EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Workshop on access to clinical trial data – next steps

22 November 2012

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Developing EMA's policy on proactive publication of clinical trial data: Next steps

Advisory groups to propose policies for adoption by the EMA:

1. Protecting patient confidentiality
2. Clinical trials data formats
3. Rules of engagement
4. Good analysis practice
5. Legal aspects

Advisory groups – Membership

All groups to have a balanced membership representing at least the following groups:

- EMA (as Co-ordinator)
- Patient groups
- Pharmaceutical industry
- Research institutions, associations, NGO's
- Healthcare professionals(associations), academia

Condition: commitment to contribute, maximum 1 member per organisation

Schedule

- Nominations for membership from 01 to 21 December 2012
- Initial sessions for each group to be convened during January/February 2013
- Final advice from each Advisory Group by 30 April 2013
- Draft EMA policy completed and posted on website for public consultation by 30 June 2013
- End of public consultation phase: 30 September 2013
- Publication of final EMA policy (including comments received): 30 November 2013
- Coming into force: 01 January 2014