EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

28 September 2012
EMA/593727/2012
ENCePP Secretariat

Minutes - ENCePP Steering Group Meeting

14 September March 2012, 09.30 to 16.30 – chaired by Peter Arlett

List of Participants	
Present:	Peter Arlett (PAR), Stella Blackburn (SB), Alfonso Carvajal (AC), Ana Corrêa Nunes (ACN), Corinne de Vries (CdV), Henry Fitt (HF), David Haerry (DH), Miriam Sturkenboom (MS) – partly, *via TC*, Morten Andersen (MA), Nicholas Moore (NMo), Nicola Magrini (NMa), Susana Perez-Gutthann (SPG), Yola Moride (YM), *EFPIA Observer*: Laurent Auclert (LA) – *via TC* *ENCePP Secretariat*: Kevin Blake (KB), Eeva Rossi (ER), Dagmar Vogl (DV) *EMA*: Nick Halsey (NH), Luis Prieto (LP), Ana Hidalgo-Simon (AHS) *ENCePP*: Swapu Banerjee (partly)
Apologies:	Hubert Leufkens, June Raine, Marcus Müllner, Xavier Kurz, Jim Slattery

Draft Agenda

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1. Welcome & Adoption of draft agenda

The draft agenda was adopted without changes.

2. General discussion / Issues raised by ENCePP partners

2.1. Draft PRO-AE guidance for ENCePP review

Swapu Banerjee, representative of ENCePP partner Pope Woodhouse, had been invited to join the meeting to present the document "Patient-Reported Outcome Measures in Safety Event Reporting". The document has been drafted by the PROSPER consortium, which approached the ENCePP Steering Group (SG) to request review of the guidance document and provide feedback to the consortium.

The document had been circulated to the group prior to the meeting, and his presentation provided a summary of the work done so far, including a list of proposed next steps.

The SG agreed that the document related to an area which is relevant to the ENCePP remit and welcomed the work done so far. However, there were a number of issues identified and suggestions made for the document. It was agreed that a list of the comments would be prepared and submitted to the consortium for clarification before any consultation of the wider ENCePP community.

Action:

- ENCePP Secretariat to prepare list of comments/suggestions and to request clarification.

2.2. Study Register – standardisation of data fields

Nick Halsey presented a progress update on the *Clinical Trials Registration and Results* (CTRR) project which focuses on standardising data fields for various international registries. He also provided a brief update on the efforts made so far in having the ENCePP study register included in the WHO ICTRP network.

PAR reminded everybody that a SG decision to get the ENCePP register recognised by WHO had already been taken a while ago. However, to be considered for inclusion some changes will have to be made to the existing database which are dependent on the availability of IT budget.

In conclusion, the SG reaffirmed its support for WHO recognition of the register and agreed that feedback on efforts to standardise with WHO would be of interest to the Plenary, and that it should be included as a brief information item on the agenda of the next plenary meeting (11 October 2012).

Action:

- ENCePP Secretariat to include information on standardisation of data fields in the presentation to the Plenary on the EU-PAS register.

2.3. ENCePP contribution to the scientific research agenda of future public-private partnership that follows IMI

KB informed the group that ENCePP had been invited to provide views on healthcare research priorities to guide work on a future biomedical research public-private partnership under the EU Horizon 2020 R&D funding programme. He stressed ENCePP had been approached for this purpose as a key stakeholder group. This survey presents preliminary groundwork only, and the results would serve as a basis for discussion with the European Commission.

The ENCePP Secretariat had prepared a draft response which took into account the results of last year's ENCePP partner survey relating to the prioritisation of research topics.

The SG members were invited to comment on the prepared draft response and provide their thoughts on the subject of research priorities, and a number of very useful suggestions arose from the ensuing discussions.

It was agreed that the outcome of the brainstorming would be worked into the response for submission. The ENCePP SG and plenary would be kept informed of developments.

Action:

- ENCePP Secretariat to add SG proposals to draft response.

Other issues

No other issues were raised.

3. Report from the Working Groups (WGs)

3.1. WG1 Progress Update

On behalf of WG1 Chair Alejandro Arana, KB highlighted the successful review of the *ENCePP Guide on Methodological Standards in Pharmacoepidemiology* and the fact that the good pharmacovigilance practice (GVP) guidance reference a number of ENCePP documents. A meeting of the working group is planned on 10 October 2012 and its main agenda items will be continued revision of the Guide on Methodological Standards including a need for stand-alone sections e.g. on vaccines, and the WG will further discuss on the survey of national accreditation of ENCePP centres.

3.2. WG2 Progress Update

On behalf of WG2 Chair Helen Dolk, HF highlighted the recent adoption by the SG of the revised plenary mandate which now includes a website statement for partners and a reference to ENCePP partners to actively work on ENCePP studies. The ENCePP partners will be informed of these changes at the upcoming plenary meeting in the feed-back from the SG Vice-Chair. The next meeting of the working group is scheduled for 10 October 2012.

