22 March 2010
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European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Minutes ENCePP Steering Group Vitero meeting

19 March 2010, 14.00-16.00 – Chaired by Peter Arlett

List of Participants	
Present:	Peter Arlett (PA), Stella Blackburn (SB), Corinne de Vries (CdV), Hans-Georg Eichler (HE), Joan-Ramon Laporte (JRL), Hubert Leufkens (HL), Jytte Lyngvig (JL), Yola Moride (YM), Ingemar Persson (IP), June Munro Raine (JMR) - *partly*, Miriam Sturkenboom (MS) - *partly*, Giuseppe Traversa (GT) *ENCePP SG Advisors*: Xavier Kurz (XK) - *partly*, Jim Slattery (JS) - *partly* *ENCePP WG2 (chair):* Helen Dolk (HD) – *partly* *ENCePP Secretariat*: Stefanie Prilla (SP), Camilla Smeraldi (CS), Dagmar Vogl (DV)
Apologies:	Henry Fitt, David Haerry, Nicholas Moore, Valerie Simmons

Agenda	
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2	**Organisational & administrative issues** 2.1 Disclosure of SG Members' Declarations of Conflict for discussion
3	**ENCePP Code of Conduct** and **Checklist of Methodological Research Standards** 3.1 Results of Public Consultation: Discussion continued from the meeting on 19 February 2010 3.2 Adoption of amended MRS Checklist
4	**General discussion / Issues raised by ENCePP Partners** 4.1 Issues raised at last meeting 4.2 Data privacy and protection 4.3 Repository of CoI
5	**Work Plan 2010:** 5.1 Adoption of Work Plan 2010 5.2 Review of WG priorities for future activities *Need for a new WG or amendments of mandate(s)?
6	**Summary of discussions & next steps**
7	**A.O.B** 7.1 Draft Agenda – ENCePP Plenary 8 June 2010

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 8416
E-mail encepp_secretariat@ema.europa.eu **Website** www.encepp.eu

1. Adoption of draft agenda

The draft agenda was adopted with the addition of point 7.1 (upon request from IP).

2. Organisational and Administrative Issues

2.1. Disclosure of SG Members' Declarations of Conflict for discussion

At the SG meeting on 19 February the question had been raised if the declarations of interest of each individual SG member should be made available for transparency reasons. PA reminded the group that these declarations had been entered in the Agency's experts database and were available on request. However, he offered that the declarations would be circulated if the SG decided that this was the preferred option. The topic will be re-addressed at the next Steering Group meeting as for technical reasons it was not possible for all SG members to comment at the time when this topic was addressed.

3. ENCePP Code of Conduct and Checklist of Methodological Research Standards

3.1. Results of Public Consultation: Discussion continued from the meeting on 19 February 2010

This part of the discussion was joined by Helen Dolk, Chair of ENCePP Working Group 2: Subgroup Code of Conduct.

Code of Conduct

SP presented a brief summary of the latest major amendments to the ENCePP Code of Conduct and the two issues which remained undecided following discussions during the SG meeting on 19 February 2010.

Issue #1: Making available information/data on request

A similar issue had been addressed at the last SC meeting. However, the present issue relates to the question who and under which circumstances third parties should be able to request access to the kind of information/data as provided for in the Code.

HD stated that researchers normally put in place an access policy specifying the cases in which access is to be granted. Access would normally only be provided to individuals with the appropriate education and expertise and for purposes such as confirmatory research. The time and resources required for dealing with requests for access can be substantial and potentially rather burdensome.

The group discussed the possibility of qualifying in the Code the conditions under which access should be granted; however, this might weaken the requirement too much. Another possible solution could be to set up a review group. This would be resource intensive and is currently not foreseen.

The question was raised whether requests for access to information on ENCePP Studies could be channelled through the ENCePP Secretariat in order to reduce the bureaucratic burden for researchers. It was decided that it should be further explored if a structured request form could be created e.g. within the registry of studies. For the time being, the current wording related to access to information on request will be kept in the Code.

Issue #2: Publication of results

Some comments received during the consultation addressed the differences in rights provided for by the Code for investigators and funders in relation to the publication of results. The group discussed the issue but decided to keep the current wording.

In addition to the two issues discussed by the group, HD highlighted that the requirement for providing information on conflicts of interests of investigators through the registry of studies should be reflected in the Code. In addition, she suggested changing the name of the Checklist from 'Checklist of Methodological Research Standards' to 'Checklist of Research Protocol Specification Standards' as the current title might implicate that the studies' quality has been assessed by and found to meet these standards.

