

# New WGs and SIGs

ENCePP Plenary - 01 December 2025, Amsterdam

Presenters: WGs/SIGs chairs

# Working Groups

- Communications and outreach
- Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology
- Independence and transparency
- Artificial Intelligence (AI) in Pharmacoepidemiology
- Diversity and Health Equity
- Real-World-Data (RWD) sources in non-interventional studies

# Special Interest Groups

- Pragmatism in Clinical Trials
- Update of the ENCePP Checklist for Study Protocols
- Supplement to the Good Practice Guide for the use of the HMA-EMA Catalogues
- Publication of selected chapters of the ENCePP Guide in PDS and Value in Health



# WG on Communications and outreach

## **Co-chairs:**

Katica Borić (RTI Health Solutions (RTI-HS))

Katarina Gvozdanović (Teaching Institute of Public Health “Dr. Andrija Stampar”)



# Objectives

- Develop an **internal communication plan** to coordinate and disseminate activities and efforts across working groups, special interest groups, the ENCePP Steering Group, and the Secretariat. This should include **establishing a system to track collaboration**, ongoing projects, and ideas for showcasing.
- **Enhance the dissemination of ENCePP's tools, guidance, and updates** to the pharmacoepidemiology and pharmacovigilance communities, thus increasing visibility and accessibility to researchers, regulators, and other stakeholders across Europe and globally.
- **Establish metrics** for evaluating the success of communication and outreach activities, allowing for continuous improvement and adaptation.



# Deliverables

Milestones/Deliverable(s)	Timelines	Status
Kick-off meeting (KoM) with representatives of the ENCePP Secretariat and Steering Group to align on objectives, tools, resources, strategies, and related matters	Q4 2025	Happening now!
Preliminary Internal Communication Plan	Q4 2025	Ongoing
Final Internal Communication Plan, including tracking tool and key performance indicators (KPIs)	Q2 2026	Ongoing
KoM for WG/SIGs leads to present the details of the internal communication plan	Q2 2026	
Report to Steering Group	Quarterly starting Q4 2025	



# Points to consider

- Close communication with the ENCePP Secretariat and other WGs is a must to avoid overlap and duplication of work.
- Building on existing activities of all WGs and SIGs.
- Initial focus on internal communication, with external communication to be expanded at a later stage.
- Focus on complementarity and added value for ENCePP.



# WG on Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology

## **Co-chairs:**

Tania Schink (Leibniz Institute for Prevention Research and Epidemiology – BIPS)

Nhung Trinh (Pharmacoepidemiology and Drug Safety Research Group (PharmaSafe), University of Oslo)



# Objectives

- Select (sub)chapters for the 12th Revision (in line with the SIG on parallel publication of selected chapters in PDS/ViH)
- Deliver 12<sup>th</sup> revision
- Develop strategy for further periodic revisions: frequency, format/structure, and other potential improvements suggested by the WG



# Deliverables

Milestones/Deliverable(s)	Timelines	Status
List of (sub)chapters selected for 12th revision	September 2025	✓
12 <sup>th</sup> Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology	November 2025	finalization
Strategy for further periodic revisions and inclusion of new chapters/annexes	New: January 2025	ongoing



# Current status of revision of the selected chapters

- Development of the study protocol: **almost done**
- Pragmatic trials and large simple trials: **PCT SIG to update (timelines?)**
- Digital health technologies for data collection: **done (change to ToC)**
- Positive and negative control exposures and outcomes: **done**
- Quantitative Bias Analysis: **almost done; to be added as subsection for Chapter 6**
- Data analysis: **to be included in major update next year**
- Multi-country database studies: **done**
- Pharmacogenomics: **done**
- Signal detection: **done**

- EMA editorial team to update Guide on website January 2026
- Foreword to be updated by ENCePP SG chairs to explain strategy and how it fits with the PDS/ViH series; and to highlight recent guidance informing contents of the Guide (e.g., ICH M14)

# WG on Independence and transparency

## **Co-chairs:**

Rosa Gini (ARS Toscana)

Elena Petelos (European Forum for Primary Care - EPFC)



# Objectives

To periodically review the **ENCePP Code of Conduct (CoC)\***

- ❖ To support use of the **CoC** and to explore ways of improving its uptake;
- ❖ To promote registration of studies in the **HMA-EMA Catalogues of real-world data studies** and **support EMA in the further development of the Catalogues** with regards to **transparency** and **use of the CoC**.

