Introduction

Reviewer’s Guides provide the Food and Drug Administration (FDA) Reviewers with additional context for datasets received as part of a regulatory submission. The Reviewer’s Guide is intended to describe data submitted for an individual study in the Module 5 (clinical) section of the Electronic Common Technical Document (eCTD). These guides purposefully duplicate information found in other submission documents in order to provide FDA Reviewers with a single point of orientation to the datasets. Due to the information in the reviewer’s guides being so standardized, it is possible to develop instructions and processes for completion in a more efficient manner and use them to improve production time of submissions.

Why This is Useful

In practice, with many programmers involved in a study, it’s realistic for multiple people to update or edit the working copy of the reviewer’s guide simultaneously. Multiple authors can easily lead to an asynchronization in terms of fonts, formatting, etc. that will detract from the final product. Having a template in place at the start of the reviewer’s guide creation can help address these issues before they occur:

▶ It will ensure that when the document is finalized to the FDA-required PDF version, it will look clean and professional.
▶ When the template is adhered to rather than starting from scratch, it can lead to a more efficient creation of links to other sections of the document.
▶ A high level of consistency that can be achieved across multiple studies, which is especially valuable when submitting a large volume of similar packages to the same sponsor.

Example: SDRG Template and Work Instruction

Reviewer’s guides vary depending on what kind of study is being submitted. Guides associated with SDTM studies, as a standard, are required by the FDA to include different information than those associated with ADaM studies, as well as any other data standards that may be adhered to.

The example shown here is specifically discussing documents related to SDTM studies submitted to the FDA. With that said, no matter the data standard, documents can be developed for applying similar instructions to simplify the work in the same manner and would allow an analogous standardization of the process.

Having a template and further explanation creates even more clarity about exactly what should be in each section, which in turn generates consistency within studies, and additionally within all submissions coming from the sponsor. The documents are intended to be utilized as a pair; reading through the work instruction while populating the necessary fields in the template. The work instruction is written in a manner that corresponds directly to the sections in the template. This is done to help work as an efficient tool in conjunction with the template.

Advantages of Implementation

If a clear and consistent process is developed early on, it becomes easy to apply and teach to others. At Covance, after working to achieve a clear process, the use of global teams was possible to help improve speed of production. This would not have been possible without a template that laid out what information belonged where and with what instructions. The sections were clearly laid out, so it was possible to communicate with the global team in a way that they could populate the document and others could read, review, and finalize this document, rather than creating it from scratch. Additionally, having templates and instructions to point global team members to prove to be invaluable when working in different time zones. If a team member encountered a question about the work, they could explore these instructions and templates rather than needing to email a question and wait for an answer.

Along with using global teams, having very standardized instructions allows lower-level programmers who might be assigned to contribute to a document like this, or interns in a company that still have much to learn, get familiar with looking at a study and taking a first pass at populating this kind of document. Working on an SDRG is an excellent place for team members to get their feet wet with SDTM studies—gaining experience with the data standard while remaining a low-risk addition to the project deadlines. In practice, it helped speed up production greatly on the documentation-side of the team, who were now beginning work with a document that needed to be reviewed and verified rather than developed. This allows the documentation team to complete and submit the entire package in a much more quick and efficient manner.

Author Contact Information

▶ jennifer.mcgrogan@covance.com