EMA Clinical Data Publication: experience to date and future direction

Continued Evolution of Data Sharing- PSI conference 2018

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Policy 0070 purpose

**Policy 0070:**
- 2 October 2014, Clinical Data Publication

**What is it:**
- Publication of clinical data supporting CHMP Assessments

**Benefits:**
- **Transparency**, continued EMA commitment
- Proactive publication enables **public scrutiny**: establishes trust, confidence
- **Better public information**: Public access enables application of new knowledge in future research, increases efficiency of medicine development, learning from experience
- **Avoids clinical trials duplication**: limits unnecessary patient exposure
- **Enhanced scientific knowledge**/value of secondary analysis: sharing scientific knowledge, contribution to public health
June 2013: draft policy for consultation

October 2014: policy adoption

January 2015: policy effective

October 2016: 1st publication
Policy implementation

**Phase I**
- Clinical reports = clinical overview, clinical summary, clinical study reports, protocol & amendments, sample case report form, documentation of statistical methods
- **EMA is working on Phase I implementation**

**Phase II**
- Individual patient data (IPD)
- **Later stage**
Online access to clinical data for medicinal products for human use

https://clinicaldata.ema.europa.eu
## Overview of 1st year data (Oct 2016- Oct 2017)

### Type of published procedure

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### Published documents

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<td>Anonymisation Report</td>
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Concept of anonymisation

• **Policy 0070** states that **adequate personal data protection needs to be ensured** and that full compliance with applicable EU legislation needs to be achieved.

• **Directive 95/46/EC** excludes anonymised data from the scope of data protection legislation. To anonymise any data, the data must be processed in such a way that it can no longer be used to identify a natural person by using “**all the means likely reasonably to be used**” by either the controller or a third party.

• **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.
Anonymisation criteria

Two options are available to establish if the data are anonymised:

1) Demonstration of effective anonymisation based on three criteria:
   ✓ Possibility to single out an individual.
   ✓ Possibility to link records relating to an individual.
   ✓ Whether information can be inferred concerning an individual.

2) Evaluation of the risk of re-identification against a pre-defined threshold.
Anonymisation process

1. Determination of direct identifiers and quasi-identifiers;
2. Identification of possible adversaries and plausible attacks on the data;
3. Evaluation of the actual risk of re-identification (and determination of the risk of re-identification threshold);
4. Data utility considerations;
5. Choice of anonymisation methodology and level of anonymisation;
6. Evaluation that the actual risk of re-identification is below threshold set after data have been anonymised.
What can impact the level of anonymisation required? (1/2)

- Context of data disclosure;
- Prevalence of disease;
- Study characteristics (i.e. sample size, number of sites, number of countries);
- Frequency of trials participants with same value on a set of quasi identifiers (i.e. group size);
- Number of quasi identifiers per trial participants (e.g. narratives);
- Data utility considerations.
What can impact the level of anonymisation required? (2/2)

- **Plausible attackers**

  - Acquaintances
  - Family members
  - Neighbours
  - Colleagues
  - Acquaintances
  - Hackers
  - Insurance companies
  - Academic researchers
  - Lawyers
  - Competitors
  - Journalists

Other aspects to consider:
- Knowledge that a specific subject is in the data set;
- Time, cost and effort: to what extent?
- Breach of law.
Risk assessment: qualitative approach

• Qualitative risk threshold to be set (e.g. low, very low);
• No calculation of re-identification risk;
• Risk assessment based on subjective evaluation;
• Analytical approach?
• Redaction as preferred technique;
• Study categorisation driven by sample size;
• Heterogeneity in the anonymisation performed.
Risk assessment: quantitative approach

• Quantitative risk threshold to be set (0.09);
• Calculation of re-identification risk;
• Transformation as additional technique (e.g. pseudo-anonymisation, offset dates, randomisation, generalisation of medical history to MedDRA HLT, HLGT and SOC);
• Less conservative assumptions (attacker knowledge, data set considered);
• Different methodologies applied.
Anonymisation: applied techniques

Reduction vs. Transformation

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Technical Anonymisation Group (TAG)

• Call for expression of interests from experts launched on April 2017;

• Composed of 20 members with a broad range of expertise, ensuring a diverse representation of the various stakeholders (e.g. data protection lawyers, experts in anonymisation standards, patient representatives);

• First TAG meeting took place on 29-30 November 2017.
Technical Anonymisation Group (TAG)

Objectives:

• To learn from the experience gained with the publication of the first clinical reports and to assess best practices in the field of anonymisation, assess patient re-identification and any privacy risk, taking into account EU law on data protection;

• To understand the challenges encountered by pharmaceutical industry while anonymising the reports for publication;

• To investigate if data transformation resulting from the anonymisation techniques used can lead to a different interpretation of the study results;

• To investigate the scientific utility of the clinical data published as a function of the methodology used by the Applicant/MAH in the anonymization of the reports, and establish whether secondary analysis of clinical data can be successfully undertaken using the data published by the Agency;

• To follow new technological developments that might impact on the anonymization of clinical reports and establish adequate measures to keep the risk of re-identification to an adequate level.
Technical Anonymisation Group (TAG)

Next steps:

- Anonymisation techniques
- Potential attackers
- Data utility
- New Technological developments
- Legal issues/GDPR
Conclusions

• Good engagement from MAHs (100 dossiers published);

• Anonymisation poses a challenge for all parties involved in the anonymisation of clinical reports;

• Confidence will be gained with the experience (public release, potential adversaries, threshold);

• Inputs from TAG will help defining best practices in anonymisation.
Any questions?

Further information

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