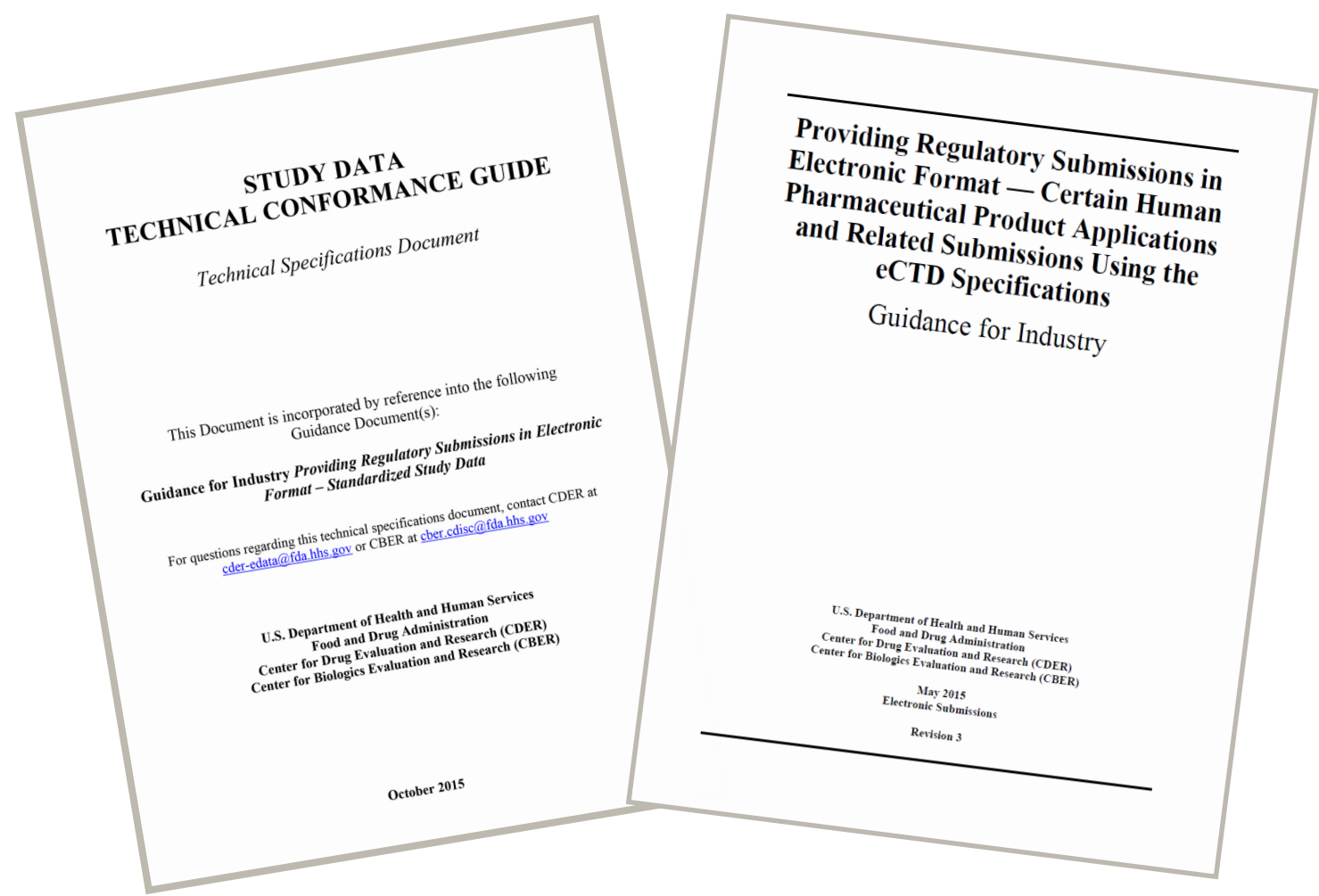


# Achieving Clarity through Proper Study Documentation: An Introduction to the Study Data Reviewer's Guide (SDRG)

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 documentation package of your trial. PhUSE 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.



### What is it? SDRG Purpose

Provides FDA Reviewers with additional context for SDTM datasets received as part of a regulatory submission. Per the Study Data Technical Conformance Guide, preparation of an SDRG is recommended as an integral part of a standards-compliant study data submission.

