EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

The ENCePP network: facilitating the conduct of PAS

Henry Fitt

Head of Best Evidence Development

2nd industry platform meeting on the implementation of Pharmacovigilance legislation - 12 January 2015

What is ENCePP?

The **E**uropean **N**etwork of **Ce**nters for **P**harmacoepidemiology & **P**harmacovigilance

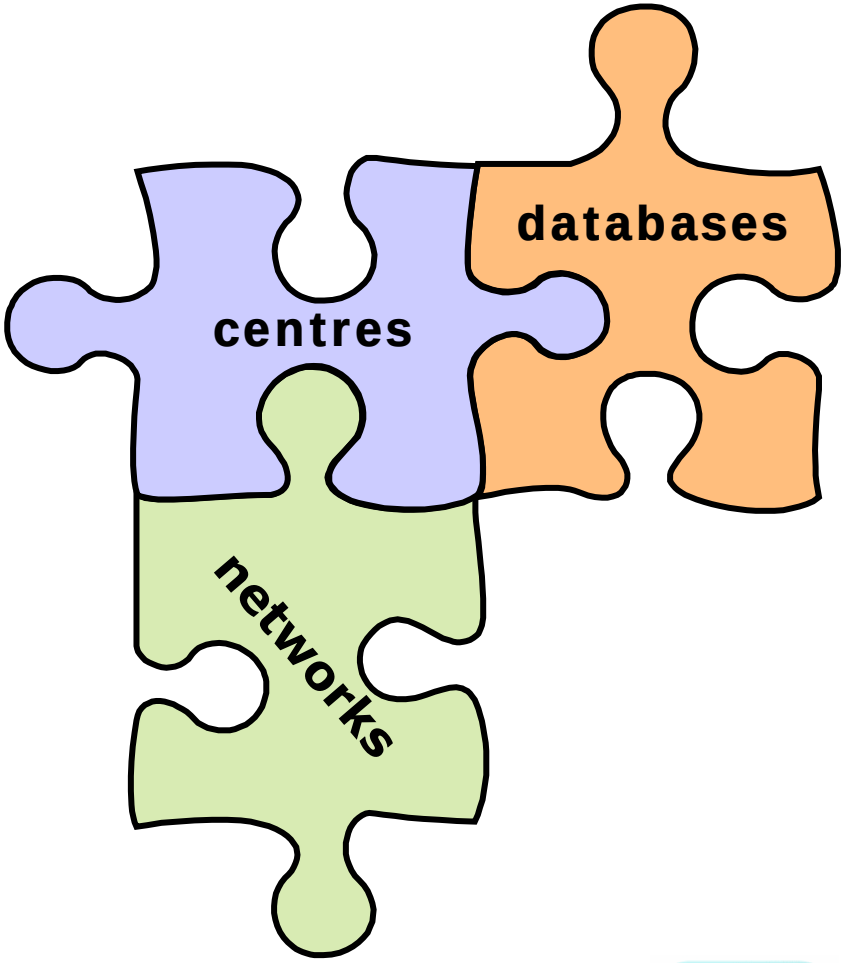
- Established in response to increasing number of PAS requested + the need to leverage e-health resources and take PhEPi to next level

- It fosters high quality pharmacoepiemiology and pharmacovigilance research for the benefit of public health by promoting best methodological and governance practices through guidance and standards.

- The aim is to improve the quality, ease, speed, transparency and reliability of post-authorisation evidence feeding into regulatory decision making (PRAC/CHMP)

Capacity to conduct high quality research

- Currently includes 147 centres, 22 networks, 51 data source owners
- Public, searchable database with information on the expertise and data sources available in ENCePP.
- Option to post announcement in ENCePP Partners Forum e.g. to elicit ideas on a study



ENCePP: what it represents

Transparency

- Registration of studies
- Publication of protocols and results

ENCePP E-Register

Independence

- Clear roles and responsibilities of all parties making studies happen for public health benefit

Standards

- Stimulate consideration of important methodological principles in study design

Methodological Standards Guide

Checklist for Study Protocols

Code of Conduct

Guidance on methodological Standards

1. General aspects of study protocol
2. Research question
3. Approaches to data collection
    - 3.1. Primary data collection
    - 3.2. Secondary use of data
    - 3.3. Research networks
    - 3.4. Spontaneous report databases
4. Study design and methods
    - 4.1. General considerations
    - 4.2. Challenges and lessons learned
        - 4.2.1. Drug exposure/outcome/covariate definition and validation
            - 4.2.1.1. Assessment of outcomes
            - 4.2.1.2. Validation
            - 4.2.1.3. Drug consumption databases
        - 4.2.2. Bias and confounding
            - 4.2.2.1. Choice of exposure risk windows
            - 4.2.2.2. Time-related bias
                - 4.2.2.2.1. Immortal time bias
                - 4.2.2.2.2. Other forms of time-related bias
            - 4.2.2.3. Confounding by indication
            - 4.2.2.4. Protopathic bias
            - 4.2.2.5. Unmeasured confounding
        - 4.2.3. Methods to handle bias and confounding

http://www.encepp.eu/standards_and_guidances/methodologicalGuide.shtml

Why use ENCePP?

- Access to best available expertise in Europe and numerous data sources
- ENCePP is at the heart of best methodological practices and study governance practices
- ENCePP is committed to the principles of research independence and transparency

ENCePP centres conduct 30% of studies requested by a regulatory body and funded by industry listed in the EU-PAS register.