



CSS 2023

The Computational Science Symposium

18–20 September
Silver Spring, MD



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Plenary Overview

Plenary Session with Updates from Health Authorities

- **Risk Based Monitoring**
Cheryl Grandinetti, *FDA*
- **Update on Transparency Aspects of the Raw Data Pilot and CTIS Guidance**
Anne-Sophie Henry-Eude, *EMA*
- **Overview of the FDA's RWE Guidances and RWE Demonstration Projects**
Marie Bradley, *FDA*
- **CSS Poster Awards**
Jean-Marc Ferran, *Independent Consultant & PHUSE Data Transparency Working Group Lead*



Poster Award Winners



PP12 – Good Transparency Practice: A Working Group Update

Abby McDonell, *Privacy Analytics* and Lauren Hepburn, *Independent*



PP12

Good Transparency Practice: A Working Group Update

Authors: Lauren Hepburn*, Abby McDonell*, Devaki Thavarajah*, Mahesh Swaminathan, et al.
*lthepburn@outlook.com, amcdonell@privacy-analytics.com, devaki.thavarajah@phuse.global

Current trends emphasise the importance of public disclosure and sharing of clinical trial documents and data. Sponsors may be required to make anonymised clinical documents publicly available to comply with health authority transparency regulations, or may choose to participate in voluntary data sharing to facilitate secondary research. This poster is designed by the Good Transparency Practice (GTP) project group (part of the PHUSE Data Transparency Working Group) to highlight guidelines and best practices that may be used to govern the anonymisation of clinical trial data for external sharing or disclosure. By outlining the distinct roles of the Data Controller, Data Anonymiser, and Data Recipient, the project aims to provide a means to achieve accountability and traceability through the anonymisation process, while providing assurance that privacy requirements are upheld.

Principles of GTP

1. Clinical trial data sharing should be conducted in accordance with the applicable regulatory requirement(s) and local legislatures.
2. Anonymisation should adequately protect the privacy of patients and prevent a serious possibility of identifying individuals in the data.
3. Prioritise retaining the maximum amount of analytically-valuable information during the anonymisation process while maintaining patient privacy.
4. The chosen anonymisation strategy should be documented in an anonymisation report made available to the Data Recipient.

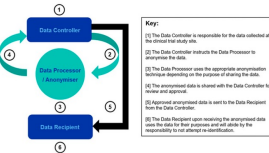


Figure 1: Relationship between the Data Controller, Data Processor/Anonymiser, and Data Recipient under GTP. The Data Controller is directly responsible for the data collected and should ensure quality assurance is maintained with the use of GTP, record keeping, and Data Protection Agreements if data processing is subsequently by a Data Processor/Anonymiser.



Figure 2: Application of anonymisation strategy following the assessment of the identification risk. The anonymisation strategy is selected by the Data Controller and applied by the Data Anonymiser. Both qualitative and quantitative risk assessment strategies may be used but should demonstrate how the chosen methodology results in a low risk of re-identification.

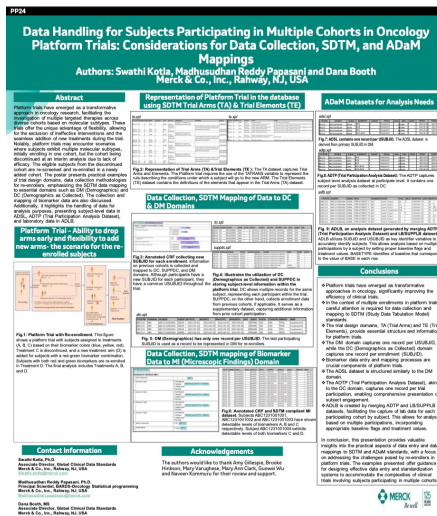
pseudonymised	generalised	suppressed	retained
Patient XXXX is a 18-25 year-old XXXX female in the Treatment 1 group and received the first dose on Study Day 1.			

KEY

- Pseudonymisation:** Masking of the unique subject ID with an encrypted value that has the same length as the original ID
- Generalisation:** Reduce the precision of the field
- Suppression:** The original value is replaced with placeholder text
- Retain:** Original values are maintained

Figure 3: Sample anonymisation strategy that is applied by the Data Anonymiser, approved by the Data Controller, and received by the Data Recipient. Multiple anonymisation strategies can be used to achieve low risk of re-identification and should be detailed in the anonymisation report.

Swathi Kotla, Merck and **Madhusudhan Papasani, Merck**







EU 2023

5-8 November
ICC Birmingham

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US 2024

25-28 February

Bethesda North Marriott Hotel & Conference Center

Iconic
Bethesda
Building

Walter Reed National
Military Medical Center



The Computational
Science Symposium

CSS 2024

3–5 June
Silver Spring, MD



January

Registration and Call for Posters Opens

March

Call for Posters & Early Bird Registration Deadline

3–5 June

PHUSE/FDA CSS 2024