EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

6 September 2017
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ENCePP Secretariat

Minutes - ENCePP Steering Group Teleconference

4 September 2017, 10.00-11.30 UK time

List of participants	
Present	Corinne de Vries, Rosa Gini, Olaf Klungel, Xavier Kurz (Chair), Tom MacDonald (Deputy Chair), Gianluca Trifirò Principal Scientific Adviser to the SG: Giampiero Mazzaglia Statistical Adviser to the SG: Jim Slattery ENCePP Secretariat: Thomas Goedecke, Eeva Rossi, Dagmar Vogl EMA: Gianmario Candore, Alexandra Pacurariu, Daniel Morales
Apologies	Kathi Apostolidis, Dinah Duarte, Vera Ehrenstein, Hans-Georg Eichler, Teresa Herdeiro, Johann Hillege, Hervé Le Louet, Yola Moride, Patrice Verpillat

1. Welcome & Adoption of draft agenda

It was confirmed that all action points from the previous meeting (TC held on 11/07/2017) had been addressed.

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

1. Consultation of ENCePP Steering Group (SG) and Working Group *Data sources and multi-source studies* (WG3) on the inventory of EU/EEA data sources for longitudinal patient-based studies.
2. Consultation of joint ENCePP-EnprEMA working group on the new Guideline on good pharmacovigilance practices (GVP) module on paediatric pharmacovigilance.

2. Common Data and Protocol Models

Rosa Gini and Gianluca Trifirò thanked all contributors for the comments received so far on the draft outline for the concept on Models for multi-database pharmacoepidemiologic studies. The Steering Group acknowledged the importance of the work to be performed.

During the discussions a number of additional suggestions were made for consideration, such as revising the different types of model presented (e.g. adding a common protocol model), adding a section on the strengths and weaknesses for each model, a section on the importance, impact and

management of heterogeneity of data, the use of validation studies and the impact of common data models on the conduct of multidatabase studies. The importance of discussing the issue of acceptability of the results of CDM studies vs studies conducted without CDM for regulators was also highlighted.

It was agreed that Rosa and Gianluca would revise the outline of the concept paper in line with the comments and circulate the new version within one week.

In terms of going forward, it was agreed that WG3 would be re-activated and existing members will be asked if they wish to continue their involvement in the group based on the revised WG3 mandate and the planned work. In addition, a general call will be made to all ENCePP partners for volunteers to contribute to the development of the concept paper on models for multi-database pharmacoepidemiology studies based on the revised outline.

To this end, the existing mandate of WG3 has been revised accordingly and will be circulated to the Steering Group for adoption in writing.

3. ISPE Guidelines for good database selection and use in pharmacoepidemiology research

Xavier reminded the Steering Group that Working Group Research Standards and Guidances (WG1) had been asked by the former SG to discuss the need to revise in collaboration with ISPE the *Guidelines for good database selection and use in pharmacoepidemiology research*. This was done in the context of discussions on the quality and need for validation of the data sets registered in the ENCePP resources database.

WG1 concluded that there is no need to change the guidelines, and it was also confirmed with ISPE that there are no plans for a revision of its guidelines. The information in the guidelines is comprehensive and provides clear recommendations. The checklist for investigators included in the guidelines partly covers information that is already available in the ENCePP resources database. Depending on the study question not all of these questions might be applicable or relevant.

Following this preliminary conclusion by WG1 EMA performed further analysis on whether the questions included in the checklist are addressed in the context of the data collection performed on longitudinal data sources and the need to collect any additional information. It was confirmed that most of the database-related questions of the checklist are already included in the inventory or are in the process of being collected by EMA. The remaining questions of the checklist are however more study-related than database-related. A general overall answer cannot be provided and should therefore be answered for each study in particular.

In line with the ENCePP work plan 2017-2019 a report on the EMA inventory of longitudinal data sources and their characteristics was circulated to the SG and WG3 for consultation. Further discussions will need to take place on how to best make use of this information and how it might be made available in the ENCePP resources database. It was confirmed that in the context of this inventory reminders were sent to data owners to update their information in the ENCePP database.

