

Case Study



Developed a Medical Rationale Document for a Global Study which also Involved Indian Patients

Objective

The client specified that they required an intensive Medical Rationale Document (MRD) to be developed for a global study involving Indian subjects. The client required us to pool out data from the raw tables and global clinical study reports (CSRs) provided for the development of the MRD.

Our Approach

We assembled all the source documents provided to us and analyzed the same thoroughly. Prior to drafting the MRD, we made a list of tables and figures that would be required for the same. The team searched the raw tables provided by the client and customized the same for the MRD. We made separate tables for baseline demographics, and outcome variables for the global and the Indian patients. We made a list of figures to be developed from the tables provided to us. We then began work on the first draft and prepared the same as per the client requirements. The document was delivered to the client within the timelines communicated to us.

Outcome

The client reviewed the first draft and acknowledged the fact that we had made a very good effort in developing the MRD from a complex set of source documents. Post review, the client mentioned that they would require additional information in the MRD and we incorporated all the requirements communicated to us. The client was happy with the quality of work delivered and was content with our approach for the development of the MRD.



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