Innovative Medicines Initiative

Introduction to IMI Procedures and Recent Project Achievements

Open Info Day, Brussels, 17 June 2011

efpia

Why to Apply ?

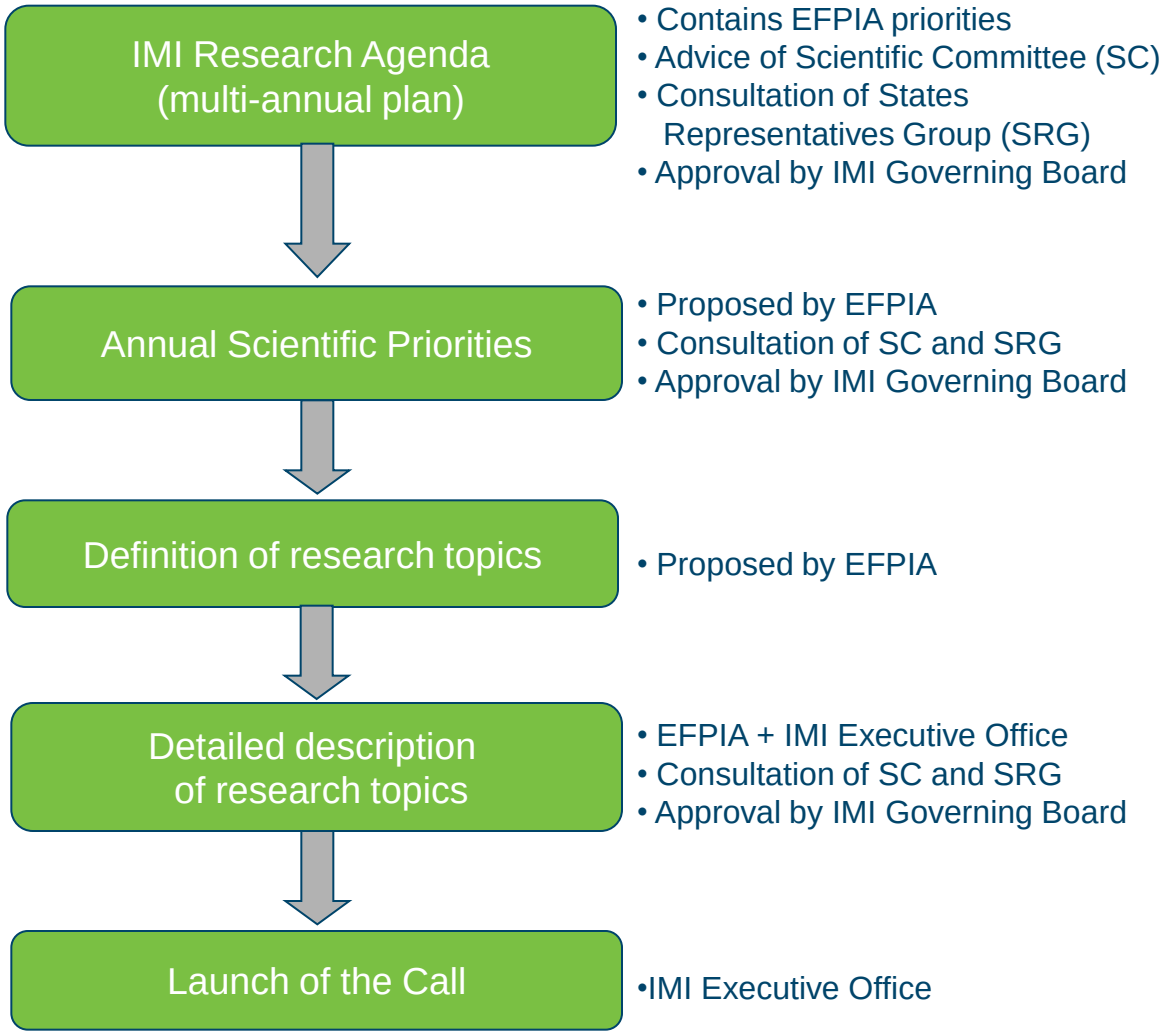
- Looking for additional funding
- Interested in patient-centric biomedical/pharmaceutical research
- Interested in collaborating with large pharmaceutical companies