The Steering Group agreed to close the related topics in the ENCePP work plan.

4. ENCePP Code of Conduct and Seal

On behalf of Working Group Independence and Transparency (WG2) Thomas Goedecke and Rosa Gini provided a brief summary of the discussions that have taken place regarding the scope and current proposals for revision of the ENCePP Code of Conduct, in particular taking into account the provisions and governance models of the ADVANCE Code of Conduct developed for collaborative vaccine studies, and the network's past experience with the practical application of the ENCePP Code.

Based on feedback from ENCePP centres, academia and pharmaceutical industry involved in the conduct of pharmacoepidemiological and pharmacovigilance research, the scope of this revision will focus on:

- improving the Code's operability with a revised structure and adaptation in line with the ADVANCE Code of Conduct;
- definition and clarification on the practical implementation of scientific independence, and
- assessment of the ENCePP Seal concept.

WG2 will hold further discussions at the end of this month in an effort to work on a more detailed proposal. Depending on the progress and to obtain feedback from ENCePP partners, it is planned to present the different options to the ENCePP Plenary in November for further discussion.

5. ENCePP 10th Anniversary

SG members were asked to comment on the draft leaflet which was created on the occasion of the 10th anniversary of ENCePP and which aims to summarise the main achievements of the network over the past ten years. The intention is to make the leaflet available to ENCePP partners for promotional purposes. A number of suggestions were made which will be taken into consideration for the final version of the leaflet. SG members were invited to provide additional written comments at their earliest convenience. The final draft will be circulated to the Steering Group for endorsement.

The SG was also informed that they would shortly be receiving for their review a draft manuscript by Xavier Kurz and Susana Perez-Gutthann on the topic of the 10 year anniversary of ENCePP. The paper will be submitted for publication on behalf of the whole Steering Group, and SG members are invited to provide their comments within two weeks.

6. ENCePP Plenary meeting 21/11/2017

SG members were invited to submit comments on the draft agenda in writing.

7. A.O.B.

7.1. Consultation of ENCePP Steering Group (SG) and Working Group Data sources and multi-source studies (WG3) on the inventory of EU/EEA data sources for longitudinal patient-based studies.

A report on the EMA inventory of longitudinal data sources and their characteristics was circulated to the SG and WG3 for consultation. SG members were invited to provide their comments, including suggestions for additional important data sources missing from the inventory, and any characteristics worth collecting.

7.2. Consultation of joint ENCePP-EnprEMA working group on the new Guideline on good pharmacovigilance practices (GVP) module on paediatric pharmacovigilance.

The draft GVP module 'Product- or population-specific considerations IV: paediatric population' which was recently published for public consultation has been circulated to the joint ENCePP-EnprEMA working group. A TC will be taking place later this month to compile individual comments and submit a common response on behalf of ENCePP.

8. Action points

- Rosa Gini and Gianluca Trifirò to revise the outline for the concept on Models for multi-database pharmacoepidemiologic studies in line with comments received (by 11 September).
- ENCePP Secretariat to circulate the revised WG3 mandate for written adoption.
- Following adoption of revised mandate:
    - ENCePP Secretariat to ask WG3 members if they wish to continue their involvement in the group based on the revised mandate and the work to be made on the concept paper on common data models.
    - ENCePP Secretariat to issue a general call to all ENCePP partners for volunteers to join WG3 and contribute to the development of the concept paper on models for multi-database pharmacoepidemiology studies.
- WG2 to hold further discussions and provide a detailed proposal for revision 4 of the ENCePP Code of Conduct. Depending on progress, WG2 to present different options for discussion at the ENCePP Plenary on 21 November 2017.
- ENCePP Secretariat to revise and circulate the anniversary leaflet to the Steering Group for endorsement.
- SG members to review the draft anniversary manuscript and provide comments by 15 September 2017.
- SG members to submit comments on the draft plenary agenda by 15 September 2017.