



14 December 2010  
EMA/781538/2010 final

## Minutes ENCePP Steering Group Vitero/TC meeting

2 December 2010, 14.00-16.00 – Chaired by Henry Fitt

### List of Participants

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

Item	Draft agenda
1.	<b>Adoption of draft agenda</b>
2.	<b>Matters arising</b>
3.	<b>ENCEPP Work Plan 2011-12</b> 3.1 Adoption of work plan 2011-12 3.2 ENCePP Working Groups – next steps <ul style="list-style-type: none"><li>➤ Call for Expressions of Interest: Task Force Access to Data</li><li>➤ Development of ENCePP Position on interventional vs non-interventional trials</li></ul>
4.	<b>ENCEPP SG Meetings Dates 2011</b>
5.	<b>Interface ENCePP - Private Insurers / Re-insurers</b>
6.	<b>Feedback from ENCePP Info Day</b>
7.	<b>Summary of discussions &amp; next steps</b>
8.	<b>A.O.B</b> - Communication



## 1. Adoption of draft agenda

The draft agenda was adopted with one addition. The item 'Communication' was added under AOB, on request of David Haerry.

## 2. Matters arising

None.

## 3. ENCePP Work Plan 2011-12

### *Adoption of Work Plan 2011-12 & ENCePP Working Groups – next steps*

The quorum of participants to the meeting could not be reached, it was therefore decided to postpone the adoption of the work plan and to use this meeting for a review of the list of deliverables and their timelines. The work plan will be adopted by written procedure within the next couple of weeks.

By way of introduction HF explained that based on the experience from the previous work plan which proved too ambitious regarding achievable timelines, it was decided to have a two-year work plan instead.

He also took this opportunity to inform the SG members that an overview of comments received to the public consultation on the Code of Conduct and MS checklist had recently been published on the ENCePP website. He explained that the delay in publication of these summaries was due to the large number of comments received which necessitated a very drawn out review process.

CS proceeded to explain the individual deliverables and timelines in more detail. These deliverables had already been circulated previously and updated following comments received during the recent ENCePP Plenary. An updated version based on today's discussions will be re-circulated to the SG. In particular, the following deliverables were discussed extensively:

#### *\*Deliverable: Review of Code of Conduct*

The SG felt that the deadline of June 2011 for the preparation of a paper on experience gained with ENCePP studies (possible breaches, problems encountered) was premature. However, since the launch of the Code a number of issues and potential conflicts of the Code's provisions in real-life settings have been brought to the attention of the ENCePP Secretariat and these should be addressed without delay. Considering that the major bone of contention which requires rapid elaboration is the issue of access to data, it was decided to include as a new milestone the setting up of a dedicated 'access to data' task force. Despite this and other issues, several ENCePP centres have expressed their interest in the ENCePP Study concept; however the existing concerns seem to have prevented some researchers from applying for the ENCePP Seal.

The SG therefore agreed that the task force needs to be convened as a matter of urgency and that the first output of the group should be available within the next 2-3 months at the latest. It was proposed that the task force should include the following volunteers:

- Helen Dolk (*proposed in absentia and Leader of task force - to be confirmed*)
- Miriam Sturkenboom
- Corinne de Vries
- Heli Malm (*proposed in absentia by MS, based on particular interest in the subject*)
- Morten Andersen (*proposed in absentia by IP*)

- Edeltraut Garbe (*proposed in absentia by MS based on particular interest in subject and comments made during Plenary*)
- Stella Blackburn
- Giuseppe Traversa (*based on discussion paper drafted previously on the subject*)
- Xavier Kurz

*\*Deliverable: Develop relationship with journal editors*

MS queried the main goal behind this deliverable - as expressed in the draft Work programme - which appears to have shifted from promoting ENCePP's principles regarding independence and transparency in research and discussing the impact of releasing important results prior to publication, to increasing the visibility of the network. HF stated that the intention is to do both and agreed to change the current wording to better reflect this. He also confirmed that this deliverable will have an international scope.

*\*Deliverable: Facilitation of conduct of multi-national studies*

CS informed the Steering Group that an EMA lawyer with particular expertise in data protection issues has been asked to contribute to this issue. In this context she reminded everybody that the European Commission has recently launched a public consultation on the data protection legislation which ends on 15 January 2011. The SG members agreed that it would be desirable for ENCePP to elaborate and submit a common position in response to this consultation. Despite the tight deadline and with the legal support in place, this should be possible. It was agreed that a draft statement would initially be elaborated by a small working group which will then be circulated to the SG by mid-December. In early January the Plenary will be consulted for feedback prior to submission of the ENCePP statement to the EC.

MS, with support from CdV, agreed to take the lead on this project. HF confirmed that he would approach Sabine Brosch and Alessandro Spina (EMA legal services) to ask for their support and input.

*\*Deliverable: Impact analysis*

MS queried whether an adequate null measurement was in place to allow for a good assessment of any changes. KB confirmed that the survey of PASS requested by CHMP in 2007 would be used as a baseline for counter-factual analysis. The report on this project is currently undergoing EMA internal peer review and will be circulated to the Steering Group once it has been submitted for publication. In addition, Xavier Kurz mentioned the possibility of using the results of an ongoing EMA study looking into the outcome of retrospectively applying the checklist of methodological standards for protocols to a number of PASS included in Risk management Plans submitted to the EMA. Kevin Blake offered to re-circulate the concept paper relating to the impact analysis of ENCePP and invited the SG to submit any additional suggestions for possible baselines.

