Nonclinical Topics Working Group

Update for CDISC SEND Spring Meeting ~ April 2026

Today's Update

- About PHUSE
- Updates on Working Group Projects
- Nonclinical Advance Event Highlights
- New Project in Planning: SEND 4.0 Implementation User Group

About PHUSE

Who We Are and What We Do

- PHUSE is an independent, not-for-profit organisation run by a worldwide team of volunteers.
- We are a global community and platform for the discussion of topics encompassing the work of data managers, biostatisticians, statistical programmers, and data scientists.
- PHUSE provides a voice for industry to regulatory agencies and standards organisations such as the FDA, EMA and CDISC.

Why We Do It

- We are passionate about our collaborative work and our collective purpose. Our community platform promises connection and knowledge sharing, which, ultimately, drives development in life sciences.

History

- Stephen Bamford, PHUSE Founder and Chairman of the Board, saw a real need to create a place for pharmaceutical programmers to share ideas and ask questions about the direction of the industry. In 2004, he founded PHUSE. From a 10-member society in the UK, PHUSE has rapidly grown into a global community.

All about PHUSE

Advancing Computational Science

- Addressing challenges across a broad set of topics
- Listed as Scientific Public Private Partnerships and Consortia with FDA CDER
- PHUSE is an EMA Stakeholder

Organizing events across the globe:

- Multiday Conferences in US, EU, and APAC
- (free) Single Day Events
- (free) Webinars, Community Forums & Multi day virtual events

Roadmap to education

- Cover broad range of nonclinical and clinical areas
- Technical and non-technical domain topics

The Nonclinical Topics Working Group

Goal:
To provide real and impactful solutions to top priority challenges using our collective experience with nonclinical data, data standards, and informatics.

We collaborate on shared challenges in nonclinical data topics with Health Authorities and members of industry

We operate with flexibility on how to work and what to work on, based on participative membership

The Nonclinical Topics Working Group

Facts about us:

- Active since 2012
- >100-member distribution list
- Currently:
  - 3 WG co-leads, meeting biweekly
  - 6 ongoing projects which meet bi-weekly or monthly, depending on activities
  - Monthly Project Leads meetings

Find out more:

- PHUSE ADVANCE HUB for information on joining working group projects
- PHUSE Global Website for events, deliverables, archive
- PHUSE TEAMS – by invitation, for individual project teams to work together, develop deliverables, maintain minutes

SEND Coding Bootcamp

Team Goals	Activities/Accomplishments

• Help those working with SEND to become more productive by teaching basic coding and visualization skills in R	• Taught 6 lessons to over 90 participants from pharma, FDA, and CROs:
	  ○ Intro to Programming in R
	  ○ Controlling Data Flow
	  ○ Plotting
	  ○ Data manipulation
	  ○ Merging data from Domains

• Expand upon skills learned in the base sessions	• Used a team survey to identify additional topics of interest for the group • Held structured lessons as well as open office hours where ad hoc questions could be discussed
• Introduction to R Shiny app development	✪ In development

Project Leads: Dan Russo, Michael DeNieu and Wenxian Wang

Developing Predictive Models to Facilitate Interpretation of Toxicology Study Results

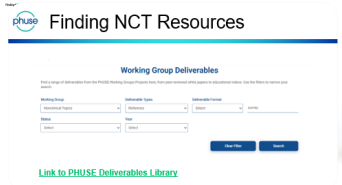
Team Goals	Activities/Accomplishments
<u>Phase 1: Show & Tell</u> • Share methods that have been developed within participants' organizations to apply predictive modeling to CDISC-SEND-formatted toxicology study data.	• Methods were presented on the following topics: ○ SEND Data Normalization/Scoring, Study Report Knowledge Labeling, ML-Based Target Organ Classificaiton, QSAR Modeling, Vehicle Name Standardization, and Synthetic Data Generation
<u>Phase 2: Working Phase</u> • Develop and validate best practices for predictive modeling methods across organizations.	<u>Subteam 1</u>: • SEND Data Normalization/Scoring <u>Subteam 2</u>: • Study Report Knowledge Labeling
Phase 3: Toolbox Phase • Collaboratively develop and publish effective methods, e.g. automated detection target organs of toxicity, prediction of human adverse events associated with nonclinical toxicity, predicting in vivo toxicity from chemical structure or in vitro assay results.	• Opportunity for the Future *Project Leads:* Kevin Snyder and Lennart Anger *Project Accepting New Members!*

Supporting the use of SEND for the Implementation of Virtual Controls

Team Goals	Activities/Accomplishments
• Develop best practices for populating SEND datasets with data from virtual control animals	• Developed recommendations for including data from virtual control animals into SEND datasets • Currently refining those recommendations and working on an example dataset
• Publish the results and share with CDISC	• Shared high-level recommendations in a published poster (Representing Virtual Control Animal Data in SEND) • Submitted new project proposal for post SENDIG v4.0 development to CDISC SEND team for consideration • White paper planned for 2026 • Planned publication of high-level concepts in journal article in 2026
• Be a venue for hosting, testing, and socializing open-source software related to virtual controls	✪ Opportunity for the future

