



Minutes of the ENCePP Steering Group meeting

22 January 2025, 14:30 – 16:30

Teams meeting

Participants

Role	Name
Chair/Vice-chair	Helga Gardarsdottir (Utrecht University) & Catherine Cohet (EMA)
Present:	SG members: Alejandro Arana, Annalisa Landi, Carla Torre, Christos Kontogiorgis, Gianluca Trifiro, Gianmario Candore, Hedvig Nordeng, Hui-Lee Wong, Iryna Vlasenko, Marco Tuccori, Nadia Amaouche, Thomas Goedecke, Vera Ehrenstein EMA: Alexandra Pacurariu, Julianna Fogd, Luca Giraldi, Patrice Verpillat

Agenda

	Topic	Speaker(s)	Objective	Indicative timing
1.	Welcome & adoption of the agenda	Helga & Catherine	Endorsement	5'
2.	Workplan review (for update on ENCePP website post-Plenary)	Catherine	Discussion	15'
3.	WGs/SIGs <ul style="list-style-type: none">• Governance• New groups• ENCePP partners engagement	All	Discussion Decision	50'
4.	(Dis)continuation of the ENCePP Seal	All	Decision	15'
5.	Qualitative research – next steps	Helga	Discussion	15'
6.	A.O.B			20'



Minutes

1. Welcome & adoption of the agenda

After welcoming the participants, Helga Gardarsdottir informed the SG that she is taking a part-time (50%) role as Seconded National Expert at EMA, focusing on RWD studies. Her role as ENCePP co-chair remains the same, she continues representing ENCePP partners on behalf of Utrecht University.

2. Workplan review (for update on ENCePP website post-Plenary)

Catherine Cohet and the SG members updated the ENCePP workplan (vs. slides presented at the Nov. 2024 Plenary).

ACTION for EMA: publish the updated workplan on the ENCePP website.

Objective 1



Update the **governance** and ways of working of ENCePP

Milestones/Deliverable(s)	Who?	Timelines	Status
1.1 - Terms of reference for establishment and maintenance of the Working Groups and Special Interest Groups <small>Link to ToRs be added</small>	Helga Gardarsdottir Gianmario Candore Laura Pizzi	Draft: Q3 2024 Final: Q4 2024	✓
1.2 - Review of the mandates (ENCePP and Steering Group) <small>Links to be added</small>	WGs Steering Group (SG) ENCePP Secretariat	At each new term of the SG	✓

Discussion point:

Objective 1.1 – [Terms of reference for the WGs/SGs](#) was published after this SG meeting on the ENCePP website, and the webpage on the WGs/SIGs (under “About us”) updated, pending information on the new groups.

Objective 2



Increase the **visibility** of ENCePP in Europe and globally

Milestones/Deliverable(s)	Who?	Timelines	Status
2.1 - Guidance for publication of news/events on ENCePP website	Vera Ehrenstein	Q3 2024	Ongoing
2.2 - Slide deck (+ videos/webinars) on history of ENCePP, governance/tools supporting sound PV/PE research <small>Adapt slides of ICPE symposium?</small>	Helga Gardarsdottir	Slide deck: Q3 2024	ICPE slides Living deck
2.3 - Publication – follow-up of PDS 2018 / part of publication series (see ENCePP Guide strategy 3.3)	Catherine Cohet WG/SG members	Publication(s): 2025 onwards	On track
2.4 - Podcasts "Conduct your study" (first series) and other potential topics	Current WG2	First one in 2024	Two posted To continue
2.5 - Explore means of using social media to promote ENCePP <small>Issue statement? In Plenary report</small>	Julianna Fogd	Q3 2024	
2.6 - Increase reach out to larger PV/PE community (RSS feed on ENCePP website) <small>News item? In Plenary report</small>	Julianna Fogd	Q2/Q3 2024	

Discussion points:

Objective 2.2 – The ICPE symposium slides are [published](#) published on the ENCePP website. ENCePP partners shall send an email to encepp_secretariat@ema.europa.eu if they wish to use the ENCePP Power Point template for any ENCePP-related communication in events/conferences.

Objective 2.4 – The group discussed that it would be beneficial to cover a broader range of topics which may be of interest for ENCePP Partners (beyond independence and transparency which is the current focus).

Objective 2.6 – The RSS feed is available on the ENCePP website. Information on how to use the feed is available in the 2024 ENCePP Plenary report, and will be added to the Q&A section of the ENCePP website.

