Harmonization of SEND Implementation to Enable Historical Control Data Analysis

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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.

Project Leads	Email
Kevin Snyder, *FDA*	kevin.snyder@fda.hhs.gov
Mark Carfagna, *Eli Lilly*	carfagna_mark_a@lilly.com
Alex Pearce, *PHUSE Project Assistant*	Alexandra@phuse.global

Objectives & Deliverables	Timelines
Develop plans for a new, re-scoped project that will focus exclusively on applying harmonisation of SEND data to facilitate implementation of virtual control groups in toxicology studies	Q2 2023
Continued work on consulting with other consortia to understand the critical data needed for virtual controls defining	Q3 2023
Host a workshop at the PHUSE CSS	Q3 2023

CURRENT STATUS **Q4 2023**

- Re-scoping the project to focus on virtual control data

Resources

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

Supporting the Use of SEND for the Implementation of Virtual Control Groups