

**Approximate study time:** 1 hour**Level:** Intermediate**Audience:** Drug Safety, Research**Category:** Drug Safety**Region:** Europe, USA, Other**CPD Points:** 1**Module outline**

- Module overview
- Study planning and data collection
- Analysis, interpretation, and communication
- Assessment

Pharmacoepidemiology is the study of the use and effects of drugs in large numbers of people. It provides a bridge between clinical pharmacology and epidemiology. The increasing demand for real-world evidence of the safety, efficacy and utility of medicinal products has focused greater attention on pharmacoepidemiological research. This module will help those who plan and conduct such research, and analyse and report the findings, to follow good practice.

**Who will benefit from this module?**

Staff working in drug safety and pharmacovigilance or clinical research departments of pharmaceutical and biotechnology companies will benefit from this module. It will also be of value to healthcare professionals.

**Learning objectives**

On completion of this module, you should be able to follow good practice in:

- Planning pharmacoepidemiological research
- Collecting data in such research
- Analysing data from pharmacoepidemiological studies
- Interpreting and communicating the results of such studies

**Module outline****Module overview**

An outline of the module's scope and objectives, and a glossary of terms.

Study planning and data collection

In this session, we:

- Outline the role and formulation of a research question and study protocol
- Discuss the choice of study design and research methods
- Identify types of data source and means of data collection
- Summarise obligations for protection of subjects
- Discuss operational definition and validation of drug exposure, outcomes, and covariates
- Give examples of good practice in data collection, management, and verification

Analysis, interpretation, and communication

In this session, we:

- Discuss data analysis and the interpretation of results
- Outline the role and formulation of a statistical analysis plan
- Describe obligations for provision of a study report and communication of findings

Assessment

Multiple-choice mastery assessment.

