EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Report from the Steering Group

ENCePP Plenary Meeting, 21 November 2017

Presented by Thomas MacDonald
Deputy Chair, ENCePP Steering Group

Key points

- Steering Group 2017-2019: Areas of focus & highlights
- Key achievements since last plenary meeting and ongoing work (update from Working Groups and Special Interest Groups)
- Some statistics: EU PAS Register & ENCePP Methods Guide

New Steering Group 2017-2019

No.	*Representing*	*Name*	*Affiliation*
1	ENCePP	**Vera Ehrenstein**	Department of Clinical Epidemiology, Aarhus University, Denmark
2	ENCePP	**Rosa Gini**	Agenzia regionale di sanità della Toscana, Florence, Italy
3	ENCePP	**Teresa Herdeiro**	iBiMED, University of Aveiro, Portugal
4	ENCePP	**Olaf Klungel**	Division of Pharmacoepidemiology & Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, The Netherlands
5	ENCePP	**Tom MacDonald**	Deputy Chair, Department of Clinical Pharmacology & Pharmacoepidemiology, Medicines Monitoring Unit (MEMO) and Hypertension Research Centre (HRC), University of Dundee, United Kingdom
6	ENCePP	**Gianluca Trifirò**	University of Messina, Italy
7	EMA	**Xavier Kurz**	Chair, European Medicines Agency
8	EMA	**Hans-Georg Eichler**	European Medicines Agency
9	EMA	**Corinne de Vries**	European Medicines Agency
10	HMA	***vacant***	
11	CHMP	**Johann Lodewijk Hillege**	College ter Beoordeling van Geneesmiddelen, Netherlands
12	COMP	**Dinah Duarte**	INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, Portugal
13	PRAC	**Marieke de Bruin**	University of Copenhagen, Denmark
14	PCWP	**Kathi Apostolidis**	ECPC - European Cancer Patient Coalition
15	ISPE	**Yola Moride**	Faculty of Pharmacy, Université de Montréal, Canada
16	ISoP	**Hervé Le Louet**	Centre de Pharmacovigilance & Information sur le médicament, Hôpital Henri Mondor, Paris, France
Observer	EFPIA	**Patrice Verpillat**	Merck Group, Germany
EMA Observer	EMA	**Gianmario Candore**	European Medicines Agency

Future direction of ENCePP: Areas of focus

- Facilitate the initiation and conduct of observational research and propose mechanisms to support multi-national and multi-database studies
- Improve the ENCePP Code of Conduct with additional tools to promote transparency, scientific independence and good governance of pharmacoepidemiological research
- Ensure the ENCePP network remains focussed on public health and supports health decision-makers such as regulatory authorities, Health Technology Assessment bodies and public health institutions
- Ensure the network embraces relevant innovative data sources and areas of activity e.g. social media information and big data
- Continue to support best methodological practices in the conduct of pharmacoepidemiology
- Further develop the “pharmacovigilance” component of ENCePP and develop a methodological framework for measuring the public health impact of pharmacovigilance activities

Steering Group highlights

6 meetings in 2017: minutes published on the ENCePP website

- Adoption of:
  - new three-year ENCePP work plan 2017-2019
  - revised WG3 mandate
  - outline for a concept paper on models for multi-database pharmacoepi studies
- Letter to EMA Chair of Operation and Relocation Preparedness (ORP) task force re. ENCePP Steering Group contribution to minimise the impact of Brexit on post-authorisation studies in Europe
- Agreement to host the EMA inventory of Registries on the ENCePP database of research resources
- 10 year anniversary of ENCePP: information leaflet & draft manuscript

ENCePP Working Groups

WG1 (Research Standards and Guidances)

Chair: Alejandro Arana

- e.g. Revision 6 of ENCePP Guide on Methodological Standards in Pharmacoepidemiology; report to SG on need to revise ISPE Guidelines for good database selection

WG2 (Independence and Transparency)

Chair: Laura Yates

- e.g. Review of the ENCePP Code of Conduct, taking into account the provisions and governance models of the ADVANCE Code of Conduct developed for collaborative vaccine studies, and the network's past experience with the practical application of the ENCePP Code

WG3 (Data sources & multi-source studies)

Chair: tbc

- Re-activated in September 2017 (first meeting in margins of plenary)
- Revised mandate including:
  - Models for multi-database pharmacoepidemiologic studies
  - Publication of overview of available EU databases relevant for phv and phepi research
  - Analysis of regulatory needs to evaluate the extent to which the existing data sources are able to meet them

Joint ENCePP-EnprEMA working group on paediatric pharmacovigilance

ENCePP Co-Chair: Andrea Margulis

- Consultation on the new Guideline on good pharmacovigilance practices (GVP) module on paediatric pharmacovigilance & submission of response on behalf of ENCePP

ENCePP Working Groups

- Individuals wishing to join a working group or contribute to particular deliverables should express their interest to the ENCePP Secretariat.
- Membership in Working Groups implies a commitment to participate actively in the development of deliverables according to the adopted work plan

