#	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	**Clinical Trial Decision Tool**	Define a question	https://decisiontool.pauljanssenfuturelab.eu/	Clinical trial decision tool developed by Paul Janssen Futurelab and the CCMO. The tool helps you in assessing whether your study is considered a clinical trial, a low-intervention clinical trial or is outside scope according to the definitions given in the Clinical Trials Regulation	2022	NO	Guideline
3	**Patient group engagement Priotization Tool**	Define a question	https://prioritizationtool.ctti-clinicaltrials.org/ https://pubmed.ncbi.nlm.nih.gov/32996107/	Web-based prioritization tool to help clinical research sponsors and patient groups identify high-priority engagement activities. Use of this tool can help sponsors and patient groups identify the engagement activities that they believe will provide the most benefit for the least investment	2020	NO	Toolbox
4	**Patient engagement resource centre**	Define a question	https://patient-engagement.eu/	Selected relevant public resources to help researchers understand the basics of patient engagement, and guide you through the different phases of patient engagement: from planning to conducting and evaluating.	2024	NO	Toolbox
5	**Short guide on patient partnership in rare disease research projects**	Define a question	https://www.ejprarediseases.org/wp-content/uploads/2021/03/SHORT-GUIDE-ON-PATIENT-PARTNERSHIPS-IN-RARE-DISEASE-RESEARCH-PROJECTS.pdf	The European Joint Programme on Rare Diseases (EJP RD) has developed, together with a working group led by EURORDIS, named Patient Engagement in Biomedical Research Projects (PENREP), a short guide on Patient Partnership in rare disease research projects.	2022	YES	Guideline

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6	**EUPATI patient involvement resource library**	Define a question	https://toolbox.eupati.eu/resources-guidance/patient-involvement-resource-library/	EUPATI Patient Involvement Resource Library, is a peer reviewed collection covering patient involvement in medicines development, including advocacy, regulation, clinical trials and digital health. The resources are free to use and share with proper referencing.	2025	NO	Toolbox
7	**ICH General considerations for clinical studies E8 (R1)**	Develop a protocol	https://database.ich.org/sites/default/files/E8-R1_Guideline_Step4_2021_1006.pdf	Describes internationally accepted principles and practices in the conduct of both individual clinical trials and overall development strategy for new medical products	2021	NO	Guideline
8	**ICH General principles for planning and design of multi-regional clinical trials E17**	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
9	**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
10	**Preparedness of medicines' clinical trials in paediatrics**	Develop a protocol	https://www.ema.europa.eu/en/documents/other/preparedness-medicines-clinical-trials-paediatrics-recommendations-enpr-ema-working-group-trial-preparedness_en.pdf	Developed by the European Network of Paediatric Research (Enpr-EMA) working group, these recommendations are a structured assessment of contributing factors that enable efficient conduct of individual clinical trials in paediatrics and were developed for sponsors, principal investigators and triallists.	2020	YES	Recommendation

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11	**ICH Harmonised guideline paediatric extrapolation E11A**	Develop a protocol	https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-e11a-pediatric-extrapolation-step-5_en.pdf	This guideline provides recommendations for harmonised approaches for paediatric extrapolation to support the development and authorisation of paediatric medicines. This guideline is to be read in conjunction with the ICH E11 guideline on clinical investigation of medicinal products in the paediatric population	2024	YES	Guideline
12	**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
13	**Advice on medicines for human use in the EU medicines regulatory network**	Develop a protocol	https://accelerating-clinical-trials.europa.eu/our-work/consolidated-advice-clinical-trials_en	With a view to clarifying the scope of current scientific and regulatory advice activities, ACT-EU Priority Action on consolidated advice has mapped information on current voluntary procedures available from EU regulators on Medicines for Human use and collated this information in the form of questions and answers	2024	NO	Guideline

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14	**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
15	**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
16	**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
17	**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
18	**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

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19	**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
20	**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
21	**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
22	**2025 SPIRIT Statement (Standard Protocol items)**	Develop a protocol	https://www.consort-spirit.org/	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.	2025	NO	Checklist

