

#	Tool Name	Section	Tool	Relevance	Year	RD/Paediatric specific?	Type
1	Cochrane PICO search	Define a question	<a href="https://www.cochranelibrary.com/about/pico-search">https://www.cochranelibrary.com/about/pico-search</a>	PICO search <sup>BETA</sup> 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	<a href="https://database.ich.org/sites/default/files/E8_Guideline.pdf">https://database.ich.org/sites/default/files/E8_Guideline.pdf</a>	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	<a href="https://database.ich.org/sites/default/files/E17EWG_Step4_2017_1116.pdf">https://database.ich.org/sites/default/files/E17EWG_Step4_2017_1116.pdf</a>	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	<a href="https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e11r1-guideline-clinical-investigation-medicinal-products-pediatric-population-revision-1_en.pdf">https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e11r1-guideline-clinical-investigation-medicinal-products-pediatric-population-revision-1_en.pdf</a>	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

5	European Medicines Agency Guidance for Applicants seeking scientific advice and protocol assistance	Develop a protocol	<a href="https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-guidance-applicants-seeking-scientific-advice-protocol-assistance_en.pdf">https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-guidance-applicants-seeking-scientific-advice-protocol-assistance_en.pdf</a>	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	<a href="https://irdirc.org/wp-content/uploads/2020/03/ODDG_TF_Building-Block-Form_E104.pdf">https://irdirc.org/wp-content/uploads/2020/03/ODDG_TF_Building-Block-Form_E104.pdf</a>	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	<a href="https://irdirc.org/wp-content/uploads/2020/03/ODDG_TF_Building-Block-Form_1421.pdf">https://irdirc.org/wp-content/uploads/2020/03/ODDG_TF_Building-Block-Form_1421.pdf</a>	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	<a href="https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-clinical-trials-small-populations_en.pdf">https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-clinical-trials-small-populations_en.pdf</a>	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

9	<b>Design and analysis of clinical trials for small rare disease populations (Hilgers et al., 2016)</b>	Develop a protocol	<a href="https://www.rarediseasesjournal.com/articles/design-and-analysis-of-clinical-trials-for-small-rare-disease-populations.html">https://www.rarediseasesjournal.com/articles/design-and-analysis-of-clinical-trials-for-small-rare-disease-populations.html</a>	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	<b>Recommendations for the design of small population clinical trials (Day et al, 2018)</b>	Develop a protocol	<a href="https://ojrd.biomedcentral.com/articles/10.1186/s13023-018-0931-2">https://ojrd.biomedcentral.com/articles/10.1186/s13023-018-0931-2</a>	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/ Guideline
11	<b>Clinical trial designs for rare diseases: Studies developed and discussed by the International Rare Cancers Initiative (Bogaerts et al., 2015)</b>	Develop a protocol	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4639696/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4639696/</a>	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	<b>Opinions and letters of support on the qualification of novel methodologies for medicine development</b>	Develop a protocol	<a href="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">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</a>	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

13	<b>COMET: Core outcome measures in effectiveness trials</b>	Develop a protocol	<a href="https://www.comet-initiative.org/">https://www.comet-initiative.org/</a>	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	<b>Cochrane Central Register of controlled trials</b>	Develop a protocol	<a href="https://www.cochranelibrary.com/central/about-central">https://www.cochranelibrary.com/central/about-central</a>	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	<b>SPIRIT Statement (Standard Protocol items)</b>	Develop a protocol	<a href="https://www.acpjournals.org/doi/10.7326/0003-4819-158-3-201302050-00583">https://www.acpjournals.org/doi/10.7326/0003-4819-158-3-201302050-00583</a>	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	<b>SPIRIT Statement (Standard Protocol items) for n-of-1 trials</b>	Develop a protocol	<a href="https://www.bmj.com/content/368/bmj.m122">https://www.bmj.com/content/368/bmj.m122</a>	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

