



## Minutes – ENCePP Steering Group meeting

25 March 2025, 14:00 – 16:00

**Chairs:** Helga Gardarsdottir (Utrecht University) & Catherine Cohet (EMA)

**ENCePP SG members:** Alejandro Arana, Annalisa Landi, Frauke Naumann-Winter, Gianmario Candore, Gianluca Trifirò, Hedvig Marie Egeland Nordeng, Iryna Vlasenko, Laura Pizzi, Marco Tuccori, Melissa Kampman, Thomas Goedecke, Vera Ehrenstein

**EMA:** Patrice Verpillat, Julianna Fogd

**Excused:** Christos Kontogiorgis, Carla Torre, Hui-Lee Wong, Nadia Amaouche

	Topic	Speaker(s)	Objective	Indicative timing
1.	Welcome & adoption of the agenda	Helga & Catherine	Endorsement	5'
	<b>WGs/SIGs</b>			
2.	1) Progress update: SIG - PDS/Value in Health publication series on ENCePP Guide selected chapters 2) Progress update: SIG - Checklist for study protocols 3) Survey to ENCePP Partners for contribution: outcome 4) Way forward	1) Helga 2) Catherine 3) Julianna 4) All SG members	Discussion Decision	1h30
3.	Proposal for honorary ENCePP membership	Catherine	Decision	10'
4.	Planning <ul style="list-style-type: none"> <li>ENCePP Plenary</li> <li>Next SG meetings</li> </ul>	All SG members	Decision	10'
5.	A.O.B			5'

### 1. Welcome & adoption of the agenda

After welcoming the SG members, Catherine Cohet introduced the new Health Canada representative in the SG, Melissa Kampman. The SG adopted the agenda, and an overview of activities since the last SG meeting (January 2025) was provided:

- **News** published on the website, with supporting email communications to ENCePP Partners:
  - 23 January: 2024 ENCePP [Plenary report](#) and [Annual activity report](#)



- 06 February: [Minutes](#) of the January 2025 SG meeting and updated ENCePP [workplan](#)
- 10 February: New tender for [procurement](#) of EMA-funded scientific studies
- 18 February: Discontinuation of the [ENCePP Seal](#)
- 19 February: [Call for interest](#) to join the new **WGs/SIGs** (closed on 17 March)
- Further email communications:
  - **Trainings** (as per request from ENCePP Partners) - "Introduction to Pharmacoepidemiology" online DSRU course ([link](#)); Pharmacoepidemiology summer school in Denmark ([link](#))

## 2. Working Groups (WGs)/Special Interest Groups (SIGs)

### 2.1. Progress update: SIG - Publication series on ENCePP Guide selected chapters

Helga Gardarsdottir gave an update on the planning for the publication of selected chapters of the ENCePP Guide in Pharmacoepidemiology & Drug Safety (PDS) and in Value in Health (ViH). ENCePP Guide chapters of special interest have been listed, the article structure agreed, and most lead authors (from current chapters in [Revision 11](#)) confirmed. The choice of chapter for each of the two journals aligns with their audience; for PDS, one selection criterion was to avoid overlap with the PDS core concept series. Alignment on timelines with PDS and ViH are ongoing. Options for open access and related costs are being explored; Laura Pizzi confirmed that ISPOR can support ViH open access.

#### Next steps:

- Meeting with PDS/ViH on April 3<sup>rd</sup> to align
- Meeting with key authors to provide practical guidance and timelines

### 2.2. Progress update: SIG - Checklist for study protocols

The SIG started its work under the former WG1, with a kick-off meeting in February.

- **Co-chairs:** Katja Hakkarainen (Parexel), Jessica Bolstad (Parexel)
- **Members:** Helga Gardarsdottir (Utrecht University), Catherine Cohet (EMA), Johann Castañeda (IQVIA), Xabier Garcia de Albeniz Martinez & Susana Perez-Gutthann (RTI), Tania Schink (BIPS)

The work is building on HARPER, ICH M14, and will be relevant for the [GVP VIII - Post-authorisation safety studies](#) revision.

