ANONYMISATION OF CLINICAL STUDY REPORTS

A medical writer's perspective

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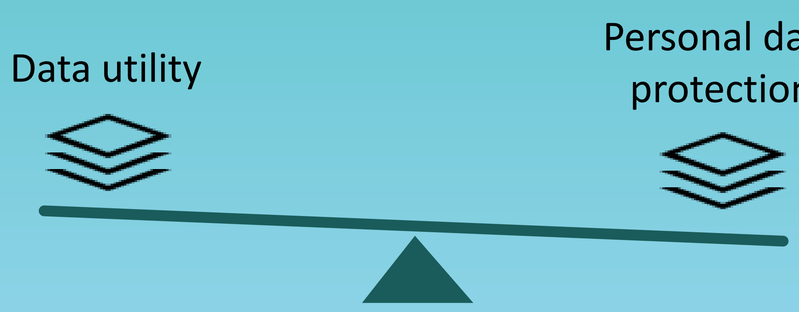


Context

Clinical trials have entered into the era of public disclosure.
Recent regulations, such as Policy 0070[1], implies public disclosure of clinical reports (mainly clinical overviews, clinical summaries, clinical study reports and some of their appendices). A consistent approach is therefore needed to allow data utility while preserving personal data confidentiality (low risk of re-identification).

Clinical study reports submitted for marketing application can be considered as pseudoanonymised aggregated data but they often contain individual patient information, which needs to be anonymised before disclosure. Effective anonymisation are define by 3 criteria (no possibility to single out an individual, no possibility to link records relating to an individual, no information can be inferred concerning an individual). When one or more criteria are not met, the risk of re-identification must also be assessed and shared[1].

Anonymisation method

Anonymisation of a CSR requires determination of 1/the direct and quasi- identifiers (safe-Habor method), 2/ the required level of anonymisation, and 3/ the methodologies to be used (keeping in mind the need to have a balance between the clinical data utility and the risk of re-identification)[2].

Methodologies include removal /masking, generalisation and randomisation[1].

In this first step of public disclosure of clinical reports, removal/masking appears to be the easiest method. Each method can have different levels of utility depending on the data set. Experience and proactive data anonymisation will lead to an increase in the use of the others methods.

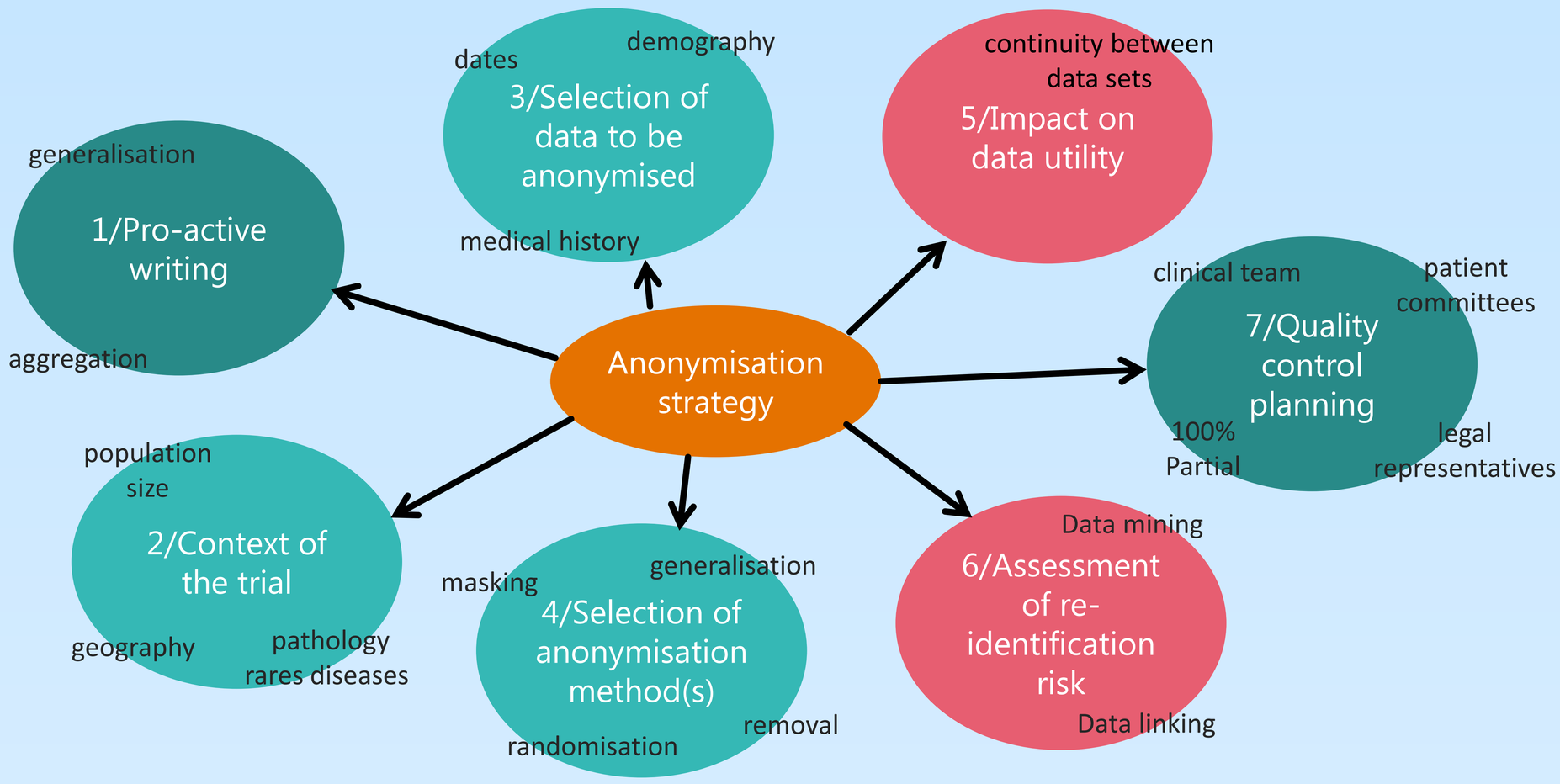
Reactive (retrospective) data anonymisation → Proactive data anonymisation

	Removal/Masking (redaction)	Generalisation (aggregation)	Replacement/ Randomisation
Data utility*	Low	Better	Medium (?)
Risk of re-identification*	Low	Linkability of records to be assessed	Medium (?)
Reliability (risk of error or « missing »)*	Medium to high	Medium to low	Low
IT tools /automatisation	Partially	Partially	Yes

* Impact of anonymisation method is strongly dependent on the study specificities and study risk level

Challenges

In all cases, the anonymisation strategy (data to be anonymised, methods) must carefully take into account the specificities of the conducted studies (study risk level). A important step to be considered is pro-active writing: Strategies such as generalisation and aggregation can be used for the primary clinical study report to facilitate anonymisation.



Conclusion

Anonymisation of clinical reports is a challenging matter which will need constant fine-tuning by a multi-disciplinary team. Anticipation and pro-active writing may be key assests for that process.

References: [1] EMA policy External guidance on the implementation of the European Medicines Agency policy on the publication of clinical datafor medicinal products for human use. Apr 2017.
[2] Transcelerate Biopharma Inc. Protection of personal data in clinical document – A model approach