Key Concepts

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

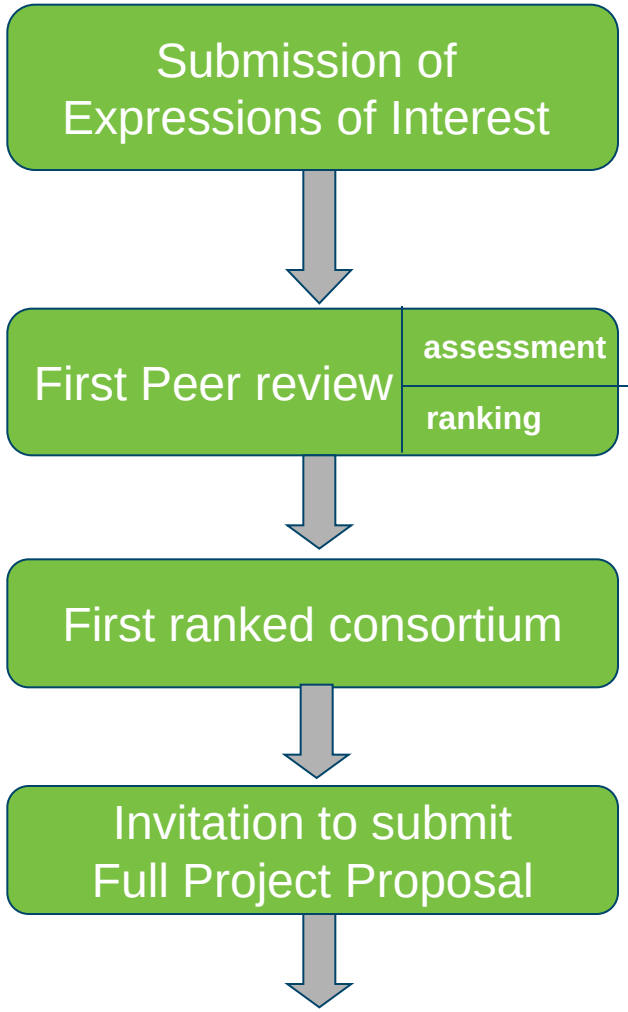
Building a IMI Project (1)

Call definition and launch



Building a IMI Project (2)

Competition between applicants' consortia
(potential IMI beneficiaries)



- By applicants' consortia (academics, SMEs, Patient org….)
- Independ. experts + EFPIA coordin.
- Independ. experts
- Approved by IMI Governing Board
- to first ranked applicants' consortium + EFPIA consortium

