

ENCePP Plenary 2025





Introduction

ENCePP Plenary - 01 December 2025, Amsterdam

Helga Gardarsdottir (Utrecht University), Catherine Cohet (EMA)
on behalf of the [ENCePP Steering Group](#)

Today's 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 on their objectives and completed/upcoming deliverables
- To continue placing the work of ENCePP in the context of the ever-changing **regulatory** and **RWE** environment, by sharing updates on **DARWIN EU**, the **EHDS**, and new EU and international **guidance**
- Following up on **methodological** sessions in past years, to dive deeper into topics of current interest



Agenda

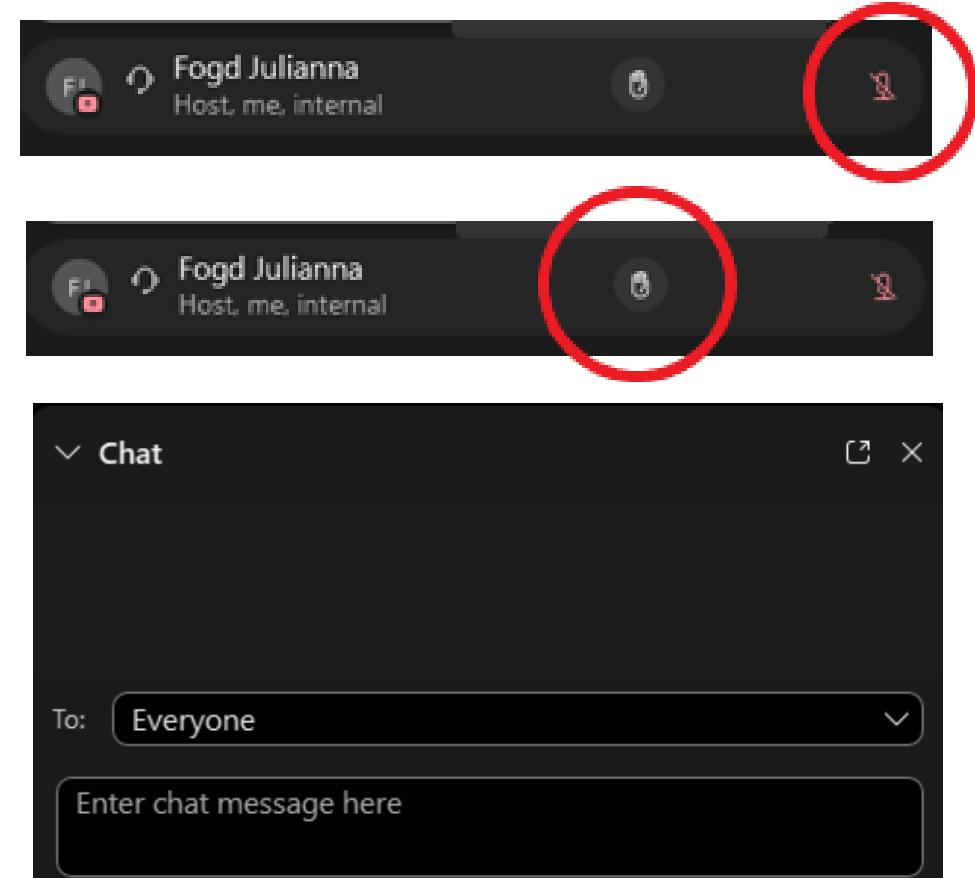
Item	Topic	Speaker(s)	Time
1.	Arrival, connection to virtual room and technical checks		08:30-9:00
2.	Welcome	Peter Arlett (EMA)	09:00-9:10
3.	Meeting objectives	Helga Gardarsdottir (Utrecht University) Catherine Cohet (EMA)	09:10-9:15
SESSION 1: Where are we 2 years into the 2024-2026 mandate? <i>Chairs: Laura Pizzi (ISPOR) & Patrice Verpillat (EMA)</i>			
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 <i>Chairs: Rosa Gini (ARS Toscana) & Daniel Morales (EMA)</i>			
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

Item	Topic	Speaker(s)	Time
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 <i>Chairs: Anna-Maija Tolppanen (University of Eastern Finland) & Alexandra Pacurariu (EMA)</i>			
10.	Target trial emulation and estimand frameworks: Current thinking and overview of the TARGET-EU project	Daniala Weir (Utrecht University)	14:00-14:45
11.	Interactive session on Pragmatic Clinical Trials	Panellists: • Isla Mackenzie (Dundee university) • Mira Zuidgeest (UMC Utrecht) • Patrice Verpillat (EMA)	14:45-15:45
Wrap-up			
12.	• Feedback from Plenary participants • Closing and next steps	Helga Gardarsdottir (Utrecht University) Catherine Cohet (EMA)	15:45-16:00
Adjournment – 16:00			



Housekeeping notes

- Each topic includes time for **discussion**, moderated by the session chairs
- Questions can be asked by **raising your hand/in the Chat** in Webex (lower right-hand side of the screen) sending to **Everyone**
- Make sure your **microphone** is **muted** when not speaking
- Presenters and participants please **switch on cameras** 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 (under Documents)



Enjoy the Plenary!

