Rules and Procedures for IMI Calls for proposals

IMI Webinar • 09 & 13 January 2017
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

3 - 6 years

5 000 compounds
10 000 compounds
250 therapies

Clinical Trials
Phase 1
Phase 2
Phase 3

1 therapy

No. patients / subjects
20-100
100-500
1000-5000

6 - 7 years

Regulatory review
Filing
Approval
HTA assessment
Price / reimbursement

2 – 5 years

Pharmacovigilance
Real world evidence
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

Other €213 m

€1.425 bn

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 life cycle

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

- **Call Launch / Evaluation / Grant award**

- **Project implementation**
  Consortium agreement, Grant agreement, implementation and reporting
What does the typical IMI project look like?

Industrial partners align themselves around a real challenge for industry and agree to work together and commit resources.

New ideas from public sector, universities, SMEs etc. are needed to address the challenge.

Scale is a key to success and is provided by IMI funding and the outcomes should be transformative for the industry as well as having a clear “public” value.
A typical IMI consortium

EFPIA

Pharma 1
Pharma 2
Pharma 3
Pharma 4
Pharma 5
Pharma 6

Associated Partners

New for IMI2

ACADEMIA

PATIENTS’ ORGANISATIONS

HOSPITALS

SMALL AND MEDIUM-SIZED ENTERPRISES

REGULATORS

INDEPENDENT MID-SIZED COMPANIES (≤ €500m)
An international, cross-sector community

- 970 academic teams
- 202 SME teams
- 552 EFPIA teams
- 31 patient orgs
- 108 other teams

Over 9,000 researchers working for:
- open collaboration
- improved R&D productivity
- innovative approaches to unmet medical needs

Figures from June 2016
IMI2 Call 10 - topics

- Topic 1 – Understanding hypoglycaemia
- Topic 2 – Big data & prostate cancer
- Topic 3 – Acute & chronic pain
- Topic 4 – Pan-European paediatric clinical trials network
- Topic 5 – Biomanufacturing 2020
- Topic 6 – Solute carrier gene-family for effective new therapies
- Topic 7 – Patient perspectives in medicines lifecycle
- Topic 8 – Personalised medicine approaches in autism spectrum disorders
IMI 2 - Call 10

- Date of Call launch: 21 December 2016

- Calls text and documents are published on the: IMI website – [http://www.imi.europa.eu/content/imi-2-call-10](http://www.imi.europa.eu/content/imi-2-call-10)

- **Deadline for short proposal submission**: 28 March 2017

- Deadline for Full proposal submission: 14 September 2017

Call 10 – NEW!

- Use of the electronic submission service of the Horizon 2020 Participant Portal:

- To access the portal and submit a proposal, applicants must have:
  - An EU Login account (previously, ‘ECAS’ account)
  - Their organisation registered on the Participant Portal Beneficiary Register, with a 9-digit Participant Identification Code (PIC) number

If you do not have an EU Login account yet, you can create an EU Login account on the Participant Portal, and register your organisation.

Call 10 – NEW!

- At stage 1 evaluation the **budget** is evaluated under criterion 3 ‘Quality and Efficiency of the Implementation’
- Applicants will need to provide a breakdown of costs (and not only the overall amount, as previously the case), by filling in the budget table in Part A of the proposal

### Budget for the proposal

<table>
<thead>
<tr>
<th>Participant</th>
<th>Country</th>
<th>(A) Direct personnel costs/€</th>
<th>(B) Other direct costs/€</th>
<th>(C) Direct costs of sub-contracting/€</th>
<th>(D) Direct costs of providing financial support to third parties/€</th>
<th>(E) Indirect Costs /€ (0.25(A+B+C))</th>
<th>(F) Special unit costs covering direct &amp; indirect costs /€</th>
<th>(G) Total estimated eligible costs /€</th>
<th>(H) Reimbursement rate (%)</th>
<th>(I) Max. EU Contribution /€</th>
<th>(J)Requested EU Contribution/€</th>
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<tbody>
<tr>
<td>Total</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
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</tbody>
</table>
Participation rules
A single set of rules

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

- Specific rules for participation

- EU Financial Regulation

- COSME

- etc.
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 independent 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, all 3 criteria are evaluated (including budget) NEW!

