



11 March 2024  
EMA/94303/2024

## ENCePP Steering Group (SG) kick-off meeting for the 2024-2026 term - Minutes

16 February 2024, virtual

Role	Name
Chair	Catherine Cohet
Present:	Annalisa Landi, Annette Cleveland Nielsen, Alejandro Arana, Carla Torre, Craig Simon, Christos Kontogiorgis, Frauke Naumann-Winter, Gianluca Trifiro, Helga Gardarsdottir, Hui-Lee Wong, Iryna Vlasenko, Julianna Fogd, Laura Pizzi, Marco Tuccori, Nadia Amaouche, Patrice Verpillat, Thomas Goedecke, Ulla Wändel Liminga, Vera Ehrenstein

### Agenda

	Topic	Speaker(s)	Indicative timing
1.	Welcome & adoption of the agenda	C. Cohet	5'
2.	Introduction of the new SG for the 2024-2026 term	New members, All	15'
3.	Decision on the ENCePP co-chair	All	10'
4.	<ul style="list-style-type: none"><li>HMA-EMA Catalogues of Real-World Data (RWD) sources and studies</li><li>Launch of the new ENCePP website</li></ul>	J. Fogd	10'
5.	Endorsement by the SG of the updated: <ul style="list-style-type: none"><li>Steering Group mandate</li><li>and ENCePP mandate</li></ul>	P. Verpillat, All	10'
6.	Update of the mandate of the Working Groups	C. Cohet, All	10'
7.	ENCePP Workplan for the 2024-2026 term	C. Cohet, All	20'
8.	A.O.B and next meeting	All	10'



### 1. Welcome & adoption of the agenda

Catherine Cohet welcomed the participants and introduced the Agenda for adoption.

### 2. Introduction of the new SG for the 2024-2026 term

The members of the new SG and the EMA attendees gave a short introduction about themselves.

### 3. Decision on the ENCePP co-chair

The ENCePP SG is coordinated by two co-chairs, one from EMA and one representing the ENCePP partners. The EMA co-chair is Catherine Cohet from EMA's Real World Evidence work stream. From the ENCePP partners, one SG member, Helga Gardarsdottir from the Utrecht Institute for Pharmaceutical Sciences, expressed interest by email before the meeting. The group welcomed her expression of interest and agreed to elect Helga as ENCePP SG co-chair for the term 2024-2026.

### 4. HMA-EMA Catalogues of Real-World Data (RWD) sources and studies; Launch of the new ENCePP website

Julianna Fogd gave an update on the launch of the HMA-EMA Catalogues and the new ENCePP website, highlighting the main changes and some of the new features.

On 15 February 2024, the EMA launched:

- The HMA-EMA Catalogues of real-world data sources and studies <https://catalogues.ema.europa.eu/>
- The new ENCePP website: [www.encepp.europa.eu](http://www.encepp.europa.eu) (new URL) with visitor redirection from the former [www.encepp.eu](http://www.encepp.eu) URL.

Important changes include:

- **ENCePP** has **no longer supervision** over the new RWD Catalogues
- **New studies, data sources, institutions** and **networks** must be submitted to the RWD Catalogues
- A different EMA team now approves the submissions (no longer the ENCePP Secretariat)
- EU PAS Register email address decommissioned; RWD Catalogues related queries to be submitted via the [RWD Catalogues contact form](#)

Some of the new key features of the Catalogues:

- New platform, updated questionnaire for submitting information
- Improved search functionalities
- Improved linkage between data sources and studies
- Downloadable data
- Entries linked to personal email addresses
- Co-authorship of entries

New ENCePP website:

- New design, new logo
- Simplified, user-friendly structure
- Search bar and filters added
- All key ENCePP outputs migrated
- Can be easily updated by the ENCePP Secretariat
- Analytics tool available for monitoring website usage

*Discussion:* Clarify what type of news will be published on the new website

**ACTION to Catherine, Helga (SG co-chairs) and Julianna:** Develop draft proposal for criteria for News selection and share with the SG for comments (e.g., trainings, conferences, career opportunities, key publications (EU/global), etc.).

