PROTECT

Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium

PROTECT

The goal of PROTECT is to strengthen the monitoring of benefit-risk of medicines in Europe by developing innovative methods that will enhance the early detection and assessment of adverse drug reactions from different data sources (clinical trials, spontaneous reporting and observational studies).

These methods will be tested in real-life situations.

PROTECT: Key participants

Public

EMA (Co-ordinator)
Danish Medicines Agency (DKMA)
IAPO
Outcome Europe
University of Munich
FICF
Spanish Medicines Agency (CEIFE)
INSERM
PGRx
Mario Negri Institute
University of Groningen
University of Utrecht
WHO UMC
MHRA
GPRD
Imperial College
University of Newcastle – Upon -Tyne

EFPIA

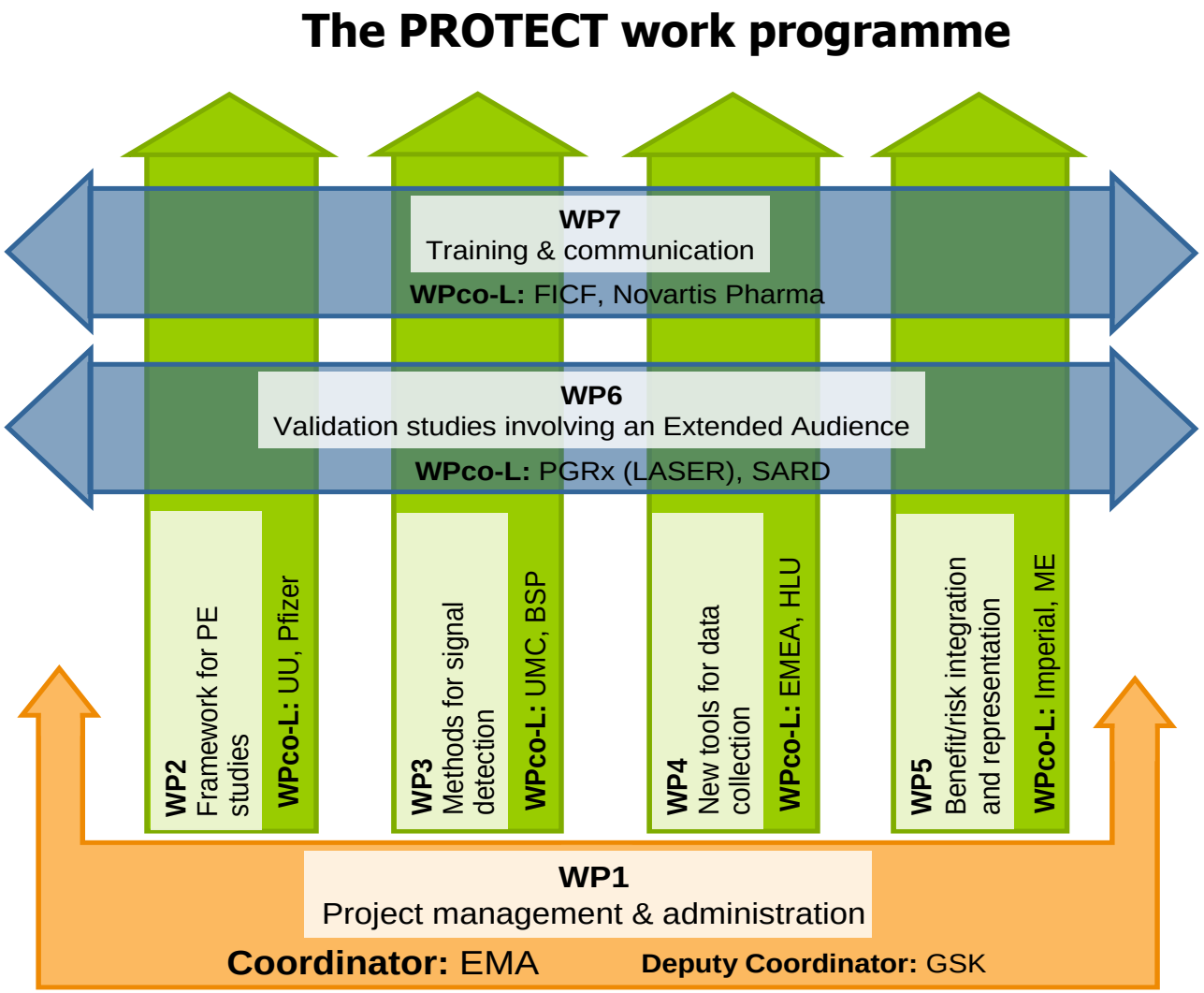
GSK (Deputy Co-ordinator)
Sanofi- Aventis
Roche
Novartis
Pfizer
Amgen
Genzyme
Merck Serono
Bayer Schering
Astra Zeneca
Lundbeck
NovoNordisk

