

PHUSE Working Groups 2025 Highlights

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PHUSE Working Groups bring together volunteers from diverse stakeholders to collaborate on projects addressing key topics in data science and clinical research, with participation open to all.

Data Transparency

This Working Group is dedicated to developing best practices and standards for data sharing, ensuring that information is accessible while protecting personal privacy and maintaining data integrity.

Nonclinical Topics

This Working Group aims to improve nonclinical assessments and regulatory science by addressing key needs and challenges. They use informatics approaches and standards for delivering ideas and solutions to nonclinical data challenges.

Real World Evidence

This Working Group's focus is to align best industry practices, through the understanding of requirements, technologies, and processes needed for data analysis, the incorporation into clinical trials and regulatory submissions.

Data Visualisation & Open Source Technology

This Working Group explores data visualisation and open source technology, addressing key questions in these areas. It highlights the natural synergy between the two, leveraging powerful tools available in today's open source languages.

Optimizing the Use of Data Standards

This Working Group focuses on enhancing data standards in clinical research. By promoting best practices and providing guidance, they improve quality, interoperability, and compliance while addressing gaps and challenges in their use.

Risk Based Quality Management

This Working Group identifies innovative approaches in the planning, conduct, and continuous improvement elements of risk based quality management that support proactive management data reliability and participant well-being.

Emerging Trends & Innovation

This Working Group identifies and evaluates trends, tools and methodologies to transform the industry, fostering knowledge sharing and driving adoption to enhance data science, analytics and regulatory processes.

pharmaverse

This Working Group is a network of companies and individuals promoting collaborative development of open source R packages for clinical reporting, aiming to ease regulatory review and expedite new treatments.

Safety Analytics

This Working Group aims to enhance 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.

Deliverables

10 DELIVERABLES PUBLISHED

Data Transparency

PHUSE Good Transparency Practice
Rare Disease Clinical Data Sharing
Participant Data Return Survey Results
Summary of the PHUSE Data Transparency Working Group's Feedback Submitted Online Via Prototype
Feedback on the MHRA Clinical Trials Regulation Guidance

Optimizing the Use of Data Standards

Implementation of Estimands (ICH E9 (R1)) using Data Standards
Dataset-JSON as Alternative Transport Format for Regulatory Submissions
SDTM ADaM FAQ

Safety Analytics

Recommendations for Analyses and Displays Associated with Hepatotoxicity with a Focus on Phase 2-4 Clinical Trials and Integrated Submission Documents Stage 1: Initial Assessment and Screening for Potential for Hepatotoxicity

Emerging Trends & Innovation

Cloud Services: A Framework for Adoption in the Regulated Life Sciences Industry

Projects

Data Transparency

Anonymization of Imaging Data

Educate the General Population on Data Privacy & Data Sharing

EU CTR Implementation

Participant Data Return

The Value of Plain Language Summaries of Trial Results

Data Visualisation & Open Source Technology

Clinical Visual Analytics for Review and Submission (CVARS)

Communication of Version Metadata for Open-Source Languages

Comparing Analysis Method Implementations in Software (CAMIS)

Demonstrating Real-World Impact of Modernization of Statistical Analytics (MSA) Framework

PharmaForest: Collaborative Repository of SAS Packages for Pharmaceutical Industry

Emerging Trends & Innovation

Cloud Adoption in the Life Science Industry

Digital Health Technologies (DHTs)

Integration of Omics Data into Clinical Drug Development

Investigating the Use of FHIR in Clinical Research

KPIs & Metrics Project – Relaunch

Nonclinical Topics

Conformance with the tumor.xpt Specification

Developing Predictive Models to Facilitate Interpretation of Toxicology Study Results

Nonclinical Study Data Reviewer's Guide

SEND Coding Bootcamp

SEND Industry Feedback Survey

Optimizing the Use of Data Standards

Bioresearch Monitoring (BIMO) Frequently Asked Questions Forum

Building a Better MDR

Clinical Integrated Study Data & Analysis Data Reviewer's Guide

Electronic Data Submission in Japan

Management of ODS Regulatory Referenced Deliverables

Real World Evidence

Applying Advanced Data Privacy Methods to Real World Data (RWD)

Estimands for RWD/RWE

Missing Data Imputation in RWD Exploration of Multiple Techniques on Open-Source Data

RWD Guideline for Programming and Analysis Processes

Submitting Real World Data

Risk Based Quality Management

End to End RBQM Education

Enhanced Risk-based Quality Management (RBQM) Approaches for First-in-Human and/or Small Clinical Trials

Enhancing the Clinical Trial Risk Assessment Process

OpenRBQM: Pre-Competitive Collaboration on Open-Source Software for RBQM

Quality Tolerance Limits – Threshold Setting Methodologies

Safety Analytics

Analyses & Displays for Hepatotoxicity

Engaging ICH on TEAE Definition Recommendations

Estimands in Safety Analytics

Interactive Analyses and Displays for Laboratory Data

Process for Aggregate Assessment of Clinical Trial AE Data

pharmaverse

pharmaverse officially became a PHUSE Working Group in 2025.

Safety Analytics Education

The Use Of Git in Statistical Programming

Supporting the Use of SEND for the Implementation of Virtual Control Groups

SDTM ADaM FAQ Implementation

Quality and Reusability of Real World Data

Using OMOP and Other Real World Data Standards to Support Regulatory Submissions

Events

15 WORKING GROUP EVENTS

2924 TOTAL ATTENDEES

Data Transparency

Data Transparency Winter Event 2025

Data Transparency Autumn Event 2025

Data Visualisation & Open Source Technology

Exploring the Synergy of Generative AI and the Teal Framework in Pharma

Emerging Trends & Innovation

Responsible AI in a Healthcare System

AI and SaMD in Healthcare: From Compliance to Patient-Centred Innovation

Real World Evidence

RWD for Regulatory Decision-Making: Learnings from Use Cases and Demonstration Projects

Real World Data Spring Event

An Introduction to the Estimands and Target Trial Emulation (TTE) Frameworks

Estimands in Real-World Evidence Studies

OMOP – A Common Data Model Enabling the Analysis of RWD

Getting the RWD We Need – From Both Sponsor and Regulator Perspectives

Risk Based Quality Management

Make the Most Out of Innovation and Ensure It's Done Right!

Revolutionising Participant Safety Monitoring with Advanced Solutions

Value-Driven Clinical Data Review, Together

Safety Analytics

Hepatotoxicity and Adverse Event Groupings

Find Out More & Get Involved

Advance Hub

Get Involved

Deliverables

2026 Events

Q4 Report

Key Highlight

EU Computational Science Symposium (CSS)