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/
Australian Bureau of Statistics	Statistical Language - What are Variables?, Australian Bureau of Statistics, October 2013	https://www.abs.gov.au/websitedbs/a3121120.nsf/home/statistical+language+-+what+are+variables#:~:text=A%20variable%20is%20any%20characteristics,be%20called%20a%20data%20item.&text=It%20is%20called%20a%20variable,change%20in%20value%20over%20time.
Australian National Data Service	Working with Data, Australian National Data Service, Accessed 9/4/2020	https://www.ands.org.au/working-with-data/data-management/data-capture
BMJ	British Medical Journal, Epidemiology for the uninitiated	https://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated/8-case-control-and-cross-sectional
CDC	What is Health Literacy? Oct 23, 2019	https://www.cdc.gov/healthliteracy/learn/index.html
CDISC	Clinical Data Interchange Standards Consortium	http://www.cdisc.org/
CONSORT	CONSORT Statement	http://www.consort-statement.org/consort-2010
CTTI (Clinical Trials Transformation Initiative)	CTTI Recommendations: Decentralized Clinical Trials, September 2018	https://www.ctti-clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/dct_recommendations_final.pdf
Deep AI	DeepAI Definitions	https://deepai.org/definitions
Deep AI	DeepAI Machine Learning Glossary and Terms	https://deepai.org/machine-learning-glossary-and-terms/deep-learning
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
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
EMA	Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007.	https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF
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
FDA	21 CFR 210.3	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3
FDA	21 CFR 3.2 (e) FAQ	https://www.fda.gov/combination-products/about-combination-products/frequently-asked-questions-about-combination-products
FDA	21 CFR 310.305	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=310.305
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 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	Acronyms and Abbreviations	https://www.accessdata.fda.gov/scripts/cder/acronyms/index.cfm
FDA	Adaptive Designs for Clinical Trials of Drugs and Biologics Guidance for Industry, FDA Nov 2019	https://www.fda.gov/media/78495/download

FDA	Biologics Guidances	http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm
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FDA	FDA Biological Product Definitions	https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf
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FDA	Guidance for Industry and Investigators Safety Reporting Requirements for INDs and BA/BE Studies	https://www.fda.gov/media/79394/download
FDA	Guidance for Industry Computerized Systems Used in Clinical Investigations, May 2007	https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070266.pdf
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FDA	Reviewer Guidance Evaluating the Risks of Drug Exposure in Human Pregnancies, April 2005	https://www.fda.gov/downloads/Drugs/Guidances/ucm071645.pdf
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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/medicinesapprovalsystem.html
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