

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	2016-08-12
FW	Individual Rodent	Provantis	2016-08-26
FW	Cage-based Rodent	Provantis	2016-08-26
FW	Individual Non-rodent	Pristima	2016-09-09
CL (Qualitative Food)	Individual Non-rodent	PDS - ToxData	2016-09-09
MA	Group summary non-rodent	PDS - ToxData	2016-11-04
MA	Group summary non-rodent	PDS - ToxData	2016-11-04 continued

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

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