Updates From The EMA Technical Anonymization Group & Policy 0070

The European Medicines Agency (EMA) has established an expert group in data anonymisation known as the technical anonymisation group (TAG) to help further develop best practices for the anonymisation of clinical reports, in the context of the Agency's policy on the publication of clinical data. The group includes members from academia, industry, patients and healthcare professionals with expertise in areas such as data protection, developing standards and guidance for anonymisation and re-analysis of clinical data. EMA established the group following a public call for applications launched in March 2017. The group will consider experience to date with EMA's publication of clinical reports. In particular, it will assess:

• patient re-identification and any privacy risks in the light of new technological developments;

• the scientific utility of the published clinical data as a function of the anonymisation methodology used;

• whether it is possible to successfully conduct a secondary analysis of the anonymised clinical data.

The European Medicines Agency policy on the publication of clinical data for medicinal products for human use (Policy 0070) is composed of two phases.

- Phase 1 of Policy 0070 entered into force on 1st January 2015
- Phase 2, which will be implemented at a later stage, pertains to the publishing of individual patient data

The TAG has been tasked to help further develop best practices for the anonymisation of clinical reports, in the context of the Agency's policy on the publication of clinical data. Currently the TAG is not focused of Phase 2 of policy 0070.

External Member of the TAG are listed below

Name	Curriculum vitae (CV)	Declaration of interests(DoI)
Khaled El Emam	Khaled El Emam CV	Khaled El Emam DoI
Jean-Marc Ferran	Jean-Marc Ferran CV	Jean-Marc Ferran DoI
Uwe Fiedler	Uwe Fiedler CV	Uwe Fiedler DoI
Christine Fletcher	Christine Fletcher CV	Christine Fletcher DOI
Cathal Gallagher	Cathal Gallagher CV	Cathal Gallagher DOI
Lukasz Kniola	Lukasz Kniola CV	Lukasz Kniola DOI
Bradley Malin	Bradley Malin CV	Bradley Malin DOI
Sarah Nevitt	Sarah Nevitt CV	Sarah Nevitt DOI
Nicola Orlandi	Nicola Orlandi CV	Nicola Orlandi DOI
Lee Parker	Lee Parker CV	Lee Parker DOI
Frank Rockhold	Frank Rockhold CV	Frank Rockhold DOI

Kristian Svendsen	Kristian Svendsen CV	Kristian Svendsen DOI
Rafal Swierzewski	Rafal Swierzewski CV	Rafal Swierzewski DOI

The following individuals are also members of the TAG:

- Monica Dias (chair, EMA)
- Ada Adriano (EMA)
- Anne-Sophie Henry-Eude (EMA)
- Frank Pétavy (EMA)
- Karen Quigley (EMA)
- Alessandro Spina (EMA)
- Giuseppe d'Acquisto (Italian data protection authority)
- Dina Kampouraki (observer, European data protection supervisor)

The first meeting of the TAG was on the 29th November in London and lasted 2 days. Below is a list of topics discussed with some highlights.

- Review of clinical reports published from October 2016 to October 2017 performed by EMA and by PhUSE;

  The findings highlighted that a qualitative risk assessment was done on most of submissions, redaction was the anonymisation method most visible. In terms of data utility aggregated summaries and tables were considered to have the most scientific value and were retained in the clinical reports.

- Experience from Pharmaceutical Industry with the anonymisation of clinical reports;

  It was recognised that the utility of the data is an area of where further improvement is needed. The Tag members were split on whether the information available on social media should be taken into account in the calculation of the risk of re-identification.

- EMA experience with the review of Anonymisation Reports;

  The section of the anonymisation report addressing data utility was generally found to be of low quality. TAG members mentioned that it is important to establish the target stakeholders for the anonymisation reports

- Review of quantitative methods to measure the risk of re-identification;

  Most tend to make conservative assumptions to avoid taking any risk of re-identification. It was agreed that further guidance on quantitative approaches was necessary.

- Data utility in anonymised clinical reports;

More effort on preserving Subject IDs and Dates in an anonymised format should be considered to enable following patients through the narratives, any potential relationships as well as timing of events.

- Adversary knowledge;

  A presentation about the data available that can be cross linked with trial data created discussions around a motivated intruder using public information or acquaintance information. This area was identified as one which requires development of further guidance.

- Legal issues with the anonymisation of clinical reports and the impact of the GDPR.

  There was a discussion about a common approach endorsed by the data protection authorities defining thresholds, process and related techniques would be valuable. The TAG discussed at length the benefits and challenges a code of conduct could have to streamline the publication of anonymised CSRs.

After this first meeting we divided the TAG into 5 subgroups. (a TAG member can be a part of more than one subgroup.) Each Sub group has an EMA Lead.

Data Utility - EMA Lead - Anne Sophie Henry-Eude

- Frank Rockhold
- Sarah Nevitt
- Jean-Marc Ferran
- Kristian Svendsen
- Khaled El-emam
- Rafał Świerzewski

Anonymisation approaches and techniques – EMA Lead - Karen Quigley

- Bradley Malin
- Christine Fletcher
- Jean-Marc Ferran
- Rafał Świerzewski
- Giuseppe d'Acquisto
- Khaled El-emam

Plausible attackers – EMA Lead - Ada Adriano

- Lukasz Kniola
- Christine Fletcher
- Bradley Malin

Legal issues/GDPR – EMA Lead - Alessandro Spina

- Uwe Fielder
- Nicola Orlandi
- Giuseppe d'Acquisto
- Lee Parker

New technological developments – EMA Lead - Frank Petavy

- Lukasz Kniola
- Rafał Świerzewski
- Cathal Callagher

The next TAG meeting has be preliminarily set for the 23rd - 24th October in London. Meanwhile the Subgroups have been meeting separately. At the next meeting w can expect to get an update from the work each subgroup has been carrying out, as well as a continued focus on data utility and discussions on how to move from redaction towards anonymisation.