Data Transparency Summer Event 2023

PHUSE would like to thank all presenters that took part in the Data Transparency Summer Event 2023. If you did not get the chance to attend the event, click the titles below to view the presentations. All recordings are available on the PHUSE Archive.

Day 1 kicked off with four engaging presentations focused on data anonymisation techniques. Nastazja Laskowski (Roche) shared with us important messages that came out of an industry survey Roche conducted. She discussed the technical challenges anonymisation of documents poses and the progress industry has made where quantitative approaches are used for risk determination. Nastazja also touched upon knowledge graphs for re-identification attacks using multiple data sources and the risk they could pose in the future.

Boris Grimm (Boehringer Ingelheim) and Jeppe Manuel (Novo Nordisk) detailed the approach outlined in TransCelerate's Privacy Methodology for Cross-industry Clinical Data Reuse white paper, which has been through a thorough public review. This new guidance touches upon seasonality and genomic data and is planned to be launched in September 2023.

Luk Arbuckle (Privacy Analytics) spoke about governance and how we can standardise processes and practices around data sharing. Luk discussed the ISO/IEC 27559 risk-based framework and its foundation as well as the different anonymisation approaches and techniques to consider.

Finally, Parveen Kumar (GENINVO) shared their experience of handling requests for CTIS redactions and the learnings they have made so far. Parveen emphasised the amount of manual work this requires and discussed automation where possible to ease the burden.

Day 2 continued to focus on data transparency operations and regulations. During the first presentation of the day, **Regulation and its Effect on Patient Data and the Progress in Science – An Ethical Approach**, Peter Kapitein (Inspire2Live) shared an insightful talk from a patient advocate's perspective regarding the ethical and moral considerations and benefits data sharing brings. Peter discussed how this can be further enhanced, to reduce the time it takes to find better treatments.

In the second presentation, **EU Protocol Synopsis – Current Trends and Best Practices**, Vidhi Vashisht (Krystelis) provided an in-depth overview of creating compliant, submission-ready EU protocol synopses in line with the current regulatory landscape and requirements based on assessment of regulation. Vidhi also spoke about her direct experience with sponsor companies. The four key elements of the EU protocol synopsis are (1) inclusion of all required elements (2) plain language (3) document length (4) availability of translated versions.

In the third presentation, **Data Transparency – Updates from EMA Policy 0070**, Karen Quigley (European Medicines Agency) provided an update regarding the current clinical trial transparency initiatives conducted by the EMA, in addition to the much anticipated re-start of clinical data publication under EMA Policy 0070 scheduled for September 2023, approximately four years after being halted to focus on the agency's relocation to Amsterdam and clinical data publication for COVID-19-related products only. The re-start will be limited to new active substances and Karen provided a useful summary of the requirements and preparation stakeholders can take prior to the launch.

The fourth and final presentation of the day, **PHUSE/Xogene Collaboration Site – Demo**, by Sanjay Bagani and Ankur Patel (Xogene) presented a live demo of the Global Compliance Portal, a powerful collaboration between PHUSE and Xogene. Sanjay and Ankur took us through the key features of how this innovative platform simplifies compliance by monitoring clinical trial transparency regulations across 50+ countries. The tool informs users about country-specific updates via a curated daily news feed to help them stay on top of the ever-evolving global regulatory requirements.

Day 3 focused on the topic of protecting sensitive information for special use cases. During the first presentation of the day, **Challenges and Best Practices in Protecting Commercially Confidential Information in Clinical Documents for Public Disclosure**, presenter Niamh McGuinness (Privacy Analytics) shared insights about how regulators define and qualify commercially confidential information (CCI)/confidential business information (CBI). Niamh went on to discuss a CCI/CBI identification workflow that is adopted in practice, including creating a list of potential CCI/CBI terms, cross-referencing the terms against the appropriate regulatory definitions and then searching the public domain for the remaining terms. Guidance was provided on how to minimise rejection by regulators through proper execution of redaction.

In the second presentation, **Challenges in Masking Patient Privacy in Rare Diseases**, Sheetal G. Bagul (GENINVO) provided an overview of risk assessment and anonymisation techniques and discussed the challenges involved in handling data pertaining to rare diseases. The official definition of rare disease differs between jurisdictions; but generally, a rare disease is a condition that affects fewer than 1 in 1,500–2,000 people. Suggestions for addressing these challenges included gaining thorough understanding of the variables in the datasets, using specific techniques for accurate risk assessment, and considering a plan that maximises data utility while mitigating risk of re-identification.

The **Sharing Data Internally – Secondary Data Use within Organisations** presentation by Lukasz Kniola (Biogen) focused on opportunities and challenges of internal data sharing, its associated risks and processes to execute requests, and suggestions for streamlining the processes.

Presentations & Recordings		
The recordings from all three days are available on the PHUSE Archive.		
Date	**Presentation**	**Author (s)**
Day 1: 20 June	What Automations Could Be Introduced for CTIS Redactions?	Parveen Kumar, *GENINVO*
	Data Transparency and Anonymisation: An Exploration of Industry Practices	Nastazja Laskowski, *Roche*
	TransCelerate's Privacy Methodology for Cross-industry Clinical Data Reuse	Boris Grimm, *Boehringer Ingelheim* & Jeppe Manuel, *Novo Nordisk*
	Standard Anonymisation: An International Framework	Luk Arbuckle, *Privacy Analytics*
Day 2: 21 June	Regulation and its Effect on Patient Data and the Progress in Science – An Ethical Approach	Peter Kapitein, *Inspire2Live*
	EU Protocol Synopsis – Current Trends and Best Practices	Vidhi Vashisht, *Krystelis*
	Data Transparency – Updates from EMA Policy 0070	Karen Quigley, *EMA*
	PHUSE/Xogene Collaboration Site – Demo	Ankur Patel & Sanjay Bagani, *Xogene*
Day 3: 22 June	Challenges and Best Practices in Protecting Commercially Confidential Information (CCI) in Clinical Documents for Public Disclosure	Niamh McGuinness, *Privacy Analytics*
	Challenges in Masking Patient Privacy in Rare Disease	Sheetal Bagul, *GENINVO*
	Sharing Data Internally – Secondary Data Use within Organisations	Lukasz Kniola, *Biogen*

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Past Events

Stephen Bamford
Janssen Research & Development

Jean-Marc Ferran
Qualiance

Devaki Thavarajah
Instem

Muhammad Oneeb Rehman Mian
Privacy Analytics

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Alternatively, you can read the high-level summaries for each event on the Working Groups Events Archive page.