\*The ENCePP CoC **provides a set of rules and principles** for pharmacoepidemiology and pharmacovigilance studies to promote. The Code is referenced in **Module VIII of the good pharmacovigilance practices (GVP)** on post-authorisation safety studies (PASS) (Rev1) relating to authorised medicinal products, published by the European Medicines Agency (EMA).



# Deliverables

Milestones/Deliverable(s)	Timelines	Status
Podcast 'Conduct Your Study' (responsible: Alexia Bikou): 2+ more episodes	Q3 2026	
Revision of ENCePP Code of Conduct (responsible: Lia Gutierrez)	Q2 2026	
Report on studies registered in the HMA/EMA Catalogue as performed in line with the ENCePP Code of Conduct (responsible: Citadel Jungco Cabasag)	Q4 2026	



# Deliverables 2026 – I

- ❖ Podcast 'Conduct Your Study'
  - Accepted invites: Catherine Cohet and Patrice Verpillat (EMA), Gianmario Candore (Industry), Jean-Michel Dogne (PRAC)
- ❖ Revision of ENCePP Code of Conduct (responsible: Lia Gutierrez)
  - Replace 'EUPAS Registry' with 'EMA/HMA Catalogues'
  - Update transparency provisions (less reference to data sharing, more to modern provisions like Transparency Badges)
  - Consider the case when a regulatory-approved protocol is proposed to the study team



- ❖ Report on studies registered in the [HMA/EMA Catalogues](#) as performed in line with the ENCePP CoC (responsible: Citadel Jungco Cabasag)
  - **Preliminary results:** out of all the studies currently recorded in the HMA/EMA Catalogue, the variable on compliance with CoC is:
    - missing in 7.6% studies;
    - 'compliant' in 5.1% studies;
    - **'non-compliant' in 86.1% studies (!)**

If you believe your study to be miscoded, please review your entry! Data will be re-downloaded beginning of February 2026

# WG on Artificial Intelligence (AI) in Pharmacoepidemiology

## **Co-chairs:**

Maurizio Sessa (Drug Safety Group, University of Copenhagen)

Ioanna Tzoulaki (School of Public Health, Imperial College London)



# Objectives

- Map current use and perception of AI in pharmacoepidemiology across the ENCePP network
- Critically appraise AI tools relevant to pharmacoepidemiology
- Collaborate with other Working Groups to ensure alignment
- Disseminate insights through educational activities like webinars
- Support updates to the ENCePP Guide and Checklist to include AI-related considerations



# Deliverables

Milestones/Deliverable(s)	Timelines	Status
<p><b>Setup a multidisciplinary WG</b> of 30 members with complementary expertise (e.g., PE, AI/ML, regulatory science, data science, and ethics – 12 seats available).</p> <p><b>How:</b> Membership-interest survey prepared (GDPR-compliant, open until 31 Dec 2025).</p>	Q4 2025	Partially Completed
<p><b>Draft and launch mapping survey</b> on AI use &amp; perception within ENCePP</p> <p><b>How:</b> Survey (GDPR-compliant, shared within ENCePP).</p>	Q4 2025 - Q1 2026	Ongoing
<p><b>Mapping survey:</b> Publish results and hold a webinar for dissemination (in collaboration with relevant WGs).</p> <p><b>How:</b> Series of live webinars hosted by the University of Copenhagen and scientific publication.</p> <p>Feedback summary to ENCePP Guide authors.</p>	Q2 2026 - Q3 2026	Planned
<p><b>Additional deliverables to be scoped after Year-1 (e.g., good practice insights, use-case catalogue, depending on SG priorities)</b></p> <p><b>How:</b> WG plenary discussion and contingent on mapping survey results and SG feedback.</p>	Q4 2026	Planned

# WG on Diversity and Health Equity

## **Co-chairs:**

Flavia Soares Peres (IQVIA)

Taichi Ochi (IADB.NL, University of Groningen)



# Objectives

The main objective of the DHE WG is to **define** and **promote awareness** for **diversity** and **equity** in relation to **pharmacoepidemiology** and **pharmacovigilance** studies. The WG aims to embed its findings into ENCePP Guidance and reduce health disparities in pharmacoepidemiology, and regulatory studies conducted in Europe and abroad



## DEFINITION

Diversity and health equity in study design, report, and database evaluation in pharmacoepidemiology, ENCePP and regulatory context



## MAPPING

**Short-term:** Understand the regulatory perspective with stakeholders from the EMA and ENCePP  
**Long-term:** EU member state mapping begins with DHE WG countries and expands EU-wide.



