



Nonclinical Topics Working Group 2019 Computational Sciences Symposium

Get ready to take the most of all the opportunities!

Dear Colleagues and Friends,

We are really looking forward to the CSS this year, and hope you can join us! We have a robust [Nonclinical Topics Breakout Session Plan](#) that will surely build knowledge and develop actions important to everyone collecting, analyzing, visualizing and submitting nonclinical data for drug development. And as always, the FDA and PhUSE have developed an agenda of plenary sessions with strong FDA participation and exchange.

Before the Symposium this year, we have prepared a list of pre-work activities that will ensure you are ready to bring your valuable contributions to, and get valuable ideas and information from, all the opportunities at this year's event. Your time is valuable and these pre-works will boost the value for you, the FDA, Industry Colleagues and PhUSE Projects!

Preparing for the Nonclinical Topics Working Group CSS Activities:

- 1. Get informed on the Working Group projects**
 - Review the [Nonclinical Topics Working Group 2019 Project Status \(stored on our WIKI\)](#), for up to date knowledge our projects' accomplishments and ambitions.
- 2. Get ready to contribute to Breakouts 1& 2:**
 - Gather a list of your company's current a) DATA ISSUES and b) CHALLENGES for SEND Implementation and bring them to PhUSE for help during Sessions 1& 2!
- 3. Get ready to contribute to Breakout 3:**
 - Listen to the Biocelerate Webinar Recording: [Leveraging CDISC SEND Data Sets for Study Analyses 05March2019](#)
 - Check-in with your company's Toxicologists and/or Nonclinical Project Representatives for their input on cross-study analysis priorities and bring their feedback with you.
- 4. Learning Opportunity:**
 - The "Going Translational with Linked Data" project (from Emerging Trends and Technologies) has invited interested Nonclinical working group members to "audit" (hands-on spots are filled) the Sunday evening workshop: [Let's Make a Knowledge Graph! An Interactive Hands-on Workshop](#)

Any questions? Contact the Nonclinical Working Group Co-Leads:

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BREAKOUT PLAN

MONDAY	TUESDAY
<p>INTRODUCTORY SESSION 11:00am - 12:00pm</p> <p>Opening Remarks – Co-Leads</p> <p>Keynote Speaker – Dr. Lilliam Rosario, Director, Office of Computational Sciences, FDA</p>	
<p>BREAKOUT 1: 1:00pm - 2:30pm <i>SEND Implementation Status and Data Issues</i></p> <ul style="list-style-type: none"> • 2019 Survey Presentation (Survey Group) (30 min) • Nonclinical Data Issues: Modeling or Implementation ? (60 min) <ul style="list-style-type: none"> • Kick-Start Issue examples <ul style="list-style-type: none"> • Paired tissues • Tissue designation in MA, OM, MI domains vs. study protocol required per exam – subtle differences • Other Examples? 	<p>BREAKOUT 3: 8:30am - 10:00am <i>Applying SEND to Cross Study Analysis</i></p> <p><i>Workshop to align on top priority cross-study analysis use cases and questions important to each of them. Determine next steps to collaborate on addressing priority questions</i></p> <ul style="list-style-type: none"> • Intro & Background: Rationale for Addressing the SEND/Cross-Study Analysis Opportunity • Presentation (BioCelerate): Variability Assessment & Input on Cross-Study Analysis Uses • Presentation (FDA): Reviewer Objectives & Priorities for Cross-Study Analysis • Working Session (All): Review & Align on Priority Cross-Study Analysis Question List • Summary & Next Steps (All): Discuss Concrete Project Opportunity
<p>BREAKOUT 2: 3:00pm - 4:30pm <i>Evolution of SEND Implementation Challenges and Managing Them</i></p> <ul style="list-style-type: none"> • Breakout by group: Consultants, Pharma, CRO, Software Vendors, Regulatory (30 min – breakout, followed by report out, 10 min/group.) • Each team to evaluate: <ul style="list-style-type: none"> • Status of Challenge List from Last Year <ul style="list-style-type: none"> • Assessment if still a challenge? If not, how were they solved? • Any new challenges • Top challenge for PhUSE project consideration 	<p>BREAKOUT 4: 10:30am – 12:00 <i>Working Group Project Management - Project Development & Team Time</i></p> <ul style="list-style-type: none"> • Current project status assessment • Working group consideration of new projects <ul style="list-style-type: none"> • Prioritization and resource planning • Team Time <ul style="list-style-type: none"> • Ongoing project team time • New project development time

[Back to top](#)

