ENCePP Code of Conduct

Rules for the independent and transparent conduct of pharmacoepidemiological & pharmacovigilance research

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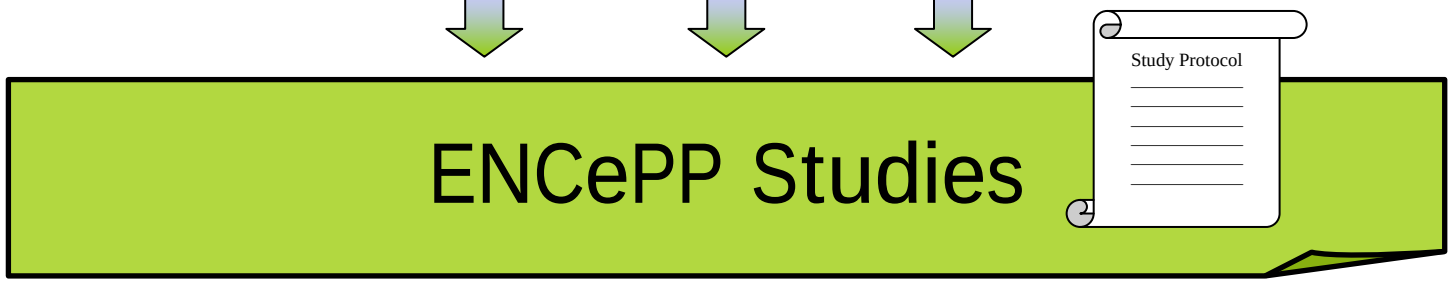
Database of Research Resources
[Centres + Data sets]



ENCePP Code of Conduct

Independence & Transparency

Register of PE & PhV studies

Checklist of Operational Research Standards

Standards, Good Practice & Quality

PV & PE Guidelines

Rationale

- Transparency on roles and responsibilities and on the details of the design and the conduct of studies is a cornerstone in building trust and confidence
- There is a need to have clarity of roles and responsibilities in studies
- It is recognised that there are areas in Pharmacoepidemiology and Pharmacovigilance research which would benefit from a higher level of openness, communication and accountability.

Scope

- **PE and PhV studies**, with an emphasis on non-interventional Post-Authorisation Studies.
- **“ENCePP studies”** (mandatory)
- Main focus on contract research / funded research
- Of note, clinical trials and methodological studies are not excluded

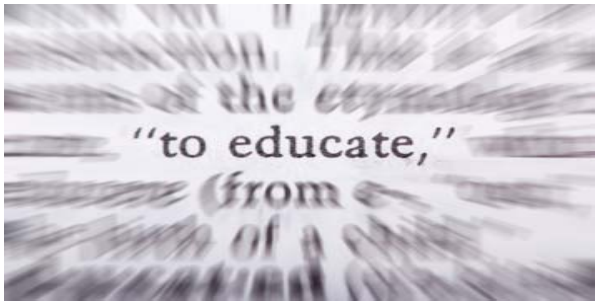
Main principles

- **Transparency**
  - throughout the research process and
  - when establishing the relationship between contractor and client (funder) in contract research
- **Independence**
  - ultimately resulting from transparency and
  - with regard to the rights and level of involvement of the investigator and the study funder

The Code - what it is NOT

- The Code does NOT include rules or guidance on methodological or scientific aspects.
- The use of the Code is NOT mandatory (except for “ENCePP studies”).
- Adherence to the Code will not guarantee integrity of study data or validity of study results - however, knowledge of the rules and a documented commitment to applying them will help to increase confidence in the research process and study findings.
- Legal provisions, including national law as applicable, need to be followed as applicable.

Definitions



1. ENCePP Study
2. ENCePP Code of Conduct
3. Post-Authorisation Study
4. Study protocol
5. Investigator
6. Responsible Investigator
7. Coordinating Study Entity
8 . Study Funder
9. ENCePP Code of Conduct
10. Contract Research
11. Contract Research Organisation
12. Pharmacoepidemiology
13. Pharmacovigilance
14. Clinical Trial
15. Transparency
16. Conflict of Interest
17. Confidential Information

ENCePP Study

Pharmacoepidemiological and Pharmacovigilance studies performed according to relevant **operational research standards** as agreed by ENCePP and in line with the rules and requirements for the independent and transparent conduct of PE and PhV research laid down in the **ENCePP Code of Conduct**, and whose **Lead Investigator** belongs to an entity that is included in the ENCePP Inventory of resources.

ENCePP Code of Conduct

A **set of rules** and recommendations laying down the responsibilities and good practices to guide the interaction between research centres, pharmaceutical industry and regulators, as well as rules and recommendations for the conduct of pharmacoepidemiological and Pharmacovigilance studies to be followed throughout the research process **in order to maximise transparency and scientific independence.**

Lead Investigator

If a study is conducted at **several study sites** by a team of Investigators, the Lead Investigator is the **Investigator who takes the lead and has overall responsibility for the study**.

(The Lead Investigator is the person authorised to represent the Coordinating Study Entity.)

Study Funder

A legal person who **provides the financing for a study**. The Funder can be the originator of the research question and is identical with the client in Contract Research.

Transparency

Transparency is based on **openness, communication and disclosure of or making information available** whilst respecting the protection of both personal data as well as commercially confidential information. Research may be labelled as (partly) transparent if some or all relevant aspects of the research are open in the sense of open access to information on the research process and data thereby facilitating an objective assessment of the quality and independence of the research and validity of the research results.

Conflict of Interest

In the context of this document, Conflicts of Interest include any **direct or indirect interests of a commercial, financial or personal nature** other than purely scientific motivation which **might compromise** (or be perceived to compromise) **the impartiality** of the persons contributing to a study and **may have an effect on relevant decisions** including the choice of the study design, interpretation of data, and publication of results etc.

