



15 February 2017
EMA/57874/2017
ENCEPP Secretariat

Minutes - ENCePP Steering Group Teleconference

2 February 2017, 9.00-11.00 UK time

List of participants

Present	Dinah Duarte, Corinne de Vries, Vera Ehrenstein, Rosa Gini, Teresa Herdeiro, Johann Hillege, Olaf Klungel, Janne Lehmann Knudsen, Xavier Kurz, Tom MacDonald, Gianluca Trifirò, Patrice Verpillat Principal Adviser to the SG: Giampiero Mazzaglia Statistical Adviser to the SG: Jim Slattery ENCEPP Secretariat: Thomas Goedecke, Eeva Rossi, Dagmar Vogl EMA: Sergio Bonini
Apologies	Kathi Apostolidis, Hans-Georg Eichler, Hervé Le Louet, Yola Moride

1. Welcome & Adoption of draft agenda

Xavier Kurz welcomed the participants to this first meeting of the new Steering Group whose first task is to agree and adopt the ENCePP work plan for the years 2017 to 2019. He welcomed Prof. Sergio Bonini, from the EMA, attending the meeting in replacement of Prof. Hans-Georg Eichler.

The agenda was adopted without changes.

2. Introduction of the new SG

The participants were invited to introduce themselves and their affiliation during a brief tour de table.

3. Election of the ENCePP SG deputy Chair

According to the SG mandate, the deputy Chair shall be elected at the inaugural meeting of the Steering Group, based on a simple majority vote. The deputy Chair is to be chosen from among the six SG members who were elected by the plenary.

As a long serving ENCePP partner and incumbent to the Steering Group, Tom MacDonald was proposed as Deputy Chair. His nomination was agreed unanimously, and the Chair thanked him on behalf of the rest of the group for accepting to take on this role.



4. ENCePP Work Plan 2017-2019

The new work plan has been drafted in consultation with the previous Steering Group, and presented at high-level to the plenary in November 2016. However, it was confirmed that it would still be possible to make amendments to the document prior to adoption by the SG.

The individual objectives, deliverables and milestones were reviewed and broadly agreed by the SG, subject to some minor amendments, including timelines. SG sponsors were identified for each deliverable and it was agreed that the updated version of the work plan - including SG sponsor names - would be circulated to the group for adoption in writing. The adopted work plan will be published on the ENCePP website.

Teresa Herdeiro expressed her interest in joining the special interest group (SIG) 'Impact'.

Olaf Klungel suggested that attention should be paid to a close cooperation between SIG Impact and the ENCePP Working Group on Research Standards and Guidances in terms of any methods-related work.

The Steering Group agreed to add one work plan deliverable relating to methods for benefit/risk integration, following a proposal by Hans Hillege.

It was agreed that the ENCePP Secretariat would circulate to the Steering Group the report and recommendations from the EMA workshop on patient registries which took place in October 2016 and which is currently being finalised. This is to support discussions on how to leverage ENCePP in the implementation of these recommendations.

5. A.O.B.

5.1. *Future direction of ENCePP*

With the 10 year anniversary of ENCePP in 2017, Xavier Kurz invited the Steering Group to reflect on the future direction of the network. He added that a plateau seems to have been reached in terms of number of centres, and efforts should be concentrated at this stage on the visibility and reach of the network in terms of increasing the quality of work being done in pharmacoepidemiology and better collaboration between centres via joint/collaborative studies.

The following items were identified as requiring further reflection by the Steering Group:

- Development of practical guidance and templates for collaborative studies, respectively advice on the adoption of existing models, e.g. Sentinel (Vera Ehrenstein).
- Lack of buy-in from industry to the ENCePP Code of Conduct - more clarity is needed on the compliance with the Code in the context of conducting studies for industry (Rosa Gini).
- Emphasise the importance of independent regulatory research and its impact on public health (Tom MacDonald).
- Optimise cooperation between regulators and academia at national level through targeted training (Gianluca Trifirò).
- Lack of funding for infrastructure / common network (Olaf Klungel).
- Gauge the need for improved interaction with the regulator in the context of industry-funded studies (Vera Ehrenstein).
- Recommendation/facilitation of common protocol models based on OMOP data model (Xavier Kurz).

5.2. Future meetings

The group was reminded of the confirmed face-to-face meeting dates during 2017:

- Friday, 12 May 2017
- Tuesday, 10 October 2017
- Tuesday, 21 November 2017 (ENCePP Plenary)

In addition, it was agreed that the ENCePP Secretariat would organise regular (two-monthly) TC meetings.

Xavier Kurz invited SG members to suggest topics of interest for discussion at future meetings.

6. Action points

- ENCePP Secretariat to amend draft work plan based on discussions and circulate to SG for adoption in writing, followed by publication on the ENCePP website.
- ENCePP Secretariat to circulate to SG the Patient Registries Workshop report.
- ENCePP Secretariat to organise two-monthly TC meetings of the Steering Group.