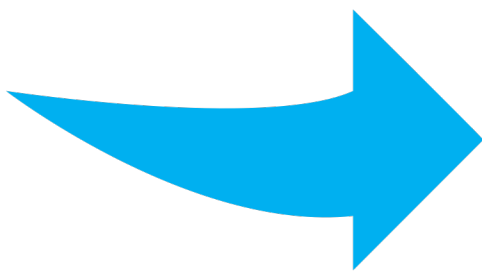
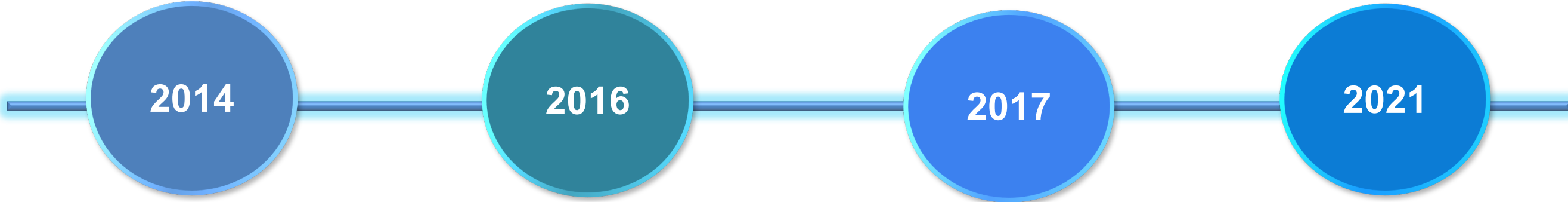


Nonclinical Study Data Reviewers’ Guide (nSDRG)



WHAT’S NEXT? Upcoming changes proposed for 2021 public review

Christy Kubin¹, Debra Oetzman², Susan DeHaven³ and nSDRG project team⁴



2013-2014 – Start of the adventure!

- Evaluation of the clinical SDRG model for Nonclinical.
- 2014 CSS Poster: *Study Data Reviewer’s Guide (SDRG): Recommendations on Use of the Clinical SDRG Model for Nonclinical Data Submission*

March 2016 – nSDRG v1.0

- Included Guideline, Template and 2 examples from repeat-dose tox studies
- Based on clinical SDRG model
- FDA issued FRN seeking public comments to evaluate the template

November 2016 – FDA TCG included link to nSDRG

March 2017 – nSDRG v1.1

- Incorporated FDA feedback from FRN public review
- Aligned with TCG
- Nonclinical specific design additions

Today

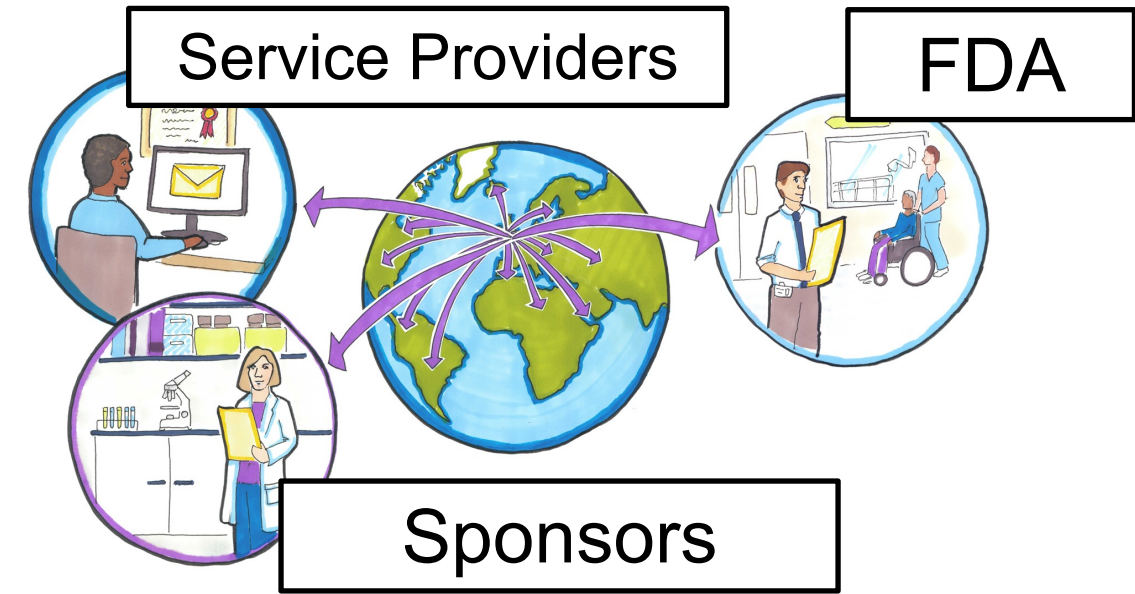
Next version planned

- v1.2 ready for PHUSE public review
- Planned release end 2021



The next version proposes changes across the nSDRG; however, this poster focuses on Section 4: Dataset Summary and Section 5: Data Standards Validation Rules, Versions, and Conformance Issues, because this is where most questions arose.

Changes informed by experiences & recommendations across stakeholders!



Changes follow personal perspectives of FDA reviewers provided thru a usage questionnaire:

Guideline 4

Description...

- Added questions based on TCG suggestions for nSDRG description



Template 4.1

Dataset Summary Table

- Removed “Observation Class” column

Guideline 4.3

Supplemental Qualifiers

- Added PCCALCN to the example table

Guideline 5

Validation Rules, Versions....and Issues

- Added description of FDA stakeholders

Guideline 5.1

Validation Outcome Summary

- Include study-specific information
- Avoid “boilerplate” language

Guideline 5.2

FDA SEND...Business Rules Versions

- Added description of Business Rules
- Not all validation rules can have automated checks - checks of these rules are still expected.

5.3 Improved Value of Issue Summary

-  One table for all dataset rules explanations (combined errors and warnings tables)
-  Added a separate table to handle define.xml validation results
-  Explain if issues affect data interpretation
-  Recommendation for issue identifiers
-  Do not include “notices” identified by validation tools that have no impact

¹Charles River Laboratories ²Instem ³Sanofi US, Inc. ⁴ Team list: <https://advance.phuse.global/display/WEL/Nonclinical+Study+Data+Reviewers+Guide>

