



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



European Network of Centres for  
Pharmacoepidemiology and  
Pharmacovigilance

1 December 2024  
EMA/533685/2023  
European Medicines Agency

## Agenda – ENCePP Plenary meeting

Friday, 1 December 2023

9:00 – 16:00 CET

Hybrid meeting (Face-to-face and WebEx)

European Medicines Agency (Room 2A), Amsterdam, The Netherlands

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## Meeting objectives

- To reflect on the work of ENCePP in recent years, and present and agree on proposed changes to the ENCePP mandate;
- To present and agree on proposed changes to the Steering Group mandate, and introduce the newly elected SG members for the 2024-2026 term;
- To present the ENCePP Workplan for 2024, including activities of the Working Groups, and seek feedback and contribution from ENCePP Partners on planned activities and deliverables;
- To update on, and seek feedback from ENCePP Partners, on the new ENCePP website and the EMA catalogues on RWD sources and on non-interventional (NIS) studies (former ENCePP Resource Database and EU PAS Register);
- To learn about, and discuss, current key data- and method-related initiatives;
- To place the work of ENCePP in the broader context of a changing regulatory environment.

## Agenda

**Chairs:** Susana Perez-Gutthann (RTI Health Solutions), Catherine Cohet (EMA)

Item	Topic	Speaker	Time
1.	Arrival, connection to virtual room and technical checks		08:45-9:00
2.	Welcome and introduction	Peter Arlett	09:00-9:10
3.	Meeting objectives	Susana Perez-Gutthann Catherine Cohet	09:10-9:15
<b>SESSION 1: Looking back at 2023</b>			
<b>Chairs: Catherine Cohet / Susana Perez-Gutthann</b>			
4.	ENCePP: history and achievements	Susana Perez-Gutthann	09:15-09:30
5.	Achievements of the Working Groups and a view to 2024 activities	Alejandro Arana (WG1) Rosa Gini (WG2) Gianluca Trifirò (WG3)	09:30-10:15
<b>SESSION 2: 2024 and beyond</b>			
<b>Chairs: Patrice Verpillat / Helga Gardarsdottir</b>			
6.	Results of the Steering Group election and introduction of the new members	Susana Perez-Gutthann	10:15-10:30
7.	2024 ENCePP workplan	Catherine Cohet	10:30-11:00
<b>Coffee break – 11:00 to 11:30</b>			
8.	Proposal for revision of ENCePP mandate and mandate of the Steering Group	Patrice Verpillat	11:30-11:55
9.	New EMA catalogues: RWD sources and non-interventional studies (former ENCePP Resource Database and EU PAS Register)	Ana Cochino	11:55-12:25
10.	The new ENCePP website: overview and key improvements	Julianna Fogd Andrej Segec	12:25-12:45
<b>Lunch break – 12:45 to 13:30</b>			
<b>SESSION 3: Key data- and method-related initiatives</b>			
<b>Chairs: Xavier Kurz / Vera Ehrenstein</b>			
11.	HealthData@EU: Update on the EHDS pilot	Denise Umuhire	13:30-13:50
12.	DARWIN EU® update	Andrej Segec	13:50-14:05
13.	Use of estimands in target trial emulation	Juan Jose Abellan	14:05-14:30
14.	Artificial Intelligence (AI) applications in pharmacoepidemiology: opportunities for the European regulatory network	Luis Pinheiro	14:30-14:50
15.	Use of negative controls in pharmacoepidemiology	Marc Suchard Daniel Morales	14:50-15:30

Item	Topic	Speaker	Time
<b>Closing address and wrap-up</b>			
16.	RWE and pharmacoepidemiology in the current regulatory environment	Emer Cooke	15:30-15:50
17.	Summary and next steps	Susana Perez-Gutthann Catherine Cohet	15:50-16:00
<b>Adjournment – 16:00</b>			

## Session chairs and speakers

- Alejandro Arana, RTI Health Solutions
- Ana Cochino, EMA
- Andrej Segec, EMA
- Catherine Cohet, EMA
- Daniel Morales, EMA
- Denise Umuhire, EMA
- Emer Cooke, EMA Executive Director
- Gianluca Trifirò, University of Messina
- Helga Gardarsdottir, Utrecht University
- Juan Jose Abellan, EMA
- Julianna Fogd, EMA
- Luis Pinheiro, EMA
- Marc Suchard, Department of Biomathematics, David Geffen School of Medicine, University of California, Los Angeles
- Patrice Verpillat, EMA
- Peter Arlett, EMA
- Rosa Gini, ARS Toscana
- Susana Perez-Gutthann, RTI Health Solutions
- Vera Ehrenstein, Aarhus University
- Xavier Kurz, external expert for the EMA Methodology Working Party