



22 March 2012
EMA/191597/2012
ENCEPP Secretariat

Minutes - ENCePP Steering Group meeting

21 March 2012, 09.30-16.30 – Chaired by Peter Arlett

List of Participants

Present:	Morten Andersen (MA), Peter Arlett (PAR), Stella Blackburn (SB), Alfonso Carvajal (AC), Ana Corrêa Nunes (ACN), Corinne de Vries (CdV), Henry Fitt (HF), David Haerry (DH), Hubert Leufkens – <i>via TC</i> (HL), Jytte Lyngvig – <i>partly</i> (JYL), Nicola Magrini (NMa), Nicholas Moore (NMo), Yola Moride – <i>via TC</i> (YM), Susana Perez-Gutthann (SPG), June Raine – <i>partly</i> (JR), Miriam Sturkenboom (MS) <i>ENCEPP SG Advisors:</i> Xavier Kurz (XK), Jim Slattery (JS) <i>EFPIA Observer:</i> Laurent Auclert (LA) <i>ENCEPP Secretariat:</i> Kevin Blake (KB), Eeva Rossi (ER), Dagmar Vogl (DV) <i>EMA:</i> Alessandro Spina (AS), Annalisa Rubino (AR), Luis Prieto (LP) <i>ENCEPP WG3:</i> Nawab Qizilbash (<i>partly – via TC</i>)
Apologies:	none

Item Draft agenda

1.	Adoption of draft agenda
2.	Tour de Table
3.	Organisational Issues 3.1 Declaration of Conflict of Interests 3.2 ENCePP SG Mandate 3.3 Election of SG Deputy Chair 3.4 Meeting Plan 2012 3.5 ENCePP: Highlights 2010-2011
4.	Data Integration 4.1 Outline of proposal: Evidence integration/pooling of data 4.2 New Legislation on Data Protection
5.	General discussion/ Issues raised by ENCePP partners 5.1 Utilisation of EC funded collaborations



Item	Draft agenda
	5.2 ENCePP Special Interest Groups 5.3 Meeting with Swiss Re – Interface ENCePP & private insurers/re-insurers
6.	Report from the Working Groups 6.1 WG1 Progress Update 6.2 WG2 Progress Update 6.3 WG3 Progress Update 6.4 Review of the Work Programme
7.	Interface ENCePP - Regulators 7.1 European Medicines Regulatory Network Strategy to Optimise Informed Regulatory Decision-Making 7.2 HTA & Integration in Pharmacoepidemiology
8.	ENCePP Plenary Meeting 3 May 2012 8.1 Draft Agenda
9.	A.O.B

1. Adoption of Draft Agenda

The Chair welcomed all Steering Group (SG) members to this first SG meeting under the new mandate, particularly those attending for the first time.

The agenda was adopted with the addition of two items under AOB:

- cooperation with FDA and Sentinel (raised by HL)
- cooperation with DSEN (raised by JR)

Post meeting note: due to a lack of time these two items were not discussed.

2. Tour de Table

The meeting continued with a round of introductions.

3. Organisational Issues

3.1 Declaration of Conflicts of Interest

HF reminded the SG of the EMA provisions relating to conflicts of interest and confidentiality listed in the Steering Group mandate. He also provided information on the practical aspects and implications of being included in the EMA database of experts. He confirmed that entries in the database need to be updated at least annually and as soon as there are new interests to declare.

JYL highlighted the importance of this issue and that the same rules apply to ENCePP SG members as for all other EMA experts and committee members.

It was agreed that the current EMA policy on handling conflicts of interest should be circulated to all SG members for information.

Post-meeting note: the two documents 'EMA policy on conflicts of interest for experts and committee members' and 'Overview of allowable interest', together with a hyperlink to the relevant page on the EMA website, were circulated to all SG members.

3.2 ENCePP SG Mandate

In his presentation, HF outlined the composition of the new SG, its roles and responsibilities and the role and expected involvement of the Deputy chair.

3.3 Election of SG Deputy Chair

Nicola Magrini was elected by consensus as Deputy Chair of the ENCePP Steering Group.

