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European Medicines Agency

EMA Technical Anonymisation Group (TAG)

Terms of reference

Background

Policy 0070 states that adequate personal data protection needs to be ensured in full compliance with applicable EU legislation. Therefore, in the context of the implementation of phase 1 of EMA Policy 0070 (publication of clinical reports on EMA's website) the Agency released in March 2016 an external guidance on the anonymisation of clinical reports. The guidance provides information to the pharmaceutical industry on the anonymisation of clinical reports, i.e. on some of the anonymisation techniques that are available to Marketing Authorisation Holders (MAHs)/applicants.

The guidance also highlights that the aim of EMA is to retain a maximum of scientifically useful information on medicinal products for the benefit of the public, while achieving adequate anonymisation.

The guidance was discussed at meetings held in June, July and September 2015 with patient and consumer organisations, pharmaceutical industry associations, and representatives from academia and research bodies.

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 major 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 and finalisation of the guidance and will seek input from experts in the field by setting up a Technical Anonymisation Group (TAG).

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Composition and rules of participation

The TAG shall be composed of experts with specific knowledge of data privacy in healthcare, anonymization of health data, in particular of clinical data and re-analysis of clinical data (accessed publicly or via a data sharing agreement). The members of the TAG will be selected according to their specific expertise following a public call.

Members shall be individuals appointed in a personal capacity. Members appointed in a personal capacity shall act independently and in the public interest.

The final composition of the TAG will be decided by the EMA (maximum of 20 members) based on the expertise of the candidates while ensuring a diverse representation of the various stakeholders.

Membership of the TAG implies a commitment to participate actively in the work of the group and to attend the meetings and tele/videoconferences.

The TAG will operate in English.

Meeting frequency

There is no limit to the number of face-to-face meetings although it is anticipated that a maximum of 2 meetings will be convened followed by subsequent tele/videoconferences. Additional face-to-face meetings might be organised, if necessary. Non–industry members may be reimbursed for attendance at face-to-face meetings (reasonable expenses in terms of accommodation and travel costs).

Organisation of meetings and reporting arrangements

Meetings are either face to face or virtual. The face to face meetings shall take place at the Agency.

The draft agenda/points for discussion for meetings shall be circulated, together with relevant documents, by the EMA in advance of the meeting. The Agency shall draft minutes of the meeting and record participants.

The group is supported by a secretariat provided by EMA.

The secretariat is responsible to agree on the meeting agendas and the questions that need to be presented to the TAG, with an indication of the expected deliverables.

Mandate

The overall objective of the TAG is to establish best practices for the anonymisation of clinical reports, by monitoring and addressing any issues arising in the context of the implementation of phase 1 of policy 0070.

EMA has identified the need to continue the work undertaken during the development and finalisation of the external guidance on the anonymisation of clinical reports. To this end 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. In particular, to understand the complexity involved in the anonymisation of clinical reports in the case of rare diseases and small populations, due to the very low number of trial participants and of overall population;
- 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 MAH/applicant 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.

Any additional tasks may be considered by the EMA Secretariat.

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

- Make the 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. The impact on the utility of the data published will also be reviewed.

Duration of activity

The TAG will start operating following confirmation of external experts' membership. The activities of the TAG are expected to last 2 years. The operation of the TAG may be extended by the EMA, if necessary.

Transparency

The progress of the TAG anonymisation and the decisions taken 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.

All members of the TAG are required to complete a declaration of interest (DoI) and submit it to the Agency together with their curriculum vitae (CV). DoIs are required to ensure full transparency on interests TAG members may have. Therefore, the DoIs will be published together with the CVs of the members.