17	<b>SPIRIT PRO Extension for inclusion of patient-reported outcomes in clinical trials protocols</b>	Develop a protocol	<a href="https://jamanetwork.com/journals/jama/article-abstract/2671472">https://jamanetwork.com/journals/jama/article-abstract/2671472</a>	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
18	<b>Measuring health-related quality of life in patients with rare disease (Lenderking et al., 2021)</b>	Develop a protocol	<a href="https://jpro.springeropen.com/articles/10.1186/s41687-021-00336-8#Sec11">https://jpro.springeropen.com/articles/10.1186/s41687-021-00336-8#Sec11</a>	This article explores some of the challenges in HRQoL assessment in rare disease, propose solutions, and consider regulatory issues	2021	YES	Article
19	<b>Patient reported outcome measures in rare diseases: a narrative review (Slade et al, 2018)</b>	Develop a protocol	<a href="https://ojrd.biomedcentral.com/articles/10.1186/s13023-018-0810-x">https://ojrd.biomedcentral.com/articles/10.1186/s13023-018-0810-x</a>	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
20	<b>COSMIN: Database of systematic reviews of outcome measurement instruments</b>	Develop a protocol	<a href="https://database.cosmin.nl/">https://database.cosmin.nl/</a>	Database of systematic reviews of outcome measurement instruments	Regular updates	NO	Database
21	<b>PARADIGM patient engagement toolbox</b>	Develop a protocol	<a href="https://imi-paradigm.eu/petoolbox/">https://imi-paradigm.eu/petoolbox/</a>	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
22	<b>EUPATICconnect</b>	Develop a protocol	<a href="https://connect.eupati.eu/">https://connect.eupati.eu/</a>	EUPATICconnect matches EUPATI patient experts with researchers to create mutually beneficial opportunities and to enhance the future of patients engagement.	2022	NO	Advisory Board

23	EURORDIS Community Advisory Board (CAB) Programme	Develop a protocol	<a href="https://www.eurordis.org/content/eurordis-community-advisory-board-cab-programme">https://www.eurordis.org/content/eurordis-community-advisory-board-cab-programme</a>	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
24	EDCTP Protocol development tool	Develop a protocol	<a href="https://edctpknowledgehub.tghn.org/protocol-development/">https://edctpknowledgehub.tghn.org/protocol-development/</a>	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
25	Assessment of short outcome of neonatal trials: Points to consider	Develop a Protocol	<a href="https://ecrin.org/projects/pedcrin/pedcrin-tools">https://ecrin.org/projects/pedcrin/pedcrin-tools</a>	PedCRIN tool: This tool lists examples of data items for the assessment short term efficacy and safety outcome of neonatal trials	2021	YES	Guideline
26	Assessment of long-term outcome of neonatal trials: Points to consider	Develop a protocol	<a href="https://ecrin.org/projects/pedcrin/pedcrin-tools">https://ecrin.org/projects/pedcrin/pedcrin-tools</a>	PedCRIN tool: This tool lists examples of data items for the assessment long term efficacy and safety outcome of neonatal trials	2021	YES	Guideline
27	Protocol development for neonatal trials: Points to consider for pharmacovigilance	Develop a protocol	<a href="https://ecrin.org/projects/pedcrin/pedcrin-tools">https://ecrin.org/projects/pedcrin/pedcrin-tools</a>	PedCRIN tool: This tool gives points to consider concerning pharmacovigilance and risk management at the time neonatal protocol development	2021	YES	Guideline
28	Exclusion criteria in neonatal trial protocols: Points to consider	Develop a protocol	<a href="https://ecrin.org/projects/pedcrin/pedcrin-tools">https://ecrin.org/projects/pedcrin/pedcrin-tools</a>	PedCRIN tool: This tool gives points to consider concerning pharmacovigilance and risk management at the time neonatal protocol development	2021	YES	Guideline
29	Exploring new uses for existing drugs: innovative mechanisms to fund independent clinical research (Verbaanderd et al., 2021)	Identify a Funder	<a href="https://pubmed.ncbi.nlm.nih.gov/33947441/">https://pubmed.ncbi.nlm.nih.gov/33947441/</a>	This paper describes and discusses funding opportunities for independent clinical repurposing research	2021	No	Article
30	Scientify research	Identify a Funder	<a href="https://www.scientifyresearch.org/">https://www.scientifyresearch.org/</a>	An open, curated and structured research funding database	Regular updates	No	Database

