PROTECT

imi efpia

Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium

Why is PROTECT so important to the EMA and drug safety in Europe?

2013 ISPE Mid Year Meeting
Munich

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Declaration

I work for the EMA and am:

Alternate Co-ordinator of PROTECT

Leader of WP4 of PROTECT

Some of my slides are “borrowed” from EMA colleagues and from PROTECT

PROTECT is receiving support from the Innovative Medicines Initiative Joint Undertaking (www.imi.europa.eu), resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution.

Rôle of the EMA

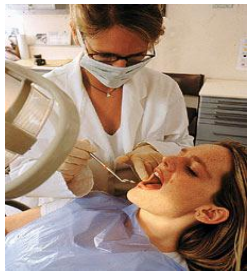
To foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health

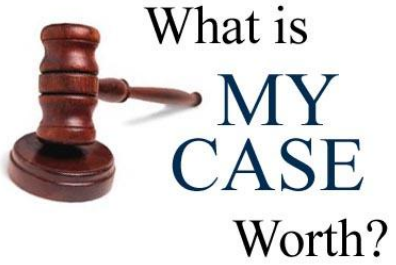
Legal requirements

Provide MSs and EU institutions with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products

Coordination of the monitoring of medicinal products for human use which have been authorised within the Union, and providing advice on the measures necessary to ensure the safe and effective use of these medicinal products……

Main sources of spontaneous adverse reaction reports





Eudravigilance Database

6.2 million ICSRs
4 million unique cases

2012 figures

- Approx. 1 million post-marketing ICSRs received
- Approx. 82,000 CT reports received
- On average 92,000 ICSRs per month (72,000 in 2011)
- Almost 100,000 duplicates assessed

Main sources of observational research

efpia

ISPE
INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMIOLOGY

INTERNATIONAL SOCIETY *for* PHARMACOEPIDEMIOLOGY
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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENEPP
European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Two studies on the use of statins and the risk of fracture done in GPRD around the same period by two different groups.

	Meier et al., 2000		Van Staa et al., 2011	
Statins only	Current use	0.55 (0.44-0.69)	Current use	1.01 (0.88-1.16)
	N prescriptions		Time since use	
	• 1-4 • 5-19 • 20	0.51 (0.33-0.81) 0.62 (0.45-0.85) 0.52 (0.36-0.76)	• 0-3 months • 3-6 months • 6-12 months • > 12 months	0.71 (0.50-1.01) 1.31 (0.87-1.95) 1.14 (0.82-1.58) 1.17 (0.99-1.40)
	Recent use	0.67 (0.50-0.92)		
	Past use	0.87 (0.65-1.18)	Past use	1.01 (0.78-1.32)
Statins (current) and type of fractures	Femur Hand, wrist or arm Vertebral Other	0.12 (0.04-0.41) 0.71 (0.52-0.96) 0.14 (0.02-0.88) 0.43 (0.23-0.80)	Hip Radius/ulna Vertebral	0.59 (0.31-1.13) 1.01 (0.80-1.27) 1.15 (0.62-2.14)

The PROTECT programme

To strengthen the monitoring of benefit-risk of medicines in Europe by developing innovative methods

to enhance early detection and assessment of adverse drug reactions from different data sources (clinical trials, spontaneous reporting and observational studies)

to enable the integration and presentation of data on benefits and risks

- These methods will be tested in real-life situations.

Partners

Public

Regulators:
EMA (Co-ordinator)
DH#MA (DK)
AEMPS (ES)
MHRA (UK)

