



Report from the Steering Group

ENCePP Plenary Meeting, 18 June 2013





Presented by: Morten Andersen



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





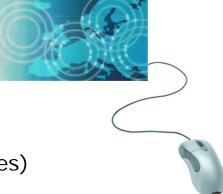
Growing network (as of 06/06/2013)

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 ENERD 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 postauthorisation 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