31	<b>OECD Recommendation on governance of clinical trials</b>	Risk Assessment	<a href="http://www.oecd.org/sti/inno/oecd-recommendation-governance-of-clinical-trials.pdf">http://www.oecd.org/sti/inno/oecd-recommendation-governance-of-clinical-trials.pdf</a>	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.	2013	NO	Recommendation
32	<b>Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products</b>	Risk Assessment	<a href="https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational_en.pdf">https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational_en.pdf</a>	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
33	<b>Risk assessment form for clinical research projects</b>	Quality management	<a href="https://www.sctoplatforms.ch/en/tools/risk-assessment-form-for-clinical-research-projects-30.html">https://www.sctoplatforms.ch/en/tools/risk-assessment-form-for-clinical-research-projects-30.html</a>	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
34	<b>Guidelines for effective Data Management Plan</b>	Data Management Plan	<a href="https://www.icpsr.umich.edu/web/pages/datamanagement/dmp/index.html">https://www.icpsr.umich.edu/web/pages/datamanagement/dmp/index.html</a>	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
35	<b>Data Management Plan Online</b>	Data Management Plan	<a href="https://dmponline.dcc.ac.uk/public_templates">https://dmponline.dcc.ac.uk/public_templates</a>	Templates for data management plans based on the specific requirements listed in funder policy documents.	Regular updates	NO	Template



36	Cambridge Clinical trials Unit SOPs and Documents	Trial Management	<a href="https://www.cctu.org.uk/governance">https://www.cctu.org.uk/governance</a>	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
37	Global Health Trials Tools and Templates library	Trial Management	<a href="https://globalhealthtrials.tghn.org/resources/templates/">https://globalhealthtrials.tghn.org/resources/templates/</a>	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
38	CTTI implementation tools	Trial Management	<a href="https://ctti-clinicaltrials.org/recommendations-and-resource/">https://ctti-clinicaltrials.org/recommendations-and-resource/</a>	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
39	UKTMN Guide to Efficient Trial Management	Trial Management	<a href="https://cdn.ymaws.com/www.tmn.ac.uk/resource/resmgr/tmn_guide/uktmng2.web.pdf">https://cdn.ymaws.com/www.tmn.ac.uk/resource/resmgr/tmn_guide/uktmng2.web.pdf</a>	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
40	NCCIH Clinical Research Toolbox	Trial Management	<a href="https://www.nccih.nih.gov/grants/toolbox#word">https://www.nccih.nih.gov/grants/toolbox#word</a>	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
41	Feasibility assessment of neonatal studies and selection of investigator sites/ study centres: Points to consider	Trial Management	<a href="https://ecrin.org/projects/pedcrin/pedcrin-tools">https://ecrin.org/projects/pedcrin/pedcrin-tools</a>	PedCRIN tool: This tool lists examples of points to consider for the feasibility assessment and selection of neonatal centres	2021	YES	Recommendation
42	Enrolment into neonatal trials: Points to consider during protocol development	Trial Management	<a href="https://ecrin.org/projects/pedcrin/pedcrin-tools">https://ecrin.org/projects/pedcrin/pedcrin-tools</a>	PedCRIN tool: This tool provides a list of points to consider during protocol development for improving the enrolment of neonatal trials	2021	YES	Recommendation



