EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Report from the Steering Group

ENCePP Plenary Meeting, 22 November 2016

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

Key points

- Looking back: key achievements since last plenary meeting
- The EU PAS Register
- Looking ahead to 2017 and beyond
- Personal reflections

ENCePP Working Groups

- WG 1 (Research Standards and Guidances)

  Chair: Alejandro Arana

  - e.g. Revision 5 of ENCePP Guide on Methodological Standards in Pharmacoepidemiology; Revision 3 of ENCePP Checklist for Study Protocols; end user survey of ENCePP Methods Guide
  - Update from meeting on 21 November 2016

No immediate ongoing business in 2016 (but with deliverables in new work plan):

- WG2 (Independence and Transparency)
- WG3 (Data sources and multi-source studies)
- Joint Enpr-EMA - ENCePP working group on paediatric pharmacovigilance

ENCePP Special Interest Groups

- ENCePP Special Interest Group ‘Drug research in pregnancy’

  Chair: Laura Yates

  - e.g. review of the “Overview of data sources for drug safety in pregnancy research”
  - Update from coordinator meeting 21 November 2016

- ENCePP Special Interest Group ‘Measuring the Impact of Pharmacovigilance Activities’

  Chair: Agnes Kant

  - Adoption of mandate and work plan
  - Update from coordinator meeting 21 November 2016

The EU PAS Register – Upgrade July 2016

- Performance enhancements:
  - Larger size limit for file uploads; confirmation email for draft entries
- New format of the unique EU PAS reference number: e.g. EUPAS123456
- Static hyperlink to study record
- New data field: 'RMP study category' (mandatory, searchable)
  - EU RMP category 1; EU RMP category 2; EU RMP category 3 (required); Non-EU RMP only; Not applicable
- New data field: 'Other study registration identification number(s)' (free text, searchable)

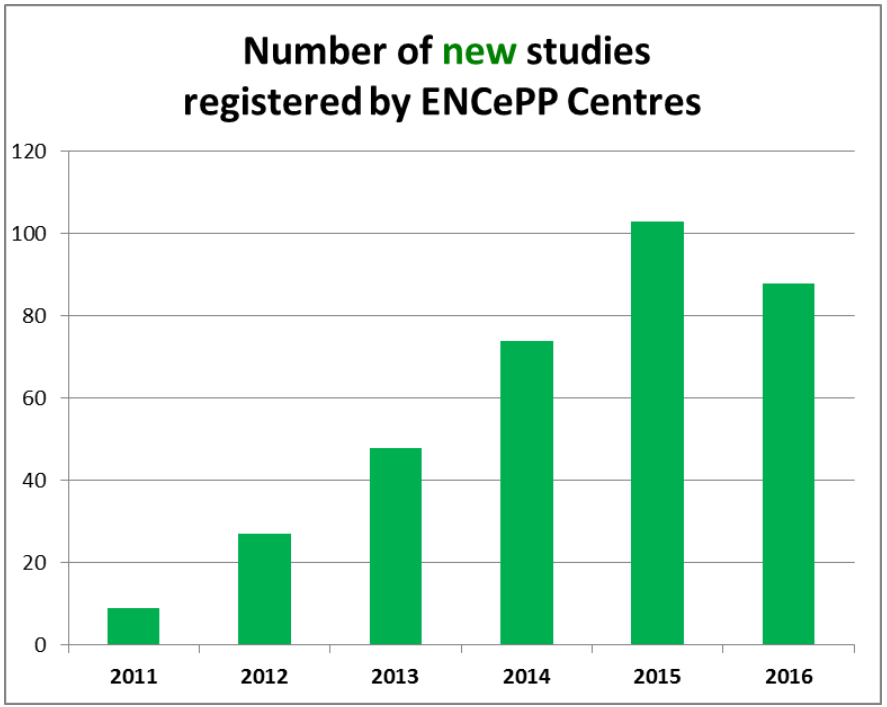
NEW compliance monitoring measures: more under agenda item 7.4.

