PRISME Forum

Pharmaceutical R&D Information Systems Management Executive Forum

EVOLVING ASPECTS OF ANONYMISATION IN DATA RE-USE

d-Wise

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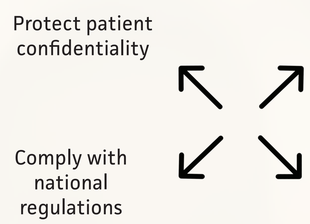
The Need to Anonymise Data

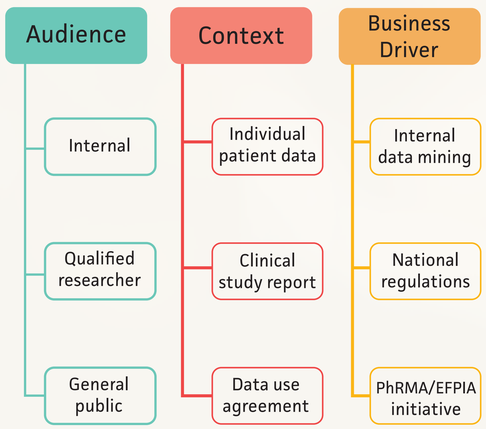
Clinical trial data sharing activities are rapidly growing across the biopharmaceutical industry. Each of these activities requires patient data to be anonymised, and each frequently requires a different anonymisation strategy.

Industry needs to ***adopt a common anonymisation approach*** for addressing the goals of these related data sharing initiatives, and that strategy must enable patient data to be anonymised efficiently and consistently, while preserving data utility.

Competing Goals



Key Factors to Consider



State of the Industry: Data Sharing Initiatives

Current	Emerging
Industry-driven – www.ClinicalStudyDataRequest.com, YODA and SOAR	EMA Policy 0070 -- Clinical study reports (CSRs) required 4Q2016; individual patient data later
Internal secondary use – Trial planning, market strategy development, new indication identification, software testing, other data mining activities	Multi-Regional Clinical Trials (MRCT) / Vivli -- Charged with directing, implementing and governing a global clinical trial data-sharing platform. Launched 03/2016
Project Data Sphere - Placebo and control arm oncology data collaboration	TransCelerate Placebo and Standard of Care (PSoC) Initiative -- Members only
On-request – Data shared with individual investigators on a case-by-base basis	International Committee of Medical Journal Editors (ICMJE) proposal – Patient data required to be provided with journal article for publication. Comments closed 04/2016

Managing Re-Identification Risk

Re-identification risk is sufficiently low in the vast majority of clinical trials AFTER applying proper de-identification techniques that ***individual trial risk calculations are not usually necessary***. Risk calculations are more likely to be required for trials conducted in areas with low-population density, racially homogenous patient populations and rare diseases.

TransCelerate BIOPHARMA INC.

"…in a secure controlled access model…data providers may decide that a statistical assessment of the risk of re-identification … is not necessary in most cases".

Institute of Medicine:
"… when appropriate re-identification standards are used, the risk of re-identification is indeed very small"

EMA: "…initially anonymisation will involve reactive data anonymisation where the assessment of risk of re-identification may be mostly qualitative"

Anonymisation Best Practices

Successful data anonymisation must be looked at comprehensively, and not as a fragmented process to be applied to individual data sharing initiatives. This individualised approach will result in data sets that are anonymised multiple times, and anonymised clinical study reports that are impossible to align to the patient level data.

For older trials that do not require the submission of CSRs to EMA, trial data should be anonymised using established industry rules, and within pharmaceutical companies this anonymised data should be used to drive all secondary use activities.

Although EMA Policy 0070 currently only requires clinical reports to be anonymised, ***both the patient-level data and the accompanying clinical report should be anonymised together***.

With the right tools, data anonymisation can be done with minimal effort, and will create durable artifacts that increase the efficiency and quality of CSR anonymisation – and, importantly, provide consistency between the data and the CSR.