



17 November 2017
EMA/449328/2017
ENCEPP Secretariat

Draft agenda - 16th ENCePP Plenary Meeting

21 November 2017, 9.30 to 16.30, room 3A

Chairs: Xavier Kurz & Tom MacDonald

Time	Item	Name
09.30	1. Welcome and adoption of agenda	
	1.1 Welcome and adoption of agenda	Chairs (10')
09.40	2. ENCePP Anniversary 2007-2017	
	2.1. 10 years of collaboration in ENCePP	Susana Perez Gutthann (15')
	2.2. Discussion / Q&A	Plenary (10')
10.00	3. Report from Steering Group	
	3.1 Report from ENCePP Steering Group including update from WGs/SIGs	Tom MacDonald (15')
	3.2. Q&A	Plenary (10')
10.30	4. Framework of collaboration between EMA and Academia	
	4.1. Update	Isabelle Moulon (15')
	4.2. Q&A	Plenary (5')
10.50	COFFEE BREAK (30 minutes)	
11.20	5. Models for multi-database studies	
	5.1. Draft concept paper: Models for multi-database pharmacoepidemiologic studies	Rosa Gini & Gianluca Trifirò (30')
	5.2. Discussion / Q&A	Plenary (30')
12.20	LUNCH (60 minutes)	
13.20	6. ENCePP Code of Conduct – Revision 4	
	6.1. Why do we need a revision?	Thomas Goedecke (15')
	6.2. Overview of proposed amendments	Rosa Gini (15')
	6.3. Discussion and perspectives from academia and industry	Plenary discussion (30') joined by Laura Yates, Patrice Verpillat, Xavier Fournie & Giovanni Fiori
14.20	7. Promoting ENCePP at national level	
	7.1. Introduction to the Italian model	Ursula Kirchmayer (10')
	7.2. Discussion / Q&A	Plenary (10')



Time	Item	Name
14.40	8. Benefit/risk assessment	
	8.1. Table of effects in benefit-risk assessments	Hans Hillege (10')
	8.2. Discussion / Q&A	Plenary (10')
<i>15.00</i>	<i>COFFEE BREAK (20 minutes)</i>	
15.20	9. EMA Patient registries initiative	
	9.1. Presentation: Outcome of the two disease registry workshops and the consequent consultation on guidance	Xavier Kurz (20')
	9.2. Discussion / Q&A	Plenary (30')
16.10	10. Update on Brexit-related issues	Noël Wathion (15')
16.25	Summary of discussions & Close of meeting	Chairs