

Evaluating Fit-for-Purpose Anonymization Strategies for Japanese Real-World Data Under EU Data Protection Standards

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Poster Preview – Full Presentation Available Onsite

This online version offers a brief preview of our work. For the complete poster, detailed findings, and discussion, please visit us at:

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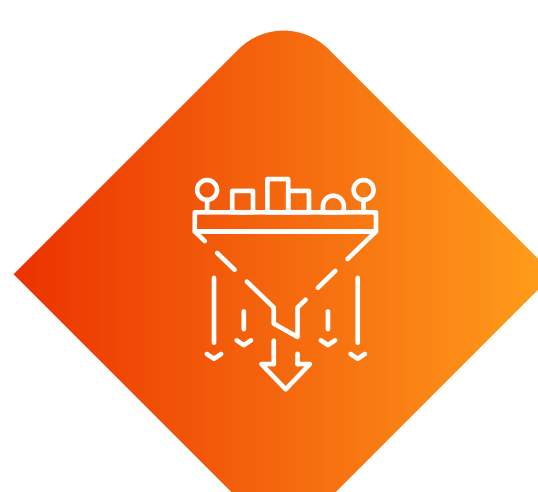
Location: Providence Hall, The Tokyo Prince Hotel

We will be available around the poster board during and beyond the dedicated session time. For further information or follow-up discussions, or a copy of the full poster, please feel free to contact us:

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OBJECTIVE:

To evaluate and apply fit-for-purpose anonymization methods for integrating Japanese real-world data (RWD) and identify refinements for ensuring global compliance with EU GDPR (General Data Protection Regulation) anonymization requirements.

METHODS:

We applied anonymization approaches to linked datasets that contained pseudonymized medical records, commercial data, and patient-reported questionnaires from Japanese patients. The process involved continuous risk assessment and a combination of techniques including randomization, noise addition, suppression, and data generalization to achieve K-anonymity. We also assessed the effectiveness of replacing pseudonymized identifiers with fully anonymized patient IDs in line with GDPR Recital 26, ensuring no retraceable mapping remained. Our assessment criteria included both the reduction of re-identification risk and the preservation of data utility for secondary analysis. The applied methods incorporated perspectives from health informatics, statistical disclosure control, and practical experience in privacy-enhancing technologies..

RESULTS:

The applied anonymization techniques resulted in datasets considered exempt under GDPR, significantly lowering the potential for re-identification. Importantly, these transformations retained sufficient analytic value to support meaningful population-level analysis and health outcomes research. In particular, the removal of linkable identifiers across data types enabled cross-source integration without compromising patient privacy.

CONCLUSIONS:

This methodological research demonstrates practical implementation of anonymization approaches tailored for Japanese RWD. The study highlights areas for further refinement, especially in balancing privacy protection with analytic needs in complex linked datasets. As regulators increasingly rely on RWD for decision-making, particularly in post-approval settings, life sciences companies using Japanese datasets can adopt these approaches to strengthen global compliance and support broader international use. Our findings provide a roadmap for stakeholders navigating evolving privacy requirements while continuing to unlock the value of real-world data.

