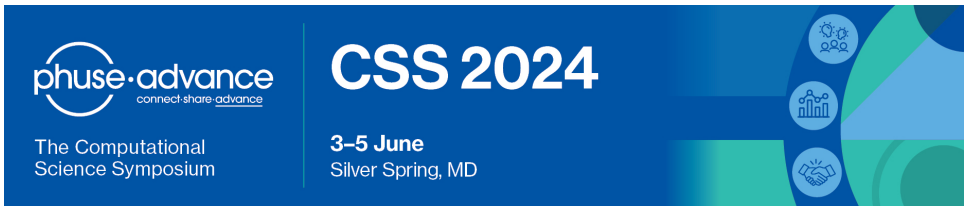
Hot Topics

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

Data Transparency Autumn Event 2024

Call for speakers is now open for the Data Transparency Autumn Event. Don't miss out on the opportunity to contribute your expertise, innovations, and research by submitting your **150-word abstract** before **14 June.**

Need guidance? Explore the curated topics below from PHUSE's Data Transparency Leads to spark inspiration for your standout abstract.

- Data Anonymisation Techniques and Experiences
- Risk Quantification
- Data Sharing Initiatives and Processes
- Registries and Results Reporting
- Synthetic Data
- Data Transparency Regulatory Submissions
- Plain Language Summaries (PLSs) and Plain Language Summaries of Publications (PLSPs)
- EU CTR

SUBMIT HERE

Open Forum: Open Source in Pharma, Regulatory Acceptance and Validation

The Open Source Technology in Clinical Data Analytics (OSTCDA) project is hosting an Open Forum on the topic of Open Source in Pharma, Regulatory Acceptance and Validation with speaker Mike Smith. This forum will be taking place on zoom on 14 June **15:00-16:00 BST / 10:00-11:00 EDT.**

REGISTER HERE

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.

The Quality Tolerance Limits project within the Risk Based Quality Management Working Group have published a new deliverable. The White Paper is on the topic of Assessing the Use of Quality Tolerance Limits in the Pharmaceutical Industry. This White Paper aims to provide the reader with valuable insights into the depth and breadth of the use of QTLs and addressing how QTLs are used in a wider scope of implementing RBQM.

Calling for Feedback

The Treatment Emergent Definitions Recommendations project within Safety Analytics Working Group has produced a White Paper '*Recommended Definition of Treatment-Emergent Adverse Events in Clinical Trials* '. This document defines treatment-emergent events in Phase 1 to 4 clinical trials and integrated summary documents across therapeutic areas. The recommendations described herein were based on the authors' collective experiences and a survey conducted by the PHUSE Treatment-Emergent Definition Recommendations project team [2] to solicit input from respondents on various TEAE scenarios for a simple clinical study design.

Please provide your comments by emailing workinggroups@phuse.global. Closing date for comments: **7 June**

Volunteer Opportunities

The Estimands for RWD/RWE, a new project within Real World Evidence Working Group is now calling for volunteers. The focus of this project is on best practices of RWD Estimands, not on their implementation using data standards. The team formed will have representation from the PHUSE Implementation of Estimands (ICH E9 (R1)) using Data Standards project team, which has a White Paper nearing publication and the Estimands Implementation Working Group (EIWG) sub team on HTA and RWE. Both with Estimands expertise, along with representation from teams under the RWE Working Group.

If you would like to volunteer or learn more about this project, email workinggroups@phuse.global. Closing date: **14 June**

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.

Announcement

The Optimizing the Use of Data Standards Working Group are pleased to welcome to two New Leads to the team! The two new leads are Sandra VanPelt Nguyen and Edwin Van Stein.

Sandra has been involved with PHUSE since 2015, leading and supporting PHUSE projects under the Optimizing the Use of Data Standards and Real World Evidence Working Groups and Edwin is an active PHUSE member, contributing to the PHUSE EU Connect as a presenter, Stream Chair and Connect Chair, and as a PHUSE Wiki Administrator. He is currently a permanent member of the EU and US Connect Planning Committee and a Working Group Lead.

They will be joining the Current Leads Jane and Owns and Janet Low, you can learn more about the new leads via the Optimizing the Use of Data Standards page.

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.