Intended to describe SDTM data submitted for an individual study in the Module 5 clinical section of the eCTD

Purposefully duplicates information found in other submission documentation (e.g. the protocol, clinical study report, define.xml, etc.) to provide FDA Reviewers a single point of orientation

Highlights SDTM version, Special/Custom Domains, Controlled Terminology, Define version, Dictionary versions, Data Conformance issues

Developed to complement the define.xml to enable the reviewers to understand the data representations included in a submission

A Living Document!

### 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
    - Provide an overview and inventory of standards used on the study.
  - Section 2: Protocol Description
    - Provide a brief orientation to the study and, if necessary, provide additional context about the Trial Design Datasets.

- When you do CRF Annotations and SDTM mapping
- Section 3: Subject Data Description
    - 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, here you can describe sponsor-specific annotated CRF conventions as needed.

- When you work through SDTM Programming
- Section 4: Data Conformance Summary
    - Document the validation inputs used to evaluate SDTM conformance and summarizes any conformance findings ("Issue Summary" Worksheet in OpenCDISC Report).

Additionally, complex derivations and other key additional content should be added as it is first 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?

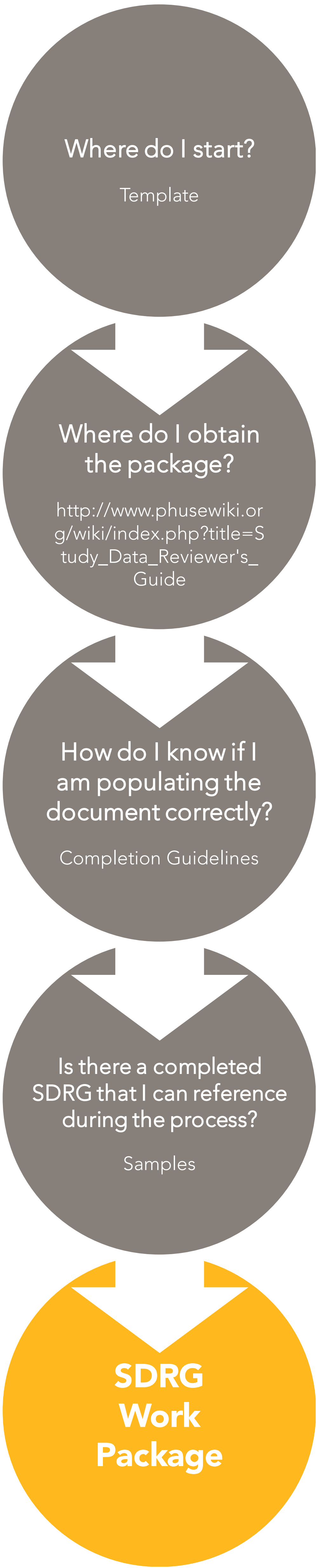
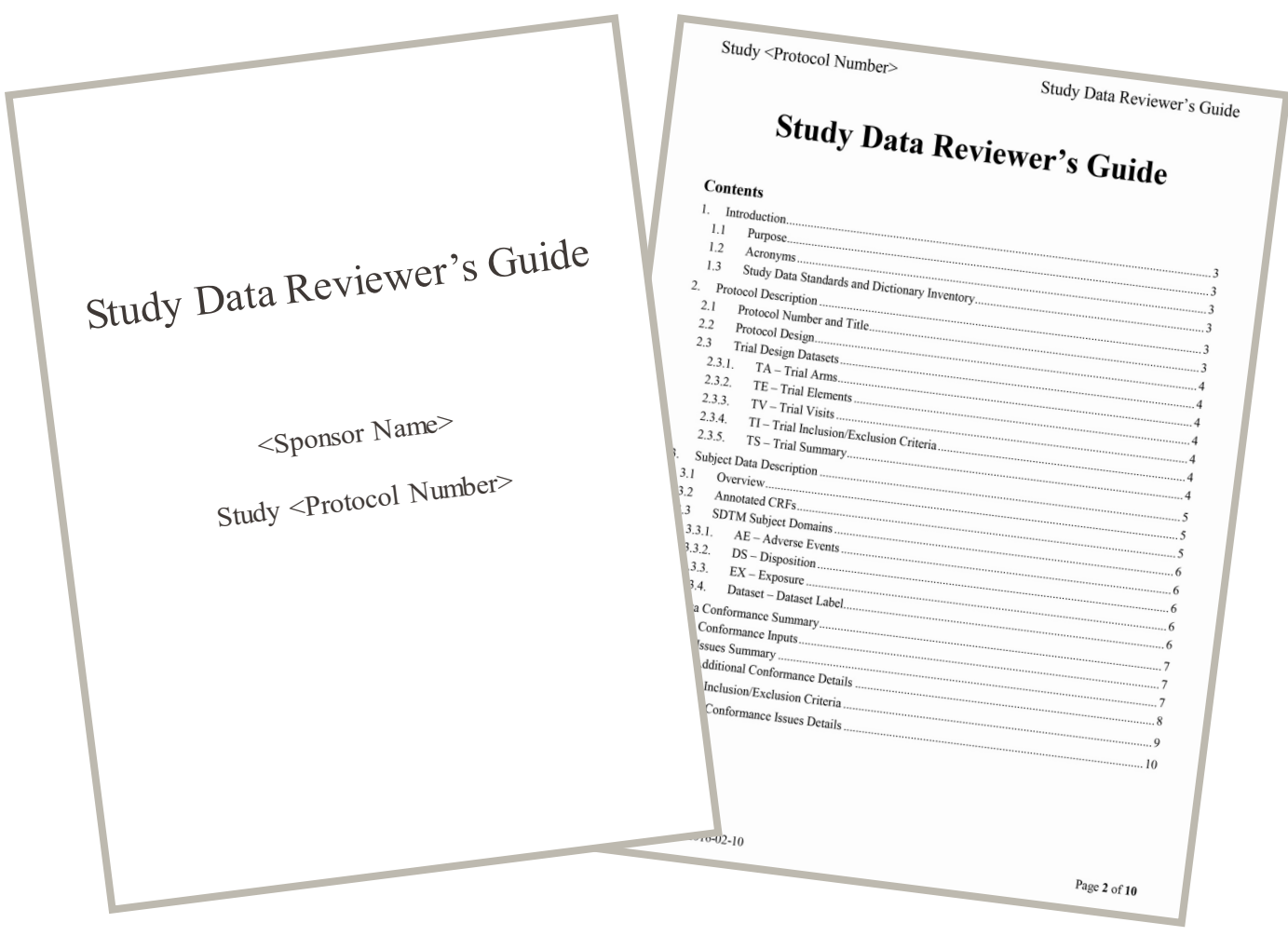
Important decisions are constantly being made throughout the course of a project, and this is where they ultimately need to be presented. Build it from the beginning, not at the end.