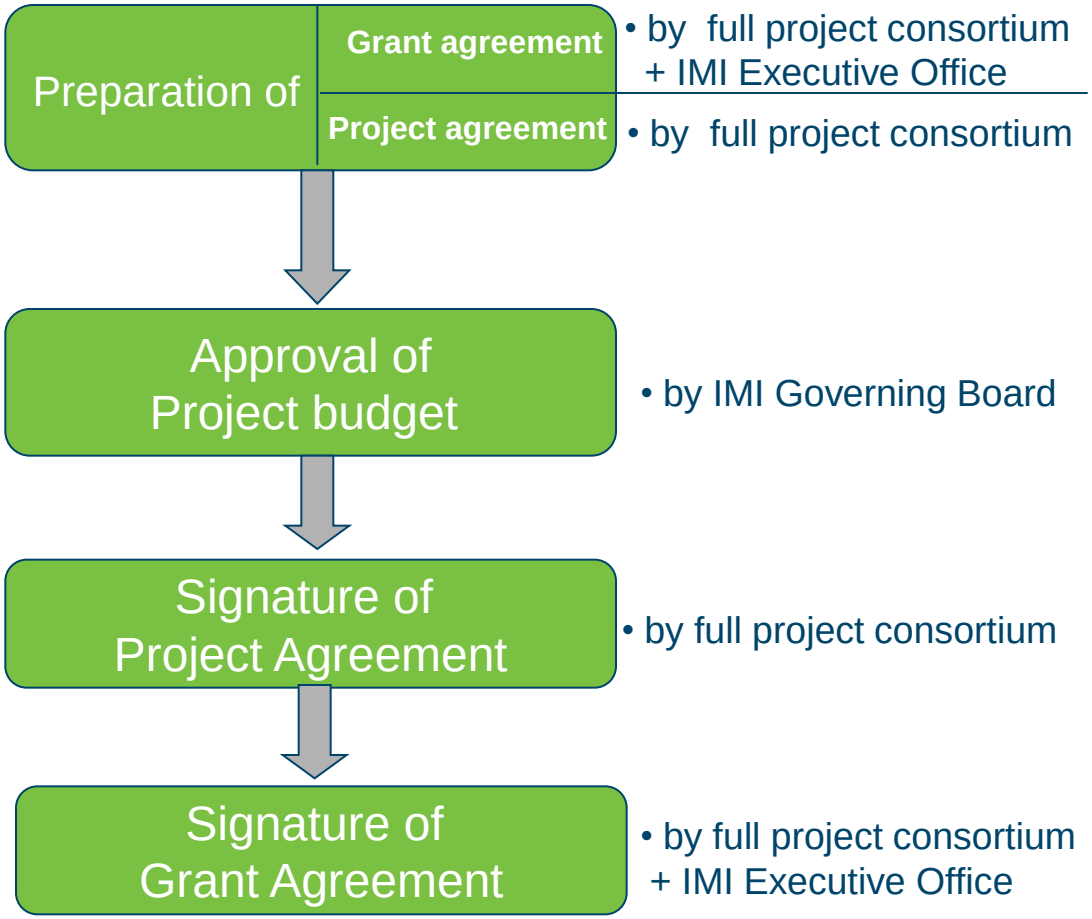
Building a IMI Project (3)

Joint Preparation of Full Project Proposal

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

Building a IMI Project (4)

Contract negotiation



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

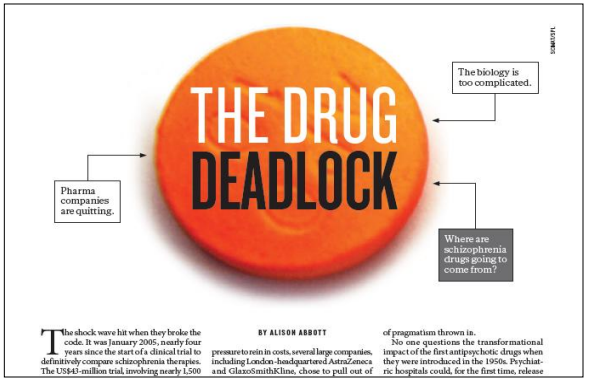
	Call 1	Call 2	Total
Projects	15	8	23
EFPIA Companies	21	21	23
Academic teams	195	103	298
SME teams	24	23	47
Patients' organisat.	9	2	11
Total Budget (M€)	281	172	453

