



Minutes – ENCePP Steering Group virtual meeting

20 June 2023, 14:00 – 16:00, Teams meeting

Chairs: Catherine Cohet (EMA), Susana Perez-Gutthann (RTI)

Participants: Alexandra Pacurariu, Andreas Kouroumalis, Andrej Segec, Arnold K. Chan, Carla Torre, Catherine Cohet, Craig Simon, Francesco Salvo, Frauke Naumann-Winter, Gianluca Trifirò, Gianmario Candore, Helga Gardarsdottir, Iryna Vlasenko, Julianna Fogd, Katerine-Christina Deli, Luca Giraldi, Narayan Nair, Patrice Verpillat, Richard J. Willke, Rosa Gini, Salvatore Crisafulli, Susana Perez-Gutthann, Thomas Goedecke, Wei Hua, Ulla Wändel Liminga

Apologies: Annette Cleveland Nielsen, Cécile Droz-Perroteau, Chantal Quinten, Daniel Morales, Daniel Prieto-Alhambra

	Topic	Speaker(s)	Indicative timing
1.	Welcome & adoption of the agenda Update from the co-chairs	C. Cohet & S. Perez-Gutthann	10'
2.	Future of ENCePP: follow-up from December 2022 Plenary	P. Verpillat	45' incl. discussion
3.	Proposed workplan (building on topic 2, for implementation second half of 2023)	C. Cohet & S. Perez-Gutthann	15'
4.	Update on migration of the catalogues and ENCePP website	K. Deli A. Segec	15'
5.	Update from the Working Groups (incl. workplan)	A. Arana R. Gini G. Trifiro	15'
6.	Upcoming meetings: <ul style="list-style-type: none">• Next Steering Group (hybrid): September• Plenary and SG meeting (hybrid):<ul style="list-style-type: none">○ Date in Nov/Dec○ Call for programme committee	C. Cohet	10'
7.	A.O.B	All	10'



1. **Welcome & adoption of the agenda; update from the SG co-chairs**

Susana Perez-Gutthann introduced the meeting. After the adoption of the agenda, Catherine Cohet gave a brief update on ongoing EMA activities of interest to ENCePP:

- DARWIN EU® is onboarding additional data sources and several new studies are ongoing or planned.
- RWE guidance:
 - The ICH Reflection Paper on “*RWE terminology, and convergence of general principles regarding planning and reporting of studies using RWD, with a focus on effectiveness of medicines*” developed in collaboration with FDA and Health Canada has been endorsed at the ICH Assembly on 12 June 2023. A public consultation will be launched shortly.
 - The public consultation on ICH M14 will be launched in Q3 (*General Principles on Planning and Designing Pharmacoepidemiological Studies That Utilize RWD for Safety Assessment of a Medicine*).

The ENCePP community will be informed and invited to comment on both ICH documents.

- A concept paper is under development by the EMA Methodological Working Party (MWP).
- The ENCePP Guide is planned to be published by mid-July.
- [GVP](#) Module VIII is under review.
- EMA is hosting a Multi-stakeholder workshop on Real World Data (RWD) quality and Real World Evidence (RWE) use on 26-27 June 2023, with the participation of some ENCePP Partners. A workshop on Registries is planned to be organised in Q1 2024.

2. **Future of ENCePP: follow-up from December 2022 Plenary**

Patrice Verpillat, new head of RWE at the EMA, introduced himself to the Steering Group and presented his views on the future of ENCePP, for discussion with the SG. As the landscape has changed in the last 10 years, the place of ENCePP needs to be revisited. The aim is to continue with ENCePP, with some suggested adaptations:

- Reactivate the network, involve, and engage new people with fresh ideas; redefine key activities, ensure active participation of members.
- Involve representatives of other bodies in the Steering Group, e.g., European Commission, pharma representatives (rather than only EFPIA), ECDC, MWP.
- SG observer role to align with other SG members.
- Ensure some degree of representativeness at the SG by having a “quota” of seats per membership type. The ENCePP membership should be kept at the organisation level, but it might be useful to create a separate so-called “ENCEPP community”, with participation at individual level.

Points on working groups; special interest groups; task forces:

- Need to redefine or confirm the mandates of the WGs.