ACTION for EMA: to publish information on the RSS feed on the ENCePP website (to be added in the update of the [ENCePP Q&A](#) sheduled in Q1 2025)

Objective 3



Increase the **impact** of ENCePP in Europe and globally

Milestones/Deliverable(s)	Who?	Timelines	Status
3.1 - Qualitative research Webcast? Publish findings?	Sharanya (Shar) Rao Helga Gardarsdottir	Q4 2024 (Plenary)	✓
3.2 - Co-branded events with learned societies	Arnold Chan (ISPE) Laura Pizzi (ISPOR) Gianluca Trifiro (ISOP)	ICPE 2024 ISPOR EU 2024 ISOP	✓ ✓ ☑
3.3 - Update and/or reinforce use of ENCePP tools and integrate regulatory/RWE/PE/PV guidance (in Guide, Protocol Checklist, CoC)	As per mandates of the WGs/SIGs Update WG/SIG webpages	2024/2025	Ongoing ☑
3.4 - Adapt, and/or create new WGs/SIGs to address the work plan	Steering Group Secretariat ENCePP Partners	Ongoing	☑
3.5. Open ENCePP to public bodies in current EU candidate countries/potential candidates	Secretariat Add link to Catalogues	2024 onwards	✓

Discussion points:

Objective 3.1 – The topic was covered in the 2024 ENCePP Plenary meeting, and further details are included in agenda topic 5 below.

Objective 3.2 – The SG agreed that it would be more feasible and effective to replace the term "co-branded events" by "engagement" (e.g., to develop webinars and other joint activities such as presenting the ENCePP tools, for example at ICPE 2026). Gianluca Trifiro suggested to explore the possibility of a webinar or presentation at ISoP 2025 in collaboration with the ISoP Big data SIG.

Objective 3-4 – See section 3 of the minutes below.

Objective 3.5 – This was started in 2024, the first countries are registered as institutions and ENCePP partners in the [HMA/EMA RWD Catalogues](#).

3. Working groups (WGs)/ Special interest groups (SIGs)

Catherine Cohet summarised the discussions held in previous SG meetings and the ENCePP Plenary on the reformation of the ENCePP WGs and SIGs – i.e., the development of Terms of Reference (ToR) for

the WGs and SIGs, and the creation of new groups to implement the ENCePP workplan. The ToR document was developed in collaboration with, and approved by the SG.

ACTION for EMA: to publish the ToR document

Post-meeting note: the [ToR document](#) and the '*Template for ENCePP WG and SIG proposal*' are now published on the [Working Groups and Special Interest Groups](#) page of the ENCePP website.

3.1. Process

The SG agreed that there should be a clear and transparent decision-making process, including SG critical review of all proposals. It is important that all proposed objectives are realistic and achievable, with timelines and deliverables clearly defined, while avoiding overlap between WGs and SIGs. It was clarified that the WGs should not create SIGs for delivering their tasks. The SIGs should be separate entities from WGs with their own objectives. The groups are expected to manage their work, as the EMA Secretariat cannot be involved in all activities.

The SG will monitor the progress of each WG/SIG and propose, when the deliverables are fulfilled, that the groups are closed.

This new process will be evaluated in a year time to assess how it worked and whether any changes are needed.

3.2. Discussion on proposals for new WGs/SIGs

As an appreciation of their past work, the chairs of the [previous WGs](#) were asked first by the SG co-chairs to send proposals for new groups, taking into account activities that they feel should continue.

The SG reviewed the list of topics proposed in Plenary and agreed on a shortlist for the creation of new WGs/SIGs, in line with the work plan and current environment:

- Update of the **Checklist for Study Protocols**: This is a clear need in the context of new developments such as HARPER and the revision of GVP Module VIII. Work as already started, led by members of the former WG1 and will be delivered under a **SIG**.
- **Communications**: As this is a broad scope, the focus of this **WG** would be on expanding the podcast series, and address other topics of the workplan, such as webinars as useful tools to reach out/engage/educate, proposals for news/events items on the website, patient engagement activities, link with learned societies etc. as well as coordination with the various WGs/SIGs to communicate on their deliverables.
- Revision of the **ENCEPP Guide**: As it represents continuous work overtime (the editor and the authors are expected to follow current trends and developments on each topic in order to propose updates), it will be a WG, open to new members. The first task should be to develop a strategy for updating the Guide including frequency of revisions, timelines, process for selecting chapters for update, etc. The SG agreed that as it is a significant piece of work (including on EMA's side), it is not feasible to update all chapters on a regular basis (or annually, as done until 2023).
- **Code of Conduct** (CoC): while the need for a focused update is acknowledged, no major revision is required. Discontinuation of the ENCePP Seal (see agenda topic 4 below) will have to be reflected. However, it is not expected that regular updates of the CoC are required.
- **AI** – A majority of SG members highlighted that artificial intelligence (AI) is a 'hot topic' impacting pharmacoepidemiology, and would deserve a SIG or WG; however, no specific objectives were mentioned. Suggestions for activities included: update of the AI chapter of the Guide; building a repository of use cases; listing/assessing tools for protocol/report writing; screening the HMA/EMA

