

Nonclinical Topics

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Conformance with the tumor.xpt Specification

Scope

The scope of the project will be to create a non-exhaustive first set of technical conformance rules with the tumor.xpt specification.

Q2 2026

Proposed
End Date

Continuing to develop rules but getting closer to a complete set.

Compile all rules into a white paper for publication.

White paper

Deliverable
Type

Key Achievements
This Quarter:

Deliverables &
Targets Planned for
the Next Quarter:

Gitte Frausing &
Hepei Chen

Leads



Project Status: Greens

- In the final stages of rule development and working towards starting writing the white paper.

Project Status

Developing Predictive Models to Facilitate Interpretation of Toxicology Study Results

Scope

A computational pipeline to build models to predict target organs of toxicity from SEND datasets has been developed and published on GitHub under PHUSE. Project team members will evaluate the feasibility and performance of this pipeline when run on data from within their organisations. The pipeline will be updated to improve compatibility with different database systems, and efforts will be made to improve its performance across disparate data sources. Additional study interpretations, e.g. adversity of findings, NOAEL determination, clinical translatability, structure activity relationship, will be explored for development of predictive models. Successful modelling approaches will be published in peer-reviewed scientific journal articles.

Q2 2026

Proposed
End Date

White paper

Deliverable
Type

Kevin Snyder &
Lennart Anger

Leads

- Shared presentations of predictive modelling methodologies being applied by project participants to inform better interpretation of CDISC-SEND-formatted toxicology study data.
- Presented methods and progress of the project at the 2025 American College of Toxicology Annual Meeting in November.

Key Achievements
This Quarter:

Establish a structure to support the testing of methods that have been presented and share results to the group.

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Green
Accepting New Members

- Wrapping up 'show and tell' phase of the project and transitioning into the 'testing' phase, during which project participants will test the application of methods that have been presented to their organisations' data to determine how well these methods work in different contexts.

Project Status

Nonclinical Study Data Reviewer's Guide

Scope

This project is to evolve the Nonclinical Study Data Reviewer's Guide (nSDRG) based on:

- Comments from the public
- FDA Technical Conformance Guide updates
- Alignment with the SEND IGs
- Alignment with the cSDRG template and guide for clinical studies.

Ongoing

Proposed
End Date

Next version of
the nSDRG v2.0

Deliverable
Type

Susan DeHaven

Leads

Key Achievements
This Quarter:

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Green
Accepting New Members

Project Status

SEND Coding Bootcamp

Scope

The CDISC-SEND data standard has created new opportunities to facilitate scientists for single-study and cross-study analyses of toxicology study data. As SEND datasets are currently in xpt format - though the Dataset-JSON format is being worked on - without tools or programming knowledge, there are still barriers for scientists to access SEND datasets in xpt or JSON format for analysis purposes. Additionally, SEND datasets are often manipulated manually using Microsoft Office software, e.g. Excel. However, these manipulations could be performed more efficiently and at a larger scale by data managers trained to write scripts using open-source software languages, e.g. R and Python.

Ongoing

Proposed
End Date

A series of
training sessions

Deliverable
Type

Michael DeNieu,
Daniel Russo &
Wenxian Wang

Leads

Completed several
additional training
sessions, with the topics
chosen by team polls,
and hosted recurring
office hours to help
individuals work
through challenges or
issues.

Key Achievements
This Quarter:

Continue alternating
training sessions and
office hours sessions

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Green
Accepting New Members

- Project is ongoing and will continue to provide sessions on team interest and look for ways to expand the scope to help industry build more skills.

Project Status

SEND Industry Feedback Survey

Scope

Execute an annual survey process to objectively collect data that enables detection of impactful issues and trends (both good and bad) that can be acted upon by the PHUSE Community.

The survey will:

- Provide SDOs with actionable information regarding improvements to their standards
- Enable CROs, software developers and data service providers with extensive data management experience an opportunity to provide actionable recommendations
- Provide sponsors with information on how they can better leverage their SEND investments.

Ongoing

Proposed
End Date

Survey

Deliverable
Type

Lindsay Eickhoff &
Vanessa Chavez

Leads

The survey for 2026 has
been released

Key Achievements
This Quarter:

Compile and analyse
results for presentation
at the February event.

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Green
Accepting New Members

- Waiting for survey completion by industry.

Project Status

Supporting the Use of SEND for the Implementation of Virtual Control Groups

Scope

This project will leverage the deep SEND knowledge and experience of the PHUSE Nonclinical Topics Working Group by focusing on the development of best practices with respect to population of SEND datasets with data from virtual control animals. As the relative importance of study design elements to the selection of appropriately matched virtual control animals is being actively investigated and publicised by other related efforts, e.g. the influence of anaesthesia protocols on electrolyte levels in rats (Gurjanov et al., 2023), feasible practices will be developed to ensure these elements are appropriately and consistently represented in SEND datasets.

**VICT3R End
Date (Feb
2028) + 1Q**

**Proposed
End Date**

**Framework &
white paper**

**Deliverable
Type**

**Kevin Snyder,
Bill Houser &
Christy Kubin**

Leads

**Resumed work after
summer break**

**Key Achievements
This Quarter:**

**Continue to compile
findings into report.**

**Deliverables &
Targets Planned for
the Next Quarter:**



**Project Status: Green
Accepting New Members**

- Preparing results for publication.

Project Status