The Nonclinical Topics WG

Our mission:

We strive to improve nonclinical assessment, translational science approaches and regulatory science through nonclinical data management topics.

Who we are:

We are an innovative working group providing a framework for collaboratively addressing key needs and challenges in the field.

Delivering since the 2016 CSS…

Nonclinical Study Data Reviewer's Guide Project

nSDRG Template Package published
FDA Intent to Use FR Notice completed
click here for templates

SEND Implementation User Group

Active knowledge base on SEND implementation > 95K views on the WIKI homepage! click here for site

Investigating Endpoint Modeling Project

White Paper: Nonclinical Biomarker [Data] Modeling
(click here for paper)

Visualization of Group Related Differences in Histopathology Data

Journal Article: "Graphical display of histopathology data from toxicology studies for drug discovery and development: an industry survey" (click to article)

Computational Science Working Groups

phuse

Delivering since the 2016 CSS…

Industry SEND Readiness Survey *2nd Annual Survey is out now: Deadline Feb 10th (click here for survey)*	**Nonclinical Script Assessment Project** *Exploring development of analysis scripts based on SEND data* *TS domain creator script to satisfy FDA Technical Rejection Criteria (click here)*
Test Submission Forum Group *Surveyed Industry for barriers to testing nonclinical submissions with FDA* *Partnered with FDA Fit for Use Pilot*	**Data Consistency: SEND Datasets and the Study Report** *Identified potential differences and will provide recommendations*
SEND Data for Analysis *Project on hold because a BABY was delivered ☺*	

Computational Science Working Groups

phuse

Engage with us at CSS!

Day 1: Standardized Data Learnings & Opportunities for Scientists

- **SEND Test Submission Industry Panel: "Lessons Learned"**
  - **Industry Feedback on Fit for Use Pilot**
  - **Final Study Report vs SEND: data consistency facts and recommendations**
- **Data Visualization & Scripts Discussion Forum**
  - **How to functionalize recommendations of histo visualization, SEND for Analysis and FDA's Kick-Start)**
  - **Leveraging IMI eTox data with SEND**
  - **Opportunities with different tools**

Computational Science Working Groups

phuse

Engage with us at CSS!

Day 2: Sharing SEND Experiences – No silos here!

- CDISC & PhUSE Collaborative : modeling and implementation challenges
  - SEND model limits, SEND example factory
  - New PC & MI efforts to improve domain use
- SEND Readiness Survey 2017 Results!
- International Session Planned (To be confirmed)
  - Looking for international perspectives on the FDA requirement for nonclinical data and the expectations regarding other regulatory agencies
- Project Pulse Check and Prioritization of new project ideas

Computational Science Working Groups

phuse

How to get involved

- Contact the Working Group Co-leads
  - Sue DeHaven susan.dehaven@sanofi.com
  - Patty Brundage patricia.brundage@fda.hhs.gov
  - Bob Dorsam robert.dorsam@fda.hhs.gov

- Visit *Nonclinical Topics Working Group* WIKI Site:
  - http://www.phusewiki.org/wiki/index.php?title=Nonclinical_Topics_Working_Group
  - Project co-leads and contacts are listed with each project

- And of course, register for the CSS in March!

Thank you!

The premier community for people working in the biometric area

phuse.eu
@PhUSETwitta
/PhUSE
phusewiki.org