

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>
Applied Clinical Trials	Estimand Framework: What it is and Why You Need it. Applied Clinical Trials. February 27, 2020	<a href="https://www.appliedclinicaltrials.com/view/estimand-framework-what-it-and-why-you-need-it">https://www.appliedclinicaltrials.com/view/estimand-framework-what-it-and-why-you-need-it</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.ands.org.au/working-with-data/data-management/data-capture">https://www.ands.org.au/working-with-data/data-management/data-capture</a>
Biomchem Med	McHugh ML. Power analysis in research. Biochem Med (Zagreb). 2008;18:263-274	
BMJ	British Medical Journal, Epidemiology for the uninitiated	<a href="https://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated/8-case-control-and-cross-sectional">https://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated/8-case-control-and-cross-sectional</a>
BMJ	British Medical Journal, Epidemiology for the uninitiated, Chapter 8, Fifth Edition, BMJ Book 2004	<a href="https://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated/8-case-control-and-cross-sectional">https://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated/8-case-control-and-cross-sectional</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(prev">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(prev</a>
CDC	Principles of Epidemiology in Public Health Practice, Third Edition. An Introduction to Applied Epidemiology and Biostatistics, Glossary, CDC 2014	<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>
CDC	Principles of Epidemiology in Public Health Practice, Third Edition, An Introduction to Applied Epidemiology and Biostatistics, Oct 2006, Updated May 2012, US DHHS	<a href="https://stacks.cdc.gov/pdfjs/web/viewer.html?file=https://stacks.cdc.gov/view/cdc/6914/cdc_6914_DS1.pdf">https://stacks.cdc.gov/pdfjs/web/viewer.html?file=https://stacks.cdc.gov/view/cdc/6914/cdc_6914_DS1.pdf</a>
CDISC	Clinical Data Interchange Standards Consortium	<a href="http://www.cdisc.org/">http://www.cdisc.org/</a>
CIOMS	Glossary of ICH Terms and Definitions	<a href="https://cioms.ch/publications/product/glossary-of-ich-terms-and-definitions/">https://cioms.ch/publications/product/glossary-of-ich-terms-and-definitions/</a>
Clinical Research Manual: Practical Tools and Templates for Managing Clinical Research	Clinical Research Manual: Practical Tools and Templates for Managing 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.	<a href="https://pubmed.ncbi.nlm.nih.gov/25167109/">https://pubmed.ncbi.nlm.nih.gov/25167109/</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>
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.	<a href="https://www.edqm.eu/en/d/513701">https://www.edqm.eu/en/d/513701</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-medicines-agency-policy-publication-clinical-data">https://www.ema.europa.eu/human-regulatory/marketing-authorisation/clinical-data-publication/support-industry/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data</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-collection_en.pdf">https://www.ema.europa.eu/documents/regulatory-procedural-guideline/reflection-paper-expectations-electronic-source-data-data-transcribed-electronic-data-collection_en.pdf</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 1998	<a href="https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-8-general-considerations-clinical-trials-step-5_en.pdf">https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-8-general-considerations-clinical-trials-step-5_en.pdf</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>
EMA	EMA NOTE FOR GUIDANCE ON STATISTICAL PRINCIPLES FOR CLINICAL TRIALS, September 1998	<a href="https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-9-statistical-principles-clinical-trials-step-5_en.pdf">https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-9-statistical-principles-clinical-trials-step-5_en.pdf</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>
EMA	EMA Glossary of Regulatory terms	<a href="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.">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.</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>
EU	EU GDPR	<a href="https://gdpr.eu/">https://gdpr.eu/</a>
EU EMA	Guideline on computerised systems and electronic data in clinical trials (europa.eu) EMA/INS/GCP/112288/2023	<a href="https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-and-electronic-data-clinical-trials_en.pdf?hcs-agent-scanner=76bbac43-e79c-254f-8ce8-685e2f03aed5">https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-and-electronic-data-clinical-trials_en.pdf?hcs-agent-scanner=76bbac43-e79c-254f-8ce8-685e2f03aed5</a>
