

PROTECT Project



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International Alliance of
Patients' Organizations

A global voice for patients

Content of Presentation

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About IAPO

- Unique global alliance of 200 national, regional and international groups representing patients
- Established in 1999
- Crossing borders and diseases
- Vision: Patients throughout the world are at the centre of healthcare



Capacity Building



Advocacy



Partnerships

Overview

PROTECT =

Pharmacoepidemiological Research on Outcomes
of Therapeutics by a European ConsorTium

Aim: To strengthen the monitoring of the benefit-risk
of medicines in Europe

Website: www.imi-protect.eu

Work Programmes

WP1: Project management and administration

WP2: Framework for pharmacoepidemiology (PE) studies

WP3: Methods for signal detection

WP4: New methods for data collection from consumers

WP5: Benefit-risk integration and representation

WP6: Validation studies involving an Extended Audience

WP7: Training and communication

Resources and Timeframe

Funded under the Innovative Medicines Initiative Joint Undertaking (IMI JU)

PROTECT will run over **five years (from September 2009)**, with a total funding of **EUR 20 million**. Half of the funding will be in-kind contributions from the participating EFPIA companies.

The Consortium Partners

The European Medicines Agency (EMA) coordinates the project and manages a multi-national consortium of 29 public and private partners.

GlaxoSmithKline is the deputy co-ordinator of PROTECT.

The Consortium Partners

EFPIA Companies

- Amgen NV
- AstraZeneca AB
- Bayer Schering Pharma AG
- F. Hoffman-La Roche AG
- Genzyme Europe BV
- GlaxoSmithKline Research and Development LTD
- H Lundbeck A/S
- Novartis Pharma AG
- Novo Nordisk A/S
- Pfizer Limited
- Sanofi-aventis Research and Development

Regulators

- Spanish Medicines Agency
- European Medicines Agency
- General Practice Research Database (part of MHRA)
- The Danish Medicines Agency
- Medicines and Healthcare products Regulatory Agency, UK
- Stiftelsen WHO Collaborating Centre for International Drug Monitoring (Uppsala)

The Consortium Partners

Academic institutions

- The Catalan Institute of Pharmacology
- The Spanish Centre for Pharmacoepidemiologic Research
- Imperial College, London
- Institut National de la Santé et de la Recherche Médicale (INSERM)
- L.A. Santé Épidémiologie Evaluation Recherche (LASER)
- Ludwig-Maximilians-Universität München
- Mario Negri Institute for Pharmacological Research
- Rijksuniversiteit Groningen
- University of Newcastle upon Tyne
- Universiteit Utrecht

SMEs

- Outcome Europe Sarl

Patient Groups

- International Alliance of Patients' Organizations

WP4: New methods for data collection from consumers

Overall objective: To develop modern methods of data collection directly from consumers in their natural language in several European Union countries, including using web-based screens and computerised telephone interviews.

Summary of study: A non-interventional, prospective study of pregnant women who agree to provide information about their medication use and certain lifestyle factors on a periodic basis throughout their pregnancy.

Countries: Denmark, The Netherlands, Poland, United Kingdom

WP4: New methods for data collection from consumers

Current status:

1. Finalising the detailed protocol
2. Developing the methodology including designing questionnaires, recruitment leaflets etc

IAPO role:

1. Providing patient perspective on all aspects of development of the work programme
2. Playing a leading role in developing the strategy for communicating with, recruiting and retaining research subjects and providing appropriate information

WP5: Benefit-risk integration and representation

Overall objective: To develop methods for use in benefit-risk assessment, including both the underpinning modelling and the presentation of the results, with a particular emphasis on graphical methods.

Summary of work: Review and assess current modelling approaches to benefit-risk analysis in order to recommend new methods of communicating benefit-risk decisions to all stakeholders (patients, healthcare providers, pharmaceutical industry and regulators).

WP5: Benefit-risk integration and representation

Current status:

1. Refining objectives and deliverables
2. Developing criteria for selecting case studies of models of benefit-risk assessment
3. Developing a list of case studies

IAPO role: Providing patient perspective on all aspects of development of the work programme

Thank You!

Any Questions?



Contact us

**Please visit our website to find out more:
www.patientsorganizations.org**

If you would like to receive our monthly email newsletter and details of other publications, please send your details to us:

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