- **Page-limits** NEW!
  SP 30 pp, FP 70 pp
Conditions for this Call for proposals

- **NEW:** Submission tool
  As of call10, SPs/FPs to be submitted through the Electronic Submission Service of the H2020 Participant Portal

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

- **Indicative contribution**
  For each topic (and sub-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 applicant coordinators will be contacted (SP details!)
Conditions for this Call for proposals

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

- Additional eligibility conditions, art.9(5) H2020 RfP
  A two stage evaluation for all topics:
  At stage 2, the pre-defined industry consortia merge with consortia 1st ranked at stage 1 (Topic 3 – 3 consortia selected under each sub-topic)

- Information on the outcome of the evaluation:
  Information to the applicants - max 5 months from submission deadline
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
  - Under Topic 3 - 1st ranked consortium selected under each (of 3) sub-topic are merged
  - Industry consortium (EFPIA companies and IMI2 Associated Partners) associated to the relevant topics
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: non-EU in-kind contribution (up to 30% at programme level)

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

Incentive to participate

Dissemination of information

Freedom of access

Compensation for IP

flexibility

trusted party
Background vs. Results

Background identification

Implementation of the action
- Results
- 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><strong>Beneficiaries for completion of the action</strong></td>
<td>Royalty-free</td>
<td>Royalty-free</td>
<td>N.A.</td>
</tr>
<tr>
<td><strong>Beneficiaries and affiliates for Research Use</strong></td>
<td>Fair &amp; reasonable conditions (e.g. Royalty-free conditions)</td>
<td>Fair &amp; reasonable conditions (e.g. Royalty-free conditions)</td>
<td>N.A.</td>
</tr>
<tr>
<td><strong>Third Parties for Research Use after the action</strong></td>
<td>Appropriate conditions</td>
<td>Appropriate conditions</td>
<td>N.A.</td>
</tr>
<tr>
<td><strong>Beneficiaries and affiliates or Third Parties for Direct Exploitation</strong></td>
<td>To be negotiated</td>
<td>To be negotiated</td>
<td>N.A.</td>
</tr>
</tbody>
</table>
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 November 2016)
  - IPR section: Articles 23a to 31

- IMI2 annotated Grant Agreement (soon)

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

1. Topic definition
   - Industry Assoc partners
   - Identification of topics and willingness to collaborate

2. Stage 1
   - Applicant consortia submit short proposals
   - Academics
   - Hospitals
   - Mid-size enterprises
   - Regulators
   - SMEs
   - Patients’ organisations

3. Stage 2
   - Full consortium submits full proposal
   - Applicant consortium
   - Industry APs

4. Grant award
   - Project Agreement
   - Grant Agreement

5. Call launch
6. Merger: applicants & industry
7. Evaluation
8. Finalisation
9. Project launch!
A single set of evaluation criteria

- Two-stage evaluation:
  all three criteria considered at both stages *NEW!*
- Thresholds and weighting in the **Call documents**
- Minimum of 3 independent experts

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 call for proposals and referred to in the IMI2 annual work plan:

- Clarity and pertinence of the proposal to meet all key objectives of the topic;
- 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, 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 as mentioned in the call for proposals;
- Added value from the public private partnership approach on R&D, regulatory, clinical and healthcare practice as relevant;
- 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
The following aspects will be taken into account:

- Coherence and effectiveness of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and budget;
- Complementarity of the participants within the consortium (where relevant);
- Clearly defined contribution to the project plan of the industrial partners (where relevant);
- Appropriateness of the management structures and procedures, including manageability of the consortium, 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
The new IMI2 MGA (v.3) will apply to Call 10
Follows H2020 Model Grant Agreement (v.3) 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
Article 41.3 - Consortium agreement may cover:

- internal organisation of the consortium, including allocation of scientific tasks among beneficiaries

Scientific Project Leadership

Scientific Project Leader may be different from Coordinator to:

- reflect the spirit of industrial co-leadership in call topics built upon EFPIA/industry scientific priorities

- address the need for strong scientific coordination and collaboration between BRFs (JU funded) and BNRFs (industry)
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
- To be agreed before the signature of the GA, IMI2 JU is not a party
- To be adapted to the specific needs of each IMI action!
- A template prepared by EFPIA shows what a consortium agreement might look like:


  Consortia may also use alternative templates if they wish.
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 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
- Consider the PPP dimension of the action (e.g. Governance, industry contribution vs IMI2 funding)
- 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)
- Dedicate sufficient time to submit the proposal: create an EU login account, obtain a PIC number - don’t wait until the last day to start the submission process
- 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
Questions & Answers
How to use GoToWebinar - questions

By phone
Click on the ‘raise hand’ icon

In writing
- Type your question
- Click on ‘Send’
Thank you!

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