

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:



➔ 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
 - Reduce the need for sponsors and CROs to develop and maintain internal SEND standards
 - 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



Send Data Harmonization (Q1 2020):

Implemented activities to facilitate recommendations for SEND data harmonization



Cross-Study Analysis Manuscript (Q3 2020):

Published a cross-study analysis proof of concept manuscript



SEND Harmonization Recommendations (Q3-Q4 2020):

Delivered proposed recommendations for SEND harmonization to CDISC SEND Leadership

Last Update: January 2022