



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

15 January 2016
EMA/512164/2015
ENCEPP Secretariat

Key messages for communication on ENCePP

Adopted by the ENCePP Steering Group 16 December 2015

Background

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP) has delivered numerous high quality outputs over recent years (such as the ENCePP Guide on Methodological Standards in Pharmacoepidemiology) and fostered collaborative research funded through the European Commission's 7th Framework Programme and the Innovative Medicines Initiative (IMI).

This document provides key messages for communication at conferences, scientific meetings and other events on:

- What is ENCePP?
- What does ENCePP deliver?
- What does it mean to be an ENCePP partner?
- What does ENCePP offer to regulators and pharmaceutical companies?

1. What is ENCePP?

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP) is a network coordinated by the European Medicines Agency. The members of this network (the ENCePP partners) are public institutions and contract and research organisations (CRO) involved in research in pharmacoepidemiology and pharmacovigilance. Research interests are not restricted to the safety of medicines but may include the benefits and risks of medicines, disease epidemiology and drug utilisation. Participation to ENCePP is voluntary.

ENCEPP aims to strengthen the monitoring of the benefit-risk balance of medicinal products in Europe by:

- Facilitating the conduct of high quality, multi-centre, independent post-authorisation studies (PAS) with a focus on observational research;
- Bringing together expertise and resources in pharmacoepidemiology and pharmacovigilance across Europe and providing a platform for collaborations;



- Developing and maintaining methodological standards and governance principles for research in pharmacovigilance and pharmacoepidemiology.

Its stakeholders are the research community, regulatory and public health authorities, patients and health care professional associations, and the pharmaceutical industry. The ENCePP website (<http://www.encepp.eu>) describes the activities of the network and provides access to its documents.

2. What does ENCePP deliver?

- A **forum** where ENCePP partners can discuss and develop research standards in pharmacovigilance and pharmacoepidemiology through written consultation or participation in plenary and working group meetings.
- A publicly available and searchable **resource database**, an electronic index of self-registered EU research organisations, networks and data sources in the field of pharmacoepidemiology and pharmacovigilance that can be used by researchers and study sponsors seeking to identify organisations and data sets for conducting specific pharmacoepidemiology and pharmacovigilance studies in Europe.
- A publicly available and searchable **register** where any pharmacoepidemiological and pharmacovigilance study can be registered by whoever initiates it; this register also serves as the “EU Post-Authorisation Study (PAS) Register” where marketing authorisation holders should register all post-authorisation studies (PAS) relating to medicines with a focus on observational research.
- The **ENCEPP Code of Conduct**, which provides a set of rules and principles for pharmacoepidemiology and pharmacovigilance studies to promote transparency and scientific independence throughout the research process.
- The **ENCEPP Guide on Methodological Standards in Pharmacoepidemiology**, which offers a **single web resource for methodological English language guidance in pharmacoepidemiology**.
- The **ENCEPP Checklist for Study Protocols**, which is a list of questions on important aspects of study design that stimulates researchers to consider important epidemiological principles when designing a pharmacoepidemiological study and promotes transparency on study methods.
- The **ENCEPP Seal** that recognises studies following the ENCePP principles of standards, transparency and independence.

3. 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.
- ENCePP partners are encouraged to publish the following statement on their websites and use the ENCePP logo in publications, presentations etc.:

We are a partner centre of the ENCePP scientific network which is coordinated by the European Medicines Agency. We are dedicated to excellence in research by adhering to the ENCePP Guide on Methodological Standards and promoting scientific independence and transparency. We register studies in the EU PAS Register, a publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies.

4. 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.

5. What ENCePP offers to the pharmaceutical 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:
 - the ENCePP Resources Database providing a robust network of research centres working in a transparent and independent manner, including data sources;
 - the EU PAS Register developed specifically for the registration of post-authorisation studies (PAS) with a focus on observational research.