Minutes of the ENCePP Steering Group meeting

04 October 2023, 14:00 – 16:30 (Teams)

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

SG members: Alexandra Pacurariu, Annette Cleveland Nielsen, Alejandro Arana, Andrej Segec, K. Arnold Chan, Carla Torre, Cecile Droz-Perroteau, Chantal Quinten, Craig Simon, Francesco Salvo, Gianluca Trifirò, Gianmario Candore, Helga Gardarsdottir, Iryna Vlasenko, Julianna Fogd, Katerine-Christina Deli, Luca Giraldi, Narayan Nair, Patrice Verpillat, Richard J. Willke, Rosa Gini, Thomas Goedecke, Ulla Wandel Liminga, Wei Hua.

Agenda

	Topic	Speaker(s)	Indicative timing
1.	Welcome & adoption of the agenda	SG chairs	5’
2.	Workplan: update and progress status	SG chairs All	20’
3.	New Steering Group election	J. Fogd	10’
4.	Revision of: • Steering Group mandate for the next term • ENCePP mandate	P. Verpillat	30’
5.	Update on migration of the catalogues	K. Deli	10’
6.	ENCePP website and logo	J. Fogd A. Segec	10’
7.	Plenary meeting: preliminary agenda topics, suggestions for external speakers	All	30’
8.	Update from the Working Groups	A. Arana R. Gini G. Trifiro	30’ (10’ each)
9.	A.O.B	All	5’

1. Welcome & adoption of the agenda

The ENCePP Steering Group (SG) co-chairs welcomed the participants, introduced the SG meeting agenda, and presented the meeting objectives.

2. Workplan: update and progress status

Catherine Cohet gave an update on the workplan and asked for feedback from the SG members.

Comments / questions from the SG on the objectives:

Objective 1 - As part of the Data discoverability objective of the HMA/EMA Big Data work plan 2022-2025, support the migration of the EU PAS Register and ENCePP resource database to the new catalogues, on NIS and data sources, resp.

- Gianmario Candore expressed interest in the testing of the new catalogues.
- Susana Perez highlighted that migration of the catalogues is critical, especially that the migration of the studies needs to run smoothly. Importance of the strong ENCePP legacy, as reflected in the recently released Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products (fda.gov).
- Patrice Verpillat: in transition/early times, the term 'former EU PAS Register' may be used to make sure there is a link between the old system and the new catalogue of non-interventional studies.
- Rosa Gini mentioned the previous request from WG2 to include a question on the CoC in the catalogue of studies. Post-meeting note: this is confirmed – the following question is included in the study questionnaire: "Is this study performed in line with the ENCePP Code of Conduct?" (answer yes/no).

Objective 2 – Support the re-building of the ENCePP website and embed solutions for increased visibility, as well as cross-fertilisation and input from ENCePP partners

- Susana Perez reminded that the current website was set up in 2007! Importance of visibility of the ENCePP deliverables.
- Iryna Vlasenko: it would be useful to have slides to promote ENCePP.

ACTION for the ENCePP Secretariat: Provide a short deck to support the visibility of ENCePP, once the catalogues and the new ENCePP website are live.

Objective 3 - Inform the ENCePP community and other relevant stakeholders on the new catalogues and website.

- Post-meeting note: can be merged with Objective 1 and 2. **ACTION** for the ENCePP Secretariat.

Objective 4 - Inform on place and impact of ENCePP in a fast-evolving environment, to support Objective 5.

- Clarification on the 2 surveys to be conducted:
  - Helga Gardarsdottir: Survey 1 to focus on the future and the positioning of ENCePP. Helga is looking for students from Utrecht University to work on this research project.
  - Rosa Gini: Survey 2 under WG2 to focus on barriers to the implementation of the Code of Conduct. Helga also to contribute.

Objective 5 - Strategic review: re-define ENCePP scope and activities.

- Rosa Gini (for topics related to WG2) and Alejandro Arana (for topics related to WG1) volunteered to support the Strategic review.
- Helga Gardarsdottir had a question on the future of the Special Interest Group (SIG) on Measuring the Impact of Pharmacovigilance Activities. P. Verpillat confirmed that it has been closed, and highlighted that SIGs and Task Forces should address specific topics and have start/end dates once

their mandate has been completed. T. Goedecke confirmed that the Impact SIG was closed, and its outcome fully integrated into the ENCePP Guide (Chapter 16.4).

- The SIG on Drug Safety in Pregnancy was also discussed, as it never formally kicked off. The topic, however, is now covered in the ENCePP Guide Annex 2 (Guidance on methods for the evaluation of medicines in pregnancy and breastfeeding), which can be further developed and could "act" as SIG. The Annex also reflects the work of the ISPE pregnancy/lactation SIG.
- Rosa Gini: suggestion to have a DUS SIG, that could be connected with ISPE's.
- K. Arnold Chan offered to facilitate interaction with ISPE's SIGs as needed.
- The Strategic review should identify needs for new SIGs.

Objective 6 – Increase visibility of ENCePP activities and deliverables through collaboration with learned societies and study registration initiatives

- K. Arnold Chan volunteered to look into how to establish formal arrangement between ISPE and ENCePP (**Action** for Arnold to follow-up).

