Tool Name	Section	Tool	Relevance	Year	RD/Paediatric specific?	Type
Cochrane PICO search	Define a question	https://www.cochranelibrary.com/about/pico-search	PICO searchBETA allows you to use PICO terms to find the Cochrane Reviews most relevant to your healthcare question. In particular, it allows you to find reviews in which a term is used specifically as a population, an intervention, a comparison, or an outcome.	2020	NO	Search tool
ICH General considerations for clinical studies E8	Develop a protocol	https://database.ich.org/sites/default/files/E8_Guideline.pdf	Describe internationally accepted principles and practices in the conduct of both individual clinical trials and overall development strategy for new medical products	1997	NO	Guideline
ICH General principles for planning and design of multi-regional clinical trials	Develop a protocol	https://database.ich.org/sites/default/files/E17EWG_Step4_2017_1116.pdf	Describe general principals for the planning and design of randomised multinational clinical trials with the aim of increasing its acceptability in global regulatory submissions	2017	NO	Guideline
ICH Clinical investigation of medicinal products in the paediatric population E11 (R1)	Develop a protocol	https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e11r1-guideline-clinical-investigation-medicinal-products-pediatric-population-revision-1_en.pdf	Provides an outline of critical issues in pediatric drug development and approaches to the safe, efficient, and ethical study of medicinal products in the pediatric population. The purpose of this addendum is to complement and provide clarification and current regulatory perspective on topics in pediatric drug development.	2017	YES	Guideline
European Medicines Agency Guidance for	Develop a protocol	https://www.ema.europa.eu/en/documents/regulatory-procedural-	This guidance document addresses a number of questions that users	2020	NO	Guideline

Applicants seeking scientific advice and protocol assistance		guideline/european-medicines-agency-guidance-applicants-seeking-scientific-advice-protocol-assistance_en.pdf	of the scientific advice or protocol assistance procedures may have. It provides an overview of the procedure to obtain scientific advice or protocol assistance and gives guidance to Applicants in preparing their request. This guidance document also explains the scope and nature of scientific advice and protocol assistance. It will enable Applicants to submit requests which are in line with Scientific Advice Working Party (SAWP) requirements and which can be validated and evaluated quickly and efficiently.			
IRDiRC E104 Building Block (National Member State Scientific Advice)	Develop a protocol	https://irdirc.org/wp-content/uploads/2020/03/ODDG_TF_Building-Block-Form_E104.pdf	Procedures set up by many (but not all) National Member State to offer scientific advice to developers of new medicines. The procedures can be similar but often less formal than for CHMP scientific advice/protocol assistance at the EMA; they may include written advice and/or face-to-face meetings. The procedures are not limited only to orphan product development and may vary between Member States.	2020	NO	Guideline
IRDiRC Building block_ Alternative designs for small population clinical trials	Develop a protocol	https://irdirc.org/wp-content/uploads/2020/03/ODDG_TF_Building-Block-Form_I421.pdf	General recommendations to select the most efficient study design for each medical condition or trial and on potential adaptations of conventional designs to the low sample size scenario	2020	YES	Guideline

EMA Guideline on clinical trials in small populations	Develop a protocol	https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-clinical-trials-small-populations_en.pdf	This Guideline considers problems associated with clinical trials when there are limited numbers of patients available to study. It has been prepared by the CHMP (Committee for Medicinal Products for Human Use) Efficacy Working Party in joint collaboration with members of the Scientific Advice Working Party (SAWP), the Committee on Orphan Medicinal Products (COMP) and the Paediatric Expert Group (PEG).	2007	YES	Guideline
Design and analysis of clinical trials for small rare disease populations (Hilgers et al., 2016)	Develop a protocol	https://www.rarediseasesjournal.com/articles/design-and-analysis-of-clinical-trials-for-small-rare-disease-populations.html	This paper refers to the current state of design and analysis methods, as well as practical conditions to be considered when conducting a clinical trial for rare diseases.	2016	YES	Guideline
Recommendations for the design of small population clinical trials	Develop a protocol	https://ojrd.biomedcentral.com/articles/10.1186/s13023-018-0931-2	Recommendations of the IRDiRC expert group on clinical trials for RD around six topics: different study methods/designs and their relation to different characteristics of medical conditions, adequate safety data, multi-arm trial designs, decision analytic approaches and rational approaches to adjusting levels of evidence, extrapolation, and patients' engagement in study design	2018	YES	Guideline
Clinical trial designs for rare diseases: Studies developed and discussed by the	Develop a protocol	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4639696/	The IRCI (International Rare Cancers Initiative) trials are each presented to exemplify possible approaches to designing credible	2015	YES	Article

