

# The Innovative Medicines Initiative (IMI)

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## The IMI Call and Evaluation Process

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# Agenda



- 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

# Eligible Consortia



- The IMI JU supports consortia who submit applications in response to a call
- 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

# Eligibility for IMI funding



<b>Eligible for funding</b>	<b>Non-eligible for funding</b>
<ul style="list-style-type: none"><li>– Academia</li><li>– SMEs (EU definition)</li><li>– Patient Organisations</li><li>– Other non-for-profit legal entities</li></ul>	<ul style="list-style-type: none"><li>– EFPIA companies</li><li>– Other companies not falling within the EU definition of SMEs</li></ul>

# Direct eligible costs



- Actual
- Incurred by the claimant
- Incurred during the project
- Incurred for work in a Member State or country associated with FP7
- Incurred for the achieving the objectives of the project

# Total eligible costs



**Direct Eligible  
Costs**

**Indirect Costs**

(max 20% of Direct  
Eligible Costs, excl.  
subcontracting)

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)



Research Activities <i>Maximum 75% of total eligible costs</i>	Other Activities, including Management and Training Activities <i>Maximum 100% of total eligible costs</i>
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# IMI Call Process is Different from the 7<sup>th</sup> Framework Programme Process



1. Research topics are approved by the IMI Governing Board (EFPIA and European Commission) based on proposals from the EFPIA Research Directors Group and after consultation with IMI Member State Representatives & IMI Sci. Committee
2. A private consortium (the EFPIA Consortium) is established for each topic & a coordinator and deputy are proposed who will lead the full Consortium

# IMI Call Process is Different from the 7<sup>th</sup> Framework Programme Process



3. Applicant Consortia submit Expressions of Interest without the involvement and participation of the EFPIA Consortia (stage 1)
4. For each topic, the best selected Applicant Consortium joins the EFPIA Consortium to form a Full Project Consortium
5. The Full Project Consortium submits a Full Proposal to stage 2 of the peer review process

