

PROTECT

Pharmacoepidemiological research on outcomes of therapeutics by a European consortium



Summary

The PROTECT project will enhance the monitoring of the safety of medicinal products. It will also contribute to better evaluate and communicate their benefit-risk profile throughout their lifecycle. To this end, innovative tools and methodological standards will be developed. The European Medicines Agency coordinates PROTECT and manages a Consortium of 29 public and private participants.

PROTECT aims at explaining discrepancies between the reported outcomes from pharmacoepidemiology studies by studying combinations of drugs and adverse events in several databases. It will identify and further explore sources of variability that may currently affect drug safety studies. Modern ways of collecting data on medication, lifestyle and risk factors directly from consumers using internet and telephony will also be explored in 4 countries with 5600 pregnant women. The ability of these systems to collect regular, accurate and complete reporting without the intervention of health professionals will be tested. Good practice recommendations for the detection of safety signals are developed based on extensive testing of existing and new methods, creation of a database of known adverse drug reactions, and exploring the use of electronic health records and clinical trials data. In addition, PROTECT will use new modeling approaches to integrate existing information from various data sources to facilitate and enhance the continuous monitoring of the benefit-risk of medicines. Particular emphasis will be given on a graphical representation of benefit-risk profiles for use by patients, healthcare professionals, regulatory agencies, and drug manufacturers.

Achievements & News

PROTECT releases reviews of benefit - risk methods and their visualisation

IMI project PROTECT has published reviews of the available methodologies for the assessment, integration and visualisation of the risks and benefits of medicines. The project team analysed a wide range of methodologies for assessing the benefits and risks of medicines; the report on this shows the links between different methods and groups them. Finally, the report sets out recommendations on the methods that merit further consideration for decision-making on medicines in different contexts. These methods will be explored further in the next stage of the PROTECT project.

PROTECT also analysed different ways of visualising benefits and risks. The report presents visual representations that could be associated with the 13 benefit-risk methodologies recommended in the benefit-risk methodology review, assesses their suitability and offers recommendations for suitable visuals for each benefit-risk assessment approach.

- Both reports, along with a number of case studies, can be found [online](#)

PROTECT project releases major pharmacovigilance databases

IMI's PROTECT project has published two key databases for pharmacovigilance on its website. The inventory of Drug Consumption Databases in Europe provides a comprehensive and structured source of information on drug consumption in Europe, while the PROTECT ADR database is a downloadable Excel file listing all adverse drug reactions (ADRs) listed in the Summary of Product Characteristics (SPC) of medicinal products authorised in the EU. 'We hope that these databases will represent useful resources for the scientific community and for regulatory and public health authorities,' said PROTECT project coordinator Xavier Kurz of the European Medicines Agency (EMA).

(February 2013)

Pregnant women needed for PROTECT survey on medicines use in pregnancy

Elsewhere, the PROTECT team has launched a major, four-country survey on drug use by pregnant women. Although automated systems can find out what medicines have been prescribed for pregnant women, they do not provide information on whether or not the patient actually took the drugs, and they do not cover medicines bought over the counter or herbal and homeopathic remedies. By gathering detailed data on pregnant women's actual medicine intake, as well as information on lifestyle factors, the PROTECT project hopes to be able to improve the advice given to pregnant women and so make pregnancies safer.

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Participants

EFPIA member companies

- GlaxoSmithKline Research and Development LTD, Brentford, UK
- Amgen NV, Brussels, Belgium
- Bayer Schering Pharma AG, Berlin, Germany
- AstraZeneca AB, Södertälje, Sweden
- Genzyme Europe B.V., Naarden, The Netherlands
- H. Lundbeck A/S, Valby, Denmark
- Merck KGaA, Darmstadt, Germany
- Novartis Pharma AG, Basel, Switzerland
- Novo Nordisk A/S, Bagsvaerd, Denmark
- Pfizer Limited, Sandwich, United Kingdom
- F. Hoffmann-La Roche AG, Basel, Switzerland
- Sanofi-Aventis Research and Development, Chilly-Mazarin, France

Universities, Research Organisations, Public Bodies & Non-Profit

- European Medicines Agency
- Lægemiddelstyrelsen (Danish Medicines Agency, Copenhagen, Denmark)
- Agencia Española de Medicamentos y Productos Sanitarios, Madrid, Spain
- Fundación Centro Español de Investigación Farmacoepidemiológica, Madrid, Spain
- Fundació Institut Català de Farmacologia, Barcelona, Spain
- International Alliance of Patients' Organizations, London, UK
- Imperial College of Science, Technology & Medicine, London, UK
- Institut National de la Santé et de la Recherche Médicale, Paris, France
- Ludwig-Maximilians-Universität München, München, Germany
- Mario Negri Institute for Pharmacological Research, Milan, Italy
- Medicines and Healthcare products Regulatory Agency, London, UK
- Rijksuniversiteit Groningen, Groningen, The Netherlands
- Stiftelsen WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden
- University of Newcastle upon Tyne, Newcastle upon Tyne, UK
- Universiteit Utrecht, Utrecht, The Netherlands

SMEs

- LA Santé Épidémiologie Evaluation Recherche, Paris, France
- Outcome Europe Sarl, St. Prex, Switzerland

Facts & Figures

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IMI funding	11 009 715
EFPIA in kind	9 984 734
Other	8 816 164
Total costs	29 810 613

Links and Documents

Project Website: www.imi-protect.eu

Publications

IMI funding per project participant

Contact

Project Coordinator
Xavier Kurz
European Medicines Agency
Pharmacovigilance and Risk Management
London
United Kingdom

EFPIA
Elizabeth Swain
GlaxoSmithKline Research and Development
LTD,
Harlow
United Kingdom

Managing entity of IMI beneficiaries
Per Helboe
Danish Medicines Agency, Licensing Division
Copenhagen
Denmark

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