International Rare Cancers Initiative			trials in rare cancers. Researchers may consider these for use in future trials and understand the choices made for each design.			
Opinions and letters of support on the qualification of novel methodologies for medicine development	Develop a protocol	https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance/novel-methodologies-biomarkers/opinions-letters-support-qualification-novel-methodologies-medicine-development	The European Medicines Agency (EMA) publishes opinions on the qualification of innovative development methods and letters of support for novel methodologies that have been shown to be promising in the context of research and development into pharmaceuticals.	Regular updates	NO	Recommendation
COMET: Core outcome measures in effectiveness trials	Develop a protocol	https://www.comet-initiative.org/	The COMET Initiative brings together people interested in the development and application of agreed standardised sets of outcomes, known as 'core outcome sets' (COS). These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition, but COS are also suitable for use in routine care, clinical audit and research other than randomised trials	Regular updates	NO	Checklist
Cochrane Central Register of controlled trials	Develop a protocol	https://www.cochranelibrary.com/central/about-central	The Cochrane Central Register of Controlled Trials (CENTRAL) is a highly concentrated source of reports of randomized and quasi-randomized controlled trials. In addition to bibliographic details (author, source, year, etc.) CENTRAL records will often include an abstract (a summary of the	Regular updates	NO	Registry

			article). They do not contain the full text of the article			
SPIRIT Statement (Standard Protocol items)	Develop a protocol	https://www.acpjournals.org/doi/10.7326/0003-4819-158-3-201302050-00583	Reporting guideline defining standard protocol items for clinical trials. The evidence-based SPIRIT recommendations were developed using systematic, transparent methodology and broad consultation with 115 experts representing diverse stakeholders involved in the design, funding, conduct, review, and publication of trial protocols.	2013	NO	Checklist
SPIRIT Statement (Standard Protocol items) for n-of-1 trials	Develop a protocol	https://www.bmj.com/content/368/bmj.m122	Extension to the SPIRIT (standard protocol items: recommendations for interventional trials) guideline, SPENT (SPIRIT extension for n-of-1 trials), to improve the completeness and transparency of n-of-1 trial protocols.	2019	YES	Checklist
Measuring health-related quality of life in patients with rare disease	Develop a protocol	https://jpro.springeropen.com/articles/10.1186/s41687-021-00336-8#Sec11	This article explores some of the challenges in HRQoL assessment in rare disease, propose solutions, and consider regulatory issues	2021	YES	Article
Patient reported outcome measures in rare diseases: a narrative review	Develop a protocol	https://ojrd.biomedcentral.com/articles/10.1186/s13023-018-0810-x	This review explores some of the current issues around the uses of PROMs in rare diseases, including small patient populations and dearth of valid PROMs. Difficulties in validating new or current PROMs for use in clinical trials and research are discussed	2018	YES	Article

COSMIN: Database of systematic reviews of outcome measurement instruments	Develop a protocol	https://database.cosmin.nl/	Database of systematic reviews of outcome measurement instruments	Regular updates	NO	Database
PARADIGM patient engagement toolbox	Develop a protocol	https://imi-paradigm.eu/petoolbox/	This project deliverable centralises all PARADIGM's co-created recommendations, tools and relevant background information to make patient engagement in medicines development easier for all. The toolbox could help develop clinical trials with a further enhanced patient-focus and improve the experience of patients participating in the trials. Developed by PARADIGM project.	2020	NO	Toolbox
EURORDIS Community Advisory Board (CAB) Programme	Develop a protocol	https://www.eurordis.org/content/eurordis-community-advisory-board-cab-programme	Patient Community Advisory Boards (CABs) are groups established and operated by patient advocates. They offer their expertise to sponsors of clinical research. For example, by being involved before a clinical study starts, patients help ensure that clinical studies are designed to take into account their real needs, resulting in higher quality research.	N/A	YES	Advisory Board
EDCTP Protocol development tool	Develop a protocol	https://edctpknowledgehub.tghn.org/protocol-development/	An initiative of the Global Health Network, this Protocol Development Toolkit has been developed to support researchers in this process, to provide the tools and guidance to produce a high-quality health research Protocol.	Regular updates	NO	Toolbox