EUPATI	EUPATI Toolbox: Within-trial decisions: Unblinding and termination. 2023	<a href="https://toolbox.eupati.eu/resources/within-trial-decisions-unblinding-and-termination/#:~:text=Unblinding%20(Code%2Dbreaking),-What%20is%20unblinding&amp;text=Unblinding%20occurs%20when%20that%20blind,treatment%20the%20participant%20is%20receiving">https://toolbox.eupati.eu/resources/within-trial-decisions-unblinding-and-termination/#:~:text=Unblinding%20(Code%2Dbreaking),-What%20is%20unblinding&amp;text=Unblinding%20occurs%20when%20that%20blind,treatment%20the%20participant%20is%20receiving</a>
FDA	21 CFR 210.3	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3</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=310.305">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=310.305</a>
FDA	21 CFR 312.42	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.42">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.42</a>
FDA	21 CFR 803.3	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=803.3">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=803.3</a>
FDA	21 CFR 820.20	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=820.20">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=820.20</a>
FDA	21 CFR Part 11	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11</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 2019	<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-related-authorities">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities</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, April 2015	<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-industry">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-health-record-data-clinical-investigations-guidance-industry</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-reactions">https://www.fda.gov/drugs/drug-information-consumers/finding-and-learning-about-side-effects-adverse-reactions</a>
FDA	Framework for FDA's Real World Evidence Program. December 2018	<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, November 2019	<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 Studies	<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/guidancecomplianceandregulatoryinformation/guidances/ucm328691.pdf">https://www.fda.gov/downloads/drugs/guidancecomplianceandregulatoryinformation/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/guidancecomplianceandregulatoryinformation/guidances/ucm072109.pdf">https://www.fda.gov/downloads/drugs/guidancecomplianceandregulatoryinformation/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, December 2009	<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 2019	<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-industry">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-health-record-data-clinical-investigations-guidance-industry</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-guidelines">https://www.fda.gov/about-fda/plain-writing-its-law/federal-plain-language-guidelines</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 2005	<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=Eloqua">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=Eloqua</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/cfcfr/CFRSearch.cfm?fr=312.21&amp;SearchTerm=Phase">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/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. December 2019	<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, November 2018	<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-and-commitments">https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments</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	<a href="https://www.fda.gov/drugs/development-resources/best-resource-taxonomy;">https://www.fda.gov/drugs/development-resources/best-resource-taxonomy;</a> <a href="https://www.ncbi.nlm.nih.gov/books/NBK338448/">https://www.ncbi.nlm.nih.gov/books/NBK338448/;</a> <a href="https://www.fda.gov/drugs/development-resources/best-resource-taxonomy">https://www.fda.gov/drugs/development-resources/best-resource-taxonomy</a>
FDA	FDA Guidance: Expansion Cohorts: Use in First-in-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics Guidance for Industry. March 2022	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expansion-cohorts-use-first-human-clinical-trials-expedite-development-oncology-drugs-and-biologics">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expansion-cohorts-use-first-human-clinical-trials-expedite-development-oncology-drugs-and-biologics</a>
FDA	45 CFR 63.32	<a href="https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-63/subpart-C/section-63.32">https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-63/subpart-C/section-63.32</a>
FDA	FDA Glossary of Terms	<a href="https://www.fda.gov/patients/clinical-trials-what-patients-need-know/glossary-terms#D-1">https://www.fda.gov/patients/clinical-trials-what-patients-need-know/glossary-terms#D-1</a>
