Achieving Clarity through Proper Study Documentation: An Introduction to the Study Data Reviewer’s Guide (SDRG)

With the ever-growing standardization requirements of FDA submissions, it can be difficult to understand where exactly you place non-conformant, essential information that does not have a home within other submission documentation. Now, with the Study Data Reviewer’s Guide (SDRG), this information has a home and can be effectively communicated. The SDRG provides reviewers with key details they will need to perform a thorough review of the data, along with a space to answer questions from the reviewer before they are asked, expediting the review of the full dataset documentation of your trial. The SDRG has provided a step-by-step template that helps you understand what to report, where to report it, and makes sure nothing is lost so that traceability is clear. This poster will help you understand why it is important to think about the SDRG from the start, how to use these documents to your advantage, and provide examples of their flexibility and utilization.

SDRG: When do I Start Creating It? The Earlier, The Better

The SDRG can be a living document throughout the life of the study. Many decisions are made throughout the course of a trial, so add the content when the decisions are made rather than trying to remember every choice at the end of a trial. Populate corresponding sections as each step of the study is started.

When you have a protocol:
- Section 1: Introduction
- Section 2: Protocol Description
- Section 3: Subject Data Description
- Section 4: Data Conformance Summary

When you work through SDTM Programming:
- Provide additional context for subject-level SDTM domains that will not be adequately documented in define.xml or the SDTM Implementation Guide and its supplements. Additionally, you can describe sponsor-specific annotated CRF conventions as needed.

Additionally, complex derivations and other key additional content should be added as it is discussed. By proactively adding this content, it reduces the risk of forgetting to add critical information for the reviewer. Ultimately, proactively adding content helps to avoid scrambling at the end of the study.

Practical Use: Using the SDRG Dynamically

This is where a reviewer is going to look for information. Why can’t your team use it dynamically throughout the project?

Important decisions are constantly being made throughout the course of a project, and this is where they ultimately need to be presented. Build it from the beginning, not at the end.

Keep a decision log. A simple spreadsheet of decisions made gives you the answers to many of the questions that a reviewer is going to have.

| Important Decision | Documentation
|-------------------|----------------|
| Subject inclusion | Include in the SDRG
| Subject exclusion | Include in the SDRG
| Subject enrollment | Include in the SDRG

You already have all the answers. The template is right there. Your team has the answers. Build it with your team.

You’re going to have questions too! If a reviewer is going to benefit from having all of the information in one place, won’t your team?

Flexibility and Customizability

The SDRG has a set structure but does allow for flexibility and customizability. Certain sections of the SDRG are expected to be populated, and other sections are subject to removal if they do not add value.

Don’t See a Section for it? Add it.
- Template is a starting point
- Section Not Necessary? Remove it.
- Not all sections in the template are required

SDRG: Sections with Additional Content

- Section 2.3 Trial Design Datasets – If no Trial Design Datasets are being submitted, this section this section should be deleted.
- Section 3.1 Overview – Essential section of the document that provides a summary orientation and should always be provided.
- Section 3.3.X Dataset – Dataset Label – Simply said, this section provides explanations beyond what is documented in define.xml or the SDTMIG. Good for any submitted data.

SDRG: Sections Subject to Removal

- Section 1.2 Acronyms – If only standard industry acronyms are used, this section can be removed.
- Section 2.2 Protocol Design – This is an optional section that provides a visual representation or brief textual description of the protocol design.
- Section 3.2 Annotated CRF’s – This is an optional section describing sponsor specific annotated CRF conventions.
- Section 4.3 Additional Conformance Details – If you are only using Pinnacle21 (OpenCDISC) then remove this section.
- Appendix I: Inclusion/Exclusion Criteria – Great place to document the Full Inclusion & Exclusion Criteria.
- Appendix II: Conformance Issues Details – Sponsors are strongly discouraged from including.

The SDRG in Action: Real Example

The SDRG provides an appropriate place to document data issues encountered throughout a study. This informs the reviewer of the issue and creates clarity. For example, in section 3.1 (Overview), you have the space to detail if a subject was accidentally randomized twice.

3.1.1 (Overview): Additional Context of Interest

In Part B, subject 9999 completed the multiphasic phase but discontinued during the DDI phase due to an adverse event. The subject subsequently enrolled in the study and completed the DDI phase as subject 9999. Records for this subject are captured under one unique subject identifier (SUBJID-212/123-999-9999) & only one record is kept in DM with first and last dates computed using combined subject records.

Under section 3.3.X (SDTM Subject domains), explanations of this data issue may be detailed for the impact to individual domains. For example:

3.3.4.9 DM - Demographics

SUBJID 212/123-999-9999 expresses SUBJID 9999 and SUBJID 9999 who is a subject that was accidentally randomized twice. The two records in the domain for these two SUBJIDs were confirmed to be one record under one SUBJID. Start and end dates were used from both records to compute STARTIC, ENDICT, REMINDIC, REMIND, and ENDMIC for each record. The first and last records in the domain were those for the subject. The second set of information for SUBJID -9999 was placed in DM.

In section 4.2 (Issue Summary), the explanation column allows you to justify Pinnacle 21 Community conformance issues that are found.

References


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