Assessment of short outcome of neonatal trials: Points to consider	Develop a Protocol	https://ecrin.org/projects/pedcrin/pedcrin-tools	PedCRIN tool: This tool lists examples of data items for the assessment short term efficacy and safety outcome of neonatal trials	2021	YES	Guideline
Assessment of long-term outcome of neonatal trials: Points to consider	Develop a protocol	https://ecrin.org/projects/pedcrin/pedcrin-tools	PedCRIN tool: This tool lists examples of data items for the assessment long term efficacy and safety outcome of neonatal trials	2021	YES	Guideline
Protocol development for neonatal trials: Points to consider for pharmacovigilance	Develop a protocol	https://ecrin.org/projects/pedcrin/pedcrin-tools	PedCRIN tool: This tool gives points to consider concerning pharmacovigilance and risk management at the time neonatal protocol development	2021	YES	Guideline
Exclusion criteria in neonatal trial protocols: Points to consider	Develop a protocol	https://ecrin.org/projects/pedcrin/pedcrin-tools	PedCRIN tool: This tool gives points to consider concerning pharmacovigilance and risk management at the time neonatal protocol development	2021	YES	Guideline
Exploring new uses for existing drugs: innovative mechanisms to fund independent clinical research	Identify a Funder	https://pubmed.ncbi.nlm.nih.gov/33947441/	This paper describes and discusses funding opportunities for independent clinical repurposing research	2021	NO	Article
OECD Recommendation on governace of clinical trials	Risk Assessment	http://www.oecd.org/sti/inno/oecd-recommendation-governance-of-clinical-trials.pdf	To facilitate international co-operation in clinical trials on medicinal products, particularly for trials initiated by academic institutions, in December 2012 the OECD Council adopted a set of principles calling for improved consistency among national	2013	NO	Recommendation

			regulations and their interpretations, and on streamlined procedures for the oversight and management of clinical trials. This framework introduces a risk-based oversight and management methodology for clinical trials.			
Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products	Risk Assessment	https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational_en.pdf	The guideline is intended to further assist stakeholders in the transition from non-clinical to early clinical development and in identifying factors influencing risk for new investigational medicinal products (IMPs). The document includes considerations on quality aspects, non-clinical and clinical testing strategies, study design and on conduct of FIH/early CTs.	2017	NO	Guideline
Guidelines for effective Data Management Plan	Data Management Plan	https://www.icpsr.umich.edu/web/pages/datamanagement/dmp/index.html	Guidance to create Data Management plans developed by the Inter-university Consortium for Political and Social Research (ICPSR), an international consortium of academic institutions and research organizations.	Regular updates	NO	Guideline
Data Management Plan Online	Data Management Plan	https://dmponline.dcc.ac.uk/public_templates	Templates for data management plans based on the specific requirements listed in funder policy documents.	Regular updates	NO	Template
Cambridge Clinical trials Unit SOPs and Documents	Trial Management	https://www.cctu.org.uk/governance	Cambridge Clinical Trials Units SOPs and templates on: pre-trial planning, protocol development, set-up; pharmacovigilance; data management and statistics;	Regular updates	NO	Template