3.4 Meeting Plan 2012

ER presented the proposed ENCePP meeting dates for 2012. PAR stressed that while the plenary meeting dates are not changeable, there is a certain degree of flexibility regarding the proposed dates for SG meetings.

The SG members made no objections and the following dates are therefore considered confirmed:

3 May 2012	ENCePP Plenary (WGS on 2 & 4 May 2012)
6 July 2012	ENCePP SG (Vitero)
14 September 2012	ENCePP SG (face-to-face)
2 October 2012	ENCePP Plenary (WGs on 1 October 2012)

3.5 ENCePP: Highlights 2010-2011

DV presented a summary of ENCePP highlights 2010-2011, reminding the SG members that activity reports for both years have been published on the ENCePP website.

Following an intervention by JR it was agreed that the need to consider an impact evaluation of ENCePP should become an integral part of the SG mandate.

Action

- ENCePP Secretariat to draft a revision of the SG mandate, incorporating a reference to the impact evaluation of ENCePP.

4. Data Integration

4.1 Outline of proposal: Evidence integration/pooling of data

As agreed at the ENCePP Plenary meeting in November 2011, Nawab Qizilbash was invited to present to the Steering Group his proposals for data integration.

In his presentation the question was raised as to whether safety data are being assembled sufficiently quickly and comprehensively to inform regulatory decision making. He presented for discussion by the SG the need for the development of both further methodological guidance on data integration and an organisational structure for data integration.

The SG agreed that there is a need to further integrate data and information, and a need to facilitate this. The SG agreed there was scope for developing further guidance. As a first step, a concept paper should be drafted setting out a purpose and scope. It was agreed that ENCePP WG1 would lead on this task, with input from N Qizilbash and WG3. S Perez-Gutthann and M Sturkenboom agreed to be SG sponsors for the task. MS noted that ENCePP WG3 is looking into the issue of structures and processes for data integration and will be collating an inventory of current practice to support further discussion on this topic.

NMo suggested involvement of the Cochrane group on non-randomised studies in the discussions on data integration. This suggestion was welcomed and ENCePP WG1 was charged with including in the concept paper a section on best use of leveraging existing external stakeholders like Cochrane. Other important topics for discussion identified are governance, funding, infrastructure and data models.

In addition, ENCePP WG1 will review the current relevant sections of the existing ENCePP Guide on Methodological Standards in Pharmacoepidemiology as part of the first revision of the Guide.

In conclusion, the Chair thanked Nawab Qizilbash for his initiative and leadership on this topic.

Action

- WG1 – with support from N Qizilbash, S Perez-Gutthann and M Sturkenboom - to draft concept paper on the development of guidance on data integration (August 2012 onwards).
- WG1 to review ENCePP Guide on Methodological Standards in Pharmacoepidemiology relating to existing guidance on data integration.
- WG3 to make recommendations for structural measures to facilitate data integration.

4.2 New Legislation on Data Protection

Alessandro Spina, the Agency's Data Protection Officer, gave a presentation highlighting the European Commission proposals to reform the European Union's 1995 data protection rules and set in context its particular references to health data. He emphasised that the proposed Regulation respects the key principle in the existing Directive 95/46/EC, but is intended to replace it, therefore reducing the scope for Member State specific measures, in that the lawfulness of only processing data for which consent has been obtained is affirmed. Situations have, however, been established where data may be processed without consent including for public health reasons. He stated that following adoption of the formal legal proposal by the Commission, the proposal is now in 'co-decision' with the Council and Parliament and will take effect two years after adoption.

He also confirmed that last year's ENCePP response submitted to the public consultation on the Commission's comprehensive approach on personal data protection in the European Union would appear to have had the desired effect of drawing DG Justice's attention to a need for specific provisions on health data.

AS agreed to provide regular updates to the Steering Group on the new proposed data protection legislation, in particular relating to delegated acts for Articles 81 and 83 of the proposed Regulation. He also agreed in response to a formal request from the Chair of WG3 to support WG3 in their work on data protection issues and sharing of data. AS clarified that in this role he may also involve the European Data Protection Supervisor as needed.