## NEW CHAPTER

Provide, refine and support the dissemination of a new chapter for the ENCePP Methods guide, with updated evidence reflecting equity-informed methods.



## CO-CREATING

Co-create with other learned societies (i.e. ISPE, ISPOR EU, ISOP) and relevant stakeholders and patient organisations plans for the disseminating and implementing the recommendations



# Deliverables

Scope	Description	Objective	Planned Delivery Date	Members interested in co-leading	Members interest in collaborating
<b>Delivery 1</b>					
Delivery 1.1	Definition	Provide definitions of 1) diversity and 2) equity, in the context of pharmacoepidemiology, ENCePP and regulatory context. This includes population diversity and health equity in study design and reporting, and development of documentation for evaluating databases.	1	Q3 Year 2	Flavia, Hedvig, Helga, Anna-Maija, <b>Enriqueta</b>
Delivery 1.2	Mapping	Provide mapping of diversity and health equity measurements across EU member states, with the aim to address gaps and harmonise future assessments. This includes conducting surveys, interviews of relevant stakeholders and revisions of current documentations. The initial mapping exercise will focus on a regulatory perspective with stakeholders from the EMA and ENCePP (short term). The broader EU member state mapping will start with countries where DHE WG members are based and expand from there to encompass all EU members states (long term).	2	Q4 Year 1	Enriqueta
<b>Delivery 2</b>					
Delivery 2.1	ENCePP new chapter	Provide, refine and support the dissemination of a new chapter for the ENCePP Methods guide, with updated evidence reflecting equity-informed methods. This includes, but not limited to, analysis stratification, determinants of health, and its applicability to main databases such as claims, registries, and primary databases. Presentations of the above new Chapter for ENCePP methods in relevant scientific congresses (e.g., ISPE, ISPOR)	3, 4	Q1 Year 2 - Q3 Year 2	Kristina (co-lead)
Delivery 2.2	Co-creating with other learned societies	Co-create with other learned societies (i.e. ISPE, ISPOR EU, ISOP) and relevant stakeholders and patient organisations plans for the disseminating and implementing the recommendations. Public communications of publications (i.e. academic, white papers, checklists) will be conducted in lay language.	1, 3, 5	Q3 Year 2	Taichi
Delivery 3		Provide Annual Report to ENCePP Steering Group	All	Q4 per annum	Flavia, Taichi

# Any comments/points to consider/extra info

WG meetings will take place every two months, alternating between Thursdays and Fridays to accommodate different schedules.

Each respective Delivery will have different leads who will be guiding the delivery of the respective Scopes.

The aim is for each sub-team to work independently to achieve each Scope while using the broader Working Group for feedback and additional support



# WG on Real-World-Data (RWD) sources in non-interventional studies

## Co-chairs:

Christos Kontogiorgis (Democritus University of Thrace, Greece)

Martín Solórzano (Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol)



# Objectives

- Developing metadata templates and feasibility tools that can be directly applied during study planning.
- Providing fitness-for-purpose frameworks to support the selection of data sources aligned with specific study objectives.
- Clarifying how existing catalogues and networks can be used in a complementary and non-duplicative way.



