

Organization	Reference	URL
AHRQ	CHI (consolidated health informatics)	<a href="https://ushik.ahrq.gov/ViewItemDetails?&amp;system=mdr&amp;itemKey=74237000">https://ushik.ahrq.gov/ViewItemDetails?&amp;system=mdr&amp;itemKey=74237000</a>
AI Multiple	The Ultimate Guide to Synthetic Data in 2020, August 29, 2020	<a href="https://research.aimultiple.com/synthetic-data/">https://research.aimultiple.com/synthetic-data/</a>
AMA	AMA Manual of Style	<a href="http://www.amamanualofstyle.com/">http://www.amamanualofstyle.com/</a>
Australian Bureau of Statistics	Statistical Language - What are Variables?, Australian Bureau of Statistics, October 2013	<a href="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.&amp;text=It%20is%20called%20a%20variable,change%20in%20value%20over%20time.">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.&amp;text=It%20is%20called%20a%20variable,change%20in%20value%20over%20time.</a>
Australian National Data Service	Working with Data, Australian National Data Service, Accessed 9/4/2020	<a href="https://www.andcs.org.au/working-with-data/data-management/data-capture">https://www.andcs.org.au/working-with-data/data-management/data-capture</a>
BMJ	British Medical Journal, Epidemiology for the uninitiated	<a href="https://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-">https://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-</a>
CDC	What is Health Literacy? Oct 23, 2019	<a href="https://www.cdc.gov/healthliteracy/learn/index.html">https://www.cdc.gov/healthliteracy/learn/index.html</a>
CDC	Principles of Epidemiology in Public Health Practice, Third Edition. An Introduction to Applied Epidemiology and Biostatistics, Lesson 3: Measures of Risk, CDC 2012	<a href="https://www.cdc.gov/csels/dsepd/ss1978/lesson3/section2.html#:~:text=Section%202%3A%20Morbidity%20Frequency%20Measures&amp;text=Measures%20of%20morbidity%20frequency%20characterize,a%20given%20time%20(prevalence">https://www.cdc.gov/csels/dsepd/ss1978/lesson3/section2.html#:~:text=Section%202%3A%20Morbidity%20Frequency%20Measures&amp;text=Measures%20of%20morbidity%20frequency%20characterize,a%20given%20time%20(prevalence</a>
CDC	Principles of Epidemiology in Public Health Practice, Third Edition. An Introduction to Applied Epidemiology and Biostatistics,	<a href="https://www.cdc.gov/csels/dsepd/ss1978/glossary.html">https://www.cdc.gov/csels/dsepd/ss1978/glossary.html</a>
CDC	How Flu Vaccine Effectiveness and Efficacy are Measured, Questions & Answers, CDC January 29, 2016	<a href="https://www.cdc.gov/flu/vaccines-work/effectivenessqa.htm">https://www.cdc.gov/flu/vaccines-work/effectivenessqa.htm</a>
CDISC	Clinical Data Interchange Standards	<a href="http://www.cdisc.org/">http://www.cdisc.org/</a>
CONSORT	CONSORT Statement	<a href="http://www.consort-statement.org/consort-2010">http://www.consort-statement.org/consort-2010</a>
CTTI (Clinical Trials Transformation Initiative)	CTTI Recommendations: Decentralized Clinical Trials, September 2018	<a href="https://www.ctti-clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/dct_recommendations_final.pdf">https://www.ctti-clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/dct_recommendations_final.pdf</a>
Deep AI	DeepAI Definitions	<a href="https://deepai.org/definitions">https://deepai.org/definitions</a>
Deep AI	DeepAI Machine Learning Glossary and Terms	<a href="https://deepai.org/machine-learning-glossary-and-terms/deep-learning">https://deepai.org/machine-learning-glossary-and-terms/deep-learning</a>
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	<a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/753688/Prevention_is_better_than_cure_5-11.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/753688/Prevention_is_better_than_cure_5-11.pdf</a>

EMA	External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use	<a href="https://www.ema.europa.eu/human-regulatory/marketing-authorisation/clinical-data-publication/support-industry/external-guidance-implementation-european">https://www.ema.europa.eu/human-regulatory/marketing-authorisation/clinical-data-publication/support-industry/external-guidance-implementation-european</a>
EMA	Guideline on good pharmacovigilance practices (GVP)	<a href="http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/09/WC500172402.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/09/WC500172402.pdf</a>
EMA	Recommendations from the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014' dd 28 June 2017	<a href="https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_06_28_recommendation_on_axmps.pdf">https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_06_28_recommendation_on_axmps.pdf</a>
