Webinar | IMI2 – Call 12
European Screening Centre: unique library for attractive biology

14.07.2017 • 16:00 CEST
Today’s webinar

Will cover all aspects of the Call topic

- Introduction to IMI programme
- Proposed project
  - Objectives, need for public-private collaborative research
  - Key deliverables
  - Structure of the project
  - Expected contribution of the applicants
  - Contribution of industry consortium

Will not cover rules and procedures

- A webinar on rules and procedures will take place on Monday 17 July, 14:30-16:00
- Register here
IMI – Europe’s partnership for health

IMI mission

IMI facilitates open collaboration in research to advance the development of, and accelerate patient access to, personalised medicines for the health and wellbeing of all, especially in areas of unmet medical need.
IMI 2 budget (2014 – 2024)

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

IMI 2 total budget
€3.276 billion

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

Associated Partners e.g. charities, non-EFPIA companies

EFPIA

€1.425 bn

Other
€213 m

€1.638 bn

IMI 2 budget (2014 – 2024)

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

IMI 2 total budget
€3.276 billion

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

Associated Partners e.g. charities, non-EFPIA companies

EFPIA

€1.425 bn

Other
€213 m

€1.638 bn
IMI – Ecosystem for innovative collaborations

- Allow engagement in a cross-sector, multi-disciplinary consortium at the forefront of cutting-edge research
- Provide the necessary scale by combining funding, expertise, knowledge, skills and resources
- Build a collaboration based on trust, creativity and innovative and critical thinking
- Learn from each other - new knowledge, skills, ways of working
- Take part in transformative research that will make a difference in drug development and ultimately patients’ lives

IMI is a neutral platform where all involved in drug development can engage in open collaboration on shared challenges.
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 through IMI funding.

Outcomes should be transformative for the industry as well as having a clear “public” value.
Typical IMI project life cycle

1. **Topic definition**
2. **Industry**
3. **Identification of topics and willingness to collaborate**
4. **Call launch**
Typical IMI project life cycle

**Stage 1**

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

**Evaluation**

- Academics
- Hospitals
- Mid-size enterprises
- Regulators
- SMEs
- Patients’ organisations

**Call launch**
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

**Evaluation**
- Applicant consortium

**Call launch**

**Merger: applicants & industry**

- Academics
- Hospitals
- Mid-size enterprises
- Regulators
- SMEs
- Patients’ organisations

**Topic definition**
- Industry
- Identification of topics and willingness to collaborate

**Stage 1**
- Applicant consortia submit short proposals

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

**Evaluation**
- Applicant consortium

**Call launch**

**Merger: applicants & industry**

- Academics
- Hospitals
- Mid-size enterprises
- Regulators
- SMEs
- Patients’ organisations

**Topic definition**
- Industry
- Identification of topics and willingness to collaborate
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

Evaluation:
- Full Proposal Consortium

Call launch:
- Merger: applicants & industry

Participants:
- Industry
- Academics
- Hospitals
- Mid-size enterprises
- Regulators
- SMEs
- Patients’ organisations
- Hospitals
- SMEs
- Mid-size enterprises
- Academics
- Regulators
- Patients’ organisations
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 Preparation**
- Project Agreement
- Grant Agreement

**Call launch**
- Merger: applicants & industry
- Grant Preparation

- Project launch!
Submitting a proposal

# Proposal Template

- Available on IMI website & H2020 submission tool
- For first stage proposals, the page limit is **30 pages**.

## Title of Proposal

## List of participants

## Table of Contents

<table>
<thead>
<tr>
<th>1.</th>
<th>EXCELLENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Objectives</td>
</tr>
<tr>
<td>1.2</td>
<td>Relation to the call topic text.</td>
</tr>
<tr>
<td>1.3</td>
<td>Concept and approach</td>
</tr>
<tr>
<td>1.4</td>
<td>Ambition</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.</th>
<th>IMPACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Expected impacts</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3.</th>
<th>IMPLEMENTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>Outline of project plan — Work packages, and major deliverables</td>
</tr>
<tr>
<td>3.2</td>
<td>Management structure and procedures</td>
</tr>
<tr>
<td>3.3</td>
<td>Consortium as a whole</td>
</tr>
<tr>
<td>3.4</td>
<td>Table 3.1a: List of work packages</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.</th>
<th>PARTICIPANTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>Participants (applicants)</td>
</tr>
</tbody>
</table>
Evaluation Criteria (1/2)

- **Excellence**
  - 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.

