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SCIENCE MEDICINES HEALTH

Anonymisation report: How to improve the quality of the reports

Technical Anonymisation Group (TAG) meeting, London, 29-30 November 2017
Agenda point 09

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General approach to AnR

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- AnR should clearly state:
  - ✓ The **process**
  - ✓ The **methodology** used: Qualitative (fulfilment of 3 criteria or risk assessment) or Quantitative
  - ✓ The **impact** of anonymisation on data utility
- AnR should be tailored to the medicine:
  - ✓ Is the medicine treating/preventing a rare **disease**?
  - ✓ Is it an **Orphan product**? Prevalence of disease?
- AnR should be tailored to the studies. To be considered:
  - ✓ The number of **study participants / study population**
  - ✓ The number of **study centres** (multi or single centre)

Identifiers

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- Only identifiers **present in the documents** should be listed in the AnR.
- Identifiers should be classified in **direct and quasi** (indirect) identifiers.
- Anonymisation applied to direct and indirect identifiers should be clearly and **independently explained**.
- **Uniqueness** should be clearly considered.
- Differentiation between identifiers **in isolation** and **in combination** must be clearly presented.

Case narratives and listings

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Case Narratives and Listings of patients data included in the body of Clinical Study Reports

- Should be **anonymised** and not by default redacted.
- The reason for full redaction of case narratives instead of anonymisation **should be clearly explained** and linked to the assessment of the risk of re-identification.
- **All identifiers** present in case narratives should be listed even if case narratives are fully redacted.

Other sections

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➢ Attackers

- Type of attackers and attack should be clearly explained.
- In some cases specific types of attackers can be envisaged (such as genetic or rare disease).
- Type of information that the attacker can have on trial participants targeted should be explained.

➢ Data utility

- Mentioning that data utility has been considered is not enough.
- Data utility should be sufficiently and clearly analysed.

Input from TAG needed to

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- Give recommendations on:
  - ✓ Choice of **methodology.**
  - ✓ Identifying potential **attackers.**
  - ✓ Analysing **data utility** (case narratives fully redacted?).
- Define **size of study population** (small, medium, large).
- Input from TAG may lead to revision of **anonymisation guidance** and **AnR templates**

Thank you

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