EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency welcomes publication of the Clinical Trials Regulation

The European Medicines Agency (EMA) welcomes the publication of the Clinical Trials Regulation in the Official Journal of the European Union (EU). This legislation will open up a new era for the conduct of clinical trials in the EU, ensuring that Europe remains an attractive centre for clinical research. This will foster European competitiveness and innovative capacity, and facilitate swifter development of new medicines for patients. In addition to simplifying clinical trial approvals, the Regulation foresees transparency on the conduct of trials in the European Economic Area, from the point of their authorisation to the publication of the results of those clinical trials.

Whilst authorisation and oversight of clinical trials remains the competence of Member States, the new legislation mandates the Agency to prepare the IT platforms to support sponsors and experts in the Member States in carrying out their roles in relation to the authorisation of trials, their supervision, safety reporting and compliance activities, as well as to enable public access to information on clinical trials.

EMA policy on publication and access to clinical trial data

The new Regulation provides for the first time a direct legal basis for the release of clinical trial results. This is directly in line with the Agency's commitment to increased transparency of these data, through its draft policy on proactive publication and access to clinical trial data. This policy, currently in the process of being finalised, will provide a bridge until the new legislation comes into force, which can be no earlier than mid-2016.

In drafting its policy, the Agency has carried out a broad public consultation, taking stock of the diverse views that were expressed. In the current absence of a specific legal framework for the proactive release of clinical trial data as soon as the authorisation procedure on a new medicine has been finalised, the challenge in this exercise was to find a balance between the often competing views that would allow the Agency to move forward with its policy.

The Agency recently completed a last round of targeted stakeholder consultations and the final policy is to be presented to the EMA's Management Board in June 2014. The Agency believes its policy finds an acceptable balance between all those competing interests. Once implemented, this policy will give all stakeholders the opportunity to learn from this first step whilst preparing for the Regulation to come into force.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The Clinical Trials Regulation is published in the European Union's Official Journal here: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2014:158:FULL&from=EN
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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