Clinical Study Report

As a requirement of Galderma's Clinical Trial Agreement (CTA), within ninety (90) days of Investigator-Initiated Study (IIS) completion, or termination, whichever occurs first, the study Sponsor agrees to provide a **Clinical Study Report (CSR)** based upon the ICH E3 Guidance for Structure and Content of Clinical Study Reports[1,2].

If an IIS is terminated early, and any subject has received treatment, the CSR shall be provided that includes the results of the study data up until the date of termination.

The following guidance provides detailed information regarding the expectations for the provision of a CSR to Galderma for supported IISs. In an effort to reduce requests for revisions to CSRs, information is included on industry regulations and best practices regarding the content of acceptable CSRs. This information may serve as a resource for Sponsors and Investigators involved in the development of CSRs. Each of the following components are detailed further in the following pages.

Clinical Study Report Overview

The purpose of a CSR is to provide an organized report containing details relating to the conduct and findings of a clinical study through objective presentation.

Contextually, a CSR is an integrated full report of an individual study of a drug or treatment conducted in patents in which the clinical and statistical description, presentations, and analyses are integrated into a single report, incorporating tables and figures into the main text of the report, or at the end of the text, and with appendices containing all study documents, including the protocol, related publications, patient data listings, analyses, etc.[1]

Clinical Study Report Types

The information on clinical investigations required under 21 CFR 314.50 should be submitted in one of three formats: (1) full study reports, (2) abbreviated reports, or (3) synopses[3].

For all IISs in which a full CSR is not required by a regulatory authority (i.e., FDA), Galderma will accept an abbreviated CSR.

Type 1: Full Clinical Study Report

Full study reports (i.e., the complete *ICH E3* report) should be submitted for all clinical studies that evaluate the safety and efficacy for the proposed indication, or that support information in the product label[1,2].

Type 2: Abbreviated Clinical Study Reports

Abbreviated study reports are condensed versions of the full CSR and should be submitted for studies not intended to support efficacy claims for the dose, regimen, population, or indication. These types of CSRs usually contain abbreviated methods and efficacy, but almost always include comprehensive safety[2].

Type 3: Synoptic Clinical Study Reports

Synoptic study reports should be submitted for studies that are not relevant to the evaluation of product effectiveness or clinical pharmacology, but that provide information the reviewer needs to evaluate the safety data from the study[2].

Submission of a synoptic CSR requires pre-approval from Galderma.

Structure and Content of Clinical Study Reports

The following industry guidelines and best practices are recommended resource documents to utilize while creating CSRs:

- **ICH E3 Guideline:** Structure and Content of Clinical Study Reports
- **ICH E3 Q&As (R1):** Questions & Answers: Structure and Content of Clinical Study Reports
- **The CORE Reference Manual and Mapping Tool:** The CORE (Clarity and Openness in Reporting: E3-based) Reference is a user manual to help medical writers navigate relevant guidelines as they create CSR content relevant for today's studies. A separate mapping tool comparing ICH E3 sectional structure and CORE Reference sectional structure is also provided.
- **Guidance for Industry:** Submission of Abbreviated Reports and Synopses in Support of Marketing Applications provides guidance to applicants on submitting abbreviated reports and synopses in lieu of full reports for certain clinical studies, both in marketing applications for new drug and biological products and in supplements to approved applications.
- **FDA Guidance:** Suggested Format for IDE Final Report provides guidance on Investigational Device Exemption (IDE) reporting.
- **FDA Guidance:** IND Application Reporting provides guidance on Investigational New Drug (IND) Application reporting.

Minimum Criteria of Clinical Study Reports

In an effort to reduce requests for revisions to your CSR, we suggest including *at least* the following elements to ensure a comprehensive presentation of data in relation to your IIS:

- Title Page
- Synopsis
- Table of Contents
- List of Abbreviations and Definitions of Terms
- Overall Study Design & Plan - Description
- Disposition of Patients
- Efficacy Evaluation
- Safety Evaluation
- Discussion & Overall Conclusions
- Tables, Figures, and Graphs
- Appendices
    - Protocol & Amendments
    - Case Report Forms
    - Adverse Events
    - Safety Data Listings

References

1. ICH Efficacy Guidelines. https://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html. Accessed 29 Jul 2020.

2. ICH Harmonised Tripartite Guideline: Structure and content of clinical study reports E3. Step 4, 1995. https://database.ich.org/sites/default/files/E3_Guideline.pdf. Accessed 29 Jul 2020.

3. FDA CDER and CBER. Guidance for Industry: Submission of abbreviated reports and synopses in support of marketing applications. 1999. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-abbreviated-reports-and-synopses-support-marketing-applications. Accessed 07 May 2020.

4. ICH E3 Guideline: Structure and content of clinical study reports questions & answers (R1). 2012. http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E3/E3_QAs_R1_Step4.pdf. Accessed 29 Jul 2020.

5. CORE Reference. https://www.core-reference.org/core-reference/. Accessed 23 Jun 2020.

6. FDA: 21 CFR 812.150: Investigational Device Exemption (IDE). IDE Reports. https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-reports. Accessed 04 Aug 2020.

7. FDA: 21 CFR 312: Investigator-Initiated Investigational New Drug (IND) Applications. https://www.fda.gov/drugs/investigational-new-drug-ind-application/investigator-initiated-investigational-new-drug-ind-applications. Accessed 04 Aug 2020.