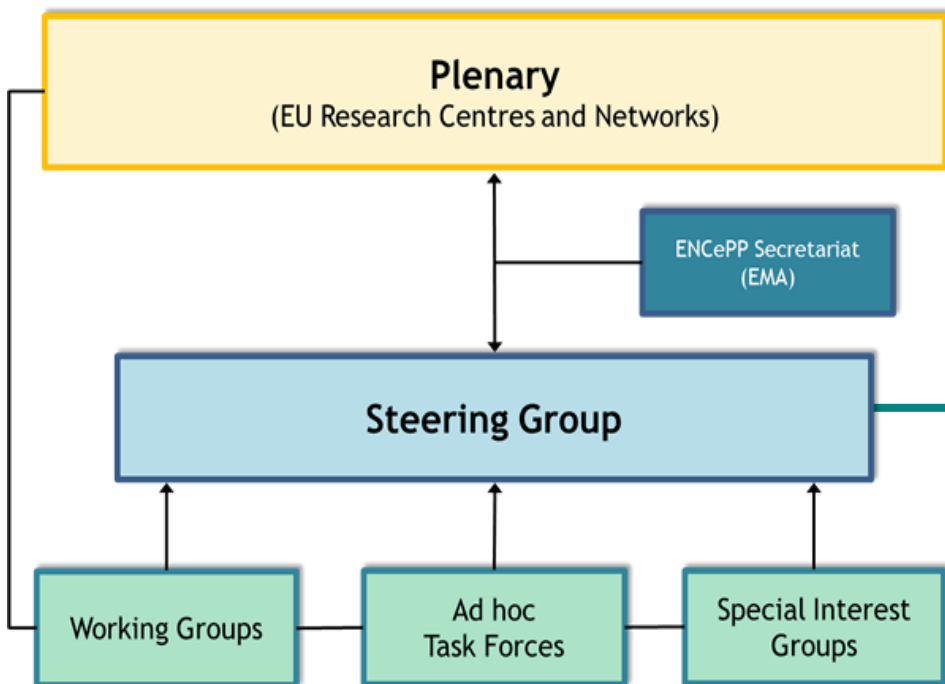


What is ENCePP?

- 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



EU PAS Register

Registration of studies

Publication of protocols and results

Independence

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



Code of Conduct

Standards

Stimulate consideration of important principles in study design



Methodological Standards Guide



Checklist for Study Protocols



Code of Conduct

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)



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

Contact us@ encepp_secretariat@ema.europa.eu



European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