MRS Checklist

Issue #1: Incomplete protocols/checklist

Currently, it is only foreseen to check submitted Checklists for completeness. However, the information provided will not be evaluated and irrespective of whether any of the standards have been taken into account in the study protocol, the study would qualify for the title "ENCePP Study" once a completed checklist has been provided. HL and XK explained that the checklist is only a starting point and that it will be followed by a Guide to be developed by the ENCePP Working Group on research standards. In addition, the Checklist should also serve as guidance on using these standards and take them into account during the study planning phase.

PA summarised the discussions: The Checklist will remain based on a self-declaration in relation to the content of the study protocol. However, the meaning of the ENCePP seal should be clearly communicated to avoid misperception.

Issue #2: Signature of Checklist

The question was raised whether the checklist should be counter-signed by the funder as currently only the signature of the principle lead investigator is requested. The group agreed that the funder should be aware of the checklist. However, as the investigator is eventually responsible for the content of the study protocol, his/her signature of the checklist would be sufficient to confirm the correctness of the information provided.

3.2. Adoption of amended MRS Checklist

The issue regarding the name of checklist as raised by HD was re-discussed. XK pointed out that the checklist *includes* methodological standards and *checks* whether and if yes, where in the protocol these have been taken into account.

The Steering Group unanimously adopted the content of the MRS Checklist (version dated 03-03-2010), but it was agreed to re-address the issue of the checklist title at the next SG meeting.

4. General discussion / Issues raised by ENCePP partners

4.1. Issues raised at last meeting

Due to time pressure it was not possible to discuss this item in detail; however, PA asked the SG members in a tour de table to try and prioritise the topics raised during the last meeting. Consequently, the list of items was prioritised as follows:

Priority Items:

- **Funding of academic research / independent studies**
- **Regulatory interface with ENCePP study requirements**
- **Repository of Declarations of Interest**
- **Dialogue with medical journals**
- **Strategy – safety issues in Europe: Explore in a pilot phase how ENCePP can react to a particular problem**
- **Data privacy & protection**
- **Evaluation of added value of the ENCePP study concept compared to the added bureaucratic burden (performance measures); measures of success of ENCePP; quality evaluation & assurance**
- **Audit/appeals/policing of ENCePP studies**

Other items:

- New Pharmacovigilance legislation as the scope of Pharmacovigilance has been widened, including also meta analysis etc.
- Multiple analysis
- Outreach / dissemination to other stakeholders
- Quality of studies: basis for better decision-making
- Accreditation of centres
- Peer review
- Publication / communication of ENCePP output

JRL would have liked to see the new pharmacovigilance legislation added to the priority list. However, PA explained that the discussions on the new PhV legislation had not progressed sufficiently yet to warrant prioritising discussions on this item. PA offered to provide further information and documents on specific provisions of the PhV legislation pertinent to the conduct of ENCePP studies. The SG members welcomed this suggestion..

4.2. Data privacy and protection

Due to time constraints, this agenda item was postponed for discussion at the next SG meeting.

4.3. Repository of CoI

Due to the absence of Nicholas Moore - who had originally raised this subject - this agenda item was postponed for discussion at the next SG meeting.

5. Work Plan 2010

5.1. Adoption of Work Plan 2010

The latest version of the ENCePP Work Plan 2010 had been circulated to all SG members in advance of the meeting. SP outlined briefly the changes agreed following the discussions of the work plan at the SG meeting on 19 February 2010.

HL said that he would have liked to see more items in relation to the promotion of ENCePP included in the work plan. PA responded that the work plan's "strategy and action plan" already includes a number of planned actions for the promotion of ENCePP. He also stressed that the promotion of ENCePP was very much dependent on the adoption of the Code of Conduct, MRS Checklist and the launch of the e-registry of studies which are *CoRe* requirements for the concept of "ENCePP studies". These elements would therefore have to be adopted before the promotion of ENCePP could start in earnest.

The ENCePP Work Plan 2010 (version dated 2 March 2010) was adopted unanimously and will be published on the ENCePP website.

5.2. Review of WG priorities for future activities

Due to time pressure, this agenda item was postponed for discussion at the next SG meeting.

Action Points arising from the discussions:

- ENCePP Secretariat to provide information on the PhV legislation.
- ENCePP Secretariat to publish the adopted work plan on the ENCePP website.

Next meetings:

- Face-to-face meeting: 7 May 2010, 09h30 – 16h00
- Vitero meeting: 16 September 2010, 14h00 – 16h00
- Vitero meeting: 2 December 2010, 14h00 – 16h00