EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

e-Register of Studies: an interim solution

Presentation by Camilla Smeraldi, ENCePP Secretariat
to the ENCePP Plenary, 8 June 2010

ENCePP Studies: how to apply?

All pharmacoepidemiological and pharmacovigilance studies can qualify as "ENCePP studies" provided that:

- the (primary) lead investigator belongs to an entity that is included in the ENCePP Inventory of Centres and Networks

AND

- the "CoRe requirements" are met

CoRe requirements for ENCePP studies

Before the study commences:

Code of Conduct: **signed declaration and checklist**

Meth***o***dological Standards for ENCePP Study Protocols: **signed checklist**

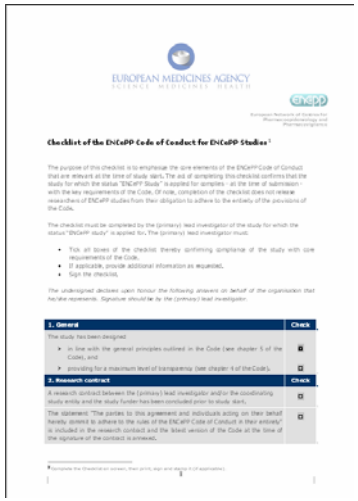
E-***Re***gister of Studies: **the study must be included in the electronic register of studies**

The signed declaration and checklists and the study protocol must be provided to the ENCePP Secretariat. The original and final versions of the protocol will be made publicly available after the final study report.

In practice…

Signed checklists and declaration to:

ENCePP Secretariat c/o EMA, 7 Westferry Circus, London E14 4HB



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\+ Registration of studies in the e-register?

Registration of studies in e-register

While a database serving as an inventory of ENCePP resources is already available through the ENCePP website, the electronic ENCePP register of studies is still under development and its release is expected for 4th Quarter 2010.

Interim solution

Interim solution for registration of studies

Why an interim solution?

- ✓ Not to delay applications for ENCePP studies seal;
- ✓ To comply with the transparency requirements laid down in the Code of Conduct for ENCePP Studies. Each entry included in the log should give the possibility to access related documentation such as the signed checklists, the signed declaration, the compiled questionnaire, etc.;
- ✓ To help us developing a better database. Questionnaire received from investigators during this phase will be used to perform testing of the database prior to its finalisation.

Interim solution for registration of studies

Investigators who wish to register an ENCePP Study must:

1. Download the data entry form from the ENCePP website: www.encepp.eu
2. Complete the questionnaire (Word document) and send it by email to ENCePP_Studies@ema.europa.eu
3. Send a copy of the original protocol either by e-mail (preferably as PDF file) to ENCePP_Studies@ema.europa.eu or by post
4. Send any other relevant document (e.g. composition of steering group, declarations of conflict of interests) either by e-mail (preferably as PDF file) to ENCePP_Studies@ema.europa.eu or by post

Interim solution for registration of studies

The ENCePP Secretariat will:

1. Check for completeness of the questionnaire submitted, of the signed declaration and checklists
2. Assign a provisional Registration number for each application received
3. Create and maintain a log of the applications received during the interim phase.
4. While the database is under development, publish the log on the ENCePP website, and update it whenever new studies are added or if the status of a study is changed.
5. Once the database is finalised, back populate the e-register of studies with the information received during this transition phase.