



Meeting Objectives

ENCePP Plenary - 22 November 2024, Amsterdam

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Catherine Cohet, EMA

Today's objectives



- To **reflect** on the work of ENCePP since the December **2023 Plenary**, and inform the ENCePP community on recent **progress**
- To provide an update on milestones and deliverables of the ENCePP **workplan**, and seek feedback and contribution from ENCePP Partners on **governance** aspects and future **activities** and **deliverables**
- To continue placing the work of ENCePP in the context of an ever-changing **regulatory environment**
- To learn about, and discuss, the strategy for the 2025 revision and dissemination of the **ENCePP Methods Guide**, as well as **methodological topics** of current interest



Agenda



SESSION 1: ENCePP today, and the near future

Chairs: Vera Ehrenstein (Aarhus University), Christos Kontogiorgis (University of Thrace)

4.	ENCePP workplan: 2024 achievements	Catherine Cohet (EMA) and Working Group leads (Alejandro Arana, Rosa Gini, Gianluca Trifiro)	9:15-9:45
5.	<ul style="list-style-type: none"> Terms of Reference for the Working Groups and Special Interest Groups Proposal for new groups 	Helga Gardarsdottir (Utrecht University), Laura Pizzi (ISPOR), Gianmario Candore (Bayer AG)	9:45-10:30

Coffee break – 10:30 to 11:00

6.	Qualitative research on the role and impact of ENCePP: key findings	Sharanya (Shar) Rao (Utrecht University)	11:00-11:40
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SESSION 2: Role of ENCePP in an ever-changing regulatory environment

Chairs: Katja Hakkarainen (Parexel), Patrice Verpillat (EMA)

7.	<ul style="list-style-type: none"> Methodology Working Party (MWP) workplan Learnings from public consultations on the MWP RWE Reflection Paper and ICH M14 	Olaf Klungel (Utrecht University)	11:40-12:00
8.	<ul style="list-style-type: none"> Recent news from EMA RWE to support EU regulatory decision-making: 2nd annual report DARWIN EU[®] update: focus on studies 	María Clara Restrepo-Méndez, Andrej Segec (EMA)	12:00-12:30

Lunch – 12:30 to 13:15

SESSION 3: Methodological topics of current interest

Chairs: Hedvig Nordeng (University of Oslo), Tania Schink (Leibniz Institute for Prevention Research and Epidemiology – BIPS)

9.	ENCePP Guide on Methodological Standards: 12 th Revision and publication strategy	Helga Gardarsdottir (Utrecht University) Alejandro Arana (RTI)	13:15-14:00
10.	Quantitative Bias Analysis	Ian Douglas (LSHTM)	14:00-14:45
11.	Prevalent new user design	Michael Webster-Clark (McGill University)	15:45-15:30

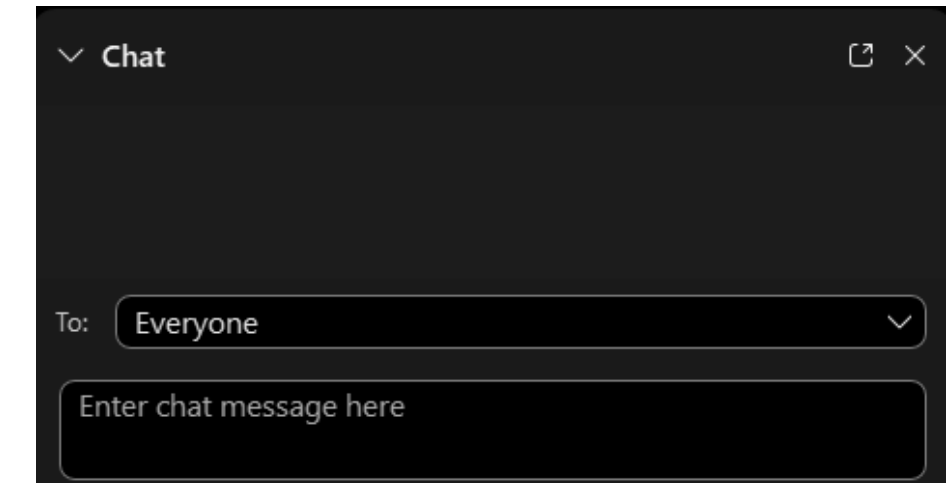
Wrap-up

12.	<ul style="list-style-type: none"> Feedback from Plenary participants on agenda topics and next steps (Slido and discussion) Closing and next steps 	Helga Gardarsdottir (Utrecht University) Catherine Cohet (EMA)	15:30-16:00
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Adjournment – 16:00

Housekeeping notes

- Make sure your **microphone** is **muted** when not speaking
- Each topic includes time for **discussion**, moderated by the session chairs
- Questions can be asked by **raising your hand** / **writing** in the **Chat** in Webex (lower right-hand side of the screen) sending to **Everyone**
- Presenters and participants are invited to **switch on** their **camera** when speaking
- **Online presenters** will get presenter rights / **In-person presenters** will get a clicker
- The **presentations** and **meeting report** will be published on the ENCePP website



Enjoy the Plenary!

We count on your input and feedback, in the room and online

