



Minutes - ENCePP Steering Group Teleconference

18 January 2021, 15.30-17.00 CET

List of participants

Present	SG members and observers: Ana-Hidalgo Simon, Andreas Kouroumalis, Arnold K. Chan, Alejandro Arana, Cécile Droz-Perroteau, Daniel Prieto-Alhambra, Craig Simon, Frauke Naumann-Winter, Gianmario Candore, Helga Gardarsdottir, Iryna Vlasenko, Kare Kemp, Lucinda Orsini, Narayan Nair, Patrice Verpillat, Susana Perez-Gutthann, Rosa Gini, Daniel Morales, Statistical adviser to the SG: Chantal Quinten Scientific adviser to the SG: Catherine Cohet EMA: Thomas Goedecke, Valerie Strassmann ENCePP Secretariat: Xavier Kurz, Valerie Muldoon, Julianna Fogd
Apologies	Francesco Salvo, Gianluca Trifiro, Johann Lodewijk Hillege, Wei Hua

1. Welcome and introduction

Xavier Kurz welcomed the newly elected Steering Group members in their first meeting and asked the participants to introduce themselves.

Following the tour de table, Xavier Kurz gave an update on the role of the ENCePP SG and its operating procedures; and explained the restricted work of ENCePP due to BCP (Business Continuity Plan due to Brexit and the Agency's move to the Netherlands) in the past few years. He announced that the co-chairs of the SG will be Gianmario Candore (EMA), and Susana Perez-Gutthann (ENCePP). The new statistical adviser will be Chantal Quinten (EMA), and Catherine Cohet (EMA) was appointed as scientific adviser.

2. Reports from WG1, WG2, SIG Impact

Rosa Gini gave an update on the role of WG2 - Independence and transparency, explaining their work on the ENCePP Code of Conduct (last revision published in March 2018) and the support on EU PAS Register and ENCePP databases. http://www.encepp.eu/structure/documents/Mandate_WG2.pdf

Alejandro Arana presented the work of WG2 - ENCePP research standards and guidances; and gave an update on the first discussion of the working group on the new the 9th revision of the *ENCePP Guide on Methodological Standards in Pharmacoepidemiology*, that will be published in July 2021.



http://www.encepp.eu/structure/documents/Mandate_WG1.pdf

Thomas Goedecke gave an update on the ENCePP SIG Impact activities in 2016-2018, explaining the SIG Mandate and its activities. Besides several publications, the SIG contributed to Revision 7 of the *ENCEPP Guide on Methodological Standards in Pharmacoepidemiology* with a new chapter on methods for pharmacovigilance impact research (5.9) and Annex 2 'Methods for pharmacovigilance impact research.

http://www.encepp.eu/structure/documents/ENCEPP_SIG_Impact_Mandate.pdf

3. ENCePP Mandate

Xavier Kurz presented the proposal for the ENCePP Mandate, which was drafted by the previous SG. The handover document outlines the current mandate of the ENCePP Network, the achievements of ENCePP, and an explanation why the ENCePP mandate is needed. The role of the new SG will be to discuss and finalise the mandate in the coming months, which will then be published on the ENCePP website.

4. ENCePP SG activities

Susana Perez-Gutthann emphasized that the SG needs to focus on methods, infrastructure and research collaboration. The composition of the working groups and the representation of SG members in each group also needs to be re-examined. Rosa Gini suggested that re-organisation of the working groups and recruit new people in each group would be beneficial. The SG members were asked to send feedback if they wish to participate in any of the working groups. During the meeting the following SG members already expressed their interest: Daniel Prieto-Alhambra – WG1 and WG3, Arnold K. Chan – WG1, Helga Gardarsdottir – WG3.

5. Action points

- ENCePP Secretariat to send the presentations and the current composition of the working groups to the SG members
- **ALL** to provide feedback on the following topics before the next SG meeting:
 - Proposal for ENCePP Mandate (presentation of Xavier Kurz)
 - Feedback on who would like to join which working group (http://www.encepp.eu/structure/structure_workingGroups.shtml)
 - Any proposal for chapters/sections of the ENCePP Guide to be revised and proposals for any new topics
- The new ENCePP co-chairs (Gianmario Candore and Susana Perez-Gutthann) to discuss the next steps in terms of work, practicalities and timelines of updating documents, next SG meetings, organisation of working groups etc., then ENCePP Secretariat to organise a Doodle poll for the date of the next SG TC
- ENCePP Secretariat to update the SG composition (chairs and EMA representatives) on the ENCePP website