



3 May 2017
EMA/253004/2017
ENCEPP Secretariat

Minutes - ENCePP Steering Group Teleconference

19 April 2017, 11.30-12.30 UK time

List of participants

Present	Kathi Apostolidis, Dinah Duarte, Marieke de Bruin, Vera Ehrenstein, Rosa Gini, Teresa Herdeiro, Olaf Klungel, Janne Lehmann Knudsen, Xavier Kurz (Chair), Tom MacDonald (Deputy Chair), Yola Moride, Patrice Verpillat <i>Statistical Adviser to the SG:</i> Jim Slattery <i>ENCEPP Secretariat:</i> Thomas Goedecke, Dagmar Vogl <i>EMA:</i> Sergio Bonini, Gianmario Candore, Alison Cave, Mireia Castillon, Patricia McGettigan
Apologies	Corinne de Vries, Hans-Georg Eichler, Johann Hillege, Hervé Le Louet, Gianluca Trifirò

1. Welcome & Adoption of draft agenda

The agenda was adopted without changes.

2. Agenda for Steering Group f-2-f meeting on 12 May 2017

The Steering Group reviewed a list of potential topics for its next face to face meeting, and it was agreed that the following topics would be included in the draft agenda:

- Governance of PE studies:
 - Independence of regulatory research and its impact on public health
 - ✓ including presentation of draft document by Tom MacDonald
- Role of ENCePP in supporting collaborative studies through common data models and common protocol models
 - ✓ including the presentation of examples/reflection by Rosa Gini, Vera Ehrenstein and Olaf Klungel
- Role of ENCePP in the implementation of the recommendations from the Patients Registries Workshop



4. Interaction with regulators (this topic could be merged with 1.):

- Optimise cooperation at national level
- Improve interaction in the context of industry-funded studies

Further topics that may be taken into consideration, subject to further clarification and/or refinement, are:

- ENCePP interface with other EMA bodies and the European Commission
- HMA/EMA big data initiative
- Benefit/risk communication
- Brexit impact

3. Common data models

Alison Cave presented a slide set on the challenges of the common data model, including a number of discussion points. Due to time constraints it was decided to address these in detail at the forthcoming SG meeting on 12 May 2017.

The SG agreed that this topic is very relevant to ENCePP and merits further discussion at the upcoming face to face meeting. Questions to be discussed include:

- experience of ENCePP SG members with a common data model approach
- predominant strengths and limitations of the common data model versus the common protocol model
- validation studies considered required to increase confidence in the approach
- place of the CDM in the landscape of European pharmacoepidemiological research in the future
- role of ENCePP in CDM approach.

Rosa Gini, Vera Ehrenstein and Olaf Klungel will present their views on this topic at the ENCePP face-to-face meeting on 12 May.

4. Patient Registry Initiative

Mireia Castillon gave a brief update on [EMA's patient registry initiative](#), highlighting the [recommendations](#) arising from the Patient Registries workshop which took place in October 2016. She informed the Steering Group that patient registry owners have been invited to have their information included in the ENCePP resources database, and that the uptake has been very positive.

It was agreed that the interaction between ENCePP and patient registries merits further discussion. A list of relevant discussion points will be prepared by Mireia Castillon and Patricia McGettigan for the SG meeting on 12 May 2017.

5. Action points

- ENCePP Secretariat to prepare and circulate draft agenda for the face to face meeting on 12 May 2017
- Tom MacDonald to prepare draft paper on potential governance models for discussion at SG meeting on 12 May 2017
- Rosa Gini, Vera Ehrenstein and Olaf Klungel to present examples for common data and protocol models at SG meeting on 12 May 2017

- Mireia Castillon and Patricia McGettigan to prepare list of questions to be addressed by the ENCePP SG on patient registries.