Legal issues with the anonymization of clinical reports: state-of-play and GDPR evolution

Nicola Orlandi, Head Data Privacy Pharma, Novartis
Lee Parker, Director EU+ Privacy, Biogen
Technical Anonymization Group (TAG)
London 29-30 November 2017

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A new era for the use of health data

- Secondary use of individual patient data for health research plays an increasing role in modernizing our healthcare systems, driving medicines innovation and fostering better patient outcomes.
- Pharma is accessing an unprecedent depth and breadth of clinical data. This significantly expands research potential, but also creates re-identification risks.
- Pharmaceutical companies are called to share results of analysis in a transparent manner.
- Individual and societal expectations as well as privacy regulations mandate the responsible use of personal data.
- A strong need for a systematic approach to privacy management and de-identification of health data is key in view of optimizing value of health data for scientific research and responding to the demand of transparency.

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Increasing demand for transparency

- Regulatory decisions to authorize a drug to be placed on the market, are granted based on the results of clinical trials
- There's an increasing demand from stakeholders for additional transparency, not only about Agency's deliberations and actions, **but also about clinical data on which regulatory decisions are based**

A systematic approach to data is key to unlock full value of data and respond to transparency expectations

Improved patient outcomes

- Better results of treatments and understanding of side effects
- targeted interventions for the better impact

Better clinical trials

- RWD will complement clinical trial data to drive medicine innovation and shape future research

Improved healthcare

- Better quality of care and increased efficiency,
- best practices identification
- sustainable healthcare systems

More transparency

- improve accountability
- build trust among industry and investigators
- strengthens science literature integrity.

Individuals and society as well as privacy regulators expect us to use personal data in a responsible manner

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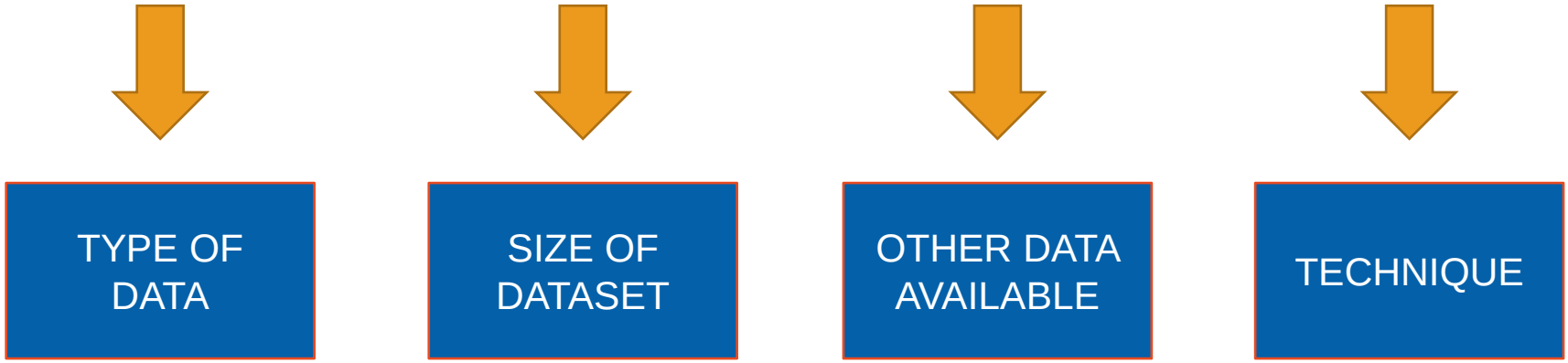
For various reasons it is hard to achieve full anonymization



A possible solution is to adopt a sound risk based approach by acknowledging that certain identification risks may remain despite all efforts to minimize them.

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What is anonymization/anonymous data?

Directive 95/46/EC: anonymization results from processing personal data in order to irreversibly prevent identification, having regard to all the means «likely reasonably» to be used for identification.

Anonymization is the process of turning data into a form that does not identify individuals and where identification is not likely to take place. It allows for a much wider use of the information.

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EU Regulation: recital 26

EU Regulation 2016/679 (rec. 26):

To determine whether a natural person is identifiable, account should be taken of all the means reasonably likely to be used, such as singling out.

To ascertain whether means are reasonably likely to be used to identify the natural person, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments.

The principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. This Regulation does not therefore concern the processing of such anonymous information, including for statistical or research purposes.

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WP29 Conclusion and recommendations

An anonymization solution preventing all three criteria under WP 29 opinion (singling out, linkability and inference) is considered to be robust against identification performed by the most likely and reasonable means the data controller or any third party may employ, and will render the data anonymous.

Whenever a proposal does not meet one of these criteria, a thorough evaluation of the identification risks should be performed.

Challenges

Anonymization techniques are not static. Therefore, we must:

a) Evaluate new risks and re-evaluate the residual risk on a regular basis.

b) Assess whether the controls for identified risks suffice and adjust accordingly.

c) Monitor and control the risks.