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



ENCePP workplan - 2025 achievements





Recap: workplan 2024-2026 in **enepp** a nutshell



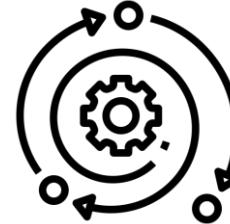
Governance

- * Review of mandates
- * Terms of reference for the Working Groups and SIGs



Visibility

- * ENCePP website
- * Podcasts
- * Social media
- * Publication(s)



Impact

- * Assess needs (w/ Utrecht Uni)
- * Collaboration w/ learned societies
- * Update/enhance ENCePP tools
- * Partner w/public bodies in EU candidate countries

Published in June 2024 following SG endorsement, updated in February 2025

<https://encepp.europa.eu/documents/work-plans>



Objective 1

Update the **governance** and ways of working of ENCePP

Milestones/Deliverable(s)	Who?	Timelines	Status
1.1 - Terms of reference for establishment and maintenance of the Working Groups and Special Interest Groups	Helga Gardarsdottir Gianmario Candore Laura Pizzi	By end 2024	Link 
1.2 - Review of the mandates (ENCePP and Steering Group)	WGs Steering Group (SG) ENCePP Secretariat	At the start of the new term of the SG	For 2024-2026 mandate  ENCePP 'About us' Steering Group



Objective 2

Increase the **visibility** of ENCePP in Europe and globally

Milestones/Deliverable(s)	Who?	Timelines	Status
2.1 - Guidance for publication of news/events on ENCePP website	Vera Ehrenstein	2024	<i>Ad hoc</i> 
2.2 - Slide deck (+ videos/webinars) on history of ENCePP, governance/tools supporting sound PV/PE research	<ul style="list-style-type: none">• Helga Gardarsdottir• Catherine Cohet• WG/SG members	Continuous activity and <i>ad hoc</i>	Several achievements: <ul style="list-style-type: none">• Slide template for partners• ICPE 2024 symposium• Report and webinar (soon online) on impact of ENCePP 
2.3 - Publication – follow-up of PDS 2018 / part of publication series (see ENCePP Guide strategy 3.3)		From 2025	On track (see SIG update)  

Objective 2

Increase the **visibility** of ENCePP in Europe and globally

Milestones/Deliverable(s)	Who?	Timelines	Status
2.4 - Podcasts "Conduct your study" and other potential topics	WG Independence and Transparency and all WGs/SIGs	First one in 2024	Two so far, and going Podcasts 
2.5 - Explore means of using social media to promote ENCePP	Julianna Fogd	Q3 2024	Via partners on their LinkedIn accounts 
2.6 - Increase reach out to larger PV/PE community (RSS feed on ENCePP website)	Julianna Fogd	Q2/Q3 2024	See Minutes SG Sept. 2024 

Objective 3

Increase the **impact** of ENCePP in Europe and globally

Milestones/Deliverable(s)	Who?	Timelines	Status
3.1 - Qualitative research	Shar Rao Helga Gardarsdottir	Q4 2024 (Plenary)	Report and webinar 
3.2 - Co-branded events with learned societies	Arnold Chan (ISPE) Laura Pizzi (ISPOR) Gianluca Trifiro (ISOP)	• ICPE • ISPOR • ISOP	  
3.3 - Update and/or reinforce use of ENCePP tools and integrate regulatory/RWE/PE/PV guidance (in Guide, Protocol Checklist, CoC)	As per mandates of current and/or new WGs/SIGs	2024/2025	Ongoing (see WGs/SIGs updates) 
3.4 - Adapt, and/or create new WGs/SIGs to address the work plan	Steering Group Secretariat ENCePP Partners	During 2025	6 WGs 4 SIGs 
3.5. Open ENCePP to public bodies in current EU candidate countries/potential candidates	Secretariat	Continuous	



Thank you!
Questions, suggestions?



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enepp

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