Rules and Procedures for IMI Calls for proposals

IMI Webinar • 20 January 2016
IMI2 Calls 7 and 8

- Calls for proposals launched on 18 December 2015

Webinars
- Webinar topic presentations and most webinar recordings: http://bit.ly/1IS4lic
IMI2 Call 7 - topics

- Validation of translational imaging methods in drug safety assessment (TRISTAN)
- Identification of druggable targets modulating misfolded proteins in Alzheimer’s and Parkinson’s diseases
- Pathological neuron-glia interactions in neuropathic pain
- Dry age-related macular degeneration: development of novel clinical endpoints for clinical trials with a regulatory and patient access intention
- A comprehensive ‘paediatric preclinical POC platform’ to enable clinical molecule development for children with cancer
IMI2 Call 7 - Topics

Topics under the Big data for better comes programme

- Coordination and support action (CSA) for the big data for better outcomes programme
- Increase access and use of high quality data to improve clinical outcomes in heart failure (HF), atrial fibrillation (AF), and acute coronary syndrome (ACS) patients
IMI2 – Call 8

- Ebola and other filoviral haemorrhagic fevers (Ebola+) programme: future outbreaks
Before we start…

- Please note that this webinar may be recorded and published on the IMI website and / or IMI YouTube channel
- Presentation slides will be published on the webinar webpage
- No participant list circulated for this webinar
IMI Calls for proposals: rules and procedures

Fabrizio Federici, IMI Legal Officer
Magda Gunn, IMI Scientific Project Manager
IMI webinar • 20 January 2016
Outline

1. Introducing IMI
2. Participation rules
3. Funding rules
4. Intellectual property rules
5. From Call to grant award
6. Writing a successful proposal
7. More information
Introducing IMI
Challenges in medicines development

**Pre-clinical research**
- Closed & open innovation
  - Drug disc.
  - Pre-clinical
    - 5 000 compounds
    - 10 000 compounds
    - 250 compounds

**Clinical Trials**
- Phase 1
- Phase 2
- Phase 3
  - 5 therapies
  - 1 therapy
  - 6 - 7 years
  - 20-100 subjects
  - 100-500 subjects
  - 1000-5000 subjects

**Regulatory review**
- Filing
- Approval
- HTA assessment
- Price / reimbursement
  - 2 – 5 years

**Pharmacovigilance**
- Real world evidence

**5 000 compounds**

**10 000 compounds**

**250 compounds**

**3 - 6 years**
IMI – key concepts

- Non-competitive collaborative research
- Competitive Calls for proposals
- Open collaboration in public-private consortia
  - Data sharing, dissemination of results…
- Industry contribution is in kind
IMI 2 budget (2014 – 2024)

EU funding goes to:
- Universities
- SMEs
- Mid-sized companies
- Patient groups etc…

IMI 2 total budget
€3.276 billion

€1.638 bn

efpia

€1.425 bn

Other
€213 m

EFPIA companies receive no funding contribute to projects ‘in kind’

Associated Partners e.g. charities, non-EFPIA companies
IMI 2 Strategic Research Agenda

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular diseases
- Diabetes
- Neurodegenerative diseases
- Psychiatric diseases
- Respiratory diseases
- Immune-mediated diseases
- Ageing-associated diseases
- Cancer
- Rare/Orphan Diseases
- Vaccines

The right prevention and treatment for the right patient at the right time
Strategic Research Agenda for Innovative Medicines Initiative 2

Aligned with WHO priorities
# IMI 2 Strategic Research Agenda

## Priority Themes
1. Neuro-degeneration
2. Immuno-inflammation
3. Metabolic disorders
4. Infection control
5. Translational Safety

## Support Technologies
1. Imaging
2. ICT
3. Medical devices….

## Enablers

*Patient access to innovative solutions (MAPPs)*
- Target validation
- Stratified medicine, precision medicine
- Innovative trials
- Data generation & interpretation
- Prevention, disease interception
- Patient adherence
- Health disease management
- Regulatory framework
- Reimbursement/patient access
A typical IMI consortium

