

Clinical study reports: A snapshot for aspiring medical writers

Surayya Taranum

Evidera-PPD, part of Thermo Fisher Scientific
Paris, France

doi: 10.56012/qett4705

Correspondence to:

Surayya Taranum

surayya.taranum@evidera.com

Abstract

Clinical study reports (CSR) are detailed documents that provide a comprehensive and transparent account of the conduct and results of a clinical trial. They are an important source of information for the regulatory authorities, healthcare professionals, and the public, and are used to assess the safety and efficacy of medical treatments. This article presents an overview of the steps involved in writing and submitting CSRs to regulatory authorities, as well as reporting clinical trial findings to the scientific community and the public.

The clinical study report (CSR) is a document that describes the results of a clinical trial and is used to assess the safety and effectiveness of a new medical treatment.¹⁻³ CSRs provide detailed information about the design, conduct, and results of clinical studies. A CSR is prepared by the sponsor of the clinical trial to report study outcomes to regulatory authorities, such as the FDA in the US or the EMA in the EU. Regulatory authorities use the information in the CSR to evaluate the safety, efficacy, and quality of the medicinal product and to determine whether it should be approved for marketing. Information provided in the CSR is also used by researchers and other stakeholders including patients and the public to evaluate the safety and efficacy of the treatment being tested and to make decisions about its potential use in clinical practice.

Types of CSRs

Different types of CSRs can be prepared depending on the specific context and purpose of the clinical trial, as well as the requirements of the regulatory authority reviewing the data.

Examples include:

- **Full CSR:** The most comprehensive type of CSR. It includes all the data and analyses from the clinical trial. Full CSRs are typically used for regulatory purposes, such as submitting data to the FDA in support of a new drug application.
- **Interim CSR:** Used to report on the progress of a clinical trial that is still ongoing. Interim CSRs are typically shorter than full CSRs, are

written once the primary and secondary endpoints are met and may be used for marketing authorisation application (MAA) before the clinical trial is complete. Data on the exploratory endpoints and long-term follow-up are included later in the full CSR.

- **Abbreviated CSR:**^{4,5} Used for studies that do not contribute to the evaluation of efficacy or provide definitive information on the clinical pharmacology of the investigational product. Abbreviated CSRs contain abbreviated method and efficacy sections, as well as a detailed safety section.
- **Synoptic CSR:**⁴ Generally prepared for studies that are not relevant in evaluating the effectiveness and clinical pharmacology of the



medicinal product but provide data for evaluating its safety (e.g. studies evaluating routes of drug administration for which marketing approval is not required, incomplete studies enrolling fewer than one-third of intended participants, and early general phase 1 safety-tolerance studies).

Structure of a CSR

The content and format of a CSR are based on The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guideline E3 on the Structure and Content of Clinical Study Reports (ICH E3),³ which was approved in 1996. The detailed structure of a CSR may vary slightly depending on the specific requirements of the regulatory authority to which it is being submitted. Medical writers use the ICH E3 template,³ the TransCelerate template,⁶ and the CORE (Clarity and Openness in Reporting: E3-based) Reference to create

CSRs that are compliant with regulatory guidelines.⁷⁻¹⁰

A CSR typically includes the following components:

- **Synopsis:** A brief overview of the main findings and conclusions of the study
- **Introduction:** Background information about the medicinal product being studied, including its intended use and the rationale for the study
- **Methods:** The study design, objectives and endpoints, patient population, interventions, and outcomes; includes information about the ethical considerations and any statistical analyses that were performed
- **Results:** The findings of the study, including both numerical data and descriptive information; also includes tables, figures, and

other visual aids to illustrate the results

- **Discussion:** The clinical implications of the study findings and limitations of the study
- **Conclusion:** The main findings and conclusions of the study
- **Appendices:** Additional information or materials that are relevant to the study such as protocols, informed consent forms, data tables, figures and listings, as well as patient narratives

The detailed structure of a CSR may vary slightly depending on the specific requirements of the regulatory authority to which it is being submitted.

Submission of a CSR

The submission process for CSRs differs depending on the regulatory authority. Under the Clinical Trials Regulation (EU) No 536/2014 (EU CTR), EU member states and European Economic Area (EEA) countries have, since January 31, 2022, been able to

use the Clinical Trial Information System (CTIS) to submit all clinical trial data.¹¹⁻¹³ The CTIS harmonises the submission, assessment, and supervision processes for clinical trials; A single application can be submitted through the CTIS for review by all EU/EEA countries. The CTIS also facilitates interactions between clinical trial sponsors and the regulatory authorities in EU/EEA countries throughout the clinical trial, and replaced the EU Drug Regulating Authorities Clinical Trials Database (EudraCT) on January 31, 2023.^{14,15} The CTIS will store all documents related to clinical trials (e.g. CSRs and clinical study protocols) and will also serve as a publicly accessible database for clinical trial data. However, the CTIS does not accept or evaluate MAAs for the commercialisation of medicinal products, which must be made separately.