			sample management; trial management; post-study procedures and archiving			
CTTI implemention tools	Trial Management	https://www.ctti-clinicaltrials.org/briefing-room/tools	CTTI-developed tools to improve the quality and efficiency of clinical trials. Tools include resources to optimize recruitment and informed consent process	Regular updates	NO	Template, guideline, recommendation
UKTMN Guide to Efficient Trial Management	Trial Management	https://cdn.ymaws.com/www.tmn.ac.uk/resource/resmgr/tmn_guide/uktmng2.web.pdf	This guideline describes the process of managing clinical trials and gives an overview of the trial management framework, both legal and operational, providing hints, tips and references to external resources	2018	NO	Guideline
NCCIH Clinical Research Toolbox	Trial Management	https://www.nccih.nih.gov/grants/toolbox#word	This toolbox contains templates, sample forms, and information materials to assist clinical investigators in the development and conduct of high-quality clinical research studies	Regular updates	NO	Toolbox
Feasibility assessment of neonatal studies and selection of investigator sites/ study centres: Points to consider	Trial Management	https://ecrin.org/projects/pedcrin/pedcrin-tools	PedCRIN tool: This tool lists examples of points to consider for the feasibility assessment and selection of neonatal centres	2021	YES	Recommendation
Enrolment into neonatal trials:Points to consider during protocol development	Trial Management	https://ecrin.org/projects/pedcrin/pedcrin-tools	PedCRIN tool: This tool provides a list of points to consider during protocol development for improving the enrolment of neonatal trials	2021	YES	Recommendation

ICF template	Trial Management	https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5c0efad4d&appId=PPGMS	ICF template model developed by the IMI funded Do-it project. Means to cover all the information to comply with GDPR rules	2019	NO	Template
ICF guidelines	Trial Management	https://i-consentproject.eu/results/	ICF guidelines developed by the H2020 funded i-consent project. Means to provide information for the development of informed consent on research involving humans	2021	NO	Guideline
Regulatory and Ethics Toolkit, ICF guidelines	Trial Management	https://www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/	GA4GH and IRDiRC have developed model consent clauses for rare diseases research, in order to improve data interoperability, to meet the informational needs of participants, and to ensure proper ethical and legal use of data sources and participants' overall protection	2021	YES	Guideline
Neonatal trials and informed consent: Points to consider	Trial Management	https://ecrin.org/projects/pedcrin/pedcrin-tools	PedCRIN tool: This tool provides a check list of practical points to consider when talking to parents about the possible inclusion of a neonate into a clinical trial	2021	YES	Recommendation
EMA list of national competent authorities in the EU	Regulatory submission	https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human	Updated list of European national competent authorities and their contact details	Regular updates	NO	Inventory
EUREC	Regulatory submission	http://www.eurecnet.org/information/index.html	List of European Research Ethics Committees in Europe	Regular updates	NO	Inventory
CAMPUS	Regulatory submission	http://campus.ecrin.org/	Search of regulatory requirements for clinical trials per country.	2015	NO	Search tool

			Launched in December 2015 by the European Clinical Research Infrastructure Network (ECRIN) – is an online database including country-specific information on regulatory and ethical requirements in clinical research across Europe.			
Comprehensive Inventory STARS	Regulatory submission	https://www.csa-stars.eu/Inventory-1721.html	The STARS (Strengthening Regulatory Science) project has developed an online Comprehensive Inventory that assists European academic drug developers in finding various support services provided by NCAs, public actors and private entities The inventory lists various support services including assistance in clinical trial application	Regular updates	NO	Inventory
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	Regulatory submission	https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf	The latest EU regulation for clinical trials on medicinal products for human use replaces national laws and describes the rules for assessing clinical trial applications and conducting clinical trials throughout the EU.	2015	NO	Legislation
ICH Good Clinical Practice E6 (R2)	Quality Management	https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice#current-version---revision-2-section	This document addresses the good clinical practice, an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. It aims to provide a unified standard	2017	NO	Guideline

