The Innovative Medicines Initiative (IMI)

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History

2000

Lisbon Strategy  Europe most competitive and dynamic knowledge-based economy by 2010

2004

European Technology Platforms
stakeholders under the lead of industry develops Strategic Research Agendas addressing bottlenecks to competitiveness

2007

7th Framework Programme for Research
Major novelties: European Research Council and Joint Technology Initiatives (JTIs)

2008

Establishment of the Joint Undertakings
to implement the Joint Technology Initiatives
COUNCIL REGULATION (EC) No 73/2008
of 20 December 2007

setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

Official Journal 04.02.2008
2 Billion EURO

Public

Private

Partnership
IMI focuses on bottlenecks in biomedical R&D

Discovery research -> Preclinical develop. -> Translational medicine -> Clinical develop. -> Pharmaco-vigilance

Knowledge Management

Education & Training

Predictive pharmacology -> Predictive toxicology -> Identification of biomarkers -> Patient recruitment -> Validation of biomarkers -> Risk assessment with regulatory authorities

Efficacy -> Safety
IMI Governance

IMI JTI = IMI JU + External Advisory Groups

<table>
<thead>
<tr>
<th>IMI Joint Undertaking (IMI JU)</th>
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<tbody>
<tr>
<td><strong>Governing Board</strong></td>
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<tr>
<td><strong>Executive Director (+ staff)</strong></td>
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<tr>
<td><strong>Scientific Committee</strong></td>
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- **Stakeholder Forum**
- **IMI States Representatives Group**
• Rules for participation
• Eligibility for funding
• Rules for submission
• Call process
  – Description of call topics
  – Submission of expressions of interest
  – Submission of full project proposals
  – Peer review evaluation
• Timelines
• Topics
Rules for Participation in IMI Consortia

• Any entity carrying out work relevant to the IMI JU in a Member State or country associated with the 7th Framework Programme

• Anyone else with the agreement of the IMI JU

BUT

• Not all participating entities are eligible for funding
## Eligibility for IMI funding

<table>
<thead>
<tr>
<th>Eligible for funding</th>
<th>Non-eligible for funding</th>
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<tbody>
<tr>
<td>- Academia</td>
<td>- EFPIA companies</td>
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<td>- SMEs (EU definition)</td>
<td>- Other companies not falling within the EU definition of SMEs</td>
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<td>- Patient Organisations</td>
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<td>- Other non-for-profit legal entities</td>
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Eligible Consortia

• Consortia must contain:
  – At least 2 legal entities eligible to receive funding
  – At least 2 research-based pharmaceutical companies who are members of EFPIA
  – All 4 entities must be independent of each other
<table>
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<tr>
<th>Direct Eligible Costs</th>
<th>Indirect Costs</th>
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<td>(max 20% of Direct Eligible Costs, excl. subcontracting)</td>
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These apply equally to all participants - to those who receive funding and to the EFPIA participants to calculate their in-kind contribution.
Upper Funding Limits
(for participants eligible for funding by the IMI JU)

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<th>Research Activities</th>
<th>Other Activities, including Management and Training Activities</th>
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<td>Maximum 75% of total eligible costs</td>
<td>Maximum 100% of total eligible costs</td>
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Call & Evaluation Process Overview

Based on Research Agenda

IMI Annual Implementation Plan

EFPIA Companies

Topics + pre-established « EFPIA Consortiums »

Executive Office

STAGE I Submit Expression of Interest

“Applicant Consortia: Academic, SMEs, & Patients

“Full Consortium”: EFPIA + Public partners

1st Peer Review

STAGE 2 Submit Full Proposal

2nd Peer Review

Approval

IMI Board
Description of the Call Topics

1. Title
2. Project description
3. Key deliverables of the project
4. EFPIA member companies participating in the project
5. Role of EFPIA participants in the project
6. Duration of the project
7. Total in kind contribution from the EFPIA member companies
8. Expectations from the Applicant consortium (science and budget guideline)
• IMI research projects will often be multidisciplinary and addressing translational medicine challenges

• Integrated approaches between non-clinical and clinical disciplines are often required

• The successful Applicant Consortium is expected to include expertise for all aspects of the areas mentioned in the description of the call topics
Description of the Expression of Interest

1. Scientific Case
   1. Approaches to meet the project objectives (2 pages)
   2. Composition of the Applicant Consortium (1/2 page per member)
   3. Unique features and complementarities of the Consortium (1 page)
   4. Summary work plan (2 pages)

