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Press Office

Press release

EMA announces final steps for its clinical trial data policy

Targeted discussions with key stakeholders in May

The European Medicines Agency (EMA) will launch a final round of targeted consultations with key stakeholders on its draft policy on proactive publication of and access to clinical trial data at the beginning of May. This will give key stakeholders and the Agency the opportunity to address any outstanding issues before the final policy is presented to the EMA's Management Board for endorsement in June 2014.

This consultation is meant to clarify and fine-tune specific aspects and achieve the broadest possible consensus and understanding of the policy. The targeted discussions will focus on the presentation by the EMA of the principles set for the possible redaction of the clinical study reports to be published. If applied, the redactions will be based on the criteria identified by the Agency for those parts of clinical trial data that exceptionally contain commercially confidential information. They will also aim to clarify how the concerned data-owners (e.g. marketing authorisation holders) will be consulted before publication of their clinical study reports, and user-friendly technical measures to make the data accessible under the new policy including their terms of use.

The Agency will liaise shortly with organisations representing patients, academia, pharmaceutical industry, as well as European Union (EU) institutions.

The Agency is committed to pursuing the objective of full transparency regarding clinical trial data because it believes that the release of data contributes to establishing trust and confidence in the system. The clinical trial data policy runs in parallel to other initiatives in the EU to increase transparency of clinical trials, most notably the new Clinical Trials Regulation which received a strong vote in favour in the European Parliament on 2 April 2014. This piece of legislation is expected to come into force in mid-2016.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the Agency's initiatives on the release of data from clinical trials is available here:

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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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