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Press Office

Press release

Public consultation on application of transparency rules of EU Clinical Trial Regulation

Stakeholders to submit their comments by 18 February

The public consultation on how the transparency rules of the European Clinical Trial Regulation will be applied in the new clinical trial database is launched by the European Medicines Agency (EMA) today. Stakeholders are invited to send their comments before 18 February 2015.

The European Clinical Trial Regulation aims to create an environment that is favourable to conducting clinical trials in the European Union (EU), with the highest standards of safety for participants. The Regulation ensures that the rules for conducting clinical trials are consistent throughout the EU. It also transforms the level of information publicly available for each clinical trial carried out in the EU by requiring transparency on the authorisation, conduct, and results of the trial. The Regulation will apply to clinical trials that are registered once the Regulation is in operation (not before 28 May 2016).

The key instrument to deal with clinical trials in a transparent way is the new clinical trial portal and database. It will be used for submission and maintenance of clinical trial applications and authorisations within the EU. It will serve as the source of public information on the clinical trial applications assessed, and all clinical trials conducted in the EU. According to the Regulation, EMA is responsible for the development and maintenance of the portal and database, while the authorisation and oversight of clinical trials will remain with the EU Member States.

The public will be able to access extensive details of each trial including the major characteristics of the trial, the start and end of recruitment, end date of the trial and substantial modifications to the trial. These details will be made public as they occur starting with the decision on the trial. A summary of results and lay summary will be published 12 months after the end of the trial. For those 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30 days after the procedure for granting the marketing authorisation has been completed or the application has been withdrawn.

The Regulation requires that the clinical trial database shall be publicly available unless one or more of the following exceptions apply:

- protection of personal data;

[1] Link to the template on page 2 corrected on 11.2.2015.

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

The document under consultation sets out proposals for the application of the transparency rules of the European Clinical Trial Regulation for stakeholders to review and comment on. The proposals aim to balance the right of patients and the public to access extensive and timely information on clinical trials, and developers' and researchers' need to benefit from investments. This will support the EU as a suitable location for innovative, cutting-edge research and development of medicines.

Stakeholders are invited to send comments using this template to CTReg@ema.europa.eu by close of business on 18 February 2015.

How is this public consultation linked to EMA's policy on the publication of clinical data?

This public consultation refers only to the practical application of transparency rules for the clinical trial portal and database that is established within the European Clinical Trial Regulation. The European Clinical Trial Regulation is distinct from EMA's policy on the publication of clinical data, which has already come into force (January 2015). There are several important differences between the provisions of the European Clinical Trial Regulation and EMA's policy. Under EMA's policy, the Agency proactively publishes the clinical study reports submitted as part of marketing-authorisation applications for human medicines. 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.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. For further information see the Questions and Answers document.
3. The Clinical Trial Regulation EU No. 536/2014 requires that the Agency develops and maintains the clinical trial portal and database to act as a single portal for submission and maintenance of clinical trial applications and authorisations within the EU, to support the coordinated assessment and exchange of information between Member States on the processes of authorisation and supervision of clinical trials, and to serve as the source of public information on clinical trial applications assessed, and clinical trials conducted in the EU, from the time of decision on each trial up to the inclusion of the results of those trials.
4. Draft proposal for an addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014".
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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