



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, 24 November 2015

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



An agency of the European Union





## 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



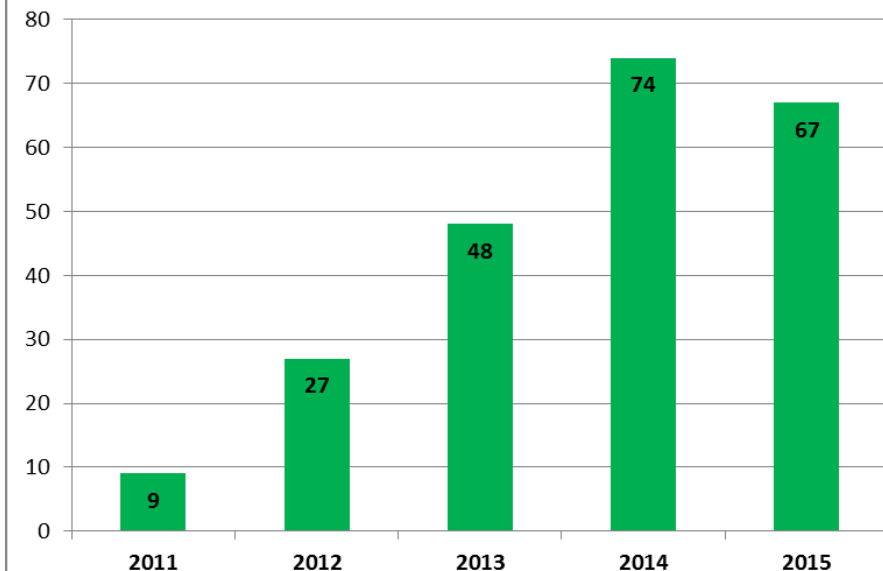
	11/11/2014	17/11/2015
<b>Studies registered by ENCePP partners</b>	149	253
<i>- Of which sponsored by industry</i>	98	183
Studies registered by others	259	413
Total studies	408	666
ENCePP Seal Studies	27	36



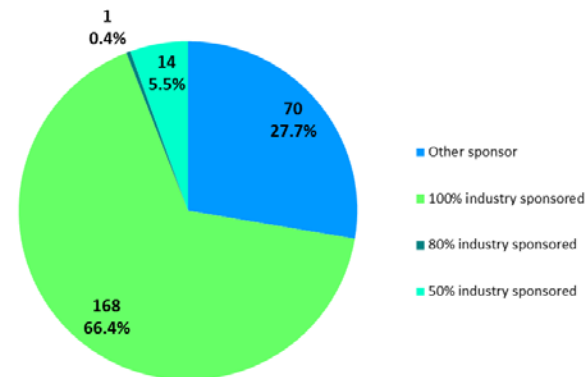
# The EU PAS Register

(as of 17/11/2015)

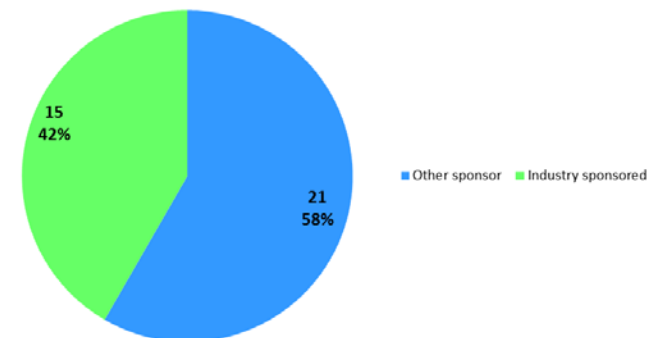
### Registration of new ENCePP Centre Studies



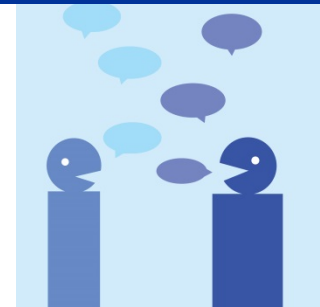
### ENCEPP Centre Studies Sponsoring



### ENCEPP Seal Studies



# 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:



The screenshot shows the ENCePP website interface. At the top, the logo 'ENCePP' is displayed next to the text 'European Network of Centres for Pharmacoepidemiology and Pharmacovigilance'. Below the logo is a navigation bar with links for Home, Sitemap, Q & A, Notice Board, Links, and Contact Us, along with a search box. The main content area is titled 'ENCePP Working Groups' and contains a paragraph explaining the nature of these groups. A list of active groups is provided, including 'Working Group Research Standards and Guidances', 'Working Group Independence and Transparency', 'Working Group Data sources and multi-source studies', and 'Working Group on Guidance for Data Integration'. A red arrow points from the 'Working Groups' link in the left-hand navigation menu to the 'Working Groups' page content. Another red arrow points from the text 'Currently, the following groups are active:' to the list of groups.

ENCePP Working Groups







The ENCePP working groups are of a temporary nature in line with the continued development of the network and the objectives and deliverables of the network's work plans. The European Medicines Agency together with the ENCePP Steering Group may therefore decide on a case-by-case basis about their tenure and composition. New working groups may also be established as appropriate.

Currently, the following groups are active:

- Working Group Research Standards and Guidances
- Working Group Independence and Transparency
- Working Group Data sources and multi-source studies
- Working Group on Guidance for Data Integration

For more information on the deliverables and milestones of these groups, see the [ENCePP Work Plan](#).

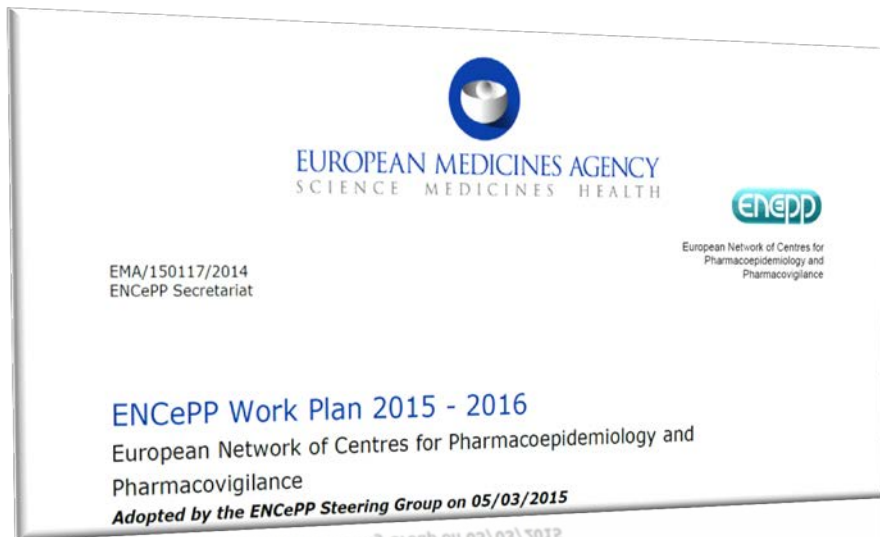
## ENCePP plenary mandate – revised section on WGs

-  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](http://www.encepp.eu)

[encepp\\_secretariat@ema.europa.eu](mailto:encepp_secretariat@ema.europa.eu)

- Mark your calendar:

15<sup>th</sup> ENCePP Plenary meeting, 22 November 2016