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”

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

Chair: Agnes Kant

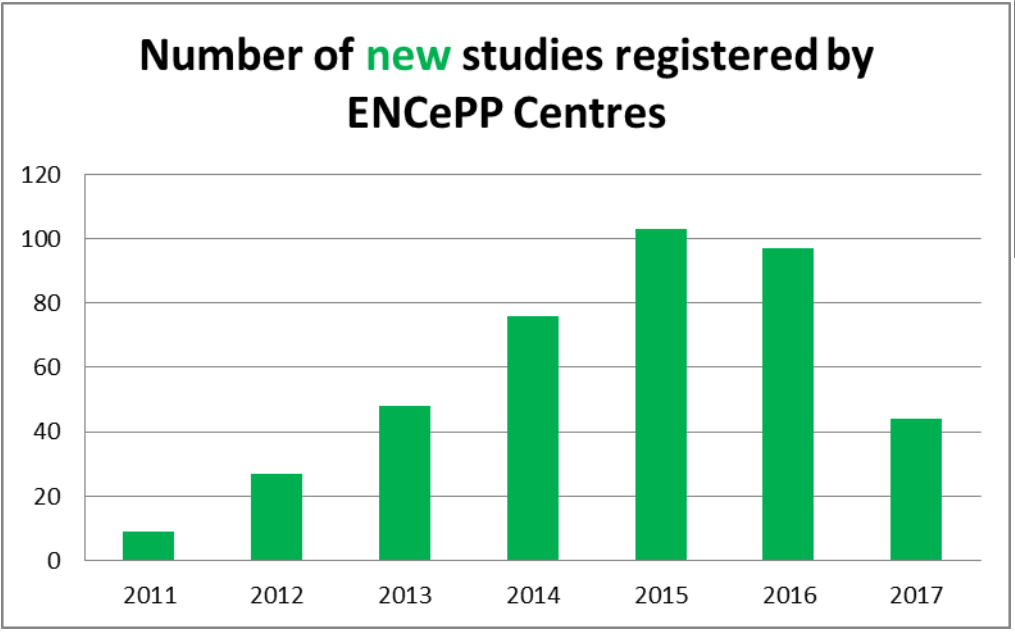
- e.g. concept paper on new chapter in ENCePP methods guide on impact research

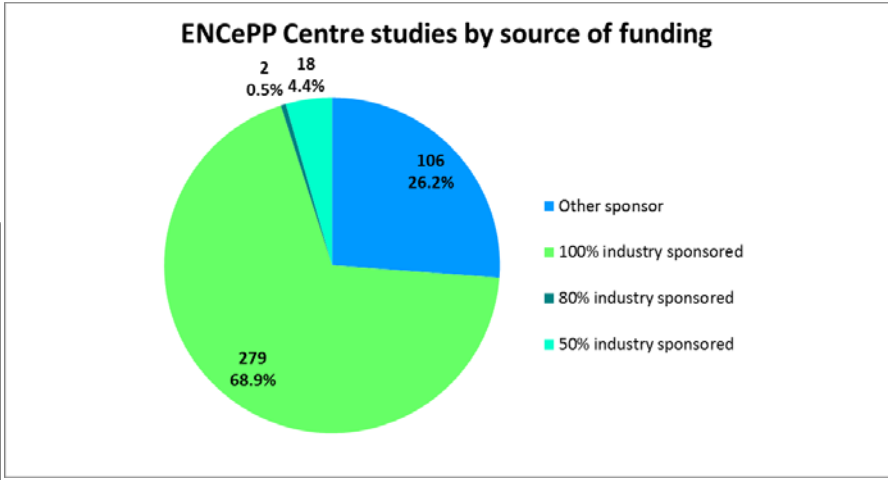
The EU PAS Register – some statistics

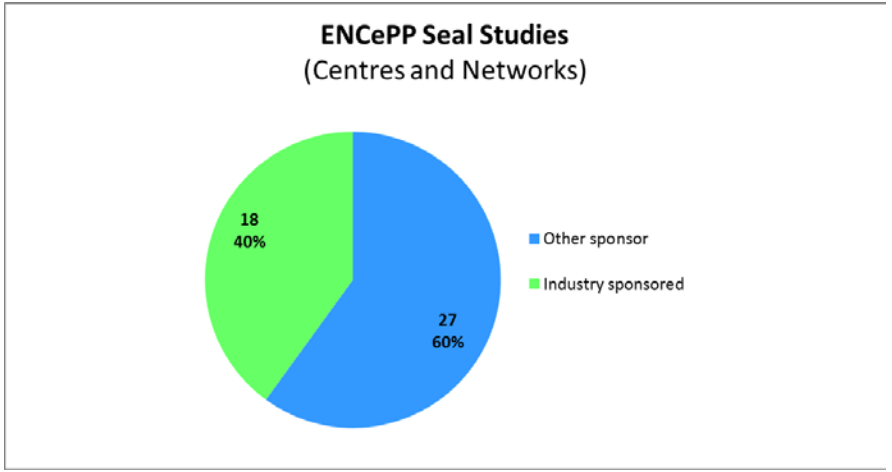
	Total as of 11/11/2014	Total as of 17/11/2015	Total as of 14/11/2016	Total as of 07/11/2017
Studies registered by ENCePP partners	149	253	349	404
- Of which sponsored by industry	*98*	*183*	*264*	*299*
Studies registered by others	259	413	579	786
Total studies	408	666	928	1191
ENCePP Seal Studies	27	36	41	45

