

# Application of SEND Data for Analysis



phuse.global

## Nonclinical Topics

### Project Overview

The project focused on use cases for SEND data related to analyses provided on tables for general toxicology studies. Commonly, the nonclinical study analyses in industry practice are performed using raw data extracts, while the SEND datasets are created outside of this in a separate process. This project examined these purposes and identified some standard analyses that could be performed using the SEND package.

The intent was to understand how these analyses relate to SEND data, and demonstrate the data quality and fitness for use possible using SEND data sets for analysis. It was the project's objective that this effort can be used to create standard scripts and fitness for use checks on SEND data.

### Identified Need/Challenge

As the implementation and exchange of SEND data is becoming more prevalent in the industry, focus is directed towards the usability and fitness for use of the SEND data. The usability of SEND data is essential in order to harvest the benefits of more efficient review and analysis.

### Project Scope

The project focused on individual SEND domains in a prioritized manor (FW, CL, MA, MI mainly). Scientific questions that may arise during review of SEND data were discussed. SEND domain specific analyses using example analysis keys (i.e. SEND variables) were identified to aid in getting the right answers from the SEND datasets.

Certain SEND variables lend themselves better to computational analysis by being subject to controlled terminology, formats and/or expectancy requirements by the standard, while other variables are under the control of the sponsor (either with population by need or choice or through sponsor controlled vocabularies). The project proposed recommendations for which variables are minimum information for any review of the data. Analyses is defined for this project as review of SEND data, and does not refer to the statistical outcomes of the study.

### Vision

To describe use cases for SEND data that may provide the industry with a common platform to communicate and assess how SEND supports data "fitness for use" and provides quality context for review of study data.

### Transverse Collaborative Investigations

- Leverage similar deliverables from Phuse Standard Scripts work group
- Cooperation with the "Visualization of histopathology" project
- Find published clinical position papers within the content of dataset review and analysis (e.g. FDA position paper)

### Deliverables

#### SEND Domains Examined

Domain Name	Data Type	Source System	Link to document page
FW	Individual Non-rodent	PDS - ToxData	<a href="#">2016-08-12</a>
FW	Individual Rodent	Provantis	<a href="#">2016-08-26</a>
FW	Cage-based Rodent	Provantis	<a href="#">2016-08-26</a>
FW	Individual Non-rodent	Pristima	<a href="#">2016-09-09</a>
CL (Qualitative Food)	Individual Non-rodent	PDS - ToxData	<a href="#">2016-09-09</a>
MA	Group summary non-rodent	PDS - ToxData	<a href="#">2016-11-04</a>
MA	Group summary non-rodent	PDS - ToxData	<a href="#">2016-11-04 continued</a>

MA	Individual Non-rodent	Provantis	2016-11-04
----	-----------------------	-----------	------------

SEND Variable Annotation Examples	
Document Name	Link to document page
ePaper	
Tox tables mapped to SEND	<a href="#">Tox tables to SEND mapping.xlsx</a>
Tox table illustration	<a href="#">Table illustration.docx</a>
Sample BW report with annotation	<a href="#">Sample BW report with annotation</a>
Sample BG Individual listing with annotation	<a href="#">Sample BG Individual listing with annotation</a>
Sample LB Clin Chem Individual listing with annotation	<a href="#">LB Clinical Chemistry individual data</a>
Sample LB urinalysis data - individual and summary	<a href="#">LB urinalysis examples reduced size</a>
Sample CL data - individual and summary	<a href="#">CL examples2</a>
Sample CL data 2 - Individual	<a href="#">Clin Obs Example</a>
Sample CL data 3 - Individual	<a href="#">Clinical Sign report</a>
Thomas' overview of study data	<a href="#">Framework for discussion of classification of information</a>
Master Thesis, Thomas	<a href="#">Analysis of SEND LB data (MSc thesis).zip</a>
Master Thesis, Thomas, Presentation	<a href="#">Analysis of SEND LB data (MSc thesis) - Examination slides</a>