3. New Steering Group election

- J. Fogd gave an update on the current SG election process and timelines. Eight applications have been received at the date of the present SG meeting, final deadline for voting is 18 October. The results will be announced during the ENCePP Plenary on 1 December 2023. The Secretariat has also started to contact the appointed representatives for either re-confirmation of membership, or nomination of new members.
- R. Gini suggested that the election should not be anonymous in the future, to avoid possible duplication of votes from the same organisations or other errors. The Secretariat agreed to consider this for the next election. A possible solution can be to indicate the institution when voting, but not the name of the individual who votes.

4. Revision of the ENCePP mandate and Steering Group mandate for the next term

- P. Verpillat presented proposals for slight revisions of the ENCePP and SG mandates.
- The catalogues (EU PAS Register and ENCePP Resource Database) will not remain part of the ENCePP mandate after the migration to the EMA website early next year, therefore deletion is to be considered. Based on these changes, the ENCePP Q&A needs to be revised as well.
- S. Perez emphasised that it is important to keep a reminder where the catalogues originate from, once they have migrated on the EMA website. The SG agreed, and P. Verpillat suggested to use the term 'former EU PAS Register' during the transition/early times after the migration, when referring to the studies.
- R. Gini suggested to use only the following identification for ENCePP partners: public and private (instead of CROs etc.).
- Other suggestions from SG members included adding to the ENCePP mandate medical devices and the extended role of EMA, mentions of epidemiology/DUS studies, and using the term 'benefit-risk' (as opposed to the historical focus on safety).
- WG1: incorporate RWD/RWE terms, e.g., "NIS using RWD".

ACTION to ALL SG members to contribute to the draft proposals. Comments to be sent by **10 November 2023.**

5. Update on migration of the catalogues

- K. Deli presented the latest update on the catalogues (currently EU PAS Register and ENCePP Resource Database), which are planned to be launched early next year, and asked the SG to recommend volunteers for the external user testing.
- Post-meeting note: a follow-up email was sent out requesting nominations of volunteers by 16 October (with reminder for public institutions 20 October). The testing will take place for 2 weeks staring 26 October, with a short training.

6. ENCePP website and logo

- J. Fogd presented the structure of the new website, that will be launched on the same date as the catalogues on the EMA website. The structure will be more user friendly, and there will be a search bar on the website that will make it easier to look for contents.
- The new colour scheme and the updated ENCePP logo were also presented, and adopted by the SG. The materials that are going to be migrated are under review, and some of them have already been updated.

7. Plenary meeting: preliminary agenda topics and suggestions for external speakers

C. Cohet proposed potential topics for the plenary, in addition to the updates, e.g., from the WGs, new website and catalogues, mandate changes and election results.

- Introduction from the EMA chief medical officer, focusing on the new pharmaceutical legislation and role of RWE (post-meeting note: EMA chief medical officer not available, EMA to further investigate alternative speaker)
- S. Perez to reflect on her two previous mandates as SG co-chair and the current work of the SG
- Update on DARWIN EU
- AI topics relevant to ENCePP

The SG members proposed the following topics:

- Update on the European Health Data Space (EHDS), implication at national level, data protection and access considerations, link with DARWIN EU
- Related to DARWIN EU: initiatives outside of Europe, e.g., in US, Canada; invite speakers from Sentinel or CNODES for contextualisation
- Vaccine Monitoring Platform
- Patients' perspective – C. Cohet confirmed it's relevant and we also had update from Iryna Vlasenko in the last plenary meeting
- Medical devices
- Patient experience data (PED), pharmacogenomics data (incl. regulatory use cases)
- Experience with pragmatic trials and regulatory use
- Target trial emulation (incl. use cases)
- New drugs and new health technologies in humanitarian crises
- Negative controls - potential speakers Eric Tchetgen Tchetgen from University of Pennsylvania or Xu Shi from University of Michigan

- ICH and international collaborations: ICH RWE Reflection paper co-authored by EMA, FDA and HC (outcome of public consultation); ICH M14; ICH vs. CIOMS
- GVP VIII update

ACTION to ALL SG members to send proposals for presenters by **10 November**

8. Update from the Working Groups

- Alejandro Arana presented the updates from WG1. No change since the last meeting. C. Cohet gave an update of the recent meeting led by the OHDSI community to introduce (and praise!) the ENCePP Guide, with OHDSI authors presenting their chapters.
- Rosa Gini presented the updates from WG2, including a podcast series (less than 20 minutes and need to align on key messages and content). Regarding LinkedIn, it is recommended not to have a specific WG2 LinkedIn page, and EMA is not able to provide support with dedicated LinkedIn profiles for working groups.
- Gianluca Trifiro presented three ongoing studies led by WG3: Regulatory outcomes of studies requested by regulators; evaluation of secondary data utilization in observational studies registered in the EU PAS Register; Post-Authorisation Studies in Paediatric population: data from the EU-PAS registry.

9. A.O.B.

C. Simon asked about the changing status for observers, and whether this means that these SG members will be able to participate actively. P. Verpillat confirmed that this is the aim.