Data Transparency Winter Event 2024

Overview

Day 1

Day 1 of the Data Transparency Winter Event started with a presentation titled 'A Cross-Sectional Study to Evaluate the Real-World Impact of Clinical Trial Transparency Initiatives' by Shalini Dwivedi (Krystelis). Shalini discussed a survey they are conducting across stakeholders (trial participants, investigators, researchers, sponsors) on the impact of data transparency. The survey remains open, and the preliminary results have revealed interesting trends. Notably, findings suggest an opportunity to raise awareness around best practices. For instance, while more than half of research requests focus on meta-analyses, more than half of surveyed sponsors enable secondary-purpose research on their own platform (versus multi-sponsor environments). Such data illustrates the level of awareness (or lack of?) from the different groups on the progress of data sharing.

The second presentation, 'Improving Data Findability Through Better Clinical Metadata' from Lukasz Kniola (Biogen), introduced a metadata repository concept developed at Biogen, incorporating summary statistics on demographics, findings, intervention and events data. This repository facilitates the search of studies while removing the need to access the data until the final set of studies is approved for reuse. The solution is both simple and efficient, and code is even provided in the slides.

Roche was one of the first sponsors to embark on the data sharing path, back in 2013. In the third presentation, Nuria Mackes and Asad Preuss-Dodhy (Roche) outlined their journey and recent work on sharing genetic data. 'Lessons Learned in Anonymizing Complex Health Data' offered insights into the WAYFIND-R project – a global real-world evidence generation initiative – and how applying stricter controls enabled them to share data with higher data utility.

The fourth and final presentation by PHUSE Good Transparency Practices (GTP) Project Leads Abby McDonell and Lauren Hepburn took us through the deliverable, which is currently in its finalisation stage. The GTP white paper has been developed with EMA and Health Canada officers as observers and touches upon governance, training and procedure matters around data sharing between data anonymisers, data controllers and data recipients. This deliverable will complement more technical deliverables from the Working Group and will soon be available for public review. Stay tuned for updates.

Day 2

Day 2 focused on data privacy governance in the current evolving landscape of clinical trial transparency initiatives.

During the first presentation of the day, 'De-Identification Beyond Borders: Global Applicability of HIPAA Safe Harbor', Obaraboye Olude (Privacy Analytics) investigated the effectiveness of HIPAA Safe Harbor de-identification in other countries by applying the same methods (that inspired HIPAA Safe Harbor de-identification) to census data from other countries at different points in time. Obaraboye also compared the definition of PHI found in the HIPAA Privacy Rule with the definition of personal data in other jurisdictions and summarised the potential for re-identification through other means such as combining de-identified data with potentially available information, which motivated the creation of HIPAA Safe Harbor. This presentation highlighted the need to adopt a more globally accepted standard for de-identification – and what this means in practice.

In the second presentation, 'The HEAL Data Ecosystem: Enabling Data Sharing within the NIH HEALInitiative®', Zixin Nie (RTI International) provided an in-depth insight into The Helping to End Addiction Long-term®Initiative, or NIH HEAL Initiative® – an NIH-wide effort to speed scientific solutions to stem the national opioid public health crisis, funding over 1,000 projects nationwide. Zixin provided an overview into the data sharing practices of the HEAL Initiative, the model used for the HEAL Data Ecosystem and how it helps enable data transparency. The tools available to make HEAL data FAIR (Findable, Accessible, Interoperable, and Reusable) were discussed, along with an emphasis on the HEAL Data Ecosystem being an important part of this effort and empowering researchers in the sharing of data.

In the third presentation, 'PSURs Public Release – Individual Patient Safety Data Disclosure Across Multiple Transparency Initiatives', Agnieszka Glowinska and Magdalena Majewska (AstraZeneca) provided insights into their experiences of transparency of COVID-19 products, particularly on publication of PSURs and Assessment Reports of COVID-19 vaccines. This relates specifically to the cumulative and reporting period exposure from post-approval (marketing) experience (Phase IV) and cumulative exposure (Phase III) with the following key aspects in mind: 1) How to ensure the privacy of clinical study participants is protected consistently and 2) Whether a unified approach can be applied to all clinical study participants, regardless of study phase or living status. Agnieszka and Magdalena discussed how to open a dialog supporting transparent sharing of safety data without linking it to the person who has trust in both sponsors and regulators. They also detailed the importance of strategies used in their chosen privacy-enhancing data de-identification framework to ensure information security, cybersecurity and privacy protection.