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]	<a href="https://www.ema.europa.eu/documents/regulatory-procedural-guideline/reflection-paper-expectations-electronic-source-data-data-transcribed-electronic-data">https://www.ema.europa.eu/documents/regulatory-procedural-guideline/reflection-paper-expectations-electronic-source-data-data-transcribed-electronic-data</a>
EMA	Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007.	<a href="https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF">https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF</a>
EMA	ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March	<a href="https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-8-general-considerations-clinical-trials-step">https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-8-general-considerations-clinical-trials-step</a>
EMA	EMA Glossary of regulatory terms	<a href="https://www.ema.europa.eu/en/about-us/about-website/glossary">https://www.ema.europa.eu/en/about-us/about-website/glossary</a>
EU	Directive 95/46/EC	<a href="https://publications.europa.eu/en/publication-detail/-/publication/335ef9fc-250a-4dfa-a76d-5583b689e91e/language-en/format-PDF/source-79725998">https://publications.europa.eu/en/publication-detail/-/publication/335ef9fc-250a-4dfa-a76d-5583b689e91e/language-en/format-PDF/source-79725998</a>
EU	Regulation (EU) 2017/745	<a href="https://publications.europa.eu/en/publication-detail/-/publication/83bdc18f-315d-11e7-9412-01aa75ed71a1/language-en/format-PDF/source-58036705">https://publications.europa.eu/en/publication-detail/-/publication/83bdc18f-315d-11e7-9412-01aa75ed71a1/language-en/format-PDF/source-58036705</a>
EU	Regulation EU No 536/2014 [EU CTR]	<a href="https://ec.europa.eu/health/human-use/clinical-trials/regulation_en">https://ec.europa.eu/health/human-use/clinical-trials/regulation_en</a>
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	<a href="https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf">https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf</a>
FDA	21 CFR 210.3	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210</a>
FDA	21 CFR 3.2 (e) FAQ	<a href="https://www.fda.gov/combination-products/about-combination-products/frequently-asked-questions-about-combination-products">https://www.fda.gov/combination-products/about-combination-products/frequently-asked-questions-about-combination-products</a>
FDA	21 CFR 310.305	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=310">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=310</a>
FDA	21 CFR 312.42	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312</a>
FDA	21 CFR 803.3	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=80">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=80</a>
FDA	21 CFR 820.20	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=82">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=82</a>
FDA	21 CFR Part 11	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRP">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRP</a>

FDA	Acronyms and Abbreviations	<a href="https://www.accessdata.fda.gov/scripts/cder/acronyms/index.cfm">https://www.accessdata.fda.gov/scripts/cder/acronyms/index.cfm</a>
FDA	Adaptive Designs for Clinical Trials of Drugs and Biologics Guidance for Industry, FDA Nov	<a href="https://www.fda.gov/media/78495/download">https://www.fda.gov/media/78495/download</a>
FDA	Biologics Guidances	<a href="http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm">http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm</a>
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	<a href="https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126396.pdf">https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126396.pdf</a>
FDA	Electronic Submission File Formats and Specifications. Orientation and Best Practices For Data Formats and Submission To The Center For Tobacco Products. January 2018	<a href="https://www.fda.gov/media/110979/download">https://www.fda.gov/media/110979/download</a>
FDA	Emergency Use Authorization of Medical Products and Related Authorities. FDA Guidance for Industry and Other Stakeholders. January 2017.	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-</a>
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,	<a href="https://www.govinfo.gov/content/pkg/FR-2015-04-13/pdf/2015-08364.pdf">https://www.govinfo.gov/content/pkg/FR-2015-04-13/pdf/2015-08364.pdf</a>
FDA	FDA Biological Product Definitions	<a href="https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf">https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf</a>
FDA	FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency Guidance for Industry, Investigators, and Institutional Review Boards March 2020 Updated on July 2, 2020	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency</a>
