



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**

Methodological Standards for ENCePP Study Protocols: signed **checklist**

E-Register 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

Checklist of the ENCePP Code of Conduct for ENCePP Studies*

The purpose of this checklist is to ensure the compliance of the ENCePP Code of Conduct with the requirements of the Code of Conduct. The aim of completing this checklist is to ensure that the study for which the status "ENCePP Study" is applied for complies with the requirements of the Code of Conduct. If any requirements of the Code of Conduct are not met, the sponsor must take the necessary measures to ensure compliance with the Code of Conduct.

The checklist must be completed by the (primary) lead investigator of the study for which the status "ENCePP Study" is applied for. The (primary) lead investigator must:

- Tick all boxes of the checklist thereby certifying compliance of the study with the requirements of the Code of Conduct.
- If applicable, provide additional information as requested.
- Sign the checklist.

The undersigned declares under penalty of the following provisions on behalf of the organization that makes requests. Signature should be by the (primary) lead investigator.

Section	Check
1. General	
The study complies with:	
• in line with the general principles outlined in the Code (see chapter 1 of the Code), and	<input type="checkbox"/>
• compliance with maximum level of transparency (see chapter 4 of the Code).	<input type="checkbox"/>
2. Research contract	
A research contract between the (primary) lead investigator and/or the coordinating study entity and the study sponsor has been concluded prior to study start.	<input type="checkbox"/>
The agreement "The parties to this agreement and individuals acting on their behalf hereby declare to adhere to the Code of the ENCePP Code of Conduct in their entirety" is included in the research contract and the latest version of the Code at the time of the signature of the contract is annexed.	<input type="checkbox"/>

* Requires the (primary) sponsor, the sponsor, sign and sign-off (signature).



Declaration on compliance with the ENCePP Code of Conduct for ENCePP Studies*

The (primary) lead investigator and a person authorized to sign on behalf of the coordinating study entity, declare under penalty of the following provisions that:

- to follow the rules and principles for the independent and transparent conduct of pharmaceutical and pharmacovigilance studies of the ENCePP Code of Conduct adapted on 28/03/2010;
- to inform the ENCePP Secretariat, without delay, of any change or decision to change that constitutes a deviation from the provisions of the Code.

It is to note that the (primary) lead investigator and the person authorized to sign on behalf of the coordinating study entity may be deviated.

Name of (primary) lead investigator: _____
 Date: 2013 / 03 / 2013 (day/month)
 Name of authorized signatory: _____
 Name of the coordinating study entity: _____
 Address: _____
 Address line 2: _____
 Name of person authorized to sign on behalf of the coordinating study entity (if different from (primary) lead investigator): _____
 Date: 2013 / 03 / 2013 (day/month)
 Stamp (if applicable) and signature: _____

The (primary) lead investigator should also complete, sign and date the Checklist of the ENCePP Code of Conduct for ENCePP Studies.
 The sponsor is asked to attach electronic signature and not an escrow photocopy of the completed Declaration and Checklist.
 * Requires the declaration of the (primary) sponsor, the sponsor, sign-off (signature).



Checklist of Methodological Standards for ENCePP Study Protocols

As adopted by the ENCePP Steering Group on 19/05/2010

The purpose of the checklist is to improve the quality of studies by stimulating consideration of important methodological principles for designing a pharmacovigilance (PV) or pharmacoepidemiology (PE) study and writing a study protocol. The checklist is intended to promote quality of such studies, and their evaluation. It includes information on design and data methods of research. However, it is advised that some of the questions below do not apply to such investigations, in which case the answer "N/A (Not Applicable)" can be checked. **Please fill the "Comments" field included at each section in situations where a later question does not apply or where your answer is "N/A". This will help ENCePP assess the Checklist of Methodological Standards for ENCePP Study Protocols in line with the developments in science and methodology.**

The (primary) lead investigator of the study for which the status of "ENCePP Study" is applied for should:

- make the following declaration by answering "yes" or "no" to each question related to the information contained in the study protocol. If the answer is "yes" (the page(s) of the study protocol where the issue is addressed should be recorded). The exact sentence at the end of each section should be used to provide comments, in particular to provide an explanation in why the answer "No" or "Not Applicable" can be checked.
- provide an electronic copy of the supporting study protocol.
- sign the checklist.
- attach and seal/sign the checklist as necessary in case of changes to the protocol.

The undersigned declares upon honour the following answers in relation to the Company or organization that makes requests. Signature should be by the (primary) lead investigator.

Section 1: Research question	Yes	No	N/A	Page Number(s)
1.1 Does the formulation of the research question clearly answer:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1.1.1 Why the study is conducted (i.e. to assess an important public health concern, a risk identified in the management plan, or a new scientific issue)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1.1.2 The objectives of the study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1.2 Does the formulation of the research question specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1.2.1 Target population (or relevant subgroup) i.e. population or subgroup to which the study results are intended to be applied	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1.2.2 Hypotheses to be tested (if appropriate, alternative hypotheses that there is no causal relationship)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

For use only by sponsor

+ 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.