



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/472048/2024
European Medicines Agency

ENCePP Plenary meeting

Friday, 22 November 2024

9:00 – 16:00 CET

Hybrid meeting (in-person and [WebEx](#))

European Medicines Agency (Room 1D), Amsterdam, The Netherlands

Meeting 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.

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

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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Agenda

Chairs: Helga Gardarsdottir (Utrecht University), Catherine Cohet (EMA)

Item	Topic	Speaker(s)	Time
1.	Arrival, connection to virtual room and technical checks		08:30-9:00
2.	Welcome	Peter Arlett (EMA)	09:00-9:10
3.	Meeting objectives	Helga Gardarsdottir (Utrecht University) Catherine Cohet (EMA)	09:10-9:15
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
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.	Recent news from EMA <ul style="list-style-type: none"> 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

Item	Topic	Speaker(s)	Time
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
Adjournment – 16:00			