SEND Implementation for Cross-Study Analysis

Enabling cross-study analysis of preclinical toxicology datasets by examining variability in current CDISC SEND structured data and developing proposals for CDISC SEND harmonization

Initiative Status:

Last Update: December 2024

Benefits:

- With consistent SEND study data packages, Organizations can:
  - More easily compare data generated across multiple studies, leading to more informed decision making to bring better compounds to patients faster
  - Generate more efficient processes to deliver data leading to decreased cycle times for both CROs and Sponsors
  - Improve the quality of data sets and reduce errors to streamline Regulatory review and analysis

Solutions:

SEND Manuscript (Q1 2020):
Published a SEND variability manuscript to highlight the difficulties with analyzing cross-study data
Cross-Study Analysis Manuscript (Q3 2020):
Published a cross-study analysis proof of concept manuscript

Send Data Harmonization (Q1 2020):
Implemented activities to facilitate recommendations for SEND data harmonization

SEND Harmonization Recommendations (Q3-Q4 2020):
Delivered proposed recommendations for SEND harmonization to CDISC SEND Leadership

Scripting and Coding Publication of Open-Source R Package (Q3 2022)
Published sendigR search script package to CRAN

Cross-Study Analyses of SEND Data (Q3 2024):
Published a manuscript to develop CDISC SEND data harmonization/transformation strategies and apply analytic techniques to enable cross-study analysis