



EUROPEAN COMMISSION

PRESS RELEASE

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Fostering EU's attractiveness in clinical research: Commission proposes to revamp rules on trials with medicines

Boosting clinical research in Europe by simplifying the rules for conducting clinical trials is what today's proposal from the Commission is about. Clinical trials are tests of medicines in humans and give patients access to most innovative treatments. At the same time, clinical research with over 20 billion Euros of investment per year in the EU makes a significant contribution to the growth policy of the Europe 2020 agenda. Clinical trials are vital to develop medicines and to improve and compare the use of already authorised medicines. The data generated in clinical trials are used by researchers in publications, and by pharmaceutical companies applying for marketing authorisations. Once implemented, the measures proposed today will speed up and simplify the authorisation and reporting procedures, while maintaining the highest standards of patient safety and robustness and reliability of data. The measures will also better differentiate the obligations according to the risk-profile of the trial, and improve transparency including on trials done in third countries.

John Dalli, European Commissioner for Health and Consumer Policy, said: *"Patients in Europe should have access to the most innovative clinical research. Clinical trials are crucial for developing new medicines and improving existing treatments. This is why today's proposal significantly facilitates the management of clinical trials, while maintaining the highest standards of patient safety and the robustness and reliability of trial data. 800 million euros per year could be saved in regulatory costs and boost research and development in the EU, thus contributing to economic growth."*

The proposed Regulation, once adopted, will **replace the 'Clinical Trials Directive' of 2001**. It has ensured high level of patient safety, but its divergent transposition and application led to an unfavourable regulatory framework for clinical research, thus contributing to a **decrease of 25% of clinical trials** conducted in the period between 2007 and 2011: in 2007, more than 5000 clinical trials were applied for in the EU while by 2011 the number had dropped to 3800.

The new legislation proposed by the Commission will take the form of a Regulation. This will ensure that the rules for conducting clinical trials are identical throughout the EU. In particular, it will make it easier to conduct multinational clinical trials in Europe. Some concrete proposals are:

- An **authorisation procedure for clinical trials** which will allow for a fast and thorough assessment of the application by all Member States concerned and which will ensure one single assessment outcome.
- **Simplified reporting procedures** which will spare researchers from submitting largely identical information on the clinical trial separately to various bodies and Member States.
- **More transparency** on whether recruitment for participating in a clinical trial is still ongoing, and on the results of the clinical trial.
- 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.

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

For more information on clinical trials:

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

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