EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

17 March 2014
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ENCePP Secretariat

Minutes - ENCePP Steering Group Meeting

21 February 2014, 09.30-16.30 – chaired by Peter Arlett

List of Participants	
Present:	Morten Andersen (MA)*, Peter Arlett (PAR), Stella Blackburn (SB), Marieke De Bruin (MDB)*, Pierre Engel (PE), Henry Fitt (HF), David Haerry (DH), Tom MacDonald (TMD), Viola Macolić Šarinić (VMS), Nicholas Moore (NM)*, Yola Moride (YM), Susana Perez-Gutthann (SPG), Nawab Qizilbash (NQ) WG Chair via TC: Alejandro Arana (AA) EFPIA Observer: Laurent Auclert* (LA) EMA Principal Advisor to ENCePP SG: Xavier Kurz (XK) ENCePP Secretariat: Kevin Blake (KB), Thomas Goedecke (TG), Eeva Rossi (ER), Dagmar Vogl (DV) **via Adobe Connect and teleconference*
Apologies:	Ana Corrêa Nunes (ACN), Teresa Herdeiro (TH), Hubert Leufkens (HL)

Agenda:

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1. Welcome & Adoption of draft agenda

On behalf of the Chair HF welcomed the new Steering Group to the first meeting of its three year mandate.

The draft agenda was adopted with the addition of the AOB item 'Collaboration between ENCePP and EMIF' (raised by NQ).

2. Tour de table

The meeting continued with a brief round of introductions by all attendants.

3. Organisational Issues

3.1. Declaration of Conflict of Interests

HF presented slides providing an overview of the European Medicines Agency's (EMA) provisions relating to declarations of interest and confidentiality, as referenced in the mandate of the ENCePP Steering Group. He also provided information on the practical aspects and implications of being included in the (publicly accessible) 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. All members of the Steering Group have completed the relevant documentation and are included in the EMA database.

3.2. ENCePP SG Mandate

HF continued by outlining the composition of the new SG, its roles and responsibilities and the role and anticipated involvement of the Deputy chair which includes occasional participation in internal stock-take meetings (via TC).

3.3. Election of SG Deputy Chair

Susana Perez-Gutthann was elected by consensus as Deputy Chair of the ENCePP Steering Group.

3.4. Meeting Plan 2014

ER presented the proposed ENCePP meeting plan for 2014. There will be a second face-to-face meeting of the Steering Group in September 2014, the date of which is still to be decided. In line with the mandate, a minimum of two additional TC/Adobe Connect meetings will be organised as needed.

The 2014 Plenary meeting is confirmed to take place on Tuesday, 25 November 2014.

Each ENCePP Working Group will have one face-to-face meeting in 2014, the dates of which will be decided based on progressing specific deliverables for each group.

3.5. Proposed topics for plenary meeting 2014

The SG members were invited to brainstorm for suitable topics for discussion at the Plenary meeting in November.

The following suggestions were made:

- Presentation of ENCePP partners scientific results and issues/challenges in ongoing research, including FP7-funded research projects. (SPG)
- Research challenges that should be brought to EMA's attention. (SPG)
- Review of PRAC activities including activities relating to risk management/post-authorisation studies – experience, capacity building, lessons learned for ENCePP. (PE)
- ENCePP support to PRAC discussions/regulatory decision-making. (VMS)
- How to increase the number of industry funded studies performed by ENCePP. (TMD)
- Depending on development, update on EU PAS web portal and projected move of EU PAS Register. (HF)
- Signal detection and management. (NQ)

It was agreed in line with a proposal from SPG to consult the plenary on topics.

4. ENCePP Work Plan

4.1. Report from Working Groups

All working group chairs had completed their inaugural overview reports for presentation to the SG members in advance of the meeting. The individual reports were presented to the SG for endorsement; as a next step these reports will be published on the ENCePP website.

WG Research Standards and Guidances (Chair: Alejandro Arana)

Alejandro Arana presented how the group had agreed on a list of additional data fields relating to 'Accreditation and quality control' for inclusion in the ENCePP database of research resources. This is in line with the mandate of the WG to explore existing accreditation methods and schemes for ENCePP partner organisations. It was confirmed that ENCePP partners will be kept informed and further consulted on any developments in this regard. An update might be provided to the Plenary meeting in November, but the proposal would be further discussed by the SG before then at its next meeting. MA proposed to run a pilot of the proposed data fields with some selected ENCePP centres.

Alejandro highlighted the group's current efforts in identifying training needs for the implementation of ENCePP standards. The SG agreed that it would be very helpful to also target national competent authorities with any training efforts.

Proposals for the next revision of the Guide on Methodological Standards were also outlined.

