PROTECT

imi efpia

Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium

Status of the WP5 (benefit-risk assessement and communication) of the IMI PROTECT Consortium

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Annual Workshop on
Visualising Benefit-Risk: the key to developing a framework that informs stakeholder perspective and clarity of decision making

Wahington 16-17th June 2011

Title

Overview

- The Innovative Medecine Initiative (IMI)
- The PROTECT project
  - Objective
  - Structure
  - Budget
- The WP 5 (B-R modeling and graphical representation)
  - Charter
  - Membership
  - Structure/organisation
  - WorkPlan and current status

Cascade and interdependencies

The Innovative Medecines Initiative (IMI)

- Mission
  - The Innovative Medicines Initiative (IMI) is Europe's largest public-private partnership aiming to improve the drug development process by supporting a more efficient discovery and development of better and safer medicines for patients.
  - IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.

The Innovative Medecines Initiative (IMI)

- Call for proposals 2008, 2009, 2010, 2011
  - 1st Call 2008 Safety:
    - **MARCAR** (BIOMARKERS AND MOLECULAR TUMOUR CLASSIFICATION FOR NON-GENOTOXIC CARCINOGENESIS)
    - **eTOX** INTEGRATING BIOINFORMATICS AND CHEMOINFORMATICS APPROACHES FOR THE DEVELOPMENT OF EXPERT SYSTEMS ALLOWING THE *IN SILICO PREDICTION OF TOXICITIES*
    - **SAFE-T** SAFER AND FASTER EVIDENCE-BASED TRANSLATION
    - **PROTECT: P**HARMACOEPIDEMIIOLOGICAL **R**ESEARCH ON **O**UTCOMES OF **T**HERAPEUTICS BY A **E**UROPEAN **C**ONSORTIUM
  - Efficay…
  - Education and training…
  - Most Deliverables lead to publications:

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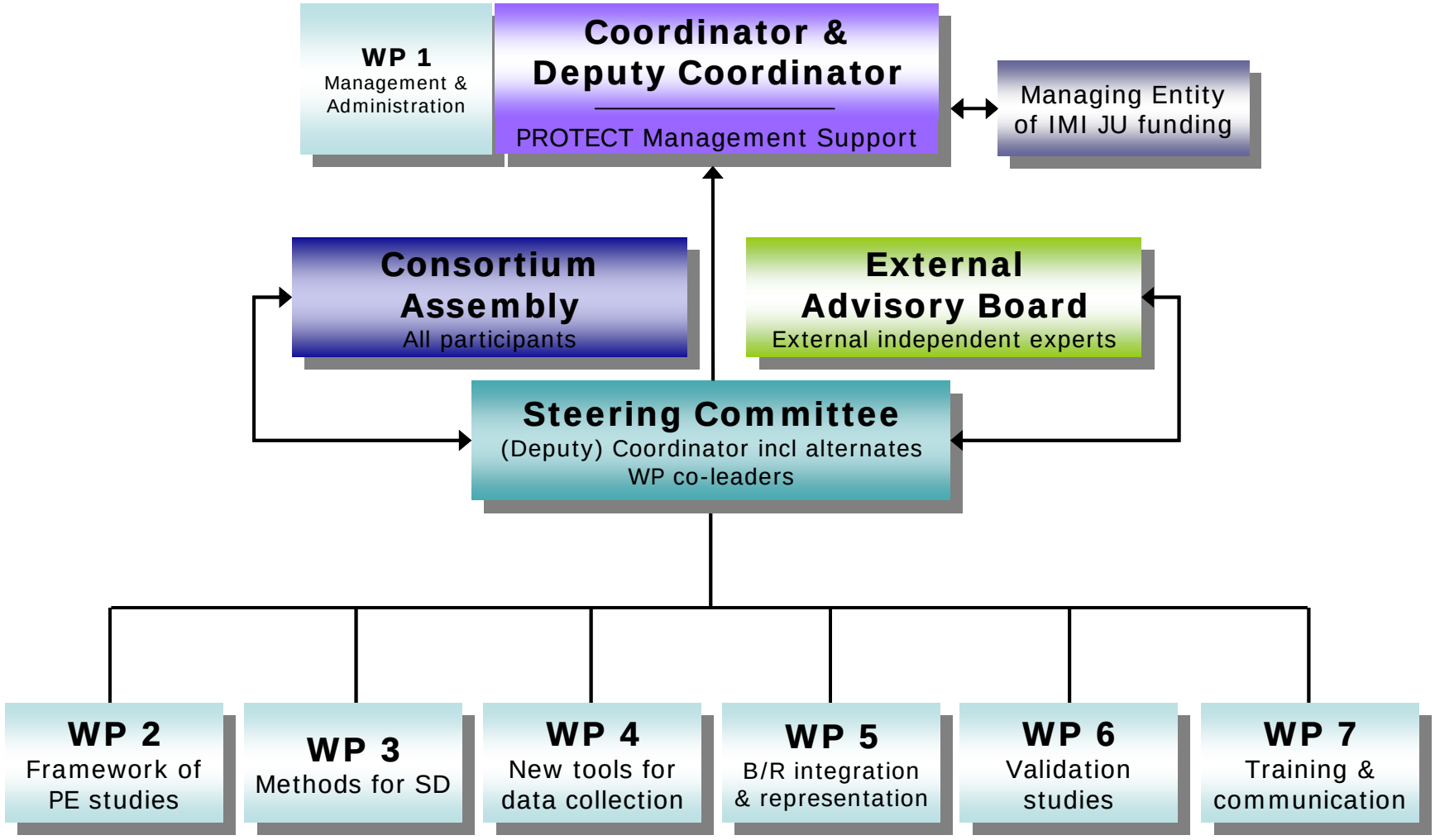
The PROTECT project (Consortium)