EFPIA
- Pharma 1
- Pharma 2
- Pharma 3
- Pharma 4
- Pharma 5
- Pharma 6

Associated Partners

ACADEMIA

SMALL AND MEDIUM-SIZED ENTERPRISES

PATIENTS’ ORGANISATIONS

HOSPITALS

REGULATORS

New for IMI2
An international, cross-sector community

- 845 academic teams
- 169 SMEs
- 26 patient orgs
- 17 regulators
- 480 EFPIA teams

Over 7000 researchers working for:
- open collaboration
- improved R&D productivity
- innovative approaches to unmet medical needs
Participation rules
A single set of rules

- Covering all H2020 research and innovation actions
- Adaptability where needed:
  - Entities eligible for funding
  - IP

EU Financial Regulation
Specific rules for participation

- COSME
- etc.
- Horizon 2020
Conditions for this Call for proposals

H2020 Rules for participation apply to IMI Call for Proposals and Actions except where specifically derogated

- **Minimum conditions for Research and Innovation Actions**
  At least three legal entities, each established in a different EU Member State or H2020 associated country

- **Two-stages**
  Stage 1 SPs from applicants requesting JU funding
  Stage 2 merging 1st-ranked SPs with industry consortia

- **Evaluation criteria**
  At stage 1, only first 2 criteria are evaluated
Conditions for this Call for proposals

- **Submission deadlines**
  Established in the Call topic text both for stage 1 and 2

- **Indicative contribution**
  For each topic, the maximum JU Contribution and the estimated industry contributions are set in the call text

- **Hearings**
  Panels may decide to held hearings during panel meetings, if so applicants 'coordinators will be invited contacted (SP details!)

- **Plan for exploitation and dissemination**
  It must be included in FPs
Attracting stakeholders

Any legal entity regardless its place of establishment carrying out work relevant to the Call objectives may be part of applicant consortia

But… not all participating entities are eligible for funding
Who is eligible for funding?

- Academic institutions
- Small & medium-sized enterprises (SMEs)
- Mid-sized enterprises (≤ €500m)
- Non-profit organisations e.g. research organisations, patient organisations, NGOs, public bodies, intergovernmental organisations etc.

Established in:
- EU Member State
- Associated Country

Other countries:
No funding unless participation deemed essential by IMI for carrying out the action
Expected consortia

Stage 1 of two stage - Short Proposals

- Consortia consisting of:
  - IMI fundable legal entities carrying out activities relevant for achieving the project objectives
  - Additional legal entities carrying out activities relevant for achieving the project objectives.
Expected consortia

Stage 2 of two stage – Full Proposals

- One Full Consortium per topic consisting of:
  - 1st ranked SP consortium - IMI fundable legal entities/additional legal entities
  - Industry consortium (EFPIA companies and IMI2 Associated Partners) associated to the relevant topics
Funding rules
IMI2 Funding model

- IMI2 is a PPP, actions are normally co-funded by:
  - JU funding to BRFs (beneficiaries receiving funding = legal entities eligible for funding)
  - In-kind/cash contribution from BNRFs (beneficiaries not receiving funding):
    - EFPIA constituents and affiliates
    - IMI2 Associated Partner
    - (future other IMI2 members)

Other legal entities may also participate as BNRFs at their own cost
One single funding rate per project - BRFs

One project = One rate
For all beneficiaries and all activities

- 100% of the eligible costs
- Indirect costs: 25% Flat Rate
JU contribution to BRFs covers:

- **Personnel**
  - Wider acceptance of average personnel costs
  - Acceptance of supplementary payments
    For non-profit organisations of up to 8000 euros/year/person
  - Less requirements for time records
- **Equipment, consumables, travels…**
- **Subcontracting**

Considering BRFs accounting and management principles

- **BRFs may also receive Financial contribution from EFPIA/APs**
  - to be reported as receipts
EFPIA and Associated Partners contribution - BNRFs

- EFPIA companies
- Other industries and partners (= Associated Partners to IMI2)
  - In-kind (actual direct and indirect costs or average FTE) and/or cash contributions
  - Based on the usual management principles and accounting practices
  - Contributions from affiliated entities as part of in-kind

When relevant to IMI2 objectives: up to 30% non-EU in-kind contribution

Annual financial reporting is disconnected from GA periodic reports
Deadlines for reporting

