Data Transparency

Working Group Scope

Active since 2014 the Data Transparency Working Group is made up of more than 70 active members from pharmaceuticals, CRO's, software and academia, as well as CDISC and data privacy experts.

Team members have since collaborated on developing a data de-identification standard for SDTM (known as the 'PHUSE de-identification standard'). Since then, the Working Group has expanded to address EMA Policy 0070 matters, create a Data Transparency Roadmap across jurisdictions, and has started to address aspects of GDPR that are relevant for the conduct of clinical trials. The Data Transparency Working Group also reviews, on a regular basis, draft deliverables, or guidance documents from regulatory bodies (e.g. the EMA, Health Canada), as well as other industry organisations such as TransCelerate, and academia (e.g, Cochrane).

In addition to the projects PHUSE have 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. The events look to meet the ongoing needs of data transparency within the clinical development arena and features thought-provoking presentations, panel discussions and Q&A sessions from experts in the data sharing field.

Current Projects

Anonymization of Imaging Data

Educate the General Population on Data Privacy and Data Sharing

EU CTR Implementation

Good Transparency Practices

Internal Clinical Study Data Sharing Process

Rare Disease/Small Population Data Sharing

Resources

- Country-Specific Requirements for Clinical Trials Disclosure: Joint Effort by PHUSE and Xogene
- PHUSE Community Forum: Data Privacy and Data Sharing in Clinical Trials –2023
- Data Transparency Winter Event 2023
- Data Privacy and Data Sharing in Clinical Trials – Introduction
- Data Privacy and Data Sharing in Clinical Trials – Importance of Clinical Trials
- Data Transparency Winter and Summer Events
- Data Transparency CSS Update – 2018
- Data Transparency Working Group Update – CSS 2018
- Data Transparency EU CSS Update – 2017

Click here to search for all Data Transparency deliverables, past projects are housed under the archived section.

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Jean-Marc Ferran is an Independent Consultant based in Copenhagen with more than 15 years of experience in the Life Sciences industry. Prior to starting his company, Qualiance, he worked as a Statistician, Standards Manager and Director of Statistical Programming at Novo Nordisk and Ferring Pharmaceuticals. Jean-Marc has led the PHUSE Data Transparency Working Group since 2014 and is an appointed member of the EMA Technical Anomymisation Group and Health Canada Stakeholder Reference Group on Public Disclosure of Clinical Documents. Jean-Marc also chaired the PHUSE Annual Conference in 2012 in Budapest, was a Director on the PHUSE Board from 2014 - 2017, and is a Lifetime Honorary member of the society for his significant contribution to the organisation over a number of years.

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Stephen is the Head of Clinical Data Standards & Transparency at the Janssen Pharmaceutical Companies of Johnson & Johnson. Stephen has been a member of the Janssen team since 2016 and has helped to implement and support a number of data-sharing initiatives during this time. He has over 25 years of experience in the management of clinical trial and research data with pharmaceutical, life science and research organisations.

In 2004, Stephen founded the PHUSE organisation. From inception, he has driven and continues to drive PHUSE, which now has over 10,000 global members. PHUSE runs over 25 well-attended events globally each year, including a data innovation symposium in partnership with the Food and Drug Administration.

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Devaki partners with pharmaceutical clients, members of the research and healthcare community globally to help meet their clinical trial transparency and disclosure requirements. She has 8 years' experience within the pharmaceutical and healthcare industry.

Her journey in the transparency and disclosure space first began in 2016 at Eisai where she led the first 3 EMA Policy 0070 submissions and the coordination of activities for plain language summary development, the release of patient-level data to qualified external researchers, along with new and upcoming health authority requirements. Devaki also had exposure to governmental sector data sharing in identifying and implementing process improvements during the critical transitionary period of organisational change for the UK's public health reform initiative and she has an understanding of multiple areas in the pharmaceutical and healthcare industry through her previous roles, including Medical Information and Drug Safety.

As part of the response to the global pandemic, Devaki contributed to the transparency project for one of the leading COVID-19 vaccines to receive approval, providing guidance to the marketing authorisation holder on the operational elements for EMA and Health Canada's request for publication of the full clinical data used to support their authorisations of this vaccine.

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Muhammad Oneeb Rehman Mian is a Senior Manager of Privacy & Data Enablement for the Clinical Trials Transparency (CTT) business stream at Privacy Analytics. He provides technical leadership and subject-matter expertise for privacy methodology and solutions. Muhammad has over 4 years of experience developing scalable risk-based anonymisation technologies for clinical trials data, evolving privacy threat modelling and identifiability metrics, and exploring solutions to practical challenges faced in the field of privacy and data protection engineering.

Previously, Muhammad worked in biomedical research, applying statistics and Big Data analytics to solve novel problems. Muhammad draws from his prior experience in medical research to enable privacy programs that ensure data is useful and accurate.