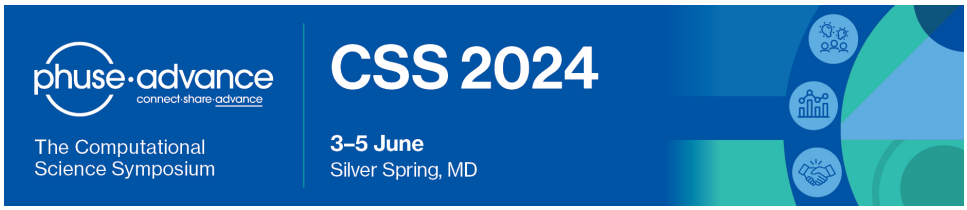
Hot Topics

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

Open Source – Open Source in Pharma, Regulatory Acceptance and Validation

Registration for the Open Source Open Forum is open!

The Open Source Technology in Clinical Data Analysis (OSTCDA) project is hosting their third Open Forum: Open Source in Pharma, Regulatory Acceptance and Validation, they will be addressing the following questions:

- How do you establish reproducibility and traceability with open-source solutions, e.g. R package management?
- How do you document your trust in an open-source solution to satisfy a third-party inquiry?

Come and be a part of the our next virtual Open Forum on **14 June at 15:00 (BST) / 10:00 (EDT)**.

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

New Deliverables

The Quality and Reusability of Real World Data project within Real World Evidence, has just published a new Blog Post, 'Understanding the Data Quality Issues in Real World Data through Real World Examples'. This blog takes a closer look at the experiences shared within the dedicated Working Group in exploring the types of data quality hurdles encountered when using RWD.

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 Educate the General Population on Data Privacy and Data Sharing project, within the Data Transparency Working Group has published video 2 of their series. The 'What Will I Receive and When Will I Receive It?' video covers topics such as the concept of consent to participate in a clinical trial, an overview of trial design and treatment procedures to develop a strong foundational understanding of clinical trials. To view the full series of videos created by this team, visit the PHUSE website.

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 Safety Analytics Working Group are pleased to welcome two new Leads to the team! The new leads are Mac Gordon and Ellis F Unger.

Mac Gordon has a master's in statistics and graduate certificates in public health, pharmacovigilance and pharmacoepidemiology and has been with Johnson and Johnson for 15 years and in industry for 20 years.

Ellis is a board-certified cardiologist, who retired from the US Food and Drug Administration following a 24-year career, where he served in senior leadership roles in the Office of New Drugs, Center for Drug Evaluation and Research (CDER).

They will be joining the current Leads Mary Nilsson, Greg Ball and Scott Proestel, you can learn more about the new leads via the Safety Analytics p age.

The Optimizing the Use of Data Standards Working Group are pleased to welcome two New Leads to the team! The 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 Owens 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.