The EU PAS Register

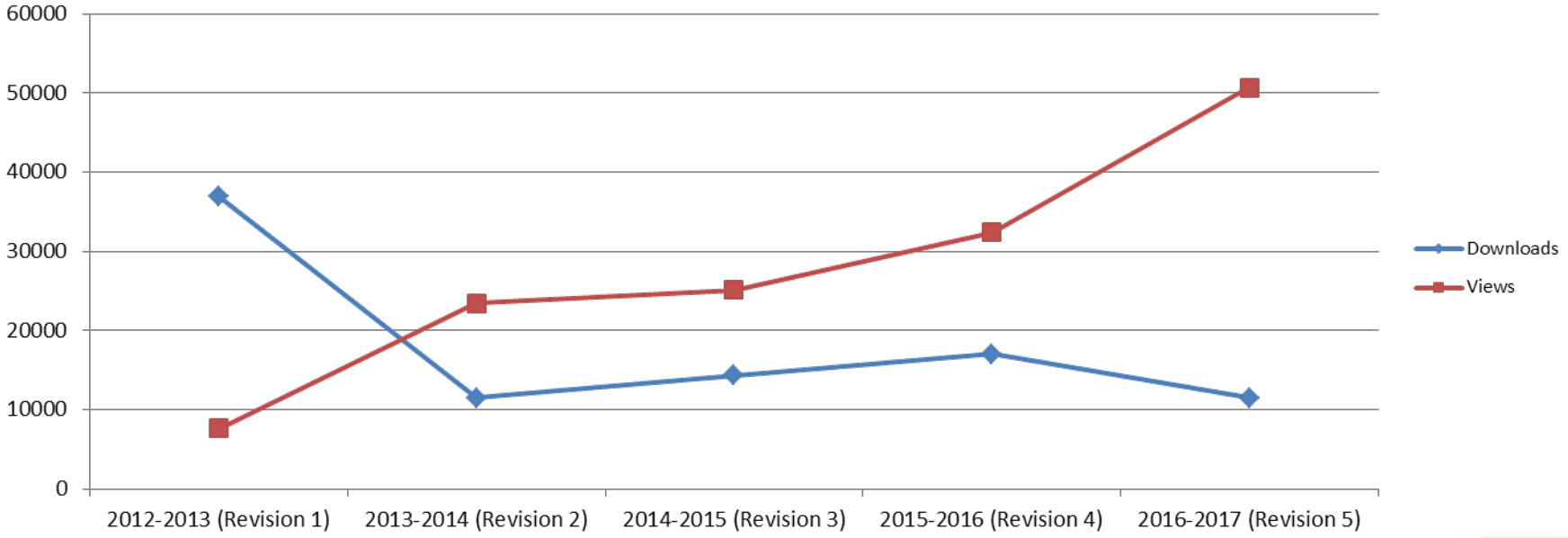
(as of 07/11/2017)







ENCePP Guide on Methodological Standards in Pharmacoepidemiology – Downloads & Views by version



ENCePP Guide on Methodological Standards in Pharmacoepidemiology – Top 10 chapters viewed (2017)

- 4.2.2. Bias and confounding
- 4.6. Research networks
- 4.2.2.2.1. Immortal time bias
- 5. Study design and methods
- 9.2.2.4. Indirect cohort (Broome) method
- 4.2.3.2. Case-only designs
- 4.2.3.6. Prior event rate ratios
- 4.2.3. Methods to handle bias and confounding
- Annex 1. Guidance on conducting systematic reviews and meta-analyses of completed comparative pharmacoepidemiological studies of safety outcomes
- 4.2.2.3. Confounding by indication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EMA/95098/2010 Rev.6

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

Guide on Methodological Standards in Pharmacoepidemiology (Revision 6)

KEYWORDS: methodological standards, pharmacoepidemiology, pharmacovigilance, ENCePP, research, guidance

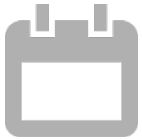
This document should be cited as follows: The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). Guide on Methodological Standards in Pharmacoepidemiology (Revision 6). EMA/95098/2010.

Available at http://www.encepp.eu/standards_and_guidances

Thank you for your attention

www.encepp.eu

encepp_secretariat@ema.europa.eu



17th ENCePP Plenary meeting - 20 November 2018

Mark you calendar!