EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Technical Anonymisation Group (TAG)

Call for applications
Industry Associations webinar, 23 March 2017

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Policy and Crisis Coordinating Officer

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).*

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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 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.

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 anonymization 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 anonymization of clinical reports, if necessary.
- draft a critical review of the impact of new technological developments on the anonymization 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 – Composition

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

- Data protection lawyers/experts
- Industry professionals with direct experience in the anonymisation of clinical data
- Professionals involved in development of de-identification standards and/or guidance
- Patients and HCPs organisations representatives

TAG Anonymisation – Applications

Individuals interested in becoming members of the TAG should send their CV and the declaration of interests form to:

TAG@ema.europa.eu by **28/04/2017**

Thank you for your attention

Further information

[Insert relevant information sources or contact details as applicable.]

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