43	ICF template	Trial Management	<a href="https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5c0efad4d&amp;appId=PPGMS">https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5c0efad4d&amp;appId=PPGMS</a>	ICF guidelines developed by the H2020 funded i-consent project. It means to provide information for the development of informed consent on research involving humans	2019	NO	Template
44	ICF guidelines	Trial Management	<a href="https://i-consentproject.eu/results/">https://i-consentproject.eu/results/</a>	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
45	Regulatory and Ethics Toolkit, ICF guidelines	Trial Management	<a href="https://www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/">https://www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/</a>	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
46	Neonatal trials and informed consent: Points to consider	Trial Management	<a href="https://ecrin.org/projects/pedcrin/pedcrin-tools">https://ecrin.org/projects/pedcrin/pedcrin-tools</a>	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
47	EMA list of national competent authorities in the EU	Regulatory submission	<a href="https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human">https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human</a>	Updated list of European national competent authorities and their contact details	Regular updates	NO	Inventory
48	EUREC	Regulatory submission	<a href="http://www.eurecnet.org/information/index.html">http://www.eurecnet.org/information/index.html</a>	List of European Research Ethics Committees in Europe	Regular updates	NO	Inventory
49	CAMPUS	Regulatory submission	<a href="http://campus.ecrin.org/">http://campus.ecrin.org/</a>	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

50	Comprehensive Inventory STARS	Regulatory submission	<a href="https://www.csa-stars.eu/Inventory-1721.html">https://www.csa-stars.eu/Inventory-1721.html</a>	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
51	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	<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>	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
52	ICH Good Clinical Practice E6 (R2)	Quality Management	<a href="https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice#current-version---revision-2-section">https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice#current-version---revision-2-section</a>	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
53	ICH Good Clinical Practice E6 (R2) Training course	Quality management	<a href="https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice/">https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice/</a>	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
54	EC, Risk proportionate approaches in clinical trials	Quality management	<a href="https://www.gmp-compliance.org/files/guidemgr/2017_04_25_risk_proportionate_approaches_in_ct.pdf">https://www.gmp-compliance.org/files/guidemgr/2017_04_25_risk_proportionate_approaches_in_ct.pdf</a>	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

55	ECRIN_Risk-Based Monitoring Toolbox	Quality management	<a href="https://ecrin.org/tools/risk-based-monitoring-toolbox">https://ecrin.org/tools/risk-based-monitoring-toolbox</a>	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
56	ICH Topic E2A: Clinical Safety Data Management	Safety reporting	<a href="https://database.ich.org/sites/default/files/E2A_Guideline.pdf">https://database.ich.org/sites/default/files/E2A_Guideline.pdf</a>	Notes for definitions and standards on Safety reporting for ICH topic E A 2	1995	NO	Guideline
57	ICH Topic E2F Development Safety Update Report	Safety reporting	<a href="https://database.ich.org/sites/default/files/E2F_Guideline.pdf">https://database.ich.org/sites/default/files/E2F_Guideline.pdf</a>	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 safety reporting among the ICH regions	2010	NO	Guideline
58	Safety training	Safety reporting	<a href="https://www.sctoplatforms.ch/en/tools/online-safety-training-57.html">https://www.sctoplatforms.ch/en/tools/online-safety-training-57.html</a>	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
59	Introduction to collecting and reporting adverse events	Safety reporting	<a href="https://globalhealthtrainingcentre.tghn.org/introduction-collecting-and-reporting-adverse-events/">https://globalhealthtrainingcentre.tghn.org/introduction-collecting-and-reporting-adverse-events/</a>	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
60	Safety reporting forms	Safety reporting	<a href="https://www.sctoplatforms.ch/en/tools/safety-reporting-forms-21.html">https://www.sctoplatforms.ch/en/tools/safety-reporting-forms-21.html</a>	Swiss Clinical Trial Organisation Tool: Set of comprehensive forms for safety reporting tailored to different types of clinical research projects.	Regular updates	NO	Template
61	Causality Assessment of Adverse Events in paediatric trials	Safety reporting	<a href="https://ecrin.org/project/pedcrin/pedcrin-tools">https://ecrin.org/project/pedcrin/pedcrin-tools</a>	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
62	Safety data analyses of neonatal trials: Points to consider	Safety reporting	<a href="https://ecrin.org/projects/pedcrin/pedcrin-tools">https://ecrin.org/projects/pedcrin/pedcrin-tools</a>	PedCRIN tool: This tool provides practical points to consider when planning for the analysis of neonatal safety data	2021	YES	Recommendation