			for the ICH regions to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.			
ICH Good Clinical Practice E6 (R2) Training course	Quality management	https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice/	This short course aims to provide the researcher with the basic principles of GCP and how these principles can be applied practically in the research setting. The course is aimed at all those involved in clinical research.	2017	NO	Training
EC, Risk proportionate approaches in clinical trials	Quality management	https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_04_25_risk_proportionate_approaches_in_ct.pdf	Recommendations of the expert group on clinical trials for the implementation of Regulation No 536/2014 (EU) No 536/2014 on clinical trials on medicinal products for human use, as per risk based quality management	2017	NO	Recommendation
ECRIN_Risk-Based Monitoring Toolbox	Quality management	https://ecrin.org/tools/risk-based-monitoring-toolbox	Provides information on tools available for risk assessment, monitoring and study conduct, the institutions where they are used, and other relevant details such as links and user feedback	2015	NO	Toolbox
ICH Topic E2A: Clinical Safety Data Management	Safety reporting	https://database.ich.org/sites/default/files/E2A_Guideline.pdf	Notes for definitions and standards on Safety reporting for ICH topic E A 2	1995	YES	Guideline
ICH Topic E2F Development Safety Update Report	Safety reporting	https://database.ich.org/sites/default/files/E2F_Guideline.pdf	Guidance on Safety Reporting. The Development Safety Update Report (DSUR) proposed in this guideline is intended to be the common standard for annual	2010	NO	Guideline

			clinical trial safety reporting among the ICH regions			
Adverse Drug Reactions Database	Safety reporting	http://www.imi-protect.eu/adverseDrugReactions.shtml	The PROTECT ADR database is a downloadable Excel file listing of all MedDRA Preferred terms or Low Level Terms adverse drug reactions (ADRs). It is a structured Excel database of all adverse drug reactions (ADRs) listed in section 4.8 of the Summary of Product Characteristics (SPC) of medicinal products authorised in the EU according to the centralised procedure	2017	NO	Database
Introduction to collecting and reporting adverse events	Safety reporting	https://globalhealthtrainingcentre.tghn.org/introduction-collecting-and-reporting-adverse-events/	This short course provides a general introduction and overview of Adverse Events and how to deal with them when they occur. This course is suitable for everyone involved in clinical research.	Regular updates	NO	Training
Causality Assessment of Adverse Events in paediatric trials	Safety reporting	https://ecrin.org/project/pedcrin/pedcrin-tools	A visual algorithm based on the Naranjo scale and specifically adapted for the paediatric population to help researchers in their assessment of causality of adverse events occurring during a clinical study	2021	YES	Recommendation
Safety data analyses of neonatal trials: Points to consider	Safety reporting	https://ecrin.org/projects/pedcrin/pedcrin-tools	PedCRIN tool: This tool provides practical points to consider when planning for the analysis of neonatal safety data	2021	YES	Recommendation
Research Data Management	Data Management	https://library-guides.ucl.ac.uk/research-data-management/	A guide to managing outputs of research projects and handling	Regular updates	NO	Guideline

			issues such as copyright and data protection laws			
Research Data Management Kit	Data Management	https://rdmkit.elixir-europe.org/index.html	This is a web-based resource for research data management, . It has been designed to guide life scientists in their efforts to better manage their research data following the FAIR Principles as well as help researchers be more productive for themselves and their collaborators.	2021	NO	Toolbox
Data Certification Standards/Data Certified Units	Data Management	https://ecrin.org/data-certification-standards	The ECRIN Data Centre Certification programme identifies non-commercial clinical trials units (CTUs) in Europe that have demonstrated they can provide safe, secure, compliant and efficient management of clinical research data.	2018	NO	Recommendation
EDCTP Data Management portal	Data Management	https://edctpknowledgehub.tghn.org/Dat-man-por/	An initiative of the Global Health Network. This tool helps to identify the areas to consider when developing a Data Management Plan, with a particular focus on data management systems and how to organise and structure data. Includes best practices for data capture, entry, processing and monitoring and how to prepare your data for analysis, sharing and archiving.	Regular updates	NO	Toolbox
EDCTP Data Sharing Toolkit	Data Management	https://edctpknowledgehub.tghn.org/data-sharing-toolkit/	An initiative of the Global Health Network, this Data Sharing Toolkit, collates practical information and resources related to data sharing, including data management basics,	Regular updates	NO	Toolbox

