

26 June 2024
EMA/277225/2024

Minutes of the ENCePP Steering Group (SG) meeting

4 June 2024, virtual

Role	Name
Co-Chairs	Catherine Cohet, Helga Gardarsdottir
Participants	Annalisa Landi, Annette Cleveland Nielsen, Alejandro Arana, Christos Kontogiorgis, Frauke Naumann-Winter, Gianmario Candore, Hui-Lee Wong, Iryna Vlasenko, Julianna Fogd, Laura Pizzi, Thomas Goedecke, Ulla Wändel Liminga, Vera Ehrenstein, Sharanya Rao
Apologies	Arnold K. Chan, Craig Simon, Gianluca Trifiro, Nadia Amaouche

Agenda

	Topic	Speaker	Objective	Indicative timing
1.	Welcome & adoption of the agenda	Co-chairs	Adoption	5'
2.	ENCEPP Workplan	Catherine	Adoption	30'
3.	Update on the qualitative survey	Helga	Information	20'
4.	ENCEPP symposium/workshop at ICPE	Arnold/Catherine	Discussion	20'
5.	Topics for F2F/hybrid SG Sept. 2024	Julianna/All	Discussion	20'
6.	A.O.B	/	/	25'

Minutes

1. Welcome & adoption of the agenda

The co-chairs of the meeting welcomed the participants and introduced the Agenda for adoption.

2. ENCePP Workplan

Catherine presented the final draft of the ENCePP workplan that was updated by the co-chairs following the SG kick-off meeting in February, and circulated for review by SG members prior to this meeting.

- The revised **ENCePP mandate** adopted earlier this year has been updated on the ENCePP website. The updated **SG mandate** also adopted will be published after the meeting.
- Prior to the SG meeting, the ENCePP co-chairs discussed with the **Working Groups** chairs the need to update the mandates of the current WGs, and to revise the governance of the WGs. In addition, creation of potential new WGs to better reflect the ENCePP workplan was discussed. The SG agreed to develop terms of reference for the WGs, incl. chairing, membership, mandate, and timeframe. Participation of industry representatives in the WGs was raised and will be discussed at Secretariat level.

ACTIONS

- **WG chairs** to finalise the update of their mandates and share with the Secretariat for review by the SG (asap)
- Volunteers to develop terms of reference for the WGs (and SIGs) for discussion and adoption at the September SG meeting: **Helga Gardarsdottir, Gianmario Candore, Laura Pizzi**
- **Communication activities** to support **increasing the impact of ENCePP** include the publication on the website of news items, events, and slide decks; podcasts; use of social media; and reaching out to the larger PV/PE community.

ACTIONS

- Drafting of categories/criteria for publication on the ENCePP website: **Vera Ehrenstein**
- Slide deck on ENCePP: **Catherine Cohet** to share a proposal for the SG to review
- First podcast "Conduct your study" by WG2 to be posted on the website (Post-meeting note: posted on 12 June: [Launch of the ENCePP 'Conduct your study' podcast series](#))
- **Julianna Fogd** to check possibility of an ENCePP LinkedIn account with the EMA Communications team
- **Julianna Fogd** to check with DIGIT (host of the ENCePP website at the European Commission) the possibility of activating the RSS feed on the ENCePP website to allow website users to stay up to date. Example: [RSS feeds | European Medicines Agency](#) (Post-meeting note: DIGIT is now checking this query)
- **Catherine Cohet & Laura Pizzi** to investigate options for an ENCePP session at the [ISPOR](#) EU conference in November, in addition to the ICPE symposium/workshop (see agenda topic 4).

The final adopted workplan will be published on the ENCePP website by the end of June.

3. Update on the qualitative survey

Helga gave an update on the qualitative study on the value and future role of ENCePP, which is currently being conducted by Shar Rao, master's student at the University of Utrecht (UU), with the involvement and supervision of the ENCePP SG co-chairs, Helga Gardarsdottir (UU) and Catherine Cohet (EMA). The project is divided into two parts: Part 1: Qualitative interviews, and Part 2: Questionnaire. In Part 1, which focusses on current and future role of ENCePP, the design of the study has been completed (February-April 2024), and stakeholder engagement has started. Part 2 will focus on assessing use of ENCePP tools and guidances.

Question on the involvement of PRAC assessors as stakeholders: Helga confirmed that for the interviews they have not been involved, but will be included for the survey.

ACTION: Ulla Wändel Liminga and Annette Cleveland Nielsen to further reflect on participation of EMA Committees to the survey given the different levels of knowledge of ENCePP and ENCePP tools among the committees, and consider proposing potential names for interviews.

4. ENCePP symposium/workshop at ICPE

Catherine gave an update on the ENCePP symposium/workshop accepted by [ICPE](#), sponsored by the ISPE [Real-World Evidence Collaborative](#). Title: '15+ years of ENCePP: What has been achieved, what's next, and what's in for ISPE.'

Moderators/co-chairs

- K. Arnold Chan (TriNetX/Taiwan University - ISPE representative on the ENCePP SG)
- Catherine Cohet (EMA - ENCePP SG co-chair)

Speakers

- Helga Gardarsdottir (Utrecht University, NL - ENCePP SG co-chair, academia)
- Rosa Gini (Agenzia Regionale di Sanita Toscana, Florence, Italy - ENCePP WG2, academia)
- Gianmario Candore (Bayer/EFPIA representative on behalf of industry trade associations)
- Massoud Toussi (Cytel – ENCePP partner, CRO)

Panellists: moderators and speakers, joined by:

- Carla Torre (University of Lisbon - ENCePP SG member and EMA MWP/CHMP member)
- Patrice Verpillat (EMA)

Additional SG representative present at ICPE who will attend: Hui-Lee Wong (US FDA)

Objectives

- To inform on recent ENCePP updates and their potential benefits for the ISPE community;
- To position the current work of ENCePP in a fast-changing and more global environment;
- To exchange views with ISPE members on future directions for ENCePP.

5. Topics for F2F/hybrid SG Sept. 2024

The next ENCePP SG meeting will be held on **27 September** at EMA premises in Amsterdam. Five SG members have so far expressed interest to attend in person.

Some suggested topics include a lookback at the HMA-EMA RWD Catalogues following the transition from ENCePP, impact of the new pharmaceutical legislation, and strategy for the revision of the ENCePP Guide incl. publication in peer-reviewed journal(s).

ACTION for ALL: propose agenda topics to the ENCePP Secretariat.

6. AOB

There were no additional topics.