FDA	FDA Guidance on Use of Electronic Health Record Data in Clinical Investigations Guidance for Industry, July 2018	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-health-record-data-clinical-investigations-guidance-">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-health-record-data-clinical-investigations-guidance-</a>
FDA	Finding and Learning about Side Effects (adverse reactions), July 2018	<a href="https://www.fda.gov/drugs/drug-information-consumers/finding-and-learning-about-side-effects-adverse-">https://www.fda.gov/drugs/drug-information-consumers/finding-and-learning-about-side-effects-adverse-</a>
FDA	Framework for FDA's Real World Evidence Pro	<a href="https://www.fda.gov/media/120060/download#targetText=FDA's%20RWE%20Program%20provides%20an,and%20strategies%20to%20address%20them.">https://www.fda.gov/media/120060/download#targetText=FDA's%20RWE%20Program%20provides%20an,and%20strategies%20to%20address%20them.</a>
FDA	General Principles of Software Validation; Final Guidance for Industry and FDA Staff	<a href="https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf">https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf</a>
FDA	Glossary of Terms	<a href="http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm">http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm</a>
FDA	Glossary Of Terms On Clinical Trials For Patient Engagement Advisory Committee Meeting	<a href="https://www.fda.gov/media/108378/download#:~:text=Enrollment,of%20answering%20the%20trial%20questions">https://www.fda.gov/media/108378/download#:~:text=Enrollment,of%20answering%20the%20trial%20questions</a>
FDA	Guidance for Industry Adaptive Designs for Clinical Trials of Drugs and Biologics,	<a href="https://www.fda.gov/downloads/drugs/guidances/ucm201790.pdf">https://www.fda.gov/downloads/drugs/guidances/ucm201790.pdf</a>

FDA	Guidance for Industry and Food and Drug Administration Staff Applying Human Factors and Usability Engineering to Medical Devices, February 2016	<a href="https://wayback.archive-it.org/7993/20190911173106/https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/applying-human-factors-and-usability-engineering-medical-devices-february-19-2016">https://wayback.archive-it.org/7993/20190911173106/https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/applying-human-factors-and-usability-engineering-medical-devices-february-19-2016</a>
FDA	Guidance for Industry and Investigators Safety Reporting Requirements for INDs and BA/BE	<a href="https://www.fda.gov/media/79394/download">https://www.fda.gov/media/79394/download</a>
FDA	Guidance for Industry Computerized Systems Used in Clinical Investigations, May 2007	<a href="https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070266.pdf">https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070266.pdf</a>
FDA	Guidance for Industry Electronic Source Data in Clinical Investigations, September 2013	<a href="https://www.fda.gov/downloads/drugs/guidancecomplianceinformation/guidances/ucm328691.pdf">https://www.fda.gov/downloads/drugs/guidancecomplianceinformation/guidances/ucm328691.pdf</a>
FDA	Guidance for Industry Exposure-Response Relationships - Study Design, Data Analysis, and Regulatory Applications, May 2003	<a href="https://www.fda.gov/downloads/drugs/guidancecomplianceinformation/guidances/ucm072109.pdf">https://www.fda.gov/downloads/drugs/guidancecomplianceinformation/guidances/ucm072109.pdf</a>
FDA	Guidance for Industry Part 11, Electronic Records; Electronic Signatures - Scope and Application, August 2003	<a href="http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf">http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf</a>
FDA	Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims,	<a href="http://www.fda.gov/downloads/Drugs/Guidances/UCM193282.pdf">http://www.fda.gov/downloads/Drugs/Guidances/UCM193282.pdf</a>
FDA	Guidance for Industry Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product, May	<a href="https://www.fda.gov/media/135612/download">https://www.fda.gov/media/135612/download</a>
FDA	Guidance for Industry, Use of Electronic Health Record Data in Clinical Investigations, July 2018	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-health-record-data-clinical-investigations-guidance-">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-health-record-data-clinical-investigations-guidance-</a>
FDA	Master Protocols: Efficient Clinical Trial Design Strategies To Expedite Development of Oncology Drugs and Biologics. Guidance for Industry. October 2018	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/master-protocols-efficient-clinical-trial-design-strategies-expedite-development-oncology-drugs-and">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/master-protocols-efficient-clinical-trial-design-strategies-expedite-development-oncology-drugs-and</a>
