BioCelerate Newsletter

November 2021

This edition of the BioCelerate newsletter includes updates on our initiatives and upcoming events.

Latest Updates:

Common Templates for Nonclinical Studies

The **Common Templates for Nonclinical Studies Initiative** team successfully completed its internal pilot with voluntary participation from all BioCelerate companies. The objective of the pilot was to assess the value and functionality of BioCelerate's Templates by comparing them to templates used by the participating companies. Feedback from this experience will help to identify points of variation that may limit the use of the BioCelerate templates and help to inform the next version of the templates.

Upcoming events: A summary of the results from BioCelerate's Nonclinical Common Protocol Template (NCPT) and Nonclinical Common Report Template (NCRT) experience pilot will be shared at the upcoming **American College of Toxicology Annual Meeting**, from November 10-19.

Check out the ePoster at the virtual poster session on Monday, November 15th from 3:30–5:30 PM EDT

- Supporting Efficiencies in Nonclinical Toxicology Studies Through Protocol and Report Templates: Progress Towards Adoption

Upcoming Events:

VIRTUAL MEETING

American College of Toxicology Annual Meeting

November 10-19, 2021

BioCelerate's Nonclinical Common Templates and SEND Harmonization for Cross-Study Analysis Collaboration team will be presenting both in a workshop session and through posters.

Top Posts:

LinkedIn: We've got some exciting news and updates coming from our BioCelerate Initiatives. Make sure you're signed up to receive our communications about BioCelerate by clicking **here**.

Twitter: Today was the **@PHUSEtwitta** Computational Science Symposium featuring the BioCelerate's SEND initiative team's work through its PPP with the FDA. Learn more **here**.

Stay up to Date!

Contact us | Visit us | Follow us | Reach us

Latest Updates:

SEND Implementation for Cross-Study Analysis

New White Paper: "Recommendations for Populating Control Type (TCNTRL) with CDISC SEND Controlled Terminology" was published on the PHUSE website. The purpose of the white paper is to propose harmonization for TCNTRL terms and definitions to enable cross-study historical background control analyses of SEND data. This is the first of four white papers that are slated to be drafted from the collaboration established between BioCelerate and PHUSE, a global healthcare data science community.

Recent virtual conference sessions: The BioCelerate-PHUSE collaboration team, Harmonization of SEND Implementation to Enable Historical Control Data Analysis Status, presented at both the PHUSE US CONNECT 2021 and PHUSE/FDA Computational Science Symposium (CSS) 2021 meetings. These interactive meetings shared 2021 project highlights and at PHUSE CSS included robust discussion on future nonclinical harmonization opportunities within the Pharmacokinetic Concentrations (PC) and Pharmacological Class (PCLASS) Domains and with dose-level to better facilitate cross-study analysis. The team also shared work in progress on search scripts that can query and collate information from SEND datasets to be used in cross-study analysis. The outcome of this work will be published as an R package to be released in early 2022.

Upcoming events: The SEND Harmonization for Cross-Study Analysis collaboration team will be hosting a workshop and presenting posters at the upcoming American College of Toxicology Annual Meeting, from November 10-19:

Attend the workshop on Monday, November 15 from 12:00 PM–3:30 PM EDT
Collaboratively Cracking the SEND Code: Unlocking the Potential Value of Standardized Toxicology Study Data

Session Chairs: Kevin Snyder, US FDA, CDER; and Mark Carfagna, Eli Lilly and Company

Presenters: Kevin Snyder, US FDA, CDER; and Mark Carfagna, Eli Lilly and Company; William Houser, Bristol Myers Squibb; Md Yousuf Ali, US FDA CDER; Philip Drew, PDS Consultants

Check out their ePosters on Monday, November 15th from 3:30–5:30 PM EDT

- SEND Data Analyses to Enable the Comparison of Multiple Studies
- Harmonization of SEND Implementation to Enable Historical Control Data Analysis: Recommendations for Exchanging Vehicle Details Using SENDIG v3.1.
- Cross-Study Analysis of SEND Datasets Using an R Package: sendigR