

Nonclinical Study Data Reviewer's Guide



Project Scope

This project is to evolve the Nonclinical Study Data Reviewer's Guide (nSDRG), based on comments from a public PHUSE review, plus to adapt it to updates of the FDA Technical Conformance Guide. The project continues to check and align with the SDRG template and guide developed by the Optimizing the Use of Data Standards Working Group for clinical studies.

Preparation of a Study Data Reviewer's Guide (SDRG) is recommended as an integral part of a CDISC standards-compliant study data submission. The challenge is to operationalise this new documentation requirement efficiently and effectively.

Challenges we seek to answer with this project:

- Provide a practical template for easy access and use
- Provide guidance document which describes expected content and options to guide nonclinical SDRG authors.
- Provide authors with examples, describing how to handle different data situations with SDRG content.

Things we expect to learn along the way:

- Exploration of ways to generate the nonclinical SDRG and who should do the job.
- The SDRG is expected to be useful by FDA reviewers. Can it also be useful for other nonclinical study stakeholders?
- Will the SDRG evolve as systems and processes gain expertise in the new SEND requirements for submission of nonclinical data?

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Published Deliverables	
nSDRG v1.2	Version 1.2, 8 April 2022
Maintaining the Clinical & Nonclinical Study Data Reviewers Guides	CSS 2018 Workshop

CURRENT STATUS Q1 2024

- Currently investigating discrepancy discovered in nSDRG package v1.2 regarding Section 1.3, to determine if a minor version issue is warranted.

Nonclinical SDRG Package

The Nonclinical SDRG package has been developed to comply with the FDA's Study Data Technical Conformance Guide. The current version of this document can be found at the website: [FDA Data Standards Resources](#). The nSDRG team continues to monitor FDA's Technical Conformance Guide updates (which occur 2X per year, expected in MAR and OCT) and also public comments received from users of nSDRG. As these new inputs are evaluated, we will post answers in the SEND Implementation Forum, and update the published documents as needed. Stay tuned for update announcements.