FDA	FDA GLOSSARY OF TERMS ON CLINICAL TRIALS FOR PATIENT ENGAGEMENT ADVISORY COMMITTEE MEETING	<a href="https://www.fda.gov/media/108378/download">https://www.fda.gov/media/108378/download</a>
FDA	What is Gene Therapy?, US FDA, 07/25/2018	<a href="https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy">https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy</a>
FDA	FDA Best Practices in Developing Proprietary Names for Human Prescription Drug Products, Guidance for Industry, December 2020	<a href="https://www.fda.gov/media/88496/download">https://www.fda.gov/media/88496/download</a>
FDA	US FDA, 21 CFR 299.4	<a href="https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-299/subpart-A/section-299.4">https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-299/subpart-A/section-299.4</a>
FDA	After US FDA, Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics Guidance for Industry, 2022	<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>
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/medicinesapprovalsysteem.html">http://www.hma.eu/medicinesapprovalsysteem.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>
ICH	ICH E9 R1 Addendum	<a href="https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e9-r1-addendum-estimands-sensitivity-analysis-clinical-trials-guideline-statistical-principles_en.pdf">https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e9-r1-addendum-estimands-sensitivity-analysis-clinical-trials-guideline-statistical-principles_en.pdf</a>
ICH	ICH E6(R2) Glossary	<a href="https://collections.nlm.nih.gov/catalog.nlm.nih.gov/uid-101734075-pdf">https://collections.nlm.nih.gov/catalog.nlm.nih.gov/uid-101734075-pdf</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 2014	<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_25Oct16_webversion.pdf">https://www.imi-getreal.eu/Portals/1/Documents/01%20deliverables/D1.3%20-%20Revised%20GetReal%20glossary%20-%20FINAL%20Updated%20version_25Oct16_webversion.pdf</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>
International Committee of Medical Journal Editors	ICMJE Recommendations	<a href="https://icmje.org/recommendations/">https://icmje.org/recommendations/</a>
IOM	National Academies of Sciences, Institute of Medicine. Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk. Washington, DC: National Academies Press, 2015, accessed 2022-09-0	<a href="https://nap.nationalacademies.org/catalog/18998/sharing-clinical-trial-data-maximizing-benefits-minimizing-risk">https://nap.nationalacademies.org/catalog/18998/sharing-clinical-trial-data-maximizing-benefits-minimizing-risk</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 information on substances	<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 medicinal product information	<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 software	<a href="https://www.iso.org/standard/35867.html">https://www.iso.org/standard/35867.html</a>
Kaplan, A; Haenlein, M (1 January 2019) Business Horizons	Kaplan, Andreas; Haenlein, Michael (1 January 2019). "Siri, Siri, in my hand: Who's the fairest in the land? On the interpretations, illustrations, and implications of artificial intelligence". Business Horizons. 62 (1): 15–25.	<a href="https://www.sciencedirect.com/science/article/pii/S0007681318301393?via%3DIihub">https://www.sciencedirect.com/science/article/pii/S0007681318301393?via%3DIihub</a>
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>
MSD Manual	Drug Interactions, By Shalini S. Lynch, PharmD, University of California San Francisco School of Pharmacy, Reviewed/Revised Jul 2022	<a href="https://www.msmanuals.com/professional/clinical-pharmacology/factors-affecting-response-to-drugs/drug-interactions">https://www.msmanuals.com/professional/clinical-pharmacology/factors-affecting-response-to-drugs/drug-interactions</a>
Multiple	Goldoni and Johnson, 2007; Ciraci et al 2014	
n/a	D.L. Patrick, "Patient-Reported Outcomes (PROs): An Organizing Tool for Concepts, Measures, and Applications," MAPI Quality of Life News Letter, 31, 1–5 (2003).	<a href="https://www.researchgate.net/publication/228734069_Patient-reported_outcomes_PROs_An_organizing_tool_for_concepts_measures_and_applications">https://www.researchgate.net/publication/228734069_Patient-reported_outcomes_PROs_An_organizing_tool_for_concepts_measures_and_applications</a>
n/a	Finkel, R, Clark, M. A., Champe, P. C. & Cubeddu, L. X. (eds) Lippincott's Illustrated Reviews: Pharmacology 4th edn (Lippincott Williams & Wilkins, 2008).	n/a
n/a	Glossary for Healthcare Standards, W.E. Hammond, 1995	n/a
n/a	L. Huber, "In Search of Standard Definitions for Validation, Qualification, Verification and Calibration," BioPharm, 12 (4) 56–58 (1999).	n/a
