Minutes of the ENCePP Steering Group virtual meeting

29 September 2022, 15:00 – 17:00, WebEx meeting

Participants

Role	Name
Co-chairs	Catherine Cohet (EMA), Susana Perez-Gutthann (RTI)
SG members	Alejandro Arana, K. Arnold Chan, Cecile Droz-Perroteau, Helga Gardarsdottir, Rosa Gini, Narayan Nair, Frauke Naumann-Winter, Filipe Salgueiro, Gianluca Trifirò, Patrice Verpillat, Iryna Vlasenko
EMA	Katerina-Christina Deli, Luca Giraldi, Xavier Kurz, Daniel Morales, Valerie Muldoon, Andrej Segec
Apologies	Hans Hillege, Daniel Prieto-Alhambra, Francesco Salvo

Agenda

Item	Topic	Name
1.	Welcome & adoption of the agenda Update from the co-chairs	C. Cohet & S. Perez-Gutthann
2.	Update from the Working Group chairs	A. Arana R. Gini G. Trifirò
3.	ENCePP Guide (Rev. 10) lessons learned	C. Cohet
4.	ENCePP website update	A. Segec
5.	Update on catalogues (EU PAS Register and ENCePP Resource Database)	K. Deli
6.	Update on DARWIN EU®	A. Segec
7.	ENCePP plans, visibility, and external interactions • ICPE highlights relevant to ENCePP • Potential publication/newsletter and other proposals from ENCePP members Update to the ENCePP work plan	All
8.	30 November ENCePP Plenary (incl. F2F WG and SG meetings on 29 Nov): suggestions for agenda topics & call for programme committee	C. Cohet / S. Perez-Gutthann / All
9.	A.O.B	All

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

The proposed agenda was adopted.

Catherine Cohet and Susana Perez-Gutthann gave an update of their current work and discussions which are mostly reflected in the agenda topics.

- Importance of (re)engaging the ENCePP community after the pandemic;
- Importance of harmonisation between ENCePP and other guidance/learned societies such as ISPE/ISPOR/ISOP;
- Large amount of data presented by different ENCePP members at ICPE in Copenhagen;
- ICMRA workshop on RWE (June 2022) and work in progress to address resulting ICMRA statement; work during the summer on monkeypox (EMA studies) and ICH M14 (Catherine).

2. Update from the WG chairs

- **WG1** – Alejandro Arana
  - Work on ENCePP Guide on methodological standards: Rev. 10 was published on 30 June 2022, 2 new chapters (RWE and pharmacoepidemiology, artificial intelligence) and a new annex on methods in pregnancy studies were included. In addition, many chapter were updated, with some major updates (CER, vaccines) and considerations on statistical significance.
- **WG2** – Rosa Gini
  - Comparison between CoC and document EMA/196298/2022 "*Note on evaluation of potential conflicts of interests in studies funded by EMA under framework contracts awarded following open procedure ref. EMA/2020/46/TDA*". EMA policy is generally compatible with the code of conduct; however, some ambiguities raised by WG2 on restrictions of the role of the PI in the EMA policy were discussed. It was clarified that the overall EMA Policy 044 on CoIs applies to all EMA activities involving external experts, and is applied at an individual level. EMA-funded studies represent a specific situation where exclusion of investigators occur only in rare circumstances when EMA framework contractors are investigators of both an EMA-funded and an industry-funded study at the same time and for the same product.

Action

WG2 will submit to EMA a list of questions for clarification. Decision as to whether the topic will be added to the agenda of the plenary will depend on discussions between WG2 and EMA before the plenary.

- **WG3** – Gianluca Trifirò
  - 3 publications were presented.
  - Work ongoing: finalisation of the specific assessment of studies registered in the EU PAS register; recommendations on how to improve the EU-PAS Register (see agenda topic 5).
  - Importance of visibility of ENCePP deliverables (the 3 publications of WG3 will be posted on the ENCePP website)

3. ENCePP Guide lessons learned

Catherine Cohet presented the lessons learned in terms of what went well (new annexes/chapters/chapter updates, new authors, increasing downloads and viewing of the guide), what went less well (EMA large amount of work to identify topics to be updated, authors' involvement) and what can be improved (Continue to draw lessons to apply in routine pharmacoepi and public health

emergencies, continue to address emerging topics/challenges, more structured process for contacting and involving new authors).