Furthermore it was agreed that he present the information to the Plenary meeting on 3 May 2012.

Actions

- ENCePP Secretariat to collate a list of key actors regarding data protection including the details of the European Data Protection Supervisor, the Rapporteur for the proposals at the European Parliament and the Chair of the Council Working Group when available for WG3.
- ENCePP WG3 to develop definitions for aggregated and non-identifiable data.
- ENCePP WG3 to develop best practice document for operational rules to protect personal data.
- ENCePP WG3 to liaise with WG1 relating to the impact of any proposed changes on data protection on methodologies currently in the ENCePP Guide.

5. General Discussion / Issues raised by ENCePP Partners

5.1 Utilisation of EC funded collaborations

Following her intervention at the Plenary meeting in November 2011, MS reiterated her desire to have consideration of a strategy for how research infrastructure that is already in place as a result of EC funded consortia may be further maintained and utilised after expiration of the specific projects for which funding was obtained.

The SG agreed that there is a need to have detailed strategic discussions on funding options for research in the EU, including developing and maintaining medium and long-term research platforms. It was also agreed that there is a need for processes to be developed, including funding options, for new and emerging issues to be explored through ongoing EC funded consortia

As a first step it is proposed to organise a dedicated TC of the Steering Group to discuss funding models. Laurent Auclert agreed to act as liaison with EFPIA in relation to this subject. As a second step it is proposed to approach EFPIA in a more formal way and organise a meeting, possibly also including IMI and DG Research.

Action

- ENCePP Secretariat to organise dedicated SG TC meeting to discuss funding models.

5.2 ENCePP Special Interest Groups

A discussion paper containing draft proposals for consideration on the formation of 'ENCEPP Special Interest Groups' (SIG) with a view to facilitating discussions between the network and EMA and its Committees had been circulated to the Steering Group prior to the meeting. To kick off the discussions, KB presented slides summarising the key points in the paper.

Overall, the SG members were supportive of the idea of networks within the network however the complexity of what was being proposed was acknowledged, as was the need for clarity regarding what purposes such SIGs might play. There was consensus that the role of such groups would have to be limited to providing access to methodologies, feasibility and structures, and that a clear mandate would need to be in place. The need to separate independent advice on scientific issues from methodological advice on conduct of studies was affirmed.

In conclusion, the SG agreed that further reflection on this topic was needed, particularly in relation to: methodological and feasibility aspects, knowledge of relevant data sources and structures, development of infrastructures, and development of guidelines linked to therapeutic areas. Framework agreements or platforms that facilitate data sharing may be considered as another option within the ENCePP network rather than selecting small groups based around therapeutic areas. The example of the Brighton collaboration approach was cited. JR advised on a possible need for a legal review on future proposals.

The group acknowledged the specific methodological challenges relating to orphan medicines.

Action

- ENCePP Secretariat to revise the existing SIG discussion paper based on Steering Group comments; revised paper for discussion at next SG meeting.

5.3 Meeting with Swiss Re – Interface ENCePP & private insurers/re-insurers

By way of introduction DH reiterated that he had been in contact with Swiss Re exploring areas of common interest between private insurers/re-insurers and ENCePP relating to the provision of aggregated data on disease epidemiology and effectiveness of treatments/interventions.

A meeting between the ENCePP Secretariat and a delegation from Swiss Re took place at the European Medicines Agency in London on 19 March 2012. KB provided a short feedback from the meeting, including a number of proposed action points relating to information sharing.

The SG agreed that the dialogue with Swiss Re should be kept open with the understanding that any potential collaboration should focus on improving patient access to insurance and research access to healthcare data.

6. Report from the Working Groups

6.1 WG1 Progress Update

XK provided a progress update for WG1. The mandate of the working group includes an exploration of merits of developing an accreditation system for ENCePP. A number of national accreditation systems are already in place, and the working group will therefore perform a survey of these existing systems soon. In this context, the group is also considering an alteration to the ENCePP Database of Resources by including a link that would capture details such as a centre's full list of publications, rather than the current limit of up to 5 publications only.