## 5. Endorsement by the SG of the updated ENCePP and SG mandates

Detailed proposals for the update of the mandates were presented at the December 2023 ENCePP Plenary meeting, and were summarised by Patrice Verpillat in the SG meeting for adoption:

ENCePP was established over 15 years ago, adaptation to the current environment is needed. For example:

- Overseeing the RWD catalogues (former EU PAS Register and ENCePP Resource Database) is no longer part of the ENCePP mandate after the migration to the EMA website.
- Special Interest Groups (SIGs) and *ad hoc* Task Forces have not been used over the past years and should be better leveraged to address specific topics.
- Steering Group governance changes: updated membership, election process, observer vs. representative role, rules for attendance.

Changes already raised during the December 2023 Plenary meeting:

- Expansion from 17 to 22 members minimises the role of the partners in the SG, if maintained to 6 representatives as before
  - Proposal to increase to 10 (to keep a proportion of ≈35%), increasing the total number of SG members to 26 for the next mandate
  - Election rules adapted to reflect this change: Two third of the seats (7 out of 10) will be reserved for public institutions and one third (3 out of 10) for private companies

Additional points raised in the last few months about UK-based centres:

- The current mandate refers to 'Europe' - revision to 'EU/EEA' needed
  - No change for the moment for UK centres already part of the network
    - Based on the principle that both the EU is gaining from the relationship with the UK in this context
    - Similar to the Horizon Europe/Copernicus situation, where the European Commission has permitted UK participation on the basis of a *quid pro quo*
- Possibility for ENCePP membership opening to EU candidate and accession countries (including training opportunities). This was considered as keeping with the purpose of ENCePP.

*Discussion:*

- Only few responses to the SG election call (6 seats, 8 applicants), this needs to be addressed. While the group should keep a reasonable size, the number of ENCePP members actually active should be reflected upon (acknowledging the volunteer nature of the contribution).

## 6. Update of the mandate of the Working Groups

Catherine Cohet discussed the need to revisit the WG mandates due to:

- Temporary nature of the WG as per ENCePP governance
- Some activities no longer relevant, some activities to be updated or added
- Size of the WGs, imbalanced contribution of the members, imbalanced representation of some organisations

*Discussion:*

- SG to evaluate continuity of the WGs, as WGs can in principle be decommissioned when their mandate is achieved, as per ENCePP governance.
- The tasks of the WGs should be aligned with EMA's and the ENCePP community needs.
- Better use the opportunity for creating Special Interest Groups (SIGs) that could be linked to specific activities of the WGs. There was one proposal to explore interface with HTA.
- The RWE guidance environment is very rich – need to identify how ENCePP can support while cascading information to the partners on important guidance developments.

**ACTION to WG chairs and EMA members of the WGs:** WG chairs to check the mandate and tasks of their WG, discuss it with the EMA representative in their group, and draft a proposal, ideally **by end of Q1 2024** in order to update the website and reflect the update mandates in the workplan (see next topic).

## 7. ENCePP Workplan for the 2024-2026 term

Catherine Cohet presented the ongoing work on the development of the workplan for the term 2024-2026, following the ENCePP Plenary meeting in December 2023 (see details in the [Plenary report](#)). The new workplan will be based on discussions with the previous SG, and adaptation to the current RWE / regulatory environment, while considering (realistic) contribution/resources among ENCePP partners.

Some of the objectives have been fulfilled, e.g., the launch of the RWD Catalogues and the new ENCePP website, and the [Multistakeholder event on the Catalogues](#) (4 March 2024).

The workplan will be finalised by the co-chairs based on the discussion/suggestions of the SG, and communicated to the SG for final endorsement, with an aim to publish on the [ENCePP website](#) by the end of Q1/early Q2.

*Discussion:* Visibility of the RWD Catalogues on the ENCePP website: EMA colleagues confirmed that although the Catalogues are no longer under ENCePP, they have a prominent place on the new ENCePP homepage, with a direct link to the new location, to guarantee that users of the former ENCePP Resource Database and EU PAS Register can easily access the new location.

## 8. AOB and next meeting

ENCePP Secretariat to send a doodle poll with possible dates for the next SG meeting (virtual, before the summer break). The Autumn SG meeting will be hybrid in Amsterdam (TBC).