As per Article 37 of the EU CTR, sponsors who have had their MAAs approved are required to submit a full CSR to the CTIS within 30 days after the marketing authorisation approval.^{9,16} Article 37(4) also requires the sponsor to submit a summary of the clinical trial results to the CTIS, irrespective of the outcome of the clinical trial, within one year from the end of the trial in adults (6 months for a clinical trial in the paediatric population), in all the EU languages in which the study was conducted.^{9,17} Sponsors are required to provide a summary of results and a lay summary after the end of each clinical trial in the EU. The CSR, summary of clinical trial



Table 1. Training courses on writing clinical study reports

Course name	Organisation	Description
Regulatory Medical Writing Bundle ⁴⁰	Regulatory Affairs Professionals Society	Introduces medical writing, different types of regulatory applications, and techniques for improving document quality
Regulatory Medical Writing Training Programme ⁴¹	Groep Biomedische Wetenschappen KU Leuven	Provides an overview of clinical development and a practical introduction to writing clinical and regulatory documents
Regulatory Affairs Training Program ⁴²	Duke University School of Medicine	Provides an overview of premarket regulatory work related to drugs, biologics, and medical devices
Regulatory Writing ⁴³	University of California San Diego Extended Studies	Provides training on writing CSRs, information on regulations, and guidance governing regulatory documents in the US and the EU
Regulatory Writing ⁴⁴	The University of Chicago	Focuses on the basics of editing regulatory documents, as well as collaborating on creating biomedical regulatory packets and navigating the writing, submission, and auditing processes
CRED Regulatory Document Writing and Management ⁴⁵	The Organization for Professionals in Regulatory Affairs	Focuses on the theory and practice of writing effective regulatory documents and communications
Writing Clinical Study Reports ⁴⁶	European Center for Clinical Research Training	Covers the principles of clinical research writing and reporting, including how to write a CSR. The course includes interactive exercises and case studies
Clinical Study Reports: Mastering the Essential Skills ⁴⁷	European Medical Writers Association	Double workshop for medical writers with little or no experience in writing CSRs. Workshops on the CORE Reference as well as variations of CSRs are also available

Abbreviations: CSR, clinical study report

results, and the lay summary are disclosed publicly. In the US, a full CSR is submitted as part of a New Drug Application (NDA) to the FDA.¹⁸ Unlike in the EU, CSRs in the US are not disclosed publicly.

Sponsors in the EU are required to submit all CSRs that are intended to be used for marketing authorisations.^{19,20} As part of an MAA, CSRs are compiled in Module 5 of the common technical document (CTD), a standardised format for submitting regulatory information to health authorities globally.^{21,22} The CTD consists of five modules that cover different aspects of the submission (e.g. quality, safety, and efficacy of the product), and includes a comprehensive overview of the clinical trials and their results.

Reporting findings published in CSRs

Findings reported in CSRs are disseminated in several ways.

The CSR, summary of clinical trial results, and the lay summary are disclosed publicly in the CTIS.

- **European Public Assessment Reports:**²³ Reports prepared by the EMA and published on the EMA website. These reports provide information on the medicinal product, including the evaluation process and the decision to approve or reject the MAA
- **Clinical trial registries:** The EudraCT or CTIS databases of the EMA, the International Clinical Trials Registry Platform of the WHO,²⁴ and the ClinicalTrials.gov registry²⁵ in the US
- **Other public disclosure platforms:** EMA clinical data website under EMA Policy 0070,²⁶ Health Canada Public Release of Clinical Information²⁷
- **Lay language summaries:** Published in the CTIS or on company websites
- **Publications:** Manuscripts in peer-reviewed journals, conference posters and presentations, abstracts, preprints, and plain-language

summaries. Good Publication Practice guidelines^{28–30} mandate that all biomedical research should be published in peer-reviewed journals in a timely manner and that reporting of biomedical research should follow all applicable laws and guidelines. Several checklists exist to ensure that findings from a CSR are reported accurately and transparently in peer-reviewed medical journals.³¹ Examples include:

- **CONSORT (Consolidated Standards of Reporting Trials):**³² A guideline for reporting randomised, controlled trials
- **STROBE (STrengthening the Reporting of OBservational studies in Epidemiology):**³³ A guideline for reporting observational studies
- **Product information:** Clinical trial results are also reported in the summary of product characteristics or prescribing information (a document prepared for healthcare professionals), as well as package leaflets (aimed at the patient).

