Organization	Reference
AHRQ	CHI (consolidated health informatics)
AMA	AMA Manual of Style
CDISC	Clinical Data Interchange Standards Consortium
CONSORT	CONSORT Statement
EMA	External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use
EMA	Guideline on good pharmacovigilance practices (GVP)
EMA	Recommendations from the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014' dd 28 June 2017
EMA	Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials [EMA/INS/GCP/454280/2010]
EU	Directive 95/46/EC
EU	Regulation (EU) 2017/745
EU	Regulation EU No 536/2014 [EU CTR]
FDA	21 CFR 210.3
FDA	21 CFR 3.2 (e) FAQ
FDA	21 CFR 310.305
FDA	21 CFR 312.42
FDA	21 CFR 803.3
FDA	21 CFR 820.20
FDA	21 CFR Part 11
FDA	Acronyms and Abbreviations
FDA	Collection of Race and Ethnicity Data in Clinical Trials, Guidance for Industry and Food and Drug Administration Staff, Document issued on October 26, 2016
FDA	Electronic Submission File Formats and Specifications. Orientation and Best Practices For Data Formats and Submission To The Center For Tobacco Products. January 2018
FDA	Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions, April 2015

FDA	Framework for FDA's Real World Evidence Program. December 2018
FDA	General Principles of Software Validation; Final Guidance for Industry and FDA Staff
FDA	Glossary of Terms
FDA	Guidance for Industry Adaptive Designs for Clinical Trials of Drugs and Biologics, November 2019
FDA	Guidance for Industry and Food and Drug Administration Staff Applying Human Factors and Usability Engineering to Medical Devices, February 2016
FDA	Guidance for Industry and Investigators Safety Reporting Requirements for INDs and BA/BE Studies
FDA	Guidance for Industry Computerized Systems Used in Clinical Investigations, May 2007
FDA	Guidance for Industry Electronic Source Data in Clinical Investigations, September 2013
FDA	Guidance for Industry Exposure-Response Relationships - Study Design, Data Analysis, and Regulatory Applications, May 2003
FDA	Guidance for Industry Part 11, Electronic Records; Electronic Signatures - Scope and Application, August 2003
FDA	Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims, December 2009
FDA	Guidance for Industry Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product, May 2019
FDA	Master Protocols: Efficient Clinical Trial Design Strategies To Expedite Development of Oncology Drugs and Biologics. Guidance for Industry. October 2018
FDA	Medical Device Development Tools (MDDT)
FDA	Patient-Focused Drug Development Glossary
FDA	Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications Guidance for Industry. January 2019
FDA	Reviewer Guidance Evaluating the Risks of Drug Exposure in Human Pregnancies, April 2005
FDA	Science & Research
FDA	Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research Guidance for Industry. March 2019
FDA	Study Data Standards Resources

FDA	Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices. Guidance for Industry and Food and Drug Administration Staff. August 2017
HHS	HIPAA
HL7	Glossary of Terms
HL7	Structured Product Labeling (SPL)
HMA	Medicines Approval system
HyperStat	Online Glossary
ICH	Efficacy Guidelines
IMDRF	"Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations Authoring Group: IMDRF Software as a Medical Device (SaMD) Working Group Date: 18 September 2014
IMI	IMI-GetReal Glossary Workgroup, 2016 GetReal - Project No. 115546, WP1: Deliverable D1.3
ISO	Health informatics -- Pseudonymization
ISO	ISO 11238 2018-07 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated information on substances
ISO	ISO 11615 2017-10 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated medicinal product information
ISO	Software engineering -- Guidelines for the application of ISO 9001:2000 to computer software
MedDRA	Medical Dictionary for Regulatory Activities
MHRA	Guidance: Medical device stand-alone software including apps
MHRA	GxP Data Integrity Guidance and Definitions, March 2018
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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 for reporting randomized trials: explanation and elaboration. Ann Intern Med. 2001 Apr 17;134(8):663-94.
NCBI	Biomarkers Definitions Working Group. Biomarkers and surrogate endpoints: preferred definitions and conceptual framework. Clin Pharmacol Ther. 2001 Mar;69(3):89-95.
NCBI	G.H. Guyatt, D.H. Feeney, D.L. Patrick, “Measuring Health-Related Quality of Life,” Ann Intern Med., 118, 622–629 (1993).
NCBI	NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource
NCI	NCI Thesaurus
NIH	ClinicalTrials.gov
NIH	Declaration of Helsinki
NIH	Office of Science Policy
NIST	Data Encryption Standard (DES)
NIST	Guide to Protecting the Confidentiality of Personally Identifiable Information (PII)
NIST	Minimum Security Requirements for Multi-user Operating Systems
Office of the Privacy Commissioner of Canada	Privacy breaches

OMB	Office of Management and Budget (OMB) Circular A-119
PhUSE	PhUSE De-identification Standard for SDTM 3.2
TransCelerate BioPharma Inc.	Clinical Data Transparency
WHO	International Programme on Chemical Safety (IPCS)
WHO	Medical Devices
WHO	The World Health Organization Quality of Life (WHOQOL)

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