



14 October 2024
EMA/462415/2024

Minutes of the ENCePP Steering Group meeting

27 September 2024, 16:00 – 16:30

Participants

Role	Name
Co-chairs	Catherine Cohet (EMA), Helga Gardarsdottir (Utrecht University)
SG members (alphabetical order)	Alejandro Arana, Annalisa Landi, Annette Cleveland Nielsen, Christos Kontogiorgis, Gianmario Candore, Frauke Neumann-Winter, Hedvig Marie Egeland Nordeng, Iryna Vlasenko, Laura Pizzi, Marco Tuccori, K. Arnold Chan, Sharanya Rao, Simon Craig, Vera Ehrenstein, Wong Hui-Lee
EMA	Julianna Fogd, Luca Giraldi, Patrice Verpillat

Agenda

	Topic	Speaker(s)	Objective	Indicative timing
1.	Welcome & adoption of the agenda	Helga & Catherine	Endorsement	5'
2.	Follow-up on actions from last SG meeting	Catherine/all	Update	15'
3.	Working Groups/SIGs – Terms of reference	Helga, Gianmario, Catherine	Decision	25'
4.	Topics for ENCePP Plenary 2024	All	Information Discussion	35'
5.	Update on qualitative survey	Helga & Shar	Discussion	20'
6.	ENCEPP WG1: Guide & checklist	Alejandro	Discussion	20'
7.	ICPE symposium feedback	Arnold	Information	15'
8.	A.O.B and closing			5'



1. Welcome & adoption of the agenda

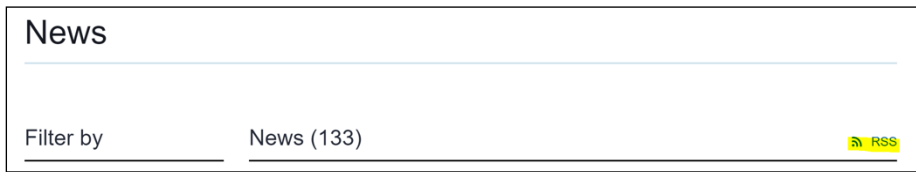
After opening the meeting, Catherine Cohet announced a change in the composition of the Steering Group (SG). As Ulla Wändel Liminga was elected as new PRAC chair in July 2024, her duties no longer allow her to contribute. Hedvig Marie Egeland Nordeng from the Norwegian Institute of Public Health will replace Ulla as PRAC representative. Welcome Hedvig!

The list of the [ENCePP Steering Group members](#) has been updated accordingly on the website.

2. Follow-up on actions from last SG meeting

The SG provided updates on the action points from the last meeting (see [minutes](#)):

- Vera Ehrenstein shared with the SG, prior to the meeting, suggestions for categories/criteria for publication of news/events on the ENCePP website. It was agreed that the current set-up works well. An improvement could be made by including events suggested by ENCePP partners (e.g., trainings, summers schools, etc.) and job offers. Proposals will be curated by the Secretariat and co-chairs, as relevant for ENCePP.
- An ENCePP slide deck including an updated template is now available for the SG members to use.
- Julianna Fogd gave an update on the possibility of subscribing to notifications of newly published ENCePP news/events. An RSS feed is available on the website, through which website visitors can easily subscribe to updates. As it is in XML format, an RSS Feed Reader plugin must be installed in browsers to change the content to HTML.



- Social media: EMA communication on social media channels is made via its main corporate channels (on X, LinkedIn and YouTube). EMA's social media policy is strictly regulated and does not allow to open individual accounts for specific projects/initiatives. It is recommended that SG members and ENCePP partners share/repost ENCePP news, as appropriate, from their own social media accounts (e.g., LinkedIn).
- Opportunity for an ENCePP event at [ISPOR Europe 2024](#): Laura Pizzi confirmed that work is in progress with the ISPOR RWE Special Interest Group (SIG) to have an ENCePP session on 19 November (speaker to be confirmed).

3. Working Groups/SIGs – Terms of reference

- Helga Gardarsdottir and Sharanya Rao from Utrecht University are working on a survey on the role and impact of ENCePP (see topic 5 below), which also reflects on the WGs.
- Building on experience so far, and the fact that there has never been a change in leadership of the WGs, the SG discussed the restructuring of the working groups and the need for a clear mandate and strategy, with a workplan and specified milestones and timelines. If a WG is set up for several years based on a relevant mandate, a rotation of the chair would be suitable. Overall, the creation and maintenance of the WGs should be based on strategic objectives, and be closed once milestones are completed. Helga Gardarsdottir and Gianmario Candore are working on a proposal for terms of reference, possibly inspired by the [ISPE Policy Manual](#) to be discussed in the Plenary.

