH E6 R2 1.38.

Monitor (noun)	Refer to ICH E6 R2.
Monitoring Plan	Refer to ICH E6 R2 1.64.
Monitoring Report	Refer to ICH E6 R2 1.39.
Multicenter Study/Trial	Refer to ICH E6 R2 1.40.

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Nonclinical Laboratory Study	Refer to 21 CFR 58.3(d).
Noncontrolled Document	Document that is not a part of the Quality System, or a printed copy of a document from the Quality System.
Noninvasive	Refer to 21 CFR 812.3(k).
Nonsignificant Risk Device (NSR Device)	Refer to FDA Guidance Significant Risk and Nonsignificant Risk Medical Device Studies

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Original Medical Record	See Source Documents.
Original Source	See Source Documents.
Outcome	Refer to FDA Clinical Trial Glossary

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Participant	See Subject.
Patient-Reported Outcome (PRO)	Refer to FDA Guidance Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims.
Preventive Action	Refer ICH Q10 Glossary.
Principal Investigator (PI)	Refer to Investigator.
Protected Health Information (PHI)	Refer to 45 CFR 160.103.
Protocol	Refer to ICH E6 R2 1.44.
Protocol Amendment	Refer to ICH E6 R2 1.45.
Protocol Non-Adherence	See Protocol Violation.
Protocol Violation	Refer to CDISC Glossary.

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Quality Assurance (QA)	Refer to ICH E6 R2 1.46.
Quality Control (QC)	Refer to ICH E6 R2 1.47.

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Regulatory Authorities	Refer to ICH E6 R2 1.49.
Remote Monitoring Visit	See Centralized Monitoring.
Risk	Refer to ICH Q9.
Risk Management	Refer to ICH Q9 and ICH Q10 Glossary.

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Safety Signal	Refer to EMA Glossary.
Screening (of study subjects/participants)	Refer to CDISC Glossary.
Screening Failure	Refer to CDISC Glossary.
Serious Adverse Drug Reaction (or Experience)	Refer to 21 CFR 312.32(a).
Serious Adverse Event (SAE)	Refer to 21 CFR 312.32(a).
Serious and Unexpected Suspected Adverse Reaction (SUSAR)	Refer to 21 CFR 312.32(c)(1)(i).
Serious Suspected Adverse Reactions	See Serious Adverse Event.
Significant Risk Device (SR Device)	Refer to 21 CFR 812.3(m).
Site Quality Management Plan	A plan developed and implemented by the clinical research site to document, track, and improve performance. Quality management planning and associated Quality Checks (real-time) and Quality Assurance (periodic) activities facilitate effective protocol implementation and compliance with regulatory and GCP requirements, verify the accuracy of data, and identify process areas in need of corrective action.
Source Data	Refer to ICH E6 R2 1.51.
Source Documents	Refer to ICH E6 R2 1.52.
Sponsor	Refer to ICH E6 R2 1.53.
Sponsor-Investigator	Refer to ICH E6 R2 1.54.
Statistical Analysis Plan	Refer to ICH E9 Glossary
Sub-Investigator	Refer to ICH E6 R2 1.56.
Subject	Refer to ICH E6 R2 1.57.
Subject Identification Code	Refer to ICH E6 R2 1.58.
Suspected Adverse Reaction	Refer to 21 CFR 312.32(a).

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Test Article	Refer to 21 CFR 58.3(b).
Trial Master File (TMF)	Refer to ICH E6 R2 8.1

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Unexpected Adverse Drug Experience (Reaction)	Refer to ICH E6 R2 1.60.
Unanticipated Adverse Device Effects (UADE)	Refer to. 21 CFR 812.3(s)

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Validation	Refer to FDA Guidance Process Validation: General Principles and Practices.
Validation of Computerized Systems	Refer to ICH E6 R2 1.65.
Version Control	See Controlled Document.
Vulnerable Subjects	Refer to ICH E6 R2 1.61.

W

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Y

Z
