EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Report from the Steering Group

ENCePP Plenary Meeting, 24 November 2015

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

Key points

- Looking back: key achievements since last plenary meeting
- ENCePP Communication
- Updated mandates
- Looking ahead to 2016

ENCePP Working Groups – examples of achievements

- WG 1 (Research Standards and Guidances)

  Chair: Alejandro Arana

  - e.g. Revision 4 of ENCePP Guide on Methodological Standards in Pharmacoepidemiology
  - Update from meeting on 23 November 2015

- WG 2 (Independence and Transparency)

  Chair: Laura Yates

  - e.g. Draft paper on research funding route for industry with focus on pregnancy
  - e.g. Definition of business requirements for EU PAS Register upgrade
  - Update from meeting on 9 November 2015

Working Group achievements - continued

- ENCePP Special Interest Group ‘Drug research in pregnancy’

  Chair: Laura Yates

  - Update from meeting 23 November 2015

- WG on Guidance for Data Integration

  Chair: Nawab Qizilbash

  - e.g. Further revision of ‘guidance on conducting systematic reviews and meta-analyses of completed comparative pharmacoepidemiological studies of safety outcomes’ (Annex I to the Guide on Methodological Standards in Pharmacoepidemiology)

Update on Working Group on Health Technology Assessment (HTA)

Merger with WG1:

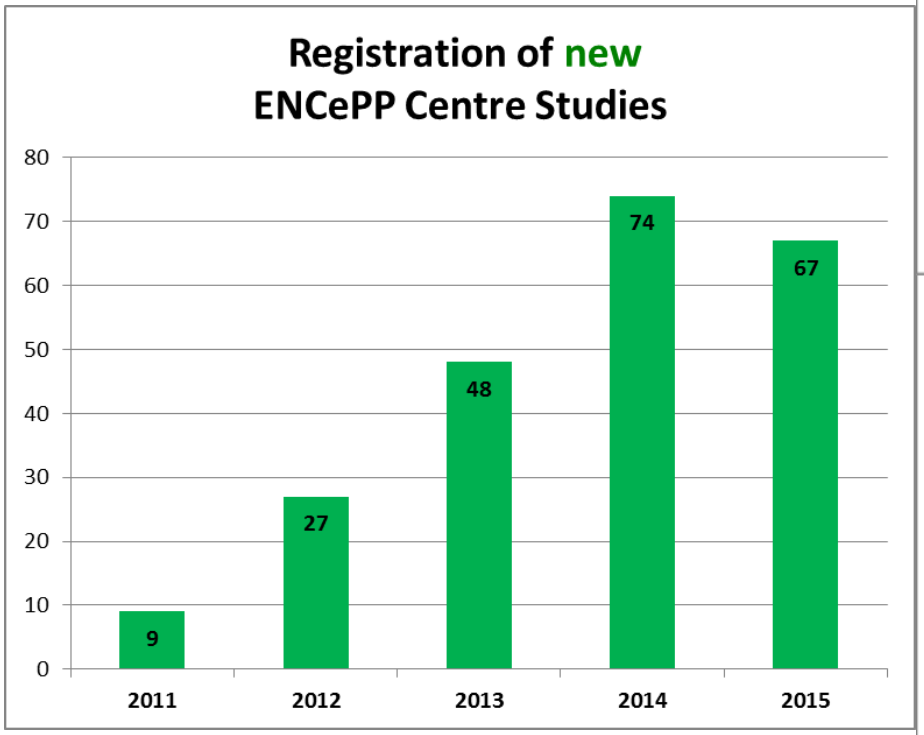
- Decision to focus activities on work around assessing **opportunities for methods and common protocols for research that combines outcomes relevant to medicines regulation and HTA** rather than continue with the stand-alone group
- **Thank you** to Co-Chairs (Marlene Sinclair & François Meyer)
- **Thank you** to all WG members (3 have joined WG1 and others have been asked to continue as ‘associated members’ for consultation on relevant matters)