The SG noted that for many chapters, no update was necessary, and that (re)engagement of the entire ENCePP community to contribute could be fostered at the plenary. It was also noted that the notion of RWE should be more emphasised – not only in Chapter 15.6, e.g. adjusting the title of the Guide.

4. ENCePP website update

Andrej Segec presented the ENCePP website current characteristics, website traffic, documents downloads and most accessed webpages, and the proposal for website upgrade to Drupal 9, including options for improvements on the layout and better information security.

The SG was supportive of the website upgrade and expressed willingness to keep the branding (colour palette, logo) and preserve the external links to EU-PAS items. Andrej will follow-up and provide further progress updates during the development phase.

WG2 can provide advice for the implementation stage – a few WG members are welcome to volunteer.

Q from the chat: Helga asked a question regarding the updates that will be done for the EU PAS register/website: during ICPE there was a session where the HARPER template was presented as well as the new Real World Evidence registry; the understanding is that there is collaboration between the EMA and this initiative: what does that mean for adjustment of the EU PAS register? Is WG3 involved in these discussions?

A: EMA certainly participated to the HARPER project (Peter Arlett and Xavier Kurz).

For example, the HARPER agreed protocol template will be taken into account for DARWIN EU studies, and protocols for these studies will be published in the EU PAS register, as usual.

5. Update on catalogues (EU PAS Register and ENCePP Resource Database)

Katerina-Christina Deli presented an update on the catalogues following the BDSG priority recommendation to improve data discoverability. Main milestones and activities of the Joint HMA-EMA BDSG Workplan 2022-2025 were presented, as well as the main developments regarding the ENCePP Resource Database and the EU PAS Register:

- data migration, cleaning, transformation and publication of the new catalogues
- updates on data source fields and studies
- ENCePP functionality implementation in the new system

Q&A:

Q: Is there a planning to introduce persistent identifier for data sources (according to FAIR)? A: yes.

Q: Will alignment/cross-updating between EMA catalogues and other existing catalogues be feasible?
A: not in first iteration, but will be considered for next iterations.
On this topic, it would be useful to have awareness of other catalogues (e.g., IMIA Yearbook, EMIF).

The mapping of catalogues could be considered as an ENCePP activity.

Q: Planning to link studies and databases. When a data source changes after it has contributed to a study, a good idea would be to freeze it in order to be documentable. Will this be possible? A: the studies included in the catalogue will be linked to the data source(s) used in the study but not to the specific version of the dataset used in the study.

For PASS categories 1 and 2, there was a discussion on the possibility for each study to link the RMP in the EU PAS register record, to increase identification of relevant regulatory documents. It was agreed that the current search function of the EU PAS Register has limitations.

6. Update on DARWIN EU®

Andrej Segec presented the implementation roadmap of the project: onboarding of data partners, number of studies conducted to increase in 2023 and beyond, and the running of first pilot studies to support EMA committees achieved.

The types of analyses and studies were briefly presented, as well as the process for conducting studies.

Q from the chat: Rosa asked whether there is any requirement for the EU-DARWIN studies in terms of compliance with the ENCePP Code of Conduct.

A: The protocols and results will be published in the EU PAS register, so all the guidance from ENCePP – methodological or in terms of governance, should be taken into account. Same principles will apply, independence and transparency.

A policy for management of conflicts of interests has been agreed for DARWIN EU, in line with EMA policy 0044.

7. ENCePP plans, visibility, and external interactions

The current ENCePP work plan covering 2017-2019 needs to be updated. The SG agreed to cover the period 2023-2025, while including a paragraph on the pandemic period.

Discussion on actions to promote and increase the visibility of ENCePP, harmonization/alignment with other initiatives and groups, showcasing ENCePP work at conferences (ISPE/ISPOR/ISOP/DIA), creation of a newsletter (including translation in different languages) is pending – to be addressed at the plenary.

Action

Call for volunteers to create a small WG dedicated to the update of the ENCePP work plan. Meet in Oct/Nov to prepare a proposal to be presented at the ENCePP plenary meeting in November.

8. ENCePP Plenary 29-30 Nov. 2022 (hybrid)

Suggestions for agenda topics & call for programme committee.

Proposal for the programme: output from DARWIN EU, updates on MPX vaccine safety and effectiveness studies, presentation from Marco Cavaleri similar to last plenary.

Patient organisations should be invited – Iryna highlighted that she is also representing a patient organisation and might cover this topic.

Action

SG members willing to contribute to the programme committee to volunteer asap to EMA (Julianna Fogd / Catherine Cohet) or Susana Perez-Gutthann.