EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Technical Anonymisation Group (TAG)

EMA-Industry Clinical Data Publication Webinar
29 January 2018

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TAG Anonymisation – Background

- The Agency published in March 2016 the External guidance on the anonymisation of clinical reports which provides information to the pharmaceutical industry on the anonymisation of clinical reports;
- The field of anonymisation, and in particular the techniques used by controllers of personal data to anonymise data, is a field of active research and rapidly evolving;
- Therefore, anonymisation poses a challenge for all parties involved in the anonymisation of clinical reports (pharmaceutical industry, CROs and EMA) as well as those wanting to access the data (patients and healthcare professionals);
- EMA has identified the need to continue the work undertaken during the development of the guidance and will seek input from experts in the field by setting up a **Technical Anonymisation Group** (TAG);
- In March 2017, EMA launched a public call for applications.

TAG Anonymisation – Composition

The TAG is composed of 20 members with a broad range of expertise, ensuring a diverse representation of the various stakeholders as follows:

- Data protection lawyers/experts from Data Protection Authorities
- Industry professionals with direct experience in the anonymisation of clinical reports
- Professionals involved in development of de-identification standards and/or guidance
- Patients organisations representative
- EMA staff members

TAG Anonymisation – Objectives (1/2)

The overall objective of the TAG is to further develop best practices for the anonymisation of clinical reports, by monitoring and addressing any issues arising in the context of the implementation of phase I of policy 0070.

The following tasks will be undertaken:

- 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.

TAG Anonymisation – Objectives (2/2)

- 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 anonymisation 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 anonymisation of clinical reports and establish adequate measures to keep the risk of re-identification to an adequate level.

TAG Anonymisation – Deliverables

The Agency, based on the outcome of the work of the TAG, will:

- make any necessary amendments to the external guidance on anonymisation of clinical reports.
- develop additional guidance (e.g. Q&A) to further clarify certain aspects of the methodology described in the external guidance on the anonymisation of clinical reports, if necessary.
- draft a critical review of the impact of new technological developments on the anonymisation of clinical reports, in particular on the methodology used to adequately anonymise clinical reports and the potential impact on the recommended threshold for public release.

TAG Anonymisation – Transparency

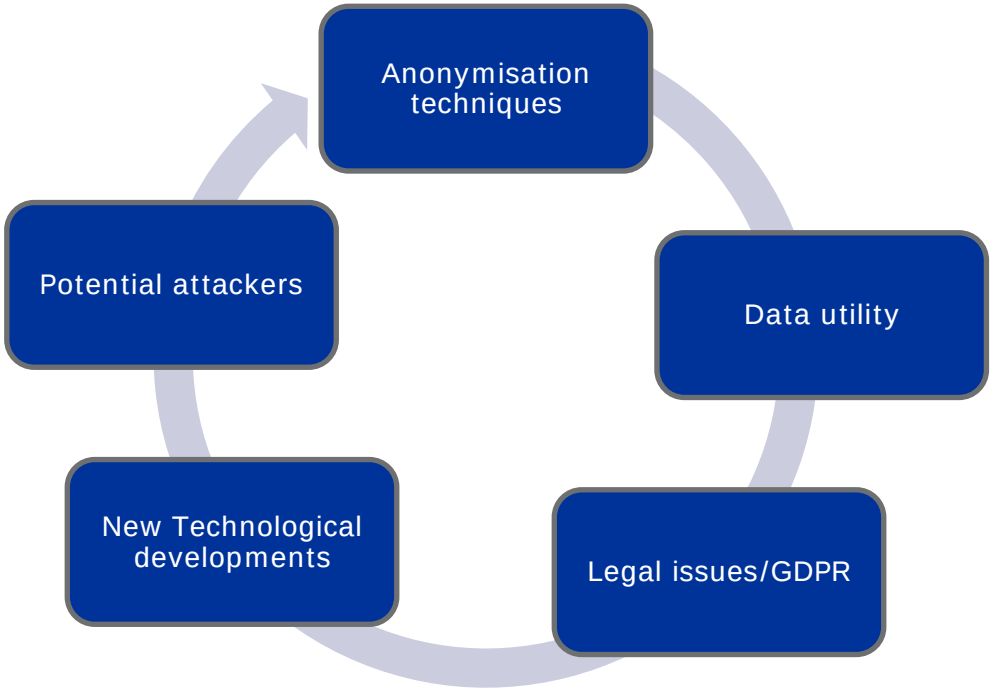
- The list of members of the TAG is published in the EMA website together with their declaration of interest (DoIs) and curriculum vitae (CV).
- The progress of the work undertaken by the TAG will be made public through the drafting of periodic reports which will subsequently be published in the Agency's website.
- Minutes and agendas of the meetings will also be published by the Agency.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001880.jsp&mid=WC0b01ac0580c77e78

TAG Anonymisation - First meeting

- The first TAG meeting took place on **29-30 November 2017**;
- Topics discussed during the meeting:
  - Review of clinical reports published from October 2016 to October 2017 performed by EMA and by PhUSE;
  - Experience from Pharmaceutical Industry with the anonymisation of clinical reports;
  - EMA experience with the review of Anonymisation Reports;
  - Review of quantitative methods to measure the risk of re-identification;
  - Data utility in anonymised clinical reports;
  - Adversary knowledge
  - Legal issues with the anonymisation of clinical reports and the impact of the GDPR.

TAG Anonymisation - Next steps



Thank you for your attention

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