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Q&A: New rules for clinical trials conducted in the EU

What are clinical trials?

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

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.

Clinical trials are not only important for pharmaceutical companies or academic researchers. They are first and foremost crucial for patients, in particular those affected by serious or rare diseases, as often they are the only way for them to have access to the most advanced, life-saving treatments.

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. In addition, approximately 40% of clinical trials in the EU are conducted by non-industry actors, such as 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 currently 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) and to ensure the reliability and robustness of the data generated. These rules are set out in the 'Clinical Trials Directive' (2001/20/EC).

Why is the current legislation being replaced?

The 2001 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.

Taken together, these restrictions have contributed to a significant decline in the number of clinical trials in the EU – a reduction of about 25 % in the last few years.

The new Regulation aims at restoring the EU's competitiveness in clinical research and the development of new and innovative treatments and medicines by cutting red-tape and bringing patient-oriented research back to Europe.

What are the main changes introduced by the Regulation?

The new Regulation will make it easier to conduct multinational clinical trials, i.e. conducted in more than one Member State, in the EU. Measures that cut red tape and simplify the current rules are:

- A **straightforward authorisation procedure** 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 EU countries to determine the roles of the bodies in charge of the assessment, on the condition that the assessment is fully independent and based on the necessary expertise.

- **Simplified reporting procedures** so that researchers no longer have to submit largely identical information on the clinical trial separately to various bodies and Member States.

- The **possibility for the Commission to conduct controls** in EU countries and third 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 Member States, in authorising and supervising the conduct of a clinical trial, base themselves on identical rules.

What role will Ethics Committees have under the new rules?

Ethics committees will be involved in the assessment of clinical trials application. However, as with the current situation, their responsibilities and detailed composition will be determined independently by each EU country. In this way the different traditions in the various Member States are respected.

The Regulation introduces the concept of tacit agreement in the assessment phase of an application. Why is this needed?

The concept of tacit agreement already exists in the current clinical trials Directive. The Regulation just extends its application to all assessors, to avoid bottlenecks and delays in the procedure. This is to alleviate an unnecessary and frustrating restriction that trial sponsors face under the current rules.

It is important, however, to emphasise that Member States will always have the possibility to stop any clinical trial which they consider could endanger the heath of the participants.

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 Regulation, while continuing to uphold patient safety, takes better account of the actual risk to which subjects will be exposed during the clinical trial and adapts the regulatory burden in relation to the risk posed. It introduces the concept of a 'low-intervention clinical trial' – an example being clinical trials comparing already authorised medicines. In such cases, the regulatory requirements will be lighter.

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.

The Regulation will ensure that, no matter where a clinical trial is being performed, the fundamental rules for the protection of subjects are applied. It therefore includes rules for clinical trials which are conducted outside the EU but referred to in a clinical trial application within the EU. For such trials, the rules call 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 has several benefits, and the Regulation strengthens the rules accordingly. Transparency avoids redundancy and duplication. It 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/).

What's next?

Following the positive vote in Parliament, the Regulation now has to be formally adopted by Council and published in the Official Journal. Its application is linked to the full functionality of the EU portal and database under development by the European Medicines Agency. It is expected to come into effect in mid-2016 at the earliest.

For more information on clinical trials in the EU:

http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm