



# Steering Group meeting

## Working Groups and Special Interest Groups: progress update

11 February 2026 (virtual)

## Working Groups (updates received by the SG ahead of the meeting as per next slides)



- 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 - Communications and outreach



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	Presentation in Plenary, completed
Preliminary Internal Communication Plan	Q4 2025	Merged with deliverable below
Final Internal Communication Plan, including tracking tool and key performance indicators (KPIs)	Q2 2026	Tracker with communication strategy per WG and SIG groups is <b>under finalization</b> . KPI discussion is ongoing.
KoM for WG/SIGs leads to present the details of the internal communication plan	Q2 2026	We will present the comms strategy/tracker in the meeting planned with SC and WG/SIGs. Continuous communication with WG/SIGs and the Secretariat will be important
Report to Steering Group	Quarterly starting Q4 2025	Feb 2026- completed



# Sneak peek

Working Group (WG)	Deliverables	Proposed Timeline	Communication opportunities	Communication target(s)	Communication channels & Responsible*	Comments	Point of contact email	KPIs
1 Communication and outreach Co-chairs: Katica Boki & Katarina Guzdovanovic	<ol style="list-style-type: none"> <li>Communication strategy plan and the tracker &amp; coordination of all communication activities.</li> <li>Develop KPIs - ongoing</li> <li>Slide deck - on who are we, what we do.</li> </ol>	<p>through out 2026</p> <p>Q2 2026</p> <p>TBD</p>				* To discuss with WG and Secretariat: possibility of internal communication- create a newsletter	kboki@stg.org	KPIs should be general for this strategy plan and defined when the communication channels are agreed upon. <b>Criteria for internal communication:</b> N° of communication assets produced per WG Tracking of dissemination impact: % of members who interact with requested LinkedIn posts <b>Webinar: attendance rates, % of WG that respond to internal requests; Extracurricular for external communication</b> LinkedIn: impressions per post, engagement rate, n° of external partner re-shares (EMA, etc)
2 Revision of the ENCaPP <sup>1</sup> Guide on Methodological Standards in Pharmacoepidemiology Co-chairs: Tania Schink & Nhung Trinh	<ol style="list-style-type: none"> <li>List of sub chapters selected for 12th revision</li> <li>12th Revision of the ENCaPP Guide on Methodological Standards in Pharmacoepidemiology. EMA editorial team to update Guide on website January 2026. Forward to be updated by ENCaPP SG chairs to explain strategy and how it fits with the PDG/VIH scales, and to highlight recent guidance informing contents of the Guide</li> <li>Strategy for further periodic revisions and inclusion of new chapters/issues</li> </ol>	<p>September 2025, N/A</p> <p>November 2025</p> <p>January 2026</p>	Dissemination of updated guide	Internal (ENCaPP members, xx) External (Stakeholders: such as xxx)	Internal: E-mail to ENCaPP members (Secretariat) E-mail to request to interact with LinkedIn posts (Corinna) External: Publish new guide in ENCaPP website (XX) LinkedIn posts by members announcing the new guide (Corinna group could the 1st post) LinkedIn post by EMA? (or report).		tschink@leibniz-bips.de nhung.trinh@fma.uni.lu.no	
3 Independence and transparency Co-chairs: Rosa Gini & Diana Pavlos	<ol style="list-style-type: none"> <li>Podcast 'Conduct Your Study' (responsible: Alexia Bikou): 2+ more episodes</li> <li>Revision of ENCaPP Code of Conduct (responsible: Lia Gulienaz)</li> <li>Report on studies registered in the HMA/EMA Catalogue as performed in line with the ENCaPP Code of Conduct (responsible: Citadel Jungco Cabasag)</li> </ol>	<p>Q3 2026</p> <p>Q3 2026</p> <p>Q4 2026</p>	Dissemination of webinars Dissemination of updated Code of Conduct Dissemination of report	Internal (ENCaPP members, xx) External (Stakeholders: such as xxx)	Internal: E-mail to ENCaPP members (Secretariat) E-mail to request to interact with LinkedIn posts (Corinna) External: Upload of podcast in... XX LinkedIn posts by members announcing the podcasts (Corinna group could the 1st post) LinkedIn post by EMA? (or report). Internal: E-mail to ENCaPP members (Secretariat) E-mail to request to interact with LinkedIn posts (Corinna) External: Publish updated CoC in ENCaPP website (XX) LinkedIn posts by members announcing the updated CoC (Corinna group could the 1st post) LinkedIn post by EMA? (or report). Internal: E-mail to ENCaPP members (Secretariat) E-mail to working group TSD with group		rosa.gini@an.toronto.it PETELOS@GMAIL.COM	
