

Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium (PROTECT)

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Research Areas



Tool Development

Clinical Trial

At a Glance

- Status: **Active Consortium**
- Year Launched: **2009**
- Initiating Organization: **Innovative Medicines Initiative**
- Initiator Type: **Government**
- Location: **Europe**

Abstract

The Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium (PROTECT) is an effort of the European Commission's Innovative Medicines Initiative that aims to advance methods for pharmacoepidemiology and pharmacovigilance, in partnership with the European Medicines Agency (EMA). The focus is to understand discrepancies between reported outcomes from pharmacoepidemiology studies by studying combinations of drugs and adverse events in several databases, to identify and explore sources of variability that may currently affect drug safety studies.

Mission

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 to develop and validate a set of innovative tools and methods that:

Consortium History

2009 – Project start date (January)

2013 – PROTECT project releases major pharmacovigilance databases (February)

2013 – The PROTECT team launches four-country survey on drug use by pregnant women

2013 – PROTECT releases reviews of benefit-risk methods and their visualization (July)

2014 – IMI published an updated version of the Drug Consumption Databases (February)

Structure & Governance

The PROTECT governance structure is a multi-layer structure comprising three components:

Governance and scientific oversight

Name	Affiliation	Expertise
Helen Dolk, PhD	Professor of Epidemiology at the University of Ulster, UK	Perinatal epidemiology, pharmacoepidemiology
Trevor Gibbs, MD	Former Head of Global Pharmacovigilance and Product Safety, GSK, UK; Chief Medical Officer at ii4sm	Pharmacovigilance, health outcomes, public health
David Haerry	European AIDS Treatment Group, Brussels, Belgium	Pharmacoepidemiology
Vicky Hogan, PhD	Director, Office of Risk Management and Science, Marketed Health Products Directorate, Health Canada	Benefit-risk assessment
Michael Lewis, MD	EPES Epidemiology, Pharmacoepidemiology and Systems Research GmbH, Berlin, Germany	Pharmacoepidemiology
Allen Mitchell, MD	Slone Epidemiology Center, Boston, USA	Perinatal epidemiology, pharmacoepidemiology
Marcus Müllner, MD	Head of AGES PharmMed (Austrian Medicines and Medical Devices Agency), Austria	Benefit-risk assessment, clinical epidemiology, pharmacovigilance
Gerald Dal Pan, M.D., M.H.S.	Director, Office of Drug Safety, Center for Drug Evaluation and Research, Food and Drug	Pharmacovigilance, drug development, public health,

Administration, USA	and risk management
Munir Pirmohamed, Department of Pharmacology and M.D.	Pharmacology, pharmacovigilance
Samy Suissa, PhD Therapeutics, University of Liverpool, UK	Pharmacoepidemiology, Biostatistics
Department of Epidemiology/Biostatistics, McGill University, Montreal, Canada	

The Steering Committee has the central role in the governance structure and the management of the project. The Steering Committee includes all Work Package co-Leaders, the coordinator, the deputy coordinator, and their alternates.

During the initiation phase of the project, the Steering Committee will in principle meet every month. In the following years, the Steering Committee will meet at least four times annually.

Main roles and responsibilities:

- Finalization and approval of the PROTECT Management Plan,
- Decisions for the initiation and execution of the activities included in the Project Management Plan,
- Approval of the budget allocation to Work Package members and the in-kind contribution from private partners,
- Review of the progress and of the quality control findings of the work program,
- Discussion of recommendations proposed by the External Advisory Board and the Consortium Assembly,
- Decisions regarding communication and dissemination of the project deliverables,
- Discussion of problems and conflicts that may arise during the course of the program when these have not been solved by the coordinator and the deputy coordinator, and
- Decisions regarding the admission of new partners from the Extended Audience.

The coordinator is responsible for the successful management and delivery of the project. He is the contact point for discussions with the IMI JU and is in charge of the execution of the work plan with the Work Package co-leaders and of the implementation of the decisions taken by the Steering Committee. The coordinator is responsible for the overall governance of PROTECT.

The deputy coordinator has three main roles: to coordinate the input (scientific and in-kind) from the private consortium (i.e., industry partners) , to support the coordinator with the development and implementation of the Project Management Plan and delivery of outcomes, and to support the coordinator with governance of PROTECT and be involved in decision-making for the project.

Work Package	Co-Leaders	Partner
WP1	Xavier Kurz	EMA
	Elizabeth Swain	GSK
WP2	Olaf Klungel	UU
	Robert Reynolds	Pfizer
WP3	Niklas Norén	UMC
	Michael Kayser	Bayer
WP4	Omer de Mol	Genzyme
WP5	Deborah Ashby	Imperial
	Alain Micallef	ME
WP6	Lucien Abenhaim	PGRx(LASER)
	Laurent Auclert	SARD
WP7	Joan-Ramon Laporte	FICF
	Elena Rivero	Novartis Pharma

Members of the Extended Audience are European centers that have established or have access to specific clinical trial data, patient registries, cohorts, or case-control resources, or individuals with expertise in specific domains to be addressed by WP6 (pharmacology, clinical expertise, pharmacoepidemiology).

Financing

This project is funded by the Innovative Medicines Initiative, a public-private partnership between the European Union (EU) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), resources of which are composed of financial contributions from the EU Seventh Framework

Programme and EFPIA companies' in-kind contributions. Large pharmaceutical companies participating in IMI projects do not receive IMI funding.

The IMI Intellectual Property (IP) Policy governs the IP regime of all projects funded by the IMI JU. To assist with specific IP queries, IMI has set up a dedicated IP Helpdesk that can be contacted by e-mailing IMI-IP-Helpdesk@imi.europa.eu. The IMI IP policy can be accessed at the following address: http://www.imi.europa.eu/sites/default/files/uploads/documents/imi-ipr-policy01august2007_en.pdf

Patent Engagement

Collection of data directly from patients is essential in many situations. PROTECT will 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.

The PROTECT project will enhance the monitoring of the safety of medicinal products. It will also contribute to better evaluating and communicating their benefit-risk profile throughout their lifecycle. To this end, innovative tools and methodological standards will be developed.

Homepage	http://www.imi-protect.eu/
Other website	http://www.imi.europa.eu/content/protect
Twitter	https://twitter.com/PROTECT_BR

Data Sharing

According to IMI's intellectual property policy, the participants undertake to disseminate the data as soon as reasonably practicable but not later than one year after the termination or expiry of the project. The Project Agreement shall include a description of the material that must be disseminated in accordance with the IP Policy and referenced in the Grant Agreement. If the participants do not disseminate within such time periods without good reason, the Executive Office has the right to disseminate such results in a manner consistent with the Grant Agreement.

Points of Contact

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Sponsors & Partners

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Sanofi-Aventis Research and Development,
Chilly-Mazarin, France

European Medicines Agency
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Agencia Española de Medicamentos y Productos Sanitarios, Madrid, Spain
Fundación Centro Español de Investigación Farmacoepidemiológica, Madrid, Spain
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