PP24

SEND Data Factory

Bob Friedman, Xybion; Kevin Snyder, FDA; Eli Miller, Covance

Abstract

The PhUSE non-clinical scripts team is developing a SEND Data Factory tool which can create example SEND datasets. This will allow industry stakeholders to produce example SEND datasets for use in the preparation of visualizations, data exchange and tools development.

The program is written in R and shared on the PhUSE Github for group collaboration or downloading and customization. It is designed to create datasets that pass the validation checks for a dataset. This factory allows selection of the study design (number of dose groups and animals per group) and it then can output .xpt dataset files including trial design, animal demographics and disposition, exposure and observation data.

Future work is planned to improve the realism of the data by allowing configuration of species and age specific ranges, and the desired distribution of pathological observations.

Design:

The SEND data factory is being developed using the “R” programming language and utilizing the R-Shiny Dashboard framework.

The Controlled Terminology (CT) sets are read from .xls files supplied by the NCI website and the SEND IG is read from the PDF supplied by CDISC.

Features

Selections for:

- Controlled Terminology versions
- Study type, species
- Number of groups and animals per group
- Recovery and TK groups
- Data selections

More complex configurations are read from a configuration file:

- Expected categories
- Non-controlled terminology, for example Clinical Observations and Macropathology
- Ranges for numeric endpoints
- Arm/Set Designation
- Additional demographic information

Figure 2: QR Code to access the Nonclinical Script Assessment Project PhUSE Wiki page

Figure 3: QR Code to access the Nonclinical Script Assessment Project Github Repository