Writing your first CSR

Medical writers specialising in regulatory documents typically spend a lot of time writing CSRs. A medical writer working on a CSR needs to have sound knowledge of how clinical trials are planned, conducted, and reported^{34–39} For an aspiring medical writer, there are several online training programs and courses on how to write a CSR (Table 1). Writing a CSR is a team effort involving multiple stakeholders including clinicians, biostatisticians, regulatory specialists, safety experts, and the clinical study management team. Therefore, the medical writer also needs strong communication and project management skills. Planning timelines and determining stakeholder roles before the start of the project can help with effective project management. CSR templates based on the ICH E3 guideline, TransCelerate template, and CORE Reference can help the medical writer create a document that meets rigorous regulatory standards.

Acknowledgements

The author thanks Stephen Gilliver, PhD (Evidera-PPD, part of Thermo Fisher Scientific) for review and editorial support.

Disclosures and conflicts of interest

The author is an employee of Evidera-PPD, part of Thermo Fisher Scientific.

References

- American Medical Writers Association. What Is a clinical study report? A medical communicator's guide [cited 2022 Dec 19]. Available from: <https://blog.amwa.org/what-is-a-clinical-study-report-a-medical-communicators-guide>.
- EMA. ICH E6 (R2) Good clinical practice – Scientific guideline [cited 2022 Dec 19]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-good-clinical-practice-e6r2-step-5_en.pdf.
- EMA. ICH Topic E 3. Structure and content of clinical study reports 1996 [cited 2022 Dec 19]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-3-structure-content-clinical-study-reports-step-5_en.pdf.
- FDA. Guidance for industry submission of abbreviated reports and synopses in support of marketing applications 1999 [cited 2023 Jan 19]. Available from: <https://www.fda.gov/files/drugs/published/Submission-of-Abbreviated-Reports-and-Synopses-in-Support-of-Marketing-Applications.pdf>.
- Alfaro V, Cullerell-Young M, Tanovic A. Abbreviated clinical study reports with investigational medicinal products for human use: Current guidelines and recommendations. *Croat Med J*. 2007;48(6):871–7. doi:10.3325/cmj.2007.6.871.
- Hamilton S, Bernstein AB, Blakey G, et al. Critical review of the TransCelerate Template for clinical study reports (CSRs) and publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table. *Res Integr Peer Rev*. 2019;4:16. doi:10.1186/s41073-019-0075-5
- CORE Reference. Clarity and openness in reporting: E3-based [cited 2022 Dec 19]. Available from: <https://www.core-reference.org/>.
- EMWA. The CORE Reference project [cited 2022 Dec 19]. Available from: <https://www.emwa.org/resources/core-reference/>.
- Hamilton S, Bernstein AB, Blakey G, et al. Developing the Clarity and Openness in Reporting: E3-based (CORE) Reference user manual for creation of clinical study reports in the era of clinical trial transparency. *Res Integr Peer Rev*. 2016;1:4. doi:10.1186/s41073-016-0009-4
- Hamilton S, D J. CORE Reference – a tool for modern clinical study reports in an era of increasing transparency and disclosure. *Medical Writing*. 2018;27(2):64–7.
- EMA. Clinical Trials Information System (CTIS) [cited 2022 Dec 19]. Available from: <https://euclinicaltrials.eu/>.
- EMA. Clinical Study Reports submission [cited 2022 Dec 19]. Available from: https://www.ema.europa.eu/en/documents/other/quick-guide-clinical-study-reports-submission-ctis-training-programme-module-13_en.pdf.
- EMA. Clinical Trials Regulation [cited 2022 Dec 19]. Available from: <https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation#clinical-trials-information-system-section>.
- EMA. EudraCT. [cited 2022 Dec 19]. Available from: <https://eudract.ema.europa.eu/>.
- EMA. Key Information for Sponsors on CTIS [cited 2022 Dec 19]. Available from: https://www.ema.europa.eu/en/documents/other/clinical-trials-information-system-key-information-sponsors-ctis_en.pdf.
- European Commission. Clinical trials – Regulation EU No 536/2014 [cited 2022 Dec 19]. Available from: https://health.ec.europa.eu/medicinal-products/clinical-trials/clinical-trials-regulation-eu-no-5362014_en#eu-clinical-trial-portal-and-database.
- Barnes A, Patrick S. Lay summaries of clinical study results: An overview. *Pharmaceut Med*. 2019;33(4):261-8. doi:10.1007/s40290-019-00285-0
- US FDA. New Drug Application (NDA) [cited 2022 Dec 19]. Available from: <https://www.fda.gov/drugs/types->



