Innovative Medicines Initiative

IMI: A Public Private Partnership Funder

25-26 July 2011, European Medicines Agency

Transatlantic workshop:

Drug-related Progressive Multifocal Leukoencephalopathy

The Innovative Medicines Initiative (IMI): the largest PPP in life sciences R&D

Why Apply ?

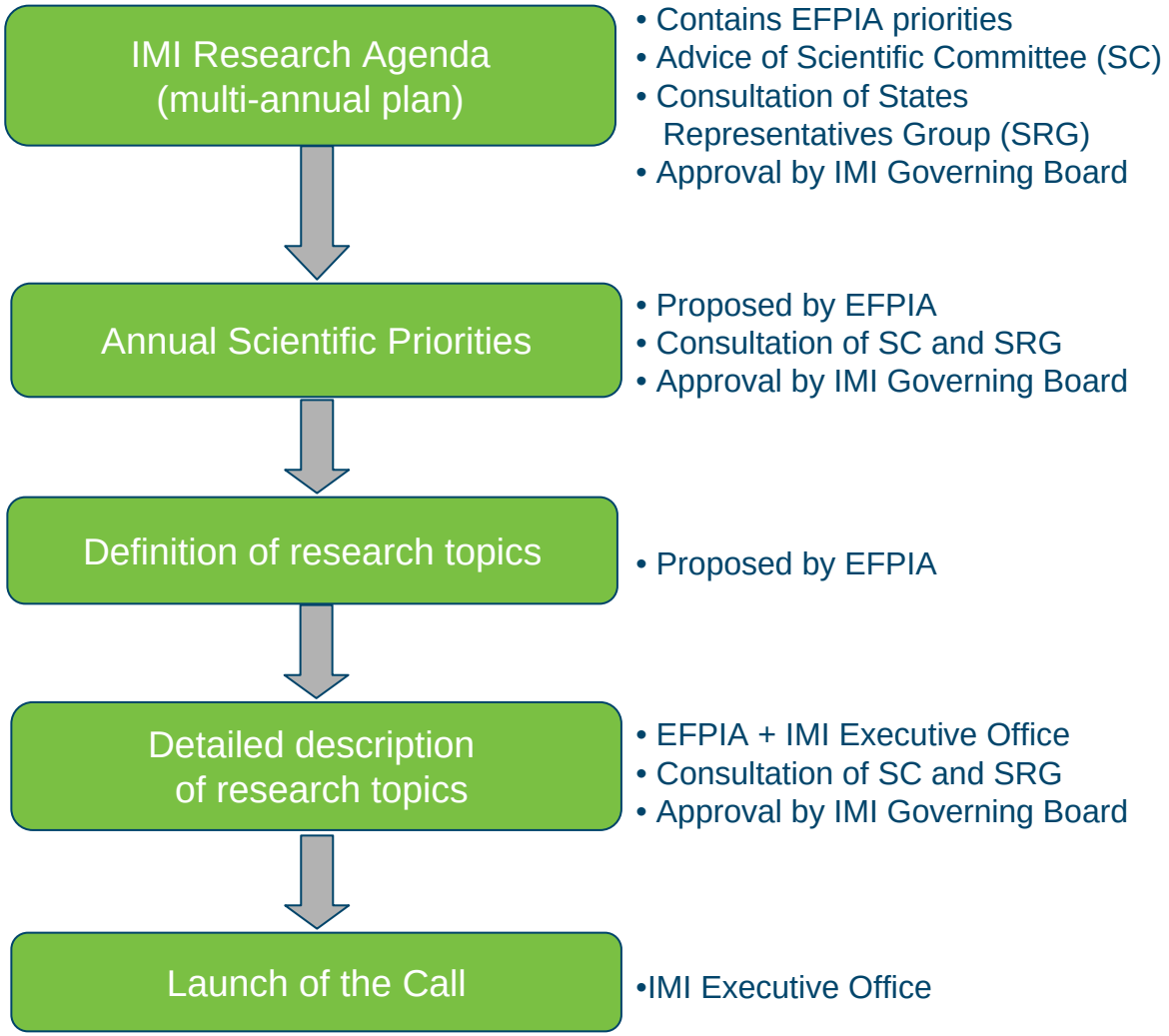
- Funding
- Addressing issues too ‘big’ to be addressed individually
- Access to data and resources not normally available
- Interested in collaborating with large pharmaceutical companies
- Interested in patient-centric biomedical/pharmaceutical research

Key Concepts

- Non-competitive research for EFPIA companies
- Competitive calls for IMI beneficiaries
- Open collaboration in final consortia

Building a IMI Project (1)

Call definition and launch



Building a IMI Project (2)

Competition between applicants' consortia
(potential IMI beneficiaries)

Submission of Expressions of Interest
- By applicants' consortia (academics, SMEs, Patient org….)