#### Next steps:

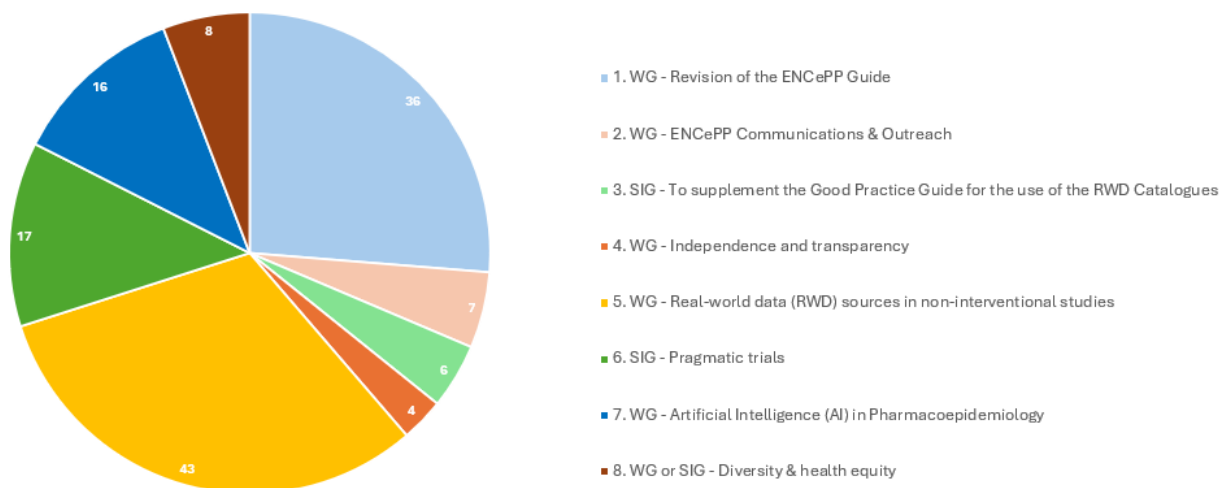
- Review and approval by the SG is currently planned by end of June, depending on progress of work
- Publication on the ENCePP website: Q3 2025

### 2.3. Outcome of survey to ENCePP Partners for contribution to the WGs/SIGs

On 19 February, a call for expression of interest from ENCePP Partners to join the new WGs and SIGs was launched via a survey, with deadline for completion of 17 March. The list of the new groups was agreed in the previous SG meeting, based on the last ENCePP plenary proposals.

The survey was disseminated to all ENCePP Partner contacts in the [RWD Catalogues](#) (339 at the time of launch) and published on the [ENCePP website](#). A total of 94 responses were received, of which 4 were invalid (from industry or non ENCePP members).

See Figure 1 for the distribution of answers per WG/SIG.



**Figure 1: Applications received per WG/SIG**

Points to consider for review of survey results by the SG included number and representation of institutions in each WG/SIG, applications for co-chairing, and relevance of the WG/SIG to support EMA needs. Several responders indicated their willingness to take a co-chair role. The SG decided to leave the decision with the groups to agree on co-chairs in their first meeting.

There was a question on the low response rate, and whether the reason might be that the “right” contacts for some institutions may not be in the RWD Catalogues. The ENCePP Secretariat reminded the SG of last year’s [ENCePP membership update](#) exercise, where ENCePP Partners were asked to update their records in the RWD Catalogues. ENCePP Partners are responsible for keeping their records up to date, as all communications are sent to the registered contact points.

The SG agreed that SG representation in the WGs/SIGs is important, and some groups will also require EMA representation. It was also reminded that membership/co-chairing should favour contribution from students/new members/members who had not contributed to the former groups.

#### **2.4. Way forward/next steps**

- A **kick-off meeting** for survey responders who expressed interest in co-chairing a group will be organised by the ENCePP Secretariat and led by the **SG co-chairs** (Helga G. and Catherine C.). The objective is to discuss the process for selection of the **WGs/SIGs co-chairs**, and brief on ways of working (size of the group based on representativeness/expertise, role of the WG/SIG co-chairs in the organisation of meetings, monitoring of member attendance and contribution, etc.).
  - The groups will then organise themselves for their first meeting; draft **objectives** with **deliverables** and **timelines** (based on the [Template for ENCePP WG and SIG](#)) for SG approval; and agree on monitoring of progress, reporting to the SG, management of large membership, etc.
  - SG members to express their interest in joining/sponsoring the WGs/SIGs
  - Feedback from the WGs/SIGs to the SG with complete description of the WGs/SIGs
  - ENCePP Secretariat to collect expression of interest from EMA colleagues to join the WGs/SIGs
- Report on progress from each group will be sought at upcoming SG meetings and at Plenary.

### **3. Proposal for honorary ENCePP membership**

Catherine Cohet put forward a proposal that Partners who significantly contributed to the work of ENCePP over the years, and individuals no longer/not belonging to an institution/network (e.g.,

retired), may be given the opportunity to continue supporting ENCePP and contribute to delivering the workplan as honorary members (e.g., by joining WGs/SIGs). This could follow a similar approach as the [ISPE Awards](#). There was no objection from the SG.

**Next steps:**

- ENCePP Secretariat to draft a proposal for a process and selection criteria
- SG to review and endorse

## **4. Planning**

### **4.1. ENCePP Plenary**

The next full-day ENCePP Plenary hybrid meeting will be on **Monday, December 1<sup>st</sup>, 2025**.

**Next step:**

- A 'save the date' email will be sent to all ENCePP Partners

### **4.2. Next SG meetings**

The next SG meeting will take place during the second part of June. Agenda topics will include reviewing the mandates submitted by the new co-chairs of the WGs/SIGs. Dates of next meetings to be further agreed.

**Next step:**

- WGs/SIGs descriptions (objectives, deliverables and timelines) to be submitted by WGs/SIGs chairs to the SG via the ENCePP Secretariat ahead of the next SG meeting (information will follow as per process in 2.4. above).