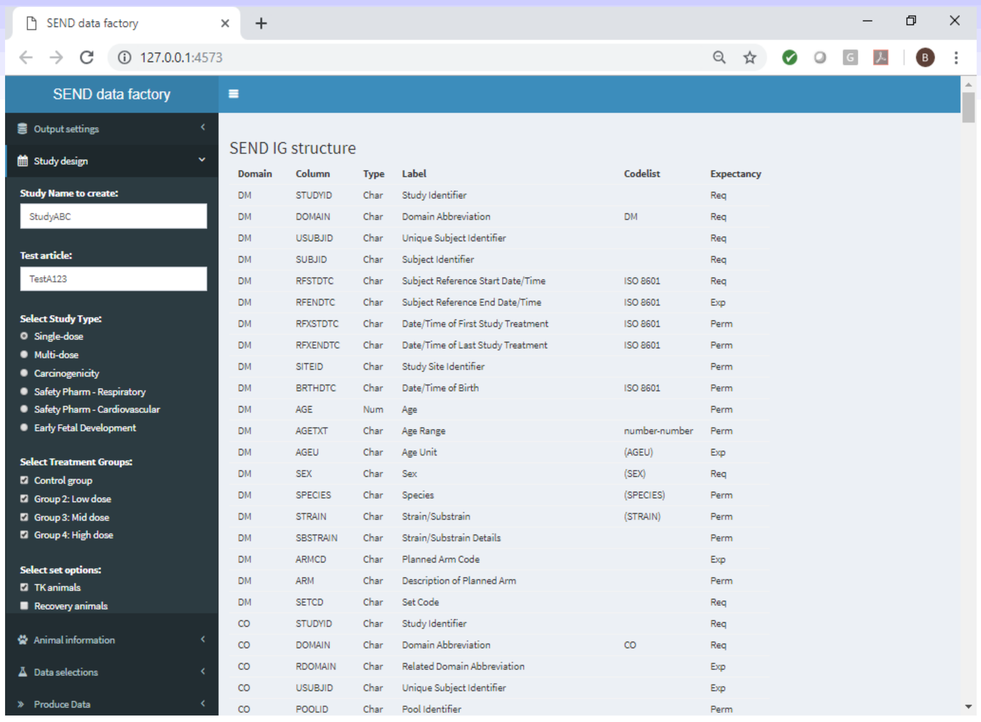

Figure 1: Study selections on the left

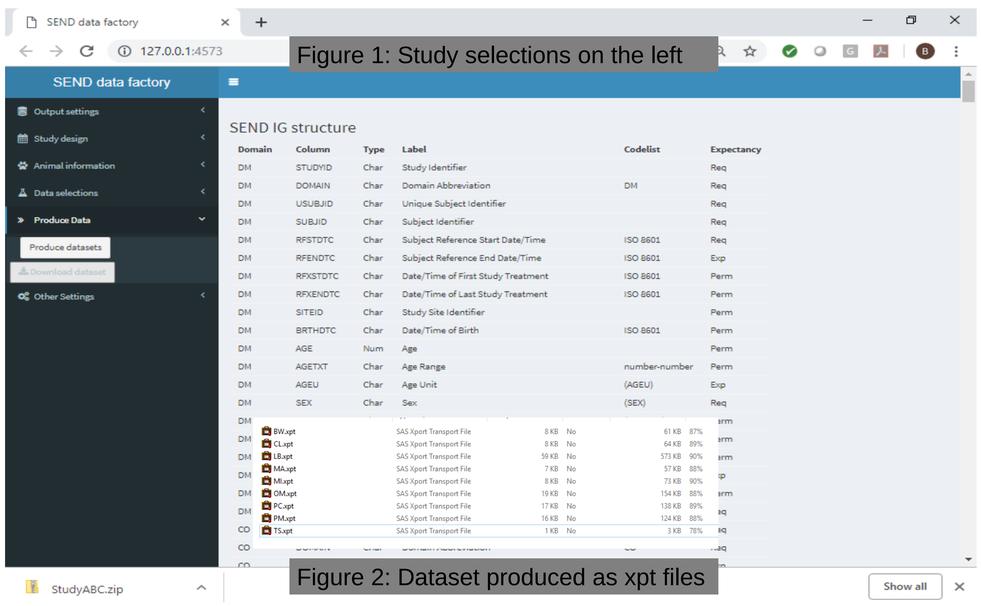

Figure 2: Dataset produced as xpt files

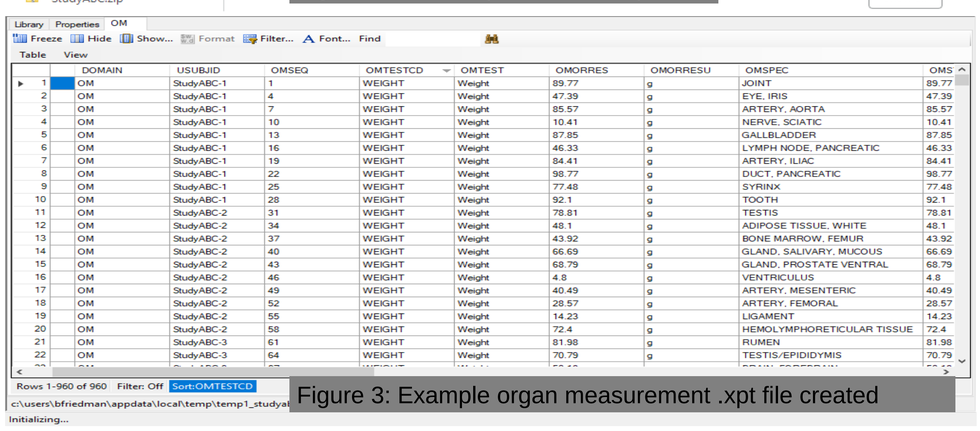

Figure 3: Example organ measurement .xpt file created

Next steps:

Add DART 1.1 capability in addition to SEND 3.1

Simulated dose responses through endpoint range and incident adjustment.

Ability to create custom and experimental domains.

This application could be used by an industry group or an organization to create proof-of-concept datasets. The application could be used in the future to test changes and enhancements to SEND by giving stakeholders an application to interact with changes in a practical way.

Note: The opinions expressed in this poster are those of the authors and do not necessarily represent the opinions of their respective organizations.