The European Network of Centres of Pharmacoepidemiology & Pharmacovigilance (ENCePP)

& The Code of Conduct

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Disclaimer

The views expressed are those of the speaker and may not necessarily be the official view of the Agency
Why we need ENCePP (or why we need to do more post-authorisation research)?

What is ENCePP?

The Code of Conduct
Public expectations

- We need access to new medicines as soon as possible
- We want drugs to be as safe as possible
Building a better system

Reactive
Proactive
Why Europe?

27 Member States
495 million people

Heterogenous population
Different health care systems

Orphan diseases may need whole of EU to get study population!

? Different target population to RoW
Increasing need for studies

- Drug utilisation
- Effectiveness
- Risk Min
- Efficacy
- Real world
- Efficacy
- Clin trials

PASS
Analysis of needs

Ability to do pro-active Pharmacovigilance
Ability to do high quality Pharmacoepidemiology studies
Increase research capacity and awareness
Ability to do studies in different EU countries
Ability to do multicentre studies across Europe

Pharmacovigilance
Pharmacoepidemiology
Centres
European
Network
What is ENCePP?

An EMA-led project

bringing together expertise in the fields of PhEpi and PhV scattered across Europe

The Aim

Strengthen further the post-authorisation monitoring of medicinal products in Europe

facilitate post authorisation studies:

• high quality
• Independent
• multi-centre
ENCePP Expertise 2011

85 partner organisations

From 18 EEA countries

13 Networks
Perception of scientific research
Perception of Sponsored research
ENCePP study

To reinforce confidence of:

- Public
- Other researchers
- Regulators

that research done under the ENCePP “seal” is as far as possible free from biases and commercial, financial and personal influences.
Development of principles

- Secretariat (EMA)
- Steering Group Governance
- EU Research Institutions & Networks Expertise

Advice
- WG Research Standard & practice
- WG Transparency & Independence
- WG Data Sources & Multi-source studies
- WG Inventory of EU research centres

Outputs
- Checklist of Methodological Standards
- Code of Conduct
- Resources database
- e-Register of studies

Task forces:
- Access to data
- Non interventional studies

Result
Requirements for ENCePP study

**Lead Investigator** from ENCePP Database of resources

+ ENCePP Code of Conduct – *signed declaration and checklist*

Methodological standards for ENCePP study protocols – *signed checklist*

Prior registration in e- Database of studies
The Code
Of
Conduct
The Code of Conduct - Rationale

- There is a need to have clarity of roles and responsibilities in studies.

- 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.

- It is recognised that there are areas in PhEpi and PhV research which would benefit from a higher level of openness, communication and accountability.
Code of Conduct History

- **May 2009**: First draft prepared by Working Group *Transparency & Independence* (chair: Helen Dolk).

- **Sept - Nov 2009**: Consultation of ENCePP partnership; Adoption of revised draft by ENCIAG.
  
  - **Nov 2009 – Jan 2010**: Public Consultation.
  
  - **Jan 2010 – April 2010**: Review and implementation of comments.

  - **May 2010**: Adoption by Steering Group.

  - **Sept 2010**: 1st revision
Objectives of the Code of Conduct

Best practice in the relationship between investigators and study funders

+ 

Transparency throughout research process

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Scientific independence of study
Main provisions of Code

Primary purpose scientific not promotional

Study not designed to achieve a particular result

Contract covering: interaction, remuneration, protocol agreement, analysis of results, publication of results

Results published or made available

Information on research process made available
ENCePP Code of Conduct for Studies

Checklist for ENCePP Studies

1. General: study designed in adherence to the CoC and max levels of transparency
2. Research contract: mention of CoC in the contract/financial agreement between funder and investigators
3. Registration of studies: in e-register of studies
4. Study protocol: latest version uploaded in the e-register, all changes need to be documented, detailed statistical analysis plan available, contribution of individuals
5. Data ownership and access to data: system in place to record data and provision to make them available when final study report available
6. Declaration of interests: collected and publically available. Once protocol finalised, exclusion from any activity that could influence results or interpretation
7. Study Steering Group: no conflict of interests, composition publicly available
8. Publication/Reporting of studies: regardless of positive/negative findings
9. Confidential information: data generated in study are not confidential!
TRANSPARENCY: Study registration & availability of protocol

Registration in publicly accessible register prior to study start (ENCePP Studies ⇒ ENCePP Register of Studies).

Publication of the study protocol after final study report: 2 versions - Initial version at study start & final version.

Documentation of relevant steps in study & changes to the protocol.

Update of entry in register, as appropriate, incl. changes to the protocol that may affect the interpretation of the study.
**TRANSPARENCY: Study results**

Always publish results!

- a summary of the main results, whether positive or negative and including results from pre-maturely terminated studies,

- ENCePP studies: abstract of the findings within 3 months after final report,

- A full report of results with a scientific or public health impact.

- Report changes to the protocol during the course of the study that may affect its interpretation

Make available reports and/or comments from reviewers (upon request).

Make available comments from the funder (publicly).
TRANSPARENCY: Affiliations and interests

Make publicly available:

• Identity, affiliations and potential conflicts of interest of investigators – in advance and when publishing.
• Information on all parties involved in writing and adoption of the protocol incl a brief description of their contribution.
• Composition of Steering Group.

Other

Make available on request:

• Reports from reviewers,
• data set used for analysis,
• research contract (actual figures may be redacted).
Declaration of Interests

Who?

All parties involved in the conduct of the study

Steering Group members (if applicable)

What?

Direct or indirect interests of a commercial, financial or personal nature that might impact the impartiality in relation to the study.
Roles of investigator & funder

**Investigator**

1. Registration of study & application for ENCePP Study Seal.
2. Final responsibility for study protocol.
3. Ultimately responsible for the study.
4. Has intellectual contribution/ownership of data.
5. Right to independently publish study results.

**Funder**

1. Requirement to follow the Code laid down in research contract.
2. Can be involved in design of protocol.
3. Will be informed about study progress; may be observer in Study Steering Group.
4. In principle, joint ownership of data recommended.
5. Right to review publications before submission & require deletion of confidential information.
Thank you

Also thanks to Stefanie Prilla