*\*Deliverable: Definition of non-interventional study*

HF informed the Steering Group that the Chair of the ENCePP SG was approached recently by the Chair of the CTFG who is keen on reaching an agreed position on this issue. A teleconference has been scheduled for next week to discuss possibilities of collaboration and avoid duplication of work.

The SG agreed that an ad-hoc working group should be set up to work on a consensus statement from ENCePP on this topic, which should then be fed into the Clinical Trial Facilitation Group (CTFG), and eventually into the revision of the clinical trials directive during the second quarter of 2011. Ideally, this group should hold its first meeting before the end of January 2011. IP and SB agreed to lead on this task, additional input will be provided by PA and JRL. Based on their input on this subject during

the recent Plenary meeting, it was suggested to ask Stephen Evans and Nicholas Moore to get involved in this group. The exact scope and detailed timelines should become clearer following the meeting with the CTFG next week. The ENCePP Secretariat will provide the SG with a report on the outcome of this meeting, including proposed next steps.

***Post-meeting note:*** Due to unavailability of key people, the TC with the Chair of the CTFG had to be postponed to early January 2011; exact date to be confirmed.

#### **4. ENCePP SG Meeting Dates 2011**

CS announced that the SG will meet at least once every quarter during 2011.

The first face-to-face meeting has been confirmed for 23<sup>rd</sup> February 2011. The aim is to hold another face-to-face meeting during September, but a meeting in the margins of the June-Plenary may also be a possibility. The ENCePP Secretariat will shortly be circulating a suggested meeting plan for 2011 and conduct availability polls for all dates.

The ENCePP Plenary dates have been fixed for 30 June and 23 November 2011.

#### **5. Interface ENCePP - Private Insurers / Re-insurers**

DH reminded the SG that he had been approached by insurance companies who were unhappy with the existing EU legislation which did not allow them to access genetic patient data. Some collaboration between Re-insurers and cohort collaborations does already exist, they are receiving survival data from HIV patients in the context of life insurance. When this was first mentioned to the Steering Group a few months ago, it was suggested that ENCePP would be open to a possible collaboration and it might be an idea to reach out to private insurers to explore further the possibility of obtaining real world aggregated data via the network.

DH informed the SG that he will be meeting with SwissRe on 16 December for this purpose. In case there is interest in collaborating, he suggested inviting insurance representatives to participate in a future SG meeting for further discussions.

PA thanked DH for enacting the call from the SG. He also noted that there might be a slight overlap with the work plan on HTA.

#### **6. Feedback from ENCePP Info Day**

HF confirmed that the feedback he had received from EMA colleagues who had attended the Info Day to learn more about ENCePP was very positive and that they had gained a good overview of what the network was about. The list of attendees was impressive, with some delegates even travelling all the way from the US to attend the event.

VS stated that from the industry point of view the Info Day was excellent; the feedback she received from industry colleagues says that it was an informative and interesting event and overall a great success.

PA echoed the very positive feedback he had received. On behalf of the Steering Group he thanked all speakers, particularly Corinne de Vries, who kindly stepped in at the last minute to cover the presentation on the Code of Conduct.

In response to a query from IP whether any more Info Days were planned, HF said that there were no such plans at the moment, but that the opportunity was in place to organise a similar event in the not too distant future. PA elaborated that – if deemed necessary - it would be relatively easy to organise another event like this through the DIA. This would be a good opportunity to give the floor to other

speakers from within the network. If such an event should go ahead, it would probably be organised within the EMA building in an effort to keep registration fees as low as possible.

## 7. Summary of discussions & next steps

### **Action Points arising from the discussions:**

- **Adoption of Work Plan 2011-2012:** written procedure to be started and completed within the next 2-3 weeks
- **Task force access to data:** to be set up as soon as possible (within the next 2-3 months).
- **Task force data protection:** EMA to decide on options for internal support to this group and report to task force leads. Elaboration of ENCePP position statement and submission to EC by 15 January 2011.
- **Measuring impact of ENCePP:** ENCePP Secretariat to re-circulate draft concept paper.
- **Non-interventional studies:** ENCePP Secretariat to provide Steering Group with a summary of the meeting outcome with Chair of CTFG and suggest way forward.
- **Meeting Plan 2011:** ENCePP Secretariat to circulate draft meeting plan and availability polls.
- **Communication Policy:** ENCePP Secretariat to provide Steering Group with a copy of the EMA Communication Strategy as soon as adopted.

## 8. AOB

DH once again raised the question of whether a working group on communications was needed within ENCePP. PA responded that the creation of such a working group would create overlap with the core activity of medicine regulators, particularly in view of the broad strategy on communication relating to medicinal problems that the EMA is currently working on. It was agreed that the ENCePP Secretariat would circulate this Communication strategy to the SG as soon as it has been adopted.

### **Next meetings:**

- Face-to-face meeting: 23 February 2011