FDA	Medical Device Development Tools (MDDT)	<a href="https://www.fda.gov/MedicalDevices/ScienceandResearch/MedicalDeviceDevelopmentToolsMDDT/default.htm">https://www.fda.gov/MedicalDevices/ScienceandResearch/MedicalDeviceDevelopmentToolsMDDT/default.htm</a>
FDA	Multiple Endpoints in Clinical Trials, Draft Guidance for Industry, January 2017	<a href="https://www.fda.gov/media/102657/download">https://www.fda.gov/media/102657/download</a>
FDA	Patient-Focused Drug Development Glossary	<a href="https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm610317.htm">https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm610317.htm</a>
FDA	Plain Writing Act of 2010, FDA	<a href="https://www.fda.gov/media/84926/download">https://www.fda.gov/media/84926/download</a> ; <a href="https://www.fda.gov/about-fda/plain-writing-its-law/federal-plain-language-">https://www.fda.gov/about-fda/plain-writing-its-law/federal-plain-language-</a>
FDA	Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications Guidance for Industry. January 2019	<a href="https://www.fda.gov/media/120094/download">https://www.fda.gov/media/120094/download</a>
FDA	Reviewer Guidance Evaluating the Risks of Drug Exposure in Human Pregnancies, April	<a href="https://www.fda.gov/downloads/Drugs/Guidances/ucm071645.pdf">https://www.fda.gov/downloads/Drugs/Guidances/ucm071645.pdf</a>

FDA	Science & Research	<a href="http://wayback.archive-it.org/7993/20180907200008/https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf">http://wayback.archive-it.org/7993/20180907200008/https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf</a>
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	<a href="https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-bio-gen/documents/document/ucm589416.pdf?utm_campaign=Recently%20Posted%20Guidance%20Documents%203%2F29%2F2019&amp;utm_medium=email&amp;utm_source=biomail">https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-bio-gen/documents/document/ucm589416.pdf?utm_campaign=Recently%20Posted%20Guidance%20Documents%203%2F29%2F2019&amp;utm_medium=email&amp;utm_source=biomail</a>
FDA	Study Data Standards Resources	<a href="https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources">https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources</a>
FDA	Study Data Technical Conformance Guide, Technical Specifications Document, March 2019	<a href="https://www.fda.gov/media/122913/download">https://www.fda.gov/media/122913/download</a>
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	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices</a>
FDA	Long Term Follow-up After Administration of Human Gene Therapy Products. FDA Guidance for Industry. JANUARY 2020	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/long-term-follow-after-administration-human-gene-therapy-products">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/long-term-follow-after-administration-human-gene-therapy-products</a>
FDA	Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products. FDA GUIDANCE DOCUMENT. MAY 1998	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-clinical-evidence-effectiveness-human-drug-and-biological-products">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-clinical-evidence-effectiveness-human-drug-and-biological-products</a>
FDA	Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products. FDA Guidance for Industry (DRAFT GUIDANCE). December 2019	<a href="https://www.fda.gov/media/133660/download">https://www.fda.gov/media/133660/download</a>
FDA	Non-Inferiority Clinical Trials to Establish Effectiveness. FDA Guidance for Industry. November 2016	<a href="https://www.fda.gov/media/78504/download">https://www.fda.gov/media/78504/download</a>
FDA	FDA Guidance for industry end of Phase 2a meetings, September 2009	<a href="https://www.fda.gov/media/72211/download">https://www.fda.gov/media/72211/download</a>
FDA	21 CFR Part 312.21 Phases of an investigation	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=312.21&amp;SearchTerm=Phase">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=312.21&amp;SearchTerm=Phase</a>
FDA	Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products Draft Guidance for Industry.	<a href="https://www.fda.gov/media/133660/download">https://www.fda.gov/media/133660/download</a>
FDA	GUIDANCE DOCUMENT, E9 Statistical Principles for Clinical Trials, SEPTEMBER 1998	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e9-statistical-principles-clinical-trials;">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e9-statistical-principles-clinical-trials;</a> <a href="https://www.fda.gov/media/71336/download">https://www.fda.gov/media/71336/download</a>
