#	Tool Name	Section	Tool	Relevance	Year	RD/Paediatric specific?	Type
1	**Cochrane PICO search**	Define a question	https://www.cochranelibrary.com/about/pico-search	PICO search[BETA] 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
2	**ICH General considerations for clinical studies E8**	Develop a protocol	https://database.ich.org/sites/default/files/E8_Guideline.pdf	Describes internationally accepted principles and practices in the conduct of both individual clinical trials and overall development strategy for new medical products	1997	NO	Guideline
3	**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	Describes 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
4	**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, provide clarification and current regulatory perspective on topics in pediatric drug development.	2017	YES	Guideline

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5	**European Medicines Agency Guidance for Applicants seeking scientific advice and protocol assistance**	Develop a protocol	https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-guidance-applicants-seeking-scientific-advice-protocol-assistance_en-0.pdf	This guidance document addresses a number of questions that users 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.	Regular updates	NO	Guideline
6	**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
7	**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
8	**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

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9	**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	Article
10	**Recommendations for the design of small population clinical trials (Day et al, 2018)**	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	Article
11	**Clinical trial designs for rare diseases: Studies developed and discussed by the International Rare Cancers Initiative (Bogaerts et al., 2015)**	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 trials in rare cancers. Researchers may consider these for use in future trials and understand the choices made for each design.	2015	YES	Article
12	**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

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13	**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
14	**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 article). They do not contain the full text of the article.	Regular updates	NO	Registry
15	**SPIRIT Statement (Standard Protocol items)**	Develop a protocol	https://pubmed.ncbi.nlm.nih.gov/23295957/	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
16	**Guidelines for Reporting Outcomes in Trial Protocols The SPIRIT-Outcomes 2022 Extension**	Develop a protocol	https://jamanetwork.com/journals/jama/fullarticle/2799547	This SPIRIT-Outcomes 2022 extension of the SPIRIT 2013 statement provides 9 outcome-specific items that should be addressed in all trial protocols and may help increase trial utility, replicability, and transparency and may minimize the risk of selective nonreporting of trial results.	2022	NO	Checklist

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17	**SPIRIT Statement (Standard Protocol items) for n-of-1 trials**	Develop a protocol	https://www.bmj.com/content/368/bmj.m122/related#datasupp	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
18	**SPIRIT PRO Extension for inclusion of patient-reported outcomes in clinical trials protocols**	Develop a protocol	https://jamanetwork.com/journals/jama/article-abstract/2671472	Extension of the SPIRIT (Standard protocol items: recommendations for interventional trials) guideline, SPIRIT PRO provides guidelines for inclusion of patient-reported outcomes in clinical trial protocols.	2018	NO	Checklist
19	**Measuring health-related quality of life in patients with rare disease (Lenderking et al., 2021)**	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
20	**Patient reported outcome measures in rare diseases: a narrative review (Slade et al, 2018)**	Develop a protocol	https://ojrd.biomedcentral.com/articles/10.1186/s13023-018-0810-x	This review explores some of the current issues around the utilisation 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

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21	**PROMs Repository**	Develop a protocol	https://erica-rd.eu/work-packages/patient-centred-research/proms-repository/	The ERICA Patient Reported Outcome Measures (PROMs) Repository is the first attempt to identify and centralize Clinical Assessment Outcomes questionnaires of relevance for rare diseases and constitutes a milestone in the Europe-wide standardization of Patient-Centered Outcome Measures (PCOMs) and PROMs for rare diseases.	Regular updates	YES	Repository
22	**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
23	**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
24	**EUPATIConnect**	Develop a protocol	https://connect.eupati.eu/	EUPATIConnect matches EUPATI patient experts with researchers to create mutually beneficial opportunities and to enhance the future of patients engagement.	2022	NO	Advisory Board
25	**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

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26	**European YPAG Network**	Develop a protocol	https://eypagnet.eu/services	The network was established to support the development of new Young Person Advisory Groups (YPAGs) within Europe. The main aim of eYPAGnet is to provide researchers with a variety of opportunities to work with children and young people in the design and conduct of paediatric clinical trials.	N/A	YES	Advisory Board
27	**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
28	**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
29	**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
30	**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
31	**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