Catalogue of RWD studies for use of AI; linking with the EMA [Reflection paper on the use of Artificial Intelligence \(AI\) in the medicinal product lifecycle](#) and EMA AI workplan.

Suggestion from the FDA representative: FDA could contribute use cases for pharmacoepidemiology and learnings thereof: [Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products | FDA](#).

- **Diversity/health equity** in pharmacoepidemiology: Proposal for a SIG has been received, including amongst other a deliverable on how diversity/health equity can be reflected in the ENCePP Guide. E.g., diversity in clinical studies: [Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies | FDA](#)
- **Pragmatic trials**: An important topic, with identified gaps such as terminology and data challenges, also reflected in the workplan of the EMA Methodology Working Party. This could be a SIG, with for example update the PCT chapter of the Guide as a deliverable.
- Engaging with **Central/Eastern Europe** countries, e.g., to assess national data sources: This could be a SIG or a deliverable of the Communication WG. Vera Ehrenstein, Helga Gardarsdottir and Irina Vlasenko are interested.
- Proposals from the chairs of the former WGs 1, 2 and 3 were received by the Secretariat and will be evaluated as part of the review of all proposals (see Next steps below).

The SG agreed to not create new groups on the following other topics that were suggested in Plenary:

- *Target trial emulation: this is addressed by the EMA [RWE Reflection paper](#), Chapter 4.2.6 of the ENCePP Guide, and ongoing initiatives by different stakeholders, therefore duplication was not considered of immediate benefit.*
- *Digital pharmacovigilance: no clear objectives could be identified.*
- *Rare diseases: while this was considered an important topic in terms of method and data source challenges, it was felt that it is covered by several topics in the ENCePP Guide, but could be considered at a later stage.*
- *Data protection and privacy: there is already a chapter in the ENCePP guide.*
- *Impact of PV activities: there was already a [SIG on Measuring the Impact of Pharmacovigilance Activities](#), now closed as deliverables were completed, and the topic has been regularly updated as part of the revisions of the ENCePP Guide (Chapter 16.4).*

3.3. Next steps

- SG to provide final endorsement of the short list of WGs/SGs as per these minutes.
- EMA to invite ENCePP Partners to express interest to join the above proposed WGs/SGs within one month (considering the ToRs). The template will be included in the email communication. Engagement of junior partners is encouraged, as ENCePP would benefit from fresh, creative ideas (e.g., PhD students with high motivation, who would also benefit from the deliverables).
- A special SG meeting dedicated to review of all proposals will be scheduled by end of Q1.

4. (Dis)continuation of the ENCePP Seal

The discussion on decommissioning the ENCePP Seal has been ongoing for several years with previous Steering Groups. There is no legal basis for the Seal to be taken into account in the assessment of protocols and reports by EMA Committees, and limited awareness and perceived added value. In addition, the number of applications since its inception is very low, potentially suggesting limited added value for MAHs as well.

Based on the above, the SG agreed to discontinue the ENCePP Seal. It was clarified that individual components of the Seal remain key.

ACTIONS:

- EMA to draft a statement on behalf of the SG for announcement on the ENCePP website.
- The change should be reflected in relevant documentation and systems (e.g., ENCePP website, HMA-EMA Catalogues).

5. Qualitative research – next steps

The results were presented at the Nov. 2024 ENCePP Plenary meeting. A report was developed by Shar Rao for her master thesis. The SG agreed that the findings would deserve to be communicated. Proposals from the SG included an IPCE abstract submission, and a webcast (similar to the ENCePP Plenary presentation) to be published on the ENCePP website.

ACTION: Helga Gardarsdottir to investigate the possibility of the above two suggestions.