



16 July 2026
EMA/157695/2026

Minutes of the ENCePP Steering Group meeting

3 July 2026, 14:00 – 15:00 – Teams meeting

Participants

Role/affiliation	Name
Co-chairs	Catherine Cohet, Helga Gardarsdottir
Present from the ENCePP SG	Alejandro Arana, Christos Kontogiorgis, Frauke Naumann-Winter, Iryna Vlasenko, Laura Pizzi, Melissa Kampman, Susan Sandler, Thomas Goedecke
Present from EMA	Patrice Verpillat, Julianna Fogd
Apologies	Annalisa Landi, Arnold K. Chan, Carla Torre, Gianluca Trifirò, Hedvig Nordeng, Hui-Lee Wong, Nadia Amaouche, Marco Tuccori, Vera Ehrenstein

Agenda

	Topic	Speaker(s)	Objective	Indicative timing
1.	Welcome & adoption of the agenda	Helga & Catherine	Endorsement	5'
2.	Future of ENCePP (discussion continued from February & April SG meetings)	All SG members Moderator: Helga	Discussion	20'
3.	Agenda for ENCePP webinar, 23 October 2026	All SG members Moderator: Catherine	Discussion & decision	15'
4.	Brief update on: - PDS/ViH publication series - ENCEPP Guide revision - Code of Conduct revision - Checklist for study protocols	Helga, Catherine	Information & discussion	15'
5.	Next SG meeting	All SG members	/	5'

1. Adoption of draft agenda

- The agenda was presented by the co-chairs and adopted.



2. Future of ENCePP (continued from February & April SG meetings)

SG members continued previous discussions on sustainability and future positioning of ENCePP, reflecting on its legacy (Code of Conduct, EUPAS Register/RWD Catalogues, Methodological Guide). The need was re-emphasised to assess the current value of ENCePP activities and identify gaps not addressed by other networks and initiatives (such as ISPE/ISPOR) which now cover similar areas.

The SG also reiterated the importance of collecting input from the broader ENCePP network during the October webinar. The co-chairs would like to create a small working group of SG members representing ENCePP centres, to develop questions to the network for the October webinar and co-lead on a future model.

ACTION

- Two-three SG members representing ENCePP centres to volunteer by sending their expression of interest to the Secretariat by 30 August – **SG members**

3. ENCePP webinar

- The 2-hour webinar to be held on 23 October 2026, 2.00pm CET, was confirmed.
- Proposed structure:
 - Interactive session on the future of ENCePP, to engage network members (as discussed above)
 - Brief updates from the Working Groups and SIGs
 - A session on methods. The following topics were suggested:
 - Transparency and reproducibility of pharmacoepidemiological studies
 - Pregnancy/breastfeeding research methodologies
 - Strategies for reevaluating polypharmacy and impact of deprescribing in routine care
 - Use case of artificial intelligence implementation in pharmacoepi/pharmacovigilance
 - Synthetic controls/digital twins
 - Health equity (in relation to the corresponding SIG)

ACTIONS

- Distribute SAVE THE DATE email to ENCePP partners for the October webinar – **ENCePP Secretariat**
- Share suggestions for webinar methodological topics – **ENCePP Partners**

4. Brief updates

• ENCePP Guide Revision

The SG supported a transition towards a living Guide. Revision 11 will be consolidated into a single PDF linked on the website to keep the last full revision dated July 2023 available. Future revisions of individual chapters will be uploaded as they become available (final version delivered and endorsed by the WG).

The SG also agreed to promptly publish the new chapter on Pragmatism in Clinical Trials recently delivered by the SIG, due to high interest from multiple stakeholders and the relevance to the workplan of the EMA Methodology Working Party.

• Code of Conduct

A draft update has been prepared by the Independence and Transparency WG. It is currently under review by the EMA and will be shared for SG review after the summer.

- **ENCePP Checklist for Study Protocols**

The SG acknowledged that the checklist remains useful as a good practice (and teaching) tool, however, its decreasing use and limited regulatory awareness require further discussion (to take place at a future SG meeting).

- **PDS/ViH publication series of selected chapters of the ENCePP Guide**

The series has been progressing well, with several manuscripts accepted or under minor/major revision, in view of simultaneous publication of the full series.

- **Working Group on Artificial Intelligence (AI) in Pharmacoepidemiology**

The WG requested to be renamed 'AI WG on Artificial Intelligence (AI) in Pharmacoepidemiology and Pharmacovigilance', which was endorsed.

5. Next SG meeting

Next meeting in September, date to be confirmed.