Case Study: Preparation of Clinical Study Report Template

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Business Need

A global clinical research organization required a standard template for their Clinical Study Report (CSR) to be used during the submission of new drug applications. The client required the template to be prepared in a short period of time, in alignment with the International Conference on Harmonization (ICH) regulations, and helpful for the medical writers to improve their efficiency and quality of the final product.

Innovative Solution

Biovalorem generated the template by performing the following activities:

1. First, a thorough research was done using the online resources to gather the regulations and guidances related to the Clinical Study Report. In order to prepare a list of requirements for the CSR template. Additional client specific requirements were obtained directly from the client team such as approval process, company legal requirements, areas requiring additional due diligence in the CSR due to the nature of their research.

2. The CSR template was prepared in compliance with the ICH regulations and included the following main areas: Synopsis, List of abbreviations and definition of terms, Study objectives, Ethics, Investigators and Study Administrative Structure, Investigational Plan, Study Patients, Efficacy Evaluation, Safety Evaluation, Discussion and Overall Conclusions, Tables, Figures and Graphs, Reference List and Appendices (Study Information, Patient Data Listings, Case Report Forms (CRFs).

3. The CSR template was aligned to the Protocol and Statistical Analysis Plan templates to ensure ease of transfer of data. The template was reviewed and approved by the sponsor and was ready to be piloted.

4. Instructions were provided throughout the template to assist the writer in understanding the template's requirements. This was designed in a user friendly method to enable reuse of information where possible.

5. The template was piloted for selected study, modified where required and implemented as a formal control document to be used by all clinical study teams.

Benefits

Biovalorem's client has obtained a Clinical Study Report template that will allow for systematic data flow from protocol and statistics into the report. The template is fully compliant with the ICH regulations and provides guidance instructions for the medical writer on how to complete the entire report to meet the client's requirements.