



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Report from the ENCePP Steering Group




Presentation by Ingemar Persson, Vice Chair of the ENCePP SG
to the ENCePP Plenary

London, 18 November 2010





Steering Group Meetings since last Plenary

1. TC (*extraordinary*): 24 June 2010 
 - To discuss key issues in relation to access to investigational data sets, laid down in the ENCePP Code of Conduct
2. Vitero meeting: 16 September 2010 
3. Vitero meeting (*extraordinary*): 21 October 2010 
 - To discuss draft agenda for ENCePP Plenary and public consultation on the ENCePP Guide on Methodological Standards in PE
4. Planned: 2 December 2010 (Vitero)



Milestones Q2 2010

- Adoption of **revision 1 of the ENCePP Code of Conduct**, including implementation guidance on providing access to study data (12 September 2010)
- Endorsement of **ENCePP Guide on Methodological Standards in Pharmacoepidemiology for public consultation** (consultation launched on 5 November 2010)
- Agreement on **list of deliverables for 2011-12**



ENCePP Work Plan 2010: Main Goal and objectives

To have in place by the end of the year a high quality, self-sustainable network in the field of independent post-authorisation monitoring of medicinal products in the EU.

To promote ENCePP as a resource and increase its usage internationally.

An ambitious plan – but all main deliverables have been achieved!



ENCePP Work Plan 2010: Main deliverables achieved

- Consolidation of ENCePP Steering Group 
- Code of Conduct 
- ENCePP database of Research Resources 
- Development of ENCePP Forum on ENCePP web page 
- Checklist of Methodological Standards for ENCePP Study Protocols 
- Electronic ENCePP register of studies 
- Guide on Methodological Standards in PE  *Public Consultation*
- Ongoing: Promotional events (Info Day, conferences, symposia...)



Looking ahead – Main Deliverables 2011

- Review of the Code of Conduct (1 year after adoption, or after 15 applications for study seal)
- Review of the Checklist of Methodological Standards for ENCePP Study Protocols
- Establish dialogue with medical journal editors (increase the visibility of the network to the broader scientific community)



Main deliverables 2011 – cont.

- Development of strategy for impact analysis
- Development of approaches to facilitate conduct of multi-national database studies in light of existing differences in data privacy laws across the EU
- Development of detailed guidance on the interaction with Regulators
- Maintain and further develop the resource database and e-register of studies



ENCePP Plenary Meetings 2011



30 June 2011
&
23 November 2011