- **Impact**
  - 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;
  - Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges;
  - Improving European citizens' health and wellbeing and contribute to the IMI2 objectives.
Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Coherence and effectiveness of the outline of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and approximate budget;
  - Complementarity of the participants within the consortium (where relevant) and strategy to create a successful partnership with the industry consortium as mentioned in the topic description in the Call for proposal;
  - Appropriateness of the proposed management structures and procedures, including manageability of the consortium.
Tips for writing a successful proposal

- Read all the call-relevant material: www.imi.europa.eu
- Begin forming your consortium early
  Partner search tools & networking events
- Provide reviewers with all the information requested to allow them to evaluate your proposal
- Finalise and submit your proposal early
- Contact the Programme Office (NOT topic writers): infodesk@imi.europa.eu
Common mistakes

- Admissibility/Eligibility criteria not met:
  - submission **deadline** missed
  - minimum of 3 legal entities from **3 member states & H2020 associated countries** not met
- The proposal does **not address all the objectives** of the topic
- A proposal is **scientifically excellent** but will have **limited impact**
- **Complementarity** with Industry consortium not well described.
Find project partners

- Network with your contacts
- Network with fellow webinar participants
- Use Partner Search Tools:
  - IMI [http://www.imi.europa.eu/content/partner-search](http://www.imi.europa.eu/content/partner-search)
  - German NCP version: [http://www.imi-partnering.eu](http://www.imi-partnering.eu)
  - Fit for health: [http://www.fitforhealth.eu/](http://www.fitforhealth.eu/)
- Get in touch with your local IMI contact point: [www.imi.europa.eu/content/states-representatives-groups](http://www.imi.europa.eu/content/states-representatives-groups)
- Talk to your Health National Contact Point (NCP)
- Network on social media (e.g. IMI LinkedIn group)
SME Participation

IMI encourages the participation of SMEs in applicant consortia as they can offer a complementary perspective to other organisations.

For example, being closer to the market, SMEs can drive the tangible outputs of the project, and help ensure these outputs are sustained beyond the project lifetime and therefore help lead to faster impact on healthcare.

Therefore, where possible, include SMEs in your Short Proposal
Topic 7: European Screening Centre: unique library for attractive biology (ES Culab)
Objective

- Enabling translation of novel biological concepts into drug discovery projects by providing access to high-quality compound libraries and high throughput screening facilities

- Creating partnering opportunities for public partners (academia, small and medium enterprises (SMEs), biotechs) and pharmaceutical companies based on screening outcome
Backgrounds: European Lead Factory
Need and opportunity for public-private collaboration

- Universities, research organisations and SMEs work on a diverse range of potential drug targets but cannot easily access suitable compound libraries and screening facilities.
- Pharmaceutical companies need access to high quality targets in order to bring innovative therapies to patients.
- Combining large high-quality compound libraries with the innovative targets in a public-private partnership offers an ideal platform to transform biological discoveries into medicines.
- Facilitating such a platform through a neutral, SME-led compound management and uHTS screening facility will allow all partners to participate in confidence that their targets will be screened in an independent way with maximal protection of their intellectual property.
Impact

- Exciting biology
- Assay development
- Screening of 550k ESCulab library
  - 350k cmpds
  - 200k cmpds
- Hit confirmation
  - QHL
  - Chemical matter
Expected impact (1)

- The project is intended to lower the hurdles for academic groups and SMEs to translate early innovative biology into chemical series.
- The delivery of up to 50 public and 135 EFPIA/IMI2 AP Qualified Hit lists (QHLs) should create value from the libraries in diseases with unmet medical need, such as cancer, immunological, respiratory, neurological and neurodegenerative diseases, anti-infectives, and neglected (tropical) diseases.
- By including phenotypic screening that mimics cellular events relevant in disease, hit series that show clear structure-activity relationships might trigger target deconvolution activities that ultimately might lead to the discovery of novel pathways / drug targets.
Maximising Impact

- Given the significant future investment needed to develop a screening result into a new medicine, it is necessary for the target owners to secure ownership of the results of their screens.
- Therefore, in the short proposal, the applicants must develop a strategy for the transfer of ownership upon generation of the screening results to the target owners.
- This strategy should be further determined between the parties at the full proposal stage and the terms be agreed between the beneficiaries as part of the consortium agreement.
Expected impact (2)

- Including SMEs in the applicant consortium should contribute to strengthening the competitiveness and industrial leadership of Europe.
- At the end of the IMI funding term, there must be a self-sustainable, well recognised screening centre with access to a high-quality library which adopts a business model relying on externally funded screens: ESCulab should be the operational partner of choice for scientists to bring modulation of their targets with small molecules from theory into practice.
Potential synergies with existing consortia

- Applicants should take into consideration, while preparing their short proposal, relevant national, European (both research projects as well as research infrastructure initiatives), and non-European initiatives. Synergies and complementarities should be considered in order to incorporate past achievements, available data and lessons learnt where possible, thus avoiding unnecessary overlap and duplication of efforts and funding.