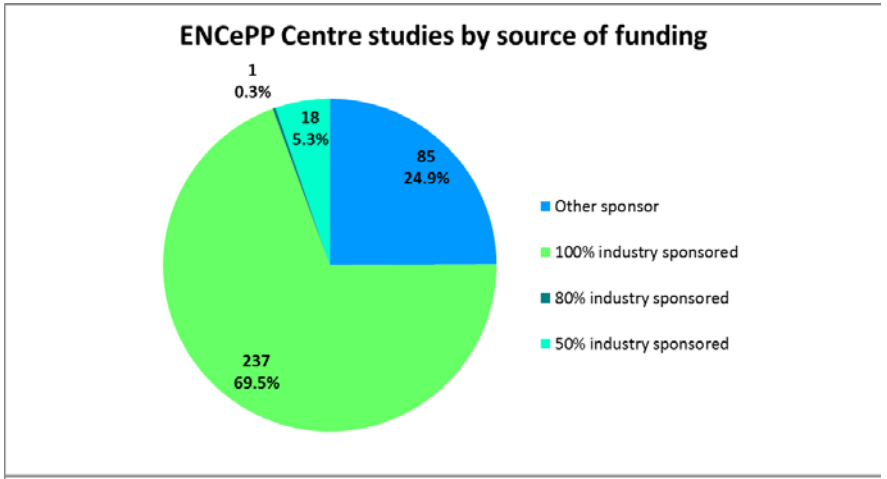
The EU PAS Register – some statistics

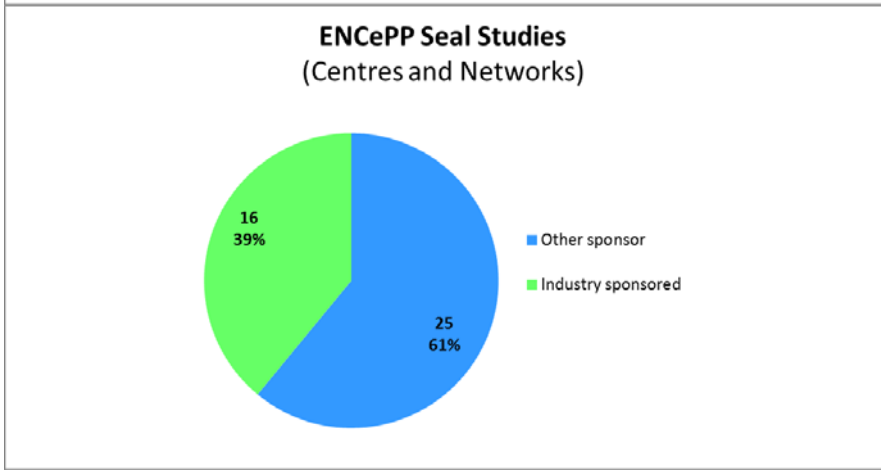
	Total as of 11/11/2014	Total as of 17/11/2015	Total as of 14/11/2016
Studies registered by ENCePP partners	149	253	349
- Of which sponsored by industry	*98*	*183*	*264*
Studies registered by others	259	413	579
Total studies	408	666	928
ENCePP Seal Studies	27	36	41

The EU PAS Register

(as of 14/11/2016)





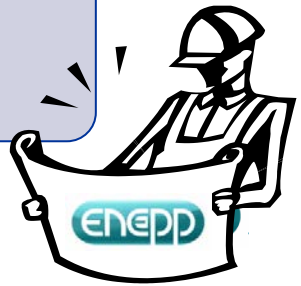


Looking ahead: ENCePP Work Plan 2017-2019

October 2016
- SG agreement on draft work plan

November 2016
- Presentation of objectives and deliverables to Plenary

December 2016
- SG adoption of new work plan
- Publication on ENCePP website



Objective	Deliverables
ENCePP delivering to the lifecycle of medicines	• ENCePP input to regulatory decision-making throughout the product lifecycle.
Develop methods for modelling health outcomes of pharmacovigilance activities for impact measurement	• Review of studies on risk minimisation effectiveness to determine health impact of pharmacovigilance activities, including selected examples from scientific literature. • Recommendations on methods of measuring effectiveness of pharmacovigilance activities.

Objective	Deliverables
Support capacity for pregnancy surveillance	• Recommendations for strategy on pregnancy research, including funding.
Explore additional models for good governance of PhEpi research	• Third party funding mechanism for PAS. • Strengthen the Code with additional tools to support good governance of pharmacoepidemiological research.

Objective	Deliverables
Address methodological aspects of the generation of evidence-based information supporting the needs of regulatory and HTA decision-making	• Gap analysis of guidance in relation to efficacy and effectiveness (PAES guideline). • Revision of ENCePP Guides on Methodological Standards in Pharmacoepidemiology and ENCePP Checklist for Study Protocols. • If needed, revision of *Guidelines for good database selection and use in pharmacoepidemiology research*, in collaboration with ISPE. • Input to EMA guidance on special populations, including paediatrics and pregnancy.
Optimise functionality and utility of the ENCePP resources database and EU PAS Register	• Improved functionality of the ENCePP resources database and EU PAS Register. • Increase study registration and status of the EU PAS Register. • Increase routine surveillance of registrations and compliance follow-up.

Objective

Implement ENCePP Communications Plan

Deliverables

- Evaluation of achievements of 10 years of ENCePP (2007 to 2017).
- Strengthen tools of communication with ENCePP partners

10th Anniversary ENCePP – Paper on the evolution of pharmacoepidemiology in Europe

Your insights about this 10 years of pharmacoepidemiology in Europe

- What was the best development/achievement/success
- What is the major challenge/area of improvement

Thank you for your attention

- Further information:

  www.encepp.eu

  encepp_secretariat@ema.europa.eu

- Mark your calendar:

  16th ENCePP Plenary meeting, 21 November 2017