Project Leads: Christy Kubin, Kevin Snyder, William Houser

SEND Industry Feedback Survey



Team Goals	Activities/Accomplishments
• 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.	• 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.
• Present annual survey results	9 years of Surveys conducted (2016-2026) • Presented at US CSS, EU CSS Nonclinical Virtual Event. • Annually drives new project ideas • Each survey is posted on PHUSE Deliverables
• Plan and execute next annual survey each year	✪ Seek trends in nonclinical sciences and develop survey theme per year ✪ Seek broader distribution lists to reach new stakeholders

Project Leads: Lindsy Eickhoff & Vanessa Chavez

Project Accepting New Members!

Conformance with the tumor.xpt Specification

Team Goals	Activities/Accomplishments
For Industry: • Automated validation compatible with existing SEND verification tools • Improved data quality through standardized accuracy checks • Reduced manual verification burden • Accelerated submission timelines	Finalize whitepaper → Publish for public review → Address comments → Publish final version → Maintenance and updates
For FDA: • Enhanced regulatory efficiency through early issue identification • Increased focus on scientific evaluation vs. format correction • Reduced sponsor communication regarding formatting • Consistent data quality across all submissions	
Overall Impact: • A critical step toward harmonizing tumor data standards and improving the efficiency of the drug development and regulatory review process.	

Project Leads: Gitte Frausing and Hepei Chen

Nonclinical Study Data Reviewers' Guide

Team Goals	Activities/Accomplishments
• Develop and maintain nSDRG template and accompanying guideline publicly available for Industry use, aligned with Study Data Technical Conformance Guide and CDISC SEND IGs	• Strong team in place with both long-term members and "new blood" bringing deeply experienced perspectives • 3 versions of template and guideline published – current version is 1.2 • New draft version 2.0, aligned with sdTCG, Dec 2025 and recently back from unofficial regulatory reviewer-review
• Listen and incorporate public, industry and regulatory agency feedback to continually improve nSDRG value for all stakeholders	• Assess comments and verify with recent March 2026 sdTCG • Move from Draft to Final publication in next few months
• Support CDISC SEND Team nSDRG references in IG and piloting activities	✪ Team will work to generate example nSDRGs to match the POC datasets for SENDIG 4.0

Project Leads: Susan DeHaven and Janessa Pierce

Project Accepting New Members!

Nonclinical Virtual Event Highlights Feb 2026

Over three days: 487 attendees from 99 unique companies across 22 countries!

Presentations day 1:

Day 1: New Approach Methodologies for Nonclinical Safety Assessment	
Watch recording	
Turning Policy into Practice: How Data Standardisation Supports NAM Evaluation	Nakissa Sadrieh & Stephanie Leuenroth-Quinn, *FDA/CDER/OND*
New Approach Methodologies for Nonclinical Safety Assessment	Véronique François, *Pistoia Alliance*
InVitro Pharmacology (IVP) Project – Pistoia Alliance	Chris Butler, *AbbVie*
In Vivo Laboratory Efficacy Data Standards	Marc Ellison, *Instem*
Pistoia Alliance In Vitro NAMs Data Standard	Kevin Snyder, *Certara*

Key take-aways:

- NAMs are moving from policy discussion toward practical regulatory implementation
- Innovation must be supported by aligned data structures, consistent terminology and collaborative frameworks to build regulatory confidence.
- Pistoia Alliance's mission to lower barriers to innovation through pre-competitive collaboration is in action with 3 high value projects

Breakout feedback:

Advancing NAMs is not only a scientific challenge, but a data and alignment challenge.

Thoughtful standardization, cross-sector collaboration and practical pilot initiatives will be key to translating potential into routine regulatory practice.

Nonclinical Virtual Event Highlights Feb 2026

Presentations day 2:

Day 2 Nonclinical Predictive Modelling & Machine Learning	
Watch recording	
Advancing Translational Applications by Turning Data into Insight with Machine Learning	Pantelis Mavroudis, *Sanofi*
Developing Predictive Models to Facilitate Interpretation of Toxicology Data	Kevin Snyder, *CertaPa*
Enabling Translational Safety: Harnessing Collaboration to Accelerate Safer Products to Patients	Lilliam Rosario, *TransCelerate*; William Houser, *Bristol Myers Squibb*

Key take-aways:

- From standards to scientific application, predictive modelling and machine learning are reshaping how nonclinical data generate translational insight.
- Innovative use of predictive analytics on CDISC SEND toxicology data is enhancing signal detection and supporting translation to human safety outcomes.
- Safety science is reaching an inflection point, where harmonised data, NAMs, and predictive analytics can better connect nonclinical observations to the clinic

Breakout feedback:

Predictive modelling in nonclinical science is no longer theoretical. Its continued impact will depend on high-quality data, thoughtful standardization and sustained cross-sector collaboration.

