Interorganizational SEND

Project Scope

Welcome to Advance Hub for our project to identify challenges and propose solutions to help Sponsors and CROs, to work efficiently together, in a world where nonclinical data, possibly derived from different organizations, will be required to be aggregated in SEND format, for submission to the FDA.

Need/Challenge

The responsibilities for creating the SEND files for a study is often shared across organizations. Clarity is needed on how these responsibilities can be effectively managed.

Project Plans

At the March 2015 meeting:

- It was determined that the remaining tasks envisioned for this group are a lower priority than the other pressing needs for collaboration in nonclinical computational sciences. As a result this project is complete.
- The following items were considered as the next work for this team; so, as priorities adjust in the future, these may be worked on again:

Create a template for PP data and enhance the PP template to provide organizations without SEND capabilities a way to provide TK data in a format that can more easily be integrated into a set of SEND datasets for a study. Pilot its use. Create a "points to consider" list. Adjust the template as needed. Publish the results on the PHUSE SEND Advance Hub and at the 2015 PHUSE/FDA Computational Sciences Symposium. Evaluate the applicability of other CDISC standards CDASH, ADaM, ODM for non-clinical studies and publish the results on the PHUSE SEND Advance Hub and at the 2015 PHUSE/FDA Computational Sciences Symposium.

Accomplished

Between March 2014 and March 2015

- Survey of industry SEND data from Small/Medium Service Providers: How prepared are they to supply data in SEND format? Template to Facilitate Creating Pharmacokinetic SEND datasets
- File: PC template with formulas.xlsx

Between March 2013 and March 2014

Summaries of actual experience with Scenario Experience

- File: MPI Research I-SEND Scenario Feedback 2013-05-03.docx
- File: INDS Testing Scenario 3.docx
- File: Scenario 1 w numbering.pdf
- File: Scenario 2 w numbering.pdf
- File: Scenario 3 w numbering.pdf

- PP13 SEND Datasets for Interorganizational studies.pdf

Points to consider list when preparing to create SEND datasets for studies that involve multiple organizations:

- SEND_Implementation_Wiki_-_SEND_between_Organizations
- File: PP08 Selecting a CRO for SEND.pdf

The role of GLP in SEND files Selecting a CRO for Creating and Integrating SEND Datasets from Multiple Organisations

Between March 2012 and March 2013

We developed a framework to classify and prioritize scenarios ine which data from multiple orginzations needs to be aggregated. We selected 3 scenarios and for each developed workfows "on-paper" to create and submit SEND datasets. While considering these scenarios we identified several questions that needed to be answered and collaboratively developed answers. These have been published on the PHUSE SEND User's Group Advance Hub: Handling of SEND in Study Documentation. We started preparing a Scenarios White Paper. We published a poster at the 2013 FDA/PHUSE Computational Science Symposium, which is available as slides File:I-SEND Poster 2013 as slides.pdf