



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



European Network of Centres for  
Pharmacoepidemiology and  
Pharmacovigilance

25 November 2022  
EMA/907257/2022  
European Medicines Agency

## Agenda – ENCePP Plenary meeting

Wednesday 30 November 2022

9:00 – 15:00 CET

Hybrid meeting (face-to-face and WebEx)

European Medicines Agency, Amsterdam, The Netherlands

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## Meeting objectives

- To present and discuss the activities of the ENCePP Steering Group and Working Groups and exchange ideas to populate the ENCePP workplan for 2023 and beyond;
- To update and seek input from ENCePP partners on upcoming developments including the new ENCePP website and the upgrading of the EU PAS Register and ENCePP Resources Database catalogues into the new RWD sources and RWD studies catalogues;
- To exchange views on how to optimise the future of ENCePP and improve visibility of ENCePP, enhance collaborations with learned societies, and consider current and future guidance initiatives in the ENCePP work plan;
- To inform the ENCePP community about latest developments on COVID-19 and monkeypox vaccines and therapeutics and the contribution of pharmacoepidemiology to EMA's decision-making;
- To update on DARWIN EU® and discuss the interface with ENCePP activities;
- To learn about, and discuss, current methodological hot topics.

## Agenda

**Chairs:** Susana Perez-Gutthann, Catherine Cohet

Item	Topic	Speaker	Time
1.	Arrival, connection to virtual room and technical checks for those online		8:45-9:00
2.	Welcome and introduction Meeting objectives	Susana Perez-Gutthann, Catherine Cohet	9:00-9:10
3.	Update on COVID-19 and monkeypox vaccines and therapeutics – how can ENCePP support public health crisis management	Marco Cavaleri	9:10-9:25
4.	DARWIN EU®: update and interface with ENCePP	Daniel Prieto-Alhambra	9:25-09:45
<b>SESSION 1: Looking back at 2022</b>			
<b>Chairs: Xavier Kurz / Massoud Toussi</b>			
5.	Update from the Steering Group	Susana Perez-Gutthann, Catherine Cohet	9:45-9:55
6.	Update from the Working Groups	Alejandro Arana (WG1) Rosa Gini (WG2) Gianluca Trifirò (WG3)	9:55-10:30
7.	ENCePP website update	Andrej Segec	10:30-10:45
8.	Update on the RWD sources and RWD studies catalogues	Katerina-Christina Deli	10:45-11:00
<b>Coffee break – 11:00 to 11:30</b>			
<b>SESSION 2: Optimising the future of ENCePP</b>			
<b>Chairs: Peter Arlett / Susana Perez-Gutthann</b>			
9.	Collaboration between ENCePP and learned societies / guidance initiatives	<ul style="list-style-type: none"> <li>• ISPE (Arnold K. Chan)</li> <li>• ISOP (Gianluca Trifirò)</li> <li>• HARPER (Susana Perez-Gutthann)</li> <li>• GVP VIII and ICH M14 (Catherine Cohet)</li> </ul>	11:30-12:00
10.	Open discussion on the future of ENCePP, including the work plan	Xavier Kurz Helga Gardarsdottir	12:00-12:45
<b>Lunch break – 12:45 to 13:30</b>			
<b>SESSION 3: Methodology</b>			
<b>Chairs: Daniel Morales / Helga Gardarsdottir</b>			
11.	Using primary data collection in pharmacoepidemiology: the SEMVAc monkeypox vaccine study	Pierre Engel	13:30-13:50
12.	Results from RTC DUPLICATE and lessons for Europe	Shirley Wang Sebastian Schneeweiss	13:50-14:10
13.	Target Trial Emulation With and Without Cloning	Xabier García de Albéniz	14:10-14:40

Item	Topic	Speaker	Time
<b>Wrap-up</b>			
14.	Patient views on use of their data in pharmacoepidemiological studies	Iryna Vlasenko	14:40-14:50
15.	Summary and next steps	Susana Perez-Gutthann, Catherine Cohet	14:50-15:00
<b>Adjournment – 15:00</b>			

## Session chairs and speakers

- Alejandro Arana, RTI Health Solutions
- Andrej Segec, EMA
- Arnold K. Chan, National Taiwan University
- Catherine Cohet, EMA
- Daniel Morales, EMA
- Daniel Prieto-Alhambra, Erasmus MC Rotterdam & University of Oxford
- Gianluca Trifirò, University of Messina
- Helga Gardarsdottir, Utrecht University
- Iryna Vlasenko, European Chapter of the International Diabetes Federation
- Katerina-Christina Deli, EMA
- Marco Cavaleri, EMA
- Massoud Toussi, IQVIA
- Peter Arlett, EMA
- Pierre Engel, Aetion
- Rosa Gini, ARS Toscana
- Sebastian Schneeweiss, Harvard Medical School
- Shirley Wang, Harvard Medical School
- Susana Perez-Gutthann, RTI Health Solutions
- Xabier García de Albéniz, RTI Health Solutions
- Xavier Kurz, EMA