Nonclinical Topics

Working Group Scope

A collaboration working to improve nonclinical assessments and regulatory science by identifying key needs and challenges in the field and then establishing an innovative framework for addressing them in a collaborative manner through limited term projects.

Our focus is on using informatics approaches and standards for delivering ideas and solutions to nonclinical data challenges. Annually, at the Computational Sciences Symposium (CSS), we present our progress and achievements and develop new projects that further the value of nonclinical data.

Conformance with the tumor.xpt Specification

Nonclinical Study Data Reviewer's Guide

SEND Implementation User Group

SEND Industry Feedback Survey

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

Resources

Click here to search for all Nonclinical Topics deliverables, past projects are housed under the archived section.

For Reference

Nonclinical Scripts

Harmonization of SEND Implementation to Enable Historical Control Data Analysis

Current Projects

susan.dehaven@sanofi.com

Susan DeHaven is a veteran of SEND standard development and implementation. She and her global team manage administration of software applications used across multiple countries for data collection, analysis, visualization and reporting, along with the associated standards governance and data management for analysis and submission. Most recently, Susan and her team have implemented data systems with tools and repositories for transforming data from sources to SEND and SDTM. Susan is a co-Lead, with FDA partners, of the PhUSE Nonclinical Topics Working Group and the CDISC/FDA SEND for CBER Initiative and is a long time member of the CDISC SEND Core Team. She has represented her opinions about pharma industry perspectives on SEND in various conference panels and has been recognized with a Collaboration Award from FDA and a PhUSE /FDA Working Group Award for Achievement. Susan is based in Bridgewater, New Jersey, USA is an avid equestrian and foxhunter, and lives on a farm in Asbury, New Jersey.

kevin.snyder@fda.hhs.gov

Dr. Kevin Snyder manages data science and informatics initiatives to support the pharmacology /toxicology review staff in the Office of New Drugs in the Center for Drug Evaluation and Research at the US FDA. These initiatives include research efforts to develop methods to optimize the regulatory use of standardized electronic CDISC-SEND-formatted toxicology study data as well as the development of software solutions to improve the efficiency of research and review activities conducted by the pharmacology /toxicology review staff. Dr. Snyder also leads an agency-wide Data Science and Software Development working group that is focused on building out the internal infrastructure necessary to support the work of data scientists across the agency and is an active collaborator with several consortia efforts, e.g. CDISC, PHUSE, and BioCelerate, to improve the implementation and use of the SEND data standard. Dr. Snyder received his Bachelors in biochemistry from the University of Maryland in 2008 and his PhD in neuroscience from the University of Pennsylvania School of Medicine in 2013.

michael.denieu@cov

Michael is a member of Global Da
Solutions at Covance, joining the
data associate generating and QC
packages, moving to a supervisor
his role has been on the quality of
initiatives to provide enhancemen
capabilities, as well as working wi
their needs and expectations are
volunteer with CDISC and an acti
domain sub-team. Michael's origi
evolutionary biology and quantitat
programming and statistical skills
during his graduate work and pos
contributed to develop an interest
use of data which led Michael to L