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23	**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
24	**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
25	**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
26	**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

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27	**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
28	**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
29	**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
30	**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
31	**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

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32	**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
33	**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
34	**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
35	**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
36	**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
37	**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

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38	**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
39	**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
40	**Scientify research**	Identify a Funder	https://www.scientifyresearch.org/	An open, curated and structured research funding database	Regular updates	NO	Database
41	**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.	Regular Updates	NO	Inventory
42	**Overview of currently open calls within the Cluster Health area (EU)**	Identify a Funder	https://www.healthncp.net/find-open-calls	Overview of currently open calls proposed by HNN. 3.0, a Horizon Europe funded project aiming to align services of national contact points of Horizon Europe Cluster Health. Among others, they are developing tools to make easier finding funding calls on the Cluster Health area.	Regular updates	NO	Inventory

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43	**Database for multicountry clinical research funding opportunities in Europe**	Identify a Funder	https://era4health.eu/results/docs/D130.pdf	Developed by the ERA4Health Partnership, this document is an inventory of funding resources available for multinational investigator-initiated clinical studies in Europe	2023	NO	Inventory
44	**OECD Recommendation on governance of clinical trials**	Risk Assessment	https://legalinstruments.oecd.org/public/doc/281/281.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
45	**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
46	**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

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47	**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
48	**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
49	**Data Management Guidelines, Version 2.0**	Data Management Plan	https://edctpknowledgehub.tghn.org/Dat.man-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
50	**Mapping of organisations providing support to multicountry IICS**	Trial Management	https://era4health.eu/results/docs/D131.pdf	This mapping describes organizations that have developed capacity for supporting planning and designing multicountry Investigator Initiated Clinical Studies	2023	NO	Inventory
51	**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
52	**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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53	**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
54	**CTTI implementation tools**	Trial Management	https://ctti-clinicaltrials.org/about/ctti-projects/	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	Toolbox
55	**UKTMN Guide to Efficient Trial Management**	**Trial Management**	https://www.tmn.ac.uk/resources/34-the-guide-to-efficient-trial-management	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	2024	NO	Guideline
56	**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
57	**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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58	**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
59	**The adaptative platform trial toolbox**	Trial Management	https://covid19trials.eu/en/adaptative-platform-trial-toolbox	This toolbox aims to collect the accumulated knowledge, experience, & resources from multiple projects and trials into a practical and guided toolbox to facilitate planning & conduct of future APTs in any therapeutic area.	Regular updates	NO	Toolbox
60	**EnprEMA Network Database.**	Trial Management	https://www.ema.europa.eu/en/partners-networks/networks/european-network-paediatric-research-european-medicines-agency-enpr-ema	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
61	**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
62	**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

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63	**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
64	**Ethical considerations for clinical trials on medicinal products conducted with minors**	Trial Management	https://health.ec.europa.eu/document/download/d721d6cb-687a-477f-b40f-8c7922e9ec9a_en?filename=2017_09_18_ethical_consid_ct_with_minors.pdf	Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use	2017	YES	Recommendation
65	**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	2023	YES	Guideline
66	**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
67	**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
68	**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

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69	**Library of participant information leaflets**	Trial Management	https://www.trialforge.org/excelsior-pil-library/	This repository of Participation Information Leaflets (PILs) and Informed Consent Forms (ICFs) used in randomised trials was collected as part of the EXCELSIOR project. The repository was used to investigate the understanding of key clinical trial concepts for example, randomisation and informed	2020	NO	Inventory
70	**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
71	**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
72	**Recruitment and informed consent procedure template**	Trial Management	https://health.ec.europa.eu/document/download/dbe5bb25-dd62-4286-95b9-bd8d3ec8678d_en?filename=informedconsent_patientrecruitmentprocedure_en.pdf	Template for describing recruitment arrangements and/or informed consent procedure for clinical trials within the scope of the Clinical Trial Regulation (CTR). This template has been endorsed by the EU Clinical Trials Coordination and Advisory Group (CTAG) to comply with CTR	2022	NO	Guideline
73	**Effective eConsent Strategies for Every Study: Utilizing the eConsent Fit-for-Purpose Study Framework**	Trial management	https://www.appliedclinicaltrialsonline.com/view/effective-econsent-strategies-fit-for-purpose-study-framework	This tool provides sponsors (and any stakeholder interested in eConsent) a guide on how to define and design the right eConsent for a particular study and how to generate effective and comparable study data on eConsent.	2024	NO	Recommendation
74	**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