2. Declaration of ethical issues (1/2 page)

3. Provisional budget plan
   1. Estimated cost per Consortium member
   2. Estimated requested IMI contribution

Written by the Applicant Consortium:
  i.e. academia, SMEs, regulators, patients organisations (without EFPIA)
Peer Review Stage 1

- Peer Review Committees
  - Ad hoc experts relevant to the call topics
  - EFPIA Consortia co-ordinators participate in evaluation of Expressions of Interest
  - For 2009 and beyond, Standing Peer Review Committees (one per Pillar of the Strategic Research Agenda) assisted by ad hoc experts

- Responsibility
  - To evaluate science of Expressions of Interest and select the winning Applicant Consortium for each topic
Evaluation of the Expressions of Interest

Four categories that will be scored:
• Scientific and/or technological excellence
• Partnership Case
• Quality of the Applicant consortium as a whole
• Quality and soundness of the work plan, including budget

First two will have thresholds

One category that will not be scored:
• Any other remarks including ethical issues
Description of the Full Project Proposal

- Written jointly by the members of the EFPIA Consortium and the winning Applicant Consortium
- Full description of research activities
  - What, who, when, and how much
- Will need a draft Project Agreement before submission
  - IPR sharing agreed between all partners
- Expectation of high probability of success

Written by the Full Project Consortium:
  i.e. academia, SMEs, patients organisations with EFPIA companies
Peer Review Stage 2

• Peer Review Committees
  – Ad hoc experts relevant to the call topics
    • Same as reviewed the Expressions of Interest
    BUT
    • Addition of experts on ethics as needed
    • No involvement of EFPIA Consortia co-ordinators
  – Standing Peer Review Committees foreseen for future years

• Responsibility
  – To evaluate Full Proposals based on science and feasibility
Evaluation will likely include consideration of the following aspects:

- Scientific and/or technological excellence
- Consistency with the original Expression of Interest
  - Scope and composition of the consortia
- Project implementation plan
- Draft Project Agreement
- Potential impact of the project results

Categories will be graded Excellent, Acceptable (subject to adjustment to points raised), or Non-acceptable
## Tentative timelines for First Call

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<thead>
<tr>
<th>Event</th>
<th>May</th>
<th>June</th>
<th>July</th>
<th>August</th>
<th>Sept</th>
<th>October</th>
<th>Nov.</th>
<th>Dec.</th>
<th>January</th>
<th>February</th>
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<td>Publication of Call</td>
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<td>Submission period for Expressions of Interest</td>
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<td>Negotiation, signature of Grant Agreements, first payments</td>
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- April 30th
- July 15th
Topics for the First Call

1. Improved predictivity of immunogenicity  13m/5y
2. Non-genotoxic carcinogenesis  2.5m/2y plus 10m/3y
3. Expert systems for in silico toxicity prediction  5m/5y
4. Improved predictivity of non-clinical safety evaluation  10m/3y
5. Qualification of Translational safety biomarkers  21m/5y
6. Strengthening the monitoring of benefit/risk  15m/5y
7. Islet cell research  10m/5y
8. Surrogate markers for vascular endpoints  20m/5y
9. Pain research  7.5m/5y
10. New tools for the development of novel therapies in psychiatric disorders  10m/5y
11. Neurodegenerative disorders  7.5m/5y
12. Understanding severe asthma  12.5m/5y
13. COPD Patient Reported Outcomes  2m/1y plus 8m/5y
14. European Medicines Research Training Network  5m/7y
15. Safety sciences for medicines training programme  3m/5y
16. Pharmaceutical medicine training programme  4m/5y
17. Integrated medicines development training programme  3m/5y
18. Pharmacovigilance training programme  3.5m/5y

EFPIA Commitment: 172.5m
Typical project 15m euros
Majority 5y duration
5-20 EFPIA partners/project
Expected outcomes

- Modernisation of the development process of medicines
- More and better quality jobs for scientists, reversing the brain drain
- Better European Expertise and know how in technologies to attract biomedical R&D investment to Europe
- Stronger competitive advantage for smaller companies (SMEs, spin-offs and start ups) by collaboration with a multitude of stakeholders to enhance Europe’s competitiveness.
The Innovative Medicines Initiative (IMI)

http://imi.europa.eu
www.imi-europe.org

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Thank you for your attention!

Questions?