# Deliverables

Objective	Deliverables	Timeline	Comments	Challenges
<b>Feasibility, Integration, and Fitness-for-Purpose Framework for NIS Data Sources</b>	<ul style="list-style-type: none"><li>- Harmonized metadata and fitness-for-purpose framework with checklist/template</li><li>- Worked examples using selected catalogue entries</li><li>- Catalogue integration and complementarity guide</li><li>- Governance and onboarding archetype guide with documentation checklist</li></ul>	Q4 2025 – Q1 2027	Establishes a harmonized, practical framework to support early NIS planning and feasibility assessment, integrating governance models and complementing existing catalogues (ENCePP, HDR UK, EHDEN, VAC4EU).	<ul style="list-style-type: none"><li>- Achieving consensus across heterogeneous RWD sources;</li><li>- ensuring practicality across different governance models and data structures.</li></ul>



Objective	Deliverables	Timeline	Comments	Challenges
<b>Harmonization and Use of Common Data Models (CDMs)</b>	<ul style="list-style-type: none"> <li>- Guidance document on CDM characteristics, adoption, challenges, and recommendations</li> <li>- Updated inventory of European data sources and CDMs in use</li> </ul>	Q3 2026	<p>Provides an overview of CDM adoption (e.g., OMOP, CONCEPTION, i2b2, PCORnet) and actionable guidance for harmonised application in NIS.</p>	<ul style="list-style-type: none"> <li>- Variability in CDM implementation;</li> <li>- limited or inconsistent metadata quality across data holders.</li> </ul>



Objective	Deliverables	Timeline	Comments	Challenges
<b>Application and Consolidation of WG Tools</b>	<ul style="list-style-type: none"> <li>- Case summary compendium</li> <li>- Consolidated WG Guidance Document</li> </ul>	Q2–Q4 2027	<p>Demonstrates real-world use of WG5 tools and synthesizes outputs into a comprehensive, user-friendly guidance document for feasibility assessment and regulatory alignment.</p>	<ul style="list-style-type: none"> <li>- Selecting representative and feasible case studies;</li> <li>- maintaining data confidentiality;</li> <li>- ensuring clarity and usability of the final guidance.</li> </ul>



## ***Impact***

The WG is designed to enhance the practical use of real-world data (RWD) in non-interventional studies (NIS) across Europe:

- **Improve Feasibility Assessment:** Provide standardized metadata, fitness-for-purpose scoring, and governance archetypes that enable researchers and sponsors to quickly identify suitable RWD sources for specific study types.
- **Support Regulatory Confidence:** Clarify data governance, quality, and CDM harmonisation considerations, facilitating regulatory-aligned study planning and execution.
- **Increase Efficiency:** Streamline study initiation through guidance on onboarding workflows, approval processes, and catalogues, reducing delays in multi-source studies.



## ***Impact***

- **Enhance ENCePP Visibility and Influence:** By delivering practical guidance, decision-support tools, and illustrative cases, WG will reinforce ENCePP's methodological leadership in RWD and observational research.
- **Promote Best Practices:** Encourage consistent approaches across EU data sources, helping multi-centre, multi-database studies produce reliable, high-quality evidence for public health and regulatory decision-making.
- **Fasten the inclusion of further data sources in regulatory studies**



WG will **bridge the gap** between existing RWD catalogues and their operational use in NIS,  
enabling **faster**, more **robust**, and **methodologically** sound studies  
that directly support ENCePP's mission.



# SIG on Pragmatism in Clinical Trials

## **Co-chairs:**

Gianmario Candore (EFPIA, Bayer)

Georgios Papazisis (Aristotle University of Thessaloniki - CRU-AUSoM)



# Rationale

- **Growing interest** in this topic, driven by the need for more flexible and context-sensitive approaches to evidence generation
- To address this, the SIG will review existing terminologies and methodologies which **could serve to support the MWP's development** of the 2026-27 "Concept Paper on the Use of Pragmatic Trials in Regulatory Decision Making"

# Members

- Currently **17 members** representing a range of institutions, including academia, CROs, regulatory network, and industry