4 Artificial Intelligence (AI) in Pharmacoepidemiology Co-chairs: Maurilio Sessa & Ioanna Tzoulaki	<ol style="list-style-type: none"> <li>Draft and launch mapping survey on AI use &amp; perception within ENCaPP How: Survey (GDPR-compliant, shared within ENCaPPs). Mapping survey: Publish results and hold a webinar for dissemination (in collaboration with relevant WGs). How: Series of live webinars hosted by the University of Copenhagen and scientific publication. Feedback summary to ENCaPP Guide authors.</li> <li>Additional deliverables to be accepted after Year-1 (e.g., good practice insights, use-case catalogue, depending on SG priorities) How: WG plenary discussion and contingent on mapping survey results and SG feedback.</li> </ol>	<p>Q1 2026</p> <p>Q3 2026</p> <p>Q4 2026</p>	Dissemination of Survey among ENCaPP members Dissemination of webinars Dissemination of additional deliverables	Internal (ENCaPP members, xx) External (Stakeholders: such as xxx)	Internal: E-mail to ENCaPP members (Secretariat) E-mail to request to interact with LinkedIn posts (Corinna, WG) External: E-mail to ENCaPP members (Secretariat) E-mail to request to interact with LinkedIn posts (Corinna) External: Promotion of Webinars through LinkedIn post by ENCaPP members TSD with group		maurilio.sessa@sund.ku.dk itzoulaki@imperial.ac.uk	
5 Diversity and Health Equity Co-chairs: Flavia Soares Pereira & Taichi Ochi	<ol style="list-style-type: none"> <li>Provide definitions of 1) diversity and 2) equity in the context of Pharmacoepidemiology Provide a mapping of diversity and health equity measurements across EU member states, by conducting surveys and interviews of relevant stakeholders</li> <li>ENCaPP methods guide new chapter, with updated evidence reflecting equity-informed methods</li> <li>Create dissemination and implementation plan with other societies and relevant stakeholders and patient organizations. Communication of publications</li> </ol>	<p>Q3 2026</p> <p>Q4 2025 - Q3 2026</p> <p>Q3 2026</p>	N/A Dissemination of Survey among relevant stakeholders Dissemination of new guide chapter Dissemination of publications	Internal (ENCaPP members, xx) External (Stakeholders: such as xxx)	TSD with group Internal: E-mail to ENCaPP members (Secretariat) E-mail to request to interact with LinkedIn posts (Corinna) External: Publish updated CoC in ENCaPP website (XX) LinkedIn posts by members announcing the NEW GUIDC (Corinna group could the 1st post) LinkedIn post by EMA? (or report). TSD with group		flavia.soarespereira@ipvia.com t.ochi@ug.nl	
6 Real World Data (RWD) sources in non interventional studies Co-chairs: Chloé Koutorgiis & Martin Solizano	<ol style="list-style-type: none"> <li>Feasibility, Integration, and Fitness-for-Purpose Framework for RWD Data Sources: Harmonized metadata and fitness-for-purpose framework with checklists/ templates Worked examples using selected catalogue entries Catalogue integration and complementarity guide Governance and onboarding archetype guide with documentation checklist</li> <li>Harmonization and Use of Common Data Models (CDMs): Guidance document on CDM characteristics, adoption, challenges, and recommendations Updated inventory of European data sources and CDMs in use</li> <li>Application and Consolidation of WG Tools: Case summary compendium Consolidated WG Guidance Document</li> </ol>	<p>Q4 2025 - Q1 2027</p> <p>Q3 2026</p> <p>Q2-Q4 2027</p>	Dissemination of checklists/templates, governance guide, etc Dissemination of Guidance Document Dissemination of Guidance Document	Internal (ENCaPP members, xx) External (Stakeholders: such as xxx)	Internal: E-mail to ENCaPP members (Secretariat) E-mail to request to interact with LinkedIn posts (Corinna) External: Publish updated CoC in ENCaPP website (XX) LinkedIn posts by members announcing the XXX (Corinna group could the 1st post) LinkedIn post by EMA? (or report). Internal: E-mail to ENCaPP members (Secretariat) E-mail to request to interact with LinkedIn posts (Corinna) External: Publish updated CoC in ENCaPP website (XX) LinkedIn posts by members announcing the XXX (Corinna group could the 1st post) LinkedIn post by EMA? (or report). Internal: E-mail to ENCaPP members (Secretariat) E-mail to request to interact with LinkedIn posts (Corinna) External: Publish updated CoC in ENCaPP website (XX) LinkedIn posts by members announcing the XXX (Corinna group could the 1st post) LinkedIn post by EMA? (or report).		ckoutorgi@med.duth.gr msolizano@idagipjol.org	

