



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

enepp

EMA/326221/2025
European Medicines Agency

ENCePP Annual Plenary Meeting

Monday, 1 December 2025

9:00 – 16:00 CET

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

European Medicines Agency (Room 2A), Amsterdam, The Netherlands

Meeting objectives

- To reflect on the progress of the ENCePP Work plan since the 2024 Plenary;
- To present the new Working Groups and Special Interest Groups, and seek feedback from the ENCePP community on their objectives and completed/upcoming deliverables;
- To continue placing the work of ENCePP in the context of the ever-changing regulatory and real-world evidence (RWE) environment, by sharing updates on DARWIN EU¹, the EHDS, and new EU and international guidance relevant to ENCePP;
- Following up on methodological sessions in past years Plenary meetings², to dive deeper into topics of current interest.

¹ [Real-world evidence | European Medicines Agency \(EMA\)](#)

² [Plenary Meetings - European Network of Centres for Pharmacoepidemiology and Pharmacovigilance](#)

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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: Where are we 2 years into the 2024-2026 mandate?			
Chairs: Laura Pizzi (ISPOR) & Patrice Verpillat (EMA)			
4.	ENCePP workplan 2024-2026: progress update	Helga Gardarsdottir (Utrecht University) Catherine Cohet (EMA)	9:15-9:30
5.	New Working Groups and Special Interest Groups: mandate and progress so far	WGs/SIGs chairs	9:30-10:30
Coffee break and networking – 10:30 to 11:00			
6.	New Working Groups and Special Interest Groups: mandate and progress so far (ctn'd)	WGs/SIGs chairs	11:00-11:45
SESSION 2: ENCePP in the current RWD/RWE environment			
Chairs: Rosa Gini (ARS Toscana) & Daniel Morales (EMA)			
7.	RWE generation at EMA: • DARWIN EU update • RWD studies: selected use cases	Andrej Segec (EMA)	11:45-12:15
8.	EHDS: latest news and testimony from Finland	Jaakko Lähteenmäki (VTT Technical Research Centre of Finland)	12:15-12:45
Lunch and networking – 12:45 to 13:30			
9.	EU/international guidance: what's new?	Catherine Cohet (EMA)	13:30-14:00
SESSION 3: 'Not so new' methodologies, new applications			
Chairs: Anna-Maija Tolppanen (University of Eastern Finland) & Alexandra Pacurariu (EMA)			
10.	Target trial emulation and estimand frameworks: Current thinking and overview of the TARGET-EU project	Daniela Weir (Utrecht University)	14:00-14:45

Item	Topic	Speaker(s)	Time
11.	Interactive session on Pragmatic Clinical Trials	Panellists: <ul style="list-style-type: none"> • Isla Mackenzie (Dundee university) • Mira Zuidgeest (UMC Utrecht) • Patrice Verpillat (EMA) 	14:45-15:45
Wrap-up			
12.	<ul style="list-style-type: none"> • Feedback from Plenary participants • Closing and next steps 	Helga Gardarsdottir (Utrecht University) Catherine Cohet (EMA)	15:45-16:00
Adjournment – 16:00			