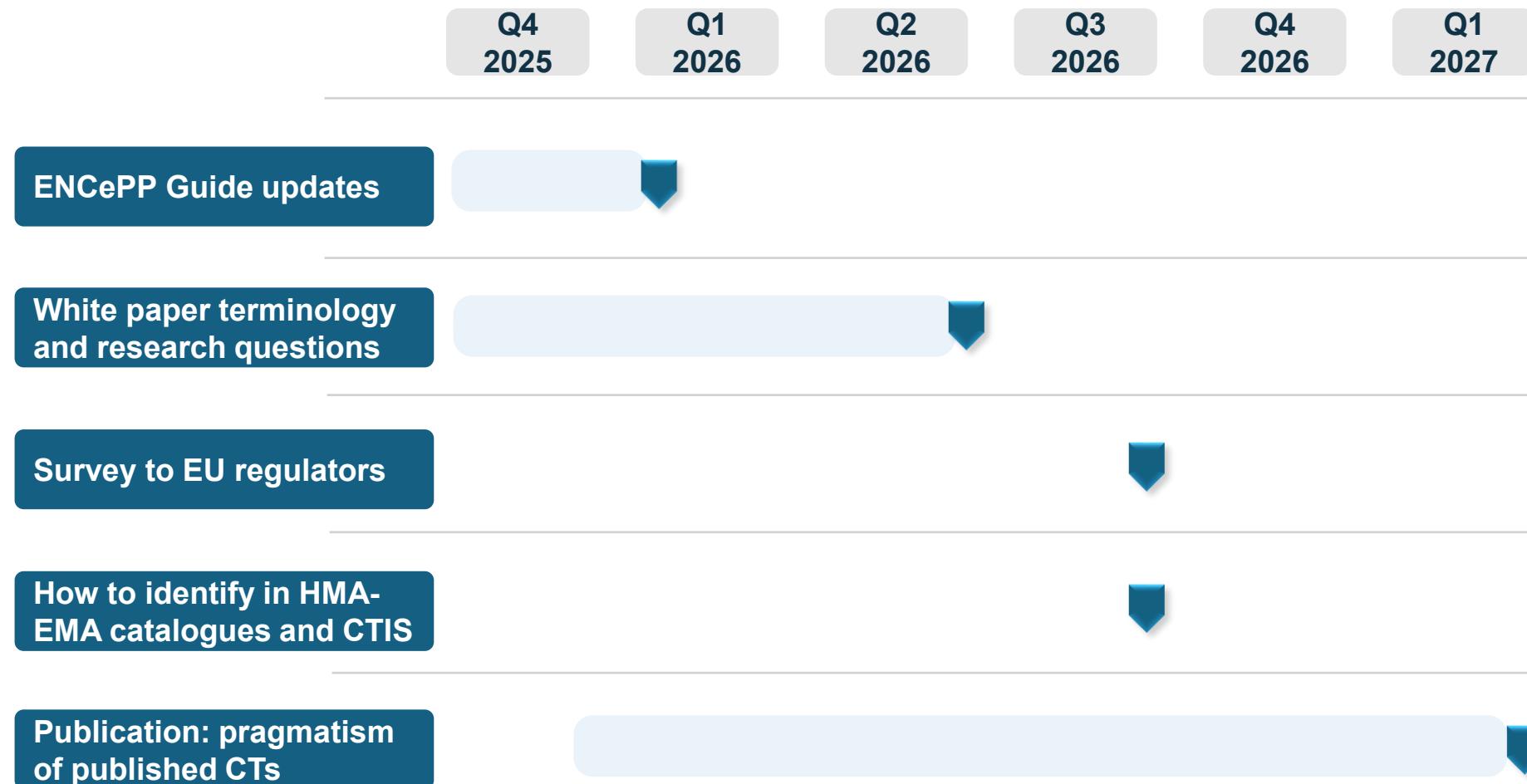


# Objectives

- Highlight the **value** of pragmatic approaches in CT, and **clarify for which context** (clinical and regulatory) **and research questions** they are most appropriate in alignment with current legislation
- Preparation for Consensus on
  - **Terminology** for commonly used concepts (pragmatic CT, trials with RWD, low intervention clinical trials, large simple trials, decentralised clinical trials, etc)
  - Core **methodological and design principles** (study aims, population and setting, interventions and comparators, randomisation and blinding, outcome measures)
  - **Data quality** control and assurance for CTs that include pragmatic elements
- Support **training** and **capacity building** by offering webinars or workshops to strengthen expertise among ENCePP partners



# Deliverables (and creation of sub-streams)



# Deliverables (and creation of sub-streams)



# SIG on Update of the ENCePP Checklist for Study Protocols

## **Co-chairs:**

Katja Hakkarainen (Parexel)

Jessica Bolstad (Parexel)



# Objectives

- To update the ENCePP Checklist for Study Protocols considering the relevant more recent regulatory and scientific guidance

Current Revision 4 (2018)