- Scientific reporting (full consortium) due at project deadlines (i.e. GA), duration reporting period: 12 months

- Financial reporting for:
  - Beneficiaries receiving JU funding, due at project deadlines (i.e. GA)
    CFS: >EUR 325k at project end
  - Beneficiaries Not receiving funding (e.g. EFPIA companies and APs), due by 31 Jan - certification by 30 April- covering previous calendar year
IMI’s Intellectual Property (IP) rules
One set of rules for multiple interests

Support to industry

Flexibility + trusted party

Incentive to participate

Freedom of access

Dissemination of information

Compensation for IP
Background vs. Results

**Background identification**

**Implementation of the action**
- Results
- Access rights
- Access rights

**Sideground**
Generated during the action but **outside of its objectives** and not needed for implementation or Research Use.
Ownership of results

Results belong to the beneficiary who generated it

Possible transfer of ownership
- within the consortium to affiliates and purchasers without prior notification
- on case-by-case basis
Joint ownership of results

Individual use of jointly owned results

provided prior notice and fair & reasonable compensation to the other joint owners

Based on previous experience
Research Use vs. Direct Exploitation

- **Research Use**
  - Use of results or background necessary to use the results for all purposes other than for completing the action or for direct exploitation

- **Direct exploitation**
  - to develop for commercialisation or to commercialise the results

Based on previous experience
## Access Rights conditions

<table>
<thead>
<tr>
<th>Access rights granted by a beneficiary to/on</th>
<th>Background (necessary and identified)</th>
<th>Results</th>
<th>Sideground</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beneficiaries for completion of the action</td>
<td>Royalty-free</td>
<td>Royalty-free</td>
<td>N.A.</td>
</tr>
<tr>
<td>Beneficiaries and affiliates for Research Use</td>
<td>Fair &amp; reasonable terms for background needed for using the results</td>
<td>Fair &amp; reasonable terms</td>
<td>N.A.</td>
</tr>
<tr>
<td>Third Parties for Research Use after the action</td>
<td>Fair &amp; reasonable terms for background needed for using the results</td>
<td>Fair &amp; reasonable terms</td>
<td>N.A.</td>
</tr>
<tr>
<td>Beneficiaries and affiliates or Third Parties for Direct Exploitation</td>
<td>To be negotiated</td>
<td>To be negotiated</td>
<td>N.A.</td>
</tr>
</tbody>
</table>

Based on previous experience

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IMI | Innovative Medicines Initiative
Access rights to results for third parties

- Only after the end of the action
- Possibility to exclude specific elements of background (only for existing background)

Based on previous experience

- Time-limits to be agreed
Reference documents

- H2020 Rules for Participation
  - IPR section: Article 1.3.c and Articles 41 to 49

- IMI2 Delegated Regulation
  - IPR section: Articles 2 to 7

- IMI2 model Grant Agreement (revised January 2015)
  - IPR section: Articles 23a to 31

- IMI2 annotated Grant Agreement (soon)

www.imi.europa.eu/content/documents
From Call to grant award
IMI life cycle

- Call topics definition
  - Scientific Research Agenda
  - Annual Work Plan
  - Strategic Governing Groups
  - Consultation Member-Associated States/Scientific Committee

- Call Launch / Evaluation / Grant award

- Grant agreement, Consortium agreement, Implementation and Reporting
Typical IMI project life cycle

**Stage 1**
- Identification of topics and willingness to collaborate
- Applicant consortia submit short proposals

**Stage 2**
- Full consortium submits full proposal

**Grant award**
- Evaluation

**Evaluation**
- Applicant consortium
- Industry APs

**Project launch**
- Call launch
- Merger: applicants & industry
- Finalisation

**Topics**
- Industry Assoc partners
- Identification of topics and willingness to collaborate

**Typical IMI project life cycle**

- Identification of topics and willingness to collaborate
- Applicant consortia submit short proposals
- Full consortium submits full proposal
- Evaluation
- Applicant consortium
- Industry APs
- Project Agreement
- Grant Agreement
- Project launch!
A single set of evaluation criteria