The fourth and final presentation of the day, 'The Final Countdown: Preparing for the 2025 CTIS Transition Deadline' by Francine Lane (Citeline), introduced key points on how to consolidate and harmonise disclosure both efficiently and consistently to meet the upcoming CTIS transition deadline. Using a high-energy race car theme, Francine first walked the audience through the toolbox of what is required, along with key takeaways, considerations for transitioning trials, expedited transitions, the differences between consolidation and harmonisation, and the new transparency rules. Throughout, there was a focus on maintaining collaboration and communication between each of the stakeholders involved in this highly fast-paced arena, as with all deliverables related to the field of clinical trial transparency.

Day 3

The final day of the Data Transparency Winter Event started with a presentation by Woo Song (Xogene) on 'From Automated to Accountable: Building Responsible AI for Trial Transparency'. Woo discussed the tremendous potential to accelerate and enhance clinical trial transparency through automated plain language summarisation of study documents, using Generative AI. Woo talked about the importance of establishing proper governance and best practices (including policies and auditing mechanisms) to maximise the benefits of using AI while minimising risks of creating inconsistent or inaccurate outputs. Using a practical example and a live demo of a tool, Woo demonstrated how various considerations in prompt engineering can be taken into account when using Generative AI to automatically condense a sample protocol into a patient-friendly synopsis. A key aspect that was highlighted was the need for humans to remain in the loop to ensure AI is used responsibly.

In the second presentation, Diwakar Angra (GENINVO) discussed 'Challenges and Solutions to Anonymization of Imaging Data (DICOM)'. DICOM (Digital Imaging and Communications in Medicine) is a standard for the communication and management of medical imaging information and related data. Diwakar outlined the challenges faced in anonymising DICOM image data, which include editing DICOM header data, diverse identifiable information in images, file numbers and sizes involved, and anonymisation in sync with study dataset and documents. On potential solutions to these challenges, Diwakar shared insights into available open-source libraries to read DICOM files, anonymisation strategies for image data, and perspectives on preserving image quality and potential for automation. Thorough testing and validation of the DICOM anonymisation process was stressed upon, to ensure compliance to privacy regulations while preserving the clinical value of the medical images.

In the third presentation of the day, Luk Arbuckle (Privacy Analytics) spoke about 'Balancing Act: The Dynamics of Legislation, AI, and Global Health Data Sharing'. Luk shared his experience acting as an expert witness on Bill C-27 Consumer Privacy, Tribunal, AI and Data at a recent Canadian parliamentary committee. He recalled how his experience over the years was an important precursor to the extensive preparation required for such meetings and explained the format of the latest parliamentary committee he testified in. Drawing on insights from his testimony before the parliamentary committee, Luk discussed the impact of data protection laws on health research and analytics, emphasising the importance of privacy-enhancing technologies and offering a perspective to balance privacy concerns with the need for efficient and effective data sharing across borders, to enable development of responsible data access models that support international collaboration and research.

To wrap up this year's Data Transparency Winter Event, Aaron Mann (CRDSA) and Luk Arbuckle (Privacy Analytics) co-presented on 'Biopharma Data Sharing Policies and Protection Methodologies'. Aaron and Luk shared the updates from CRDSA's systematic review on biopharma sponsor data sharing policies and protection methodologies, first conducted in 2022 and updated last year. The results highlighted a 20.7% increase in number of data contributors, with increased commitment (exceeding 80%) to share across all tiers based on sponsor size. Co-presenters noted that consistency and interpretation of data protection methodologies and terminologies remains a key challenge, even for domain subject-matter experts. CRDSA hopes the systematic review will help create meaningful benchmarks to inform data contributor policy development, as well as highlight areas where continued work is needed. CRDSA is conducting a summit on Thursday 29 February 2024, to share expert insights into the latest developments in responsible reuse of patient data. Interested individuals can register at: https://crdsalliance.org/news-events/.

Presentations & Recordings

PHUSE would like to thank all presenters who took part in the Data Transparency Winter Event 2024. If you did not get the chance to attend the event, click the titles below to view the presentations.

The recordings from days 1 and 3 are available on the PHUSE Archive.

