



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP Plenary meeting – Introduction and workshop objectives

ENCePP Plenary webinar – 18 November 2021

Presented by Susana Perez-Gutthann and Gianmario Candore – ENCePP SG chairs

An agency of the European Union





Objectives of the meeting

- 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](#), 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 to [upgrade 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 (slide 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

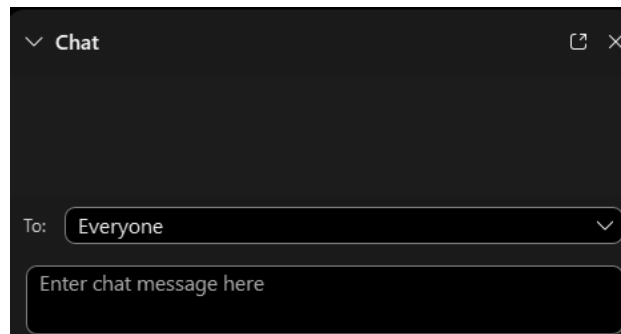
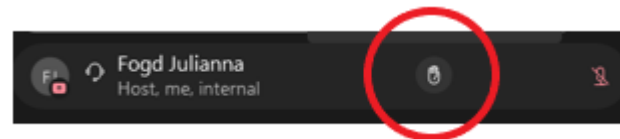


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SESSION 3: ENCePP Resource Database			
<i>Chairs: Gianluca Trifirò, Paolo Alcini</i>			
13.	Survey results on the resource database	Ana Cochino	14:00 – 14:20
14.	Discussion on the survey results and the resource database (slide and Q&A)	Gianluca Trifirò, Paolo Alcini	14:20 – 14:45
SESSION 4: Observational studies for COVID-19			
<i>Chairs: Olaf Klungel, Catherine Cohet</i>			
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
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			

Housekeeping notes

- Make sure **your microphone is muted** when not speaking
- Each session will be followed by a Q&A session, managed by the co-chairs
- Questions can be asked by
 - **Raising your hand** to speak or
 - **Send your questions** through the **Chat** function in WebEx (lower right-hand side of the screen) and select the option to send your question to **Everyone**



Housekeeping notes

- Mention your **name and organisation** when you speak
- **Presenters** are invited to **switch on their camera** before speaking
- Presenters will **get control to change their slides** (click on the up/down arrows on the left-hand side to change slides)
- The Plenary report and the presentations will be **published on the ENCePP website**



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- To update on the **work programme** of the HMA-EMA Big Dat ENCePP activities. Topics for discussion include the creation **Pharmacoepidemiology and Biostatistics**, an update on the I European Union (**DARWIN EU**) and the pilots for data analy
- To discuss the result of the surveys and agree on the amen functionalities to upgrade the EU PAS Register and ENCePP
- To exchange views on the activities of the ENCePP Steering renewal of the WGs, and the proposed new ENCePP activiti



Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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

Telephone +31 (0)88 781 6000

Send us a question Go to www.ema.europa.eu/contact

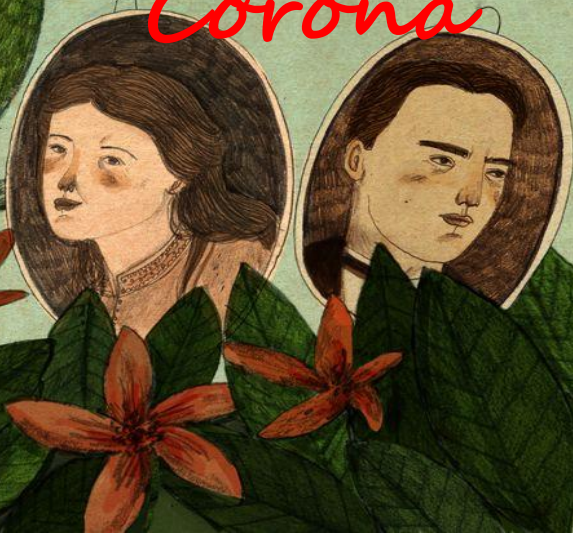
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Gabriel García Márquez

ENCePP

~~Love~~ in the
Time of
~~Cholera~~

Corona



ENCePP webinar

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