- There was a suggestion to keep WG1 responsible only for the [ENCePP Guide on Methodological Standards](#), with a focus on periodicity and extent of revision of the Guide. A dedicated WG could be created for the revision of the [Checklist for Study Protocols](#).
- A WG dedicated to communications of ENCePP activities and deliverables was also suggested (e.g., to embed the recently launched '[Conduct your study](#)' podcast series by the current WG2).
- Other suggestions for new WGs/SIGs included focus on methods-related hot topics (e.g., target trial emulation, hybrid designs, use of AI).

ACTION: Gianmario Candore and Helga Gardarsdottir to develop draft guidance/terms of reference for the WGs and share with the SG (deadline tbd, ideally for discussion in Plenary).

4. Topics for ENCePP Plenary 2024

The following suggestions were made by the SG (no specific ranking):

- Presentation of the findings of the ENCePP qualitative research (see topic 5 below)
- Update of GVP Modules (VIII, XVI)
- Positioning ENCePP in the changing guidance landscape (with focus on methods and data networks)
- Update on AI in pharmacoepidemiology
- Quantitative bias analysis
- Hybrid trials, randomised pragmatic trials
- Pregnancy and lactation studies (building on Annex 2 of the Guide)
- Impact of the new pharmaceutical legislation on pharmacoepidemiology and pharmacovigilance (to be further checked if not too premature)
- Pharmacogenomic studies (genetic confounding/genetic susceptibility, use of polygenic risk scores)
- Prevalent new user designs/digital twins
- *Post-meeting note* - Only one suggestion was received following the call for topics made to all ENCePP Partners as part of the Plenary announcement: how will the European Health Data Space (EHDS) shape pharmacoepidemiological research in Europe, and significance for ENCePP.

ACTION: ENCePP Secretariat and ENCePP co-chairs to draft Plenary agenda.

5. Update on qualitative research

Shar Rao from Utrecht University gave an update on the interviews and the survey she is conducting, and presented preliminary findings. The survey is part of a larger qualitative research study investigating the [Role and impact of ENCePP](#). The overall strategy and final results will be presented at the November ENCePP Plenary meeting.

(Details in the slides.)

6. Working Group 1: ENCePP Guide & protocol checklist

- Alejandro Arana gave an update following the recent meeting of WG1. The group discussed the update of the [ENCePP Checklist for Study Protocols](#), for which work is anticipated to be finalised by end of Q1 2025. The update will consider existing documents, such as the [EMA Reflection paper](#), [ICH M14](#), the [HARPER](#) template, and other relevant guidance.

- With regards to updating the [ENCePP Guide on Methodological Standards](#), WG1 will make a proposal for a combined strategy, with selection of some chapters for update in the traditional format (new revision), and publication of selected chapters in the form of a special issue for publication in *Pharmacoepidemiology and Drug Safety (PDS)*, following discussion with the PDS Editorial board at [ICPE](#) in August 2024. Catherine Cohet as EMA editor of previous revisions recommended that WG1 finalises the strategy and identifies lead(s) asap, in view of presentation at the November Plenary and kick-off meeting in January.

7. ICPE symposium feedback

There were approximately 50-60 attendees ('competition' with concurrent DARWIN EU/Sentinel symposium).

(Details in the slides.)

Feedback received from the audience:

- "ENCePP doesn't exist without the partners" (supporting work ENCePP is on a voluntary basis)
- The ENCePP Guide on Methodological Standards was praised as a "landing place" for methods, and a reference for new methods, highly used for academic education; there was a reminder of the importance of HARPER (as reflected in the Guide, which was acknowledged)
- The recent opportunity for institutions in EU candidate countries to join as ENCePP partners was welcomed
- Importance to maintain the 'link' between ENCePP and the [HMA-EMA Catalogues of real-world data sources and studies](#) after the migration from ENCePP to EMA, to continue supporting pre-registration of studies. It was highlighted that many different repositories exist for protocol/reports – ideally, there should be interoperability based on FAIR principles
- ISPE and ENCePP share an innate role on methods development and promotion
- What is the place of the ENCePP Seal in regulatory decision-making? Answer: this will be addressed by the ongoing qualitative research (see item 5 above)
- Importance of visibility of ENCePP, esp. via social media
- Importance of explaining the link between RWE and pharmacoepidemiology/pharmacovigilance. Link between ENCePP and RWE guidelines: how to know if methods recommended by ENCePP are applied appropriately in guidelines?