Doc.Ref. EMA/540136/2009

EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

ENePP

European Network of Centres for  
Pharmacoepidemiology and  
Pharmacovigilance

**ENCePP Checklist for Study Protocols (Revision 4)**

Adopted by the ENCePP Steering Group on 15/10/2018

The [European Network of Centres for Pharmacoepidemiology and Pharmacovigilance \(ENCePP\)](#) welcomes innovative designs and new methods of research. This Checklist has been developed by ENCePP to stimulate consideration of important principles when designing and writing a pharmacoepidemiological or pharmacovigilance study protocol. The Checklist is intended to promote the quality of such studies, not their uniformity. The user is also referred to the [ENCePP Guide on Methodological Standards in Pharmacoepidemiology](#), which reviews and gives direct electronic access to guidance for research in pharmacoepidemiology and pharmacovigilance.

For each question of the Checklist, the investigator should indicate whether or not it has been addressed in the study protocol. If the answer is "Yes", the section number of the protocol where this issue has been discussed should be specified. It is possible that some questions do not apply to a particular study (for example, in the case of an innovative study design). In this case, the answer 'N/A' (Not Applicable) can be checked and the "Comments" field included for each section should be used to explain why. The "Comments" field can also be used to elaborate on a "No" answer.

This Checklist should be included as an Annex by marketing authorisation holders when submitting the protocol of a non-interventional post-authorisation safety study (PASS) to a regulatory authority (see the [Guidance on the format and content of the protocol of non-interventional post-authorisation safety studies](#)). The Checklist is a supporting document and does not replace the format of the protocol for PASS presented in the Guidance and Module VIII of the Good pharmacovigilance practices (GVP).

**Study title:**

**EU PAS Register® number:**  
**Study reference number (if applicable):**

<b>Section 1: Milestones</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Section Number</b>
1.1 Does the protocol specify timelines for 1.1.1 Start of data collection <sup>1</sup> 1.1.2 End of data collection <sup>2</sup> 1.1.3 Progress report(s) 1.1.4 Interim report(s) 1.1.5 Registration in the EU PAS Register <sup>3</sup> 1.1.6 Final report of study results.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<sup>1</sup> Date from which information on the first study is first recorded in the study dataset or, in the case of secondary use of data, the date from which data extraction starts.  
<sup>2</sup> Date from which the analytical dataset is completely available.

# Deliverables

Milestones/Deliverable(s)	Timelines	Status
Updated ENCePP Checklist for Study Protocols	Q1 2026	<ul style="list-style-type: none"><li>• Updated based on other regulatory and scientific guidance* but final ICH M14 and upcoming revision of GVP Module VIII</li><li>• 2 review rounds by SIG completed</li><li>• Update based on final ICH M14 ongoing</li><li>• Update based on the ongoing revision of GVP module VIII pending; final timeline subject to how and when the revision will influence the protocol checklist</li></ul>

\*See next slide for the considered regulatory and scientific guidance

# Considered regulatory and scientific guidance

Regulatory and scientific guidance considered	Status of considering the guidance
<a href="#">EMA Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence for regulatory purposes</a> (final Mar 2025)	Completed
<a href="#">FDA Guidance for Industry - Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products</a> (final Jul 2024)	Completed
<a href="#">HARPER protocol template; HARmonized Protocol Template to Enhance Reproducibility of hypothesis evaluating real-world evidence studies on treatment effects: A good practices report of a joint ISPE/ISPOR task force</a> (Wang et al. 2023)	Completed
<a href="#">Process guide for inferential studies using healthcare data from routine clinical practice to evaluate causal effects of drugs (PRINCIPLED): considerations from the FDA Sentinel Innovation Center - PubMed (nih.gov)</a>	Completed
<a href="#">ENCePP Methodological Guide - European Union (europa.eu)</a> ; selected sections	Completed
<a href="#">ICH M14 Guideline on general principles on planning, designing, analysing, and reporting of non-interventional studies that utilise Real-World Data for safety assessment of medicines</a> (final Sep 2025)	Completed for draft (May 2024) Ongoing for final (Sep 2025)
<a href="#">Ongoing revision of Guideline on good pharmacovigilance practices (GVP) Module VIII – Post-authorisation safety studies (Rev 3) (2017); Addendum 2020</a>	Pending; timeline TBC by EMA

