HealthManagement
Promoting Management and Leadership

Volume 15, Issue 1, 2013 - Pharma Supplement

Pharmacovigilence

EU PROTECT Project Achieves Key Objectives

The PROTECT project, a public-private partnership for innovative methodologies in pharmacovigilance and pharmacoepidemiology coordinated by the European Medicines Agency, has reached a crucial stage with the delivery of two databases which will offer access to important data resources for pharmacovigilance activities and pharmacoepidemiological studies.

The PROTECT Project

The goal of PROTECT is to strengthen the monitoring of the benefit-risk of medicines in Europe. The project is developing a set of innovative tools and methods that will enhance the early detection and assessment of adverse drug reactions from different data sources, and enable the integration and presentation of data on benefits and risks. These methods will be tested in real-life situations in order to provide all stakeholders (patients, prescribers, public health authorities, regulators and pharmaceutical companies) with accurate and useful information supporting risk management and continuous benefit-risk assessment.

The overall objective of PROTECT is to strengthen the monitoring of the benefit-risk of medicines in Europe. In order to achieve this overall goal, PROTECT has been designed as a comprehensive and integrated project aiming to develop and validate a set of innovative tools and methods that will:

- Enhance data collection directly from consumers of medicines in their natural language in several European Union countries, using modern tools of communication;
- Improve early and proactive signal detection from spontaneous reports, electronic health records and clinical trials;
- Develop, test and disseminate methodological standards for the design, conduct and analysis of pharmacoepidemiological studies applicable to different safety issues and using different data sources;
- Develop methods for continuous benefit-risk monitoring of medicines, by integrating data on benefits and risks from clinical trials, observational studies and spontaneous reports, including both the underpinning modelling and the presentation of the results, with a particular emphasis on graphical methods; and
- Test and validate various methods developed in PROTECT using a large variety of different sources in the European Union (e.g. clinical registries) in order to identify and help resolve operational difficulties linked to multi-site investigations.

A methodological framework for pharmacoepidemiological studies will be developed and tested to enable data mining, signal detection and evaluation in various types of datasets, including data of spontaneous reports, registries and other electronic databases. Means of combining results from clinical trials, spontaneous reporting and observational data will be developed, comparing Bayesian modelling, multi-criteria decision analysis and other analytical methods. Methods for graphical expression of benefitrisk will be tested with different stakeholders.

Collection of data directly from patients is essential in many situations. PROTECT will trial direct patient data collection in natural languages using web-based, telephone and text messaging systems. It will test the transferability of the data into a common language and explore linkages to data from electronic health records and registries.

Using methods developed in the project, validation studies performed with additional data resources available in the European Union will help create the foundation for multi-site investigations. Development will continue beyond the initial Innovative Medicines Initiative (IMI) funding, with training given and results disseminated using the EMEA-led European Network of Centres for Pharmacovigilance and Pharmacoepidemiology and relevant publications.

PROTECT consists of 33 public and private partners coordinated by the European Medicines Agency. It is managed by a Coordinator and Deputy Coordinator with extensive experience in pharmacovigilance, aided by a strong governance structure, including a Steering Committee, an experienced project management team and a distinguished international External Advisory Board.

Two Databases Delivered

The project has reached a crucial stage with the delivery of two databases, which will offer access to important data resources for pharmacovigilance activities and pharmacoepidemiological studies.

The first of these two databases, the Drug Consumption Database, is a comprehensive and structured source of information on drug

consumption in Europe. It is the result of reviewing, compiling and updating knowledge about European sources of data on drug utilisation in the out- and in-patient healthcare settings. Information is currently available for 17 EU countries (Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Latvia, Norway, Poland, Portugal, Spain, Sweden, The Netherlands, and The United Kingdom) up to October 2012. Work is in progress to expand data available.

The second database, the PROTECT ADR database, is a listing of all adverse drug reactions (ADR) contained in section 4.8 of the summary of product characteristics (SmPC) of medicinal products centrally authorised in the EU. It is based on the Medical Dictionary for Regulatory Activities (MedDRA) terminology. The goal of this database is to improve the efficiency of the detection process of ADRs by allowing quick identification and filtering or flagging of listed and unlisted ADR. This database is updated every 6 months and currently contains information up to 30 June 2012.

For further information, please visit: www.imi-protect.eu

Published on : Fri, 22 Mar 2013