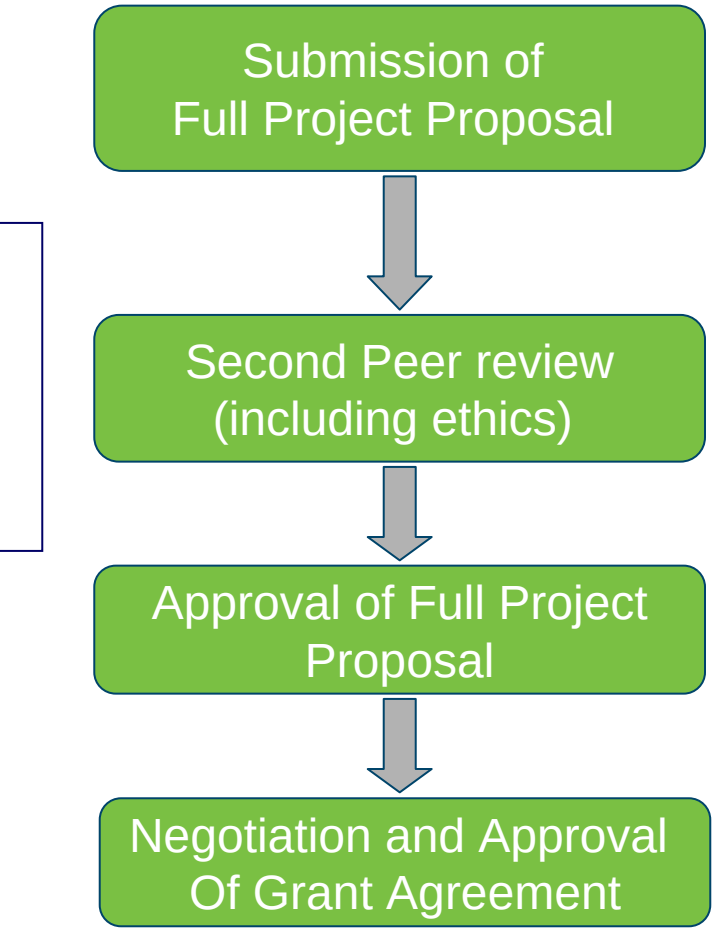
First Peer review
- assessment: Independ. experts + EFPIA coordin.
- ranking: Independ. experts

First ranked consortium
- Approved by IMI Governing Board

Invitation to submit Full Project Proposal
- to first ranked applicants' consortium + EFPIA consortium

Building a IMI Project (3)

Joint Preparation of Full Project Proposal



- By full project consortium (first ranked applicants' consortium + EFPIA consortium)
- Independent experts
- by IMI Governing Board
- by full project consortium + IMI Executive Office

Eligibility for IMI JU funding

- Eligible **for funding**
  - Academia
  - SMEs (EU definition)
  - Patient Organisations
  - Non-profit research organisations
  - Intergovernmental organisations

- Non-eligible **for funding**
  - EFPIA companies (in-kind contribution)
  - Companies not falling within the EU definition of SMEs
  - Others

Funding Rules

- Direct costs (personnel, consumables, equipment,…)
- Indirect costs **= overheads**

  Flat-rate of 20% of direct eligible costs

  or

  actual indirect costs (**NEW!**)

- **Funding rates**
  - Research activities

    -> 75% of total eligible costs
  - Other activities, including management and training

    -> 100% of total eligible costs

Intellectual Property Policy: Guiding Principles

- **Aligned with IMI objectives**
  - to promote knowledge creation
  - to facilitate dissemination and exploitation
  - to achieve fair allocation of rights
  - to reward innovation
  - to achieve a broad participation of private and public entities

- **Provides flexibility for participants**

Ownership: Basic Principles

- **Background** remains the exclusive property of each participant
- **Foreground** (Project results) are owned by the generator(s)
- Possibility to **freely license, assign or otherwise dispose** of its ownership rights provided access rights to other partners are respected
- **Possible transfer** of ownership

