Data Transparency

Working Group Scope

More than 30 participants from pharmaceuticals, CRO's, software and academia, as well as CDISC and data privacy experts have collaborated on developing a data de-identification standard for SDTM (known as the 'PHUSE de-identification standard'). Since then, the project 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 (eg, the EMA, Health Canada), as well as other industry organisations such at TransCelerate, and academia (eg, Cochrane).

Current Projects

Educate the General Population on Data Privacy and Data Sharing

EU CTR Implementation

Internal Clinical Study Data Sharing Process

Rare Disease/Small Population Data Sharing

Stakeholders' Deliverables Review

Synthetic Data

Good Transparency Practices

Resources

- Data Transparency 2021 Summer Event
- Data Transparency 2021 Winter Event
- Data Transparency 2020 Summer Event
- 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.

Jean-Marc Ferran: Working Group Lead

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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.

Stephen Bamford: Working Group Lead

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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 organizations.

In 2004, Stephen founded the PHUSE organization. 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.

Sarah Balay: Working Group Lead

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Dr. Sarah Balay is a Senior Anonymization Expert and Technical Lead with Privacy Analytics' Clinical Trial Transparency (CTT) business unit. Sarah completed her PhD in Neuroscience from the University of Ottawa in 2016. She studied mechanisms of neuronal death in the laboratory of Dr. David Park and was the recipient of numerous scholarships and awards during her graduate studies. Sarah joined Privacy Analytics in the earliest days of CTT. Her numerous skills gained during her time at the University of Ottawa, such as problem solving, multi-tasking and keen attention to detail proved ideal to help Privacy Analytics parlay its CTT expertise in data de-identification. Her expertise and work ethic have helped to shape the company's CTT methodology and the toolsets that enable the team to meet clients' most stringent deadline requirements. Currently she leads a dedicated team of Anonymization Analysts in the anonymization of unstructured data from over 800 clinical trials and is a guiding hand for one of Privacy Analytics' most complex and demanding pharmaceutical client engagements.