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Real World research on medicinal products: key contribution of the European Network of Centres in Pharmacoepidemiology and Pharmacovigilance (ENCePP)[1]

Webinar's Agenda

8 March 2021

10:00 – 12:00 (CET)

Virtual meeting

Targeted audience: ***Academia communities / Learned societies***

[1] ENCePP website: http://www.encepp.eu/index.shtml

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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. Following 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 resources database to provide more detailed information on the quality of datasets.

In line with its Regulatory Science Strategy Plan to 2025, EMA is committed to further develop the existing interactions between the EU regulatory network and Academia, in view to keep each other informed of relevant scientific innovations and research, as well as to identify solutions to regulatory needs and challenges[2]. This webinar will provide the opportunity for the Academia communities / Learned societies to learn more about ENCePP and how it may improve pharmaco-epidemiological research especially in circumstances such as a pandemic.

Objectives:

- To raise Academia's/Learned societies' awareness about ENCePP
- To highlight ENCePP's contribution to pharmaco-epidemiological research and post-authorisation safety surveillance of medicinal products
- To learn from ENCePP members' experience and understand how the network supports Academia's/Learned societies observational research
- To discuss methodological challenges for observational studies and tools available to all researchers

[2] See also the document Framework of collaboration between the European Medicines Agency and academia adopted by the EMA Management Board in March 2017

Agenda

Item	Topic	Speaker	Time
1.	- Welcome and introduction - Webinar's objectives	Co-chairs of the ENCePP SG 2021-2023[3]: Gianmario Candore, EMA / Susana Perez-Gutthann, RTI Health Solutions	5'
2.	What is ENCePP and why is it relevant to Academia?	Xavier Kurz, EMA	5'
3.	How does ENCePP support Academia? Review of the ENCePP tools	Francesco Salvo, University of Bordeaux	10'
4.	The EU register of post-authorisation studies: why is it important to register studies and lessons learned?	Gianluca Trifiro, University of Verona	10'
5.	How can ENCePP contribute to research? Experience from an EU academics	Jetty Overbeek, PHARMO	10'
6.	How can ENCePP contribute to research? Experience from a non-EU academics	K. Arnold Chan, National Taiwan University	10'
7.	ENCePP and Covid-19: Considerations on good practice in observational research on Covid-19	Helga Gardastottir, Utrecht University	15'
8.	ENCePP and Covid-19: How does ENCePP contribute to the monitoring of therapeutics and vaccines?	Daniel Prieto-Alhambra, Erasmus Medical Centre	15'
9.	What's next for ENCePP?	Gianmario Candore, EMA / Susana Perez-Gutthann, RTI Health Solutions	10'
Questions and Answers			
End of meeting – 12:00			

[3] ENCePP Steering Group composition: http://www.encepp.eu/structure/structure_steeringGroup.shtml