

Harmonization of SEND Implementation to Enable Historical Control Data Analysis

Project Scope

The scope of this project is to evaluate and recommend approaches for SEND harmonization to better enable analysis of historical control data. SEND harmonization strategies include creation of new variables, controlled terminology, preferred terms, reference lists and/or analysis strategies (scripts) to enable cross study analysis. Developing a solution framework for variability that includes representation of stakeholders involved in the creation and use of SEND datasets will enable more efficient routine analysis of warehoused SEND data.

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Objectives & Deliverables	Timelines
Prioritised list of domains/variables required for harmonisation	Q32020
Develop harmonisation recommendations for selected domains/variables and create white paper(s) for specific domains/variables as needed	Q22021
Poster presentation and update of current Working Group progress at CSS	Q32021
PHUSE Publication or White Paper	Q22022

Project Members	Organisation
Annika Kreuchwig	Bayer
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CURRENT STATUS Q12022

Recommendations for Consistent Representation of Test Facilities, Test Sites, and Subject Metadata Using SEND Controlled Terminology White Paper sent out for public review

Resources

[Recommendations for Populating Control Type \(TCNTRL\) with CDISC SEND Controlled Terminology](#)