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.

| Domain             | Variable             | Issue                  | Resolution                  |
|--------------------|----------------------|------------------------|-----------------------------|
| <Impacted domains> | <Impacted variables> | <Description of issue> | <Description of resolution> |

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

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 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 that which 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 (Overview):  
Additional Content of Interest

In Part B, subject 9999 completed the multiple-dose phase but discontinued during the DDI phase due to an AE on Day 10. The subject subsequently rejoined the study and completed the DDI phase as subject 9998. Records for this subject are captured under one unique subject identifier (USUBJID=ZJ123-1234-999-9999). 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 DM – Demographics**

USUBJID ZJ123-1234-999-9999 represents SUBJID=9999 and SUBJID 9998 who is a subject that was randomized twice. The two records in this domain for these two SUBJID's were combined into one record under one USUBJID. Start and end dates were used from both records to compute RFSTDTC, RFENDTC, RFXSTDTC, RFENDTC. Age is from first record. ARM and ARMCD were different for each record. The first randomized ARM was used for this subject. The second set of information for SUBJID = 9998 was placed in SUPPDM.

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

| Dataset | Diagnostic Message        | Severity | Count | Explanation                                                                                            |
|---------|---------------------------|----------|-------|--------------------------------------------------------------------------------------------------------|
| LB      | SD11117-Duplicate records | Warning  | 9     | USUBJID ZJ123-1234-999-9999 was randomized twice and entered the study twice so has duplicate records. |
| PC      | SD11117-Duplicate records | Warning  | 9     | USUBJID ZJ123-1234-999-9999 was randomized twice and entered the study twice so has duplicate records. |

### References

SDRG Package v1.2 2015-01-26 Study Data Reviewer's Guide Final Work Package [http://www.phusewiki.org/wiki/index.php?title=Study\_Data\_Reviewer%27s\_Guide]

Study Data Technical Conformance Guide v2.3 [http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf]

Final Guidance for Industry: Providing Regulatory Submissions in Electronic Format – eCTD Specifications [http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf]

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