Advice to the European Medicines Agency from the clinical trial advisory group on Protecting Patient Confidentiality - Discussion document

10 January 2012

Introductory note

This is a draft proposal intended to stimulate and structure the upcoming discussion among members of the advisory group on protecting patient confidentiality, which is set up to inform the upcoming EMA policy on clinical trial data transparency. The draft document is not intended to pre-empt the content of the policy the agency will ultimately adopt. All proposals are deliberately kept at a high level to enable discussion. It is expected that more detail will be added during the discussion process.

Problem statement

How can EMA ensure through its policy that patient and other personal information will be adequately protected i.e., that patients cannot be retroactively identified when clinical trial data are released, and that applicable legislation, standards, and rules regarding personal data protection will be respected?

Discussion proposal

1. Scope and definitions

    1.1. This advice refers to any information containing clinical data (e.g., electronic raw data, clinical study reports, line listings, case narratives) that are part of a submission for marketing authorisation to the Agency.

    1.2. Personal data: Data related to any persons, in particular to individuals included in clinical trials (e.g., patients or healthy volunteers and their legal representatives, hereinafter referred to as “subjects”), and any other individual (investigators, study site personnel, sponsor representatives, contracted workers, etc., hereinafter referred as “clinical trial personnel”).

    1.3. Anonymising data: Data transformation methods for removing the information that could identify subjects directly or indirectly. Similar terms are “data redaction” or “de-identification of data”.

    Are the definitions and scope agreed?

2. Clinical Trial Personnel’s Data

    2.1. Personal data of clinical trial personnel (name, CV, affiliation, etc.) are considered as professional information that is essential to be made public justified by grounds of important public interest in the area of public health protection and scientific research.

    Is this agreed?

    2.2. Applicant companies should not submit any additional personal information related to clinical trial personnel that are not essential to be made public for assessing the trial.

    Is this always possible?

3. Subjects' Data

3.1. All data allowing to identify subjects directly shall be submitted in an anonymised format (e.g., using a subject identification code instead of the subject's name).

This is already the standard practice.

3.2. Apart from direct identification, there is a risk that clinical trial data may allow to identify the subjects indirectly, through a combination of potential indirect identifiers.

Should other risks be mentioned here?

3.3. For each document to be submitted to the Agency (e.g., study report, data set), including any subsequent revisions, the applicant company shall assess the risk of compromising subjects' identity in case of publication of that document.

Is it agreed that this should be the responsibility of the applicant company?

3.4. If for any document the risk is considered to be absent or sufficiently low, the applicant company shall clearly label the document as "SUITABLE FOR PUBLICATION".

Is "sufficiently low" risk an acceptable and useful term? Should there be a clearer definition?

3.5. If for any document the risk cannot be considered to be absent or sufficiently low, the applicant company shall produce two documents, the original document clearly labelled as "NOT FOR PUBLICATION, and an anonymised document clearly labelled as "SUITABLE FOR PUBLICATION".

Is it agreed that applicant companies should be asked to produce two sets of documents when necessary?

3.6. Applicant companies may use different transformation methods to anonymise the data. A minimum standard for anonymising data sets to ensure patient privacy when sharing clinical research data is described in Hrynaszkiewicz et al. (1)

Can this standard be generally agreed? Should the Agency develop further guidance?

3.7. Anonymisation methods shall be individually tailored to the specific dataset and situation to ensure that a maximum of information is available while at the same time ensuring sufficient personal data protection.

Can one be more specific about how methods should be "individually tailored"?

3.8. Applicant companies shall describe in general terms and justify for each document the anonymisation methods used.

Is this agreed?

3.9. The Agency will not systematically verify that the data submitted as anonymised data contain no personal data – this is considered the responsibility of the applicant company.

Can this responsibility of the applicant companies be agreed?

3.10. The Agency may verify that the stated methodology conforms to standard transformation methods to anonymise the data. If the anonymisation methods are deemed insufficient or excessive, the Agency shall ask the applicant company to further justify and if necessary modify the anonymisation method.

Can this approach be agreed? Should it be done systematically for all documents?

3.11. Upon request, the Agency shall provide advice to applicant companies, (where necessary involving relevant patient groups and members of the public), on the adequacy of the methods for anonymising data.

Can this approach be agreed?

4. References

(1) Hrynaszkiewicz, I., M. L. Norton, et al. (2010). "Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers." BMJ **340**: c181.

Additional points for discussion: