



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



ENCePP

The European Network
of Centres for
Pharmacoepidemiology and
Pharmacovigilance



A network of excellence strengthening 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 monitoring of medicinal products in Europe.

ENCePP fosters high quality medicines research for the benefit of public health by promoting best methodological and governance practices through guidance and standards.

ENCePP is globally acknowledged for its expertise and outputs.



Introduction

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) aims to strengthen the monitoring of medicinal products by facilitating the conduct of multi- centre, independent studies focusing on safety and on benefit-risk throughout the product life-cycle.

ENCePP brings together over 200 academic and hospital-based research centres, providers of healthcare data and specialised networks across Europe in a functioning network of excellence.

Organisational structure

The network consists of the following elements:

- ENCePP Plenary (annual meeting of partner organisations);
- ENCePP Steering Group;
- ENCePP Secretariat (provided by EMA);
- Working groups (currently six);
- Special Interest Groups;
- 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 their main focus is pharmacovigilance or pharmacoepidemiology research and they perform third party commissioned studies.

ENCePP has grown to become an important contributor to observational research and the

use of real world data on use of medicines in the European Union (EU).

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 contact details for 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.

Thus, ENCePP seeks to take pharmaco-epidemiology to the next level.¹

The need for investigators to consistently consider methodological issues arising in observational research resulted in the development of the **ENCePP Checklist for Study Protocols** complemented by the **ENCePP Guide on Methodological Standards in Pharmacoepidemiology**.

Both documents are referenced in Module VIII of the good pharmacovigilance practices (GVP) on post-authorisation safety studies (PASS).

¹ Blake, K. V., deVries, C. S., Arlett, P., Kurz, X., Fitt, H. for the European Network of Centres for Pharmacoepidemiology 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 of data sources. This electronic index, accessed via the ENCePP web portal (www.encepp.eu) serves as a publicly available contact point for study sponsors and researchers seeking to collaborate or to commission the conduct of post-authorisation studies (PAS).

Companies seeking collaboration with an ENCePP partner can either contact the organisation directly via the details available on the ENCePP website or submit a more general request via the ENCePP Secretariat for posting in the dedicated ENCePP Partners Forum.

ENCePP e-Register (EU PAS Register)

The ENCePP e-Register provides a free and publicly accessible resource for the online registration of studies with a particular focus on observational research. Its main purpose is to increase transparency and reduce publication bias.

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



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