



7 January 2013  
EMA/817442/2012  
ENCePP Secretariat

## Minutes - ENCePP Steering Group Meeting (Adobe Connect)

18 December 2012, 14.00 to 16.00 – chaired by Peter Arlett

List of Participants	
Present:	<p>Peter Arlett (PAR), Stella Blackburn (SB), Alfonso Carvajal (AC), Ana Corrêa Nunes (ACN), Corinne de Vries (CdV), Henry Fitt (HF), David Haerry (DH), Morten Andersen (MA), Nicholas Moore (NMo), Marcus Müllner (MM), Hubert Leufkens (HL)</p> <p><i>EFPIA Observer:</i> Laurent Auclert (LA)</p> <p><i>ENCePP Secretariat:</i> Kevin Blake (KB), Eeva Rossi (ER), Dagmar Vogl (DV)</p> <p><i>EMA:</i> Xavier Kurz (XK)</p>
Apologies:	<p>Miriam Sturkenboom, Susana Perez-Gutthann, Yola Moride, June Raine, Nicola Magrini, Jim Slattery</p>

### Draft Agenda

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## 1. Welcome & Adoption of draft agenda

PAR welcomed Marcus Müllner (MM), who attended his first SG meeting following his appointment as representative of the Heads of Medicines Agencies (HMA).

The draft agenda was adopted without changes.

## 2. ENCePP Checklist for study protocols

### 2.1. Revision 2 of checklist

XK explained that this latest revision was triggered following the reference in GVP module VIII that the ENCePP checklist be included as an annex to study protocols. In order to align the checklist with the new legislation, it became necessary to re-order the sections and to adapt some of the terminology.

The version submitted to the Steering Group for adoption had been revised and agreed by Working Group 1. XK highlighted the major changes to the document which now also includes a reference to the "[Guidance on the format and content of the protocol of non-interventional post-authorisation safety studies](#)".

The SG endorsed the revised checklist in principle, however a number of editorial and scientific comments were raised relating to specific questions included in the checklist. It was agreed that these comments will be taken into consideration before circulating the final revision to the SG for adoption by written procedure during the 1<sup>st</sup> week of January 2013.

The SG also agreed that, in addition to publishing the revised checklist on the ENCePP website, an accompanying news item should be prepared for publication on the EMA website.

#### **For action:**

- XK to finalise revision 2 of ENCePP Checklist for Study Protocols.
- ENCePP Secretariat to circulate revised document to SG for adoption.

## 3. PROSPER Guidance Document

### 3.1. Revised version

The document "Patient-Reported Outcome Measures in Safety Event Reporting" drafted by the PROSPER consortium had been presented to the Steering Group at its meeting on 14 September 2012 for review and feedback. At that stage the SG made a number of comments on the document which were submitted to the consortium with a request for clarification.

The revised document had been received by the ENCePP Secretariat recently and KB highlighted the changes to the Steering Group that were made in response to the previous SG comments.

### 3.2. Next steps

It was agreed that there would be no formal ENCePP endorsement of the document. However, it was also agreed to offer the consortium placement of the document in the ENCePP Partner's Forum for direct comment by ENCePP partners.

#### **For action:**

- KB to provide feedback to the consortium and to liaise with consortium regarding placement in the Partner's Forum.

## 4. ENCePP Work Plan

### 4.1. Draft Work Plan 2013-14

Following endorsement of the ENCePP draft work plan 2013-2014 by the individual ENCePP Working Groups earlier in December 2012, the work plan was tabled for review and adoption by the Steering Group.

The key deliverables and related milestones were reviewed one by one and agreed with some minor amendments.

The SG adopted the work plan on the understanding that the changes discussed during the meeting will be taken on board. It was agreed that the work plan will be published on the ENCePP website as soon as possible. The assignment of SG sponsors to each Working Group key deliverable will be dealt with in due course.

#### **For action:**

- ENCePP Secretariat to update the work plan, taking on board SG comments, and publish the document on the ENCePP website.

## 5. A.O.B

Corinne de Vries announced that she will be leaving University of Bath and join the European Medicines Agency in the spring of 2013.

On behalf of the Steering Group and the whole network PAR thanked Corinne for her major contribution to ENCePP over the past years.