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32	**Exploring new uses for existing drugs: innovative mechanisms to fund independent clinical research (Verbaanderd et al., 2021)**	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
33	**Scientify research**	Identify a Funder	https://www.scientifyresearch.org/	An open, curated and structured research funding database	Regular updates	No	Database
34	**NIRO (Navigating Innovation & Research Opportunities)**	Identify a Funder	https://niroglobal.com/	This tool is designed to help single entities or teams from the private and public sector, not-for-profit organisations, and academia identify which R&I initiatives and programme opportunities could be the right fit, including initiatives and programmes sponsored by the European Commission, as well as national ministries, agencies and not-for-profit organisations within and beyond the European Union.		NO	Inventory
35	**OECD Recommendation on governance of clinical trials**	Risk Assessment	https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0397 file:///C:/Users/bzafirova/Downloads/OECD-LEGAL-0397-en.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 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.	2022	NO	Recommendation
36	**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 the conduct of FIH/early CTs	2017	NO	Guideline

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37	**Risk assessment form for clinical research projects**	Risk Assessment	https://www.sctoplatforms.ch/en/tools/risk-assessment-form-for-clinical-research-projects-30.html	Swiss Clinical Trial Organisation Tools: Risk Assessment of potential risks of a clinical research project-in line with current requirements (ICH GCP E6(R2))	Regular updates	NO	Guideline
38	**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
39	**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
40	**Data Management Guidelines, Version 2.0**	Data Management Plan	https://edctpknowledgehub.tghn.org/Dataman-por/resources/	The European & Developing Countries Clinical Trials Partnership (EDCTP) has partnered with The Global Health Network to develop this 'Knowledge Hub', which aims to provide researchers with the tools and guidance to enable them to undertake high-quality health research.	2022	NO	Inventory
41	**Guidance for good randomized trials (The Good Clinical Trials Collaborative)**	Trial Management	https://www.goodtrials.org/guidance	The guidance is intended to support all individuals and organizations involved in the planning, conduct, analysis, oversight, interpretation, funding, and regulation of RCTs of any health intervention for any purpose in any setting.	Regular updates	NO	Guideline
42	**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; sample management; trial management; post-study procedures and archiving	Regular updates	NO	Template

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43	**Global Health Trials Tools and Templates library**	Trial Management	https://globalhealthtrials.tghn.org/resources/templates/	Developed by the Global Health Trials Knowledge Hub , this library of templates includes clinical trials´ general logs and trackers, documents for finances management, patients enrolment and study, site and staff management	Regular updates	NO	Template
44	**CTTI implementation tools**	Trial Management	**https://ctti-clinicaltrials.org/recommendations-and-resource/**	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
45	**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
46	**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
47	**PORTICO Clinical Trials Toolkit**	Trial Management	https://www.porticocenter.org/toolkit-modules	The toolkit is a curated series of publicly accessible videos and links covering essential operational details that early investigators need to know before embarking on a clinical trial with a special focus on pediatric trials. Topics address study startup, study documents, consent, oversight, management, and safety.	Annual updates	YES	Toolbox

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48	**PANDA: A practical Adaptive & Novel Designs and Analysis toolkit**	Trial Management	https://panda.shef.ac.uk/techniques/general-considerations-about-adaptive-trials/categories/2#top	PANDA is aimed at trialists and researchers in clinical trials who are keen to learn about adaptive designs, their practical application, potential benefits and limitations. The target audience includes, but is not limited to, trial statisticians, clinicians, health economists, grant proposal developers, trial managers, data managers, and reviewers of grant applications	2022	NO	Toolbox
49	**EnprEMA Network Database.**	Trial Management	http://enprema.ema.europa.eu/enprema/index.php	Developed by the European Network of paediatric research at the EMA, his database includes research networks and centres with recognised expertise in performing clinical studies in children.	Regular updates	YES	Database
50	**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
51	**Improving inclusion of under-served groups in clinical research: Guidance from INCLUDE project**	Trial Management	https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435	This guidance summarises what an under-served group is, a roadmap suggesting intervention points to improve inclusion, examples of under-served groups and barriers to inclusion	2020	YES	Guideline
52	**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
53	**Informed Consent for Paediatric Trials in Europe**	Trial Management	https://www.ema.europa.eu/en/documents/other/informed-consent-paediatric-clinical-trials-europe-2015_en.pdf	This document lists the country-specific requirements for informed consents for paediatric clinical trials in Europe	2015	YES	Guideline

