



7 July 2014
EMA/395047/2014
ENCEPP Secretariat

Minutes - ENCePP Steering Group Meeting

30 June 2014, 14:00-16:00 (TC), chaired by Peter Arlett

List of Participants

Present:	Morten Andersen (MA), Peter Arlett (PAR), Marieke De Bruin (MDB), Corinne de Vries (CdV), Pierre Engel (PE), Henry Fitt (HF), David Haerry (DH), Teresa Herdeiro (TH), Tom Mac Donald (TMD), Yola Moride (YM), Susana Perez-Gutthann (SPG), Nawab Qizilbash (NQ)
	<p><u>Other participants:</u></p> <ul style="list-style-type: none"> • WG2 Chair: Laura Yates (LY) • EMA Principle Advisor to the SG: Xavier Kurz (XK) • EMA Statistical Advisor to the SG: Jim Slattery (JS) <p>ENCEPP Secretariat: Kevin Blake (KB), Eeva Rossi (ER), Dagmar Vogl (DV)</p>
Apologies:	Ana Corrêa Nunes, Hubert Leufkens, Viola Macolić Šarinić, Nicholas Moore

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1. Welcome & Adoption of draft agenda

The agenda was adopted without changes.

2. ENCePP Work Plan 2015-2016

KB presented a high-level overview of the draft work plan for 2015-2016. He explained that the deliverables listed in the document had been divided into three overarching themes, i.e. 'Supporting regulatory decision-making', 'Communication & Training' and 'Methodologies'. In particular the Steering Group (SG) was asked for its initial thoughts on the proposal of exploring leveraging ENCePP to support epidemiology throughout the product life-cycle, including early drug development (e.g. paediatrics/investigation plans, orphan/prevalence data and scientific advice/registries).

The Steering Group agreed that there could be potential interest and expertise within the network to engage in such an initiative and broadly supported the idea of exploring this new approach, albeit carefully and without neglecting the core scope of ENCePP.

As a next step, the ENCePP Secretariat will prepare a more mature version of the draft work plan for further discussion at the next face-to-face meeting of the SG (date to be confirmed). Meanwhile, SG members are invited to submit further comments on the draft list of deliverables by email.

For action:

- SG members are invited to submit comments on the existing list of draft deliverables in general, and in particular on the proposed leveraging of ENCePP to support epidemiology through the product life-cycle.
- ENCePP Secretariat to develop a mature draft work plan 2015-2016 for discussion at next SG meeting.

3. Proposals for discussion

3.1. ENCePP and risk minimisation measures

NQ had submitted a proposal to the Steering Group to discuss the need for an ENCePP working group on risk minimisation. He presented a list of apparent gaps in the monitoring of risk minimisation measures, the possible remit of such a group, its scope and a list of deliverables/outputs. The Steering Group was invited to discuss the need for such a risk minimisation group in ENCePP.

CdV reminded the group that it is a legal obligation for the European Medicines Agency (EMA) in collaboration with national competent authorities to measure the impact of the new pharmacovigilance legislation and provided an overview of numerous ongoing EMA activities in the area of risk minimisation. MDB listed some of the regulatory science projects ongoing in the area.

The Steering Group agreed that while NQ's proposal is very relevant, a duplication of effort should be avoided. It was agreed that a gap analysis should be performed in the context of the next work plan. This exercise will be led by NQ and CdV, with support from MDB, YM and TH.

Since the topic of 'risk management planning' might be of interest to the whole ENCePP community, it was proposed to consider including a session on this topic at the plenary meeting in November.

For action:

- Perform gap analysis in relation to additional risk minimisation measures (NQ/CdV/MDB/YM/TH).
- SG to consider including a session on 'risk management planning' at November plenary meeting.

3.2. “Lessons learned on the design of PASS since July 2012”

PE informed the group of progress made with his work, in liaison with MDB, relating to lessons learned on the design and conduct of PASS since July 2012. An abstract has been accepted for the next ICPE and he is now proposing to publish the work already done and to expand it further based on an analysis of assessment reports from PRAC.

The SG members welcomed this initiative and PE was requested to circulate for comments a detailed outline of the scope and key messages.

For action:

- PE to circulate draft proposal relating to publication of ‘lessons learned’-project.

4. Survey of ENCePP Centres on E-Register and ENCePP Seal

Laura Yates (Chair of Working Group 2) provided a summary of results from the recent survey of ENCePP partners on the E-Register and the ENCePP Seal. A good response rate had been achieved and some key issues identified from the survey responses which will feed into the new communication strategy. In particular, the need to further engage with academics and journal editors was highlighted.

It was agreed that WG2 would be tasked with elaborating proposals for the improvement and simplification of current processes relating to the E-Register and ENCePP seal applications based on the survey responses.

The upgrade of the E-Register of studies is a matter of priority and should be included in the next work plan.

For action:

- WG2 to elaborate proposals for process improvements and simplification.
- ENCePP Secretariat to include ENCePP system upgrade in new work plan.

5. ENCePP Communication Strategy

Following on from the discussions at the previous meeting, HF briefly presented a list of stakeholder groups relevant to ENCePP, including proposed objectives and key messages. It was agreed that the groups ‘public at large’ and ‘academic researchers’ would be added to the list of stakeholders, and that priorities would be assigned to the various groups.

The document will be amended accordingly. SG members are invited to send comments, in advance of a more substantial discussion at the next face-to-face meeting (September/October 2014 – tbc).

For action:

- ENCePP Secretariat to amend draft Communication Strategy for discussion at next SG meeting.
- SG members to send comments.

6. ADVANCE survey on models of partnership

Prior to the meeting a set of slides presenting results from a survey performed by the ADVANCE project among ENCePP partners had been circulated to the Steering Group for information. The objective of the survey was to collect experience from existing models of partnership and share lessons learned. XK informed the SG that more detailed survey results will become available later and proposed to present these to the ENCePP Plenary in November if considered of interest.

For action:

- SG to consider plenary session on 'ADVANCE survey on models of partnership'.

7. A.O.B.

7.1. EFPIA observer on ENCePP SG

PAR informed the Steering Group that Laurent Auclert, the EFPIA observer to the SG, had recently retired and that the ENCePP Secretariat was in contact with EFPIA regarding the nomination of a replacement.

Post meeting note:

On 1 July 2014 EFPIA informed the ENCePP Secretariat of the nomination of Patrice Verpillat (Lundbeck) as its observer to the ENCePP Steering Group.

7.2. ENCePP/EMA and data transparency

The Steering Group supported the proposal to keep any future discussions relating to ENCePP and EMA data transparency initiatives at SG level, rather than at the level of individual working groups.

For action:

- ENCePP Secretariat to add the topic of 'ENCEPP and EMA data transparency' to the agenda of the next SG meeting.

7.3. ENCePP Methods Guide

XK informed the group that the final contributions to revision 3 of the Methods Guide had been received, including a new section on pharmacogenomics with input from ISPE. The update of the document is in hand and Revision 3 should be available on the ENCePP website by mid July.