			data sharing steps and a repository finder.			
Sharing and reuse of individual participant data from clinical trials: principles and recommendations	Data Management	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5736032/	This article lists recommendations on providing access to individual participant data from clinical trials, using a broad interdisciplinary approach	2017	NO	Article
Evaluation of repositories for sharing individual-participant data from clinical studies	Data Management	https://pubmed.ncbi.nlm.nih.gov/30876434/	This article analyzes the current landscape of data repositories to create a detailed description of available repositories and assess their suitability for hosting data from clinical studies, from the perspective of the clinical researcher	2019	NO	Article
ICH Topic E 11 Clinical Investigation of Medicinal Products in the Paediatric Population	Investigational Product	https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-1.pdf	This document provides an outline of critical issues in pediatric drug development and approaches to the safe, efficient, and ethical study of medicinal products in the pediatric population. The purpose of this addendum is to complement and provide clarification and current regulatory perspective on topics in pediatric drug development.	2001	YES	Inventory
EudraLex - Volume 10 - Clinical trials guidelines_Chapter III_Quality of the investigational medicinal Product.	Investigational Product	https://ec.europa.eu/health/documents/eudralex/vol-10_en	Volume 10 of the publication "The rules governing medicinal products in the European Union" contains guidance documents applying to clinical trials.	Regular updates	NO	Guideline

EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use	Investigational Product	https://ec.europa.eu/health/documents/eudralex/vol-4_en	Good manufacturing practice (GMP) describes the minimum standard that a medicines manufacturer must meet in their production processes. The European Medicines Agency (EMA) coordinates inspections to verify compliance with these standards and plays a key role in harmonizing GMP activities at European Union (EU) level. The Annex also includes guidance on ordering, shipping, and returning clinical supplies, which are at the interface with, and complementary to, guidelines on Good Clinical Practice.	2010	NO	Guideline
Clinical trials toolkit: Trial Supply	Investigational Product	https://www.ct-toolkit.ac.uk/downloads/Trial%20Supplies%20Guide%20v4.1_March2018.pdf	Guide prepared by MODEPHARMA to codify good practice on drug management in publicly funded clinical trials	2018	NO	Toolbox
Collection, storage and use of biological samples and related data in paediatric trials	Laboratory Processes	https://ecrin.org/project/pedcrin/pedcrin-tools	PedCRIN tool: A checklist developed to help researchers, sponsors, and other affiliated personnel actors to verify that all key aspects required to properly manage samples and related data in the context of paediatric trials are taken into consideration	2021	YES	Checklist
Reflection paper on laboratory processes for clinical trials	Laboratory Processes	https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/reflection-paper-laboratories-perform-analysis-evaluation-clinical-trial-samples_en.pdf	The purpose of this reflection paper is to provide laboratories that perform the analysis or evaluation of human samples collected as part of a clinical trial, with information that will help them develop and maintain quality systems which will comply with	2010	NO	Reflection paper

			relevant European Union Directives, national regulations and associated guidance documents. It will also provide information on the expectations of the inspectors who may be assigned by national monitoring authorities to inspect facilities that perform work in support of human clinical trials			
Good clinical laboratory practice	Laboratory Processes	https://globalhealthtrainingcentre.tghn.org/good-clinical-laboratory-practice-course/	Good Clinical Laboratory Practice (GCLP) guidelines describe the application of those Good Laboratory Practice principles that are relevant to the analyses of samples from clinical trials while ensuring the purpose and objectives of the Good Clinical Practice principles are maintained.	Regular updates	NO	Guideline
GCLP (Good clinical laboratory practice) Guidance	Laboratory processes	https://www.who.int/tdr/publications/documents/gclp-web.pdf	This guidance identifies systems required and procedures to be followed within an organization conducting analysis of samples from clinical trials in compliance with the requirements of Good Clinical Practice (GCP). It thus provides sponsors, laboratory management, project managers, clinical research associates (CRAs) and quality assurance personnel with the framework for a quality system in analysis of clinical trial samples, ensuring GCP compliance overall of processes and results.	2009	NO	Guideline