Special Interest Group (SIG)	Deliverables	Proposed Timeline	Communication opportunities	Communication target(s)	Communication channels & Responsible	Comments	Point of contact email	KPIs
1 Pharmabot in Clinical Trials	ENCaPP Guide updates White paper: terminology and research questions	Q1 2026 Q2 2026	Dissemination of updated					

## WG Co-Chairs

- **Katica Borić** ([RTI Health Solutions \(RTI-HS\)](#)) & **Katarina Gvozdanović** ([Teaching Institute of Public Health “Dr. Andrija Stampar](#))

## WG Members

- **Elena Petelos** (European Forum for Primary Care (EPFC), Maastricht University, University of Crete, European Public Health Association)
- **Kristina Garuolienė** (Pharmacy and Pharmacology center, Faculty of Medicine, Vilnius University (PharmCenter VU))
- **Christos Kontogiorgis** (Democritus University of Thrace, Greece)
- **Marco Tuccori** (Pharmacology Unit - Veneto Pharmacovigilance Centre (Pharmacol UNIVR), University Hospital Verona)



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



Milestones/Deliverable(s)	Timelines	Status
List of (sub)chapters selected for 12 <sup>th</sup> revision	September 2025	✓
12 <sup>th</sup> Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology	February 2025	finalization: peer-review
Strategy for further periodic revisions and inclusion of new chapters/annexes	March 2026	ongoing: draft document by chairs, first round of discussions



# Current status of updates

- Development of the study protocol: peer review
- Pragmatic trials and large simple trials: postponed to next update
- Digital health technologies for data collection: peer review
- Positive and negative control exposures and outcomes: peer review
- Quantitative Bias Analysis: peer review
- Data analysis: to be included in the major update 2026
- Multi-country database studies: peer review
- Pharmacogenomics: peer review
- Signal detection: peer review

