Clinical study reports: A snapshot for aspiring medical writers

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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.

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:** 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:** Generally prepared for studies that are not relevant in evaluating the effectiveness and clinical pharmacology of the

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. 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.
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), 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, the TransCelerate template, and the CORE (Clarity and Openness in Reporting: E3-based) Reference to create CSRs that are compliant with regulatory guidelines.

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

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. 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. 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. 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. 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
Clinical study reports

Table 1. Training courses on writing clinical study reports

<table>
<thead>
<tr>
<th>Course name</th>
<th>Organisation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Medical Writing Bundle</td>
<td>Regulatory Affairs Professionals Society</td>
<td>Introduces medical writing, different types of regulatory applications, and techniques for improving document quality</td>
</tr>
<tr>
<td>Regulatory Medical Writing Training Programme</td>
<td>Groep Biomedische Wetenschappen KU Leuven</td>
<td>Provides an overview of clinical development and a practical introduction to writing clinical and regulatory documents</td>
</tr>
<tr>
<td>Regulatory Affairs Training Program</td>
<td>Duke University School of Medicine</td>
<td>Provides an overview of premarket regulatory work related to drugs, biologics, and medical devices</td>
</tr>
<tr>
<td>Regulatory Writing</td>
<td>University of California San Diego Extended Studies</td>
<td>Provides training on writing CSRs, information on regulations, and guidance governing regulatory documents in the US and the EU</td>
</tr>
<tr>
<td>Regulatory Writing</td>
<td>The University of Chicago</td>
<td>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</td>
</tr>
<tr>
<td>CRED Regulatory Document Writing and Management</td>
<td>The Organization for Professionals in Regulatory Affairs</td>
<td>Focuses on the theory and practice of writing effective regulatory documents and communications</td>
</tr>
<tr>
<td>Writing Clinical Study Reports</td>
<td>European Center for Clinical Research Training</td>
<td>Covers the principles of clinical research writing and reporting, including how to write a CSR. The course includes interactive exercises and case studies</td>
</tr>
<tr>
<td>Clinical Study Reports: Mastering the Essential Skills</td>
<td>European Medical Writers Association</td>
<td>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</td>
</tr>
</tbody>
</table>

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. 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. 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. 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.

- **European Public Assessment Reports**: 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, and the ClinicalTrials.gov registry in the US.
- **Other public disclosure platforms**: EMA clinical data website under EMA Policy 0070, Health Canada Public Release of Clinical Information.
- **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 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. Examples include:
  - **CONSORT (Consolidated Standards of Reporting Trials)**
  - **STROBE (STrengthening the Reporting of Observational studies in Epidemiology)**
  - **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. 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.

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Clinical study reports  |  Taranum

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