WG Independence and Transparency (Chair: Laura Yates)

On behalf of the group's chair KB reported the WG's agreement on an editorial revision of the Code of Conduct that had arisen from feedback from stakeholders. Next the WG will finalise a survey among ENCePP partners regarding the uptake of the ENCePP Seal and entry of studies in the E-Register which should provide a reflection of the centres' experience in dealing with industry funded studies.

A further milestone of the group will be the development of an action plan on how to better monitor/verify compliance of ENCePP Seal studies with the Code.

WG Data Sources and Multi-Source Studies (Chair: Miriam Sturkenboom)

KB highlighted on behalf of the WG chair, as the group's major deliverable the survey of publicly funded research to map current practice in pooling of multi-source database studies. Based on the outcome of the survey a paper for submission for publication has been drafted and circulated for comments among the researchers targeted in the survey.

He further informed the SG of the progress of the new general data protection regulation through the EU parliament. A brief summary of the parliamentary committee report has been published, and the indicative date for the next parliamentary discussion is 11 March 2014. The plan remains for the working group to provide expert input, as appropriate, on the development of any relevant delegated acts and implementing guidances once the Regulation has been adopted.

Finally it was highlighted that there are now a number of data sources from outside the EU in the ENCePP Resources database.

WG Health Technology Assessment (Chair: Marlene Sinclair)

On behalf of the WG chair, KB stated that a survey of ENCePP centres on their HTA experience is being proposed. The draft survey is currently under review by the working group, and a meeting of the group is scheduled at end of March to finalise the content of the survey and agree next steps. He added that the outcome of the survey might trigger changes to the ENCePP database of research resources, and that an abstract has been submitted to ICPE on the survey results.

WG Guidance for Data Integration (Chair: Nawab Qizilbash)

NQ explained that the guidance on data integration for observational studies is currently under development and it is expected that a mature draft will be ready to be shared with the plenary in November. The intention is to develop the guidance in cooperation with other groups, e.g. CIOMS, international regulators, industry associations. In order to speed along the development of the guidance, each section has been assigned an internal reviewer, and a face-to-face meeting of the group will be organised soon.

For action:

- ENCePP Secretariat to publish WG Chair reports on ENCePP website.

4.2. ENCePP Work Plan: 'red flags' in current WP

KB presented slides illustrating a progress report of the current ENCePP work plan, listing achievements/milestones completed and highlighting pending milestones whose completion has been delayed. It was agreed none of the milestones highlighted gave rise to concern.

Due to the new composition of the Steering Group, it has become necessary to appoint new SG sponsors for some of the current work plan deliverables. The following replacements were agreed:

Work plan deliverable	***NEW SG sponsor(s)*** **(in bold and underlined)**
Managing the transition to the new PhV legislation and Guideline on good pharmacovigilance practices (GVP), including review of ENCePP documents and supporting regulatory decision-making with best evidence.	B. Leufkens **V. Macolić Šarinić**
Promotion of the ENCePP Study Seal concept to increase uptake, including by the ENCePP community and the pharmaceutical industry	**M. Andersen**
Development of a stand-alone ENCePP Guide on Data Integration and Pooling of Studies	**N. Qizilbash** S. Perez-Gutthann
Map current practice for multi-source (two or more) PhEpi studies, including methodological approaches	**N. Qizilbash** S. Perez-Gutthann
Keeping up to date with the revision of EU data protection rules with expert input to legal rules or guidance considered relevant to the ENCePP mandate	**N. Qizilbash**
On-going impact analysis of ENCePP on current research practices and on regulatory activities	B. Leufkens **M. de Bruin**

4.3. Brainstorming for next work plan

The progress report on the current ENCePP work plan was followed by a brainstorming session for the next work plan 2015 – 2016 which will have to be developed and agreed by the end of 2014.

The SG members were requested to reflect on possible new work plan deliverables in the context of optimising the use of existing working groups and bearing in mind anticipated relevant topics on the horizon such as:

- Implementation of data protection regulation
- Moves to further support product development for the benefits of patients' unmet medical needs
- Enhancing ENCePP support regulatory decision making including at the level of EMA Committees and National Competent Authorities

KB reminded the SG that learning from previous experience the new work plan topics need to be clear in scope with a clear set of deliverables from the outset.

The overriding theme emerging from the ensuing discussions was the need for increased engagement of the academic community, which represents the largest constituency in ENCePP. The SG members agreed that there is a need to increase engagement and explore how to make optimal use of existing resources.

VMS highlighted that the interaction with regulators is of utmost importance in an effort to increase engagement between industry and ENCePP.

In conclusion, KB informed the meeting that a first draft of the new work plan will be presented at the next SG meeting.

For action:

- ENCePP Secretariat to prepare first draft of new work plan for discussion at next SG meeting.

5. ENCePP Code of Conduct

TG presented revision 3 of the Code as part of the on-going work of WG2. This revision is editorial and no changes to the key principles of the Code were made. The changes aim to improve readability, to explain the concept of scientific independence more clearly in a dedicated new chapter and to provide clarification on the conditions for the ENCePP Seal.

