European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

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2ND ENCEPP MEETING WITH CENTRES AT THE EMEA

MINUTES OF WORKING GROUP 4:
Inventory of EU PV & PE research centres in ENCePP

18 April 2008

Chairperson: Mary Teeling

Present:	Abenhaim, Lucien	Liakou, Aikaterini
	Anes, Ana Marta	Löfroth, Emil
	Blackburn, Stella (EMEA)	Lyngvig, Jytte (ENCIAG)
	Carvajal, Alfonso	Maier, William
	de Vries, Corinne	Naldi, Luigi (ENCIAG)
	Drewelow, Bernd	Teeling, Mary (Chairperson)
	Fored, Michael	Theodorakis, Michael
	Grimaldi-Bensouda, Lamiae	Vasco, Ana (EMEA)
	Heinemann, Lothar AJ	Woodvine, Phil

Apologies: Bowler, Ursula; Kos, Mitja

1. Introduction

The group comprised experts from academia / research centres, regulatory authorities and SMEs, representing approximately half of the EU member states.

The group reviewed the 4 points of the mandate as currently written in order to address the questions posed to the group.
It was noted that in 2006 the Committee for Medicinal Products for Human Use (CHMP), the CHMP's Pharmacovigilance Working Party and the International Society for Pharmacoepidemiology (ISPE) were contacted in order to identify research centres / database owners etc from all EU member states. A questionnaire was circulated to the identified organisations and the results were used to create a preliminary Inventory of ENCePP members and to organise the first ENCePP meeting. Therefore basic data on a number of research organisations were already available.

2. Draft Mandate of Working Group 4 (WG 4)

The following draft mandate was presented to the group for discussion

Comprehensive Inventory of EU PV & PE research resources (centres) in ENCePP

- Develop a questionnaire allowing collection of essential information on the research centres/organisations[1]. The information gathered through the questionnaire should allow at a later stage complex searches of the Inventory by terms like location (country), expertise, main field of research, but also outcome related terms like ADRs, drug-drug-interaction etc
- Identify additional existing EU Ph'Epi and Ph'V research resources; define exclusion/inclusion criteria for participating centres/organisations, e.g. source of funding, size of CROs, etc.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

- Develop an electronic Inventory: Identify needs and deliverables of such a tool; liaise with EMEA IT project manager
- Input to the design of the EMEA web page

([1] e.g. academic centres or other clinical research organisations, as well as existing EU networks)

3. List of Questions

The following questions regarding the WG's mandate and the organisation of its future work were put to the group:

Q 1. Does the Working Group agree with the proposed mandate?

This generated huge debate as to the function and long-term goals of the proposed inventory, as outlined in bullet point no. 1 of the mandate. The WG felt that the following points needed to be addressed by either the plenary ENCePP group or ENCIAG:

1. Who are the proposed stakeholders of the Inventory (i.e. accessibility internal to ENCePP group / regulatory authorities only or freely available to the pharmaceutical industry and other potential trial sponsors?) This needs to be defined because the database design needs to reflect what questions are likely to be asked of it. Furthermore this could have privacy implications for some centres
2. Method of compiling data – self-completed questionnaire or other? To assist searching, it was felt that too much free text should be avoided.
3. Updating procedures – method and timing. Since it will be a living database, how, when and by whom it will be updated needs to be established.
4. Auditing procedures – who is accountable for the content of the database and who will audit it? Should it be audited?
5. Inclusion into Inventory? (i.e. all possible centres included or just those that successfully achieve a certain standard in terms of facilities, expertise etc (need to be aware of a possible conflict of interest if existing centres decide who will be admitted)
6. The value of being on the Inventory - ? EMEA "seal of approval"

The WG felt that these issues (which are at the heart of the question relating to function and long-term goals of the inventory) needed to be addressed before the wording of the mandate could be finalised.

Q 2. Are there additional topics which need to be included?

In order to address this question, answers to those points in Q1 are required. It was noted that point 2 of the mandate relating to inclusion / exclusion criteria would have to be revisited in terms of the overall functions of the Inventory as apparently some of the larger CROs (so-called service CROs) were already expressing an interest in being involved in this initiative.

Additional areas which were discussed for possible inclusion in the Inventory:

- Established relationships between centres – which centres have worked together or are part of a network
- Any disease areas that the centres specialise in
- Any therapeutic areas that the centres specialised in
- Any particular methodologies that the centres specialise in/ have developed
- Any special populations that the centres specialise in eg children, elderly
- Description of people working in the centres – qualifications – but need to bear in mind that this sort of data will require frequent updates

Q 3. Are there any possible conflicts of interest/issues which might preclude a specific topic being developed through a (successful) IMI proposal? Not addressed.

Q 4. Are there topics which overlap with other groups? If so, how should this be addressed?

The WG felt that the work of all the other WGs would impact on this group. Specifically, both this WG and WG 1 will be involved in the establishment of the accreditation/certification system.

