# PP24 Ohuse

## 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

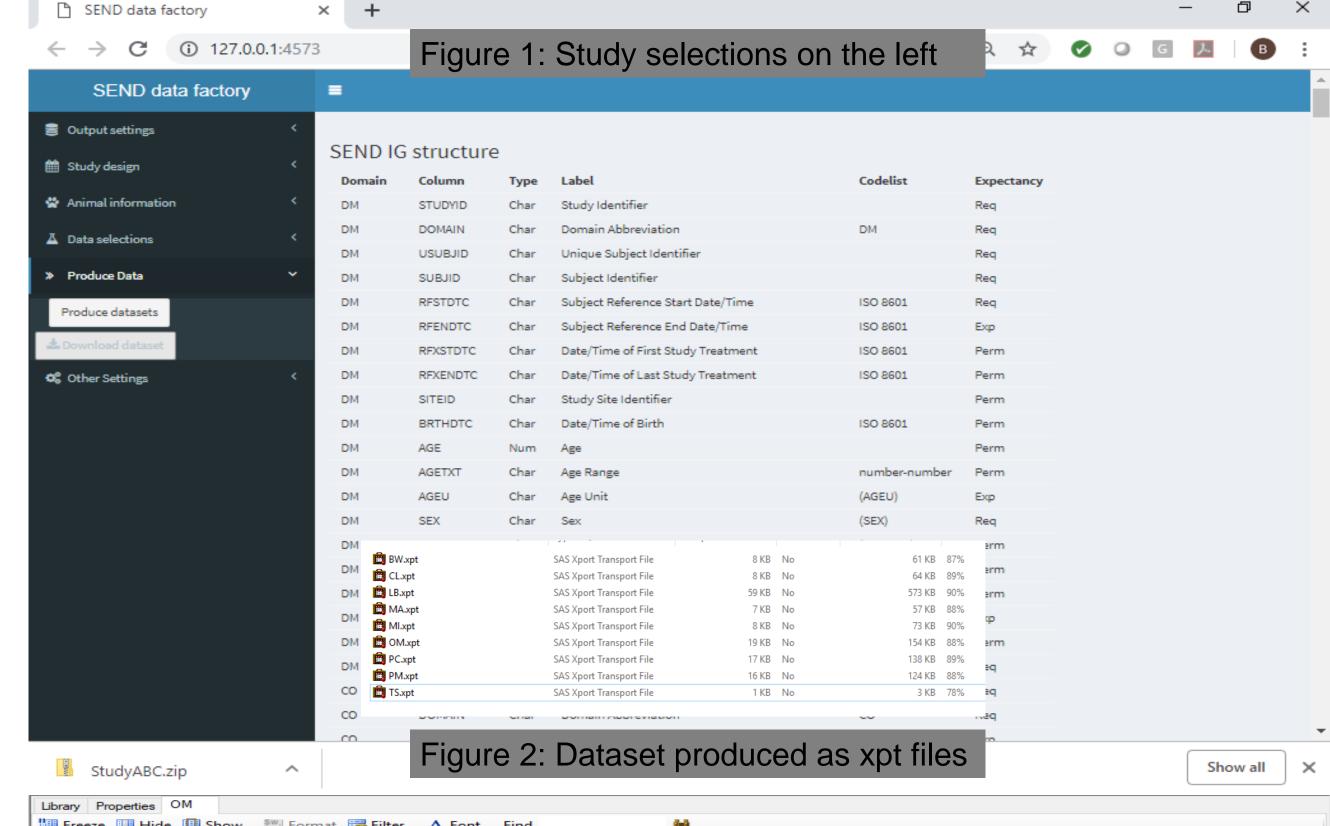




Figure 2: QR Code to access the Nonclinical Script Assessment Project PhUSE Wiki page

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

 SEND data factory
 ★
 C
 ★
 C
 ★
 C
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★
 ★



	DOMAIN	USUBJID	OMSEQ	OMTESTCD	▼ OMTEST	OMORRES	OMORRESU	OMSPEC	OM
- 1	OM	StudyABC-1	1	WEIGHT	Weight	89.77	g	JOINT	89.7
2	ОМ	StudyABC-1	4	WEIGHT	Weight	47.39	g	EYE, IRIS	47.3
3	OM	StudyABC-1	7	WEIGHT	Weight	85.57	g	ARTERY, AORTA	85.
4	ОМ	StudyABC-1	10	WEIGHT	Weight	10.41	g	NERVE, SCIATIC	10.4
5	ОМ	StudyABC-1	13	WEIGHT	Weight	87.85	g	GALLBLADDER	87.
6	ОМ	StudyABC-1	16	WEIGHT	Weight	46.33	g	LYMPH NODE, PANCREATIC	46.
7	ОМ	StudyABC-1	19	WEIGHT	Weight	84.41	g	ARTERY, ILIAC	84.
8	ОМ	StudyABC-1	22	WEIGHT	Weight	98.77	g	DUCT, PANCREATIC	98.
9	ОМ	StudyABC-1	25	WEIGHT	Weight	77.48	g	SYRINX	77.
10	ОМ	StudyABC-1	28	WEIGHT	Weight	92.1	g	тоотн	92.
11	ОМ	StudyABC-2	31	WEIGHT	Weight	78.81	g	TESTIS	78.
12	ОМ	StudyABC-2	34	WEIGHT	Weight	48.1	g	ADIPOSE TISSUE, WHITE	48.
13	ОМ	StudyABC-2	37	WEIGHT	Weight	43.92	g	BONE MARROW, FEMUR	43.
14	ОМ	StudyABC-2	40	WEIGHT	Weight	66.69	g	GLAND, SALIVARY, MUCOUS	66.
15	OM	StudyABC-2	43	WEIGHT	Weight	68.79	g	GLAND, PROSTATE VENTRAL	68.
16	ОМ	StudyABC-2	46	WEIGHT	Weight	4.8	g	VENTRICULUS	4.8
17	ОМ	StudyABC-2	49	WEIGHT	Weight	40.49	g	ARTERY, MESENTERIC	40.
18	ОМ	StudyABC-2	52	WEIGHT	Weight	28.57	g	ARTERY, FEMORAL	28.
19	ОМ	StudyABC-2	55	WEIGHT	Weight	14.23	g	LIGAMENT	14.
20	OM	StudyABC-2	58	WEIGHT	Weight	72.4	g	HEMOLYMPHORETICULAR TISSUE	72.
21	ОМ	StudyABC-3	61	WEIGHT	Weight	81.98	g	RUMEN	81.
22	ОМ	StudyABC-3	64	WEIGHT	Weight	70.79	g	TESTIS/EPIDIDYMIS	70.
22		0. 1.000	0-7	· · · · · · · · · · · · · · · · · · ·		F0 40		DD.111 FOREDD.111	

#### **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.