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Proposal for a Clinical Trials Regulation - Questions and answers

What are clinical trials?

Clinical trials are a vital step in the development of new and safe medicines and in improving medical treatment.

Human volunteers are enrolled in a clinical trial for the following reasons: to test the safety and effectiveness of new medicines, to test new indications for existing medicines or to compare two standard treatments.

The data generated in clinical trials are published in medical journals. These data can be used by companies applying for marketing authorisations. Published data also add to the knowledge base upon which medical professionals can base their decisions. For example, based on published data of a clinical trial, a doctor may prescribe a patient medicine shown to be more effective or have fewer side effects than the one currently taken.

Who conducts clinical trials?

Clinical trials are mainly conducted by the pharmaceutical industry in order to generate data on the safety and efficacy of medicinal products they are developing. There is however an increasing interest by non-industry actors with approximately 40% of clinical trials in the EU being conducted by academics, foundations, hospitals, or research-networks (often referred to as 'non-commercial sponsors'). Usually, these actors conduct clinical trials in order to improve and compare treatments with existing (authorised) medicines.

What legislation is in place to regulate clinical trials?

The conduct of clinical trials in the EU is tightly regulated. This is to uphold the rights and ensure the safety of clinical trial participants (referred to as 'subjects' in the proposed Regulation) as well as the reliability and robustness of the data generated. These rules are set out in the 'Clinical Trials Directive' (2001/20/EC).

Why is the Commission proposing to replace this legislation?

The Clinical Trials Directive has been criticised by patients, researchers and industry alike for its disproportionate regulatory requirements. High costs and a lack of harmonisation of the applicable rules necessary for multinational clinical trials are a few examples.

This has contributed to a significant decline of clinical trials in the EU. Between 2007 and 2011 the number of clinical trials conducted in the EU fell by 25%. The number of clinical trials applied for in 2007 (5000) dropped to 3800 by 2011.

Therefore, the Commission is proposing new legislation to cut red-tape and bring patient-oriented research back to Europe. The objective is to restore European Union's competitiveness in clinical research and the development of new and innovative treatments and medicines for the ultimate benefit of patients.

What are the main changes proposed by the Commission?

The new legislation proposed by the Commission will make it easier to conduct multinational clinical trials, i.e. trials conducted in more than one Member State.

The proposed Regulation introduces the following changes in particular:

- A **simplified authorisation procedure**¹ allowing for a fast and thorough assessment of the application by all Member States concerned and resulting in one single assessment outcome. The authorisation procedure allows the individual Member State to appoint the body or bodies in charge of the assessment, on the condition that the assessment is fully independent and based on the necessary expertise.
- **Simplified reporting procedures** which spare researchers from submitting largely identical information on the clinical trial separately to various bodies and Member States.
- The **possibility for the Commission to conduct controls** in Member States and other countries to make sure the rules are being properly supervised and enforced.

Finally, the new legislation will take the legal form of a Regulation. This will ensure that the rules for conducting clinical trials are identical throughout the EU. This is vital to ensure that in authorising and supervising the conduct of a clinical trial, Member States base themselves on identical rules.

How are risks to clinical trials subjects addressed in the new legislation?

The risk to subjects participating in clinical trials varies depending whether the trial is to test a new medicine or to compare existing medicines. The regulatory framework needs to be sufficiently flexible to respond to this.

The proposal, while continuing to uphold patient safety, takes better account of the actual risk the subjects will be exposed to during the clinical trial and adapts the regulatory burden accordingly. It introduces the concept of a 'low-intervention clinical trial', i.e. the proposal specifically addresses clinical trials where the additional risk for a patient compared with receiving a treatment in normal clinical practice is negligible. In these cases, the regulatory requirements will be less burdensome and the timeline for authorisations shorter.

What about clinical trials conducted outside the EU?

There is a trend towards increased clinical trials in areas with emerging economies such as Asia, South America and Russia.

¹ Addressing only the non-ethical aspects of clinical trials, for reasons of subsidiarity.

The Commission is committed to ensuring that, no matter where a clinical trial is being performed, the fundamental rules for the protection of subjects are applied. The proposal therefore includes rules for clinical trials which are conducted outside the EU but referred to in a clinical trial application within the EU. In these cases, the proposal provides for compliance with regulatory requirements at least equivalent to those in the EU, including rules on transparency

Why is transparency important for clinical trials?

Transparency on the conduct and results of clinical trials avoids redundancy and duplication. It also ensures that even clinical trials with unfavourable results are made public, thereby avoiding 'publication bias'. Finally, transparency gives patients the possibility to find out about on-going clinical trials in which they may wish to participate.

Clinical trials authorised in the EU are published in an official EU-register since May 2011 (<https://www.clinicaltrialsregister.eu/>). Today's proposal strengthens the rules on transparency further, by ensuring that information on whether recruitment for a clinical trial is still ongoing is publicly available.

What's next?

The legislative proposal is now going to be discussed in the European Parliament and in the Council. It is expected to come into effect in 2016.

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