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European Medicines Agency

Selection of members of the Technical Anonymisation Group (TAG)

Call for applications

1. 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 Agency has identified the need to continue the work undertaken during the development and finalisation of the external guidance on the anonymisation of clinical reports for publication and will seek input from experts in the field by setting up a Technical Anonymisation Group (TAG).

EMA is calling for applications with a view to selecting members of the group. Work undertaken will be non-remunerated, although reimbursement of reasonable expenses in terms of accommodation and travel costs can be undertaken.

2. Features of the group

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 EMA Policy 0070.

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Composition

The group shall consist of up to 20 members. Members shall be individuals appointed in a personal capacity. Members appointed in a personal capacity shall act independently and in the public interest.

Appointment

Members shall be appointed by EMA from applicants complying with the requirements referred to in section 5 of this call.

Members shall be appointed for a maximum of 2 years, which can be renewed.

Rules of engagement and operation of the group

The group will be chaired by an EMA staff member.

The TAG is set up on the basis of terms of reference defined by EMA. The TAG shall be dissolved as soon as their mandate is fulfilled.

Approximately two face to face meetings per year will be organised in addition to tele/videoconferences. EMA shall provide the meeting agendas, the minutes and the final documents.

Members should be prepared to attend meetings systematically, to contribute actively to discussions in the group, to be involved in preparatory work ahead of meetings, to examine and provide comments on documents under discussion.

As a general rule, working documents will be drafted in English and meetings will be also conducted in English.

On a proposal by and in agreement with EMA the group shall adopt its rules of procedure on the basis of the standard rules of procedure for EMA technical groups.

Transparency

EMA shall make available all relevant documents, including the agendas, the minutes and the final reports, on EMA's website.

Personal data shall be collected, processed and published in accordance with Regulation (EC) No 45/2001.

3. Application procedure

Interested individuals are invited to submit their application to EMA. An application will be deemed admissible only if it is sent before the deadline and includes the documents referred to below. All documents submitted by applicants should be duly filled in, legible, signed and numbered sequentially.

Each application shall include the following documents:

- A *curriculum vitae* (CV), preferably not exceeding three pages. All CVs shall be submitted in the European format (https://europass.cedefop.europa.eu/en/documents/curriculum-vitae/templates-instructions).
- Applicants must disclose any circumstances that could give rise to a competing interest by submitting a declaration of interests ('DoI') form on the basis of the standard EMA DoI form for experts and committee members which is attached to this call. Submission of a duly completed DoI form is necessary in order to be eligible to be appointed in a personal capacity.
- Additional supporting documents (e.g. publications) may be requested.

Deadline for application

The applications must be sent by email to TAG@ema.europa.eu by 28 April 2017 at the latest.

4. Eligibility criteria

Applicants must have:

- a university degree,
- demonstrated relevant professional experience, in positions such as
  - Healthcare manager at local, regional, national or international level, in primary health care services, hospitals, insurance organisations, health authority or international organisations;
  - Senior researcher/fellow in health systems, epidemiology, public health or social policy;
  - Policy maker or advisor on public health and health policies in the area of data privacy;
  - Data scientist, statistician and/or epidemiologist;
  - Data protection lawyer/expert.

5. Selection criteria

The Agency will take the following criteria into account when assessing applications:

- proven excellence in one or preferably several fields of expertise covered by the TAG, namely:
  - data privacy in healthcare;
  - anonymization of health data, in particular of clinical data;
  - re-analysis of clinical data (accessed publicly or via a data sharing agreement)
- good knowledge of the English language allowing active participation in the discussions.

6. Selection procedure

The selection process will consist of three stages:

- verification of the admissibility of the applications (as defined in Section 3) and eligibility of applicants against the criteria set in Section 4;
- evaluation of applications against the criteria set in Section 5;
- establishment of a list of the most suitable applicants.

When defining the composition of the group, EMA shall aim at ensuring, as far as possible, a high level of expertise, as well as a balanced representation of relevant know how and areas of interest, while taking into account the specific tasks of the group, the type of expertise required, as well as the relevance of the applications received.

For any further information please contact TAG@ema.europa.eu

7. Data privacy statement

All personal data provided by applicants will be processed in compliance with Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. This applies in particular to the confidentiality and security of such data. The submission of personal data by applicants will be collected by the Agency for the sole purpose of selecting candidates with particular knowledge in the areas of expertise identified for the establishment of a TAG (as indicated in section 5). This is consistent with the broader functional need of the Agency in relation to the implementation of phase 1 of EMA Policy 0070. Such data will be used in this specific context only and accessed by staff members with defined responsibilities within the Agency's Administrative Division (namely the Administrative and Corporate Management Division). Such information will be stored in a secure and protected database for a maximum period of two years. All applicants have a right to access their personal data concerning them and they also have a right to update or correct at any time those data, together with all the other rights under the abovementioned Regulation. Data subjects may at any time consult the Agency's Data Protection Officer (dataprotection@ema.europa.eu). Applicants also have recourse at any time to the European Data Protection Supervisor if they consider that their rights under this Regulation have been infringed as a result of the processing of their personal data.

Annex 1

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).

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.

Annex 2

- Public declaration of interests