



19 May 2022
EMA/294784/2022

Draft Minutes of the ENCePP pre-SG virtual meeting

18 May 2022, 16:00 – 17:30, Teams meeting

Role	Name
Chairs:	Catherine Cohet (EMA), Susana Perez-Gutthann (RTI)
Present:	Alejandro Arana, Rosa Gini, Patrice Verpillat EMA: Andrej Segec, Julianna Fogd, Luca Giraldi, Xavier Kurz
Apologies:	Cécile Droz-Perroteau, Daniel Prieto-Alhambra, Franceso Salvo, Gianluca Trifirò , Helga Gardarsdottir, Valerie Muldoon

Agenda:

Item	Topic	Name	Mins
1.	Welcome, adoption of draft agenda	C. Cohet	5'
2.	Update from the co-chairs	C. Cohet / S. Perez- Gutthann	10'
3.	Update from the WG chairs	WG chairs	15'
4.	ENCePP website	A. Segec	30'
5.	ENCePP Guide Rev. 10: progress update	C. Cohet	10'
6.	Agenda and date for the full SG meeting	C. Cohet / S. Perez- Gutthann	15'
7.	A.O.B	All	5'

1. Welcome, adoption of draft agenda

The draft agenda was adopted.



2. Update from the co-chairs

Catherine Cohet took over the ENCePP co-chair role from Gianmario Candore in March 2022.

Catherine and Susana gave an update of their current discussions and plans, including:

- Address how to re-engage the ENCePP community
- Harmonise work with ISPE, ISPOR and other forums
- Possible new ENCePP publication, e.g., 10+1 anniversary of the ENCePP Guide.
- Cross-fertilise with DARWIN EU®
- Recognised importance of the ENCePP guide by different stakeholders, largely used as a basis to support development of the ICH M14 guideline

Catherine Cohet mentioned the plans for reshaping the ENCePP website (details under agenda topic #4.).

Xavier Kurz proposed to nominate Gianmario Candore as Deputy EFPIA observer in the ENCePP Steering Group, the group agreed.

3. Update from the WG chairs

- **WG1** – Alejandro Arana: Work on ENCePP Guide Rev. 10 is ongoing (details of progress under agenda topic #5.)
- **WG2** – Rosa Gini:
 - Ongoing work:
 - Contribute to EU PAS Register revision to introduce variables aimed at monitoring compliance with the ENCePP CoC provisions – *request delivered in February, waiting for feedback from EMA*
 - Develop guidance on transparency in data analytics documentation: from sharing of raw data, to sharing of analytic programs, to structuring code execution on synthetic datasets – SHARING scoping review
 - WG2 asked for a mandate to conduct comparative analysis of EMA Policy 044 and ENCePP CoC. Rosa mentioned that this may be an opportunity to resume promotion of the ENCePP CoC that was interrupted due to Brexit/Covid.
 - The group agreed, but it was clarified that the different scope of these documents should be taken into account when making the comparison. Rosa Gini suggested to bring the results of this exercise to the SG (September meeting) to discuss the need to update the ENCePP CoC.
- **WG3** – Gianluca Trifirò post-meeting update: WG3 Teleconference on 16 February 2022 to discuss ongoing and future works:
 - Ongoing work on papers:
 1. Regulatory outcomes of multiple database studies performed in Europe, by revising also the PRAC minutes, led by IQVIA
 2. Differences across study types contained in the EU PAS Register based on the Countries contributing data, led by University of Thrace, who has already shared the first draft.

3. Post-authorization studies in pediatric population contained in the EU PAS Register, led by TEDDY Network: this article is mainly aimed at assessing the possible impact of regulatory initiatives in promoting the clinical research in pediatric population and describing the epidemiological research framework in this population

– 2 articles published this year:

1. A general paper analysing and describing the studies that were registered in the EU PAS register from its inception till the end of 2018, providing additional information on data type and study design (Sultana J, Crisafulli S, Almas M, et al. Overview of the European post-authorization study register post-authorization studies performed in Europe from September 2010 to December 2018. *Pharmacoepidemiol Drug Saf.* 2022;31(6):689-705).

2. A paper describing a landscape analysis of clinical and observational studies focusing on pregnancy and breastfeeding registered in the EU PAS register and ClinicalTrials.gov (Roque Pereira L, Durán CE, Layton D, et al. A Landscape Analysis of Post-Marketing Studies Registered in the EU PAS Register and ClinicalTrials.gov Focusing on Pregnancy Outcomes or Breastfeeding Effects: A Contribution from the ConcePTION Project. *Drug Saf.* 2022;45(4):333-344).

4. ENCePP website

Andrej Segec gave an overview of the plans to upgrade the ENCePP website.

- The present SG members and WG chairs (WG1 and WG2) supported the website update. Full SG will be consulted in September, volunteers to be identified to advise on structure/website changes, supporting the EMA colleagues
- No objection raised to the proposed EWPP platform, and there was full support for maintaining ENCePP branding
- Comment related the other project (catalogues): importance of migration of historical contents, need to consider how the (existing external) links in publications etc. regarding performed studies can be preserved/redirected once EU-PAS Register is migrated
- **EMA to confirm** to the provider (DIGIT) that their proposed platform is in principle acceptable, with the ENCePP branding to be preserved.

5. ENCePP Guide Rev. 10: progress update

Catherine Cohet gave an update on the progress, several chapters have been already received, still waiting for a few updates and the 3 new chapters.

The 3 new chapters will be shared with WG1 and SG on 2nd week of June for information.

- *Pregnancy chapter*: 1st draft is not yet available, decision if it can realistically go ahead will be made after the meeting with co-authors on Monday, 23 May.
- *RWE chapter*: Chapter drafted by WG1 with Xavier's lead, comments from Massoud and Alejandro have been implemented (post-meeting note: latest version approved by them). Under internal finalisation, will be shared with SG for review (post-meeting note: has been done today, 20 May).
- *AI chapter*: expected from authors during week of 23 May.

Comparative effectiveness research chapter has not been updated for many years, this is under review with new authors, to be updated by end May. Due to larger update, this chapter will also be shared with WG1 and SG.

All chapters need to be finalised for week 13 June, to be able to prepare everything for publication and publish the Guide by the beginning of July (plan 1 July, as last year).

6. Agenda and date for the full SG meeting

In September a meeting will be organised for the full SG.

Date needs to be fixed (EMA to check options with the invitees of the pre-SG meeting and WG leads) – note: avoid week 19 September due to ISoP Annual meeting held on 20-23 Sept. – see actions points in post-meeting notes in topic #7.”

Possible topics for the agenda:

- ENCePP website
- Catalogues (EU PAS and Resource database) update
- DARWIN EU update
- ENCePP Guide update
- Working groups updates
- Agenda topics for Plenary in November (might be face to face, internal confirmation needed from management, plus depending on pandemic situation). If face-to-face meeting can go ahead – as in general only 1 person can attend in person per organisation – hybrid meeting to be organised.
- Publication/newsletter

7. Post-meeting notes

Alexandra Pacurariu will represent EMA in ENCePP WG3. Alexandra will be on maternity leave from July to April 2023. A back-up will be nominated by EMA (in the meantime, Catherine Cohet can act as back-up).

Action points to all:

- to confirm availabilities for the 1.5-2 hour SG meeting, possible dates: **27, 28, 29 September, 4, 5, 6 October**
- to confirm availabilities for the full day November plenary meeting for **week of 28 November** (preferably middle of the week)