- Possible creation of new SIGs that can deal with specific topics of interest, with clear deliverables and within agreed timelines.
- Proposal to delete the Task Forces from the ENCePP structure.

Ongoing changes, and planned activities:

- The ENCePP Database of Research Resources and the EU PAS Register will move to the EMA website.
- Check the use and relevance of the checklist for study protocols.
- Check how to optimise the update and use of the ENCePP Guide.
- Check the value of, and barriers to the ENCePP Code of Conduct and Seal adoption.

Some additional points were also made regarding the ENCePP 'brand' visibility; on how to position ENCePP in regards to relevant European initiatives (e.g., [BDSG](#)); and on the possibility of a brainstorming during the next ENCePP Plenary to further redefine the ENCePP scope and activities.

There was overall positive and optimistic feedback from the SG, including the following comments:

- Susana Perez-Gutthann agreed with the need for actions, especially on the engagement with the 'new generation' of scientists, and the need to expand the visibility and representativeness of the ENCePP network. Importantly, ENCePP is not only focusing on methods but also on how the community works and engages with partners.
- Rosa Gini acknowledged and appreciated the renewed engagement of the Agency on ENCePP after a quiet period due to Brexit and the pandemic. She challenged the stratification of the SG elected members by categories such as private/public/universities. However, this was supported by other SG members. She highlighted that ENCePP is a network of experts supporting EMA, and there is a need to restore this support. She also mentioned that WG2 has included in the workplan presented in November the investigation on barriers to compliance with the Code of Conduct.
- Helga Gardarsdottir mentioned that the ENCePP tools are already in use for teaching students in pharmacoepidemiology.
- Carla Torre agreed that the MWP should have a place in the SG, and the representativeness of different parties needs to be checked in the SG like it is done in other networks (e.g. ISPE).
- Francesco Salvo asked about the current role of pharmacovigilance activities in ENCePP. It was mentioned that pharmacovigilance was a more active domain compared to pharmacoepidemiology in Europe when ENCePP was created, therefore the need to focus on pharmacoepidemiology. Susana expressed that both pharmacoepidemiology and pharmacovigilance remain important, and a link with ISOP should be maintained.

3. **Proposed workplan (building on topic 2, for implementation second half of 2023)**

Catherine and Susana presented the draft ENCePP workplan for the remainder of 2023 and for 2024 (to be published later), calling for SG co-leads for the proposed topics. The workplan includes activities related to the new catalogues (including a webinar to the ENCePP community) and new ENCePP website; the strategic review and the visibility of ENCePP; and WGs related activities.

Focus will be on reaching out to the ENCePP community and the public to regularly inform in recent development and engage more to foster increased contribution. Specific proposed deliverables include webinars and a qualitative survey.

Susana expressed the wish to have insight from EMA on the new pharma legislation, and potential aspects related to the work of ENCePP. Catherine will follow-up on this topic.

ACTION: SG members and WG chairs to contribute and express their interest in co-leading/participating in the proposed topics by 15 July 2023.

4. Update on migration of the Catalogues and ENCePP website

Katerina-Christina Deli gave an update on the current status of the Catalogues (migration of the EU PAS Register and the ENCePP Resource database). During the development of the catalogues, the comments from the ENCePP Partners have been taken into account. Work is ongoing, the different features are continuously being tested by a dedicated EMA group.

Andrej Segec gave an update on the progress of the new ENCePP website and presented the draft layout of the different pages. The possibility of a new, more modern logo is under discussion. The new website (www.encepp.europa.eu) is planned to be launched on the same day as the new catalogues on the EMA website.

5. Update from the Working Groups (incl. work plans)

The chairs of the 3 working groups gave an update on their work, building on their proposals at the December 2022 plenary. WG2 presented a proposal for a communication plan around the ENCePP Code of Conduct. A more detailed plan will follow and be discussed at the Autumn SG meeting.

6. Upcoming meetings:

- Next Steering Group: fully virtual meeting in September (exact date TBC)
- ENCePP Plenary meeting: 1 day hybrid meeting at the EMA (late November, early December – exact date TBC)

ACTION: Call for programme committee – SG members to express their interest by 15 July 2023.