



21 October 2010
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European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

Minutes ENCePP Steering Group Vitero meeting

21 October 2010, 13.00-14.00 – Chaired by Peter Arlett

List of Participants

Present:	Peter Arlett (PA), Stella Blackburn (SB), Corinne de Vries (CdV), Hans-Georg Eichler (HE), Henry Fitt (HF), Jytte Lyngvig (JL), Yola Moride (YM), Nicholas Moore (NM), Ingemar Persson (IP), Giuseppe Traversa (GT) <i>EFPIA Observer:</i> Valerie Simmons <i>ENCEPP SG Advisor:</i> Jim Slattery (JS) <i>ENCEPP Secretariat:</i> Kevin Blake (KB), Rocio Fernandez Fresquet (RFF), Eeva Rossi (ER), Camilla Smeraldi (CS), Dagmar Vogl (DV)
Apologies:	Joan-Ramon Laporte, David Haerry, Hubert Leufkens, June Munro Raine, Miriam Sturkenboom

Item	Draft agenda	Initials	Mins
1	Adoption of draft agenda	PA	5
2	Draft Agenda ENCePP Plenary meeting on 18 November 2010	PA	30
3	Public Consultation – ENCePP Guide on Methodological Standards in PE	PA	15
4	A.O.B - ENCePP Centres	All	10

1. Adoption of draft agenda

The draft agenda was adopted.

2. Draft Agenda ENCePP Plenary meeting on 18 November 2010

PA introduced item by item the current draft agenda for the ENCePP Plenary on 18 November 2010.

IP agreed to give a **report to the Plenary from the SG**. The ENCePP Secretariat will assist in preparing slides for this purpose.



CdV agreed to give a brief presentation on her experience in participating in a procurement procedure for a drug safety study funded by the EMA. This presentation will be given in the context of the agenda item "**ENCePP studies**". PA welcomed CdV's constructive feedback and expressed the EMA's hope that it will encourage other ENCePP partners to make use of this funding opportunity, and help them in the registration and tendering process.

Furthermore, one of the investigators involved in the first ENCePP study to be awarded the ENCePP seal will be invited to speak about their experience of the process.

Another presentation by CS will summarise the lessons learned from these initial experiences and whether these should be taken into consideration in the upcoming review of the Code of Conduct for ENCePP Studies.

The SG members welcomed the suggestion of including an item on the **new PhV legislation**. PA will be giving a presentation on the highlights of the new legislation, including those that are most relevant to ENCePP. The presentation will be followed by a discussion round giving ENCePP partners the opportunity to express their views and request clarification.

RF outlined her presentation on the new **ENCePP database of studies** which will include a demo of the database and provide feedback from the pilot phase. Following a query from IP it was confirmed that it was still possible to participate in the pilot phase. RF agreed to re-circulate the link to the electronic register for this purpose.

The next agenda item includes a presentation of the new **ENCePP Guide on Methodological Standards in Pharmacoepidemiology**. The presentation will be given jointly by KB of the ENCePP Secretariat and Susanna Perez Gutthann, Chair of WG1 Subgroup Guidances and Recommendations. The document was circulated to all SG members earlier this week in view of getting their approval for the launch of a public consultation in early November. This would mean that at the time of the Plenary the document would be out for consultation and the meeting could serve as an opportunity to call for comments. The SG members unanimously endorsed the document and agreed that it should be released for public consultation. Nicholas Moore and Yola Moride agreed to encourage ISOP and ISPE members - respectively - to provide feedback in the consultation.

The SG members were also asked for their opinion on whether or not authors should be listed on the final guideline. PA proposed that the authors should be mentioned in an appendix to the document, with an acknowledgement of all contributors. This proposal was endorsed by the SG.

The next agenda item will include a presentation by CS of the **implementing rules for access to data**, as adopted recently by the SG. The presentation will be followed by an opportunity for ENCePP Centres to express their views on this subject. As there are a number of issues outstanding in relation to access to data, it was proposed to create a task force to further discuss these issues and to present a proposal to the Steering Group prior to the 1st review of the Code. The Steering Group agreed to this approach.

Finally, CS outlined the contents of her planned presentation on the **ENCePP Work Programme 2011** and the next steps for the ENCePP Working Groups. As discussed at the previous SG meeting on 16 September 2010, the SG reconfirmed their decision not to establish a new WG for Communication for the time being. However some of the points previously raised by David Haerry on this topic could again be considered for discussion at the Plenary in November .

3. Public Consultation – ENCePP Guide on Methodological Standards in PE

This item was discussed under 2. Draft Agenda ENCePP Plenary.

4. AOB

ENCePP Centres

Prompted by the recent submission by a large CRO to join ENCePP, SB raised the subject of the definition of an ENCePP Centre and whether large CRO's could be accepted to join the network. The SG agreed that no distinction should be made, as long as the applicant fulfils the basic principles of performing PhV and PhEpi studies for third parties. NM added that accepting CROs would further broaden ENCePP's exposure vis-à-vis industry.

5. Action Points arising from the discussions

- ENCePP Secretariat to prepare slides for IP's report to the Plenary.
- ENCePP Secretariat to circulate ENCePP Info Day flyer for onward circulation.
- ENCePP Secretariat to re-circulate link to electronic register of studies for pilot phase.
- ENCePP Secretariat to launch public consultation of Guide on MS in PhV.
- ISPE and ISoP to encourage comments from their members on ENCePP Guide on Methodological Standards in Pharmacoepidemiology.

Next meetings:

- ENCePP Plenary meeting: 18 November 2010
- ENCePP Infoday: 26 November 2010
- Vitero meeting: 2 December 2010, 14h00 – 16h00