- Two-stage evaluation: only **Excellence** and **Impact** considered at stage 1
- Thresholds and weighting in the **Call documents**
- Minimum of **3 independent experts** (possibility of 2 in a two-stage process)

**NEW!** Each proposal **evaluated ‘as it is’, not as ‘what could be’**
Evaluation Criteria (RIA)

1. Excellence
The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the IMI2 annual work plan:

- Clarity and pertinence of the objectives
- Credibility of the proposed approach
- Soundness of the concept, including trans-disciplinary considerations, where relevant
- Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art
- Mobilisation of the necessary expertise to achieve the objectives of the topic and to ensure engagement of all relevant key stakeholders
Evaluation Criteria (RIA)

2. Impact

The following aspects will be taken into account, to the extent to which the outputs of the project should contribute at the European and/or International level:

- The expected impacts of the proposed approach listed in the IMI2 annual work plan under the relevant topic
- Enhancing innovation capacity and integration of new knowledge
- Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges
- Improving European citizens' health and wellbeing and contribute to the IMI2 objectives
- Any other environmental and socially important impacts
- Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant
Evaluation Criteria (RIA)

3. Quality and efficiency of the implementation (full proposals only)

The following aspects will be taken into account:

- Coherence and effectiveness of the project work plan, including appropriateness of the allocation of tasks and resources
- Complementarity of the participants within the consortium (when relevant)
- Clearly defined contribution to the project plan of the industrial partners (when relevant)
- Appropriateness of the management structures and procedures, including risk and innovation management and sustainability plan
Keeping the momentum

Maximum Time To Grant: 8 months from submission of full proposal

5 months for informing applicants of scientific evaluation

3 months for signature of grant agreement

NEW Legal entity validated in parallel
IMI2 Grant Agreement

- Follows H2020 Model Grant Agreement with IMI2 specificities. An Annotated Model Grant Agreement for IMI2 will soon be available.
- Signed between IMI2 JU and Coordinator only. Accession forms for other beneficiaries.
- EFPIA and Associated Partners are beneficiaries not receiving funding (BNRFs) (Art.9) - their financial report occurs outside the GA.
Consortium agreement

- Contractual arrangement **between all participants** to set out their rights and obligations, especially governance, liability and IPR
- Shall comply with the **IMI2 model Grant Agreement**
- Before the signature of the grant agreement with the IMI Office
- **To be adapted to the specific needs of each IMI action!**
Tips for success
Common Mistakes

- Admissibility/Eligibility criteria not met:
  - submission **deadline** missed
  - proposal **out of scope**
    (if you have doubts on how to respond to the Call contact us)
  - A minimum of **three legal entities** (RIA)
Common Mistakes

- The proposal does not address all the **objectives** (in some cases proposals have nothing to do with the topic!)
- Submitted text does not respect the proposal template (sometimes received even slides!)
- Applicants do not have the **capabilities** to address all of the objectives or there is redundancy between partners
- A proposal is scientifically excellent but will have **limited impact**
- **Ethical issues** not addressed
Tips

- Read all the Call-relevant material that is provided on the IMI website – www.imi.europa.eu
- Understand IMI 2 rules and respect them
- If in doubt, ask a member of the Programme Office
- Your proposal should provide reviewers with all the information requested to allow them to evaluate it
- Start working early (pre-materials available before)
- Finalise and submit your submission
- More tips: www.imi.europa.eu/content/tips-applicants
Submitting a proposal
Partner Search Tool

www.imi.europa.eu/content/partner-search

http://www.fitforhealth.eu/
Stay in touch

- Visit our website www.imi.europa.eu
- Sign up to our newsletter bit.ly/IMInewsletter
- Follow us on Twitter @IMI_JU
- Join our LinkedIn group bit.ly/LinkedInIMI
- E-mail us infodesk@imi.europa.eu
Your contact points

At the IMI Programme Office

- General queries: infodesk@imi.europa.eu
- IP queries: IMI-IP-Helpdesk@imi.europa.eu

Local contacts

- IMI States Representatives Group: bit.ly/IMISRG
- Horizon 2020 Health National Contact Points: bit.ly/H2020_NCPs
Contact IMI

infodesk@imi.europa.eu

www.imi.europa.eu

@IMI_JU