Welcome to CTAG3

Clinical Trial Advisory Group on Rules of engagement

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Housekeeping: Please…

- Note this meeting is recorded to ensure we capture all comments
- Use a headset with microphone if you have one
- Mute your microphone (please do so now)
- Raise your hand if you want to speak (please do so now)
- Lower your hand only after you are done speaking (please do so now)
- Unmute your microphone when you have the floor
- Use the comment box for technical issues only (IT support present)

Ground rules

- Data *will* be made accessible
- This is an *Advisory* Group
- Consensus would be ideal, opposing views are accepted
- Comments will be invited after this initial meeting (in a fixed format)
- Output of this group will be a written advice to the EMA

Time line

- Five advisory groups were established **January 2013**
  1. Protecting patient confidentiality
  2. Clinical trials data formats
  3. Rules of engagement
  4. Good analysis practice
  5. Legal aspects
- 2-3 Meetings to take place **January to April 2013**
- Final advice from each group by **30 April 2013**
- Draft EMA policy for public consultation by **30 June 2013**
- End of consultation phase **30 September 2013**
- Publication of final EMA policy **30 November 2013**
- Coming into force **01 January 2014**

Today's menu…

1. Should requesters be required to identify themselves?
2. Should requesters be required to 'Agree' to respect personal data protection?
3. Should requesters be required to 'Agree' to refrain from (to be defined?) commercial uses of information retrieved?
4. Should requesters be made aware of quality standards for additional / secondary analyses?
5. Should requesters be required to declare whether they wish to upload a protocol / analysis plan? (Click yes/no) If yes, an opportunity for uploading would be provided on the screen
6. Sharing of data
7. Timelines
8. Feedback
9. Cross-group communication

1. Should requesters be required to identify themselves?

Explanatory note: in the spirit of two-way transparency, should anonymous downloads be allowed? If no, should the name and affiliation of the requester be logged and made public, as well as the information retrieved? Technical implementation to be discussed (how can we ensure true information is provided?)

Different level of data

Group view that for aggregate level (risk negl.) no hurdles to access. Where risk exists some hurdles could apply.

General agreement by majority

2. Should requesters be required to 'Agree' to respect personal data protection?

Explanatory note: Should the requester be reminded of and have to commit to respecting applicable personal data protection rules / legislation? (e.g.: At the end of the page a 'read and accepted' tick box will appear which needs to be ticked before the requester can open the next screen). Is this acceptable and legally and practically feasible?

Two positions

If yes: only if requester can be identified and if legal repercussions can be taken

3. Should requesters be required to 'Agree' to refrain from (to be defined?) commercial uses of information retrieved?

Explanatory note: The intention of this step would be to prevent requesters from using data for competitive, commercial (as opposed to public health) purposes. At the end of the page there could appear a 'read and accepted' tick box which needs to be ticked before the requester can open the next screen. Is this acceptable and legally and practically feasible?

4. Should requesters be made aware of quality standards for additional / secondary analyses?

Explanatory note: The intention of this step would be to inform / remind requesters of applicable quality standards for different types of secondary analyses (e.g. meta-analysis), and/or what is deemed acceptable quality standards by the agency. It is understood that this step would do little to prevent substandard analyses from being conducted and published but it may help the agency deal with such analyses. At the end of the page there could appear a 'read' tick box which needs to be ticked before the requester can open the next screen. Is this acceptable and legally and practically feasible?

Reference to guidance document

5. Should requesters be required to declare whether they wish to upload a protocol / analysis plan? (Click yes/no) If yes, an opportunity for uploading would be provided on the screen.

Explanatory note: It is good scientific practice to finalize the analysis plan before conducting a study. This is mainly to guard against 'fishing expeditions' where data dredging exercises will be presented as 'confirmatory evidence'. Should requesters therefore be given an opportunity to publicly log their analysis plan before gaining access to the data? There is no intention to make uploading of an analysis plan a condition for access; neither does the agency intend to evaluate plans at the time of data accessing. However, any uploaded information (or lack thereof) would be placed in the public domain once data have been accessed. The intention of this step would be to inform the scientific community's interpretation of published results of secondary /additional analyses.

6. Sharing of data
7. Timelines
8. Feedback

Meeting document will be sent to all via email
Comments document form will be attached
Doodle request for 4 or 8 March to follow