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

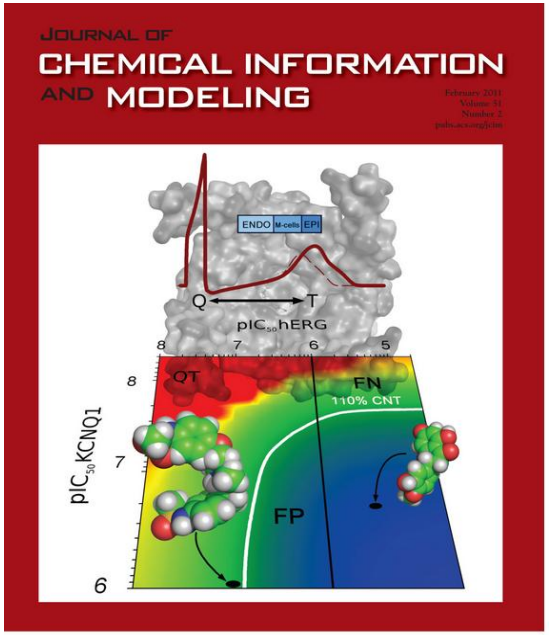
Develops innovative methodological strategies and novel software tools to better predict in silico the toxicological profiles of new molecular entities in early stages of the drug development pipeline, using its database background

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]

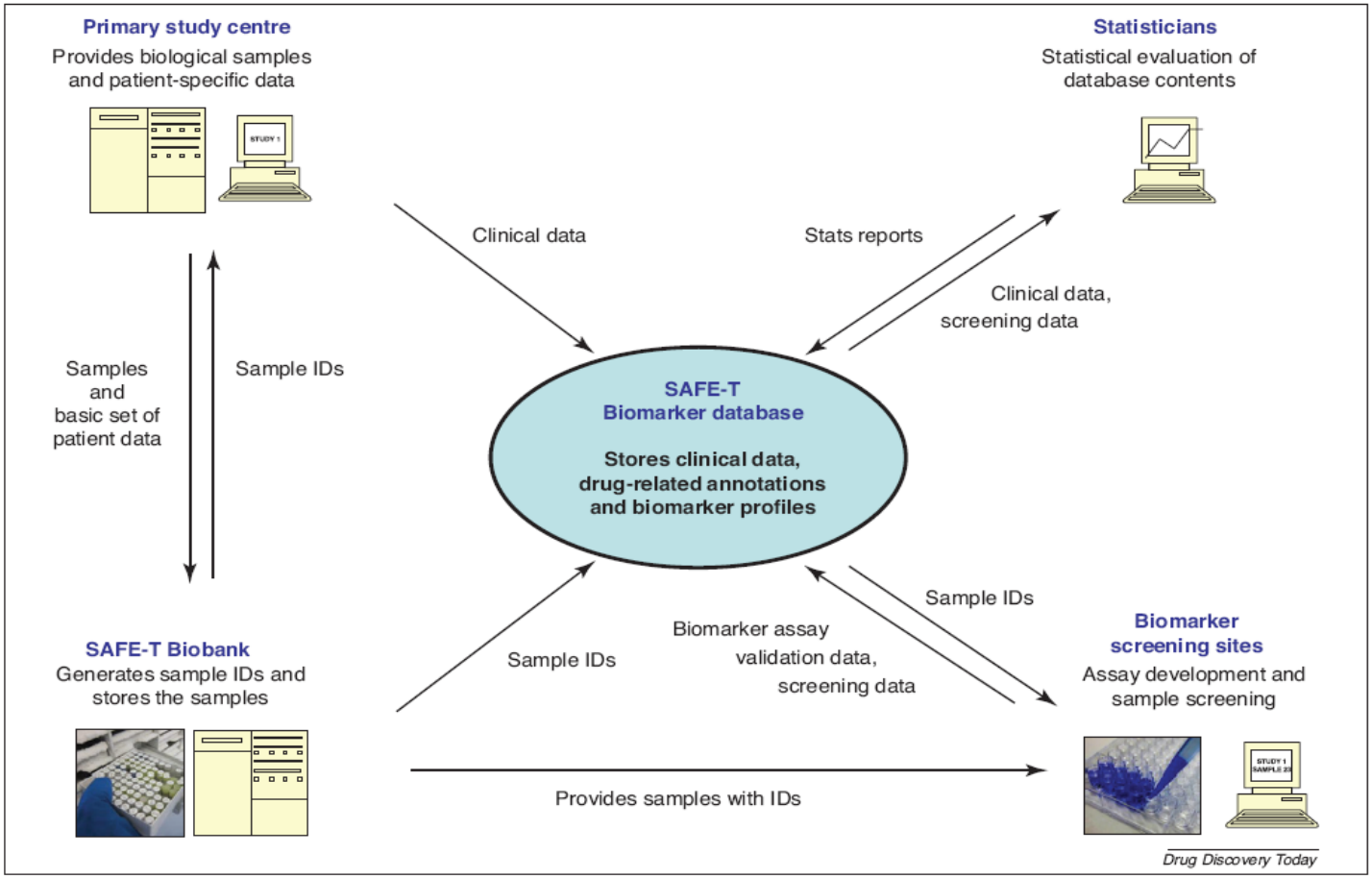
[1] Boehringer-Ingelheim Pharma GmbH & Co. KG, Biberach, Germany
[2] Novartis Pharma AG, Basel, Switzerland
[3] Interface Europe, Brussels, Belgium
[4] Tel-Aviv (Souraski) Medical Center, Tel-Aviv, Israel
[5] Barcelona Cardiovascular Research Center (ICCC-CISC), Barcelona, Spain
[6] Sanofi-Aventis, Paris, 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).

