Nonclinical Topics

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phuse

Conformance with the tumor.xpt Specification

Description

This project will develop an initial, non-exhaustive set of technical conformance rules for the FDA's tumor.xpt specification. Since 1999, industry has been required to submit tumour data in this format alongside SEND datasets. However, unlike SEND - which includes CDISC-provided conformance rules - tumor.xpt has no formal validation framework and cannot be checked using standard automated tools. Because tumor.xpt is not a CDISC standard, CDISC will not supply such rules, leaving industry to manually verify compliance with FDA requirements.

This project will create the first validator rules that can be implemented within existing SEND verification tools, reducing manual review effort and improving the overall quality and consistency of tumor.xpt files. Automating these checks is expected to shorten preparation time, decrease sponsor–FDA back-and-forth, and provide clearer insight into potential issues. If adopted by the FDA, these rules could also streamline regulatory review by identifying format problems earlier.

Q2 2026

Proposed End Date

White paper

Deliverable

Deliverable out for public comments.

Key Achievements This Quarter:

Address all public comments received and publish production version.

Deliverables & Targets Planned for the Next Quarter:

Gitte Frausing & Hepei Chen

Leads

Project Status: Green
Accepting New Members

- Currently addressing received public comments.

Project Status

phuse

Developing Predictive Models to Facilitate Interpretation of Toxicology Study Results

Description

This project will evaluate and enhance the PHUSE computational pipeline designed to predict target organs of toxicity using SEND datasets. Team members will assess the pipeline's feasibility and performance on internal organisational data, update it for broader compatibility with diverse database systems, and improve its robustness across heterogeneous data sources. The project will explore additional study-level interpretations - such as adversity, NOAEL determination, clinical translatability and structure-activity relationships - to expand the range of predictive modelling approaches. Successful methods will be submitted for publication in peer-reviewed journals.

SEND has enabled the creation of large toxicology databases suitable for training models on expert interpretations of historical studies. These models can streamline future study review by predicting likely interpretations, reducing manual effort for both industry toxicologists and regulators. They may also highlight which endpoints are most informative for predicting specific toxicities, such as hepatotoxicity or nephrotoxicity.

Q4 2027

Proposed End Date

White paper

Deliverable

- Subteams 1 and 2 have established goals and regular meeting cadences to support progress towards these goals.
- Subteam 1 created a GitHub repository and started development of an R package to support SEND data normalisation/scoring.
- Subteam 2 is working on updating the SR domain to support predictive modelling use cases.
- The FDA precisionFDA challenge team provided an update on the SEND-based toxicology predictive modelling challenge project.
- · Deliverables from the precisionFDA challenge project will be incorporated into the PHUSE project.

Key Achievements This Quarter:

- Subteam 1 will finalise a version 1.0 of the SEND normalisation/scoring R package.
- Subteam 2 will finalise modifications to the SR domain to support predictive modelling use cases.
- Deliverables from the precisionFDA challenge project will be evaluated for use by Subteam 1 or future use cases.

Deliverables & Targets Planned for the Next Quarter:

Kevin Snyder & Lennart Anger

Leads

Project Status: Green

- Deliverables are actively being developed.

Project Status

Nonclinical Study Data Reviewer's Guide

Description

This project will advance the Nonclinical Study Data Reviewer's Guide (nSDRG) by incorporating feedback from public PHUSE review and stakeholders, while aligning it with updates to the FDA Technical Conformance Guide. It will also ensure continued consistency with the published CDISC SEND standards and clinical SDRG template developed by the Optimizing the Use of Data Standards Working Group.

Because the SDRG is a recommended component of CDISC-compliant submissions, the project aims to make its creation effective and practical. Key objectives include delivering an accessible template, providing clear guidance on expected content, and offering examples that illustrate how to address common data scenarios.

As the work progresses, the team will explore approaches for generating the nSDRG, identify who is best positioned to author it, and assess its usefulness beyond FDA reviewers. The project will also consider how the nSDRG should evolve as organisations gain experience with SEND and as systems mature.