The SG endorsed the proposed editorial changes presented chapter by chapter, but further clarification might be needed in the next revision regarding

- Reference to publication of abstract/synopsis of study results in the ENCePP E-Register;
- Concept of study 'sponsor';
- Involvement of industry researchers in study activities (chapter 6);
- Which studies should/must be published in the ENCePP E-Register in context of pharmacovigilance legislation and ENCePP Seal (chapter 11);
- New clinical trials regulation.

The SG further discussed the need for a public consultation of this editorial revision and the SG agreed to publish without a further consultation as there had previously been a public consultation on the content of the Code. However, further dialogue with stakeholders on the applicability of the principles of the Code should be continued.

For action:

- ENCePP Secretariat to publish revision 3 of Code of Conduct.

6. ENCePP and industry

6.1. Reflection paper for further ENCePP dialogue with pharmaceutical industry

KB presented a revised document which had been updated following the discussions at the most recent plenary meeting.

During a meeting with industry in 2013 the general feedback was that the methodological guidance developed by ENCePP was well received, but more clarity was needed relating to the provisions of the

ENCePP Code of Conduct. Industry also raised the issue of the accreditation of ENCePP centres and on whether ENCePP ensured the quality of studies and also the ability of third parties to deliver results in an appropriate timeframe

In general, it has also been suggested that the available ENCePP resources are potentially of most use to small and medium sized industry. This was acknowledged by the observer from EFPIA who suggested that ENCePP could provide a framework for e.g. joint studies related to off-patent drugs.

While there was no disagreement from the SG to continue the dialogue with industry, a number of different views were expressed about the best way forward.

In conclusion, PAR proposed that the dialogue with industry could be managed by EMA, and in the context of medicines regulation, rather than via ENCePP. This proposal was welcomed by the Steering Group and it was agreed that the plenary will be updated accordingly at its meeting in November.

For action:

- ENCePP Secretariat to add the topic 'Update on EMA dialogue on ENCePP with pharmaceutical industry' to the November Plenary agenda.
- EMA to progress the dialogue with industry.

7. ENCePP Communication Strategy

7.1. Draft Proposal for an ENCePP Communication Strategy

HF explained it was envisaged to develop a dedicated ENCePP communication strategy and presented some initial ideas on how this strategy could be developed.

VMS suggested the European regulatory network as one specific group that should be targeted strategically.

A number of further practical suggestions were made by the Steering Group on how to develop the strategy.

It was agreed that the first step will be to create a list of stakeholders, and to then define the messages that ENCePP wishes to convey to each of these groups. A first draft of this document will be discussed at the next SG meeting.

For action:

- List of stakeholders and key messages to be defined for discussion at next SG meeting.

7.2. DIA ENCePP Information Day

HF informed the group that an ENCePP Information Day had not been held since November 2011, and it was therefore decided to tentatively plan another such day in 2014, the exact date of which is still to be confirmed.

The Steering Group endorsed the organisation of the information day in principle, but it was agreed that the organisation of this should be informed by any EMA initiative vis-à-vis industry (see item 6.1).

8. Issues raised / A.O.B.

8.1. ENCePP cooperation with EUCROF

PAR informed the Steering Group about a recent teleconference with a representative of an ENCePP partner centre who is also a member of EUCROF (the European CRO Federation) to explore possible avenues of cooperation between the two networks.

The Steering Group was supportive of encouraging the dissemination of ENCePP principles among EUCROF and its members. Furthermore, EUCROF members are encouraged to join ENCePP as representatives of their centres for an opportunity to directly contribute in any common initiatives. It was clarified that participation in e.g. working groups was on an individual basis and not considered representative of any organisation per se.

For action:

- ENCePP Secretariat to inform EUCROF of outcome of SG discussions.

8.2. Development of standards for data safety monitoring boards

NM raised the question of whether it would be useful for ENCePP to look into developing standards and principles for committees, advisory boards and similar bodies.

The Steering Group considered that the area of best practice for various advisory groups for studies is relevant to the mandate of ENCePP. However, the scope would need to be carefully considered. The opinion was expressed that any such guidance should not be integrated in the Code of Conduct, although there is an existing sub-section in the Code on Study Steering Groups.

It was agreed that the SG would consider this topic for the future work plan.

8.3. A.O.B.

NQ informed the group about a recent meeting with representatives from the European Medical Information Framework (EMIF) - an IMI project aiming to develop a common framework for patient level data. During the meeting EMIF had expressed interest in closer collaboration with ENCePP.

The Steering Group agreed that it would be helpful to get more information on this initiative and that EMIF should be invited to give a presentation at the next SG meeting.

For action:

- NQ to invite EMIF to present at next SG meeting (date to be confirmed).