

# 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

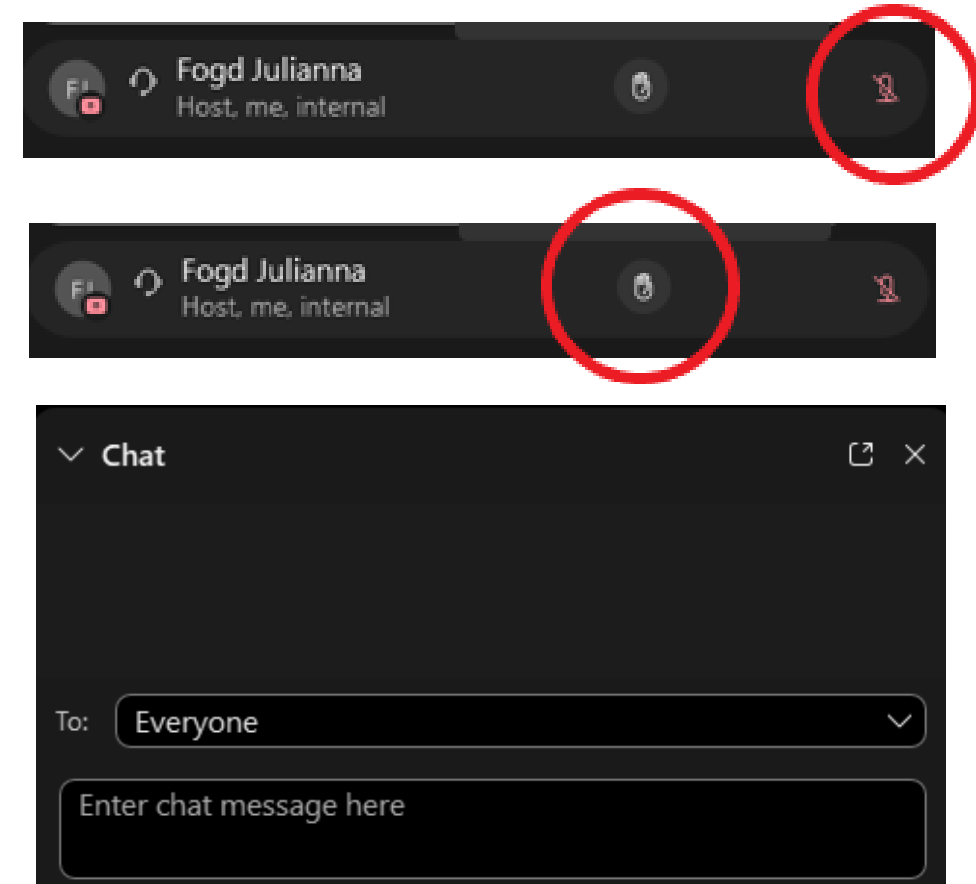


Item	Topic	Speaker(s)	Time
1.	Arrival, connection to virtual room and technical checks		08:30-9:00
2.	Welcome	Peter Arlett (EMA)	09:00-9:10
3.	Meeting objectives	Helga Gardarsdottir (Utrecht University) Catherine Cohet (EMA)	09:10-9:15
<b>SESSION 1: Where are we 2 years into the 2024-2026 mandate?</b> <i>Chairs: Laura Pizzi (ISPOR) &amp; 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
<b>Coffee break and networking – 10:30 to 11:00</b>			
6.	New Working Groups and Special Interest Groups: mandate and progress so far (ctn'd)	WGs/SIGs chairs	11:00-11:45
<b>SESSION 2: ENCePP in the current RWD/RWE environment</b> <i>Chairs: Rosa Gini (ARS Toscana) &amp; 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
<b>Lunch and networking – 12:45 to 13:30</b>			
9.	EU/international guidance: what's new?	Catherine Cohet (EMA)	13:30-14:00
<b>SESSION 3: 'Not so new' methodologies, new applications</b> <i>Chairs: Anna-Maija Tolppanen (University of Eastern Finland) &amp; Alexandra Pacurariu (EMA)</i>			
10.	Target trial emulation and estimand frameworks: Current thinking and overview of the <a href="#">TARGET-EU</a> 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
<b>Wrap-up</b>			
12.	• Feedback from Plenary participants • Closing and next steps	Helga Gardarsdottir (Utrecht University) Catherine Cohet (EMA)	15:45-16:00
<b>Adjournment – 16:00</b>			

# 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



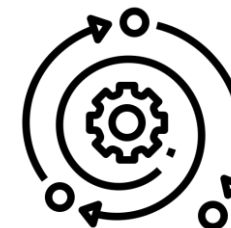
### Governance

- \* 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 <b>Working Groups</b> and <b>Special Interest Groups</b>	Helga Gardarsdottir Gianmario Candore Laura Pizzi	By end 2024	<a href="#">Link</a> 
1.2 - Review of the <b>mandates</b> (ENCePP and Steering Group)	WGs Steering Group (SG) ENCePP Secretariat	At the start of the new term of the SG	For 2024-2026 mandate  <a href="#">ENCePP 'About us' Steering Group</a>






# 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 <b>ENCePP website</b>	Vera Ehrenstein	2024	<i>Ad hoc</i> 
2.2 - <b>Slide deck</b> (+ videos/webinars) on history of ENCePP, governance/tools supporting sound PV/PE research	<ul style="list-style-type: none"><li>• Helga Gardarsdottir</li><li>• Catherine Cohet</li><li>• WG/SG members</li></ul>	Continuous activity and <i>ad hoc</i>	Several achievements: <ul style="list-style-type: none"><li>• Slide template for partners</li><li>• <a href="#">ICPE 2024 symposium</a></li><li>• <a href="#">Report</a> and webinar (soon online) on impact of ENCePP</li></ul> 
2.3 - <b>Publication</b> – 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 - <b>Podcasts</b> "Conduct your study" and other potential topics	WG Independence and Transparency and all WGs/SIGs	First one in 2024	Two so far, and going <a href="#">Podcasts</a> 
2.5 - Explore means of using <b>social media</b> to promote ENCePP	Julianna Fogd	Q3 2024	Via partners on their LinkedIn accounts 
2.6 - Increase <b>reach out</b> to larger PV/PE community (RSS feed on ENCePP website)	Julianna Fogd	Q2/Q3 2024	See <a href="#">Minutes SG Sept. 2024</a> 

# Objective 3



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

Milestones/Deliverable(s)	Who?	Timelines	Status
3.1 - <b>Qualitative research</b>	Shar Rao Helga Gardarsdottir	Q4 2024 (Plenary)	<a href="#">Report</a> and webinar 
3.2 - Co-branded events with <b>learned societies</b>	Arnold Chan (ISPE) Laura Pizzi (ISPOR) Gianluca Trifiro (ISOP)	• ICPE • ISPOR • ISOP	  
3.3 - Update and/or reinforce use of ENCePP <b>tools</b> and integrate regulatory/RWE/PE/PV <b>guidance</b> (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 <b>WGs/SIGs</b> to address the work plan	Steering Group Secretariat ENCEPP Partners	During 2025	<b>6 WGs</b> <b>4 SIGs</b> 
3.5. Open ENCePP to public bodies in current EU candidate countries/potential candidates	Secretariat	Continuous	



Thank you!  
Questions, suggestions?



Website: [www.encepp.eu](http://www.encepp.eu)



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