# Call & Evaluation Process

## Call definition



**Research Agenda**

**Annual Implementation  
Plan**

**Call Topics**

**Call**

**Call definition**

# 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)

## Description of the call topics 2



- 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

# Call & Evaluation Process

## Stage 1



Research Agenda

Annual Implementation  
Plan

Call Topics

Call

Call definition

Expression of Interest

1<sup>st</sup> Peer Review

Invitation to Submit Full  
Project Proposal

Stage 1: Scientific  
excellence

≈ 5 months



# 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

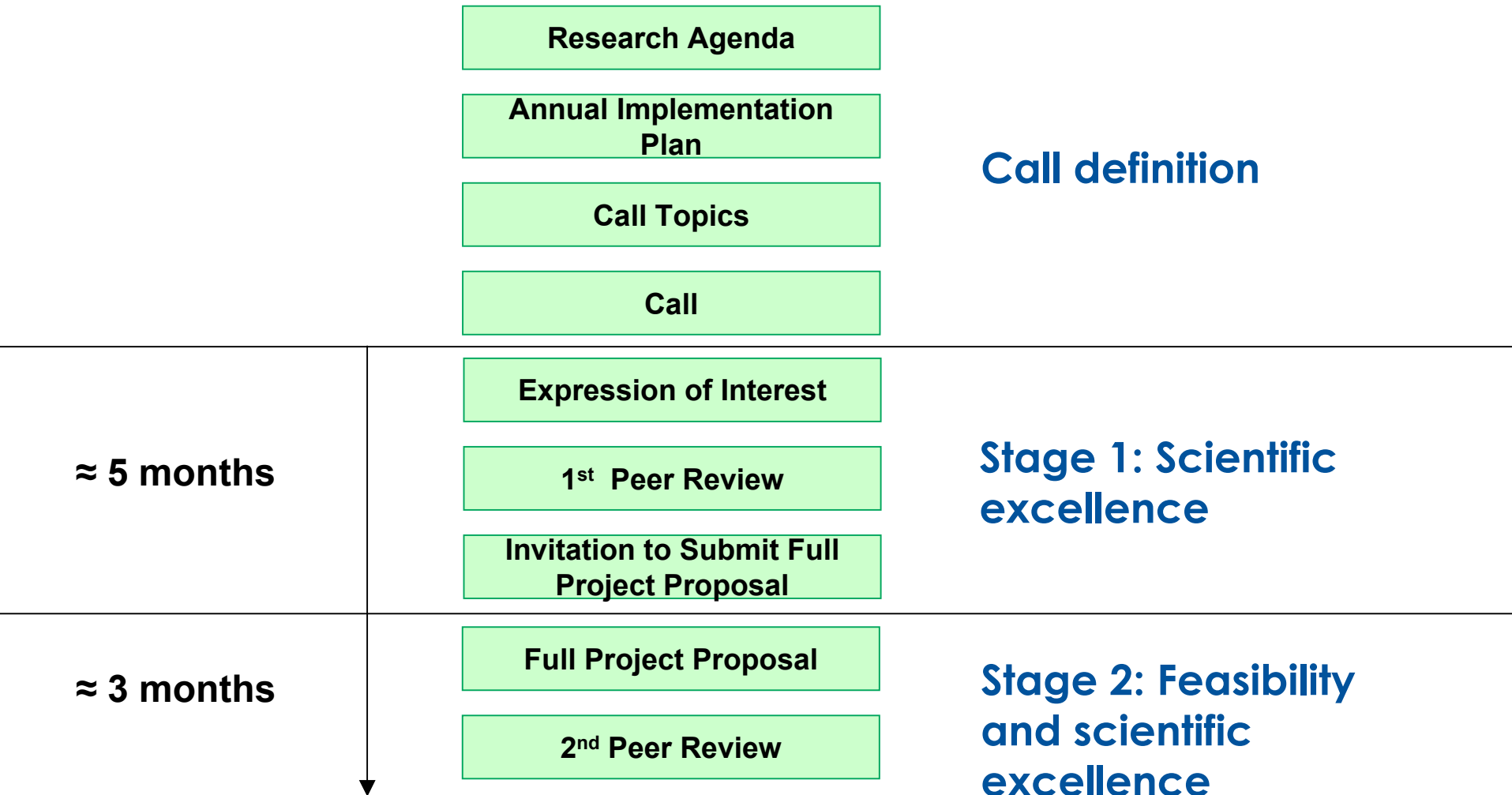
## First two will have thresholds

## One category that will not be scored:

- Any other remarks including ethical issues

# Call & Evaluation Process

## Stage 2



# 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 of the Full Project Proposal

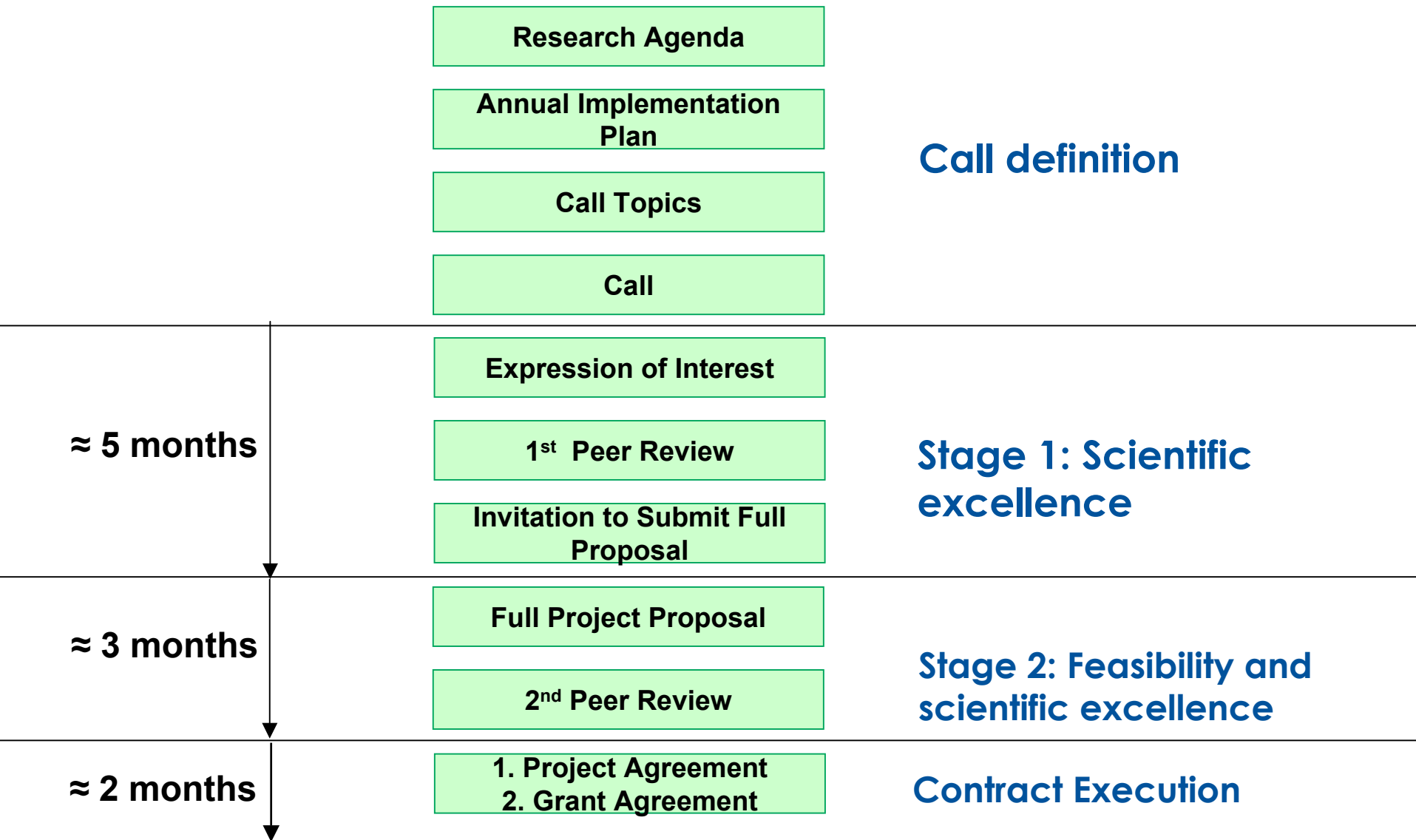


Evaluation will likely include consideration of the following aspects:

- 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

# Call & Evaluation Process





# 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**  
**5-10 EFPIA partners/project**