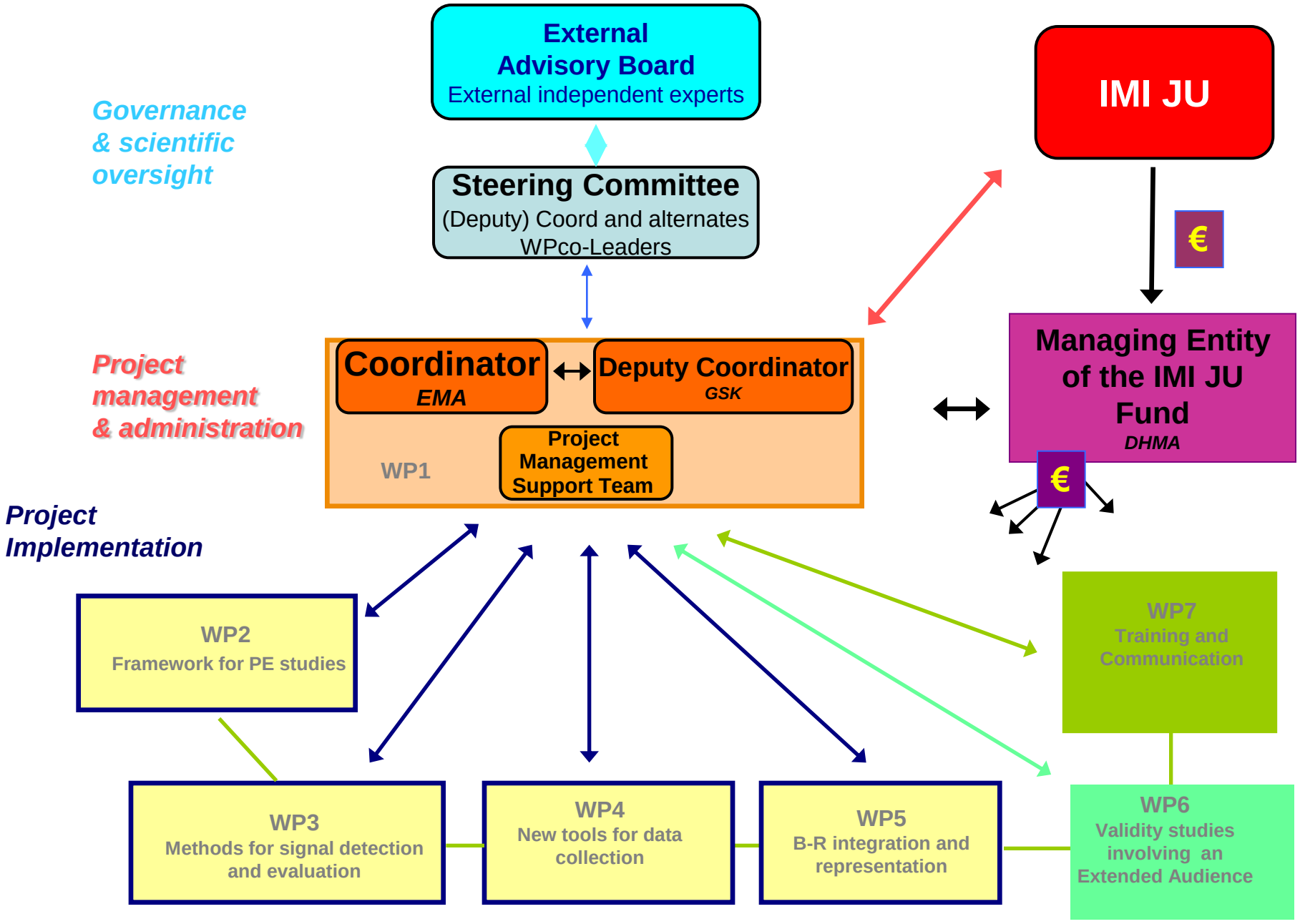
Academic Institutions:
Aarhus University
University of Munich
FICF (Barcelona)
INSERM (Paris)
Mario Negri Institute (Milan)
Poznan University of Medical Sciences
University of Groningen
University of Utrecht
Imperial College London
University of Newcastle

Others:
WHO UMC
GPRD
IAPO
CEIFE

SMEs:
Outcome Europe
LASER

Private

EFPIA companies:
GSK (Deputy Co-ordinator)
Sanofi- Aventis
Roche
Novartis
Pfizer
Amgen
Genzyme
Merck Serono
Bayer
Astra Zeneca
Lundbeck
NovoNordisk
Takeda
Eli Lilly and companies


External
Advisory Board
External independent experts
IMI JU
Governance
& scientific
oversight
Steering Committee
(Deputy) Coord and alternates
WPco-Leaders
€
Project
management
& administration
Coordinator
EMA
Deputy Coordinator
GSK
Managing Entity
of the IMI JU
Fund
DHMA
WP1
Project
Management
Support Team
€
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Implementation
WP2
Framework for PE studies
WP7
Training and
Communication
WP3
Methods for signal detection
and evaluation
WP4
New tools for data
collection
WP5
B-R integration and
representation
WP6
Validity studies
involving an
Extended Audience

More information?

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