n/a	M.L. Schuyl and T. Engel, "A Review of the Source Document Verification Process in Clinical Trials," DIA Journal, 33, 789–797 (1999).	<a href="https://journals.sagepub.com/doi/abs/10.1177/009286159502900431?journalCode=dijb">https://journals.sagepub.com/doi/abs/10.1177/009286159502900431?journalCode=dijb</a>
n/a	Rubio DM, Schoenbaum EE, Lee LS, Schteingart DE, Marantz PR, Anderson KE, Platt LD, Baez A, Esposito K. Defining translational research: implications for training. Acad Med. 2010 Mar;85(3):470-5.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/20182120">https://www.ncbi.nlm.nih.gov/pubmed/20182120</a>
n/a	Song JW, Chung KC. Observational studies: cohort and case-control studies. Plast Reconstr Surg. 2010 Dec;126(6):2234-42.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/20697313">https://www.ncbi.nlm.nih.gov/pubmed/20697313</a>
n/a	Woodcock J, LaVange LM. Master Protocols to Study Multiple Therapies, Multiple Diseases, or Both. N Engl J Med. 2017 Jul 6;377(1):62-70.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/28679092">https://www.ncbi.nlm.nih.gov/pubmed/28679092</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).	<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, 2001. Value Health. 2003 Sep-Oct;6(5):522-31.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/14627058">https://www.ncbi.nlm.nih.gov/pubmed/14627058</a>
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.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/11304107">https://www.ncbi.nlm.nih.gov/pubmed/11304107</a>
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>
NCBI	G.H. Guyatt, D.H. Feeney, D.L. Patrick, "Measuring Health-Related Quality of Life," Ann Intern Med., 118, 622–629 (1993).	<a href="https://www.ncbi.nlm.nih.gov/pubmed/8452328">https://www.ncbi.nlm.nih.gov/pubmed/8452328</a>

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=nu">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=nu</a>
NCI	NCI's Dictionary of Cancer Terms	<a href="https://www.cancer.gov/publications/dictionaries/cancer-terms">https://www.cancer.gov/publications/dictionaries/cancer-terms</a>
NCI-EVS	NCI	<a href="https://evsexplore.semantics.cancer.gov/evsexplore/welcome">https://evsexplore.semantics.cancer.gov/evsexplore/welcome</a>
NHS	What are side effects?, August 2018	<a href="https://www.nhs.uk/common-health-questions/medicines/what-are-side-effects/">https://www.nhs.uk/common-health-questions/medicines/what-are-side-effects/</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>
NIH	<a href="https://grants.nih.gov/policy/clinical-trials/protocol-template.htm">https://grants.nih.gov/policy/clinical-trials/protocol-template.htm</a>	<a href="https://grants.nih.gov/policy/clinical-trials/protocol-template.htm">https://grants.nih.gov/policy/clinical-trials/protocol-template.htm</a>
NIH	Patient Recruitment Healthy Volunteer, NIH Clinical Center, 05/18/2022, Webpage accessed 2023-03-30	<a href="https://www.cc.nih.gov/recruit/volunteers.html">https://www.cc.nih.gov/recruit/volunteers.html</a>
NIH	CTCAE	<a href="https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm">https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm</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.txt">https://csrc.nist.gov/csrc/media/publications/nistir/5153/final/documents/ir5153.txt</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-119-1.pdf">https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-119-1.pdf</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 Apr;1(2):189-95.	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC534924/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC534924/</a>
S.H.Park, et al. In Situ Tissue Regeneration: Host Cell Recruitment and Biomaterial Design. Chapter 12. 2016	Chapter 12 - Functionalized Polymeric Biomaterials for In Situ Tissue Regeneration. S.H.Park, B.K.Lee, M.S.Kim. In Situ Tissue Regeneration, Host Cell Recruitment and Biomaterial Design. 2016, Pages 215-228	<a href="https://www.sciencedirect.com/science/article/pii/B978012802225200012X">https://www.sciencedirect.com/science/article/pii/B978012802225200012X</a>
SOCRA	SOCRA	<a href="https://www.socra.org/resources-and-faq/key-competencies/">https://www.socra.org/resources-and-faq/key-competencies/</a>
Statistics in Medicine	Discussion in Peter B. Gilbert. SOME DESIGN ISSUES IN PHASE 2B VERSUS PHASE 3 PREVENTION TRIALS FOR TESTING EFFICACY OF PRODUCTS OR CONCEPTS. Stat Med. 2010 May 10; 29(10): 1061-1071.	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2929839/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2929839/</a>
StatPearls	Shreffler J, Huecker MR. Hypothesis Testing, P Values, Confidence Intervals, and Significance. [Updated 2023 Mar 13]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: <a href="https://www.ncbi.nlm.nih.gov/books/NBK557421/">https://www.ncbi.nlm.nih.gov/books/NBK557421/</a>	<a href="https://www.ncbi.nlm.nih.gov/books/NBK557421/">https://www.ncbi.nlm.nih.gov/books/NBK557421/</a>