Ongoing

Proposed End Date

- Next version of the nSDRG v2.0
- Examples of completed nSDRG documents that represent CDISC proof of concept datasets prepared to support SEND IG 4.0

Deliverable

Received and started review of informal comments on the nSDRG draft, provided by the FDA. Developed a team plan for progressing the nSDRG update and nSDRG POC datasets as separate, but dependent, activities. Decision to increase meetings to bi-weekly from monthly.

Key Achievements This Quarter:

Next draft of the nSDRG, accommodating FDA informal comments + Appendix I in the Study Data Technical Conformance Guide.

Deliverables & Targets Planned for the Next Quarter:

Janessa Pierce & Susan DeHaven

Lead

Project Status: Green
Accepting New Members

- NSDRG draft in team review to address comments received.

Project Status

SEND Coding Bootcamp

Description

The SEND Coding Bootcamp is designed to help professionals working with SEND datasets become more efficient by learning essential coding and plotting skills. Through a series of hands-on sessions, participants will learn the fundamentals of programming in R, including reading, writing, manipulating and visualising SEND datasets in .xpt format. Basic SEND knowledge is expected, but no prior programming experience is required.

As SEND enables broader single-study and cross-study toxicology analyses, scientists still face barriers accessing and analysing datasets stored in xpt or emerging JSON formats without programming tools. Many tasks are still performed manually in Excel, despite being more scalable and reliable when scripted in open-source languages such as R or Python.

Data managers, while skilled in SEND preparation and review, increasingly need coding capabilities to address complex data science questions. Upskilling this workforce strengthens organisations by enabling internal advancement into data science roles and reducing reliance on external hires.

Ongoing

Proposed End Date

A series of training sessions

Deliverable

On hold while we develop new content.

Key Achievements This Quarter:

Start the next phase of the project on R Shiny.

Deliverables & Targets Planned for the Next Quarter:

Michael DeNieu & Wenxian Wang

Leads

Project Status: Amber
Accepting New Members

- Drafting lessons on R Shiny focused on the production of simplified TS files.

Project Status

phuse

SEND Industry Feedback Survey

Description

This project will run an annual survey to objectively capture insights that reveal meaningful trends and issues - positive and negative - across the PHUSE Community. The goal is to generate actionable information that supports continuous improvement in the development, use and governance of data standards.

The survey will deliver value across key stakeholder groups. It will provide SDOs with clear, evidence-based feedback to guide enhancements to their standards. It will give CROs, software developers and data service providers a structured channel to share practical recommendations informed by their extensive data management experience. It will also equip sponsors with insights into how to better leverage and optimise their SEND investments.

Ongoing

Proposed End Date

Survey

Deliverable

Drafting of survey questions initiated.

Key Achievements This Quarter:

Compile the 2027 survey questions.

Deliverables & Targets Planned for the Next Quarter:

Lindsy Eickhoff & Vanessa Chavez

Leads

Project Status: Green
Accepting New Members

- We are actively collaborating to refine the survey content, including the topics to be addressed and the questions to be incorporated.

Project Status

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

Description

This project will draw on the PHUSE Nonclinical Topics Working Group's extensive SEND expertise to develop best practices for populating SEND datasets with data from virtual control animals. As other initiatives continue to clarify how study design factors influence virtual control selection - such as the impact of anaesthesia protocols on rat electrolyte levels (Gurjanov et al., 2023) - the project will also define how these factors should be consistently represented within SEND. If gaps in the current SEND standard are identified, recommendations for CDISC updates will be drafted.

Initially, the scope will focus on study types long established in SEND to ensure sufficient data for evaluating best practices. The team will also consider future needs for study designs not yet fully modelled in SEND. In parallel, the project will collaborate with the Nonclinical Scripts initiative to provide an open forum for sharing and hosting open-source tools supporting virtual control selection and database infrastructure.

VICT3R End Date (Feb 2028) + 1Q

Proposed End Date

Framework & white paper

Deliverable

Bill Houser, Christy Kubin & Kevin Snyder

Leads

Latest sdTCG (appendix I) impacts the content of the white paper (i.e. communicating the context of the virtual control selection in the study report). The TCG content is aligned with team thinking.

Key Achievements This Quarter:

Discussion ongoing regarding the white paper content. Target end of the year for white paper availability.

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green

Project Status