Clinical Trials Transparency

The desire for greater transparency of clinical studies is not new, but last year's introduction of the European Medicines Agency's (EMA) policy 0070 has placed a renewed emphasis on clinical trials transparency.

While trial sponsors have shown a commitment to transparency and to making their data available for secondary analysis and research, publishing the clinical study report (CSR) or sharing the individual participant data (IPD) creates risks to the privacy of the trial's participants.

In addition, trial sponsors face challenges in their implementation of clinical trials transparency initiatives, including:

- Uncertainty about how fast the demand for clinical trials data will rise and whether it is sustainable;
- Concerns in making big investments in infrastructure and staffing to prepare for data sharing with this demand uncertainty;
- Requiring expertise with disclosure control methods, and uncertainty about the effort and cost to develop such expertise internally; and,
- The internal costs of data de-identification and financial scalability.

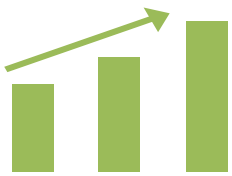
Privacy Analytics

Privacy protection is achieved through applying risk-based de-identification (or anonymization) on all information before it is released. It ensures that the analytic utility of the de-identified data is sufficient to reproduce original study results and allow innovative analysis. Privacy Analytics provides a risk-based methodology that offers high data quality aligned with globally accepted regulations, standards and guidelines for anonymization. This includes HIPAA, the EU General Data Protection Regulation, HITRUST Alliance, the Institute of Medicine, PhUSE, the Council of Canadian Academies and the European Medicines Agency.

De-identification – As a Service

Privacy Analytics offers Clinical Trials Data and Document de-identification services (CTDD) which utilizes experts in the field of health data de-identification. In conjunction with Privacy Analytics' software, this service scales and automates the de-identification of clinical trials datasets. Privacy Analytics will certify the compliance of IPD datasets and CSR documents. Sponsors can be confident they are compliant when sharing clinical data for secondary use.

Ensure Trial Participant Privacy



Enable Analytics and Research

Stay Compliant with Global Standards

PRIVACY ANALYTICS
a QuintilesIMS company

CLINICAL TRIALS TRANSPARENCY

CTDD de-identification services allow trial sponsors to:

- Rapidly initiate or expand clinical trials transparency initiatives with minimal upfront investments;
- Ensure greater legal certainty with datasets that are certified to have a low risk of re-identification;
- Meet existing standards and guidelines for best practices around de-identification;
- Gain high quality data for expanded research;
- Achieve more predictable costs for trials transparency initiatives;
- Scale de-identification efforts and investments based on demand for data; and,
- De-identify both IPD and CSR data using the same vendor and same risk-based approach.

Privacy Analytics: The only proven, responsible way to unlock the value of health data.

For more information on how Privacy Analytics can help your organization establish best practices to for sharing clinical trials data, download our white paper, https://www.privacy-analytics.com/de-id-university/white-papers/achieving-clinical-trials-transparency/

Risk-based Standards & Guidelines	Safe Harbor-based Standards & Guidelines
Institute of Medicine	TransCelerate
Council of Canadian Academies	
HITRUST	
PhUSE	
UK Information Commissioner's Office	
Canadian Institute for Health Information	
EMA Policy 0070	
Health and Human Services Office of Civil Rights (HIPAA)	
International Pharmaceutical Privacy Consortium	

Globally, regulators and industry groups are moving to a risk-based approach to de-identify clinical data.

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