EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Lesson learned from first ENCePP Studies

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Aide memoire: Requirements for ENCePP Studies

1. (Primary) Lead investigator:
   - Must belong to an entity that is included in the ENCePP Inventory of Centres and networks

2. Code of Conduct:
   - Signed declaration and checklist. Paper copies to be sent to ENCePP Secretariat

3. Methodological Standards for ENCePP Study Protocols:
   - Signed checklist. Paper copy to be sent to ENCePP Secretariat

Aide memoire: Requirements for ENCePP Studies

4. E-register of studies:
   - Study must be included in e-register of studies prior to its start

5. Protocol: initial version
   - Uploaded in the e-register of studies as PDF file
     - At this stage not visible to the general public unless investigator wishes to do so
   - In case of technical problems sent to ENCePP Secretariat as paper copy

Aide memoire: Requirements for ENCePP Studies

6. Declaration of interest:
   - Uploaded in the e-register of studies as PDF file

7. Steering Group composition
   - Uploaded in the e-register of studies as PDF file

Aide memoire: Obligations placed by ENCePP Seal

1. E-register of studies:
   - The entry in the register must be updated
     - as milestones are reached: e-mail reminders from database
     - in case of changes to the protocol that may affect interpretation of the study
2. Checklist of Methodological Standards
   - To be updated and resubmitted via the e-register in case of changes to the protocol that may affect the interpretation of the study

Aide memoire:
Obligations placed by ENCePP Seal

3. Protocol: after finalisation of the study report

- Final version (if different from initial) to be uploaded in the e-register of studies as PDF file

  Both the original and the final versions of the protocol will be made publicly available on the ENCePP e-Register of studies at that stage.

4. Study results:

- Abstract of the study results to be uploaded in the database within 3 months following the final study report

Aide memoire: ENCePP Seal

- ✓The seal is granted “a priori”
- ✓Can be removed if the study deviates from or no longer follows the rule of the Code of Conduct
- ✓No guarantee on the quality of the study

First ENCePP Studies

- Concept of ENCePP Studies launched in June 2010
- 3 applications for ENCePP Seal received/ 3 ENCePP Seals granted:
  1. Long-term outcomes and adverse events of therapy with inhaled corticosteroids, long-acting beta-2-agonists and anticholinergic drugs in hospitalised patients with Chronic Obstructive Pulmonary Disease (COPD) - a cohort study based on health information systems in three Italian regions.

     Coordinator: Department of Epidemiology Lazio Region, Italy
  2. International Active Surveillance Study of Women Taking Dienogest for Endometriosis: Visanne Post-approval Observational Study

     Coordinator: ZEG Berlin
  3. International Active Surveillance study - Folate and Oral Contraceptive Utilization Study

     Coordinator: ZEG Berlin
- E-register now fully functional and open to the public

Overview of studies

Study type:

- Observational studies (2)
- Active surveillance (1)

Primary scope:

- Risk assessment (2)
- Effectiveness evaluation (1)

Design:

- Cohort studies

Overview of studies

Source of funding:

- Pharmaceutical companies (2)
- Government body

Countries where the studies are conducted?

- National (1)
  - Italy
- International (2)
  - Austria, Germany, USA
  - Austria, France, Germany, Poland

Overview of studies

Final study reports (expected):

- June 2013 (COPD)
- July 2017 (dienogest for endometriosis)
- June 2025 (folate and oral contraceptives)

Lesson learned from experience

- Code of Conduct aimed at ensuring adherence to the principles of transparency and independence in the research process

- Adherence to the Code should not place unnecessary bureaucratic burden on the investigators

- Is there need to review some of the provisions included in the current version of the Code of Conduct?

Example

Code of Conduct:

... The research 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 statement should be translated into the language of the contract. The relevant version of the Code at the time of the signature of the research contract should be annexed to the contract for reference

Example

- Funding of the study received under the “2008 Call for proposals for independent research on drugs” by AIFA (Italian medicines Agency)
- Contract under signature at the time of the adoption of the ENCePP Code of Conduct
- Impossible to amend template contract from AIFA at that stage
- The following information, in accordance with the Code of Conduct, was already included in the Contract:

✓ The main objectives and a brief description of the intended methods of research as well as a clear assignment of tasks and responsibilities.

✓ The procedure for achieving an agreement on the study protocol as well as the involvement of the funder in the development of the study protocol.

✓ The amount of the financial support and the payment scheme

✓ Ownership of and access to the data produced during the study

✓ A communication strategy for the scheduled interim (if applicable) and final results

Example

- Code of Conduct, undersigned by the Lead Investigator, annexed to the research contract

  Considering that same level of transparency and same provisions for access and ownership of data requested by the Code of Conduct were covered in the research contract, the study has been granted the ENCePP Seal

- Is there need to review some of the provisions included in the current version of the Code of Conduct?