EMA/556759/2020

Agenda – Webinar: ENCePP in the Time of Covid

20 November 2020

09:30 – 16:30 (CET)

Virtual meeting

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
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Background

The aim of the European Network of Centres in Pharmacoepidemiology and Pharmacovigilance (ENCePP) is to strengthen the monitoring of the benefit-risk balance of medicinal products in Europe by facilitating the conduct of high quality, multi-centre, independent observational post-authorisation studies, by bringing together expertise and resources in pharmacoepidemiology and pharmacovigilance across Europe, and by developing and maintaining best practice for research. ENCePP also provides and maintains a publicly available and searchable resource database and the European Union Post-authorisation study (PAS) Register.

These objectives are at the core of ENCePP but changes in the research environment over the last years require ENCePP to address new challenges. In addition to the Covid-19 public health emergency, these challenges include the availability of new data sources and new approaches for their use, new fields of research like pharmacogenomics, increased expectations on transparency of studies, and the need for interactions with a broader range of stakeholders such as learned societies (e.g. ISPE, ISPOR and ISoP), Health Technology Assessment bodies, payers and patients' associations.

In 2020, the scale and novelty of the COVID-19 pandemic have created an unprecedented need for high-quality evidence supporting regulatory and public health decision-making, covering disease epidemiology, evaluation of safety and effectiveness of treatments repurposed to COVID-19 indications and monitoring of vaccines when they become available. On the eve of the authorisation of new Covid-19 vaccines, ENCePP could take an important role in Europe to promote use of best methodological standards and high-quality data.

The 2020 HMA-EMA Joint Big Data Task Force report proposed to establish a sustainable platform to access and analyse healthcare data from across the EU and an EU framework for data quality and representativeness. It also recommended expansion of the scope and utility of the ENCePP resource database to provide more detailed information on the quality of datasets.

In this time of Covid, the webinar will therefore provide a forum where ENCePP will discuss the orientations and activities that may strengthen the role of the network ENCePP in this changing environment. The webinar will also give an opportunity to establish the new ENCePP Steering Group.

Objectives

- To discuss 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.
- To present the 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 discuss the interface between ENCePP activities and the Task Force recommendations.
- To summarise the 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.

Agenda

Item	Topic	Speaker	Time
1.	Connection to virtual room and technical checks	-	09.00
2.	- Welcome and introduction - Workshop objectives	- Tom MacDonald - Xavier Kurz	09.15
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

Item	Topic	Speaker	Time
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			