Presented on behalf of PhUSE Working Group 4:
Helena Svilgin (FDA), Douglas Warfield (FDA), Steve Wilson (FDA), John Brega (PharmaStat),
Joanna Koft (Biogen Idec), Gail Stoner (J&J), Scott Bahlavooni (Genentech), and David Brega (PharmaStat)

PhUSE Working Group 4 developed an SDTM Study Data Reviewer’s Guide (SDRG) template to supplement the information found in define.xml for drug submissions.

This sample Study Data Reviewer’s Guide document illustrates the intended use of the template and demonstrates what a finished document should look like.

- This template was produced with FDA participation.
- A reviewer’s guide is not required for SDTM submissions yet, but could be in the future.
- This template is open-ended. It supports many possible study data scenarios.
- The questionnaire format gives the finished SDRG a consistent look and feel, to help reviewers find the information they need.
- We’ve started the document for you, you just have to fill it out!

- This reviewer’s guide fills in gaps in current submission documentation.
- The design and testing of this package may inform future documentation standards.
- Include your SDRG in Module 5 of the eCTD with the study’s SDTM datasets.