101172693 – VICT3R

Developing and implementing Virtual Control Groups to reduce animal use in Toxicology Research

WP2 – Data management, curation and quality control (Repeated Dose Toxicity Studies, RDT)

D2.5 Workshop with SEND experts

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Definitions

Participants of the VICT3R Consortium are referred to herein according to the following codes:

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44. INSTITUT SERVIER DE MEDECINE TRANSLATIONNELLE (ISMT)
45. ZOETIS BELGIUM SA (ZOETIS)

Grant Agreement	The agreement signed between the beneficiaries and the IHI for the undertaking of the VICT3R project (101172693).
Project	The sum of all activities carried out in the framework of the Grant Agreement.

Consortium	The VICT3R Consortium, comprising the above-mentioned legal entities.
Consortium Agreement	Agreement concluded amongst VICT3R beneficiaries for the implementation of the Grant Agreement (GA). Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the GA.

Executive Summary

On September 11, 2025, Fraunhofer ITEM organized the VICT3R - CDSIC Workshop that was focused on the intersection of the VICT3R initiative and CDISC applying and developing the Standard for Exchange of Nonclinical Data (SEND standard), emphasizing the importance of data standardization in nonclinical research. The workshop featured multiple presentations that addressed current challenges, innovative solutions, and the ongoing development of SENDIG v4.0.

This workshop provided a crucial platform for collaboration among industry experts to advance data standardization efforts, ultimately enhancing the quality and reliability of nonclinical data reporting.

Topics which were discussed:

- Challenges in Standardization: Discussions highlighted the difficulties faced in standardizing heterogeneous terms and the need for clear, structured descriptions to ensure data consistency.
- SENDIG v4.0 Development: The upcoming version of SENDIG introduces new domains and variables, enhances controlled terminology, and aims to improve data integrity and compliance.
- Necessity of harmonizing data reporting across various domains, such as demographics, trial summaries, and microscopic findings.
- Stakeholder Engagement: The importance of feedback from industry leaders, regulatory agencies, and stakeholders was emphasized, with a call for participation in the public review process of SENDIG v4.0.

Following the workshop, VICT3R experts were invited to present the project and its data standardization initiatives to CDISC on November 12, 2025.

Introduction

The integration of standardized data reporting practices is essential in the field of nonclinical research, particularly as it pertains to regulatory compliance and the efficacy of clinical and nonclinical studies. The recent CDSIC Workshop, held on September 11, 2025, brought together leading experts in the field to discuss the current state and future direction of CDISC SEND standards, particularly the anticipated release of SENDIG v4.0. In total 28 participants attended the workshop, namely:

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The online workshop brought together experts to discuss current challenges and progress in data standardization within nonclinical research environments. A key focus was on ensuring consistent and validated data to improve the quality and reliability of scientific assessments. Sylvia Escher and Sascha Fischer from Fraunhofer ITEM emphasized that missing values, heterogeneous terminology, and incorrectly formatted variables remain common obstacles that can distort statistical analyses and impair decision-making. To enable standardized reporting and facilitate harmonized data structures, they presented established workflows and supporting tools that address these issues, including the ongoing curation and standardization of multiple SEND domains carried out in the VICT3R project

The workshop featured presentations from industry leaders, including Christy Kubin, Keith Moseley, Ben Sefing, and William Houser, who provided insights into the ongoing development of SENDIG and its implications for data standardization.

The progress in data curation performed for the VICT3R project was presented by Sylvia Escher, Jenny Irwan, Sascha Fischer (Fraunhofer ITEM) and Frank Bringezu (Merck).

Participants explored various challenges associated with standardizing terms across multiple domains, the introduction of new data types, and the need for controlled terminology to facilitate consistent data reporting.

Through collaborative discussions, the workshop aimed to foster a deeper understanding of the complexities involved in data standardization and to encourage active participation in the continuous improvement of SEND standards. This document summarizes the key presentations and discussions from the workshop, highlighting the critical steps being taken to enhance data integrity and compliance in nonclinical research.

The methodologies applied during the CDSIC Workshop included a combination of presentations, interactive discussions, and breakout group sessions aimed at fostering collaboration among participants. Presenters utilized structured frameworks to introduce key concepts related to data

standardization, particularly focusing on the development of SENDIG v4.0 and its implications for various domains. Participants engaged in breakout sessions that encouraged hands-on problem-solving and the sharing of best practices for addressing challenges in data harmonization. Additionally, the workshop incorporated feedback mechanisms, allowing attendees to contribute their insights and experiences, which were crucial for identifying gaps and opportunities in the current standardization processes. This collaborative approach ensured that a diverse range of perspectives was considered, ultimately enriching the discussions and outcomes of the workshop.

Summary of the sessions

Status of Current Data Curation Efforts

The workshop discussions demonstrated that substantial progress has been achieved in advancing standardized data structures across several key SEND domains. Examples from the current data curation activities done in VICT3R highlighted improved consistency in demographics, trial summary, and laboratory results, while ongoing curation efforts continue to reduce ambiguity, technical errors, and missing information. Despite these improvements, multiple domains — including microscopical findings and clinical pathology — still show significant variability in terminology and units, requiring continuous refinement of mapping rules and validation procedures. The workflow presented by VICT3R, including the use of dedicated curation tools, proved effective in identifying non-standard entries and enabling iterative updates of the mapping tables, thereby supporting a more robust and harmonized data environment.

