

Organization	Reference	URL
AHRQ	CHI (consolidated health informatics)	https://ushik.ahrq.gov/ViewItemDetails?&system=mdr&itemKey=74237000
AI Multiple	The Ultimate Guide to Synthetic Data in 2020, August 29, 2020	https://research.aimultiple.com/synthetic-data/
AMA	AMA Manual of Style	http://www.amamanualofstyle.com/
Applied Clinical Trials	Estimand Framework: What it is and Why You Need it. Applied Clinical Trials. February 27, 2020	https://www.appliedclinicaltrialsonline.com/view/estimand-framework-what-it-and-why-you-need-it
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BMJ	British Medical Journal, Epidemiology for the uninitiated, Chapter 8, Fifth Edition, BMJ Book 2004	https://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated/8-case-control-and-cross-sectional
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CDC	Principles of Epidemiology in Public Health Practice, Third Edition. An Introduction to Applied Epidemiology and Biostatistics, Lesson 3: Measures of Risk, CDC 2012	https://www.cdc.gov/csels/dsepd/ss1978/lesson3/section2.html#:~:text=Section%202%3A%20Morbidity%20Frequency%20Measures&text=Measures%20of%20morbidity%20frequency%20characterize,a%20given%20time%20(prev alence
CDC	Principles of Epidemiology in Public Health Practice, Third Edition. An Introduction to Applied Epidemiology and Biostatistics, Glossary, CDC 2014	https://www.cdc.gov/csels/dsepd/ss1978/glossary.html
CDC	How Flu Vaccine Effectiveness and Efficacy are Measured, Questions & Answers, CDC January 29, 2016	https://www.cdc.gov/flu/vaccines-work/effectivenessqa.htm
CDC	Principles of Epidemiology in Public Health Practice, Third Edition, An Introduction to Applied Epidemiology and Biostatistics, Oct 2006, Updated May 2012, US DHHS	https://stacks.cdc.gov/pdfjs/web/viewer.html?file=https://stacks.cdc.gov/view/cdc/6914/cdc_6914_DS1.pdf
CDISC	Clinical Data Interchange Standards Consortium	http://www.cdisc.org/
CIOMS	Glossary of ICH Terms and Definitions	https://cioms.ch/publications/product/glossary-of-ich-terms-and-definitions/
Clinical Research Manual: Practical Tools and Templates for Managing Clinical Research	Clinical Research Cavalieri Jennifer and Rupp Mark Clinical Research Manual: Practical Tools and Templates for Managing Clinical Research 336pp US\$44.95 Sigma Theta Tau 9781937554637 1937554635 [Formula: see text]. Nurs Manag (Harrow). 2014 Aug 28;21(5):13.	https://pubmed.ncbi.nlm.nih.gov/25167109/
CONSORT	CONSORT Statement	http://www.consort-statement.org/consort-2010
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Deep AI	DeepAI Definitions	https://deepai.org/definitions
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Department of Health and Social Care, UK	Prevention is better than the cure: Our vision to help you live well for longer. Department of Health and Social Care, UK. 05 November 2018	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/753688/Prevention_is_better_than_cure_5-11.pdf
EDQM	EDQM Standard Terms controlled vocabularies for pharmaceutical dose forms Version 1.2.0 2019. Internal controlled vocabularies for pharmaceutical dose forms. Version 1.2.0 - 28 January 2019.	https://www.edqm.eu/en/d/513701
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-medicines-agency-policy-publication-clinical-data
EMA	Guideline on good pharmacovigilance practices (GVP)	http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/09/WC500172402.pdf
EMA	Recommendations from the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014' dd 28 June 2017	https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_06_28_recommendation_on_axmps.pdf
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]	https://www.ema.europa.eu/documents/regulatory-procedural-guideline/reflection-paper-expectations-electronic-source-data-data-transcribed-electronic-data-collection_en.pdf

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EMA	EMA Glossary of regulatory terms	https://www.ema.europa.eu/en/about-us/about-website/glossary
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EMA	EMA Glossary of Regulatory terms	https://www.ema.europa.eu/en/glossary/label-use#:~:text=Off-label%20use%20%7C%20European%20Medicines%20Agency%20Home%20Glossary.unapproved%20age%20group%2C%20dosage%2C%20or%20route%20of%20administration.
EU	Directive 95/46/EC	https://publications.europa.eu/en/publication-detail/-/publication/335ef9fc-250a-4dfa-a76d-5583b689e91e/language-en/format-PDF/source-79725998
EU	Regulation (EU) 2017/745	https://publications.europa.eu/en/publication-detail/-/publication/83bdc18f-315d-11e7-9412-01aa75ed71a1/language-en/format-PDF/source-58036705
EU	Regulation EU No 536/2014 [EU CTR]	https://ec.europa.eu/health/human-use/clinical-trials/regulation_en
EU	REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC	https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf
EU	EU GDPR	https://gdpr.eu/
EU	Article 4 GDPR Definitions	https://gdpr-info.eu/art-4-gdpr/
EU EMA	Guideline on computerised systems and electronic data in clinical trials (europa.eu) EMA/INS/GCP/112288/2023	https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-and-electronic-data-clinical-trials_en.pdf?bcs-agent-scanner=76bbac43-e79c-254f-8ce8-685e2f03aed5
EUPATI	EUPATI Toolbox: Within-trial decisions: Unblinding and termination. 2023	https://toolbox.eupati.eu/resources/within-trial-decisions-unblinding-and-termination/#:~:text=Unblinding%20(Code%2Dbreaking).-What%20is%20unblinding&text=Unblinding%20occurs%20when%20that%20blind.treatment%20the%20participant%20is%20receiving
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FDA	21 CFR Part 11	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11
FDA	Acronyms and Abbreviations	https://www.accessdata.fda.gov/scripts/cder/acronyms/index.cfm
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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	https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126396.pdf
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FDA	Glossary of Terms	http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm
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HL7	Glossary of Terms	https://www.hl7.org/documentcenter/public/calendarofevents/FirstTime/Glossary%20of%20terms.pdf
HL7	Structured Product Labeling (SPL)	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=96
HMA	Medicines Approval system	http://www.hma.eu/medicinesapprovalsysteem.html
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USP	USP Nomenclature Guidelines (last revision on March 30, 2020)	https://www.usp.org/sites/default/files/usp/document/usp-nomenclature-guidelines.pdf
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WHO	Medical Devices	http://www.who.int/medical_devices/full_definition/en/
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WHO	Basic Epidemiology, R. Bonita and others, WHO 2006	https://apps.who.int/iris/bitstream/handle/10665/43541/9241547073_eng.pdf;sequence=1
WHO	After World Health Organisation, Health products policy and standards, INN and medicines classification	https://www.who.int/teams/health-product-and-policy-standards/inn
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