GCP Lab guidance	Laboratory processes	https://web.archive.org/web/20100506014710/http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON051910&RevisionSelectionMethod=Latest	MHRA Guidence on the maintenance of regulatory compliance in laboratories that perform the analysis or evaluation of clinical trial samples	2009	NO	Guideline
ICH Statistical Principles for clinical trials E9	Statistical Analysis Plan	https://database.ich.org/sites/default/files/E9_Guideline.pdf	This guidance is intended to give direction to sponsors in the design, conduct, analysis, and evaluation of clinical trials of an investigational product in the context of its overall clinical development. The document will also assist scientific experts charged with preparing application summaries or assessing evidence of efficacy and safety, principally from clinical trials in later phases of development.	1998	NO	Guideline
Guideline for the Content of Statistical Analysis Plans in Clinical Trials	Statistical Analysis Plan	https://lctc.org.uk/SAP-Statement	A checklist of 32 minimum items for inclusion in SAPs that was developed with the primary intention of being applicable to the final analyses of later-phase randomized clinical trials addressing the minimum recommended content of a SAP	2017	NO	Guideline
ECRIN Metadata Repository	Statistical Analysis Plan	https://ecrin.org/clinical-research-metadata-repository	Search of metadata (including protocols and Statistical Analysis Plans) on published clinical trials.	2020	NO	Repository
Clinical Trials Registry (NIH)	Statistical Analysis Plan	https://clinicaltrials.gov/	Database of publicly and privately funded clinical studies conducted around the world. The Study Documents tab allows search for	Regular updates	NO	Registry

			SAP (Statistical Analysis Plan), protocols and Informed consents			
Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic)	Archiving	https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-content-management-archiving-clinical-trial-master-file-paper/electronic_en.pdf	The EMA guideline on the content, management and archiving of the TMF provides guidance relating to the media used for storage of documents (including requirements when original records are transferred to electronic media for the purpose of archive).	2018	NO	Guideline
ICH E3 guideline on Structure and Content of Clinical Study Reports (ICH E3)	Trial report	https://database.ich.org/sites/default/files/E3_Guideline.pdf	The objective of this guideline is to allow the compilation of a single core clinical study report (CSR) acceptable to all regulatory authorities of the ICH regions	1995	NO	Guideline
CONSORT statement	Trial report	http://www.consort-statement.org/	CONSORT Statement is an evidence-based, minimum set of recommendations for reporting randomized trials. It offers a standard way for authors to prepare reports of trial findings	2010	NO	Checklist
CONSORT statement on N-of-1 trials (extension of the CONSORT Statement)	Trial report	http://www.consort-statement.org/extensions/overview/n-of-1	A CONSORT extension for N-of-1 trials that provides guidance on the reporting of individual and series of N-of-1 trials	2015	YES	Checklist
EUPATI tutorial: Reporting and recording clinical trial results	Dissemination	https://toolbox.eupati.eu/resources/recording-and-reporting-clinical-trial-results/	EUPATI tutorial about recording and reporting clinical trial results	Regular updates	NO	Training
EudraCT (European Union Drug	Dissemination	https://eudract.ema.europa.eu/	European Clinical Trial CT Database. Since 2014, it is the	Regular updates	NO	Registry

Regulating Authorities Clinical Trials Database)			responsibility of sponsors to ensure that the protocol information and results of all clinical trials is submitted in EudraCT; this information is publicly available through the EU Clinical Trials Register (EU CTR).			
Technical guideline on the format of the data fields of results-related information on clinical trials	Dissemination	https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/2013_01_22_tg_en.pdf	Technical guideline on the format of the data fields of results-related information on clinical trials to publish on the EU Clinical Trials Register	2013	NO	Guideline
Tutorials on posting results on EudraCT	Dissemination	https://eudract.ema.europa.eu/multimedia_tutorials.html	Tutorials on posting results on the European Union Drug Regulating Authorities Clinical Trials Database (EudraCT)	Regular updates	NO	Training
Summaries of clinical trial results for laypersons	Dissemination	https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/2017_01_26_summaries_of_ct_results_for_laypersons.pdf	Guideline provides sponsors and investigators with guidelines and templates for the production of summaries of clinical trial results for laypersons	2017	NO	Guideline