- applications/new-drug-application-nda.
19. EMA. Marketing authorisation [cited 2022 Dec 19]. Available from: <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation>.
 20. EMA. Obtaining an EU marketing authorisation, step-by-step [cited 2022 Dec 19]. Available from: <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/obtaining-eu-marketing-authorisation-step-step>.
 21. EMA. ICH M4 Common technical document (CTD) for the registration of pharmaceuticals for human use - organisation of CTD - Scientific guideline [cited 2022 Dec 19]. Available from: <https://www.ema.europa.eu/en/ich-m4-common-technical-document-ctd-registration-pharmaceuticals-human-use-or-organisation-ctd#documents-section>.
 22. ICH harmonisation for better health. M4: The Common Technical Document [cited 2022 Dec 19]. Available from: <https://www.ich.org/page/ctd>.
 23. EMA. European public assessment reports: Background and context [cited 2022 Dec 19]. Available from: <https://www.ema.europa.eu/en/medicines/what-we-publish-when/european-public-assessment-reports-background-context>.
 24. WHO. International Clinical Trials Registry Platform (ICTRP) [cited 2022 19 Dec]. Available from: <https://www.who.int/clinical-trials-registry-platform>.
 25. US National Library of Medicine. ClinicalTrials.gov [cited 2022 Dec 19]. Available from: <https://www.clinicaltrials.gov/>.
 26. EMA. Clinical data publication [cited 2023 Jan 19]. Available from: <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication>.
 27. Health Canada. Guidance document on Public Release of Clinical Information: Profile page [cited 2023 Jan 19]. Available from: <https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/profile-public-release-clinical-information-guidance.html>.
 28. Battisti WP, Wager E, Baltzer L, et al. Good publication practice for communicating company sponsored medical research: GPP3. *Ann Intern Med.* 2015;163(6): 461–4. doi:10.7326/m15-0288
 29. DeTora LM, Toroser D, Sykes A, et al. Good publication practice (GPP) guidelines for company-sponsored biomedical research: 2022 update. *Ann Intern Med.* 2022;175(9):1298-304. doi:10.7326/m22-1460
 30. ISMPP. Introducing GPP 2022 [cited 2022 Dec 19]. Available from: <https://www.pathlms.com/ismpp>.
 31. Equator Network. Enhancing the QUALity and Transparency Of health Research [cited 2022 Dec 19]. Available from: <https://www.equator-network.org/>.
 32. CONSORT. Consolidated Standards of Reporting Trials [cited 2022 Dec 19]. Available from: <https://www.consort-statement.org/>.
 33. STROBE. Strengthening the reporting of observational studies in epidemiology [cited 2022 Dec 19]. Available from: <https://www.strobe-statement.org/>.
 34. Friedman LM, CD F. Fundamentals of Clinical Trials. 4th ed2010.
 35. LF W. Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics2009.
 36. RAPS. Fundamentals of US Regulatory Affairs. 11th ed.
 37. RAPS. Regulatory Writing: An Overview. 2nd ed.
 38. RAPS. Fundamentals of EU Regulatory Affairs. 9th ed.
 39. RAPS. Key Regulatory Topics: eCTD.
 40. Regulatory Affairs Professionals Society. Regulatory Medical Writing Bundle [Complete Package] [cited 2022 Dec 19]. Available from: <https://www.raps.org/products/regulatory-medical-writing-bundle-complete-package>.
 41. Groep Biomedische Wetenschappen KU Leuven. Regulatory Medical Writing Training Programme [cited 2022 Dec 19]. Available from: https://gbiomed.kuleuven.be/english/phd/PhD_Researchers/Skills/medical-writing-training-programme.
 42. Duke University School of Medicine. Regulatory Affairs Training Program [cited 2022 Dec 19]. Available from: <https://medschool.duke.edu/research/research-support/research-support-offices/office-regulatory-affairs-and-quality-3>.
 43. UC San Diego Extended Studies. Capstone: Regulatory Writing [cited 2022 Dec 19]. Available from: <https://extendedstudies.ucsd.edu/courses-and-programs/capstone-regulatory-writing>.
 44. The University of Chicago. Regulatory Writing [cited 2022 Dec 19]. Available from: <https://professional.uchicago.edu/find-your-fit/non-credit-certificates/regulatory-writing>.
 45. TOPRA. CRED Regulatory Document Writing and Management [cited 2022 Dec 19]. Available from: https://www.topra.org/TOPRA/TOPRA_Member/Events/Event_Display.aspx?EventKey=DOC22O.
 46. European Center for Clinical Research Training. Writing Clinical Study Reports [cited 2022 Dec 19]. Available from: <https://ecrct.com/writing-clinical-study-reports/>.
 47. EMWA. Clinical study reports –Mastering the essential skills (double workshop) [cited 2023 Jan 19]. Available from: http://filemaker.emwa.org/workshops/view_workshop.php?recid=1318



Author information

Surayya Taranum, PhD, is a Senior Medical Writer at Evidera-PPD, part of Thermo Fisher Scientific. She is also Regional Director of Corporate Relations (Operations & Insights) at the Healthcare Businesswomen's Association (Europe), and a member of the EMWA Sustainability Special Interest Group (SUS-SIG).