63	Research Data Management	Data Management	<a href="https://library-guides.ucl.ac.uk/research-data-management/">https://library-guides.ucl.ac.uk/research-data-management/</a>	A guide to managing outputs of research projects and handling issues such as copyright and data protection laws	Regular updates	NO	Guideline
64	Research Data Management Kit	Data Management	<a href="https://rdmkit.elixir-europe.org/index.html">https://rdmkit.elixir-europe.org/index.html</a>	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
65	Data Certification Standards/Data Certified Units	Data Management	<a href="https://ecrin.org/data-certification-standards">https://ecrin.org/data-certification-standards</a>	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
66	EDCTP Data Management portal	Data Management	<a href="https://edctpknowledgehub.tghn.org/Dat-man-por/">https://edctpknowledgehub.tghn.org/Dat-man-por/</a>	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
67	EDCTP Data Sharing Toolkit	Data Management	<a href="https://edctpknowledgehub.tghn.org/data-sharing-toolkit/">https://edctpknowledgehub.tghn.org/data-sharing-toolkit/</a>	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
68	Sharing and reuse of individual participant data from clinical trials: principles and recommendations (Ohmann et al., 2017)	Data Management	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5736032/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5736032/</a>	This article lists recommendations on providing access to individual participant data from clinical trials, using a broad interdisciplinary approach	2017	NO	Article

69	Evaluation of repositories for sharing individual-participant data from clinical studies (Banzi et al., 2019)	Data Management	<a href="https://pubmed.ncbi.nlm.nih.gov/30876434/">https://pubmed.ncbi.nlm.nih.gov/30876434/</a>	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
70	EudraLex - Volume 10 - Clinical trials guidelines_Chapter III_Quality of the investigational medicinal Product.	Investigational Product	<a href="https://ec.europa.eu/health/documents/eudralex/vol-10_en">https://ec.europa.eu/health/documents/eudralex/vol-10_en</a>	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
71	EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use	Investigational Product	<a href="https://ec.europa.eu/health/documents/eudralex/vol-4_en">https://ec.europa.eu/health/documents/eudralex/vol-4_en</a>	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
72	Clinical trials toolkit: Trial Supply	Investigational Product	<a href="https://www.ct-toolkit.ac.uk/downloads/Trial%20Supplies%20Guide%20v4.1_March2018.pdf">https://www.ct-toolkit.ac.uk/downloads/Trial%20Supplies%20Guide%20v4.1_March2018.pdf</a>	Guide prepared by MODEPHARMA to codify good practice on drug management in publicly funded clinical trials	2018	NO	Toolbox
73	Collection, storage and use of biological samples and related data in paediatric trials	Laboratory Processes	<a href="https://ecrin.org/project/pedcrin/pedcrin-tools">https://ecrin.org/project/pedcrin/pedcrin-tools</a>	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

74	Reflection paper on laboratory processes for clinical trials	Laboratory Processes	<a href="https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/reflection-paper-laboratories-perform-analysis-evaluation-clinical-trial-samples_en.pdf">https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/reflection-paper-laboratories-perform-analysis-evaluation-clinical-trial-samples_en.pdf</a>	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
75	Good clinical laboratory practice training	Laboratory Processes	<a href="https://globalhealthtrainingcentre.tghn.org/good-clinical-laboratory-practice-course/">https://globalhealthtrainingcentre.tghn.org/good-clinical-laboratory-practice-course/</a>	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
76	GCLP (Good clinical laboratory practice) Guidance	Laboratory processes	<a href="https://apo.who.int/publications/i/item/good-clinical-laboratory-practice-(gclp)">https://apo.who.int/publications/i/item/good-clinical-laboratory-practice-(gclp)</a>	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
77	GCP Lab guidance	Laboratory processes	<a href="https://web.archive.org/web/20100506014710/http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&amp;dDocName=CON051910&amp;RevisionSelectionMethod=Latest">https://web.archive.org/web/20100506014710/http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&amp;dDocName=CON051910&amp;RevisionSelectionMethod=Latest</a>	MHRA Guidance on the maintenance of regulatory compliance in laboratories that perform the analysis or evaluation of clinical trial samples	2009	NO	Guideline

