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.

phuse.eu/cs-working-groups.aspx
Delivering since the 2016 CSS...

<table>
<thead>
<tr>
<th>Nonclinical Study Data Reviewer’s Guide Project</th>
<th>SEND Implementation User Group</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>nSDRG Template Package published</em></td>
<td><em>Active knowledge base on SEND implementation</em></td>
</tr>
<tr>
<td><em>FDA Intent to Use FR Notice completed</em></td>
<td><em>&gt; 95K views on the WIKI homepage!</em></td>
</tr>
<tr>
<td><a href="#">click here for templates</a></td>
<td><a href="#">click here for site</a></td>
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</tbody>
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<tr>
<th>Investigating Endpoint Modeling Project</th>
<th>Visualization of Group Related Differences in Histopathology Data</th>
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<tr>
<td><em>White Paper: Nonclinical Biomarker [Data] Modeling</em></td>
<td></td>
</tr>
<tr>
<td><a href="#">click here for paper</a></td>
<td><em><a href="#">Journal Article: &quot;Graphical display of histopathology data from toxicology studies for drug discovery and development: an industry survey&quot;</a></em></td>
</tr>
</tbody>
</table>

**Computational Science Working Groups**

**phuse**
## Delivering since the 2016 CSS...

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<tr>
<th>Industry SEND Readiness Survey</th>
<th>Nonclinical Script Assessment Project</th>
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<td>2nd Annual Survey is out now: Deadline Feb 10th (<a href="#">click here for survey</a>)</td>
<td>Exploring development of analysis scripts based on SEND data TSDomain creator script to satisfy FDA Technical Rejection Criteria (<a href="#">click here</a>)</td>
</tr>
<tr>
<td>Test Submission Forum Group</td>
<td>Data Consistency: SEND Datasets and the Study Report</td>
</tr>
<tr>
<td>Surveyed Industry for barriers to testing nonclinical submissions with FDA Partnered with FDA Fit for Use Pilot</td>
<td>Identified potential differences and will provide recommendations</td>
</tr>
</tbody>
</table>

### SEND Data for Analysis

*Project on hold because a BABY was delivered 😊*
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
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
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:
    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

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