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75	**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
76	**Recommendations on cross-border access to clinical trials**	Trial Management	https://eu-x-ct.eu/recommendations	To address the current challenges faced by cross-border participants in clinical trials, the EU-X-CT initiative has developed general recommendations on key aspects of clinical trial management and conduct. The recommendations aim to improve safe and equitable access to cross-border clinical trials	2025	NO	Recommendation
77	**Trials@Home recommendations on t**	Trial Management	https://trialsathome.com/	The Trials@Home consortium, a public-private partnership funded by the Innovative Medicines Initiative has published a comprehensive set of recommendations covering methodological, regulatory, ethical, technical, operational, and social aspects of Decentralized Clinical Trials.	2025	NO	Recommendation
78	**Recommendation paper on decentra**	Trial Management	https://health.ec.europa.eu/document/download/2ccc46bf-2739-4b9a-ab6b-6f425db78c61_en?filename=mp_decentralised-elements_clinical-trials_rec_en.pdf	Recommendations on the introduction of decentralised elements in the conduct of clinical trials in the EU/EEA, regardless of any health crisis, and in consideration of the currently limited national guidances.	2025	NO	Recommendation
79	**ERDERA Management of multination**	Trial Management	https://ecrin.org/training	This three-hour programme familiarises investigators and site teams with the specific challenges of initiating and managing multinational rare-disease trials. It is solution-oriented, addressing common barriers such as differing national implementations of European clinical	2025	YES	Training
80	**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
81	**EUREC**	Regulatory submission	http://www.eurecnet.org/information/index.html	List of European Research Ethics Committees in Europe	Regular updates	NO	Inventory

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82	**RED (Regulatory and Ethical Database)**	Regulatory submission	https://red.ecrin.org/en	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
83	**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
84	**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
85	**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
86	**Clincal Trials Regulation (EU) No 536/2014 in Practice**	Regulatory submission	https://health.ec.europa.eu/system/files/2023-12/mp_ctr-536-2014_guide_en.pdf	Quick guide on the rules and procedures of the EU Clinical Trials Regulation drawn up by the Clinical Trials Coordination and Advisory Group (CTAG) as its members are the National Contact Points defined in the abovementioned Regulation	Regular Updates	NO	Guideline

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87	**Clinical Trials Coordination Group Fees for clinical trials submitted under the Clinical Trial Regulation (CTR)**	Regulatory submissioin	https://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/03-Working_Groups/CTCG/2025-1-Fees-for-clinical-trials-submitted-under_CTR.pdf	Description of Fees for clinical trials submitted under the Clinical Trial Regulation (CTR) in the Clinical Trial Information System (CTIS) for EU/EEA member states, including information about fees reduction	Regular updates	NO	Guideline
88	**Eudralex - Templates CTIS Application Part I and Part II CTA**	Regulatory subimission	https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en	Templates documents for Part I and Part II documentation for CTIS applications	Regular updates	NO	Guideline
89	**MedTechEthics, National Part II CTA Requirements**	Regulatory submission	https://health.ec.europa.eu/document/download/7ae68dce-da1a-40e5-81ed-25d6211cda0b_en?filename=mp_ct_medethicseu_deliverables_cta-per-ms_en.pdf	This report provides an overview of the required part II documentation of 21 MS in EU/EEA.	Regular updates	NO	Guideline
90	**ICH Good Clinical Practice E6 (R3)**	Quality Management	https://www.ema.europa.eu/en/ich-e6-good-clinical-practice-scientific-guideline#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	2024	NO	Guideline
91	**ICH Good Clinical Practice E6(R3) Training course (Global Health Network)**	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	2025	NO	Training
92	**ICH Good Clinical Practice E6(R3) Training material (EMA)**	Quality management	https://accelerating-clinical-trials.europa.eu/our-work/good-clinical-practice-modernisation_en	EMA has developed Interactive training materials on the Revised ICH E6(R3) principles and Annex 1	2025	NO	Training

