



17 June 2021
EMA/349682/2021
ENCEPP Secretariat

Minutes - ENCePP Steering Group Teleconference

15 June 2021, 16.00-17.00 CET

List of participants

Present	<p>SG members and observers: Ana-Hidalgo Simon, Arnold K. Chan, Cécile Droz-Perroteau, Daniel Prieto-Alhambra, Gianmario Candore (chair), Iryna Vlasenko, Narayan Nair, Patrice Verpillat, Susana Perez-Gutthann (chair), Rosa Gini, Daniel Morales, Richard Willke, Wei Hua</p> <p>Statistical adviser to the SG: Chantal Quinten</p> <p>Scientific adviser to the SG: Catherine Cohet</p> <p>EMA: Ana Cochino</p> <p>ENCEPP Secretariat: Xavier Kurz, Julianna Fogd</p>
---------	---

1. Adoption of draft agenda

The SG members adopted the draft agenda:

Item	Topic	Action	Initials	Mins
1.	Adoption of draft agenda	Adoption	All	5'
2.	ENCEPP Guide on Methodological Standards in Pharmacoepidemiology - Revision 9	Information and adoption	C. Cohet	25'
3.	Working Groups <ul style="list-style-type: none"> Current members Need for new WGs? Process on how experts can join	Discussion	J. Fogd	10'
4.	Rebuilding of catalogues	Information	A. Cochino	15'
	A.O.B.			

2. ENCePP Guide on Methodological Standards in Pharmacoepidemiology - Revision 9

Catherine Cohet, the EMA editor of the 9th revision of the ENCePP Guide gave a status update on the ongoing review. The revised guide will have an updated table of content, the reorganisation of the



chapters had been discussed and approved by WG1. Most of the chapters are updated with a selection of current COVID-related references.

ACTIONS:

- ENCePP Secretariat to circulate to SG the updated chapters by 18 June
- SG to provide feedback if any, the latest by 25 June
- ENCePP Secretariat to publish the guide in the beginning of July on the ENCePP website

3. Working Groups

As a result of the last SG meeting, where a topic was raised to refresh the ENCePP WGs, Julianna Fogd presented a short EMA proposal for the recruitment of new members to the ENCePP WGs, as there is no current process in place. A few SG members had already volunteered to be members of the WGs in the January SG meeting, and their membership was approved now. The current members will be asked if they wish to stay as a member of the WGs, before an expression of interest will be circulate among ENCePP members.

ACTIONS:

- ENCePP Secretariat to draft a flowchart of the process
- ENCePP Secretariat to check with current members if they wish to stay in the WGs
- ENCePP Secretariat to circulate expression of interest email among ENCePP members to join WGs
- ENCePP Secretariat to send list of candidates to ENCePP SG then SG to decide about the composition of the new members

4. Rebuilding of catalogues

Ana Cochino gave a presentation on the rebuild of catalogues with the key recommendations of the Big data taskforce: Enable data discoverability; Strengthen EU Network processes for Big Data submission.

As part of the intention to rebuild the current EU PAS Register and ENCePP Resource catalogues, EMA is seeking input on various practical aspects of this activity (e.g.: user experience, data that should be collected, functionalities needed such as search, export etc.), and ENCePP WG1 and WG3 will be consulted to provide feedback. A dedicated kick-off meeting will be held in July with WG1 and WG3, the objective is to provide background information on this activity, agree on a process for the consultation and get initial feed-back on improvements to be implemented.

A survey collecting input on specific points is planned to be sent out to all ENCePP members following the kick-off meeting.

Based on the survey results other dedicated follow-up meetings will be organised if necessary.