Objectives of PROTECT (http://www.imi-protect.eu)

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;
- 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.

The PROTECT project (governance)



PROTECT Consortium External Advisory Board

Name	Affiliation	Expertise
Corinne De Vries, PhD	Department of Pharmacy and Pharmacology, University of Bath, UK	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 (EATG), Brussels, Belgium	Pharmacoepidemiology
Vicky Hogan, PhD	Director, Office of Risk Management and Science, Marketed Health Products Directorate (MHPD), 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 (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	Department of Epidemiology/Biostatistics, McGill University, Montreal, Canada	Pharmacoepidemiology, Biostatistics

The PROTECT project (Consortium)

Project Name (short)	**PROTECT**
Project Name (full)	**Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium**
Dates	
Start date:	**01 September 2009**
Total duration:	**60 months**
End date:	**31 August 2014**
Coordination	
Coordinator	**European Medicines Agency**
Deputy Coordinator	**GlaxoSmithKline Research and Development LTD**
Project Information	
Website:	**http://www.imi-protect.eu**
Funding	
Funding scheme	**Innovative Medicines Initiative Joint Undertaking (http://imi.europa.eu)**
IMI Grant Agreement	**No. 115004**
IMI maximum cash funding	**€ 11.009.715**
EFPIA in kind contribution	**€ 9.865.235**
Other contribution	**€ 61.948**
Total Project Funding	**€ 20.936.898**

Work Package 5 of PROTECT

- Charter
  - Scope
    - post -approval, while recognising the relevance of pre - approval B-R assessment
    - individual and population- based decision making
    - the perspectives of patients, physicians, regulators and other stakeholders (hTA)
    - possible interdependencies with other PROTECT Work Packages as well as other relevant external initiatives.
  - Review and selection of methodologies and of visualisation methods
  - Choice and implementation of case studies
  - Visualisation
  - Communication (publications)

Work Package 5 of PROTECT (membership)

- **Public**
  - EMA
  - DKMA
  - AEMPS
  - MHRA
  - Imperial College (co-leader)
  - Mario Negri Institute
  - GPRD
  - WHO Upsala
  - IAPO
- **Private**
  - AstraZeneca
  - Bayer
  - GSK
  - Lundbeck
  - Merck KGaA (co-leader)
  - Novartis
  - Novo
  - Pfizer
  - Roche
  - Sanofi-Aventis
  - Takeda

Work Package 5 of PROTECT (organisation)

- 6 Workstreams

  - Charter (Alain Micaleff; Merck KGaA)
  - Review of methodologies and graphical tools (Ioana Tzoulakis; Imperial)
  - Choice of Case studies (2 waves) (John Pears; AZ)
  - Collection of data (Larry Philipps; EMA)
  - Software to support application of methodologies and graphical tools (Deborah Ashby; Imperial)
  - Application to case studies (R. Nixon; Novartis + G. Quartey; Roche)

Work Package 5 of PROTECT

- Achievements Year 1
  - Charter completed (re-opened for inclusion of recommendations from EAB)
  - Protocol for review of methodologies
  - Selection Case studies wave 1 (Tysabri, Raptiva, Acomplia, Ketek)
  - Framework for data collection (PrOACT)
  - Interaction with other initiatives
    - OMOP
    - Sentinel
    - BRAT (22 June, 10 Nov 2010)
  - Numerous presentations at congresses, conferences, meetings

Work Package 5 of PROTECT

- Ongoing activities Year 2
  - Conduct review of B-R methodologies and visualisation methods (planned publication)
  - Criteria for and selection of wave 2 case-studies
  - Determine and gather data for case studies

Thank you for your attention

Questions ? (there are back-up slides)

WP 5 back-up documents

- Charter

Microsoft Office
rd 97 - 2003 Docum

- Membership

Microsoft Office
Word Document

- Year 1 summary report

Microsoft Office
Word Document

- EAB recommendations:

Microsoft Office
Word Document