



4 May 2026
EMA/105977/2026

Minutes of the ENCePP Steering Group meeting

30 April 2026, 13:00 – 14:30 – Teams meeting

Participants

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

Agenda

	Topic	Speaker(s)	Objective	Indicative timing
1.	Connection time & adoption of the agenda	Helga & Catherine	Endorsement	5'
2.	Proposal for extension of the SG mandate by one year	Catherine	Discussion & endorsement	20'
3.	Future of ENCePP (continued from February SG meeting)	Catherine & all SG members Moderator: Helga	Discussion	30'
4.	ENCePP webinar 2026 (to replace this year's hybrid Plenary): timing, topic(s)	All SG members	Discussion & decision	20'
5.	Next SG meeting & A.O.B	All SG members	/	15'



1. Adoption of draft agenda

- The meeting was opened by Helga Gardarsdottir, and the agenda approved by the SG members. No additional topic was raised.

2. Proposal for extension of the SG mandate by one year

- Catherine Cohet presented a proposal from EMA to extend the 2024-2026 Steering Group mandate by an additional year, based on the following rationale:
 - Significant effort was invested in 2024/2025 by the current SG, with focus on new governance, and development and implementation of a new workplan, which will deliver beyond the end of 2026.
 - The new Working Groups (WGs) and Special Interest Groups (SIGs) endorsed in 2025 have only become significantly operational end of 2025 and in 2026.
 - Supporting efficiency by:
 - Monitoring the progress of the workplan by the SG who developed it, and ensure completion of all deliverables by the WGs/SIGs.
 - Continuing to assess future directions for ENCePP by this same SG, benefiting from its experience with the current mandate.
 - Limited candidate pool in previous SG elections.
- Broad support was expressed by all SG members, who noted the importance of allowing ongoing work to conclude meaningfully. The voluntary nature of the members' contributions to ENCePP was also acknowledged.
- The proposal to extend the SG mandate to the end of 2027 was endorsed.

ACTION - ENCePP Secretariat to inform the network about the extension of the SG mandate via a news item on the ENCePP website.

3. Future of ENCePP

- Catherine shared EMA's perspective on ENCePP's future direction, to continue the discussion started at the [February SG meeting](#). ENCePP was established in 2008 to "*foster high quality, independent PASS and provide methodological standards and a collaborative forum for researchers*", with highly recognised impact. Since then:
 - Evolution of methodologies and scientific and regulatory guidance, with gaps now addressed by EU and international standards and guidelines.
 - EU PAS Register and Resources Database no longer anchored in, and managed by ENCePP since transition to the [HMA-EMA Catalogues of real-world data sources and studies](#) in 2024.
 - With some exceptions for the Methods Guide and the Code of Conduct, limited regulatory use and impact of other ENCePP tools: Protocol Checklist, and ENCePP Seal (which was the reason for its decommissioning in February 2025).
 - While ENCePP was initially envisioned as a collaborative network, its current functioning does not fully reflect this original ambition.
 - Based on the above, overall reduced strategic impact for EMA in recent years.
- The Steering Group reflected that:
 - ENCePP has delivered substantial historical value and methodological leadership, especially at the beginning, to fill obvious gaps in the fields of pharmacovigilance and pharmacoepidemiology; however, as these fields have matured, with fewer gaps remaining and parallel initiatives now contributing to many of the initial ENCePP objectives, it is becoming less clear what distinct role ENCePP currently plays beyond what is addressed elsewhere.

- There is indeed a need to re-think about the place and future of ENCePP in the current environment and shift the focus to ENCePP’s legacy.
- The discussion further touched upon:
 - Recognition that not all activities require continued EMA oversight.
 - WGs/SIGs:
 - Variable levels of engagement among WGs and SIGs - while recognising some active contributions – and concern that some groups have deliverables planned beyond 2027–2028, questioning realistic delivery.
 - Need to prioritise deliverables of highest value (e.g., on AI, or pragmatism in clinical trials) and support group chairs to define realistic outcomes and timelines.
 - Importance of communication: the SG debated on whether to conduct a network-wide survey to seek feedback on future direction for ENCePP, or to allow for real-time engagement with ENCePP Partners in a webinar format. Concern was raised about possibly low response rate to a survey (as observed in previous surveys), unclear impact, and risk of raising expectations. Consensus therefore emerged to not proceed with an online survey, unless a very specific purpose can be identified. It was agreed that direct interaction with ENCePP Partners is more appropriate (see ENCePP webinar topic below).

ACTIONS - ENCePP Secretariat to schedule next SG meeting to continue the discussion (late June–early July 2026); SG and EMA to review and reprioritise (as needed) WGs/SIGs deliverables to align with the extension of the SG mandate to the end of 2027.

4. ENCePP webinar 2026

- The in-person (hybrid) ENCePP annual Plenary will be replaced in 2026 by a virtual event/webinar. Rationale: decreasing engagement from the network and prioritisation of other events for EMA.
- The SG agreed to organise a webinar (virtual, approx. 2 hours) in Q3 or Q4 2026 to communicate on its current reflection on ENCePP’s future direction and provide a live forum for feedback and questions from all ENCePP Partners.
- Contents of the webinar, also including (a) methodological topic(s), will be further discussed at the next SG meeting.

5. AOB

- ENCePP Special series publication in *Pharmacoepidemiology and Drug Safety* (PDS) and *Value in Health*: all manuscripts have now been submitted, with several undergoing peer-review. Publication planning of the full series with both journals is underway. Appreciation from the SG was expressed for Helga’s leadership and for the contributions from all authors.