SAFE-T


Primary study centre
Provides biological samples and patient-specific data
Statisticians
Statistical evaluation of database contents
Clinical data
Stats reports
Clinical data, screening data
Samples and basic set of patient data
Sample IDs
SAFE-T Biomarker database
Stores clinical data, drug-related annotations and biomarker profiles
Sample IDs
Biomarker assay validation data, screening data
Sample IDs
SAFE-T Biobank
Generates sample IDs and stores the samples
Biomarker screening sites
Assay development and sample screening
Provides samples with IDs
Drug Discovery Today

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 (1)

Cluster A: Medical Information System

- A European medical information framework (EMIF) of patient-level data to support a wide range of medical research
- eTriks: European translational information and knowledge management services

Cluster B: Chemistry, Manufacturing and Control

- Delivery and targeting mechanisms for biological macromolecules
- In vivo predictive biopharmaceuticals tools for oral drug delivery
- Sustainable chemistry – Delivering medicines for the 21st century

CALL 4 TOPICS (2)

Cluster C: Technology and Molecular Disease Understanding

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

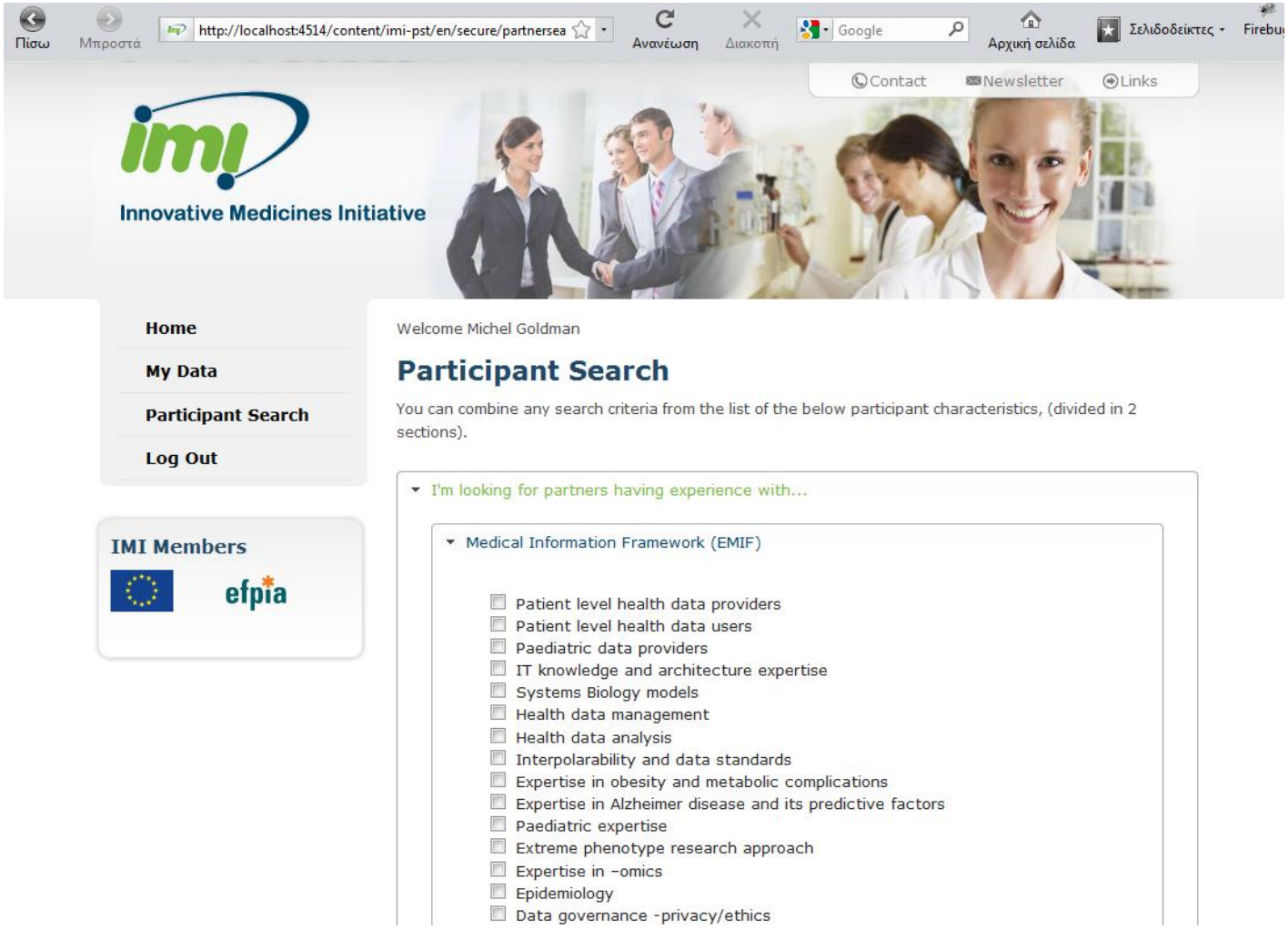
Indicative total financial contribution from IMI JU for the 7 full projects

Up to 105 M€

CALL 4 TIMELINE

