The Importance of Embracing Anonymization of Personal Information

The Preferred Strategy of Global Health Authorities

Policy and Guidance

European Medicines Agency

EMA Policy 0070 (Section 5.1), states:

- *"EMA understands that in an initial phase redaction... pharmaceutical companies will have to anonymize their data retrospectively (reactive data anonymization), i.e. after the clinical report has already been submitted for scientific review.* **Importantly, redaction alone is more likely to decrease the clinical utility of the data compared to other techniques.**

- *Therefore, EMA is of the view that applicants/MAHs...should transition to other anonymization techniques that are more favored in order to optimize the clinical usefulness of the data published (proactive data anonymization). Pharmaceutical companies are encouraged to use these anonymization techniques* **as soon as possible**, *whilst ensuring data anonymization is achieved."*

Health Canada

The Public Release of Clinical Information (PRCI) Guidance (section 6.1) recommends anonymization, as opposed to traditional redaction techniques that retain no information utility. The guidance states, *"In order to maximize the release of analytically-valuable information and to retain the most utility of the published clinical information, the anonymization of clinical information should be guided by the following principles*:

1. *All transformation of data should be conducted for the sole purpose of preventing the disclosure of personal information;*
2. *All data transformations should be accompanied by robust justification, and be applied to limited variables that risk re-identification;*
3. *Data transformation should favor methods that retain analytical value, e.g. generalization, randomization and offsetting, as opposed to redaction."*

Benefits of Anonymization

- Aligns with health authority policies and regulations
- Preserves data utility for the research community, showing good corporate citizenship
- Allows for quantitative risk measurement
- Safeguards patient privacy
- Only method that allows for datasets and documents to be consistently prepared for publication

Anonymization Solutions

TrialAssure® ANONYMIZE R

An anonymization application for reports and documents that gives sponsors the ability to redact or anonymize written documents associated with clinical trials, including Adobe PDF and Microsoft Word formats.

TrialAssure® ANONYMIZE DS

An anonymization application for datasets that allows sponsors to anonymize all structured clinical trial data, including datasets and tables, with ease.

TrialAssure is a global clinical trial transparency suite with unmatched experience in helping clients navigate complex regulatory submission and reporting challenges. TrialAssure helps meet regulatory compliance goals through a flexible, scalable, and streamlined platform that supports trial registration, disclosure, data sharing, anonymization, and plain language summary activities.

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