- Balance between level of detail considered against usability for end users

# SIG on Supplement to the Good Practice Guide for the use of the HMA-EMA Catalogues

## **Co-chairs:**

Pierre Engel (IQVIA)

Martín Solórzano (IDIAPJGol)

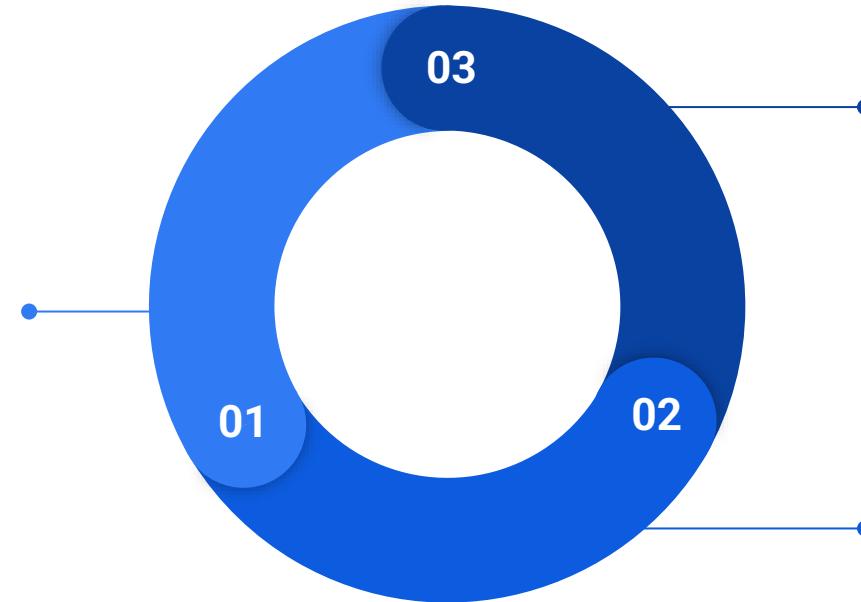


# Key Purposes

The SIG supports the broader goals of ENCePP 2025 Work Plan, which focuses on strengthening governance, increasing visibility, and amplifying impact within the European network for pharmacoepidemiology and pharmacovigilance.

## Real-World Examples

Develop and test practical examples using HMA-EMA Catalogues.



## Expanded Use Cases

Explore broader applications and improve catalogue tools

## Visibility & Education

Create user guide and demo video to improve accessibility.

# Objectives

01

## Develop Use Cases and Examples

- Use the Good Practice Guide as the foundation for defining use cases.
- Expand with additional relevant use cases to cover broader scenarios.
- Identify concrete study examples to illustrate catalogue application.

02

## Test the Catalogue

- Agree on a methodological approach for testing the catalogue using the defined use cases.
- Test use cases with real examples to identify best practices, optimal use, and existing gaps.

03

## Translate Findings into Guidance

- Develop clear guidance and training materials based on testing outcomes.
- Identify gaps and deliver recommendations to inform future catalogue improvements.

# Stakeholder Perspectives Considered

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## Patients & Public Health Stakeholders

- Promote transparency in the use of real-world data.
- Strengthen trust in research and regulatory decision-making.
- Support meaningful and responsible secondary use of data that impacts public health.

## Industry & Marketing Authorization Holders (MAHs)

- Improve feasibility assessments for PASS and other regulatory obligations.
- Support data-source benchmarking and planning of regulatory-grade studies.
- Facilitate clearer alignment with regulatory expectations.

## Data Holders & Data Custodians

- Ensure accurate representation of data structure, governance, and capabilities.
- Enable appropriate secondary use of data for research and regulatory purposes.
- Harmonize communication regarding data availability and strengths.

## Research & Scientific Community

*Investigators, Methodology & Standards Groups*

- Improve study planning, feasibility evaluation, and protocol development.
- Identify suitable data sources and understand methodological constraints.
- Advance harmonization of metadata standards and good methodological practices.
- Adhere to good study conduct by publicly registering study protocols.