Objectives

The objectives and deliverables will be addressed in PROTECT using six distinct Work Packages (WPs), each developing certain specific scientific components of the overall Project. One additional WP will be responsible for the governance and management of the Project.

Work Package	**Work Package title**
1	Project management and administration
2	Framework for pharmacoepidemiological studies
3	Methods for signal detection
4	New tools for data collection from consumers
5	Benefit-risk integration and representation
6	Validation studies involving an Extended Audience
7	Training and communication

Project Plan



WP2: Framework for Pharmacoepidemiological Studies

Objective

To develop, test and disseminate methodological standards for the design, conduct and analysis of pharmacoepidemiological studies, applicable to different safety issues using different data

Example

To develop study protocols between selected drugs and key AEs

To provide guidelines on how to identify public health impact of AEs

To investigate discrepancies in results between databases and explore differences with other data sources

To evaluate identified signal from signal detection strategies in electronic health databases

WP3: Methods for Signal Detection

Objective

To develop new methods, and assess existing ones, for signal detection from spontaneous reports, electronic health records and clinical trials

Example

To provide advice on good signal detection practices

To develop new methods for signal detection

To implement and examine the value of screening methods in EHR

To evaluate the performance of disproportionality analysis based on novel grouping tools applied to adverse reactions

WP4: New Tools for Data Collection from Consumers

Objective

To develop modern methods of data collection directly from consumers in their natural language in several EU countries, including using web-based screens, text messaging and computerised telephone interviews

Example

To assess the feasibility, efficiency and usefulness of these tools

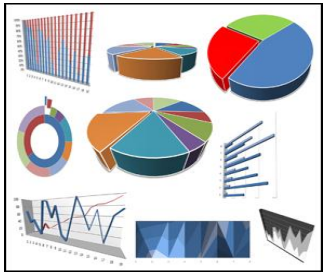
To pilot approaches between data sources

To measure the acceptability of these methods and assess the transferability of data collection methods in different countries and for other conditions

WP5: Benefit-Risk Integration and Representation

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



Example

To identify, characterise and test methods of collating data on benefit and risks from various data sources

To identify, test and compare modelling approaches that would allow continuous benefit-risk modelling along the lifecycle of the products

To develop methods of graphical expression of the benefits and risk of the medicinal products

Work Packages

WP6 Objective

To validate methods developed in WP2 to 5 in various data sources owned or managed by Consortium Partners or members of the Extended Audience

WP7 Objective

To identify training opportunities and support training programmes in the fields addressed by PROTECT

Dissemination of Results

The Project will generate a number of reports providing standards and recommendations which Will be widely disseminated through:

PROTECT web portal

It will include a webpage accessible to the general public where relevant deliverables for public Use will be posted http://www.imi-protect.eu/index.html

