



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

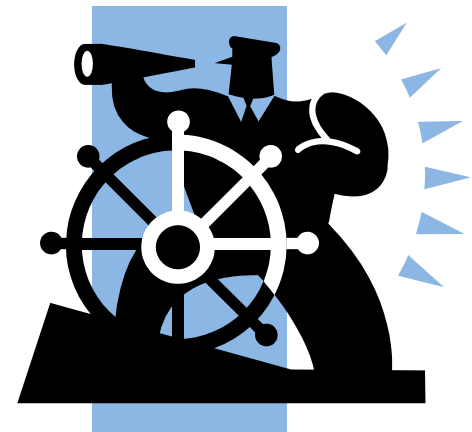


European Network of Centres  
for Pharmacoepidemiology and Pharmacovigilance

## Report from the Steering Group

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ENCePP Plenary Meeting, 11 October 2012



Presented by: Stella Blackburn

An agency of the European Union





## In this presentation

- Key deliverables – ENCePP Work Plan 2013-2014
- ENCePP HTA task force
- ENCePP guidance on data integration of pooling of studies
- Revision to plenary mandate to promote ENCePP
- ENCePP contribution to the scientific research agenda of any future public private partnership that follows IMI
- ENCePP plenary dates 2013



# ENCePP Work Plan 2013-2014

## Key deliverables: Evolution



- Managing the transition to the new PhV legislation and GVP, including review of relevant ENCePP documents.
- Promoting pharmaceutical industry understanding of the ENCePP study concept to increase the uptake of the ENCePP study seal.
- Promoting public registration of non-interventional studies, including from outside Europe.
- Exploring inclusion of non-EU research centres and networks in ENCePP.



# ENCePP Work Plan 2013-2014

## Key deliverables: Development



- Optimising ENCePP's contribution to monitoring of drug safety in special populations (e.g. paediatrics, elderly, pregnancy).
- Development of ad-hoc special interest groups, including on drug utilisation, based on suggestions from the ENCePP community.
- Further investigate potential for cooperation with other sources of healthcare data.
- Progressing the scope of ENCePP in terms of delivering data and information for health technology assessment.



# ENCePP Work Plan 2013-2014

## Key deliverables: Guidelines and Standards

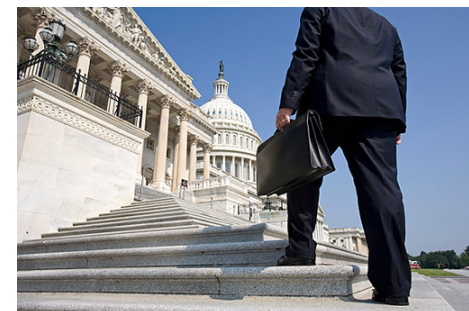
- Development of a stand-alone *ENCePP Guide on Data Integration and Pooling of Studies*.
- Development of guidance for multi-source pharmacoepidemiology research in light of data privacy legislation.
- Development of ENCePP methodological guidance on efficacy research in every-day clinical practice.





# ENCePP Work Plan 2013-2014

## Key deliverables: Advocacy



- Continued representation of ENCePP non-interventional researchers when developments in policy, legal and societal change.
- Keeping up to date with the revision of EU data protection rules and provide expert input to legal rules or guidance relevant to ENCePP mandate.





## ENCePP HTA Task Force



- ENCePP HTA Survey (May 2012)
  - Very good response rate reflecting experience in HTA
  - A number of partners interested in joining in a **leading role**
- Next steps:
  - **Inaugural meeting** (in margins of plenary meeting 11/10/2012)
    - Election of Chair
    - Drafting of mandate



## ENCePP guide on data integration & pooling of studies

- Agreement for stand-alone guidance
- Drafting Group to be formed
  - Nawab Qizilbash has agreed to Chair the group
  - Susana Perez-Gutthann and Miriam Sturkenboom are SG Sponsors



Volunteers with relevant expertise

will

be sought shortly







# Revision of ENCePP Plenary mandate



ENCEPP partners are encouraged to publish the following statement on their websites:

*We are a partner centre of the ENCePP scientific network which is coordinated by the European Medicines Agency. We are dedicated to excellence in research by adhering to the ENCePP Guide on Methodological Standards and promoting scientific independence and transparency. We register studies in the ENCePP E-Register of Studies, a publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies.*

Partners are also encouraged to use the ENCePP logo which is available to download from the ENCePP Partners Forum



## Revision of ENCePP Plenary mandate



- in the spirit of the ENCePP partnership, each ENCePP centre is expected to actively work within each calendar year on at least one study which is registered with the ENCePP E-Register*



*Plenary mandate:*

<http://www.encepp.eu/publications/documents/RulesofProcedureandMandateoftheENCEPPPlenary.pdf>



# ENCePP contribution to scientific research agenda of any future public private partnership that follows IMI



- Invitation to ENCePP to provide views on healthcare research priorities to guide work on a future biomedical research public-private partnership under the EU Horizon 2020 R&D funding programme
- Survey presents preliminary groundwork only & serves as a basis for discussion with EC
- SG response submitted on 20/09/2012 (taking into account results of least year's ENCePP partner survey relating to the prioritisation of research topics)



# Mark your calendar!

## ENCePP Plenary meeting dates 2013



- ✓ Tuesday, 18 June 2013
- ✓ Tuesday, 12 November 2013