



CSS 2024

The Computational Science Symposium

3-5 June
Silver Spring, MD



phuse.global



Plenary Overview

The Future of Enabling Health Authority Access to Information

- **Welcome**
Lilliam Rosario, *FDA & CSS Chair*
- **10 Years of the Data Transparency Working Group**
- **Dataset-JSON as Alternative Transport Format for Regulatory Submissions**
Sam Hume, *CDISC*, Jesse Anderson, *FDA* & Stuart Malcolm, *PHUSE/Veramed*
- **PRISM**
Ginny Hussong, *FDA*
- **precisionFDA: Transforming the Future of Regulatory Science**
Elaine Johanson, *FDA*
- **Awards**
Chris Price, *Roche & CSS Chair*

2014 – The Inception

The Working Group is founded! The first meeting is held during PHUSE's 10th EU Connect in London.

2015

The PHUSE Data De-Identification Standard is released.

2016

The EMA participates in the PHUSE EU CSS in Basel. The PHUSE Data De-Identification Standard is referenced in EMA Policy 0070 External Guidance.

2017

The EMA and Health Canada select representation from the PHUSE Working Group in the EMA TAG and HCRG PRCI, respectively.

2018

The PHUSE Data Transparency Working Group comments on the Health Canada PRCI Guidance.

2019

An FDA officer joins the PHUSE Data Transparency Working Group.

2020

The first Data Transparency Event takes place and receives a 98% attendee satisfaction rate! As well as this, the FDA, the EMA and Health Canada participate in the virtual CSS.

2021

The FDA refers in a press release to the Working Group for their efforts in developing anonymisation standards and best practices.

2022

The EMA and Health Canada participate in the Good Transparency Practices project.

2023

The PHUSE Data Transparency Working Group releases its first blog post on EUCR to help the Community prepare.

2024

The PHUSE Data Transparency Working Group contributes to the EMA's ACT EUCr Workshop.

Celebrating 10 Years of the Data Transparency Working Group

Working Group Leads



Jean-Marc Ferran
Qualiance



Stephen Bamford
Johnson & Johnson



Devaki Thavarajah
Independent



Muhammad Oneeb
Rehman Mian
Privacy Analytics

Reflecting on a decade of the PHUSE Data Transparency Working Group, it's evident that our journey has not just been about enhancing transparency but about pioneering a culture of openness and collaboration in clinical trials. This milestone marks a significant chapter in our commitment to innovation and ethical data sharing, which will continue to resonate across the industry.



Stephen Bamford, PHUSE Founder and Head of Clinical Data Standards & Transparency at Johnson & Johnson

What makes the PHUSE Data Transparency Working Group such a useful forum for our Community is the spirit of collaboration, mutual respect and the desire to share rather than hoard knowledge. It's a place where diverse voices, standards are agreed, and best practices are defined. Whether you're an expert or a novice, everyone can contribute and everyone can learn.



Lukasz Krol, Associate Director/
Data Transparency at Biogen

It has been an honour and a privilege to work with the PHUSE Data Transparency Working Group for nearly a decade, driving forward many cutting-edge projects and initiatives which have changed best practice within the pharmaceutical industry, academia and the wider clinical trial data community alike.



Sarah Nevitt, Senior Research Fellow at the University of York

PHUSE's Data Transparency Working Group has been pivotal in advancing the field of data transparency. While Co-Lead of this Working Group, I've witnessed the transformative impact of our collaborative efforts. Together, we've set new standards and fostered knowledge exchange across industry, academia and regulatory groups. We've established the widely successful virtual Data Transparency Events, which further help share knowledge and drive the field forward. Congratulations to all involved – this is a monumental achievement, and I can't wait to see what the group does next.



Sarah Bailey, Associate Director/
Strategic Operations at KJWA

The PHUSE Data Transparency Working Group is an invaluable forum for discussing regulatory initiatives and hearing the perspectives of regulators, clinical trial sponsors and privacy experts. It has been especially helpful in understanding the complexities of the EU Clinical Trials Regulation.



George Allan, Document Anonymisation Director at Johnson & Johnson

Together, our project teams is developing a super-engaging and creative set of collaborative solutions for our health data transparency initiatives. I look forward to each group meeting, and we are given maximum autonomy to bring our ideas to life, along with all the necessary backend support to succeed in our goals.



Devaki Thavarajah, Independent

There's been an amazing journey from developing the PHUSE Data De-Identification Standard back in 2014, to having it referenced in EMA Policy 0070 External Guidance and being adopted by all leading sponsors in the space to develop their anonymisation solutions. In where we are today with over 25 deliverables in the public domain providing full open access to experts to advance the field. We've always strived to provide practical guidance to help stakeholders safely share high-quality data, and the support we have received from the Community has been incredible.