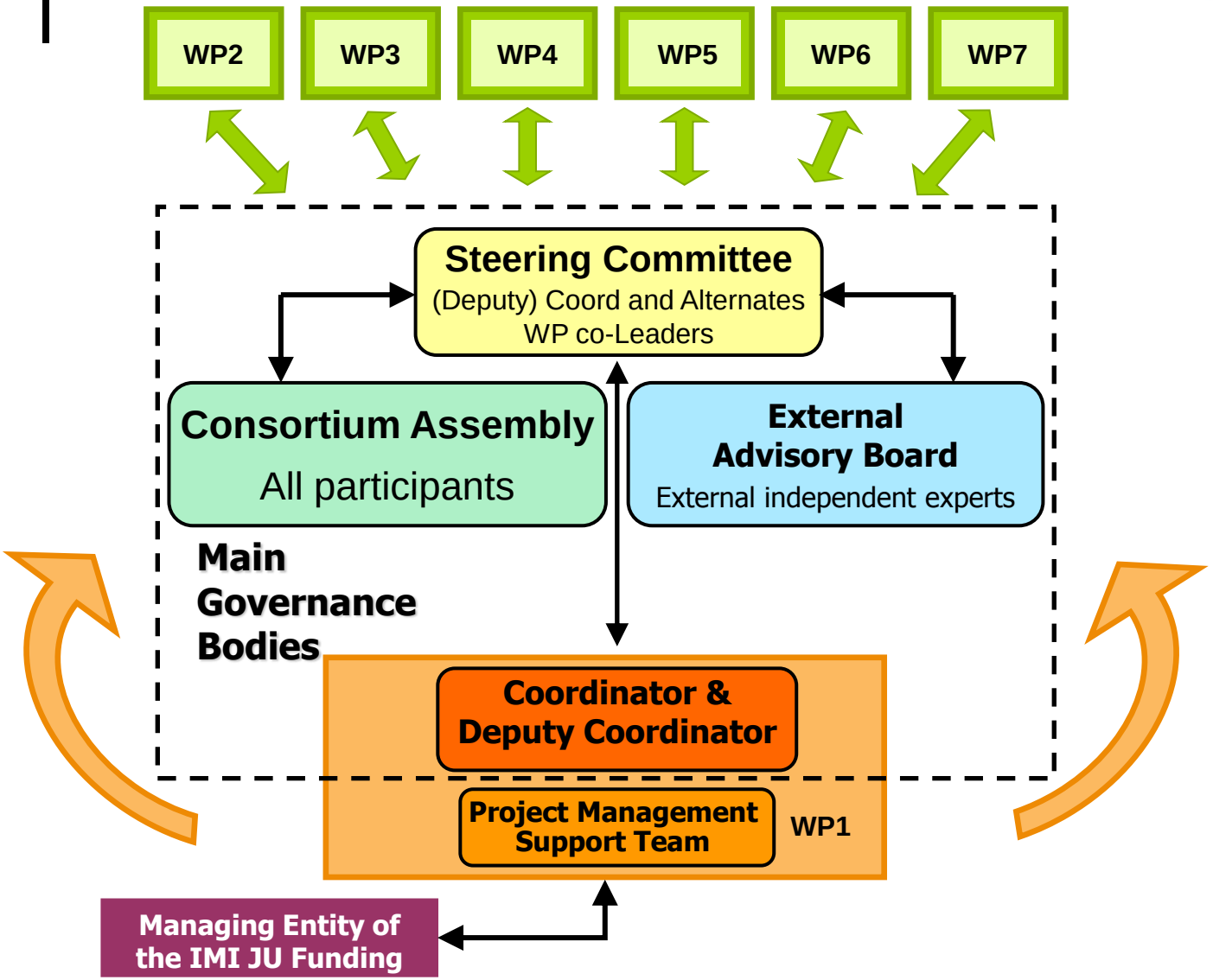
Publications

Most deliverables of the project will be produced in the first instance as reports delivered to the IMI JU and they will also be published and disseminated through the appropriate mediums

ENCePP network

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance is a project led by the EMEA intended to further strengthen the post-authorisation monitoring Of medicinal products in Europe. The results of the PROTECT programme will be made available to all ENCePP members.

Management structure



List of members of the External Advisory Board

Name	Affiliation	Expertise
De Vries Corinne, PhD	Department of Pharmacy and Phamacology, University of Bath, UK	Pharmacoepidemiology
Trevor Gibbs, MD	Former Head of Global Pharmacovigilance and Product Safety, GSK, UK	Pharmacovigilance Health Outcomes Public Health
David Haerry	European AIDS Treatment Group (EATG), Brussels, Belgium	Public Health Patients' preference
Vicky Hogan, MSc	Associate Director General, Marketed Health Products Directorate (MHPD), Health Canada, Canada	Benefit-risk assessment
Michael Lewis, MD	EPES Epidemiology, Pharmcoepidemiology 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 (CDER), Food and Drug Administration (FDA), USA	Pharmacovigilance Drug development Public Health & Risk management
Munir Pirmohamed, MD	Department of Pharmacology and Therapeutics, University of Liverpool, UK	Pharmacology Pharmacovigilance
Samy Suissa, PhD	Division of Epidemiology/Biostatistics, McGill University, Montreal, Canada	Biostatistics Pharmacoepidemiology