3.3. WG3 Progress Update

MS informed the group that the IT changes to the resource database in order to simplify the registration process for data sources were almost finalised.

A further WG3 task is a review of privacy issues across Europe. A number of responses have been received which are currently under review by the EMA Data Protection Officer.

Finally, a questionnaire on methodologies had been circulated to investigators of public funded studies to see what are the current practices relating to cross-linkage data. The next meeting of the working group is scheduled for 10 October 2012.

- *Update: Drafting Group 'ENCePP Guide on Data Integration and Pooling of Studies'*
  In order to start the group, it is envisaged to organise a TC with key ENCePP partners including the Steering Group Sponsors to discuss next steps. As agreed previously, the meeting should involve representatives from WG1 and WG3.

In conclusion, PAR posed the question of whether enough and the right kind of support is being provided to the working groups for them to fulfil their mandates.

The SG confirmed that the support from EMA was very good and maintaining this level would be key to fulfilling the working groups' mandates. The general feeling is that additional face to face meetings would be helpful to increase interaction between WG members outside those meetings. More use of e.g. Adobe Connect or TCs should also be considered.

There appears to be an imbalance in the working group mandates, and in an effort to make the work of the groups more efficient, a re-distribution of tasks may be considered.

It was agreed that a meeting of WG Chairs and EMA leads should be organised soon to discuss the mandates of the groups, streamline the work and agree on a manageable workload for each of them.

Action:

- ENCePP Secretariat to organise a meeting of WG Chairs and EMA leads to discuss workloads and streamlining of mandates.

3.4. Update: ENCePP HTA Task Force

Following on from his presentation at the previous SG meeting, LP announced that the kick-off meeting of the ENCePP HTA task force will be taking place in the margins of the ENCePP plenary meeting on 11 October 2012, and that those centres that had voiced their interest in leading the task force have been invited to attend.

Nicholas Moore agreed to be the SG liaison on the HTA task force. Furthermore, it was agreed that EUnetHTA will be approached formally asking to consider representation on the task force.

Action:

- ENCePP Secretariat to formally approach EUnetHTA regarding participation in ENCePP HTA task force.

4. ENCePP Work Plan

4.1. Progress Report Work Plan 2011-12

DV presented slides showing the progress on deliverables and milestones achieved over the past two years.

4.2. Draft Work Plan 2013-14

With a view to drafting the new ENCePP work plan, the SG members were invited to discuss the network's key deliverables for the next two years.

The work plan will undergo a number of consultation rounds with the aim of adopting the final version before the end of the year.

Action:

- ENCePP Secretariat to revise draft work plan 2013-14 taking into consideration the SG discussions.
- ENCePP Secretariat to circulate new draft work plan for further round of consultation.

5. ENCePP Plenary Meeting

5.1. Draft Agenda – Plenary 11 October 2012

The plenary agenda was agreed with some minor changes.

SPG agreed to give a presentation on requirements for studies in the new EU pharmacovigilance legislation, as this topic was deemed to be of great interest to the plenary.

The SG further agreed that the following items be taken into consideration for future plenary meetings:

- Feedback from Ulf Bergman regarding study of estimating renal function in the elderly (results of pilot).
- Anti-coagulants, mini survey to partners
- Report from European Commission DG Research funded research, incl. results (logistics and frequency to be decided)

Action:

- ENCePP Secretariat to publish draft agenda of October plenary on the ENCePP website.
- N. Magrini to provide bullet points regarding anti-coagulants topic.

5.2. Plenary dates 2013

ER confirmed that the dates for the 2013 plenary meetings are as follows:

- Tuesday, 18 June 2013, and
- Tuesday, 12 November 2013

6. ENCePP Impact Evaluation

6.1. Methodology & contents

With a view to the impact evaluation scheduled for later this year, the SG was invited to make suggestions on how to formally evaluate the impact of ENCePP, further to the existing strategy document.

The SG agreed that feedback from industry on what benefits they can see from ENCePP and actual use of ENCePP guidance and standards in their work would be helpful and key to understanding the impact of ENCePP.

It was agreed that feedback from the industry associations should be sought. In addition, ENCePP should engage with the industry R&D group within ISPE. This should not delay publication of an impact analysis that takes account of other parameters including quantitative measures.

Action:

- ENCePP Secretariat to liaise with EU industry associations and industry R&D group within ISPE.

7. ENCePP Discussion Paper

7.1. ENCePP Network – Defining a network

SB introduced the discussion paper aiming at providing an operational definition of an ENCePP network. There have been cases recently where networks have applied to become ENCePP partners where the network has no obvious link to an ENCePP centre. It was therefore considered useful to have a definition and eligibility criteria for networks wishing to join ENCePP.

Action:

- Document to be revised taking on board SG comments.
- ENCePP Secretariat to circulate revised document for adoption by written procedure.

8. A.O.B

None.