Date	Presentation	Author (s)
Day 1: 6 February	A Cross-Sectional Study to Evaluate the Real-World Impact of Clinical Trial Transparency Initiatives	Shalini Dwivedi, *Krystelis*
	Improving Data Findability Through Better Clinical Metadata	Lukasz Kniola, *Biogen*
	Good Transparency Practices: A Working Group Update	Abby McDonell, *Privacy Analytics* and Lauren Hepburn, *Rare Disease Sponsor*
	Lessons Learned in Anonymising Complex Health Data – Maximising Data Utility While Minimising Risk	Nuria Mackes, *xValue* and Asad Preuss-Dodhy, Roche Diagnostics
Day 2: 7 February	De-Identification Beyond Borders: Global Applicability of HIPAA Safe Harbor	Obaraboye Olude, *Privacy Analytics*
	The HEAL Data Ecosystem: Enabling Data Sharing within the NIH HEALInitiative®	Zixin Nie, *RTI International*
	PSURs Public Release – Individual Patient Safety Data Disclosure Across Multiple Transparency Initiatives	Agnieszka Glowinska and Magdalena Majewska, *Astra Zeneca*
	The Final Countdown: Preparing for the 2025 CTIS Transition Deadline	Francine Lane, *Citeline*
Day 3: 8 February	From Automated to Accountable: Building Responsible AI for Trial Transparency	Woo Song, *Xogene*
	Balancing Act: The Dynamics of Legislation, AI, and Global Health Data Sharing	Luk Arbuckle, *Privacy Analytics*
	Challenges and Solutions to Anonymisation of Imaging Data (DICOM).	Diwakar Angra, *GENINVO*
	A Review of Biopharma Sponsor Data Sharing Policies and Protection Methodologies – Results from the 2023 Survey.	Aaron Mann, *Clinical Research Data Sharing Alliance* & Luk Arbuckle, *Privacy Analytics*

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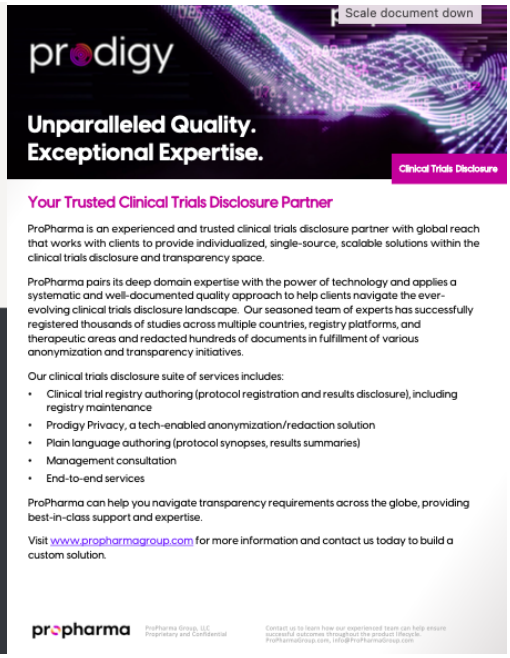
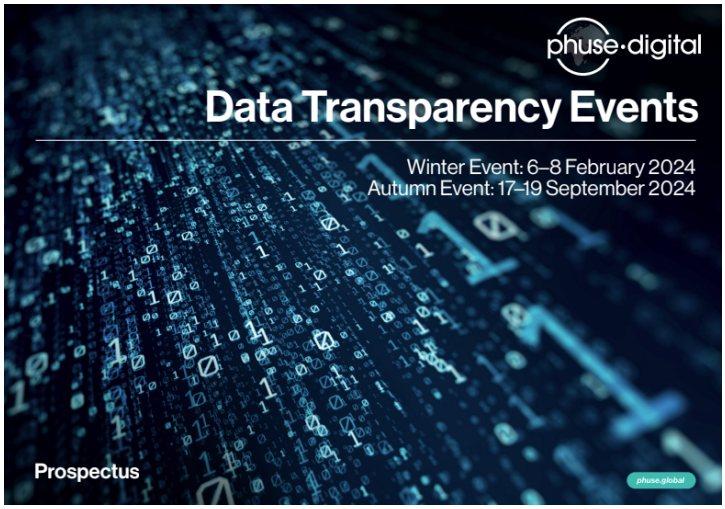


Sponsorship

Hosting the Data Transparency Events digitally means that no matter where you are in the world you can participate. It provides the industry with a broader opportunity to share knowledge on a global scale, connecting through the virtual event platform. The sponsor options offer a range of benefits with ample company exposure. See the prospectus for more detail.



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