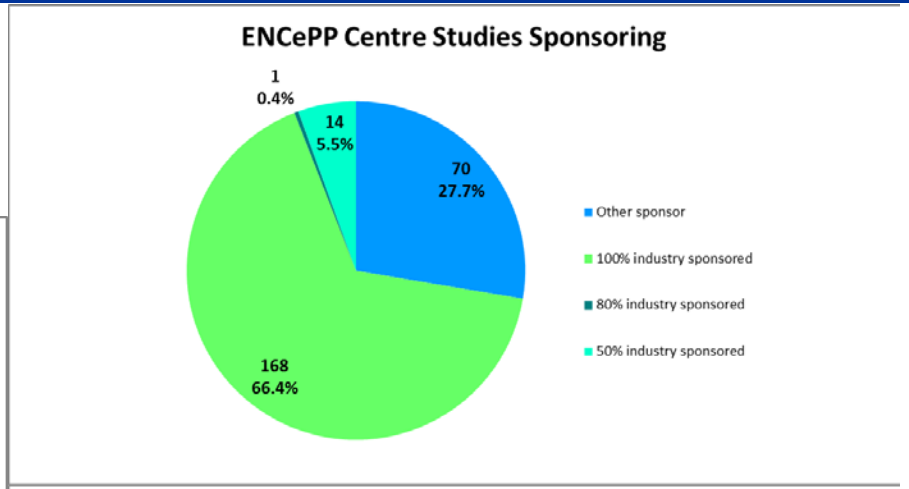
The EU PAS Register

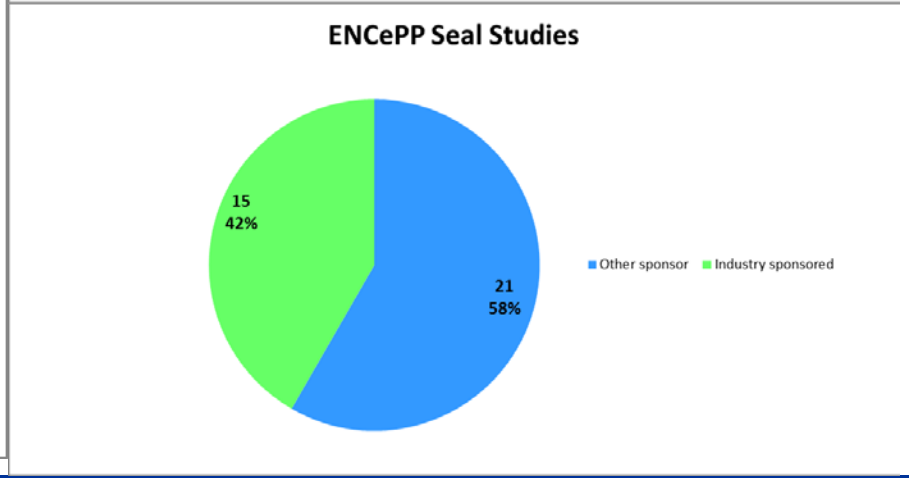
	11/11/2014	17/11/2015
Studies registered by ENCePP partners	149	253
- Of which sponsored by industry	*98*	*183*
Studies registered by others	259	413
Total studies	408	666
ENCePP Seal Studies	27	36

The EU PAS Register

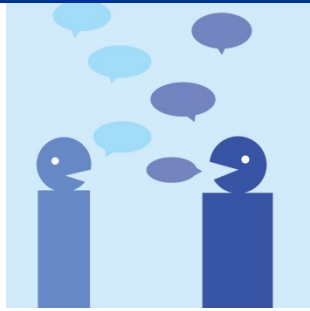
(as of 17/11/2015)







Key messages for communication on ENCePP



What does it mean to be an ENCePP partner?

All ENCePP partners are registered in the ENCePP Resources Database.

Being an ENCePP partner means a commitment to:

- adhere to the principles of the ENCePP Code of Conduct and ENCePP Guide on Methodological Standards in Pharmacoepidemiology ,
- register their post-authorisation studies in the EU PAS Register,
- participate in the development of research and good practice standards by contributing to, or commenting on, draft proposals prepared by working groups or the ENCePP secretariat,
- collaborate with other ENCePP partners, e.g. in multi-centres studies, and share their research experience.

Key messages - **Regulators**

ENCePP supports regulatory decision-making on the benefit-risk of medicines at the European Medicines Agency's Scientific Committees and at national medicines agencies by:

- Building capacity through independent pharmacoepidemiological research for monitoring the safety and effectiveness of authorised medicines;
- Conducting post-authorisation studies according to principles of good practice, good governance and transparency;
- Analysing data on clinical use of medicines in everyday practice;
- Developing and implementing methodological standards in pharmacovigilance and pharmacoepidemiology supporting regulatory guidelines;
- Providing access to ENCePP Centres with expertise in specific areas.