Jean-Marc Ferran, Director, Qualiance

About

Since 2014, the Data Transparency Working Group, comprising data privacy experts, and members from pharmaceuticals, CROs, software, academia, and CDISC, has developed the PHUSE De-Identification Standard for SDTM. It now tackles EMA Policy 0070, creates data transparency roadmaps, and addresses GDPR aspects for clinical trials. The group regularly reviews draft deliverables from regulatory bodies such as the EMA and Health Canada, industry organisations such as TransCelerate, and academia such as Cochrane.

Current Projects

- Anonymization of Imaging Data
- Educate the General Population on Data Privacy and Data Sharing
- EUCR Implementation
- Good Transparency Practices
- Internal Clinical Study Data Sharing Process
- Rare Disease/Small Population Data Sharing

70+ members



2 virtual meetings per year



29 deliverables published



CSS Breakout Sessions with regulators



Data Transparency Events

Since the first Data Transparency Event in 2020, PHUSE has continued to strengthen its place as the world's largest home for data transparency events, by sharing vital knowledge of the field and creating a space where questions can be asked and challenges addressed.

These events look to meet the ongoing needs of data transparency within the clinical development arena and feature thought-provoking presentations, panel discussions and Q&A sessions from experts in the data sharing field.



PHUSE Working Groups

Data Transparency

Data Visualisation &
Open Source
Technology

Emerging Trends &
Technologies

Nonclinical Topics

Optimizing the Use
of Data Standards

Real World Evidence

Risk Based Quality
Management

Safety Analytics



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Let's welcome our new Working Group Leads!



Optimizing the Use of Data Standards

**Sandra (Sandy)
VanPelt Nguyen**



**Edwin van
Stein**





Safety Analytics

**Robert (Mac)
Gordon**



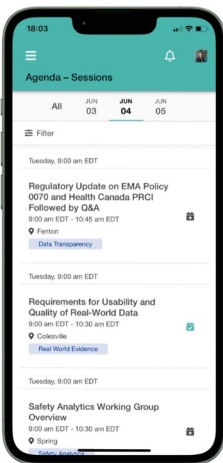
Ellis F Unger





NEW FOR 2024...

Enhance Your Event Experience with the PHUSE CSS App!



IOS



ANDROID

SUPPORTED BY:



Key App Features

- Network with fellow attendees
- Create a tailored agenda
- Take detailed session notes
- Stay updated with event notifications
- Explore contributor profiles
- Share your experience on the Activity Feed

Should you require technical support when using the App, please contact events@phuse.global or speak to a PHUSE Team member onsite.



Plane Builder Award Winners





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Working Groups

Data Transparency

Dan Bilodeau





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Working Groups

Data Visualisation & Open



Source Technology

Melvin Munsaka



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Working Groups

Emerging Trends & Technologies



Radha A Railka & Ying Su



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Working Groups

Nonclinical Topics

SEND Survey Project Team





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Working Groups

Optimizing the Use of Data Standards



Christine Rossin



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Working Groups

Real World Evidence



Dhruba Sikdar



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Working Groups

Risk Based Quality Management

Chris Wells & Mireille Lovejoy





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Working Groups

Safety Analytics



Aimee Basile



Time for a special
thank you...



Thank You

Jane Owens



- Working Group Lead for the Optimizing the Use of Data Standards Working Group for many years
- Contributor and driver of many projects in the Optimizing the Use of Data Standards Working Group
- Driver and major contributor to the regulatory referenced SDSP
- Instigator of the process for managing and maintaining PHUSE regulatory referenced deliverables



Thank You

Mary Nilsson



- Safety Analytics and previously Safety Analytics and Code Sharing Working Group Lead
- A Working Group Lead since the first CSS in 2012
- Contributor and driver of many Safety Analytics White Papers
- Driver and major contributor to the safety analytic content of PHUSE Education



Thank You

Stephen Wilson



- One of the initial “Instigators” for PHUSE partnering with FDA to run CSS
- A driving force behind and at the annual CSS
- Invaluable contributions to multiple working group projects
- His (many) references to "Building the plane while it is flying" inspired the naming of the "PHUSE Plane Builder Awards"



PHUSE Recognition





PHUSE Recognition

evolution of PHUSE for 20 years, from its inception up until his passing in September 2023. This is the highest award within PHUSE, the list of recipients also incorporates all those who previously were recognised as Lifetime Members.

Crystal Allard

Crystal has been an energetic liaison between PHUSE and the FDA. She has demonstrated her enthusiasm and passion for this collaboration in her promotion of PHUSE activities within the FDA, in her contributions to the annual CSS both as an organiser and a presenter, and in her contribution to individual Working Groups and projects. Crystal is a large part of the reason why the Working Groups continue to be successful in driving their mission forward.

**Stephen
Bamford**

Stephen is the co-founder of PHUSE. Since chairing the first two PHUSE Conferences, and delivering on his vision of a conference for statistical programmers, Stephen has continued to be the driving force on the Board, serving as both Chair of the Board and Events Director.

Chris has made significant contributions across PHUSE, most notably in his role in initiating the PHUSE CSS, where he served as the industry and FDA



PHUSE Recognition





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Wishing you all a **productive** and **fulfilling** CSS.
Let's make every moment count!