Access Rights: basic principles

- Granted on **written request**, unless otherwise agreed
- **Non-exclusive** basis approach
- **No sub-licences**, unless otherwise agreed
- Not affected by the termination of participation
- Guiding framework for participants, affiliates and third parties
- Terms: royalty-free basis / fair and reasonable / to be negotiated

Calls 1 & 2: Consolidated Figures

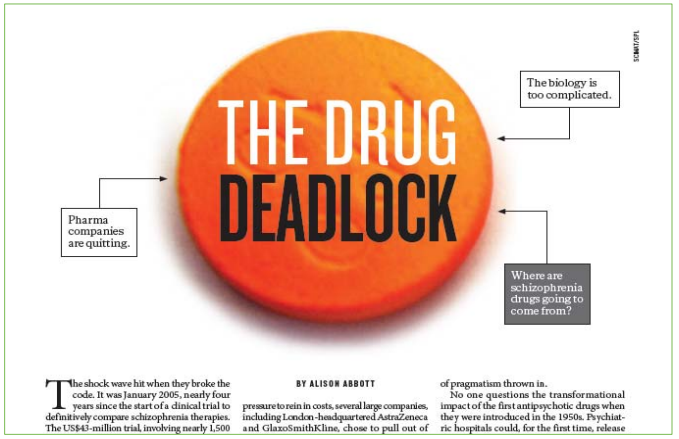
	Call 1	Call 2	Total
Projects	15	8	23
EFPIA Companies	21	21	23
Academic teams	195	103	298
SME teams	24	23	47
Patients' organisat.	9	2	11
Total Budget (M€)	281	172	453

NEWMEDS

Develops biomarkers and tools and models to allow better targeted treatments for schizophrenia and depression

19 Partners

- 9 EFPIA companies
- 7 Public organisations
- 3 SMEs



Nature, 11 November 2010

First achievements

- ✓ Has assembled the largest known repository of antipsychotic clinical trial data.
- ✓ The database contains information on 23 401 patients from 67 industry sponsored studies.
- ✓ Bringing together data from public projects and 3 companies on the genetics and clinical response in 1800 well characterized patients with depression.

U-BIOPRED

By comparing data from several hundreds of people, the team will characterise different kinds of severe asthma, paving the way towards a new classification of asthma *and personalised treatments for patients*

38 Partners

- 9 EFPIA companies
- 23 Academic institutions
- 3 Patients' organisations
- 3 SMEs
- 1 non-SME company

First achievements

✓ Consensus statement on the definition of severe refractory asthma

Diagnosis and definition of severe refractory asthma: an international consensus statement from the Innovative Medicine Initiative (IMI)

Elisabeth H Bel,[1] Ana Sousa,[2] Louise Fleming,[3] Andrew Bush,[4] K Fan Chung,[5] Jennifer Versnel,[6] Ariane H Wagener,[1] Scott S Wagers,[7] Peter J Sterk,[1] Chris H Compton,[8] on behalf of the members of the Unbiased Biomarkers for the Prediction of Respiratory Disease Outcome (U-BIOPRED) Consortium, Consensus Generation[9]

ABSTRACT

Patients with severe refractory asthma pose a major healthcare problem. Over the last decade it has become increasingly clear that, for the development of new targeted therapies, there is an urgent need for further characterisation and classification of these patients. The

DIAGNOSIS AND DEFINITION OF SEVERE ASTHMA OVER THE LAST 15 YEARS

Various documents proposing different clinical definitions of 'severe asthma' in adults and children have been published over the last 15 years by international task forces, workshops, networks and

Thorax, in press

eTOX

Builds a large searchable database containing drug toxicity-related data extracted from relevant pharmaceutical pre-clinical legacy reports

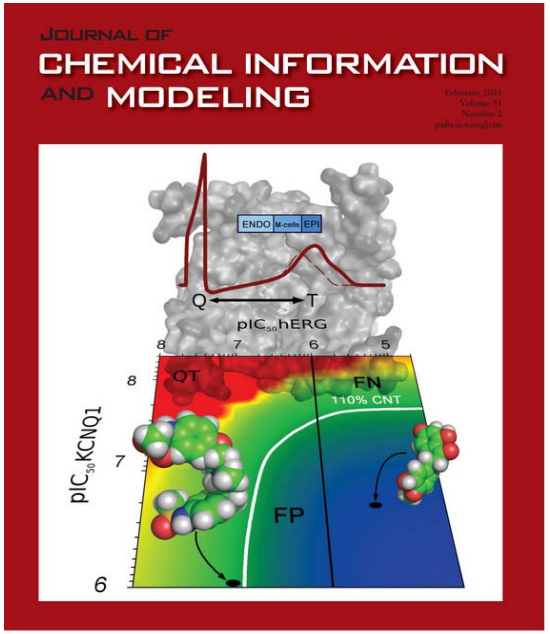
Develops innovative methodological strategies and novel software tools to better predict in silico the toxicological profiles of new molecular entities in early stages of the drug development pipeline, using its database background