Nonclinical Virtual Event Highlights Feb 2026

Presentations day 3:

Day 3 PHUSE Project Contributions & Developments	
Watch recording	
SEND Industry Feedback Survey	Vanessa Chavez, *Labcorp*; Lindsy Eickhoff & Chloe Bosworth, *Inotiv*
Conformance with the Tumor.xpt Specification	Gitte Frausing, *Data Standards Decisions*; Erin Tibbs-Slone, *Charles River Laboratories*
Nonclinical Study Data Reviewer's Guide	Janessa Pierce, *Merck*; Sue DeHaven, *Sanofi*
SEND Coding Bootcamp	Daniel Russo, *Merck*; Wenxian Wang, *Bristol Myers Squibb*
Supporting the Use of SEND for the Implementation of Virtual Control Groups	Christy Kubin, *Charles River Laboratories*; William Houser, *Bristol Myers Squibb*

Key take-aways:

- 'What's possible' to 'What needs to work well' – focusing on practical SEND implementation, quality, and how the community can better support consistent data use beyond submission.
- A key message was the need for clearer communication and stronger shared resources for the community.
- Momentum building for practical programming and data-handling skills across sponsors, CROs and regulators, with a growing focus on a applied learning.

Breakout feedback:

Discussion generated strong, actionable ideas for future PHUSE work.

See the PHUSE Blog post for more details

New Project in Planning: SENDIG 4.0 Implementation User Group

"I feel lack of exposure to SEND related 'things' is a major pain point in our industry."

~Chloe Bosworth, new CDISC SEND Team Co-Lead

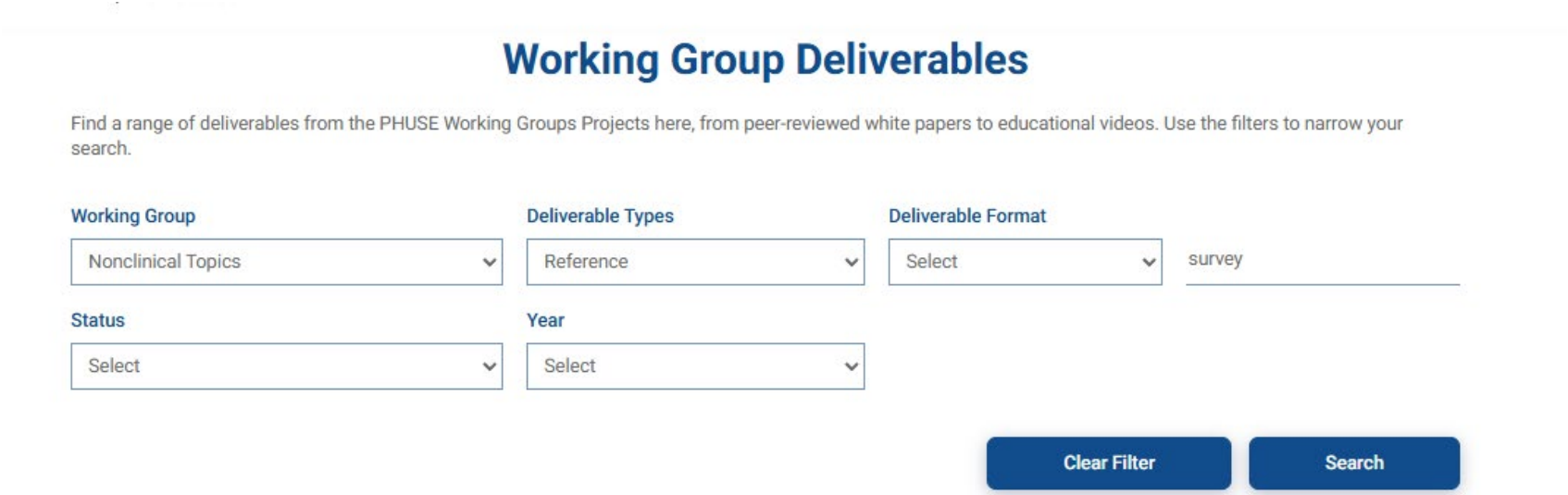
- Communication, Education, Change Management, Collaboration, and more… All strong incentives for PHUSE to support implementation of the SENDIG 4.0 for the whole stakeholder community
- Our most recent survey response says it: 85% agreement among respondents in wanting a SENDIG User Group, with 65% stating they would allocate time to it.
- *Plenty of ideas! Monthly news blog, Webinar Platform, Event Platform, Education Platform, with both PHUSE and CDISC hosting public facing tools to support them.*
- *We need CDISC advice: When is the right time, how to ensuring expertise…*

Let's partner together!

- *Contact Kevin, Michael, Sue and Chloe with your interest to help us make this a reality at the right time, with the right information and the right tools.*

Backup

Finding NCT Resources



[Link to PHUSE Deliverables Library]