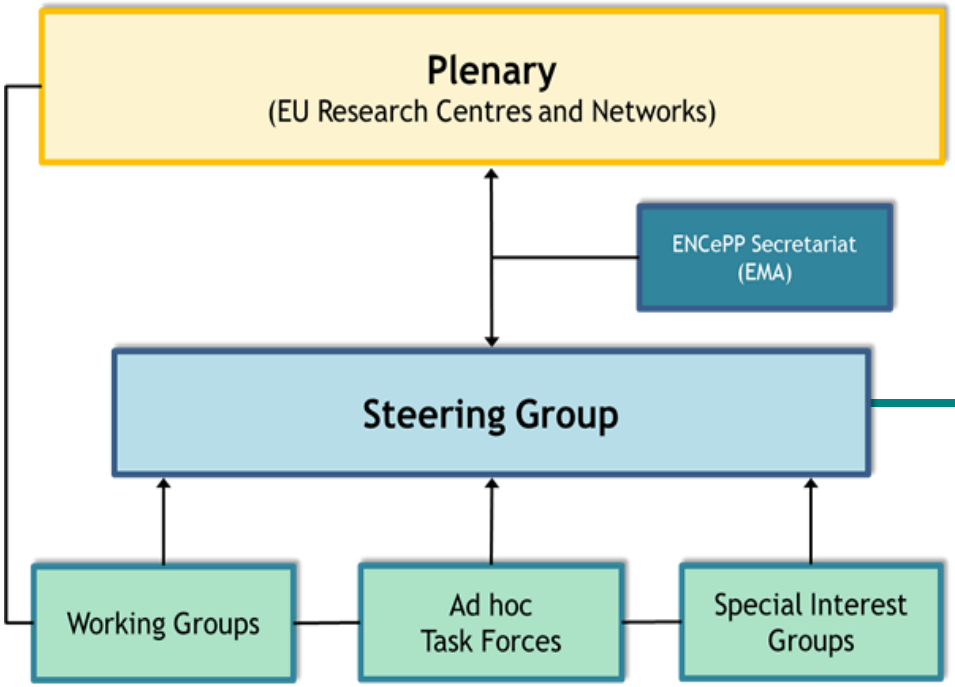
What is ENCePP?

- 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

17 members in total:

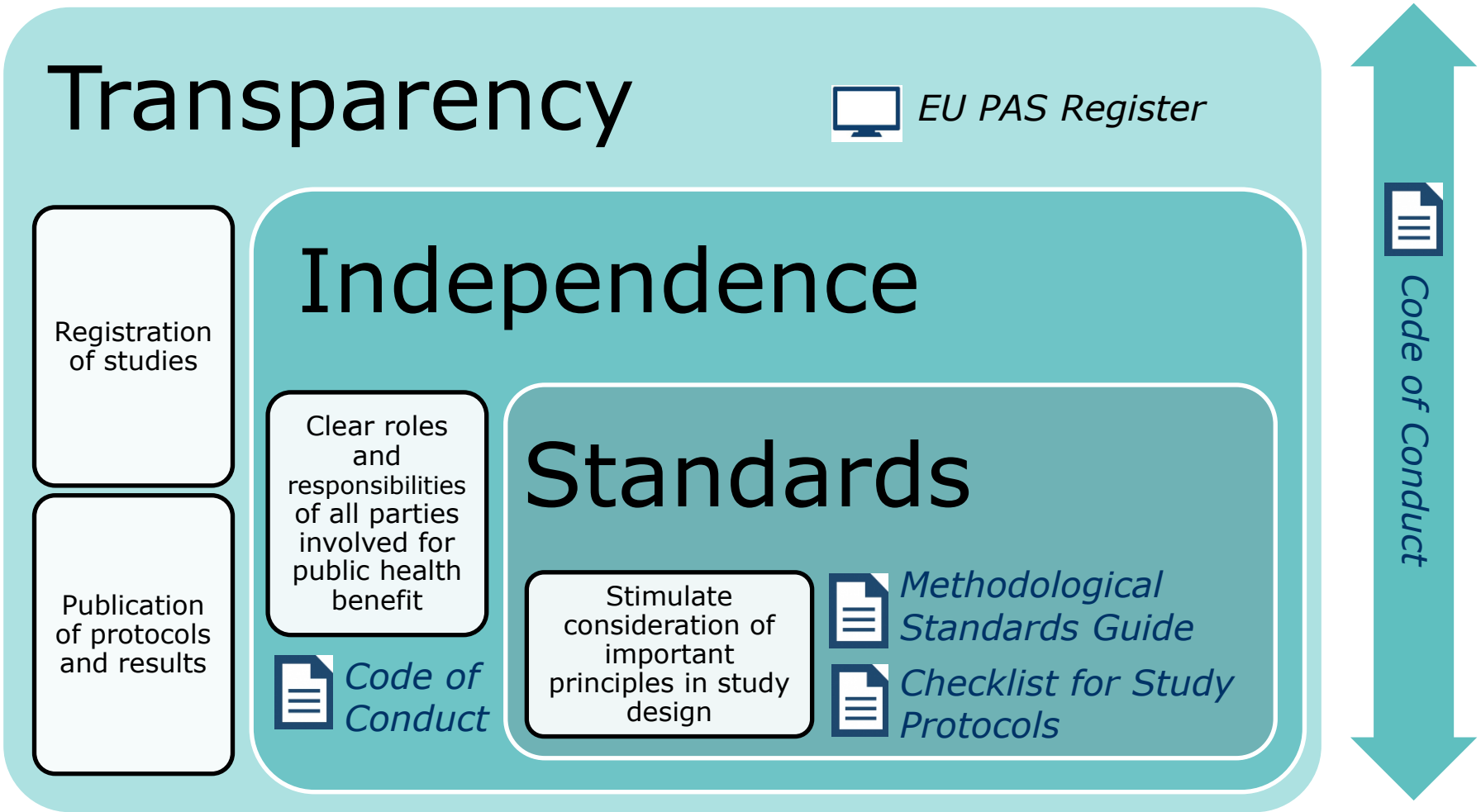
6 elected from network (including co-chair)
8 appointed from:
- Heads of Medicines Agencies (HMA)
- Committee for Medicinal Products for Human Use (CHMP)
- Committee for Orphan Medicinal Products (COMP)
- Pharmacovigilance Risk Assessment Committee (PRAC)
- CHMP's Patient and Consumers Working Party (PCWP)
- International Society of Pharmacoepidemiology (ISPE)
- International Society of Pharmacovigilance (IsoP)
- International Society for Pharmacoeconomics and Outcomes Research (ISPOR)

3 members from EMA (including co-chair)

Observers:
- Representatives from the pharmaceutical industry: European Federation of the Pharmaceutical Industries & Associations (EFPIA) (1 observer + 1 deputy observer)

- Representatives from International regulatory agencies

ENCePP guiding principles and tools



Who are the ENCePP partners?

Centres (more than 200)

- Public (university, hospital, government, charities)
- Others (CROs, consultants)

Networks (more than 30)

- 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 (more than 160)

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?

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Contact us@ encepp_secretariat@ema.europa.eu