What is ENCePP?

- The **European Network of Centres for Pharmacoepidemiology & Pharmacovigilance (ENCePP)** is an initiative that **brings together expertise and resources** in pharmacoepidemiology and pharmacovigilance across Europe. ENCePP is coordinated by the European Medicines Agency.

- ENCePP aims to **strengthen the monitoring of the benefit:risk balance of medicinal products**. This will be achieved by facilitating the conduct of high quality, multi-centre, independent post-authorisation studies (PAS) with a focus on observational research.

- ENCePP is comprised of research centres and networks referred to as **‘ENCePP partners’**. Participation in ENCePP is voluntary.

- ENCePP is **globally acknowledged** for its expertise and outputs.
How is ENCePP organised?

**ENCePP Steering Group**
16 members in total:
- 6 elected: from network
- 7 appointed:
  - Heads of Medicines Agencies (HMA),
  - Committee for Medicinal Products for Human Use (CHMP),
  - Committee for Orphan Medicinal Products (COMP)
  - Pharmacovigilance Risk Assessment Committee (PRAC),
  - CHMP’s Patient and Consumers Working Party (PCWP),
  - International Society of Pharmacoepidemiology (ISPE),
  - International Society of Pharmacovigilance (ISoP)
- 3 members from EMA
- 1 observer: European Federation of the Pharmaceutical Industries & Associations (EFPIA)
ENCePP guiding principles and tools

Transparency
- Registration of studies
- Publication of protocols and results

Independence
- Clear roles and responsibilities of all parties involved for public health benefit

Standards
- Stimulate consideration of important principles in study design

Code of Conduct
- EU PAS Register
- Methodological Standards Guide
- Checklist for Study Protocols
Who are the ENCePP partners?

**Centres (>150)**
- Public (university, hospital, government, charities)
- Others (CROs, consultants)

**Networks (>20)**
- International
- National
Special interests: psychiatry, rheumatology, respiratory, effectiveness, teratology, pharmacogenetics, congenital abnormalities, women’s health, paediatrics, psoriasis, severe cutaneous adverse reactions to drugs;

**Data sources (>50)**

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What does it mean to be an ENCePP partner?

- All ENCePP partners are **registered in the ENCePP Resources Database**.
- Being an ENCePP partner means a **commitment** to:
  - **adhere** to the principles of the **ENCePP Code of Conduct** and ENCePP Guide on Methodological Standards in Pharmacoepidemiology,
  - **register** their post-authorisation studies in the **EU PAS Register**,
  - participate in the **development of research and good practice standards** by contributing to, or commenting on, draft proposals prepared by working groups or the ENCePP secretariat,
  - collaborate with other ENCePP partners, e.g. in multi-centres studies, and share their research experience.
What ENCePP offers to industry

ENCePP supports the conduct of **high quality industry-funded post-authorisation studies (PAS)** by:

- Supporting the conduct of **joint studies** by facilitating collaborations;
- Providing opportunities to participate, through consultations, in the development of **pharmacoepidemiological research standards and methods** for the post-authorisation safety surveillance of medicinal products;
- Developing and maintaining **methodological, transparency and governance tools** for the planning, design, conduct and reporting of studies according to standards recommended in the EU Good Pharmacovigilance Practices (GVP).
- Giving access to dedicated tools for the conduct of studies:
  - **ENCePP Resources Database** for research centres and data sources;
  - **EU PAS Register** for the registration of PAS with focus on observational research.
What ENCePP offers to regulators

ENCePP supports regulatory decision-making on the benefit-risk of medicines at the European Medicines Agency’s Scientific Committees and at national medicines agencies by:

- Building capacity through independent pharmacoepidemiological research for monitoring the safety and effectiveness of authorised medicines;
- Conducting post-authorisation studies according to principles of good practice, good governance and transparency;
- Analysing data on clinical use of medicines in everyday practice;
- Developing and implementing methodological standards in pharmacovigilance and pharmacoepidemiology supporting regulatory guidelines;
- Providing access to ENCePP Centres with expertise in specific areas.
Questions?

Visit us@ www.encepp.eu

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