ENCePP webinar

20 November 2020
09:15 – 16:30 (CET)
Virtual meeting

Objectives

- Key methodological considerations for observational studies on Covid-19 and how ENCePP could promote best practice, especially in the current context of preparedness for the monitoring of the safety and effectiveness of Covid-19 vaccines.

- Recommendations of the HMA-EMA Big Data Task Force and the proposed platform for a Data Analysis and Real-World Interrogation Network in the European Union (DARWIN EU), and interface between ENCePP activities and the Task Force recommendations.

- Achievements of the current ENCePP Steering Group at the end its term, introduce the members of the new ENCePP SG and discuss proposals for a draft ENCePP mandate.

SESSION 1:

The COVID-19 pandemic, vaccines monitoring and the contribution from ENCePP

Chairs: Tom MacDonald – Xavier Kurz

3.	Key methodological considerations for observational studies on Covid-19 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 All	09:30 09:50
4.	Development and authorisation status of Covid-19 vaccines	Marco Cavaleri	10:15
5.	On-going projects for COVID-19 vaccines safety and effectiveness monitoring - EU network vaccine monitoring strategy - ACCESS - CONSIGN - I-MOVE - DRIVE Discussion: How could ENCePP contribute vaccine surveillance and in appropriate communication on vaccine safety and effectiveness?	Georgy Genov Miriam Sturkenboom Marta Valenciano Javier Diez-Domingo All	10:30
	BREAK – 12.00		

SESSION 2:

ENCePP mandate and new ENCePP Steering group
Chairs: Catherine Cohet – Gianmario Candore

6.	Achievements of the current ENCePP Steering Group, 2016-2020	Tom MacDonald	12:30
7.	Report from ENCePP Working Group and Special Interest Group activities	WG and SIG Chairs	12:45
8.	Presentation of the new ENCePP SG – 2021-2023	Julianna Fogd	13:05
9.	The EU PAS Register: review of registered post-authorisation studies (ENCePP WG3)	Gianluca Trifiro	13:15
10.	Proposals for an ENCePP mandate and next steps Discussion	Xavier Kurz All	13:35 13:45
BREAK – 14.00			

SESSION 3:

Interface between ENCePP and the HMA-EMA Big Data Task Force recommendations on real-world evidence
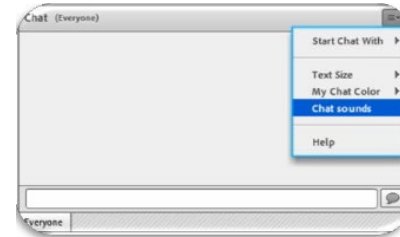
Chairs: Peter Arlett –Nikolai Brun

11.	HMA-EMA Big Data Task Force: Recommendations and workplan	Nikolai Brun	14:15
12.	The Data Analysis and Real-World Interrogation Network in the European Union (DARWIN EU)	Gianmario Candore François Domergue	14:45
13.	Metadata for electronic health care records	Katerina-Christina Deli	15:10
14.	Discussion: Interface between ENCePP and new initiatives in Big Data and Real-World Evidence	All	15:30
15.	Summary of discussion and proposal for next steps	Peter Arlett	16:00
16.	**Wrap-up of meeting**	Xavier Kurz	16:20

End of meeting – 16:30

Housekeeping notes

- Discussion at the end of each session

- For Q: Please raise your hands (top of screen)

- You can also write in the chat box (bottom left)

- We aim to respond to all questions, either during the workshop or afterwards in writing

- In case of technical issues, please contact virtualmeetings@ema.europa.eu