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Questions and answers

Public consultation on implementation of transparency requirements of the European Clinical Trial Regulation

What is the European Clinical Trial Regulation about?

The Clinical Trial Regulation EU No. 536/2014 ensures that the rules for conducting clinical trials are consistent across the European Union (EU). The goal of the Regulation is to create an environment that is favourable to conducting clinical trials in the EU with the highest standards of safety for participants.

The Regulation also aims to increase transparency in the conduct of clinical trials in the EU, from the point of authorisation of the trials to the publication of the results, thereby improving the information available to patients, carers and healthcare professionals on ongoing clinical trials. This is also expected to foster innovation and stimulate research, as well as helping avoid unnecessary duplication of clinical trials, and repetition of trials that have been terminated due to major safety or efficacy failures.

What are the transparency requirements of the European Clinical Trial Regulation?

The European Clinical Trial Regulation aims to make publicly available information about all clinical trial applications assessed and all clinical trials conducted in the EU.

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The information that will be made public for all clinical trials will include amongst other: the major characteristics of the trial; treatment population characteristics and number of subjects; inclusion and exclusion criteria, main objectives and endpoints; the dates of the start and end of recruitment; substantial modifications made to protocol during the trial; the end date of the trial and, 12 months later, the summary of results and a lay summary.

For clinical trials included in a marketing authorisation application in the EU, clinical study reports will also be published 30 days after the procedure for granting the marketing authorisation has been completed or the applicant for marketing authorisation has withdrawn the application.

Although the Regulation states that information on clinical trials shall be publicly available, confidential information will be withheld. The Regulation states that confidentiality is justified on any of the following grounds:

- protecting personal data;
- protecting commercially confidential information, in particular taking into account the marketing authorisation status of the medicine, unless there is an overriding public interest;
- protecting confidential communication between Member States in the preparation of their assessment;
- ensuring effective supervision of the conduct of clinical trials by Member States.

What is the role of the European Medicines Agency in implementing the Regulation?

While authorisation and oversight of clinical trials remains the competence of EU Member States, the European Clinical Trial Regulation requires the Agency to develop and maintain a clinical trial portal and database to be used for the submission, authorisation and supervision of trials in the EU, and to allow public access to information on clinical trials.

In particular, the Regulation requires the Agency to draw up a proposal on the way the EU database is expected to work. The Functional specifications for the EU portal and EU database to be audited (europa.eu) of the EU database were agreed in December 2014. At the time it was also agreed that a specific proposal would be made on how to apply the exceptions that the Regulation makes to its transparency requirements. This proposal is at the core of the document that is now open for consultation, and the revised text will be added to the 'functional specifications'.

What is the purpose of the Agency consultation?

The aim of the consultation is to receive feedback on the proposal regarding the application of the transparency requirements of the European Clinical Trial Regulation. The goal is to balance carefully the information needs of patients and the public with the needs of academia and industry to protect confidential or commercially sensitive information.

The proposal now open for consultation can be found Draft Proposal for addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014" (europa.eu).

How is the proposal under consultation addressing the transparency requirements of the Regulation?

Although the European Clinical Trial Regulation identifies the types of information to be made public, it also establishes a set of exceptions where publication is not justified because confidentiality principles apply. These relate to the protection of both personal data and commercial information. Based on this, a proposal has been drafted on how to apply the confidentiality principles in practice, taking into consideration the fact that information considered confidential at one time may no longer be confidential at a later time.

For example, certain documents which are entered into the clinical trial database are considered to contain significant confidential information, particularly for trials on medicines without a marketing authorisation. These documents include the clinical trial protocol and the related subject information sheet, the investigational medicinal product dossier, and the investigator brochure. A number of proposals are presented for the timing of when these documents should be made public. The time of publication is linked to key time points of the clinical trials and the status of the marketing authorisation of the medicine, as well as the development stage of the product (Phase I, II, III and IV trials and low intervention trials).

Stakeholders are now invited to comment on the proposal, i.e. on how the transparency requirements of the Regulation will be implemented and when and which information will be made public.

Is the proposal now open for consultation the same as the 'EMA policy on publication of clinical data'?

No, these are two different initiatives. The document now open for consultation describes how it is proposed to implement the transparency requirements of the European Clinical Trial Regulation, and when and which information on clinical trials conducted in the EU should be made public. The EMA policy on publication of clinical data determines how EMA will publish information on clinical trials that are part of marketing authorisation applications for medicines that have been authorised via EMA.

The European Clinical Trial Regulation provides new requirements for the release of an extensive set of information on all clinical trials conducted in the EU. This is in line with, but separate from, the Agency's commitment to increase transparency of clinical trial data through its policy on the publication of clinical data, which entered into force on 1 January 2015. Under this policy, the Agency will proactively publish the clinical reports[1] submitted to the Agency for human medicines, once the medicines are authorised. This means that the policy applies to clinical reports of studies that are beyond the scope of the European Clinical Trial Regulation as it, for example, also includes clinical trials that are conducted outside the EU but submitted to EMA for marketing authorisation in Europe.

More information on EMA's policy on the publication of clinical data can be found Clinical data publication | European Medicines Agency (europa.eu).

How is the consultation planned and will comments be published?

The proposal now open for consultation contains specific questions that all stakeholders are invited to address. In some cases the text offers different proposals, and stakeholders are invited to express

[1] Clinical reports shall mean the clinical overviews (generally submitted in module 2.5) and clinical summaries (generally submitted in module 2.7) and the clinical study reports (generally submitted in module 5, "CSR"), together with appendices to the CSRs no. 16.1.1 (protocol and protocol amendments), 16.1.2 (sample case report form) and 16.1.9 (documentation of statistical methods).

their preference and to provide a brief rationale for their preferred choice explaining why they consider it best meets the objectives and requirements of the Clinical Trial Regulation.

The deadline for comments is 18 February 2015. All the comments that EMA will receive will be published on the EMA website.