Nonclinical Topics Archive



Completed Projects	Deliverable	Project Page
SEND Dataset QC Best Practices	White Paper & CSS 22 Poster	SEND Dataset QC Best Practices
Roadmap	Accomplishments	Nonclinical Standardization Roadmap Team
Define.xml Code List Handling	SEND FAQ - DEFINE.XML section	Demystifying Define.xml Codelists for Nonclinical Studies
Clinical Endpoint predictivity	Activities completed	NICE: Nonclinical data Interconnectivity for Clinical Endpoint predictivity
Historical Controls	Completed tasks	Nonclinical Historical Controls
Histopathology Visualization	Deliverables	Visualization of Group Related Differences in Histopatholgy Data
Interorganizational SEND	Accomplishments	Interorganizational SEND
Industry Discussion	See project page for comments accumulated	Nonclinical Working Group Industry Discussion Group
Emerging Technologies	IG search tool (to add link)	Emerging Technologies Collaboration
Test Submission Forum	See page for discussion	Test Submission Forum Group
Biomarkers	Poster and White Paper	Investigating Endpoint Modeling - Biomarkers
SEND Data for Analysis	Annotated examples	Application of SEND Data for Analysis
Data Visualization	CSS 2019 Poster	Data Visualisation as an Enabler for Nonclinical Safety Signal Detection
Data Consistency	White Paper	Data Consistency: SEND Datasets and Study Report
Testing Simplified TS Examples Against FDA Technical Rejection Criteria	Presentation and eCTD Sequence submitted to the FDA	Testing Simplified TS Examples Against FDA Technical Rejection Criteria

Resources

2022
Recommendations for SEND Dataset QC Best Practices SEND Dataset QC Best Practices – Common explanations for FDA / CDISC validation issues

2019
Nonclinical SEND Implementation Survey 2019 Five Perspectives on SEND Implementation Challenges 2019 Cross-Study Analysis Workshop - BioCelerate and FDA

2016

- The SEND Implementation Wiki- Crowd-sourced Practical SEND Information
- Investigating Endpoint Modeling for SEND Datasets
- The Nonclinical SDRG *Winner: FDA/PHUSE Collaboration Award!*
- Graphical Display of Histopathology Data from Toxicology Studies: An Industry Survey
- FDA SEND Submissions: Does the Pinnacle 21 Open-source Community Validator Predict FDA Findings?

Click here for all posters and presentations displayed at the 2016 CSS in Silver Spring

2015

- Template and User Guide for the Nonclinical Study Data Reviewer's Guide (SDRG)
- Mapping Micronucleus, Motor Activity and Ocular Irritation Study Data in SDTM Using the Nonclinical Custom Domain Resource
- SEND data from Small/Medium Service Providers: How prepared are they to supply data in SEND format?
- Template to Facilitate Creating Pharmacokinetic SEND datasets
- SEND Implementation Guide Search Tool
- Adding In Vivo Mammalian Cytogenetics Data to SEND and ToxML

Click here for all posters and presentations displayed at the 2015 CSS in Silver Spring

2014

- Steps in the generation of SEND datasets between multiple organisations
- Application of a Quality System to the Generation and Submission of SEND Files
- Selecting a CRO for Creating and Integrating SEND Datasets from Multiple organisations
- Recommendations on Use of the Clinical SDRG Model for Nonclinical Data Submission
- How to Design a Custom SDTM Domain for Nonclinical Data
- Community opinions on the the Collection and Use of Historical Control Data in Nonclinical Toxicity Studies
- Communication: So, we have a new standard; now what?

Click here for all posters and presentations displayed at the 2014 CSS in Silver Spring