

A network of excellence to strengthen the post-authorisation monitoring of medicines in Europe

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) is a project led by the European Medicines Agency intended to further strengthen the post-authorisation monitoring of medicinal products in Europe by facilitating the conduct of high-quality, multi-centre, independent post-authorisation studies focusing on safety and benefit-risk.

It brings together available expertise and research experience in the fields of pharmacoepidemiology and pharmacovigilance across Europe in a network of excellence, comprising relevant research centres, medical-care centres, healthcare databases, electronic health registries and existing European networks covering rare diseases, therapeutic fields and adverse drug events of interest.



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ENCePP

The European
Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance





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Organisational structure

The ENCePP network consists of the following elements:

- ENCePP Plenary (totality of research centres, networks, data sources);
- ENCePP Steering Group;
- ENCePP Secretariat (European Medicines Agency);
- working groups (currently three):
 - ENCePP research standards and guidance,
 - independence and transparency,
 - EU data sources and methodological approaches for multi-source studies.

Ad-hoc task forces and new working groups may be established as appropriate.

Central to ENCePP is a comprehensive, publicly accessible inventory of existing EU research centres and networks with expertise in pharmacoepidemiology & pharmacovigilance, and of pertinent databases, registries and other relevant data sources.

'CoRe' research values

The ultimate goal of the network is to facilitate and improve pharmacoepidemiological research and post-authorisation safety surveillance of medicinal products in Europe, by offering access to a robust network of resources working in a transparent and independent manner, according to the highest scientific standards.

To this end the concept of '**ENCePP Study**' was introduced. In short, all pharmacovigilance and pharmacoepidemiological studies can qualify as an ENCePP study provided that the (primary) lead investigator belongs to an entity that is included in the ENCePP Inventory of resources and that the '**CoRe requirements**' are met:

- **Code of conduct** for scientific independence and transparency in the conduct of pharmacoepidemiological & pharmacovigilance studies (*signed declaration and checklist*)
- **checklist of methodological standards** (*signed checklist*)

The signed declaration and checklists must be provided to the ENCePP Secretariat before the study commences. The original and final versions of the protocol will be made publicly available after the final study report.

- **e-Register** of studies

The study must be included in the electronic ENCePP register of studies before it commences.

ENCePP Database of Research Resources

The Database is a public, fully searchable electronic index of the available EU research resources in the field of pharmacoepidemiology and pharmacovigilance. It has two components, the **Inventory of ENCePP research centres and networks**, and the **Registry of EU data sources**. It is available via the ENCePP web portal (<http://www.encepp.eu>).

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

The Database offers access to the available sources of information and research expertise across Europe, and serves as a central resource for both study sponsors and researchers seeking to identify organisations and data sets to conduct specific pharmacoepidemiology and pharmacovigilance projects in Europe.

Electronic register of studies

The e-Register of studies (<http://www.encepp.eu/encepp/studiesDatabase.jsp>) 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 encouraged for all post-authorisation studies. It is mandatory for 'ENCePP studies'.