# Legal framework and available standards

Anonymisation

- EU data protection legislation (Directive 95/46/EC); now repealed by the GDPR

- Article 29 Data Protection Working Party opinion of anonymisation techniques (Opinion 05/2014)*

- Information Commissioner's Office (ICO) Code of Practice. Anonymisation: managing data protection risk

- Sharing clinical trial data: Maximizing benefits, minimizing risk. Institute of Medicine (IOM)

- Pharmaceutical Users Software Exchange (PhUSE) de-identification standards for CDISC SDTM 3.2

- Transcelerate BioPharma Inc., Clinical Study Reports Approach to Protection of Personal Data and Data De-identification and Anonymisation of Individual Patient Data in Clinical Studies – A Model Approach
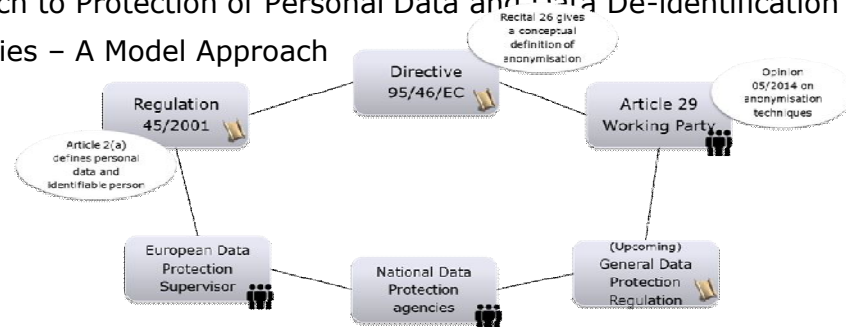
* basis of the guidance developed

Article 29 Working Party Opinion on anonymisation techniques

- Article 29 Opinion on anonymisation provides **two options** to establish if a dataset is anonymised:

1. Demonstrate that after anonymisation it is no longer possible to:

   - *Singling out:* possibility to isolate some records of an individual in the dataset*;

   - *Linkability:* ability to link, at least, two records concerning the same data subject or a group of data subjects (in the same database or in two different databases);

   - *Inference:* the possibility to deduce, with significant probability, the value of an attribute from the values of a set of other attributes

   OR

2. Perform an analysis of re-identification risk.

   * In the context of phase 1 of policy 0070, dataset are the set of clinical reports published by the Agency

External guidance on anonymisation of clinical reports for publication

- – The Agency developed guidance to pharmaceutical industry on anonymisation of clinical reports, in the context of phase 1 of the policy on publication of clinical data (policy 0070);

- – The guidance aims at **assisting companies by recommending methodologies and a process that could be applied to clinical reports**, for the purpose of achieving adequate anonymisation while retaining a maximum of scientifically useful information on medicinal products for the benefit of the public.

Anonymisation techniques

- Several anonymisation techniques* are available to MAHs/Applicants

- It is a field of active research and rapidly evolving

- From the anonymisation techniques described by the Article 29 Working Party, examples of techniques that could be applicable to clinical reports are:

    - Masking

    - Randomisation - noise addition and permutation (data utility limitations)

    - Generalisation - aggregation and k-anonymity

*The legislation is not prescriptive about the techniques to be used by data controllers.

Anonymisation of *direct* and *quasi identifiers*

- Anonymisation of *unique key-coded identifiers*

  - e.g. patient ID

- Anonymisation of *quasi identifiers* (not always necessary to redact all quasi identifiers)

  - Dates – individual patient dates can be offset
  - Geographical location - aggregate or generalise from country to region or continent
  - Small populations and rare diseases – risk assessment is key to ensure adequate anonymisation

EMA recommendation to MAHs/Applicants on how to best achieve anonymisation (1/2)

- Guidance is not intended to mandate any specific methodology but to highlight to MAHs/Applicants the available techniques and those the EMA considers most relevant in the context of the anonymisation of clinical reports

  - Masking is likely to be used by MAHs/Applicants initially since pharmaceutical companies will have to anonymise their data retrospectively, i.e. after the clinical report has already been written. However, redaction used alone is more likely to decrease the clinical utility of the data compared to other techniques

  - Therefore, randomisation and generalisation techniques are recommended in order to optimise the clinical usefulness of the information published

EMA recommendation to MAHs/Applicants on how to best achieve anonymisation (2/2)

- It is up to a company taking due account of the ultimate purpose and use of the clinical reports (i.e. publication subject to ToU) on the basis of the guidance made available to decide

  - Which option to use (demonstrate that after anonymisation all three criteria are fulfilled - singling out, linkability and inference, **or** perform a risk assessment)

  - Which anonymisation techniques to use in order to achieve adequate anonymisation while retaining a maximum of scientifically useful information

EMA consultation of the EDPS

✓ **EMA consulted the EDPS** on the implementation of the Proactive Publication Policy 0070, and in particular the **draft External Guidance on Anonymisation**.

✓ EDPS provided a reply to the consultation in January 2016 - recognized the inherent conflict between transparency and protection of privacy and praised EMA "*for the considerable effort to provide practical guidance on how to achieve these conflicting objectives*".

✓ **EDPS acknowledges** that for Policy 0070 there are constraints which make the **very low likelihood of possible re-identification** of the data subject the only consistent safeguards for the protection of personal data; EDPS does not take a final view on this and **invites EMA to follow scientific development**.

✓ EMA remains responsible for the operation of the database and for any data protection issues (creation of an *alert mechanism*).

Thank you for your attention

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