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Risk factor and assessment

Anonymization and re-identification are active fields of research and new discoveries are regularly published, and even anonymized data, like statistics, may be used to enrich existing profiles of individuals, thus creating new data protection issues.

Anonymization should not be regarded as a one-off exercise and the attending risks should be reassessed regularly by data controllers.

Risk factor is inherent to anonymization and has to be considered in assessing the validity of any anonymization technique. Severity and likelihood of this risk should be assessed.

An anonymized dataset can still present residual risks to data subjects.

Current EU approach focus on efforts necessary to re-identify a person

«means reasonably likely to be used» (Recital 26 of the GDPR) to re-identify an individual

- Recital 26 GDPR: account should be taken of all objective factors
- Art. 29 Working Party: criteria for assessing the robustness of an anonymization process
- The European Court of Justice has confirmed that a relative approach is possible (ECJ C.582/14)

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Anonymization : a possible approach

Approach	When performing anonymization of health data for the purpose of Secondary Use, one can follow a **risk –based** and **relative approach**, considering all circumstances that may result in a (re-)identification of a Data Subject
Techniques	When deciding which anonymization technique/s shall apply, aim for choosing the maximum degree of anonymization that is reasonably acceptable with a view to the context of Secondary Use

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Anonymization : circumstances

Circumstances for consideration

- **To which extent can the Personal Data at issue be anonymized.**

- **What are the risks of re-identification in light of the envisaged secondary use and with or without the possible anonymization measures.**

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Anonymization : measures

Measures to maintain anonymization

Data sharing agreements	Data protection policies and procedures	Control mechanisms	Re-evaluation assessments
Obligation not to attempt to re-identify data etc.	In order to ensure a proper management of data	Security measures protecting anonymized data	Re-assessments of data to identify new risks and take appropriate steps

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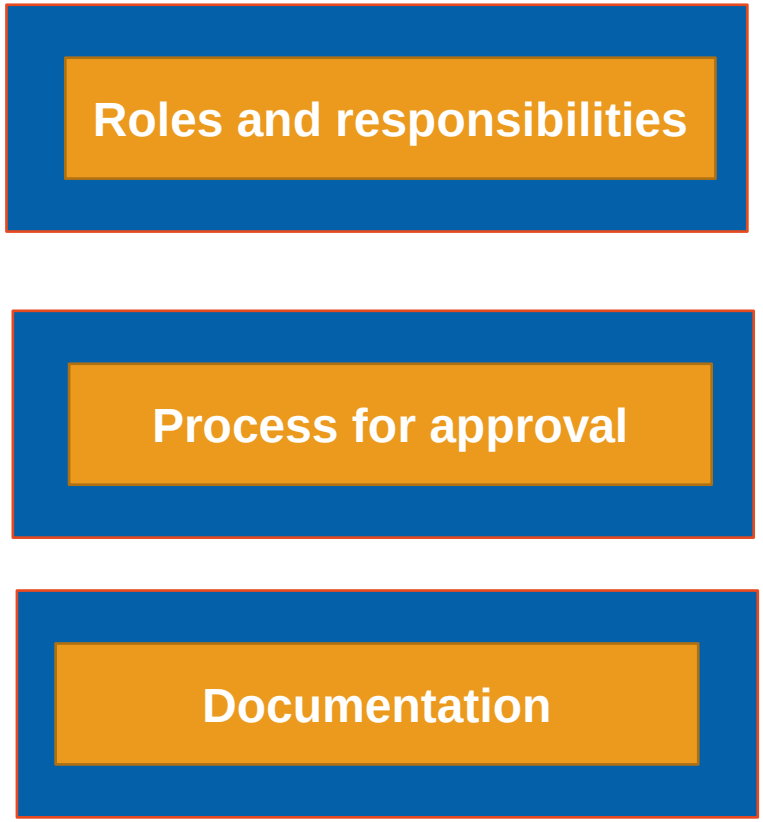
Anonymization : focus on



EFPIA Data Protection Working Group

- European Federation of Pharmaceutical Industries and Associations
- Data Protection Working Group
- Belongs to EFPIA Innovation Board Sponsored Committee (BSC)
- Representatives of all EFPIA pharma companies and member associations
- Meet every quarter

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DPWG Priorities over 2017/18

1 **GDPR implementation**	• Harmonised and research-friendly GDPR implementation
2 **Access to data**	• Shape the EU legal framework for the digital single market
3 **International transfers**	• Improve legal certainty on international data transfers for the pharmaceutical sector through code of conduct
4 **Build trust in industry practices and intentions**	• Collective efforts to develop next generation data protection standards • Principles of responsible health data use
5 **Tell strong value story around health data**	• Awareness of health data promise for public health, financial sustainability and patient benefit

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Questions for discussion

1. Would it be possible to move to a common approach to be discussed with or endorsed by Data Privacy Authorities defining thresholds, risk assessment and applicable techniques?
2. Does it make sense to have different thresholds covering different cases?
3. Could the approach above be based on a dedicated guidance covering process and related techniques?
4. How do we keep up to date with new techniques and, in such a case, how to approach an on going review of datasets?