

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
PHUSE Publication of White Paper: Recommendations for Consistent Representation of Test Facilities, Test Sites, and Subject Metadata Using SEND Controlled Terminology	Q2 2022

CURRENT STATUS	Q2/3 2022
	<ul style="list-style-type: none"> Attended CDISC SEND F2F Currently collaborating on a White Paper Working on a Poster for PHUSE /FDA CSS 2022

Resources
Recommendations for Populating Control Type (TCNTRL) with CDISC SEND Controlled Terminology

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