The first revision of the Guide is currently ongoing and will be completed in Q2/2012 in advance of the coming into effect of the new Pharmacovigilance legislation and the associated Good Pharmacovigilance Practices (GVP). The revised version will be finalised at the WG meeting on 2 May 2012. The cross references to GVP will raise the profile of the Guide, and a presentation at this year's ICPE meeting is under consideration. The collection of guidelines from vaccine experts is currently underway and a chapter on vaccines may be included in subsequent revisions of the Guide.

6.2 WG2 Progress Update

HF gave a summary of the outcome of the WG2 meeting last November where the group's mandate was reviewed and topics were assigned priority. The meeting focussed on the promotion of the use of the Code, and issues preventing centres from applying the Code or applying for the ENCePP seal. The group came up with a number of suggestions which now need to be developed further, prior to consultation of the Steering Group. A meeting (TC) of WG2 is scheduled to take place on 28 March 2012.

6.3 WG3 Progress Update

In her progress update MS reported on the teleconference of the WG that had taken place the previous day (20 March 2012). MS confirmed that WG3 is undertaking a number of approaches to tackling the low registration rate of data sources in the ENCePP database, including a new initiative whereby the ENCePP Secretariat will add to the database details of data sources that will be obtained through a survey being undertaken by a project coordinated by MS ("Bridge to Data"). Secondly, the WG will liaise with A Spina relating to data protection issues including identification of current issues in relation to national requirements. The working group is also undertaking a review of current practice of data models used by the 10 existing EC FP7 funded consortia and the EMA funded studies.

Action

- It was agreed that efforts be made to increase the frequency of WG meetings including teleconferences and Vitero to optimise the output.

6.4 Review of the Work Programme

This item was not discussed due to time pressure.

7. Interface ENCePP - Regulators**7.1 European Medicines Regulatory Network Strategy to Optimise Informed Regulatory Decision-Making**

AR presented the background and thinking behind the paper currently under development entitled 'European Medicines Regulatory Network Strategy to Optimise Informed Regulatory Decision-Making'.

PAR added that the aim of the document was to better communicate and explain how various initiatives in relation to research, funding, regulatory science and international collaborations fit together.

The SG welcomed this important initiative, the ensuing discussion raised a number of points that the SG would like to see included or further elaborated in the draft paper:

- a clear definition of challenges;
- a comprehensive look at funding, including new streams;
- training;
- working with industry, including through third parties;
- communication.

In conclusion, PAR thanked AR and KB for their work done so far on this important document and stressed that it has become clear following today's discussions that a lot more work will be necessary. The draft strategy document will be presented to the SG at a future meeting.

Action

- K Blake and A Rubino to revise draft strategy document based on SG comments.

7.2 HTA & Integration in Pharmacoepidemiology

Luis Prieto presented slides on Health Technology Assessment with the aim of exploring possible areas of collaboration specifically between EUnetHTA and ENCePP.

The Steering Group welcomed the initiatives taken so far and broadly supported ENCePP collaboration with HTA in a bridging role to obtain data to serve both regulatory and HTA needs. The suggestion of setting up a specific ENCePP task force was supported by the SG. Corinne de Vries indicated that she would be available to support the group as SG sponsor from September 2012 onwards.

Actions

- ENCePP Secretariat to draft task force mandate for adoption by SG.
- ENCePP Secretariat to announce call for expressions of interest for centres to join the task force at Plenary meeting on 3rd May.

8. ENCePP Plenary Meeting 3 May 2012

8.1 Draft Agenda

The SG was consulted on a list of possible topics proposed for discussion at the ENCePP Plenary meeting on 3 May 2012.

9. AOB

In her role as ISPE representative on the ENCePP Steering Group, YM offered to act as a facilitator should ENCePP wish to consult ISPE on any issues arising from SG discussions.

Next meetings: 6 July 2012 (Vitero/TC)