

PP18. The Importance of Work Instructions When Creating Reviewer’s Guides

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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 it work as an efficient tool in conjunction with the template.

SDRG Template Excerpt

Study <Protocol Number>

Study Data Reviewer’s Guide

1. Introduction

1.1 Purpose

This document provides context for tabulation datasets and terminology that benefit from additional explanation beyond the Data Definitions document (define.xml). In addition, this document provides a summary of SDTM conformance findings.

1.2 Acronyms

Acronym	Translation

1.3 Study Data Standards and Dictionary Inventory

Standard or Dictionary	Versions Used
SDTM	
Controlled Terminology	
Data Definitions	
Medications Dictionary	
Medical Events Dictionary	
Other standards (optional)	

2. Protocol Description

2.1 Protocol Number and Title

Protocol Number:
Protocol Title:
Protocol Versions:
(Note here changes in protocol amendments that affected data collection or interpretation)

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SDRG Work Instruction Excerpt

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2. SDRG Template Content Sections

The following section numbering corresponds directly to the SDRG Template.

1. Introduction

The introduction provides an overview and inventory standards used on the study.

1.1 Purpose is a required section. Complete with standard text from the SDRG template [ClIF > CDISC and Submissions Standards > Shared Documents > 01 Standards Reference Documents > Reviewer’s Guides > Current versions > SDRG v1.2 2015_01_26 > SDRG_Template_2015-01-26].

1.2 Acronyms is an optional section. If sponsor-specific or non-industry standard acronyms are used elsewhere in the SDRG, document them in this section. Otherwise, state that this section is not applicable.

1.3 Study Data Standards and Dictionary Inventory is a required section. Populate the Standards and Dictionaries table in the SDRG template with the versions that are used throughout the submission.

2. Protocol Description

The protocol description provides a brief orientation to the study and, if necessary, provides additional context about the Trial Design Datasets.

2.1 Protocol Number and Title is a required section. Provide the protocol number or identifier, title, and versions included in the submission. If an amendment occurred, note any significant changes which impacted data collection or interpretation.

2.2 Protocol Design is an optional section. Place a graphic or text here to describe the protocol design. This information can be taken directly from the protocol or developed specifically for the SDRG.

2.3 Trial Design Datasets is a required section. Populate the SDRG Template by stating if Trial Design datasets are included in the submission. If not, no further information is required.

If this section is included, list the labels and descriptions for these domains, and populate with information following what is found in the SDRG Completion Guidelines [ClIF > CDISC and Submissions Standards > Shared Documents > 01 Standards Reference Documents > Reviewer’s Guides > Current versions > SDRG v1.2 2015_01_26 > SDRG_Completion_Guidelines_2015-01-26]. If

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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 proved 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—getting 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.

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