



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

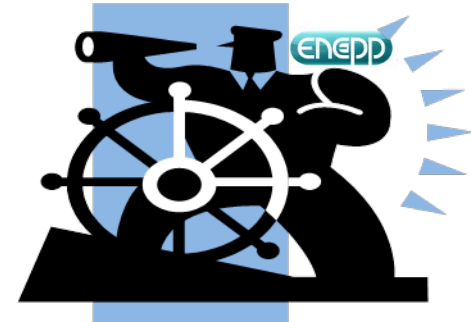


European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Report from the Steering Group

ENCePP Plenary Meeting, 25 November 2014

Presented by Susana Perez-Gutthann
Deputy Chair, ENCePP Steering Group



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Key points

- Looking back: key achievements since last plenary meeting November 2014
- Looking forward: draft work plan 2015-2016
- Communication: need for the network to promote itself and its activities/outputs



Key achievements



The network continues to grow significantly (now 145 centres, 22 networks and 50 data sources)



This brings opportunities but also challenges, particularly in terms of engaging new partners and representing varied although shared interests



As before, the Working Groups are the engines that translate the principles and proposed activities of ENCePP via the Steering Group into outputs that can be used in practice to take pharmacoepidemiology to the next level

ENCePP Working Groups – examples of achievements

- WG 1 (Research Standards and Guidances)

Chair: Alejandro Arana

- e.g. Revision 3 of ENCePP Guide on Methodological Standards in Pharmacoepidemiology

- WG 2 (Independence and Transparency)

Chair: Laura Yates

- e.g. editorial revision of the Code of Conduct
- e.g. ENCePP survey on E-Register and ENCePP Seal – *presentation later today*

- WG 3 (Data sources and multi-source studies)

Chair: Miriam Sturkenboom

- e.g. Publication on ENCePP website of survey of methodologies for EU publicly funded multi-database safety studies http://www.encepp.eu/publications/documents/Survey_Multi-source_studies.pdf



Working Group achievements - continued

- WG on Health Technology Assessment (HTA)

Chairs: Marlene Sinclair & François Meyer

- e.g. Survey of ENCePP on experience in research which outcomes that directly support HTA - *presentation later by Yvonne Lis, representing the WG*

- WG on Guidance for Data Integration

Chair: Nawab Qizilbash

- e.g. Draft Guide for conducting systematic reviews and meta-analysis of pharmacoepidemiology studies investigating drug safety - *presentation on progress later*

- ENCePP Special Interest Group Pregnancy

- Update from meeting 24 November 2015

- Joint EnprEMA – ENCePP paediatric WG

- e.g. contribution to revision of paediatric pharmacovigilance guideline





ENCePP pregnancy SIG mandate

- The work of the group will lead and inform, where applicable, future activities of ENCePP in terms of medicines used in pregnancy and lactation.
- The group will liaise with the ISPE medicines in pregnancy SIG to support the development of guidance for studies of pregnant women.
- Provision of a forum
 - to share information regarding study plans and progress with ENCePP partners;
 - to share experiences and insights regarding study methods specific to drug use, safety and efficacy in pregnancy research and to discuss methodological issues encountered in drug safety in pregnancy research.
- Respond to specific queries on methodological approaches to pregnancy research from the ENCePP Steering Group and other stakeholders such as the EMA.
- Periodically review the document “Overview of data sources for drug safety in pregnancy research” and update as necessary.



SIG meeting update

- Updates from EUROmediCAT and ENTIS; EUROmediCAT funding will finish early 2015 but avenues for continuation and widening participation are being explored.
- The valproate art 31 referral outcome includes a PASS, imposed on the MAHs, to measure the impact of risk minimisation activities; the SIG discussed possible contributions.
- The SIG discussed a proposal for a common funding route for pharmaceutical companies to fund PhV related to medicine safety in pregnancy – to be further developed.
- Proposal to WG1 to write an addendum to the methods guide with methodological considerations specific to drug use & safety in pregnancy research.

The ENCePP E-Register/EU PAS Register



	29/10/2013	11/11/2014
Studies registered by ENCePP partners	64	149
<i>- Of which sponsored by industry</i>	n/a	98
Studies registered by others	101	259
Total studies	165	408
ENCePP Seal Studies	20	27

These are the numbers, but Laura Yates will be presenting on their interpretation later



ENCePP Work Plan 2015-2016: objectives and deliverables

Main goal and objective:

Continuing to consolidate the network as an important resource in the field of pharmacovigilance and pharmacoepidemiology, the focus during 2015 and 2016 will be on extending the scope of the network to support regulatory decision-making across the product life cycle.

This will continue to consolidate ENCePP as a key provider for data and information for regulatory and health-care decision-making and patients.





Objective

Deliverables

Define clear mechanisms to support product life-cycle through epidemiology, including drug development

- Map of available ENCePP resources using Resources Database (filter by speciality)
- Review of ENCePP mandate in terms of the current focus on post-authorisation monitoring of medicinal products
- Establish a business case for upgrade of functionality of ENCePP Resources Database (including accreditation fields already developed by WG1 and proposal to develop for HTA)
- Input to guidance on special populations

Objective

Deliverables

Finalise guidance on Data Integration

- Stand-alone guidance on data integration from completed observational studies
- Assessment report on need for stand-alone guidance on pooling of data from multiple sources

On-going review of existing ENCePP methodological guidances

- Gap analysis of existing guidance documents in relation to efficacy and effectiveness, in particular taking account of new guidance on PAES
- Report validating impact of results from methodology research projects (e.g. PROTECT)
- Revision of ENCePP Guide on Methodological Standards in Pharmacoepidemiology including possible new chapters on special populations/topics



Objective

Deliverables

Develop role of ENCePP in training

- Concept paper on leveraging existing ENCePP training resources to be developed in line with EMA initiatives on training

Implement ENCePP Communications Strategy

- Define a Communication Plan in line with the agreed 2014 Communications Strategy





Engaging the ENCePP community in communication



Some examples of how YOU could help

- Testimonials on how ENCePP has benefited your research and/or the added value you see in working with ENCePP,
- Displaying ENCePP links/logo on the websites of your organisation,
- Reference to ENCePP in your publication (newsletters, articles in peer-reviewed journals),
- Reference to ENCePP in your presentations at congresses, symposia, etc.



ENCePP: key messages

- ENCePP fosters high quality pharmacoepidemiology and pharmacovigilance research for the benefit of public health by promoting best methodological and governance practices through guidance and standards.
- Being part of ENCePP means and being part a unique opportunity to shape observational research in pharmacoepidemiology.
- ENCePP is globally acknowledged for its expertise and outputs.

*ENCePP – it's **your** network*

