



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Report from the Steering Group

ENCePP Plenary Meeting, 18 June 2013



Presented by: Morten Andersen

An agency of the European Union





Key points

- Announcement of ENCePP special interest group (SIG) 'Pregnancy' (first meeting of group in margins of today's meeting)
- Continued growth of the network
- Significant milestone reached: more than 100 studies in the ENCePP Register (currently serving as the EU PAS Register)
- Progress report on specific SG deliverables in the ENCePP Work Plan 2013-2014
- Reminder – next ENCePP plenary



Growing network (as of 06/06/2013)



- **119 centres**
 - 93 not for profit (university, hospital, government, charities)
 - 26 for profit (CROs, consultancies)


- **19 existing networks**
 - 12 International
 - 7 National (France, Italy, Spain, Belgium, Austria, Sweden)

- **46 data sources**



e-Register of Studies (as of 06/06/2013)



Total no. of studies	111
ENCePP Seal Studies 	15
Studies registered by  centres	52
Other studies	59



SG deliverable:

Progress update:

Review of ENCePP support to EMA Committees in terms of providing evidence to support regulatory decision-making

- Ongoing – good progress (more on this later today...)

Promotion of the ENCePP study seal concept

- Industry survey, followed by meeting with industry associations 22nd May (more on this later today...)

Discuss and agree the level of involvement of non-EU research centres and networks in ENCePP

- Postponed



SG deliverable:

Progress update:

Continued input to developments in policy, legal and societal change that impact on research, including network responses to public or other consultations

- Ongoing (e.g. submission of response from HTA WG to EC public consultation on post-authorisation efficacy studies)

Further investigate potential for cooperation with other sources of healthcare data

- No significant developments awaiting finalisation of the General Data Protection Regulation

Impact analysis of ENCePP on current research practices and on regulatory activities

- Ongoing (measures listed in ENCePP annual activity report)



Mark your calendar!

2nd ENCePP Plenary meeting 2013



✓ Tuesday, 12 November 2013