Nonclinical Topics

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phuse

Conformance with the tumor.xpt Specification

Scope

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

Proposed End Date

Q2 2026

Deliverable Type

White paper

Leads

Gitte Frausing & Hepei Chen

Key Achievements This Quarter:

Deliverables sent for public review

Deliverables & Targets Planned for the Next Quarter:

Public review comments addressed, Final deliverable published

Project Status

Project Status: Green
Accepting New Members - *Experience with data validation*

- Project deliverable is in public review

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 developing predictive models. Successful modelling approaches will be published in peer-reviewed scientific journal articles.

Q4 2027

Proposed End Date

White paper

Deliverable Type

Kevin Snyder & Lennart Anger

Leads

Launched new phase of project with two subteams, who will be testing and developing best practices for methods relating to transformation of raw SEND data into tox endpoint signal scores that can be fed into machine learning models and structured extraction of key study findings from narrative study report documents

Key Achievements This Quarter:

These two subteams will develop and test initial methods

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green

- White paper deliverable describing best practices is not ready to draft, as best practices have not yet been developed. A white paper describing the landscape analysis conducted during the first phase of the project could be considered.

Project Status

phuse

Nonclinical Study Data Reviewer’s Guide

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.

Ongoing

Proposed End Date

Next version of the nSDRG v2.0

Deliverable Type

Janessa Pierce & Susan DeHaven

Lead

No update

Key Achievements This Quarter:

No update

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. Because 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.

Ongoing

Proposed End Date

A series of training sessions

Deliverable Type

- Completed main series
- On hold while we work on developing training for R Shiny

Key Achievements This Quarter:

Planning for new bootcamp series to begin in May and run for 3-5 sessions

Deliverables & Targets Planned for the Next Quarter:

Michael DeNieu & Wenxian Wang

Leads

Project Status: Amber
Accepting New Members

- Daniel is working on putting together past lessons into a training programme that can be done independently while new content is being created

Project Status

phuse

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 the PHUSE Community can act on.

The survey will:

- Provide SDOs with actionable information regarding improvements to their standards
- Give 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

Lindsy Eickhoff & Vanessa Chavez

Leads

Compiled the 2026 SEND Survey results data and presented a shortened version at the Nonclinical Working Group virtual single day event

Key Achievements This Quarter:

Working on gathering questions for the 2027 SEND Survey; finalising the full presentation of the 2026 SEND Survey at a future virtual event; waiting to hear back from the PHUSE Leadership Team about collaboration with ACT and/or SOT.

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green
Accepting New Members

- Project progressing

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 initially 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 various 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), best practices will also be developed to ensure that these elements will be appropriately and consistently represented in SEND datasets. Recommendations to CDISC will be drafted and communicated if it becomes evident that the SEND data standard will need to be modified in order for this data to be appropriately represented. Initially, the project scope will be restricted to include only study types that have been clearly modelled in SEND for long enough that data availability will not be a limiting factor in the development and evaluation of best practices, but thought will be given to best practice and data standard development opportunities to support the implementation of virtual control groups in study designs that have yet to be clearly modelled in SEND.

VICT3R End Date (Feb 2028) + 1Q

Proposed End Date

Framework & white paper

Deliverable Type

No update

Key Achievements This Quarter:

No update

Deliverables & Targets Planned for the Next Quarter:

Bill Houser, Christy Kubin & Kevin Snyder

Leads

Project Status: Green

Project Status