



13 November 2014
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ENCePP Secretariat



European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

Draft agenda - 13th ENCePP Plenary Meeting

25 November 2014, 09.30 to 16.30, room 2A

Chairperson: Peter Arlett

Time	Item	Name
09.30	1. General Matters	
	1.1 Welcome and Adoption of Agenda	Chair
	1.2 Introductory remarks	Chair
	<ul style="list-style-type: none"> ➤ <i>Introductory remarks will include brief updates on:</i> <ul style="list-style-type: none"> ○ <i>Reporting requirements for PAS</i> ○ <i>Impact of regulatory actions (need for ENCePP support for studies)</i> ○ <i>EMA dialogue on ENCePP with industry</i> ○ <i>Publication of survey on multi-source studies on ENCePP website</i> ○ <i>'Estimation of renal function in the elderly' – PK Guideline</i> 	
09.50	2. Report from the Steering Group	
	2.1 Report from the ENCePP Steering Group	Susana Perez-Gutthann
	<ul style="list-style-type: none"> ➤ <i>The report will highlight key achievements 2014 and introduce the main deliverables of the draft ENCePP work plan 2015-2016</i> 	
	2.2 Discussion of work plan	Plenary
10.15	3. ENCePP and methods	
	3.1 Use of routinely collected electronic healthcare data – lessons learned	Massoud Toussi & Alison Bourke
	3.2 ENCePP Guide on Data Integration of observational studies of harm	Nawab Qizilbash
	<ul style="list-style-type: none"> ➤ <i>Progress report & next steps</i> 	
	3.3 PROTECT project outcome	Xavier Kurz
	<ul style="list-style-type: none"> ➤ <i>Assessment of impact on regulatory science</i> 	
	3.4 Discussion / Q&A	Plenary
11.15	COFFEE BREAK (30 minutes)	
11.45	4. ENCePP and research in practice	
	4.1 CODEMISUSED project	Marie-Claire Van Hout
	4.2 Lessons learned on post-authorisation safety studies (PASS)	Pierre Engel



Time	Item	Name
	➤ <i>Report on the experience of PRAC review and lessons learned on the design of PASS under the new PhV legislation</i>	
	4.3 Open discussion – feedback from ENCePP partners	Hubert Leufkens & Plenary
12.45	LUNCH (1 hour)	
13.45	5. ENCePP supporting product life-cycle	
	5.1 ENCePP and research that supports HTA ➤ <i>Including results from the recent survey of ENCePP on experience in conducting research supporting HTA</i>	Yvonne Lis
	5.2 Report on Agency pilot on adaptive licensing	Francesca Cerreta
	5.3 Registries ➤ <i>Update on the development of a strategy on registries by EMA</i>	Jim Slattery
	5.4 Discussion / Q&A	Plenary
15.00	COFFEE BREAK (15 minutes)	
15.15	6. Governance models for collaborative studies	
	6.1 Results of ENCePP partner survey on registering studies and the ENCePP Study Seal	Laura Yates
	6.2 ADVANCE – feedback from survey on models for public-public and public-private interactions	Xavier Kurz
	6.3 Discussion / Q&A	Plenary
16.15	Summary of discussions & next steps	Chair
	A.O.B	Chair
16.30	Close of meeting	