Organization	Reference	URL
AHRQ	CHI (consolidated health informatics)	https://ushik.ahrq.gov/ViewItemDetails?&system=mdr&itemKey=74237000
AMA	AMA Manual of Style	http://www.amamanualofstyle.com/
CDISC	Clinical Data Interchange Standards	http://www.cdisc.org/
CONSORT	CONSORT Statement	http://www.consort-statement.org/consort-
EMA	External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use	https://www.ema.europa.eu/human-regulatory/marketing-authorisation/clinical-data-publication/support-industry/external-guidance-implementation-european-
EMA	Reflection paper on expectations for electronic source data and data transcribed to electronic data collection	https://www.ema.europa.eu/documents/regulatory-procedural-guideline/reflection-paper-expectations-electronic-source-data-data-
EMA	Guideline on good pharmacovigilance practices (GVP)	http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/09/WC
EU	Regulation EU No 536/2014 [EU CTR]	https://ec.europa.eu/health/human-use/clinical-
EU	Directive 95/46/EC	https://publications.europa.eu/en/publication-detail/-/publication/335ef9fc-250a-4dfa-a76d-5583b689e91e/language-en/format-
EU	Regulation (EU) 2017/745	https://publications.europa.eu/en/publication-detail/-/publication/83bdc18f-315d-11e7-9412-01aa75ed71a1/language-en/format-
FDA	21 CFR 820.20	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=820.20
FDA	21 CFR Part 11	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11
FDA	21 CFR 312.42	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.42
FDA	21 CFR 803.3	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=803.3
FDA	21 CFR 210.3	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3
FDA	21 CFR 310.305	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=310.305
FDA	Glossary of Terms	http://www.fda.gov/Drugs/InformationOnDrugs
FDA	Acronyms and Abbreviations	https://www.accessdata.fda.gov/scripts/cder/a
FDA	General Principles of Software Validation; Final Guidance for Industry and FDA Staff	https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDo
FDA	Science & Research	http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMateri
FDA	Medical Device Development Tools (MDDT)	https://www.fda.gov/MedicalDevices/ScienceandResearch/MedicalDeviceDevelopmentTools
FDA	Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life	https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf
FDA	Guidance for Industry Electronic Source Data in Clinical Investigations, September	https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/
FDA	Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling	http://www.fda.gov/downloads/Drugs/Guidances/UCM193282.pdf
FDA	Guidance for Industry Computerized Systems Used in Clinical Investigations,	https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidanc

FDA	Guidance for Industry Part 11, Electronic Records; Electronic Signatures - Scope	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf
FDA	Collection of Race and Ethnicity Data in Clinical Trials, Guidance for Industry and Food and Drug Administration Staff,	https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126396.pdf
FDA	Patient-Focused Drug Development Glossary	https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm610317.htm
FDA	Guidance for Industry Adaptive Designs for Clinical Trials of Drugs and Biologics,	https://www.fda.gov/downloads/drugs/guidances/ucm201790.pdf
FDA	Guidance for Industry and Investigators Safety Reporting Requirements for INDs	https://www.fda.gov/downloads/Drugs/Guidances/UCM227351.pdf
FDA	Guidance for Industry Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein	https://www.fda.gov/downloads/drugs/guidances/ucm291134.pdf
FDA	Reviewer Guidance Evaluating the Risks of Drug Exposure in Human Pregnancies,	https://www.fda.gov/downloads/Drugs/Guidances/ucm071645.pdf
FDA	Guidance for Industry Exposure-Response Relationships - Study Design,	https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/
FDA	Guidance for Industry and Food and Drug Administration Staff Applying Human Factors and Usability Engineering to	https://www.fda.gov/downloads/medicaldevices/.../ucm259760.pdf
HHS	HIPAA	https://www.hhs.gov/hipaa/index.html
HL7	Structured Product Labeling (SPL)	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=96
HL7	Glossary of Terms	https://www.hl7.org/documentcenter/public_temp_4918EBFB-1C23-BA17-0C217648ABC1D9E1/calendarofevents/FirstTime/Glossary%20of%20terms.pdf
HMA	Medicines Approval system	http://www.hma.eu/medicinesapprovalsystem.