25 Partners

- 13 EFPIA companies
- 8 Public organisations
- 4 SMEs

First achievements

✓ An innovative multi-scale modelling strategy for the prediction of cardiotoxicity has been developed, successfully tested and published



J. Chem. Inf. Model. 2011; 51:483-92

SAFE-T

Addresses the current lack of sensitive and specific clinical tests to diagnose and monitor drug-induced injury to the kidney, liver and vascular tissues in man, which is a major hurdle in drug development

20 Partners

- 11 EFPIA Pharma Companies
- 5 Academic Institutions
- 4 SMEs

A generic operational strategy to qualify translational safety biomarkers

Katja Matheis[1], David Laurie[2], Christiane Andriamandroso[3], Nadir Arber[4], Lina Badimon[5], Xavier Benain[6], Kaïdre Bendjama[7], Isabelle Clavier[6], Peter Colman[8], Hüseyin Firat[7], Jens Goepfert[9], Steve Hall[8], Thomas Joos[10], Sarah Kraus[4], Axel Kretschmer[11], Michael Merz[2], Teresa Padro[5], Hannes Planatscher[9], Annamaria Rossi[8], Nicole Schneiderhan-Marra[9], Ina Schuppe-Koistinen[12], Peter Thomann[7], Jean-Marc Vidal[13] and Béatrice Molac[7]

[1] Boehringer-Ingelheim Pharma GmbH & Co. KG, Biberach, Germany
[2] Novartis Pharma AG, Basel, Switzerland
[3] Interface Europe, Brussels, Belgium
[4] Tel-Aviv (Souraski) Medical Center, Tel-Aviv, Israel
[5] Barcelona Cardiovascular Research Center (ICCC-CISC), Barcelona, Spain
[6] Sanofi-Aventis, Paris, France
[7] Firalis SAS, 35 rue du Fort, 68330 Huningue, France
[8] Pfizer Ltd, Sandwich, UK
[9] Natural and Medical Sciences Institute, Reutlingen, Germany
[10] Experimental & Diagnostic Immunology GmbH, Reutlingen, Germany
[11] Bayer Schering Pharma AG, Leverkusen, Germany
[12] AstraZeneca R&D, Södertälje, Sweden
[13] EMA, London, UK

Drug Discov Today, in press

First achievements

- ✓ 153 potential biomarker candidates for drug-induced injury of the kidney, liver and vascular system have been evaluated and are currently undergoing clinical evaluation.
- ✓ The strategy adopted has been agreed with the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA).

MARCAR

MARCAR Consortium

Developing biomarkers that will allow the prediction of unwanted non-genotoxic carcinogen (NGC) effects of drugs at a very early stage of their development