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54	**Assent / Informed Consent Guidance for Paediatric Clinical Trials with Medicinal Products in Europe**	Trial Management	https://www.ema.europa.eu/en/documents/other/assent/informed-consent-guidance-paediatric-clinical-trials-medicinal-products-europe_en.pdf	Developed by Enpr-EMA's Working Group on Ethics, this document is intended to be used as an overview tool of the contents for assent/informed consent forms for all stakeholders (such as patients, sponsors and investigators) to support the conduct of high quality paediatric clinical trials in Europe across all paediatric age groups, from birth to less than 18 years of age.	2021	YES	Guideline
55	**ICF template**	Trial Management	https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5baeb8ee4&appId=PPGMS https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5be8756d7&appId=PPGMS	ICF template model developed by the IMI funded Do-it project. It means to cover all the information to comply with GDPR rules	2019	NO	Template
56	**ICF guidelines**	Trial Management	https://zenodo.org/record/4563938#.Y5IOx3bMLIU	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
57	**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
58	**Neonatal trials and informed consent: Points to consider**	Trial Management	https://ecrin.org/projects/pedcrin/pedcrin-tools	PedCRIN tool: This tool provides a checklist of practical points to consider when talking to parents about the possible inclusion of a neonate into a clinical trial	2021	YES	Recommendation

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59	**Guidelines for Good Operational Practice Version 3.0**	Trial Management	https://www.sctoplatforms.ch/en/publications/guidelines-for-good-operational-practice-44.html	Swiss Clinical Trial Organisation Tools: The Guidelines for Good Operational Practice (GGOP) are a framework of common standards for professional and operational practice in clinical research.	2017	NO	Guideline
60	**Easy Guide to Clinical Studies (Easy GCS) Beta**	Trial Management	https://www.easy-gcs.ch/entrypage.html#phase	Swiss Clinical Trial Organisation tool: This interactive guide provides comprehensive and concise information and guidance on how to plan and conduct your study.	2023	NO	Guideline
61	**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
62	**EUREC**	Regulatory submission	http://www.eurecnet.org/information/index.html	List of European Research Ethics Committees in Europe	Regular updates	NO	Inventory
63	**CAMPUS**	Regulatory submission	http://campus.ecrin.org/	A search tool for regulatory requirements on clinical trials per country. Launched in December 2015 by the European Clinical Research Infrastructure Network (ECRIN) – this is an online database including country-specific information on regulatory and ethical requirements in clinical research across Europe	2015	NO	Search tool
64	**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 applications	Regular updates	NO	Inventory

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65	**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
66	**International Compilation of Human Research Standards, 2021 Edition**	Regulatory submission	https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html	US Department of Health and Human Services developed listing of over 1,000 standards on human subjects protections in 131 countries and from many international organizations. These standards may include laws, regulations, and/or guidelines.	2021	NO	Inventory
67	**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 for the ICH regions to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions	2017	NO	Guideline
68	**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
69	**EC, Risk proportionate approaches in clinical trials**	Quality management	https://www.gmp-compliance.org/files/guidemgr/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
70	**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

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71	**Guidelines for Risk-Based Monitoring, Version 3.0**	Quality management	https://www.sctoplatforms.ch/en/publications/guidelines-and-reports/guidelines-for-risk-based-monitoring-61.html	Swiss Clinical Trial Organisation tool: Guidelines for Risk-Based Monitoring	2022	NO	Guideline
72	**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	NO	Guideline
73	**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 clinical trial safty reporting among the ICH regions	2010	NO	Guideline
74	**Guideline on good pharmacovigilance practices (GVP) Product- or Population-Specific Considerations IV: Paediatric population**	Safety reporting	https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-product-population-specific-considerations-iv_en-0.pdf	Guidance on the conduct of pharmacovigilance for medicines used by paediatric population. It is directed towards marketing authorisation holders and competent authorities. It is also of relevance to all those involved in the conduct of paediatric clinical trials.	2017	YES	Guideline
75	**Safety training**	Safety reporting	https://www.sctoplatforms.ch/en/tools/online-safety-training-57.html	Swiss Clinical Trial Organisation Tools: Safety training to consolidate investigator´s knowledge of patient safety and reporting issues in clinical research	Regular updates	NO	Training
76	**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
77	**Safety reporting forms**	Safety reporting	https://www.sctoplatforms.ch/en/tools/safety-reporting-forms-21.html	Swiss Clinical Trial Organisation Tool: Set of comprehensive forms for safety reporting tailored to different types of clinical research projects.	Regular updates	NO	Template

