



Clinical Study Report (CSR) Template

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Template scope and purpose

This Clinical Study Report (CSR) Template is specifically designed to be used in conjunction with the Clinical Study Protocol (CSP) Template.

The structure and sections as well as their order and content follow the International Council for Harmonisation (ICH) E3 guidelines for CSRs, as recommended by the Food and Drug Administration (FDA). As such, this CSR Template is the foundation for an "integrated" full report of any study with a therapeutic, prophylactic, or diagnostic agent (i.e., drug or treatment) conducted in patients or healthy volunteers.

Note that, if conducting a study with healthy volunteers, these may be referred to as "subjects" instead of "patients", except where subjects have become patients due to adverse events (AEs).

Per the ICH guidelines, the clinical and statistical description, presentation, and analyses are to be integrated into a single report (i.e., the CSR), incorporating tables and figures into the main text of the CSR or at the end of the text, with appendices containing such information as the CSP, sample case report forms, and investigator-related information. Information related to the test drugs/investments (TOC), products (also referred to as study products), including active control/comparators, is to be technical statistical documentation, related publications, patient data, as long as technical statistical details, such as derivations, computations, and reported per computer output. Note that the CSR of a study should not be created and reported per a separate clinical and statistical report. Although this CSR Template was developed for the most common efficacy and safety clinical studies (e.g., as clinical trials), the basic principles and structure can be adapted to other studies, such as clinical pharmacology studies (e.g., pharmacokinetic studies), biomarker of exposure [BOE] studies). Depending on the nature of the study, such studies, a less detailed report might be acceptable.

- For more information on ICH guidelines for CSRs, see <https://www.ich.org/page/efficacy-guidelines>.

Fda Clinical Study Report

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