A network of excellence strengthening post-authorisation monitoring of medicines in Europe

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) is a collaborative scientific network coordinated by the European Medicines Agency (EMA) to strengthen the post-authorisation monitoring of medicinal products in Europe.

ENCePP brings together over 170 academic and hospital-based research centres, providers of healthcare data and specialised networks across Europe in a functioning network of excellence.

ENCePP facilitates the conduct of high-quality, multi-centre, independent studies of medicines focusing on safety and benefit-risk.

EUROPEAN MEDICINES AGENCY
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ENCePP

ENCePP Secretariat

European Medicines Agency
Patient Health Protection
Pharmacovigilance and Risk Management

7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom

Telephone +44 (0)20 7523 7655
E-mail encepp_secretariat@ema.europa.eu
Website **www.encepp.eu**

ENCePP

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

An agency of the European Union

Organisational structure

The network consists of the following elements:

- ENCePP Plenary (all partner organisations).
- ENCePP Steering Group.
- ENCePP Secretariat (provided by the EMA).
- Working groups (currently four).
- Ad-hoc task forces.

While the focus of ENCePP is on public and not-for-profit organisations, other organisations may also qualify for participation, provided they perform studies commissioned by third parties and their main focus is pharmacovigilance and pharmacoepidemiology research.

ENCePP has grown rapidly to become, de facto, the European Union (EU) organisation for non-interventional research.

This is reflected in the network having been invited to take part in stakeholder consultations and having published position papers on a number of policy topics relevant to pharmaco-epidemiology.

The network has also established itself as a key element in generating evidence to support regulatory decision-making by the EMA and its committees.

ENCePP guiding principles

The network facilitates research by offering access to a robust network of available expertise and resources for parties seeking to collaborate with others, or to commission studies to be conducted on their behalf. The research is subsequently conducted in a transparent and independent manner, in line with best methodological practices, thereby improving post-authorisation surveillance of medicines. Thus, ENCePP seeks to take pharmacoepidemiology to the next level[1].

To this end, the '**ENCePP Seal Study**' was developed for instant recognition of a study being conducted in line with the ENCePP guiding principles of transparency, scientific independence and highest-quality methodological standards.

A pharmacovigilance or pharmacoepidemiology study whose lead investigator belongs to an ENCePP partner organisation can qualify as an ENCePP Seal Study, provided a commitment is made to meet a set of '**CoRe requirements**' in advance of the study start, including:

- adherence to the ENCePP **C**ode of Conduct throughout study planning and conduct;
- completion of the ENCePP Checklist for Study Pr**o**tocols; and
- inclusion in the ENCePP e-**Re**gister of Studies.

The signed declarations and checklists that are required as markers of this commitment must be provided to the ENCePP Secretariat before the study commences.

[1] Blake, K. V., deVries, C. S., Arlett, P., Kurz, X., Fitt, H. for the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance. Increasing scientific standards, independence and transparency in post-authorisation studies: the role of ENCePP. Pharmacoepidem Drug Saf 2012; 21: 690–696. doi:10.1002/pds.3281.

ENCePP database of research resources

Central to ENCePP is a comprehensive, searchable database of participating partner organisations and a registry of data sources. This electronic index, accessed via the ENCePP web portal (www.encepp.eu), serves as a publicly available access point for study sponsors and researchers seeking to collaborate or to commission the conduct of post-authorisation studies (PAS).

Companies seeking **help or advice** on how to conduct a PAS can submit a request to the ENCePP Secretariat, which will be shared with ENCePP partners only.

ENCePP e-Register (EU PAS Register)

The ENCePP e-Register provides a free and publicly accessible resource for the online registration of pharmacoepidemiological and pharmacovigilance studies. Its main purpose is to increase transparency and reduce publication bias. Registration of studies is mandatory for ENCePP Seal Studies.

The ENCePP e-Register currently serves as the EU-PAS Register defined in Module VIII of the guideline on good pharmacovigilance practice (GVP).