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93	**WHO Guidance for best practice for clinical trials**	Quality management	https://www.who.int/publications/i/item/9789240097711	The WHO guidance for best practice for clinical trials provides a comprehensive framework for the design, conduct, registration, oversight, and reporting of clinical trials globally. It aims to ensure ethical, scientific, and methodological integrity in clinical research.	2024	NO	Guideline
94	**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
95	**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
96	**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
97	**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
98	**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

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99	**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
100	**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
101	**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
102	**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
103	**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
104	**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
105	**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

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106	**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
107	**Guideline on computerised systems and electronic data in clinical trials**	Data Management	https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-and-electronic-data-clinical-trials_en.pdf	This guideline addresses the use of computerised systems—including instruments, software, and 'as a service' platforms—in the creation, capture, and management of electronic clinical data. It aims to ensure the quality and reliability of trial data, safeguarding participant rights and supporting robust decision-making processes	2023	NO	Guideline
108	**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
109	**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
110	**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
111	**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

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112	**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
113	**Mapping of Data-Sharing Repositories for Paediatric Clinical Research—A Rapid Review (Felisi et. al., 2024)**	Data Management	https://www.mdpi.com/2306-5729/9/4/59	This paper looked at existing data-sharing repositories (DSRs) for the re-use of individual paediatric patient data from clinical trials	2024	YES	Article
114	**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
115	**Guidelines 01/2025 on Pseudonymisation European Data Protection Board**	Data Management	https://www.edpb.europa.eu/system/files/2025-01/edpb_guidelines_202501_pseudonymisation_en.pdf	These guidelines intend to clarify the use and benefits of pseudonymisation for controllers and processors	2025	NO	Guideline
116	**Guidelines for data sharing of investigator-initiated clinical studies**	Data Management	https://zenodo.org/records/14904510	This document provide general guidance for preparing data sharing plan for clinical studies, including guidance on informed consent (ICF) for secondary use of data and long-term storage of data, especially Individual Patient Data (IPD) in repositories following the FAIR (Findable, Accessible,	2024	NO	Recommendation
117	**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

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118	**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.	Regular updates	NO	Guideline
119	**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
120	**Clinical trials toolkit: Trial Supply**	Investigational Product	https://www.ct-toolkit.ac.uk/media/1011/download	Guide prepared by MODEPHARMA to codify good practice on drug management in publicly funded clinical trials	2018	NO	Toolbox
121	**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

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122	**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
123	**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
124	**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
125	**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

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126	**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
127	**ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials**	Statistical Analysis Plan	https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e9-r1-addendum-estimands-and-sensitivity-analysis-clinical-trials-guideline-statistical-principles-clinical-trials-step-5_en.pdf	The addendum aims to improve the alignment between clinical trial objectives and statistical analyses by introducing the concept of "estimands" — precise descriptions of the treatment effect a trial intends to estimate. This approach facilitates clearer communication among clinicians, statisticians, and regulators.	2020	NO	Guideline
128	**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
129	**ECRIN Metadata Repository**	Statistical Analysis Plan	https://newmdr.ecrin.org/Search	Search of metadata (including protocols and Statistical Analysis Plans) on published clinical trials.	2020	NO	Repository
130	**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

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131	**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
132	**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
133	**CONSORT 2025 statement**	Trial report	https://jamanetwork.com/journals/jama/fullarticle/2832868	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	2025	NO	Checklist
134	**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
135	**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
136	**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

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137	**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
138	**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
139	**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
140	**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
141	**Summaries of clinical trial results for laypersons**	Dissemination	https://health.ec.europa.eu/system/files/2021-10/glsp_en_0.pdf	Guideline for the production of summaries of clinical results for laypersons	Regular updates	NO	Guideline