



ENCePP workplan - 2024 achievements

ENCePP Plenary - 22 November 2024, Amsterdam

Catherine Cohet (EMA), on behalf of the **ENCePP Steering Group**

February 2024

enepp English Search

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Home About us ENCePP toolkit Newsroom Publications Documents Q&A

ENCePP Seal
Methodological Guide
Code of Conduct
ENCePP Checklist for Study Protocols

About ENCePP

The European Network of Centres for Pharmacoepidemiology & Pharmacovigilance (ENCePP) is an initiative that brings together expertise and resources in pharmacoepidemiology and pharmacovigilance across Europe. ENCePP is coordinated by the European Medicines Agency.

EMA | RWD Catalogues Log in Search

Home Data Sources Studies Institutions Networks What's new Support

HMA-EMA Catalogues of real-world data sources and studies

The Catalogues for real-world data sources, studies, institutions and networks replace and enhance the previous EU PAS Register® and ENCePP Resource Database.

The HMA-EMA Catalogues are repositories of metadata collected from real-world data (RWD) sources and RWD studies. They are intended to help **regulators, pharmaceutical companies** and **researchers** to identify and use such data when investigating the use, safety and effectiveness of medicines.

The Catalogue of RWD sources replaces the ENCePP Resources Database, while the Catalogue of RWD studies replaces the EU PAS Register®. Additionally, Catalogues of institutions and networks are also available to support the RWD sources and RWD studies catalogues. Together, these Catalogues offer an improved and more efficient service for researchers, regulators, and pharmaceutical companies to:

- **Facilitate the discoverability** of adequate data sources to generate real-world evidence for regulatory purposes (e.g., identification of RWD data sources suitable for investigating a specific research question);
- **Aid in the suitability assessment** of data sources by providing clear and easy access to information from the study protocol and study report;
- **Improve interoperability** between studies and data sources;
- **Improve transparency.**



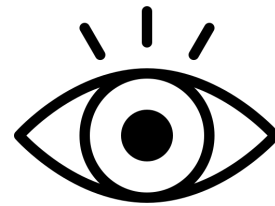
Workplan 2024-2026 in a nutshell

enepp



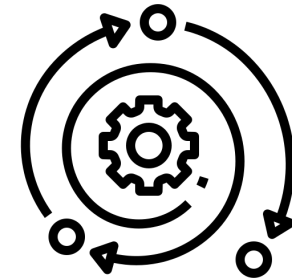
Governance

- * 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/reinforce ENCePP Tools
- * Partner w/public bodies in EU candidate countries

Published in June 2024 following Steering Group endorsement
<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	Draft: Q3 2024 Final: Q4 2024	 For discussion today 
1.2 - Review of the mandates (ENCePP and Steering Group)	WGs Steering Group (SG) ENCePP Secretariat	At each new term of the SG	2024-2026 



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	Q3 2024	Ongoing 
2.2 - Slide deck (+ videos/webinars) on history of ENCePP, governance/tools supporting sound PV/PE research	Helga Gardarsdottir	Slide deck: Q3 2024	ICPE slides  Living deck
2.3 - Publication – follow-up of PDS 2018 / part of publication series (see ENCePP Guide strategy 3.3)	Catherine Cohet WG/SG members	Publication(s): 2025 onwards	On track 
2.4 - Podcasts "Conduct your study" (first series) and other potential topics	Current WG2	First one in 2024	Two!  Activity to continue 
2.5 - Explore means of using social media to promote ENCePP	Julianna Fogd	Q3 2024	
2.6 - Increase reach out to larger PV/PE community (RSS feed on ENCePP website)	Julianna Fogd	Q2/Q3 2024	

Objective 3



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

Milestones/Deliverable(s)	Who?	Timelines	Status
3.1 - Qualitative research	Sharanya (Shar) Rao Helga Gardarsdottir	Q4 2024 (Plenary)	+ F/up
3.2 - Co-branded events with learned societies	Arnold Chan (ISPE) Laura Pizzi (ISPOR) Gianluca Trifiro (ISOP)	ICPE 2024 ISPOR EU 2024 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
3.4 - Adapt, and/or create new WGs/SIGs to address the work plan	Steering Group Secretariat ENCePP Partners	Ongoing	For discussion today
3.5. Open ENCePP to public bodies in current EU candidate countries/potential candidates	Secretariat	2024 onwards	



Thank you!
Questions?



Website: www.encepp.eu



ENCePP Secretariat

encepp_secretariat@ema.europa.eu

catherine.cohet@ema.europa.eu