



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)

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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
3.	Update on COVID-19 vaccines	Marco Cavaleri	10.00 – 10.25
SESSION 1: CHMP Guideline on registry-based studies; EU PAS Register			
Chairs: Alejandro Arana, Xavier Kurz			
4.	Update on PAS: CHMP Guideline on registry-based studies	Kelly Plueschke	10:25 – 10:40
5.	Update on the rebuilding of the Real world data sources catalogue and observational studies catalogue	Xavier Kurz	10:40 – 10:55
6.	Survey results on EU PAS Register	Ana Cochino	10:55 – 11:15
7.	Discussion on the survey results and the EU PAS Register (slido and Q&A)	Alejandro Arana, Xavier Kurz	11:15 – 11:45
BREAK – 11:45 – 11:55			
SESSION 2: Update on Big Data SG and ENCePP SG			
Chairs: Daniel Morales, Peter Arlett			
8.	HMA-EMA Big Data workplan and update on DARWIN EU	Francois Domergue	11:55 – 12:10
9.	Curricula in Data Science, Pharmacoepidemiology and Biostatistics	Stefania Simou	12:10 – 12:25
10.	Artificial Intelligence in Medicine Regulation	Luis Pinheiro	12:25 – 12:40
11.	Update on the activities of the ENCePP Steering Group and Working Groups (WGs)	Susana Perez-Gutthann, Gianmario Candore and WG chairs	12:40 – 12:55
12.	Questions and answers	Daniel Morales, Peter Arlett	12:55 – 13:15
LUNCH BREAK – 13:15 – 14:00			
SESSION 3: ENCePP Resource Database			
Chairs: Gianluca Trifirò, Paolo Alcini			
13.	Survey results on the resource database	Ana Cochino	14:00 – 14:20
14.	Discussion on the survey results and the resource database (slido and Q&A)	Gianluca Trifirò, Paolo Alcini	14:20 – 14:45
SESSION 4: Observational studies for COVID-19			
Chairs: Olaf Klungel, Catherine Cohet			
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-Alhambra	15:05 – 15:25

Item	Topic	Speaker	Time
BREAK – 15:25 – 15:35			
17.	Steroids and the E-CORE network	Deborah Layton	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
END OF MEETING – 16:30			