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78	**Causality Assessment of Adverse Events in paediatric trials**	Safety reporting	https://ecrin.org/paediatric-tools	PedCRIN tool: 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
79	**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
80	**Research Data Management**	Data Management	https://library-guides.ucl.ac.uk/research-data-management/	A guide to managing outputs of research projects and handling issues such as copyright and data protection laws	Regular updates	NO	Guideline
81	**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
82	**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
83	**EDCTP Data Management portal**	Data Management	https://edctpknowledgehub.tghn.org/Datman-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

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84	**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, data sharing steps and a repository finder	Regular updates	NO	Toolbox
85	**Sharing and reuse of individual participant data from clinical trials: principles and recommendations (Ohmann et al., 2017)**	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
86	**Evaluation of repositories for sharing individual-participant data from clinical studies (Banzi et al., 2019)**	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
87	**Sharing and reuse of health-related data for research purposes: WHO policy and implementation guidance**	Data Management	https://www.who.int/publications/i/item/9789240044968	This document clarify the policy and practice on the reuse and onward sharing for research purposes of health data collected under the auspices of WHO technical programmes. It covers use in both emergency and non-emergency situations.	2022	NO	Guideline
88	**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
89	**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 harmonising 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

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90	**Guideline on pharmaceutical development of medicines for paediatric use**	Investigational Product	https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-pharmaceutical-development-medicines-paediatric-use_en.pdf	The principles of this guideline should be considered during the pharmaceutical development of all paediatric medicines as proposed in marketing-authorisation applications (MAAs) or applications to extend or vary marketing authorisations to the paediatric population (MAVs)	2013	YES	Guideline
91	**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
92	**Collection, storage and use of biological samples and related data in paediatric trials**	Laboratory Processes	https://ecrin.org/paediatric-tools	PedCRIN tool: A checklist developed to help researchers, sponsors, and other affiliated personnel 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
93	**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 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	2010	NO	Reflection paper
94	**Good clinical laboratory practice training**	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	Training

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95	**GCLP (Good clinical laboratory practice) Guidance**	Laboratory processes	https://apo.who.int/publications/i/item/good-clinical-laboratory-practice-(-gclp)	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
96	**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 Guidance on the maintenance of regulatory compliance in laboratories that perform the analysis or evaluation of clinical trial samples	2009	NO	Guideline
97	**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
98	**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
99	**ECRIN Metadata Repository**	Statistical Analysis Plan	https://www.crmdr.org/	Search of metadata (including protocols and Statistical Analysis Plans) on published clinical trials.	2020	NO	Repository

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100	**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 SAP (Statistical Analysis Plan), protocols and Informed consents	Regular updates	NO	Registry
101	**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
102	**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
103	**CONSORT statement**	Trial report	https://www.elsevier.com/__data/promis_misc/CONSORT-2010-Checklist.pdf	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
104	**Guidelines for Reporting Outcomes in Trial Reports: The CONSORT-Outcomes 2022 Extension**	Trial report	https://jamanetwork.com/journals/jama/fullarticle/2799401	The CONSORT-Outcomes 2022 extension provides evidence- and consensus-based guidance for reporting outcomes in published clinical trial reports, extending the CONSORT 2010 statement checklist with 17 additional reporting items and harmonizing reporting ecommendations with guidance from the SPIRIT-Outcomes 2022 extension.	2022	NO	Checklist
105	**CONSORT statement of N-of-1 trials (extension of the CONSORT statement)**	Trial report	https://www.jclinepi.com/action/showPdf?pii=S0895-4356%2815%2900225-5	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

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106	**TranspariMED: Clinical trial transparency tools**	Trial report	https://www.transparimed.org/resources	Collection of hands-on tools and case studies that universities and other institution can use to improve their registration and reporting of clinical trials.	2019	NO	Toolbox
107	**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
108	**EudraCT (European Union Drug Regulating Authorities Clinical Trials Database)**	Dissemination	https://eudract.ema.europa.eu/	European Clinical Trial CT Database. Since 2014, it is the 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).	Regular updates	NO	Registry
109	**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
110	**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
111	**Summaries of clinical trial results for laypersons**	Dissemination	https://ec.europa.eu/health/system/files/2021-10/glsp_en_0.pdf	Guideline for the production of summaries of clinical results for laypersons	Regular updates	NO	Guideline