ZWIERS
Regulatory Consultancy
A ProductLifeGroup Company

Navigating types of clinical study reports for optimal reporting of trial results

Clinical Study Reports (CSR) are integrated reports of clinical studies for therapeutic, prophylactic, or diagnostic agents conducted in human subjects and the most crucial documents resulting from clinical trials.

CSRs are used for the following purposes:

- To address legal (FDAAA 801, final rule of 2017 [42 CFR Part 11] and Commission Guideline 2012/C 302/03) and regulatory (International Council on Harmonization E6 guideline) requirements
- To inform Sponsor decisions regarding the clinical strategy plan of their medicinal product
- To support marketing authorization (as part of the Common Technical Document [Module 5])
- To support labeling information and promotional materials.

The main points discussed in a CSR are:

- The choice of critical design features of the study
- The study plan, methodology, and conduct
- Data on participating subjects, efficacy, safety, and/or pharmacokinetics/pharmacodynamics (PK/PD), depending on study objectives.

Successful CSR completion requires information from the clinical trial protocol, statistical analysis plan/report, and tables, listings, and figures obtained after statistical data analysis. Useful additional documents are study reference manual, Investigator's Brochure, imaging and/or operational manuals, depending on the trial.

Considering the recently released FDA pilot program to publish information from CSRs for transparency purposes, choosing the correct CSR type is of utmost relevance.

Type 1: Full CSRs
Their purpose is to support approval by the regulatory agency and/or product label information. Full CSRs contain comprehensive clinical and statistical descriptions of the study conduct, and full output sections (efficacy, safety and, if applicable, PK/PD).

FDA, EMA, and PMDA all provided clear ICH E3 guidance on the structure and content of full CSRs.

Type 2: Abbreviated CSRs
These are condensed versions of full CSRs, evaluating whether the findings cast doubt on the safety claims and used for studies not intended to support the efficacy claim for the dose/regimen/population/indication. The structure and content of both abbreviated and synoptic CSRs is addressed in a specific FDA guidance, with abbreviated CSRs containing condensed study design/conduct, subjects, efficacy, and appendices sections, but including comprehensive safety.

An abbreviated CSR can be used for:

- Controlled studies examining conditions unrelated to the main claim (e.g., failed indication)
- Uncontrolled/other studies not designed to establish efficacy (e.g., studies with different indication/dosage forms not being registered)
- Flawed/aborted studies, including unsuccessful pivotal studies FDA agreed to be abbreviated
- Open-label extensions, including total exposure

Type 3: Synoptic CSRs
Synoptic CSRs only contain an expanded synopsis with full safety data (or referenced publications), no in-text tables (unless the serious adverse events [SAEs] need one) and summarized disposition/clinical pharmacology/efficacy data.

Synoptic CSRs are acceptable for:

- Different indications/dosage forms/administration routes not being registered
- Studies with defective design/conduct/data analysis, or uncontrolled/incomplete/discontinued studies
- Early general Phase I safety-tolerance (but not required toxicity) studies

Type 4: Supplemental CSRs
Supplemental CSRs provide relevant safety and/or efficacy results from cross-study analyses or (un)planned analyses not completed in time to be included in the full CSR, which is generally referenced. While there are no dedicated guidelines, supplemental CSRs can follow the ICH E3 guideline, with its structure typically including an introduction, objectives, methods, results, and discussions sections.

Keen to know which type of CSR fits your study? We can support you!