78	ICH Statistical Principles for clinical trials E9	Statistical Analysis Plan	<a href="https://database.ich.org/sites/default/files/E9_Guideline.pdf">https://database.ich.org/sites/default/files/E9_Guideline.pdf</a>	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
79	Guideline for the Content of Statistical Analysis Plans in Clinical Trials	Statistical Analysis Plan	<a href="https://lctc.org.uk/SAP-Statement">https://lctc.org.uk/SAP-Statement</a>	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
80	ECRIN Metadata Repository	Statistical Analysis Plan	<a href="https://ecrin.org/clinical-research-metadata-repository">https://ecrin.org/clinical-research-metadata-repository</a>	Search of metadata (including protocols and Statistical Analysis Plans) on published clinical trials.	2020	NO	Repository
81	Clinical Trials Registry (NIH)	Statistical Analysis Plan	<a href="https://clinicaltrials.gov/">https://clinicaltrials.gov/</a>	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
82	Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic)	Archiving	<a href="https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-content-management-archiving-clinical-trial-master-file-paper/electronic_en.pdf">https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-content-management-archiving-clinical-trial-master-file-paper/electronic_en.pdf</a>	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
83	ICH E3 guideline on Structure and Content of Clinical Study Reports (ICH E3)	Trial report	<a href="https://database.ich.org/sites/default/files/E3_Guideline.pdf">https://database.ich.org/sites/default/files/E3_Guideline.pdf</a>	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



84	CONSORT statement	Trial report	<a href="http://www.consort-statement.org/">http://www.consort-statement.org/</a>	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
85	CONSORT statement of N-of-1 trials (extension of the CONSORT statement)	Trial report	<a href="http://www.consort-statement.org/extensions/overview/n-of-1">http://www.consort-statement.org/extensions/overview/n-of-1</a>	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
86	EUPATI tutorial: Reporting and recording clinical trial results	Dissemination	<a href="https://toolbox.eupati.eu/resources/recording-and-reporting-clinical-trial-results/">https://toolbox.eupati.eu/resources/recording-and-reporting-clinical-trial-results/</a>	EUPATI tutorial about recording and reporting clinical trial results	Regular updates	NO	Training
87	EudraCT (European Union Drug Regulating Authorities Clinical Trials Database)	Dissemination	<a href="https://eudract.ema.europa.eu/">https://eudract.ema.europa.eu/</a>	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
88	Technical guideline on the format of the data fields of results-related information on clinical trials	Dissemination	<a href="https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/2013_01_22_tg_en.pdf">https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/2013_01_22_tg_en.pdf</a>	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
89	Tutorials on posting results on EudraCT	Dissemination	<a href="https://eudract.ema.europa.eu/multimedia_tutorials.html">https://eudract.ema.europa.eu/multimedia_tutorials.html</a>	Tutorials on posting results on the European Union Drug Regulating Authorities Clinical Trials Database (EudraCT)	Regular updates	NO	Training
90	Summaries of clinical trial results for laypersons	Dissemination	<a href="https://ec.europa.eu/health/system/files/2021-10/gisp_en_0.pdf">https://ec.europa.eu/health/system/files/2021-10/gisp_en_0.pdf</a>	Guideline for the production of summaries of clinical results for laypersons	Regular updates	NO	Guideline