12 Partners

- 5 EFPIA Pharma Companies
- 6 Academic Institutions
- 1 SME

marcar
towards novel biomarkers
for cancer risk assessment

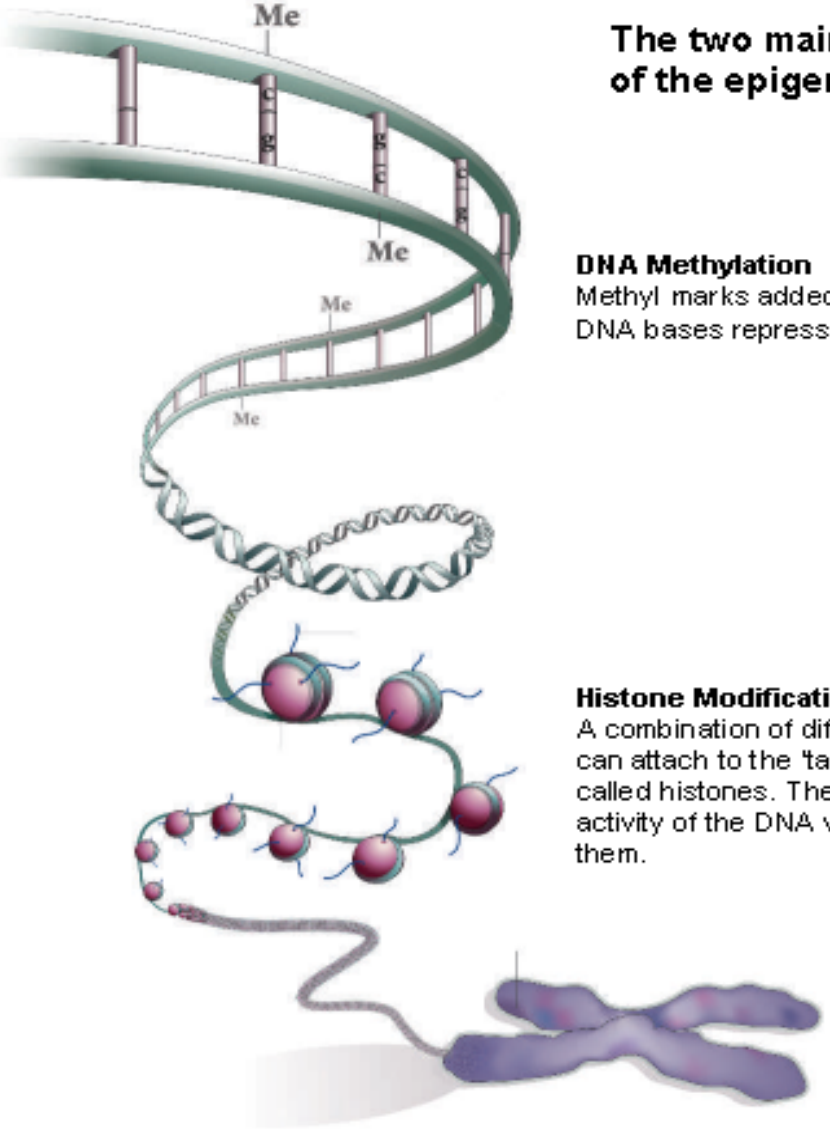
marcar

towards novel biomarkers
for cancer risk assessment

Phenobarbital mediates an epigenetic switch at the constitutive androstane receptor (CAR) target gene Cyp2b10 in the liver of B6C3F1 mice.

Lempiäinen H, Müller A, Brasa S, Teo SS, Roloff TC, Morawiec L, Zamurovic N, Vicart A, Funhoff E, Couttet P, Schübeler D, Grenet O, Marlowe J, Moggs J, Terranova R.

PLoS One. 2011 Mar 24;6(3):e18216.



The two main components of the epigenetic code

DNA Methylation
Methyl marks added to certain DNA bases repress gene activity

Histone Modification
A combination of different molecules can attach to the 'tails' of proteins called histones. These alter the activity of the DNA wrapped around them.

efpia

PROTECT

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

- 19 Partners
  - 12 EFPIA companies
  - 15 Public organisations
  - 2 SMEs

- ✓ Comparison of data held in public databases for 5 classes of drugs and 5 ADRs
- ✓ Inventory of public sources of information from across Europe
- ✓ Development of new simulation models
- ✓ Database containing summary of product characteristics has been constructed for 348 substances

- **EMA co-ordinating the project**

IMI Education & Training Projects

- ✓ First course in Nov 2010 on drug discovery development
- ✓ Certificate and Master courses in pharmacovigilance and pharmacoepidemiology in Sept 2011
- ✓ EU syllabus on pharmaceutical medicine
- ✓ Database on over 700 master courses, 110 professional development courses, 380 learning tools

Call 4 topics

Medical Information System

1. A European Medical Information Framework (EMIF) of patient-level data to support a wide range of medical research (includes opportunities for Alzheimer's and obesity experts)
2. eTRIKS: European translational information and knowledge management services

Chemistry, Manufacturing and Control

3. Delivery and targeting mechanisms for biological macromolecules
4. *In vivo* predictive biopharmaceutics tools for oral drug delivery
5. Sustainable chemistry – delivering medicines for the 21st century

Technology and Molecular Disease Understanding

6. Human induced pluripotent stem (hiPS) cells for drug discovery and safety assessment
7. Understanding and optimising binding kinetics in drug discovery

Innovative Medicines Initiative

www.imi.europa.eu

THANK YOU !