Therefore, it would be important to review their agreed mandates and guideline documents when finalising the wording of this WG's mandate and drawing up guidelines for content of the Inventory. There is likely to be an overlap between WG3 and WG4 because many databases are located within research centres. In order to further distinguish between WG 3 and WG 4, it was proposed to change the title of WG 4 to

"Inventory of EU PV & PE research centres in ENCePP".

Q 5. How would the WG suggest prioritising the topics?

The WG needed clarification from ENCIAG or EMEA regarding the points raised under Q1. It was agreed that Drs Jytte Lyngvig and Luigi Naldi (members of the ENCIAG) who were fully involved in the WG discussion would be able to discuss these issues in the ENCIAG forum.

Q 6. How will the topics be addressed (including suggestions for lead persons for topics if appropriate)?

- ENCIAG to be asked for clarification
- An example of a self-completed questionnaire for the ISPOR Digest of International Databases is available on http://www.ispor.org/DigestOfIntDB/EditDB.aspx). Although the questionnaire specifically addresses Health Care databases, it might serve as an example and starting point when developing the ENCePP Inventory of research centres
- The group had preliminary discussions on how the questions might be generated – each question to be drawn up on the basis of expected benefit to the ENCePP process of the outcome (bearing in mind preliminary / basic data already available from the initial trawl for information).
- In addition, it was noted that there were many other sources of data available on the internet which could help to identify expertise(s) in the area of PV and PE and that these might be useful in gathering data as well.
- The group agreed to keep in touch via email once clarification on the above issues had been received. Two members were identified as possible rapporteurs for initiating work on the questionnaire, once the group was ready to move forward with the mandate.

Post meeting note:

The following answers were received from the ENCePP Secretariat at the June 08 ENCIAG meeting:

1) *Who are the proposed stakeholders of the Inventory (i.e. accessibility internal to ENCePP group / regulatory authorities only or freely available to the pharmaceutical industry and other potential trial sponsors?)*

As to the availability of the Inventory, it was noted that the ultimate aim of ENCePP was to promote the conduct of PE & PV studies eg. by facilitating the identification of research organisations available to address a particular research question. Therefore the aim is that ultimately the Inventory should be available to the public, allowing sponsors of studies to search the Inventory for appropriate research resources. However, it is likely that there may need to be some fields which are not publicly available and these will need to be identified during the design of the Inventory.

2) What method of compiling the data should be used - self-completed questionnaire or other?

The level of detail foreseen for the characterisation of the research centres in the final ENCePP Inventory will require completion of a questionnaire by each organisation. However, the group should discuss whether and to which extent a review by the ENCePP Secretariat or associated WGs is needed.

3) What should be the method and timing of updating the Inventory?

For discussion by the group. Suggestions including pro and cons could be presented to ENCIAG.

4) Who is accountable for the content of the Inventory and who will audit it? Should it be audited?

ENCIAG confirmed that initially, only the ENCePP partners should be listed in the Inventory. A two-step approach was found appropriate, where firstly no selection criteria should apply, but at a later stage ENCePP partners should be approved to carry the ENCePP seal. WG 1 will look into the merits of developing a (self-)accreditation system. However, both groups need to liaise to define the precise role of each WG in the development of an accreditation/certification/auditing system.

5) Who should be included in the Inventory?

In general, the ENCePP Inventory should be open and comprehensive. Highly qualified as well as less experienced centres should be able to participate in the network. Long-term, an accreditation/certification system should be applied to the ENCePP centres. The group should discuss an appropriate structure of the Inventory to display accredited/certified centres. This should be in accordance with WG 1, which will be involved in the development of the accreditation system.

6) What will be the value of being on the Inventory (e.g. EMEA "seal of approval")?

Incentives for being part of the ENCePP Inventory should be discussed by the group, but include carrying the "ENCePP seal", i.e. conduct of research according to the ENCePP Code of Conduct and harmonised high standards, access of sponsors of studies to the Inventory, strengthening the European PV & PE community, exchange of experience, eg. through training programs, etc

ANNEX – Amended Mandate of ENCePP Working Group 4

Working Group 4

Scope	***Inventory of EU PhV & PhEpi research centres in ENCePP***
Chair: **Rapporteur(s):** **ENCIAG:**	Mary Teeling Stella Blackburn, Ana Vasco Luigi Naldi, Jytte Lyngvig
Mandate	▪ Develop a questionnaire allowing collection of essential information on the research centres/organisations[1]. The information gathered through the questionnaire should allow at a later stage complex searches of the Inventory by terms like location (country), expertise, main field of research, but also outcome related terms like ADRs, drug-drug-interaction etc ▪ Identify additional existing EU Ph'Epi and Ph'V research resources; define exclusion/inclusion criteria for participating centres/organisations, e.g. source of funding, size of CROs, etc. ▪ Develop an electronic Inventory: Identify needs and deliverables of such a tool; liaise with EMEA IT project manager ▪ Input to the design of the EMEA web page ([1] e.g. academic centres or other clinical research organisations, as well as existing EU networks)