



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



European Network of Centres for  
Pharmacoepidemiology and  
Pharmacovigilance

12 October 2021  
EMA/524559/2021

## Agenda – ENCePP Plenary webinar

**18 November 2021**

**09:45 – 16:30 (CET)**

**Virtual meeting (WebEx)**

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



## Objectives

- To learn about key results from observational studies on Covid-19, methodological challenges that remain to be addressed, and how ENCePP could further promote best practice for Covid-19 research
- To present the recently finalised CHMP Guideline on registry-based studies
- To update on the work programme of the HMA-EMA Big Data Task Force and discuss the interface with ENCePP activities. Topics for discussion include the creation of curricula in Data Science, Pharmacoepidemiology and Biostatistics, the upgrading of the EU PAS Register and ENCePP Resources Database, an update on the Real-World Interrogation Network in the European Union (DARWIN EU) and the pilots for data analytics with EMA committees
- To discuss the result of the surveys and agree on the amendments needed for the metadata and functionalities of the EU PAS Register and ENCePP Resources Database
- To exchange views on the activities of the ENCePP Steering Group and Working Groups (WGs), the renewal of the WGs, and the proposed new ENCePP activities (e.g. new SIGs)

## Agenda

Chairs: Susana Perez-Gutthann, Gianmario Candore

Item	Topic	Speaker	Time
1.	Connection to virtual room and technical checks	-	09:30 – 09:45
2.	Welcome and introduction Workshop objectives	Susana Perez-Gutthann, Gianmario Candore	09:45 – 10:00
<b>SESSION 1: EU PAS Register</b>			
<b>Chairs: Alejandro Arana, Xavier Kurz</b>			
3.	Update on PAS: CHMP Guideline on registry-based studies	Kelly Plueschke	10:00 – 10:10
4.	Update on the rebuilding of the Real world data sources catalogue and observational studies catalogue	Xavier Kurz	10:10 – 10:30
5.	Survey results on EU PAS Register	Ana Cochino	10:30 – 10:50
6.	Discussion on the survey results and the metadata	Alejandro Arana, Xavier Kurz	10:50 – 11:20
<b>BREAK – 11:20 – 11:30</b>			
<b>SESSION 2: Update on Big Data SG, CHMP Guideline on registry-based studies, and ENCePP SG</b>			
<b>Chairs: Daniel Morales, Peter Arlett</b>			
7.	HMA-EMA Big Data workplan and update on DARWIN EU	Francois Domergue	11:30 – 11:45
8.	Curricula in Data Science, Pharmacoepidemiology and Biostatistics	Stefania Simou	11:45 – 12:00
9.	Use of Artificial Intelligence in regulation (title TBC)	Luis Pinheiro	12:00 – 12:15
10.	Update on the activities of the ENCePP Steering Group and Working Groups (WGs)	Susana Perez-Gutthann, Gianmario Candore and WG chairs	12:15 – 12:25
11.	Questions and answers	Daniel Morales, Luis Pinheiro	12:25 – 12:50
<b>LUNCH BREAK – 12:50 – 13:35</b>			
<b>SESSION 3: ENCePP Resource Database</b>			
<b>Chairs: Gianluca Trifirò, Paolo Alcini</b>			
12.	Survey results on the resource database	Ana Cochino	13:35 – 13:55
13.	Discussion on the survey results and the metadata	Gianluca Trifirò, Paolo Alcini	13:55 – 14:20
<b>SESSION 4: Observational studies for COVID-19</b>			
<b>Chairs: Olaf Klungel, Catherine Cohet</b>			
14.	Update on Covid-19 vaccines	Marco Cavaleri	14:20 – 14:45
15.	Update on Covid-19 vaccine studies	Miriam Sturkenboom	14:45 – 15:05
16.	Thrombosis and coagulopathy in Covid-19 patients and vaccine recipients	Daniel Prieto	15:05 – 15:25
<b>BREAK – 15:25 – 15:35</b>			

Item	Topic	Speaker	Time
17.	Steroids and the E-CORE network	Someone from IQVIA	15:35 – 15:55
18.	Discussion: How could ENCePP contribute to good practice in observational research on Covid-19, incl. quality of data sources, study design and analysis, transparency, communication	Olaf Klungel, Catherine Cohet	15:55 – 16:20
19.	Wrap-up		16:20 – 16:30
<b>END OF MEETING – 16:30</b>			