



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/investigational products (also referred to as study products), including active control/comparators, and technical statistical documentation, related publications, patient data, as long as technical statistical details, such as derivations, computations, and computer output. Note that the CSR of a study should not be created as 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 applied to other studies, such as clinical pharmacology studies (e.g., biomarker of exposure [BOE] studies). Depending on the nature of such studies, a less detailed report might be acceptable.

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

Clinical Study Report Organization Safety First

Jiyuan Zhang



Clinical Study Report Organization Safety First:

Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics Linda Fossati Wood, MaryAnn Foote, 2008-11-18 This book describes the authors standard or best practices used in writing regulated clinical documents for the drug and biologics industry The fundamental premise of this book is that the end documents submitted to a health authority is dependent on the beginning the planning and strategy that go into organizing written documentation Each regulatory document inherently exists within a constellation of related documents This book attempts to show the relationships between and among these documents and suggests strategies for organizing and writing these documents to maximize efficiency while developing clear and concise text At all times and irrespective of applicable laws and guidelines good communication skills and a sense of balance are essential to adequately accurately and clearly describe a product s characteristics At no time should the reader perceive these suggestions to be the only viable solution to writing regulatory documents nor should the reader expect that these suggestions guarantee product success The audience for this book is the novice medical writer or those who would like to explore or enhance regulatory writing skills We assume the reader will have a basic understanding of written communication but little experience in applying this skill to the task of regulatory writing Extensive knowledge of science clinical medicine mathematics or regulatory affairs law is not required to use the best practices described in this book

FDA Quarterly Activities Report United States. Food and Drug Administration. Program Information and Analysis Group, 1988

Annual Proceedings National Association of Corporation Training, 1916 Vol 1 includes proceedings of the organizing convention New York Jan 24 1913

The Organic Development of Business National Association of Corporation Schools, 1916

Biennial Report Nebraska. Department of Labor, 1918 Includes reports of the Dept of Compensation 1917 18 Dec 1923 1930 1932 1933 1934

Oregon Safety News ,1925

Journal of the American Medical Association American Medical Association, 1912 Includes proceedings of the Association papers read at the annual sessions and list of current medical literature

Annual Convention National Association of Corporation Schools (U.S.), 1916

Textile World Walter S. Kelley, Henry G. Lord, Walter Bradford Guild, Henry Gratton Kittredge, Samuel Sherman Dale, Charles Hiram Clark, Vernon E. Carroll, Clarence Hutton, 1881-, Douglas Gordon Woolf, 1917

Textile World and Industrial Record ,1917

International Labour Review ,1930

National Safety News ,1921

The Spectator ,1915

Industrial Safety Survey ,1925

Engineering Index Annual ,1930

PAIS Bulletin ,1917

Bulletin of the Public Affairs Information Service Public Affairs Information Service, 1917

Congressional Record Index ,1973 Includes history of bills and resolutions

Congressional Record United States. Congress, 1973

Official Proceedings Pacific Logging Congress, 1919

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Clinical Study Report Organization Safety First Introduction

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