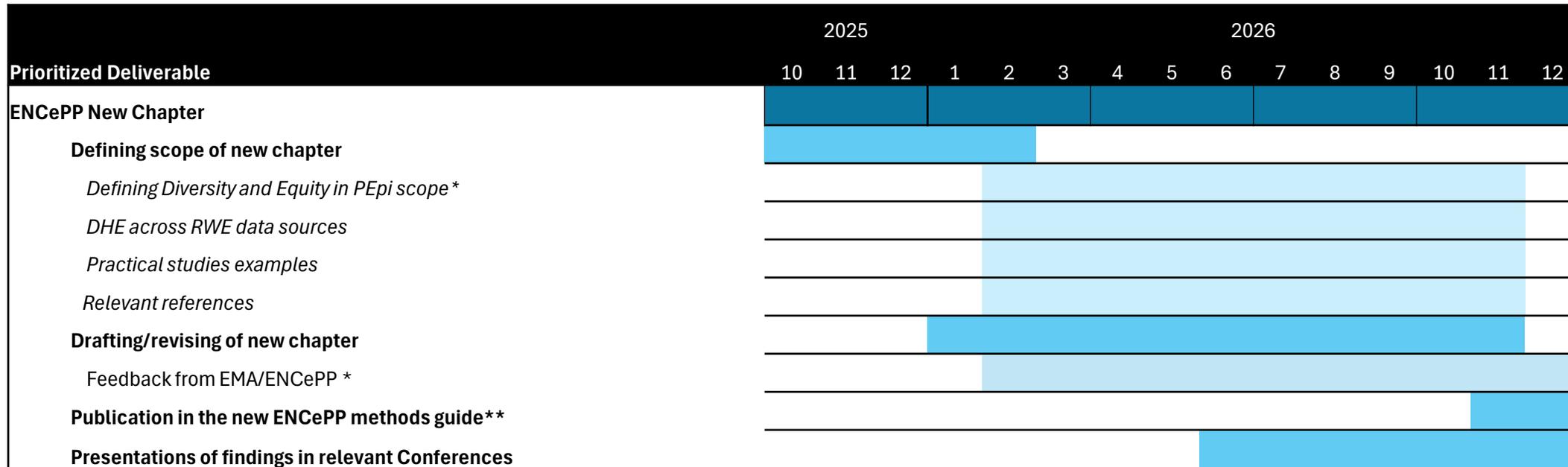


WG informed at December 2025 Plenary that activities should have milestones set for December 2026, the overall WG timelines have been updated  
Initially, four main activities planned: Definition, Stakeholder Mapping, ENCePP new chapter, and co-creation with society

The group met to make deliverables **leaner, more optimized, and integrated**, to remove silos and **meet the December 2026 milestone**

- New activities focus on the **ENCEPP new chapter**, planned to include the following subchapters: **general considerations, DHE definitions within RWE, DHE across RWE data sources, and practical study examples**, supported by relevant references
- The stakeholder mapping aiming at understanding the regulatory perspective with stakeholders from EMA/ENCEPP on relevant DHE topics will be assessed through the bodies feedback on the ENCePP new chapter
- In addition to the new chapter, the group is engaged in scientific communications and is actively working on publications for major pharmacoepidemiology conferences (ICPE, ISPOR)

# GANTT CHART



\* Prior stand-alone deliverable, embedded into the Deliverable of the ENCePP new chapter

\*\* Or to be agreed with ENCePP/EMA for the timelines related to the new ENCePP Methods Guide.