HyperStat	Online Glossary	http://davidmlane.com/hyperstat/glossary.html
ICH	Efficacy Guidelines	http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html
ISO	Health informatics -- Pseudonymization	https://www.iso.org/standard/63553.html
ISO	ISO 11615 2017-10 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of	https://www.iso.org/standard/70150.html
ISO	ISO 11238 2018-07 Health informatics -- Identification of medicinal products -- Data elements and structures for the	https://www.iso.org/standard/69697.html
ISO	Software engineering -- Guidelines for the application of ISO 9001:2000 to computer	https://www.iso.org/standard/35867.html
MedDRA	Medical Dictionary for Regulatory	https://www.meddra.org/
MHRA	GxP Data Integrity Guidance and Definitions, March 2018	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/687246/MHRA_GxP_data_integrity_gu
MHRA	Guidance: Medical device stand-alone software including apps	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_d
n/a	Glossary for Healthcare Standards, W.E.	n/a
n/a	L. Huber, “In Search of Standard Definitions for Validation, Qualification, Verification and Calibration,” BioPharm,	n/a
n/a	D.L. Patrick, “Patient-Reported Outcomes (PROs): An Organizing Tool for Concepts, Measures, and Applications,”	n/a

n/a	M.L. Schuyl and T. Engel, “A Review of the Source Document Verification Process in Clinical Trials,” DIA Journal,	n/a
National Databases of Indian Medical Journals	R. Khosla, D.D. Verma, A. Kapur et al.,“Efficient Source Data Verification,” Indian J. Pharm, 32, 180–186 (2000).	http://medind.nic.in/ibi/t00/i3/ibit00i3p180.pdf
NCBI	Biomarkers Definitions Working Group. Biomarkers and surrogate endpoints: preferred definitions and conceptual	https://www.ncbi.nlm.nih.gov/pubmed/11240971
NCBI	Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D, Gotzsche PC, Lang T; CONSORT GROUP (Consolidated Standards of Reporting Trials). The revised CONSORT statement	https://www.ncbi.nlm.nih.gov/pubmed/11304107
NCBI	Acquadro C, Berzon R, Dubois D, Leidy NK, Marquis P, Revicki D, Rothman M; PRO Harmonization Group. Incorporating the patient's perspective into drug development and communication: an ad hoc task force report of the Patient-	https://www.ncbi.nlm.nih.gov/pubmed/14627058
NCBI	NIH-FDA BEST (Biomarkers, Endpoints,	https://www.ncbi.nlm.nih.gov/books/NBK3384
NCBI	G.H. Guyatt, D.H. Feeney, D.L. Patrick, “Measuring Health-Related Quality of	https://www.ncbi.nlm.nih.gov/pubmed/8452328
NIH	ClinicalTrials.gov	https://clinicaltrials.gov/
NIH	Office of Science Policy	https://osp.od.nih.gov/clinical-research/clinical-
NIH	Declaration of Helsinki	https://history.nih.gov/research/downloads/hel
NIST	Data Encryption Standard (DES)	https://csrc.nist.gov/publications/detail/fips/46/
NIST	Guide to Protecting the Confidentiality of Personally Identifiable Information (PII)	https://csrc.nist.gov/publications/detail/sp/800-122/final
NIST	Minimum Security Requirements for Multi-user Operating Systems	https://csrc.nist.gov/csrc/media/publications/nistir/5153/final/documents/ir5153.txt
Office of the Privacy Commissioner of Canada	Privacy breaches	https://www.priv.gc.ca/en/privacy-topics/privacy-breaches/
PhUSE	PhUSE De-identification Standard for	http://www.phuse.eu/Data_Transparency_acc
TransCelerate BioPharma Inc.	Clinical Data Transparency	http://www.transceleratebiopharmainc.com/assets/clinical-data-transparency/
WHO	The World Health Organization Quality of	http://www.who.int/mental_health/publications/
WHO	Medical Devices	http://www.who.int/medical_devices/full_deffini
WHO	International Programme on Chemical	http://www.who.int/ipcs/about_ipcs/coordinator
XML Files	Extensible Markup Language	http://www.XMLfiles.com