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

**blocked URL**

**Project Scope**

This project will leverage the deep SEND knowledge and experience of the PHUSE Nonclinical Topics Working Group by initially focusing on the development of best practices with respect to population of SEND datasets with data from virtual control animals. As the relative importance of various study design elements to the selection of appropriately matched virtual control animals is being actively investigated and publicised by other related efforts, e.g. the influence of anaesthesia protocols on electrolyte levels in rats (Gurjanov et al., 2023), best practices will also be developed to ensure that these elements will be appropriately and consistently represented in SEND datasets. Recommendations to CDISC will be drafted and communicated if it becomes evident that the SEND data standard will need to be modified in order for this data to be appropriately represented. Initially, the project scope will be restricted to include only study types that have been clearly modelled in SEND for long enough that data availability will not be a limiting factor in the development and evaluation of best practices, but thought will be given to best practice and data standard development opportunities to support the implementation of virtual control groups in study designs that have yet to be clearly modelled in SEND.

As there are several ongoing collaborative projects attempting to develop and evaluate selection procedures and the necessary database infrastructure required to implement these procedures, this project will leverage the Nonclinical Scripts project within the Nonclinical Topics Working Group and provide an open venue for the socialisation and hosting of open-source software solutions related to selection procedures and database infrastructure.

| Project Leads | Email |
|---|---|
| Kevin Snyder, *FDA* | kevin.snyder@fda.hhs.gov |
| William Houser, *Bristol-Myers Squibb* | william.houser@bms.com |
| Laura Lotfi, *Charles River Laboratories* | laura.lotfi@crl.com |
| Alex Pearce, *PHUSE Project Assistant* | Alexandra@phuse.global |

| Objectives & Deliverables | Timelines |
|---|---|
| Provide relevant recommendations to CDISC for SEND v4.0 | 3 Months |
| Develop best practices for the representation of virtual control animals in SEND in SEND v4.0 and publish white paper | Development 9 months, White Paper 12-18 Months |
| Develop recommendations to CDISC for future versions of SEND | 12-24 Months |
| Hosting and socialising open-source software projects related to implementation of virtual control groups | 12-18 Months |

CURRENT STATUS **Q2 2024**

- Actively developing best practices for representation of VCG data by testing out various practices via generation of mock SEND datasets implementing different approaches.

**Resources**

Harmonization of SEND Implementation to Enable Historical Control Data Analysis