STROBE	<a href="http://www.strobe-statement.org">www.strobe-statement.org</a>	<a href="http://www.strobe-statement.org">www.strobe-statement.org</a>
Tetrascience	Tetrascience ALCOA++ principles for data integrity Fact Sheet	<a href="https://go.tetrascience.com/rs/152-SBL-014/images/Data-Integrity-Fact-Sheet.pdf">https://go.tetrascience.com/rs/152-SBL-014/images/Data-Integrity-Fact-Sheet.pdf</a>
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>
UK MHRA	MHRA GXP Data Integrity Guidance and Defintions, Revision 1, March 2018	<a href="https://www.gov.uk/government/publications/guidance-on-gxp-data-integrity">https://www.gov.uk/government/publications/guidance-on-gxp-data-integrity</a>
UK MHRA	MHRA GXP Data Integrity Guidance and Defintions, Revision 1, March 2018	<a href="https://www.gov.uk/government/publications/guidance-on-gxp-data-integrity">https://www.gov.uk/government/publications/guidance-on-gxp-data-integrity</a>
US FDA	FDA 21 CFR Part 11	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11</a>
US FDA	US FDA 21 CFR 50.20	<a href="https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50/subpart-B/section-50.20">https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50/subpart-B/section-50.20</a>
US FDA	US FDA (CDER) guidance, New Chemical Entity Exclusivity Determinations for Certain Fixed Combination Drug Products Guidance for Industry, October 2014	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/new-chemical-entity-exclusivity-determinations-certain-fixed-combination-drug-products">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/new-chemical-entity-exclusivity-determinations-certain-fixed-combination-drug-products</a>
US FDA	US FDA. (04/08/2024). Novel Drug Approvals at FDA. Retrieved from URL <a href="https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda#:~:text=Certain%20drugs%20are%20classified%20as%20new%20molecular%20entities,products%20frequently%20provide%20important%20new%20therapies%20for%20patients.%20Webpage%20access%202024/04/18">https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda#:~:text=Certain%20drugs%20are%20classified%20as%20new%20molecular%20entities,products%20frequently%20provide%20important%20new%20therapies%20for%20patients.%20Webpage%20access%202024/04/18</a>	<a href="https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda#:~:text=Certain%20drugs%20are%20classified%20as%20new%20molecular%20entities,products%20frequently%20provide%20important%20new%20therapies%20for%20patients.%20Webpage%20access%202024/04/18">https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda#:~:text=Certain%20drugs%20are%20classified%20as%20new%20molecular%20entities,products%20frequently%20provide%20important%20new%20therapies%20for%20patients.%20Webpage%20access%202024/04/18</a>
US FDA	US FDA, Evaluation of Therapeutic Equivalence, Draft Guidance for Industry, July 2022	<a href="https://www.fda.gov/media/160054/download">https://www.fda.gov/media/160054/download</a>

US FDA	US FDA, Evaluation of Therapeutic Equivalence, Draft Guidance for Industry, July 2022	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-therapeutic-equivalence">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-therapeutic-equivalence</a>
US FDA	US FDA (CDER) guidance, New Chemical Entity Exclusivity Determinations for Certain Fixed Combination Drug Products Guidance for Industry, October 2014	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/new-chemical-entity-exclusivity-determinations-certain-fixed-combination-drug-products">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/new-chemical-entity-exclusivity-determinations-certain-fixed-combination-drug-products</a>
US FDA	FDA Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans, Final Rule Sept 2010	<a href="https://www.govinfo.gov/content/pkg/FR-2010-09-29/pdf/2010-24296.pdf">https://www.govinfo.gov/content/pkg/FR-2010-09-29/pdf/2010-24296.pdf</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>
USP	USP Nomenclature Guidelines (last revision on March 30, 2020)	<a href="https://www.usp.org/sites/default/files/usp/document/usp-nomenclature-guidelines.pdf">https://www.usp.org/sites/default/files/usp/document/usp-nomenclature-guidelines.pdf</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;sequence=1">https://apps.who.int/iris/bitstream/handle/10665/43541/9241547073_eng.pdf;sequence=1</a>
WHO	After World Health Organisation, Health products policy and standards, INN and medicines classification	<a href="https://www.who.int/teams/health-product-and-policy-standards/inn">https://www.who.int/teams/health-product-and-policy-standards/inn</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>