



20 July 2017  
EMA/436233/2017  
ENCEPP Secretariat

## Minutes - ENCePP Steering Group Teleconference

11 July 2017, 14.30-16.30 UK time

### List of participants

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

## 1. Welcome & Adoption of draft agenda

The agenda was adopted without changes.

## 2. Common Data and Protocol Models

Rosa Gini and Gianluca Trifirò provided an update on their approach to coordinating the collection and analysis of information on common data and protocol models in Europe.

A *Dropbox* folder has been set up to share publications and other material regarding common data models, and an invitation has been sent to all Steering Group members to populate the folder with information they consider relevant, i.e. key publications in the area and also presentations (such as the ones from the big data workshop held in November 2016, or from the ISPE meeting at the end of August). Based on the material collected, a concept paper will be drafted expanding on the strengths and weaknesses of the different models. SG members were invited again to share key documents. To this end, it was agreed that the ENCePP Secretariat would re-circulate the *Dropbox* access information to all SG members.

In terms of next steps it was agreed that Rosa and Gianluca would draft within the next week a short (maximum two pages) document outlining the objectives and scope for agreement in writing by the Steering Group. Once the SG has agreed the criteria for an objective assessment, the discussion will be taken to a wider ENCePP audience with a view to start developing a concept paper which is proposed to be presented to the ENCePP Plenary in November.



In the context of these activities the Steering Group also discussed the future of ENCePP Working Group 3 'Inventory of EU data sources and methodological approaches for multi-source studies'. It was agreed that it would be useful to involve the group in the development of the concept paper, and that the mandate should be amended to reflect these new tasks. The SG recommended that the membership of the group be refreshed, whilst existing members should be invited to continue their contribution on the basis of the new mandate.

Further reflection is required on whether the revised mandate should include a contribution to EMA's patient registries initiative.

### **3. ENCePP Code of Conduct and Seal**

Thomas Goedecke gave a brief update on behalf of WG2 'Independence and Transparency' which has been mandated to reflect on a justification for the removal of the ENCePP Seal and to outline the objectives of a revision of the Code with regard to adapting the Code's structure in line with the ADVANCE Code of Conduct to improve operability, and to further clarify the concept of scientific independence as appropriate.

As a first step, key principles have been extracted from the Code into a table to allow cross-reference with the ADVANCE Code of Conduct and to help detect ambiguities and redundancies. This table will be reviewed by WG2 later this month, followed by SG consultation on the outcome of these discussions.

The ultimate goal is to incorporate the current provisions of the ENCePP Seal linking the core principles of the Code with the scientific standard of the protocol checklist into the Code, and to make it more operational. The principles of (financial) independence with regards to industry funded research should be maintained. Any perception of lowering scientific standards by removing the Seal must be avoided and the objectives of the revision appropriately communicated to the network and research community.

### **4. ENCePP Plenary meeting 21/11/2017**

Steering Group members were invited to propose items for this year's meeting agenda. The suggestions include:

- Concept paper on common data models and alternatives
- Outcome of discussions on the ENCePP Code of Conduct (depending on progress made by WG2)
- Governance model proposal for joint industry studies
- 10 year anniversary of ENCePP
- Patient registries initiative
- Update on Brexit-related issues
- HTA (EUnetHTA, reimbursement schemes)
- Creating an effect table for presenting benefits and risks of medicines

SG members were invited to submit further ideas for topics to the ENCePP Secretariat which will circulate a full list for information.

#### **4.1. A.O.B.**

Rosa Gini and Xavier Kurz provided a brief summary of recent discussions with the European CRO Federation (EUCROF) regarding potential cooperation between the EUCROF and ENCePP.

## 5. Action points

- ENCePP Secretariat to circulate the Dropbox access information to all SG members.
- Rosa Gini and Gianluca Trifirò to draft an outline of the objectives and scope of the common data model exercise for agreement in writing by the Steering Group (by 21 July 2017).
- ENCePP Secretariat to circulate a proposal for revision of the WG3 mandate. Once the mandate has been agreed, existing WG3 members will be asked to express their interest in continuing to work with the group, and new members may be invited to join from the ENCePP plenary.
- WG2 to submit to SG its proposal for revision of the Code (by Q3 a proposal to SG and Q4 Plenary discussion).
- ENCePP Secretariat to circulate a list of potential agenda items for the November plenary meeting.
- ENCePP Secretariat to organise an additional Steering Group TC meeting in September.