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New rules for clinical trials conducted in the EU

(European Commission - MEMO/14/254 02/04/2014)

The 2001 Clinical Trials Directive has been criticized by patients, researchers and industry for its disproportionate regulatory requirements, high costs and a lack of harmonization of the applicable rules necessary for multinational clinical trials. 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. The new Regulation will make it easier to conduct multinational clinical trials, i.e. conducted in more than one Member State, in the EU.

More info on: http://europa.eu/rapid/press-release_MEMO-14-254_en.htm