EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency sets out next steps on access to clinical-trial data

Agency invites expressions of interest for advisory groups

The European Medicines Agency today published a report highlighting the outcomes of the workshop on access to clinical-trial data and transparency which was hosted at the Agency on 22 November 2012.

The report summarises the key interventions of the six panellists and other speakers, and outlines the next steps proposed by the Agency with regard to proactive publication of clinical-trial data once the marketing-authorisation process has ended.

The Agency has also published a video recording of the workshop and a photo gallery today. The slides presented by the Agency's Executive Director, Guido Rasi, and Senior Medical Officer, Hans-Georg Eichler, are also available, together with a full list of participants.

Expressions of interest for advisory groups

As follow-up to the workshop, 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.

The Agency is forming advisory groups with broad representation from all parties, which will start working on these topics in early 2013.

For more details on these advisory groups and how to express interest in joining one or more, please click on the following link:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000556.jsp&mid=WC0b01ac0580614159

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Notes

1. This press release, together with all related documents, is available on the Agency's website
2. Link to Report on Workshop on Access to Clinical-Trial Data: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2012/12/WC500135841.pdf
3. Link to photo gallery: http://www.flickr.com/photos/europeanmedicinesagency/sets/72157632131147432/
4. Link to video of event: http://www.youtube.com/watch?v=upinaTryTho&feature=share&list=PL7K5dNgKnawYrjJQQSTTr2rdy3SImxCdZ
5. You can follow discussions on this topic on Twitter with the hashtag #ctdata
6. More information on the work of the European Medicines Agency can be found on its website www.ema.europa.eu and on Twitter @EMA_News

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