



13 November 2015
EMA/603690/2015
ENCEPP Secretariat

Draft agenda - 14th ENCePP Plenary Meeting

24 November 2015, 09.30 to 16.30, room 3A

Chair: Peter Arlett & Xavier Kurz

Time	Item	Name
09.30	1. General Matters	
	1.1 Welcome and adoption of agenda	Chair (10')
09.40	2. Report from the Steering Group	
	2.1 Report from the ENCePP Steering Group	Susana Perez-Gutthann (10')
	<ul style="list-style-type: none"> ➤ <i>Key achievements 2015</i> ➤ <i>Key messages for communication on ENCePP</i> ➤ <i>Revised Working Group mandates</i> ➤ <i>Revised plenary mandate (WG refresh)</i> ➤ <i>Looking ahead to 2016</i> 	
	3. Report from Working Groups	
	3.1 Report from WG1 'Research Standards and Guidances'	Alejandro Arana (10')
	3.2 Report from WG2 'Independence and Transparency'	Laura Yates (10')
	3.3 Report from SIG 'Drug Research in Pregnancy'	Laura Yates/Corinne de Vries (10')
	3.4 Discussion / Q&A	Plenary (10')
10.30	COFFEE BREAK (20 minutes)	
10.50	4. Looking towards the future: Brainstorming on funding mechanisms for PAS	
	Session Chairs: Alison Bourke & Miriam Sturkenboom	
	4.1 Introduction	Xavier Kurz (10')
	4.2 Scenario 1: Central mechanism for industry-funded studies	Tom Mac Donald (15')
	4.3 Scenario 2: Medication safety in pregnancy	Helen Dolk (15')
	4.4 Scenario 3: Collaborative studies on vaccines	Xavier Kurz (15')
	4.5 Discussion & way forward	Plenary (45')
13.00	LUNCH (45 minutes)	
13.45	5. Facilitating better use of existing data and joint studies	
	Session Chair: Teresa Herdeiro	
	5.1 OFSEP – The French Registry of Multiple Sclerosis	Eric van Ganse (15')
	5.2 Lessons learned from PROTECT on common protocols for multi-	Olaf Klungel (15')



Time	Item	Name
	database studies	
	5.3 Pilot phase on better use of existing patient registries	Peter Mol (15')
	5.4 Discussion: How can ENCePP facilitate better use of existing data?	Plenary (30')
<i>15.00</i>	COFFEE BREAK (15 minutes)	
15.15	6. Methods for measuring impact of regulatory activities Session Chair: Luisa Ibañez	
	6.1 Why do we need methods to measure impact?	Jacoline Bouvy (15')
	6.2 A pilot experience on disseminating EMA alerts – Impact on medical prescribing at the Catalan Institute of Health	Joan Ramon Laporte(15')
	6.3 Monitoring and Evaluating the Effect of Regulatory Action: Some Recent Case Studies	Andrew Thomson (15')
	6.4 Discussion	Plenary (15')
16.00	7. Estimation of renal function; implications for drug dosing in the elderly	Ulf Bergman (20')
16.20	Summary of discussions & next steps	Chair
	A.O.B	Chair
16.30	Close of meeting	