FDA	FDA Draft Guidance, Meta-Analyses of Randomized Controlled Clinical Trials to Evaluate the Safety of Human Drugs or Biological Products Guidance for Industry,	<a href="https://www.fda.gov/media/117976/download">https://www.fda.gov/media/117976/download</a>



FDA	FDA Webpage Postmarketing Requirements and Commitments: Introduction, 01/12/2016	<a href="https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-">https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-</a>
FDA	FDA Draft Guidance, Data Standards for Drug and Biological Product Submissions Containing Real-World Data, OCTOBER 2021	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-drug-and-biological-product-submissions-containing-real-world-data">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-drug-and-biological-product-submissions-containing-real-world-data</a>
FDA	BEST Resource Taxonomy, FDA 07/23/2018	<a href="https://www.fda.gov/drugs/development-resources/best-resource-taxonomy">https://www.fda.gov/drugs/development-resources/best-resource-taxonomy</a>
HHS	HIPAA	<a href="https://www.hhs.gov/hipaa/index.html">https://www.hhs.gov/hipaa/index.html</a>
HHS	Guidance on Withdrawal of Subjects from Research: Data Retention and Other Related Issues, September 21, 2010	<a href="https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/subjectwithdrawal.pdf">https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/subjectwithdrawal.pdf</a>
HL7	Glossary of Terms	<a href="https://www.hl7.org/documentcenter/public/calendarofevents/FirstTime/Glossary%20of%20terms.pdf">https://www.hl7.org/documentcenter/public/calendarofevents/FirstTime/Glossary%20of%20terms.pdf</a>
HL7	Structured Product Labeling (SPL)	<a href="http://www.hl7.org/implement/standards/product_brief.cfm?product_id=96">http://www.hl7.org/implement/standards/product_brief.cfm?product_id=96</a>
HMA	Medicines Approval system	<a href="http://www.hma.eu/medicinesapprovalsystem.html">http://www.hma.eu/medicinesapprovalsystem.html</a>
HyperStat	Online Glossary	<a href="http://davidmlane.com/hyperstat/glossary.html">http://davidmlane.com/hyperstat/glossary.html</a>
ICH	Efficacy Guidelines	<a href="https://www.ich.org/page/efficacy-guidelines">https://www.ich.org/page/efficacy-guidelines</a>
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	<a href="http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf">http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf</a>
IMI	IMI-GetReal Glossary Workgroup, 2016 GetReal - Project No. 115546, WP1: Deliverable D1.3	<a href="https://www.imi-getreal.eu/Portals/1/Documents/01%20Deliverables/D1.3%20-%20Revised%20GetReal%20glossary%20-%20FINAL%20updated%20version_25">https://www.imi-getreal.eu/Portals/1/Documents/01%20Deliverables/D1.3%20-%20Revised%20GetReal%20glossary%20-%20FINAL%20updated%20version_25</a>
Institute for Work and Health	Primary, Secondary, and Tertiary Prevention, Institute for Work and Health, Published: April 2015	<a href="https://www.iwh.on.ca/what-researchers-mean-by/primary-secondary-and-tertiary-prevention">https://www.iwh.on.ca/what-researchers-mean-by/primary-secondary-and-tertiary-prevention</a>
ISO	Health informatics -- Pseudonymization	<a href="https://www.iso.org/standard/63553.html">https://www.iso.org/standard/63553.html</a>
ISO	ISO 11238 2018-07 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated	<a href="https://www.iso.org/standard/69697.html">https://www.iso.org/standard/69697.html</a>
ISO	ISO 11615 2017-10 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated	<a href="https://www.iso.org/standard/70150.html">https://www.iso.org/standard/70150.html</a>
ISO	Software engineering -- Guidelines for the application of ISO 9001:2000 to computer	<a href="https://www.iso.org/standard/35867.html">https://www.iso.org/standard/35867.html</a>
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MedDRA	Medical Dictionary for Regulatory Activities	<a href="https://www.meddra.org/">https://www.meddra.org/</a>

MHRA	Guidance: Medical device stand-alone software including apps	<a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/717865/Software_flow_chart_Ed_1-05.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/717865/Software_flow_chart_Ed_1-05.pdf</a>
MHRA	GxP Data Integrity Guidance and Definitions, March 2018	<a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/687246/MHRA_GxP_data_integrity_guide_March_edited_Final.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/687246/MHRA_GxP_data_integrity_guide_March_edited_Final.pdf</a>
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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).	<a href="https://doi.org/10.1016/j.cct.2016.09.003">https://doi.org/10.1016/j.cct.2016.09.003</a>
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-Reported Outcomes (PRO) Harmonization Group meeting at the Food and Drug Administration, February 16,	<a href="https://www.ncbi.nlm.nih.gov/pubmed/14627058">https://www.ncbi.nlm.nih.gov/pubmed/14627058</a>