Key messages – **Pharmaceutical industry**

ENCePP supports the conduct of high quality industry-funded post-authorisation studies (PAS) by:

- Supporting the conduct of joint studies by facilitating collaborations;
- Providing opportunities to participate, through consultations, in the development of pharmacoepidemiological research standards and methods for the post-authorisation safety surveillance of medicinal products;
- Developing and maintaining methodological, transparency and governance tools for the planning, design, conduct and reporting of studies according to standards recommended in the EU Good Pharmacovigilance Practices (GVP).
- Giving access to dedicated tools for the conduct of studies:
  - the ENCePP Resources Database providing a robust network of research centres working in a transparent and independent manner, including data sources;
  - the EU PAS Register developed specifically for the registration of observational studies.

Communication on ENCePP – partner statement

- ENCePP partners are encouraged to publish the following statement on their websites and use the ENCePP logo in publications, presentations etc.:

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 EU PAS Register, a publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies.

- ENCePP slide set available to partners

ENCePP WG and SIG mandates

All WG and SIG mandates have been updated to align with the ENCePP work plan 2015-2016

- Latest updates are available on the ENCePP website:

ENCePP plenary mandate – revised section on WGs

Invitation to f2f meetings dependent on responsibilities and assigned deliverables.

Membership linked to active participation in development of deliverables according to adopted work plan.

Request to periodically express commitment to active participation.

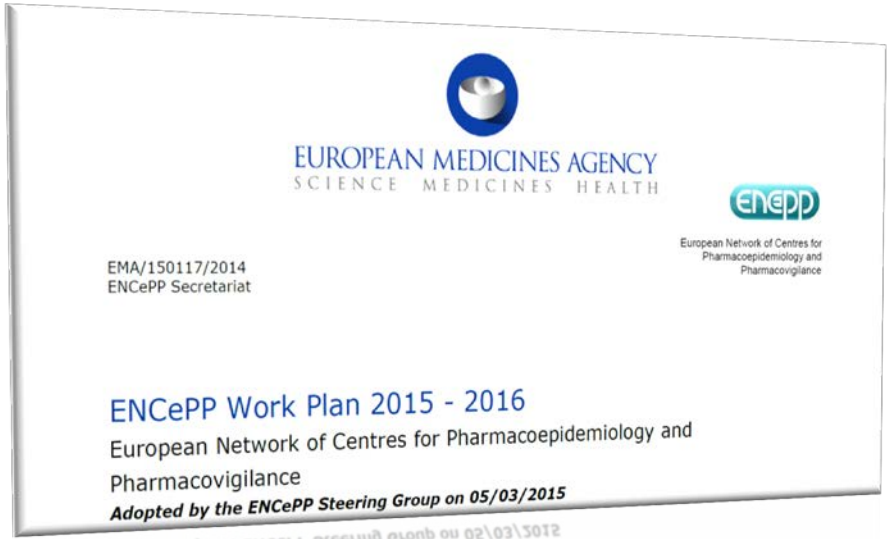
New members may be proposed to ensure progress of work plan deliverables.

WG Chairs appointed by consensus from amongst members.

Regular reports by Chairs to SG in line with work plan deliverables.

ENCePP Work Plan: looking ahead to 2016

http://www.encepp.eu/publications/documents/ENCePPWorkPlan2015-2016.pdf



Objective	Deliverables
ENCePP as a forum for consultation on development of methods and guidance	• Input to EMA strategy on registries (*planned 2016*) • Input to EMA guidance on special populations, including paediatrics and pregnancy (*planned 2016*)
Explore additional models to support the Code of Conduct	• Assessment of the need to supplement the Code with additional tools to support good governance e.g. joint PASS, joint registries, other partnerships, such as Enpr-EMA (*planned 2016*)

Objective	Deliverables
Promote the ENCePP guiding principles of scientific independence and transparency	• Revision of Q&A clarifying the issues identified in the 2014 ENCePP survey (*ongoing*)
Monitor impact of public funding on pharmacoepidemiology in the EU	• Defining approaches to assess the impact of changes in EU public funding on the conduct of pharmacoepidemiology (*ongoing*)

Objective

On-going review of existing ENCePP methodological guidances

Deliverables

- Gap analysis of existing guidance documents in relation to efficacy and effectiveness, in particular taking account of new guidance on PAES (*planned 2016*)
- Revision 5 of ENCePP Methods Guide (*planned 2016*)

Thank you for your attention

- Further information:

  www.encepp.eu

  encepp_secretariat@ema.europa.eu

- Mark your calendar:

  15th ENCePP Plenary meeting, 22 November 2016