Confidential Information

Confidential Information means all information, facts, data and any other matters communicated between the Investigator(s), the Coordinating Study Entity and the Study Funder in the framework of the study undertaken which are clearly identified or marked as being confidential at the moment of their disclosure.

For the purpose of this document, Confidential Information shall be understood as information which may not be disseminated without the direct or indirect approval of the owner of such information as agreed between the above mentioned parties. This especially includes commercial or financial information other than information on the identity of the Study Funder or information related to patents or copyrights. Data derived from a study shall reasonably be treated confidentially especially taking into account data privacy and intellectual ownership rights.

5. Application and Compliance

- In principle voluntary, but mandatory for ENCePP studies
- “Self-Policing” by research community only
- Breaches & withdrawals will result in deprivation of the title “ENCePP Study” and will be included in the annual reports.

5. Application and Compliance

-  **Checklist** (Annex 2)

- **Declaration** (Annex 3)

- Copy of the agreed full **study protocol** (at the time of submission)

8. Funding Contract

- The funding contract shall specifically refer to the ENCePP Code of Conduct and shall include the statement

  "The parties to this agreement and individuals acting on their behalf hereby commit to adhere to the rules of the ENCePP Code of Conduct in their entirety".

- The relevant version of the Code at the time of the signature of the funding contract should be annexed to the contract for reference.
- (…) the ENCePP Secretariat may request to see the funding contract to reconfirm adherence to the Code.

9. Rights & obligations of investigator and funder

- The (Responsible) Investigator shall be responsible for the content of the assigned research project including the design of the protocol, the conduct of the study, the analysis and interpretation of the study results and the preparation and publication of the study outcome.
- Any involvement of the Study Funder shall be specified in the Study Protocol.

6.1 Registration of the study before it commences in the ENCePP Register of Post-Authorisation Studies

(to be regularly updated as appropriate and including documentation of any amendments to the Study Protocol).

10. Development of the study protocol

- Involvement of the Funder in the design of the protocol is permitted but any involvement shall be specified in the funding contract - **information on the degree of the Funder's involvement shall be made publicly available**.
- The person responsible for the first draft of the Study Protocol as well as his/her affiliation should be identified.
- The study protocol needs to be provided to the ENCePP Secretariat before the study commences **– will be made publicly available**.
- Any deviation from the initial protocol should be duly justified and documented including the date of the change.

11. Data ownership and access

- To be agreed in the funding contract.
- Data to be maintained under secure conditions in line with data protection legislation.
- All data collected and generated in a study shall be recorded in an accurate way that allows access e.g. for the purpose of verifying the published results at all time with personal data protection being guaranteed.

12. Study conduct

12.1 Data Analysis

12.2 Study Steering Group

- The potential members shall declare any Conflicts of Interest and should only be appointed if no Conflict of Interest exists.
- Other (interested) parties and stakeholders including the Study Funder, if they have a substantial Conflict of Interest, may only participate in meetings of the steering group as observers and shall have no voting rights.
- The composition of the steering group, including observers participating in its meetings, shall be made publicly available.

13. Publication of study results

- An abstract of the study findings shall be provided to the ENCePP Secretariat for publication on the ENCePP webpage within 3 months after the final study report.
- The (Lead) Investigator should have the right to independently prepare publications of the study results independent of data ownership.
- The Study Funder shall be entitled to view the final results prior to the publication and to comment on the results and interpretations of the findings in advance of publication within a reasonable time limit as agreed in the funding contract and without unjustifiably delaying the publication.

13. Publication of study results

- The Investigator is free not to take the comments of the Funder into account and the Funder may only require that interpretation of results or their presentation be changed based on sound scientific reasons or to delete Confidential Information.
- Any comments of the Funder should be made publicly available.

Annex 3: Declaration

Declaration

The (Lead) Investigator and a person authorised to sign on behalf of the Coordinating Study Entity hereby declare for the purpose of conducting the study <include study name and identifier/registration no.>

I. to follow the rules and requirements for the independent and transparent conduct of pharmacoepidemiological and Pharmacovigilance research of the ENCePP Code of Conduct from --/--/-- <(include revisions)>

II. to inform the ENCePP Secretariat, without delay, of any change which constitutes a deviation from the provisions of this Code or of any decision

Name of the Coordinating Study Entity:

_____

Address:

_____

_____

Name of (Lead) Investigator :

_____

Date: xx/yy/zzzz

Stamp and signature:

Mandatory supporting documentation to be provided in support of the above declaration:

Figure: 1. identification of the (Lead) Investigator
Figure: 2. identification of the Coordinating study entity
Figure: 3. identification of the Study Funder

Of note, in order to comply with this obligation it might be sufficient to submit the Study Protocol provided that the above mentioned persons and entities are clearly identified.

Applicants are requested to note that supporting documents provided must relate to legal persons and/or natural persons including, where considered necessary by EMEA, directors or any person with powers of representation, decision-making or control in relation to the candidate.

If there is any doubt about the mandatory documentation required, it is strongly recommended that the appointed person at EMEA is contacted for clarification since failure to provide the correct documents may lead to elimination from the procedure.

The (Lead) Investigator should also sign and date the checklist. EMEA is unable to accept electronic signatures and will not accept photocopies of the completed declaration.

Next steps

Today !	• Agreement on core elements of the Code by ENCePP Plenary
September/ October 2009	• Circulation of the Code to ENCePP community for comments
October/ November 2009	• ENCIAG to agree on revised version of the Code
November 2009	• Public Consultation
11 Dec 2009	• Endorsement at 2nd ENCePP Plenary