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NCBI	Biomarkers Definitions Working Group. Biomarkers and surrogate endpoints: preferred definitions and conceptual framework. Clin Pharmacol Ther. 2001 Mar;69(3):89-95.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/11240971">https://www.ncbi.nlm.nih.gov/pubmed/11240971</a>
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NCBI	NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource	<a href="https://www.ncbi.nlm.nih.gov/books/NBK338448/">https://www.ncbi.nlm.nih.gov/books/NBK338448/</a>
NCI	NCI Thesaurus	<a href="https://ncit.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&amp;version=19.11d&amp;ns=ncit&amp;code=C103180&amp;key=1599980774&amp;b=1&amp;n=null">https://ncit.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&amp;version=19.11d&amp;ns=ncit&amp;code=C103180&amp;key=1599980774&amp;b=1&amp;n=null</a>
NHS	What are side effects?, August 2018	<a href="https://www.nhs.uk/common-health-questions/medicines/what-are-side-">https://www.nhs.uk/common-health-questions/medicines/what-are-side-</a>
NIH	ClinicalTrials.gov	<a href="https://clinicaltrials.gov/">https://clinicaltrials.gov/</a>
NIH	Office of Science Policy	<a href="https://osp.od.nih.gov/clinical-research/clinical-trials/">https://osp.od.nih.gov/clinical-research/clinical-trials/</a>
NIH	Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual: Premature Termination or Suspension of a Clinical Trial, 19 January 2021	<a href="https://www.niaid.nih.gov/sites/default/files/score-premature-termination-or-suspension-of-clinical-trial.pdf">https://www.niaid.nih.gov/sites/default/files/score-premature-termination-or-suspension-of-clinical-trial.pdf</a>
NIST	Data Encryption Standard (DES)	<a href="https://csrc.nist.gov/publications/detail/fips/46/3/archive/1999-10-25">https://csrc.nist.gov/publications/detail/fips/46/3/archive/1999-10-25</a>
NIST	Guide to Protecting the Confidentiality of Personally Identifiable Information (PII)	<a href="https://csrc.nist.gov/publications/detail/sp/800-122/final">https://csrc.nist.gov/publications/detail/sp/800-122/final</a>
NIST	Minimum Security Requirements for Multi-user Operating Systems	<a href="https://csrc.nist.gov/csrc/media/publications/nistir/5153/final/documents/ir5153.tx">https://csrc.nist.gov/csrc/media/publications/nistir/5153/final/documents/ir5153.tx</a>
Office of the Privacy Commissioner of Canada	Privacy breaches	<a href="https://www.priv.gc.ca/en/privacy-topics/privacy-breaches/">https://www.priv.gc.ca/en/privacy-topics/privacy-breaches/</a>
OMB	Office of Management and Budget (OMB) Circular A-119	<a href="https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-119-">https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-119-</a>
PhUSE	PhUSE De-identification Standard for SDTM 3.2	<a href="http://www.phuse.eu/Data_Transparency_access.aspx">http://www.phuse.eu/Data_Transparency_access.aspx</a>
Publication	Russell Katz, Biomarkers and Surrogate Markers: An FDA Perspective, NeuroRx. 2004	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC534924/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC534924/</a>
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TransCelerate BioPharma Inc.	Clinical Data Transparency	<a href="http://www.transceleratebiopharmainc.com/assets/clinical-data-transparency/">http://www.transceleratebiopharmainc.com/assets/clinical-data-transparency/</a>



US Federal Government	FDAAA	<a href="https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-amendments-act-fdaaa-2007">https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-amendments-act-fdaaa-2007</a>
W3C	W3C Extensible Markup Language (XML)	<a href="https://www.w3.org/XML">https://www.w3.org/XML</a>
WHO	International Programme on Chemical Safety (IPCS)	<a href="http://www.who.int/ipcs/about_ipcs/coordinator_report.pdf">http://www.who.int/ipcs/about_ipcs/coordinator_report.pdf</a>
WHO	Medical Devices	<a href="http://www.who.int/medical_devices/full_definition/en/">http://www.who.int/medical_devices/full_definition/en/</a>
WHO	The World Health Organization Quality of Life (WHOQOL)	<a href="http://www.who.int/mental_health/publications/whogol/en/">http://www.who.int/mental_health/publications/whogol/en/</a>
WHO	Basic Epidemiology, R. Bonita and others, WHO 2006	<a href="https://apps.who.int/iris/bitstream/handle/10665/43541/9241547073_eng.pdf;seq">https://apps.who.int/iris/bitstream/handle/10665/43541/9241547073_eng.pdf;seq</a>
WMA	Declaration of Helsinki	<a href="https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/">https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/</a>







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