Overview of Current SEND Development

The workshop opened with an overview of the current state of SEND (Standard for Exchange of Nonclinical Data), led by industry experts including Christy Kubin, Keith Moseley, Ben Sefing, and William Houser. They discussed the ongoing development of SENDIG v4.0, emphasizing the importance of this initiative in enhancing data standardization and compliance.

Agenda for SENDIG v4.0

The agenda outlined key areas of focus for SENDIG v4.0, including new domains (see further below), modified variables, structured vehicle descriptions, updates on subject characteristics, and trial summary parameters. The presentations highlighted the need for controlled terminology to ensure consistent data reporting.

Major Revisions in SENDIG v4.0

SENDIG v4.0 represents a significant revision from the previous version (SENDIG v3.1.1). It includes the modeling of additional data types, introduction of new domains and variables, and updates to controlled terminology lists. The revisions aim to improve readability and reduce ambiguity in data reporting.

Introduction of New Domains

New domains introduced in SENDIG v4.0 include:

- **Genetic Toxicology - In Vivo (GV)**: For subject-level genetic toxicology data.
- **Cell Phenotyping (CP)**: To support tests associated with cell phenotyping components.
- **Immunogenicity Specimen Assessments (IS)**: For assessing immune responses.
- **Ophthalmic Examinations (OE)**: For findings related to eye examinations.

These new domains address industry requests for more comprehensive data submission capabilities.

Controlled Terminology and Future Development

The presentation discussed the importance of controlled terminology in SENDIG v4.0, detailing how requests for new terms are managed through the National Cancer Institute-Enterprise Vocabulary Service (NCI-EVS). It emphasized the need for consistency across code lists and the ongoing efforts to develop new terms specific to nonclinical studies.

Stakeholder Engagement and Feedback Mechanisms

Feedback from stakeholders, including regulatory agencies and industry representatives, will guide future project priorities. The presentation highlighted the importance of public review comments in the SENDIG development process, inviting attendees to participate in the review of SENDIG v4.0 during its public review period.

Closing Remarks

The workshop concluded with an acknowledgment of the collaborative efforts in advancing SEND standards and a call to action for continuous engagement in the development process. Participants were thanked for their contributions to the workshop and encouraged to stay involved in future discussions.

This comprehensive overview of the CDISC SEND presentation highlights the ongoing efforts to enhance data standardization in nonclinical research and the collaborative approach taken by industry leaders.

Breakout Groups

Breakout Group 1: Study Design & Special Purpose Domains / Current Status Data Curation Overview

Presented by Frank Bringezu (Merck, VICT3R) and Timur Tug (Fraunhofer ITEM, VICT3R).

This session focused on innovative approaches to data standardization and the alignment of the VICT3R initiative with CDISC SEND standards. Emphasis was placed on data integrity and the harmonization of information within key special purpose domains, particularly demographics, species, strain, sex, and age. The correct definition and reporting of study dates were also highlighted as essential for ensuring comparability across studies.

The presenters provided an overview of the status of data curation in the demographics (DM) and trial summary (TS) domains carried out in VICT3R. Progress has been made in standardizing entries such as age and species, but challenges remain due to inconsistent formats, heterogeneous data sources, and recurring technical errors. When addressing these issues, curated fields are created while original values are retained to preserve traceability. The VICT3R DCS R package was introduced as an important tool supporting this dual-layer approach, enabling improved standardization while managing the integrity of data inputs from multiple contributors.

Breakout Group 2: MI Domain / Data Standardization Process in the VICT3R Project

Presented by Jenny Irwan and Sascha Fischer (Fraunhofer ITEM, VICT3R).

In this breakout group the complexities of the MI (Microscopic Findings) domain, where heterogeneous terminology and the lack of standardized terms in SEND continue to pose major challenges were discussed. The approach presented involves maintaining the original wording while simultaneously developing curated and controlled terminology to ensure consistency across datasets.

The presenters also elaborated on the broader standardization workflow established within the VICT3R project. Given the variability in data structures and definitions among different sponsors, the project must systematically address issues such as missing values and non-standardized entries to enable reliable analyses — especially when generating virtual control groups. The outlook emphasized ongoing refinement of the standardization procedures and continuous adaptation to emerging requirements within the SEND framework.

Conclusion

The workshop aimed to promote a better understanding of the complex challenges involved in data standardization and encourage participants to contribute to the continuous improvement of SEND standards through collaborative discussions. It fostered an engaging dialogue on the importance of data standardization in non-clinical research, emphasizing the need for joint efforts to improve the quality and integrity of data reporting in line with CDISC standards. The outcomes of this workshop will continue to inform future collaborations and standardization efforts within the VICT3R initiative, building on the insights gained. In this context, VICT3R experts have been invited to present the project and its data standardization initiatives to CDISC in November 2025, marking an important step towards the future alignment and integration of research data standards.

Repository for primary data

We acknowledge that the presentations and the agenda held during the workshop have been shared. They are available to the VICT3R consortium members for internal review on the VICT3R SharePoint (20250911_CDISC Workshop).