Expertise and collaboration in pharmacovigilance and pharmacoepidemiology in Europe

10 years of collaboration to strengthen the monitoring of benefits and risks of medicines in Europe.

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) is a network coordinated by the European Medicines Agency (EMA).

The members of this network (the ENCePP partners) are public institutions and contract and research organisations (CRO) involved in research in pharmacoepidemiology and pharmacovigilance.

Methodological guidance


- 5000 views on average per month in 2017 (www.encepp.eu)
- 850 downloads on average per month in 2017 (www.encepp.eu)
- 424 references selected, commented and updated by 31 authors

Governance principles

- **ENCePP Checklist for Study Protocols**
  - Supporting best practice in study design
  - Promoting transparency on study methods

- **ENCePP Code of Conduct**
  - Promoting transparency and scientific independence throughout the research process

Increased transparency in high quality, multi-centre, independent non-interventional post-authorisation studies (PAS)

ENCePP hosts the public **European Union electronic Register of Post-Authorisation Studies (EU PAS Register®)**.

- 1145 PAS registered (By type, July 2017)
  - 84% Active surveillance
  - 19% Observational study
  - 10% Clinical trial
  - 4% Other

- 50% of registered studies were requested by a regulator:
  - 40% Europe
  - 6% United States
  - 4% Rest of the World

Public institutions and research organisations 168

European countries 18

Data sources (by type, July 2017)

- Disease registry 35%
- Spontaneous reporting database 19%
- Prescription event monitoring 10%
- Claims/administrative databases 5%
- Electronic healthcare records 4%
- Medicine registry 4%
- Other 4%

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