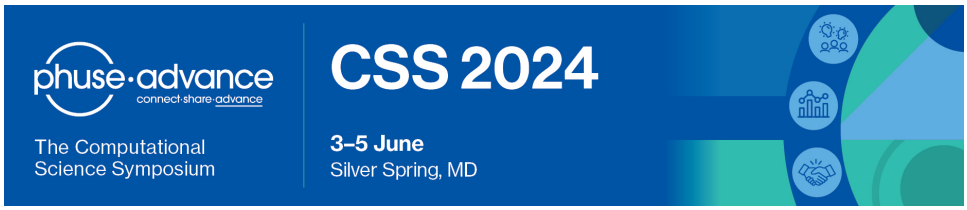
Hot Topics

Working Groups Hot Topics

PHUSE collaborations are organised into a number of specialist Working Groups, each with a broad topic area. The Working Groups have specific projects designed to achieve a set of particular objectives. This page will highlight the latest news and information from our projects. Participation is open to anyone who wants to contribute and if you would like to get involved, please email workinggroups@phuse.global.

PHUSE/FDA CSS 2024



Registration for the PHUSE/FDA CSS 2024 is open!

Come and be a part of the PHUSE/FDA Computational Science Symposium 2024 (CSS) taking place **3–5 June** in Silver Spring, MD. Share your insights, discoveries and solutions with the PHUSE Community, who are eager to learn and collaborate.

REGISTER HERE

Community Forums

The Open Source Technology in Clinical Data Analytics (OSTCDA) will be hosting an Open Forum 'Open Forum: Open Source – Solutions of the People, by the People, for the People' on **26 April 15:00 – 16:00 (BST) 10:00 – 11:00 (EDT)**. Michael Rimler, *PHUSE Open Source Technologies Director,* will be moderating this forum and will address the following questions:

- How do we transform the traditional Statistical Analyst in Pharma into the future Data Scientist?
- How do we support users in managing an ever-evolving environment of open-source packages?

REGISTER HERE

Calling For Feedback

The Good Transparency Practices project within the Data Transparency Working Group, is now calling for feedback! This White Paper aims to define a set of best practices for data transparency and create a Good Transparency Practices guidance. The best practices will aim to ensure anonymised data is compliant with the legal requirements as defined by Regulators, as well as preserves as much data utility as possible.

- Good Transparency Practice
- Appendix 1. Best Formatting Practices
- Appendix 2 Examples of Structured IPD Anonymisation_Public Review
- Appendix 3. Examples of Unstructured IPD Anonymisation

Please send in your comments to workinggroups@phuse.global by **3 May.**

New Deliverables

The Best Data Practices for Rare Disease Patient Foundations and Researchers within the Real World Evidence Working Group, has published a new deliverable in the form of a poster. The poster provides an overview of Ensuring Registry Data Relevance and Reliability for Regulatory Use.

The PHUSE data standards community, which is comprised of leaders and experts responsible for the governance and implementation of data standards across the biopharmaceutical industry, have authored and new White Paper. The Data Standards White Paper highlights current challenges in data standardisation across the biopharma industry and identify opportunities where we can work together to tackle them.

The SDTM ADaM Implementation FAQ within Optimizing the Use of Data Standards Working Group have published a new FAQ! The question they have answered is '**Naming Convention for Split RS Domain',** you can view this question and the teams response via Validation/Conformance Rules page. You can see all the FAQ this project has answered so far via here.

Do you have a SDTM ADaM question? You can send your questions to the team by emailing workinggroups@phuse.global.

Volunteer Opportunities

The Data Visualisation & Open Source Technology Working Group has a new project, Demonstrating Real-World Impact of Modernization of Statistical Analytics (MSA) Framework. This project aims to extend the MSA framework by creating a reference architecture that takes into account real-world scenarios and design solutions to remediate them, ultimately providing a practical guide to building an end-to-end validated environment for regulated work. Companies seeking to build an open-source programming environment for regulatory reporting can leverage the MSA framework for guidance. However, since the framework is designed to be both flexible and extensible, implementing it may prove challenging for companies, resulting in situations where risks are not sufficiently mitigated. While the original MSA paper provided conceptual guidance, the PHUSE handover of the project will seek to provide an overview of practical implementations of the framework being applied.

This project is calling for volunteers, to join contact workinggroups@phuse.global by **26 April**.

The Safety Analytics Working Group is looking for a new Working Group Lead to join their team. This Working Group is a cross-disciplinary collaboration working to improve the content and implementation of clinical trial safety analyses for medical research, leading to better data interpretations and increased efficiency in the clinical drug development and review processes.

Click here to see a list of current projects within this Working Group.

Learn more about the roles and the responsibilities of a Working Group Lead and apply by emailing workinggroups@phuse.global. Closing date **26 April.**

Multiple projects within Working Groups are open to join. PHUSE welcomes new members who can apply their knowledge to bring fresh ideas and contribute to the ongoing work of PHUSE projects. For more information, click here, read the Welcome Pack or email workinggroups@phuse.global.

PHUSE Communications

Working Groups Report: Includes project updates, recent and upcoming deliverables and future plans for each Working Group.

Monthly Mailings: The monthly newsletter. Here you will find a full update from each month of the year, easily accessible and divided into key areas of PHUSE.

PHUSE Blogs: Fancy a quick read? A blog is a perfect way to catch up on all things Working Groups. Get the lowdown on the latest events from across the globe and stay updated on industry topics brought to you by industry professionals.

New Project Idea?

Initiate and lead a new project under the PHUSE Working Groups umbrella. The new project must address problems of significant relevance to computational science related to drug, biological and device development and must meet all of the guidelines for projects within the collaboration, including the following mandatory requirements:

- The projects must address significant research issues relevant to Computational Science
- The project must not attempt to address FDA policy issues
- There must be at least one Project Lead personally involved in planning and carrying out the project

New projects can be submitted anytime during the year, click here to submit.