# WG members

	Name	Email	Institution
1	Andrew Marley	<a href="mailto:andrew.marley@parexel.com">andrew.marley@parexel.com</a>	Parexel, US
2	Anna-Maija Tolppanen	<a href="mailto:anna-maija.tolppanen@uef.fi">anna-maija.tolppanen@uef.fi</a>	University of Eastern Finland
3	Christos KONTOGIORGIS	<a href="mailto:ckontogi@med.duth.gr">ckontogi@med.duth.gr</a>	Democritus University of Thrace, Greece
4	Denise Umuhire	<a href="mailto:denise.umuhire@ema.europa.eu">denise.umuhire@ema.europa.eu</a>	EMA
5	Elena Ramirez	<a href="mailto:elena.ramirez@salud.madrid.org">elena.ramirez@salud.madrid.org</a> ; <a href="mailto:elena.ramirezg@uam.es">elena.ramirezg@uam.es</a>	Universidad Autonoma de Madrid , Spain
6	Enriqueta Vallejo-Yagüe	<a href="mailto:enriqueta.vallejo@unibe.ch">enriqueta.vallejo@unibe.ch</a>	University of Zurich
7	Flavia Soares Peres (co-chair)	<a href="mailto:enriqueta.vallejoyaguee@uzh.ch">enriqueta.vallejoyaguee@uzh.ch</a> <a href="mailto:flavia.soaresperes@iqvia.com">flavia.soaresperes@iqvia.com</a>	IQVIA, Portugal
8	Hedvig Nordeng	<a href="mailto:h.m.e.nordeng@farmasi.uio.no">h.m.e.nordeng@farmasi.uio.no</a>	University of Oslo/ EMA
9	Helga Gardarsdottir	<a href="mailto:h.gardarsdottir@uu.nl">h.gardarsdottir@uu.nl</a>	Division of Pharmacoepidemiology and Clinical Pharmacology, Faculty of Science, Utrecht University
10	Kristina Garuolienė	<a href="mailto:kristina.garuoliene@mf.vu.lt">kristina.garuoliene@mf.vu.lt</a>	Vilnius University, Lithuania
11	Li Wei	<a href="mailto:l.wei@ucl.ac.uk">l.wei@ucl.ac.uk</a>	University College London
12	Olga Rogozina	<a href="mailto:olga17021@hotmail.com">olga17021@hotmail.com</a>	Autonomous University of Madrid, Spain
13	Philippe Botteron (pending confirmation)	<a href="mailto:philippe.botteron@ubc.com">philippe.botteron@ubc.com</a>	United BioSource Corporation (UBC)
14	Taichi Ochi (co-chair)	<a href="mailto:t.ochi@rug.nl">t.ochi@rug.nl</a>	University of Groningen



# SIG - Pragmatism in Clinical Trials

Co-chairs: Gianmario Candore and Georgios Papazisis

- Highlight the **value** of pragmatic approaches in CT, and **clarify for which context** (clinical and regulatory) **and research questions** they are most appropriate
- Build 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)
- Support **training** and **capacity building** by offering webinars or workshops to strengthen expertise among ENCePP partners



# Deliverables, sub streams and status update



	Q4 2025	Q1 2026	Q2 2026	Q3 2026	Q4 2026	Q1 2027	Status
<b>ENCePP Guide updates</b>	[Progress bar: 10% complete, arrow at end]						<b>On-going</b> <ul style="list-style-type: none"> <li>• First draft delivered</li> <li>• Planned completion by mid-March</li> </ul>
<b>White paper terminology and research questions</b>	[Progress bar: 30% complete, arrow at end]						<b>On-going</b> <ul style="list-style-type: none"> <li>• Revision terminologies in authorities' documents and seminal manuscripts</li> </ul>
<b>Survey to EU regulators</b>	[Progress bar: 50% complete, arrow at end]						<b>Started</b> <ul style="list-style-type: none"> <li>• Plan agreed</li> </ul>
<b>How to identify in HMA-EMA catalogues and CTIS</b>	[Progress bar: 60% complete, arrow at end]						<b>Started</b> <ul style="list-style-type: none"> <li>• Investigated fields available in the repositories</li> </ul>
<b>Publication: pragmatism of published CTs</b>	[Progress bar: 80% complete, arrow at end]						<b>Started</b> <ul style="list-style-type: none"> <li>• Screening of the literature started</li> </ul>



# Deliverables, sub streams and status update



	2025	2026	H1 2027	H2 2027	H1 2028	H2 2028	Status
Identification of regulatory case studies				↓			Not started
ENCePP webinar						↓	Not started
Recommendations and best practice						↓	Not started



# 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



# SIG - 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 5 6</sup>

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)