



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction

ENCePP Plenary 2022
Wednesday 30 November 2022

Susana Perez-Gutthann
Catherine Cohet

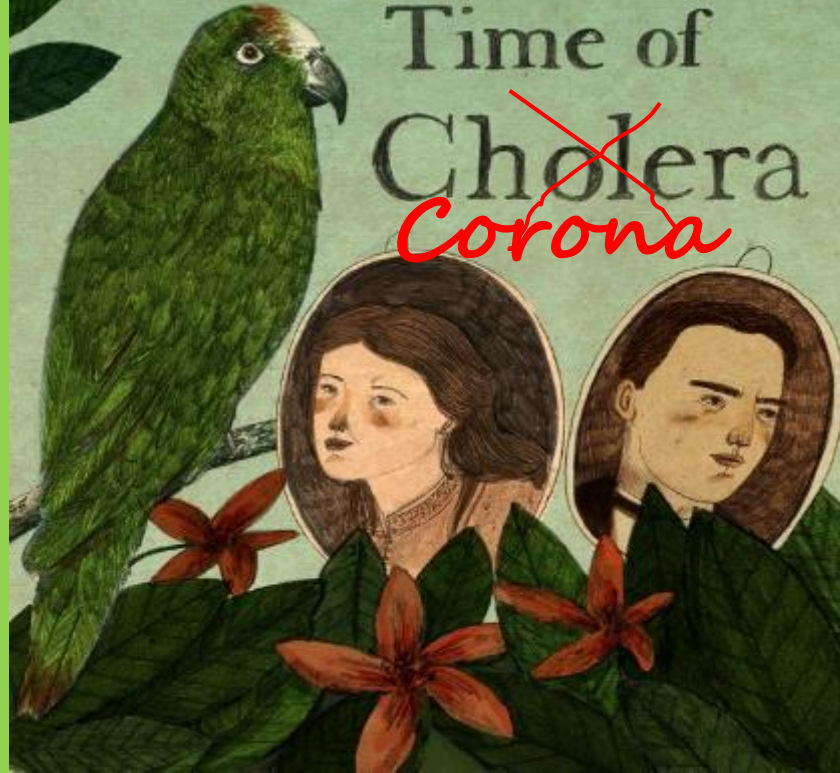


Gabriel García Márquez

ENCePP

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

Corona



ENCePP webinar

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



Objectives of the meeting

- To present and discuss the activities of the ENCePP **Steering Group** and **Working Groups** and exchange ideas to populate the ENCePP **workplan** for 2023 and beyond
- To update and seek input from ENCePP partners on upcoming developments including the new ENCePP **website** and the upgrading of the EU PAS Register and ENCePP Resources Database **catalogues** into the new RWD sources and RWD studies catalogues
- To exchange views on the **future** of ENCePP and how to improve **visibility**, enhance **collaborations** with learned societies, and consider current and future **guidance** initiatives in the ENCePP work plan
- To inform the ENCePP community about latest developments on COVID-19 and MPX vaccines and therapeutics and the contribution of pharmacoepidemiology to EMA's **decision-making**
- To update on **DARWIN** EU and discuss the interface with ENCePP activities
- To learn about, and discuss, current **methodological** hot topics



Agenda

1.	Arrival, connection to virtual room and technical checks for those online		8:45-9:00
2.	Welcome and introduction Meeting objectives	Susana Perez-Gutthann, Catherine Cohet	9:00-9:10
3.	Update on COVID-19 and monkeypox vaccines and therapeutics – how can ENCePP support public health crisis management	Marco Cavaleri	9:10-9:25
4.	DARWIN EU®: update and interface with ENCePP	Daniel Prieto-Alhambra	9:25-09:45

SESSION 1: Looking back at 2022

Chairs: Xavier Kurz / Massoud Toussi

5.	Update from the Steering Group	Susana Perez-Gutthann, Catherine Cohet	9:45-9:55
6.	Update from the Working Groups	Alejandro Arana (WG1) Rosa Gini (WG2) Gianluca Trifirò (WG3)	9:55-10:30
7.	ENCEPP website update	Andrej Segec	10:30-10:45
8.	Update on the RWD sources and RWD studies catalogues	Katerina-Christina Deli	10:45-11:00

Coffee break – 11:00 to 11:30

SESSION 2: A new era for ENCePP?

Chairs: Peter Arlett / Susana Perez-Gutthann

9.	Collaboration between ENCePP and learned societies / guidance initiatives	<ul style="list-style-type: none"> ISPE (Arnold K. Chan) ISOP (Gianluca Trifirò) HARPER (Susana Perez-Gutthann) GVP VIII and ICH M14 (Catherine Cohet) 	11:30-12:00
10.	Open discussion on new directions for ENCePP, and impact on the work plan development	Xavier Kurz Helga Gardarsdottir	12:00-12:45

Lunch break – 12:45 to 13:30

SESSION 3: Methodology

Chairs: Daniel Morales / Helga Gardarsdottir

11.	Using primary data collection in pharmacoepidemiology: the SEMVAC monkeypox vaccine study	Pierre Engel	13:30-13:50
12.	Results from RTC DUPLICATE and lessons for Europe	Shirley Wang Sebastian Schneeweiss	13:50-14:10
13.	Target Trial Emulation With and Without Cloning	Xabier García de Albéniz	14:10-14:40

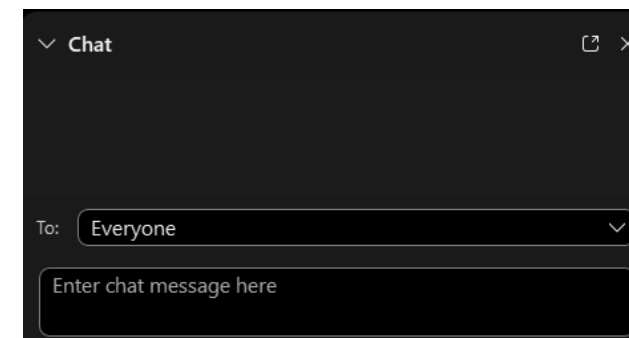
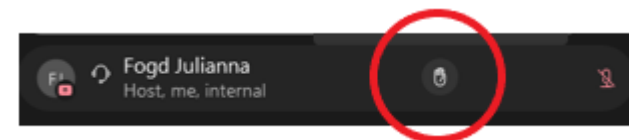
Wrap-up

14.	Patient views on use of their data in pharmacoepidemiological studies	Iryna Vlasenko	14:40-14:50
15.	Summary and next steps	Susana Perez-Gutthann, Catherine Cohet	14:50-15:00

Adjournment – 15:00

Housekeeping notes

- Each topic will include a few minutes **Q&A**, moderated by the session chairs
- Make sure **your microphone is muted** when not speaking
- Questions can be asked by:
 - **Raising your hand** to speak, or
 - **Asking** through the **Chat** function in WebEx (lower right-hand side of the screen), to **Everyone**
- Please mention your **name and organisation** when speaking
- **Presenters** are invited to **switch on their camera**; EMA will advance the slides
- **Lunch** will be in the **EMA restaurant**
- The Plenary report and presentations will be **published** on the **ENCePP website**





Enjoy the Plenary!

