Nonclinical Topics

Project Leads:
Gitte Frausing & Hepei Chen

Deliverable:
White paper

Key Achievements This Quarter:

Project paused

Proposed Project End Date:
Q2 2026

Conformance with the tumor.xpt Specification

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

Project Status:
Amber

Project Accepting New Members: No

Deliverables & Targets Planned for the Next Quarter:

Leads to follow up on next steps

Developing Predictive Models to Facilitate Interpretation of Toxicology Study Results

Project Leads:
Kevin Snyder & Lennart Anger

Proposed Project End Date:
Q2 2026

Project 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.

Deliverable:
White paper

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

Continuing to host talks from project members highlighting the use cases for predictive modelling of toxicology data in their organisations

Deliverables & Targets Planned for the Next Quarter:

Continue presentation series

Project Lead:
Susan DeHaven

Proposed Project End Date:
Ongoing

Project 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.

Current work:
Develop the next version to support the next SEND IG v4.0, to enhance effectiveness for reviewers while improving operational aspects.

Deliverable:
Next version of the nSDRG v2.0

Nonclinical Study Data Reviewer's Guide

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

No update given

Deliverables & Targets Planned for the Next Quarter:

No update given

SEND Coding Bootcamp

Project Leads:
Michael DeNieu, Daniel Russo & Wenxian Wang

Proposed Project End Date:
Ongoing

Project 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 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.
During the PHUSE CSS 2025, participants expressed a desire to learn coding to be able to work with SEND datasets more efficiently.

Deliverable:
The SEND Coding Bootcamp will include a series of sessions focused on teaching students coding so they can analyse studies using SEND datasets.

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

The workshop series was a success, and the leadership group is working on organising follow-ups. A survey has been sent to participants to identify key areas to focus on next.

Deliverables & Targets Planned for the Next Quarter:

Sessions likely focusing on visualisation and data summarisation.

Project Leads:
Lindsy Eickhoff &
Vanessa Chavez

Deliverable:
Annual survey

Proposed Project End Date:
Ongoing

SEND Industry Feedback Survey

Project 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.

Results of the survey were presented at the PHUSE/FDA CSS 2025.

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

Discussions have begun for the content of the survey for 2026

Deliverables & Targets Planned for the Next Quarter:

Survey to be rolled out to PHUSE mailing list for responses

Project Leads:
Kevin Snyder, Bill Houser & Christy Kubin

Proposed Project End Date:
VICT3R End Date (Feb 2028) + 1Q

Project 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.

Deliverable:
Feasible framework for the representation of virtual control animals in available versions of SEND communicated via technical publication and a white paper.

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

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

Project was paused for the summer

Deliverables & Targets Planned for the Next Quarter:

Active meetings will be starting again in October