- Open Info Day: 17 June 2011
- Official Launch: End June 2011
- Deadline submission of Expression of Interests: End October 2011
- Peer-review Evaluation: November 2011
- Deadline submission Full Project Proposals: March 2012
- Approval of Full Project Proposals: May 2012

Partner Search Tool



www.imi.europa.eu

efpia

WEBINARS on Call 4 Topics

Call Topic	Webinar Date	Time
Building up a European Medical Information Framework (EMIF)	21 June 2011	15:00 – 17:00
eTRIKS: European Translational Information & Knowledge Management Services	22 June 2011	15:00 – 16:30
Delivery and targeting mechanisms for biological macromolecules	28 June 2011	12:00 - 13:00
In vivo predictive biopharmaceutics tools for oral drug delivery	28 June 2011	10:30 – 11:30
Sustainable Chemistry – delivering medicines for the 21st century	28 June 2011	15:00 – 16:00
Human Induced Pluripotent Stem (hiPS) Cells for drug discovery and safety assessment	27 June 2011	16:00 – 17:00
Understanding and optimising binding kinetics in drug discovery	30 June 2011	15:00 – 16:00
→ Instructions and updates at **www.imi.europa.eu/content/events**		

Further Questions ?

- IMI Info Booth (lunch area)
  - IP Policy
  - Financial rules, Rules for participation ...
  - Partner Search Demo
- USB key + IMI website
  - Presentations
  - Call documents
- Latest updates: www.imi.europa.eu

Innovative Medicines Initiative

www.imi.europa.eu

THANK YOU !