## Regulatory & Public Health Authorities

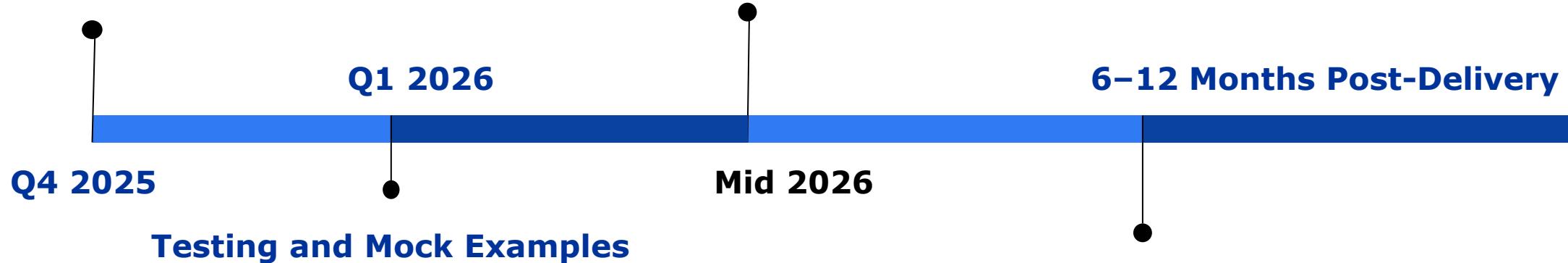
### *Regulators, EMA, Public Agencies*

- Enhance transparency and understanding of data sources and fitness-for-use.
- Support oversight of regulatory commitments and regulatory-grade evidence generation.
- Strengthen alignment with institutional frameworks, tools, and public health priorities.

# Timeline and deliverables

## Initiation and Planning

- 3–5 defined use cases agreed with EMA
- Two workstreams established: Examples & Testing / AI & UX
- Set of EMA-validated research questions to guide all examples and tests



## Delivery of Key Outputs

- User Guide on how to use the catalogue for study planning
- 5-minute demo video showing catalogue navigation and key functions

## Testing and Mock Examples

- Mock study workflows for study planning and data-source identification
- Catalogue testing results using hypothetical research questions (utility + gaps)
- Targeted improvement list for navigation, search, and query support

## Optional Follow-Up Work

- Additional use cases (protocol/report assessment, benchmarking, data-source analysis)

# Scope, Challenges & Responses

Scope needed / Challenges	Response
Need to provide practical guidance for diverse stakeholders (including EMA)	Develop guidance and training materials aligned with real-world examples and stakeholder perspectives.
Ensuring effective use of the HMA-EMA catalogues	Create use cases, mock studies, and best-practice examples to demonstrate optimal use.
Supporting study planning with real-world data	Use real-world scenarios to illustrate feasibility assessments and data-source selection.
Identifying improvement areas through SIG work	Test catalogue functionality systematically and document gaps.
Informing future HMA - EMA updates	Translate findings into concise recommendations for catalogue evolution.
Enhancing usability and relevance of the catalogues	Propose UX and navigation improvements based on testing and stakeholder feedback.

# SIG on Publication of selected chapters of the ENCePP Guide in PDS and Value in Health

**Chair:**

Helga Gardarsdottir (Utrecht University)



Review > *Pharmacoepidemiol Drug Saf.* 2025 Nov;34(11):e70263. doi: 10.1002/pds.70263.

## Strengthening Pharmacoepidemiology in a Changing Research Environment: The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

Xavier Kurz <sup>1</sup>, Catherine Cohet <sup>2</sup>, Susana Perez-Gutthann <sup>3</sup>, Shar Rao <sup>4</sup>,  
Helga Gardarsdottir <sup>4</sup> <sup>5</sup> <sup>6</sup>

## Status

- Four accepted papers!
- One submitted, two ready for submission

1. Introduction: History and evolution of ENCePP
2. Research question and assessing feasibility (Chapter 2)
3. Data quality (Chapter 13.2, 13.4)
4. Data protection and ethical aspects (Chapter 15 )
5. Conducting systematic reviews and meta-analyses (Chapter 10)
6. Target trial emulation + estimand framework (Chapter 4.2.6)
7. Evaluating medicines in pregnancy and breastfeeding (Annex 2 )
8. Pharmacovigilance impact research (Chapter 16.4)
9. AI in pharmacoepi (Chapter 16.5)





**Thank you to all WGs and SIGs!**