



EUROPEAN MEDICINES AGENCY
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Press release

Workshop on access to clinical-trial data and transparency kicks off process towards proactive publication of data

Advisory groups to be formed to solve practical issues

“The European Medicines Agency is committed to proactive publication of clinical-trial data, once the marketing-authorisation process has ended. We are not here to decide if we publish clinical-trial data, but how”, this is how Guido Rasi, Executive Director of the Agency, opened the workshop on access to clinical-trial data and transparency held on 22 November 2012.

This event marks the first step in the process to proactive publication of clinical-trial data, a decision the Agency made earlier this year. This decision aims to build trust and confidence in the system by allowing re-analysis of clinical-trial data by stakeholders.

The Agency is aware that there are practical issues and other considerations that need to be addressed and resolved. The workshop allowed the Agency to gather the views, interests and concerns from a broad range of institutions, groups and individuals.

Based on these discussions, Hans-Georg Eichler, Senior Medical Officer at the Agency, presented the next step of the process. The Agency will establish policies in close dialogue with its stakeholders in five different areas identified during the workshop. These are:

- protecting patient confidentiality;
- clinical-trial-data formats;
- rules of engagement;
- good analysis practice;
- legal aspects.

Advisory groups with broad representation from all parties will be formed and will start working on these topics in early 2013. Final advice from each group is expected by the end of April 2013. The proactive publication of clinical-trial data is expected to come into force on 1 January 2014. Details



about how to express interest in participating in these advisory groups will be published shortly on the Agency's website.

While the work on proactive disclosure is ongoing, the Agency's approach to reactive disclosure of data remains unchanged. Since November 2010, the Agency has released over 1.5 million pages of clinical-trial data in response to safety-related requests.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The Agenda of the workshop is available at:
http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2012/07/WC500130161.pdf
3. The Agency's decision to move towards proactive disclosure was first outlined in the article 'Open Clinical trial Data for All? A View from Regulators', PLoS Medicine, April 2012. This article is available at:
<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001202>
4. Biographies of the speakers who participated in the workshop are available at:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/11/WC500134994.pdf
5. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

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