- Applicants should consider any relevant projects from IMI, FP7, H2020, as well as other relevant European research infrastructures such as EU-OPENSSCREEN (www.eu-openscreen.eu) and other initiatives outside the EU.
Suggested Architecture

1. Target recruitment
2. Review board to approve target/programme proposals
3. Library hosted by public partner who is responsible for compound logistics
4. Assay development
5. Screening of 550k ESCulab library
6. Hit confirmation
7. IT system to collate data and allows for secure data handling
8. Overarching project management

QHL

Library hosted by public partner who is responsible for compound logistics

QHL

Library hosted by public partner who is responsible for compound logistics

IMI

Innovative Medicines Initiative
Suggested Architecture

- The final architecture of the full proposal will be defined by the participants in compliance with the IMI 2 JU rules and with a view to the achievement of the project objectives.
- The allocation of a leading role within the consortium will be discussed in the course of the drafting of the full proposal to be submitted at stage 2.
- To facilitate the formation of the final consortium, until the roles are formally appointed through the consortium agreement, the proposed project leader from among EFPIA beneficiaries/large industrial beneficiaries shall facilitate an efficient negotiation of project content and required agreements. All beneficiaries are encouraged to discuss the project architecture and governance and the weighting of responsibilities and priorities therein.
Expected (in kind) contributions of industry consortium

- All EFPIA participants contribute screening compounds (350,000) and will run screens of the compound library in the course of the ESCulab project.
- Assay development and screening efforts are EFPIA participants’ in-kind contributions. With these, EFPIA participants enhance the database for developing public QHLs and increase the value of hits from the public compound collection.
- For the sustainability of the platform beyond the ESCulab lifetime, the EFPIA partners will negotiate terms to maintain the compound library after the project ends.
Expected contributions of the applicants (1)

- A library of approximately 200 000 screening compounds available for HTS. Applicants should demonstrate that their compounds are novel, drug-like, not commercially available, with high sp³ count (sp³ count > 0.48, MW ~430, clogP ~2.3), clearly differentiated from vendor libraries.
- A centralised unit for carrying out the HTS operations on the targets originating from public target owners. Preferably, the HTS operations are performed in a country with research exemption limiting IP complexity.
- Software to support the blinding and un-blinding of information
- A firewalled IT infrastructure to handle data related to the compound library.
Expected contributions of the applicants (2)

- Strong European-wide network for public target recruitment with outreach to ongoing and future IMI projects and other European and national initiatives.

- Professional, industry-like management of compound logistics processes centred around a single entity for the collection, storage, distribution and management of the ESCulab compound library.

- The consortium must include a specialised party (‘honest data broker’) who can manage and broker (blinded and un-blinded) confidential information on compounds and screening results data according to the honest data broker concept, i.e. one single, centralised unit with dedicated staff bound by confidentiality and non-use obligations.
Expected contributions of the applicants (3)

- Strong experience in assay development, miniaturisation, validation for HTS both employing platform techniques and introducing novel experimental approaches. Capabilities to develop HTS/High Content Screening (HCS) ready target-focused and phenotypic cellular assays.

- Extensive experience in the execution of HTS to industry standards, providing solutions also for complex experimental protocols, e.g. with multiple liquid handling and signal detection steps, kinetic readouts, etc. Necessary expertise in molecular and cellular pharmacology and medicinal chemistry to drive a rigorous hit characterisation process.

- Industrial-like experience and proven track record for successful hit confirmation including expertise in medicinal chemistry and pharmacology.
Expected contributions of the applicants (4)

- Extensive experience in applying IT solutions to the management of compound collections, HTS data management from quality control to chemo-informatic analysis of HTS results.

- Project management capabilities supporting overall governance and steering and experience developing business plans to ensure the long-term sustainability of the project.

- In their short proposal, applicants should provide an initial plan for the sustainability of the platform beyond the IMI2 JU funding term. This outline plan should also benchmark the proposed ESCulab project against existing screening infrastructures.
Deliverables

@ EFPIA

130 screens in 5 yrs  130 QHLs

100+ targets  50+ ADs  50 screens in 5 yrs  +5 screens for EFPIA AP  55 QHLs

Target recruitment  Assay development  Screening of 550k ESCulab library  Hit confirmation

350k cmpds

200k cmpds library hosted by public partner

@ Public Screening Centre
Expected key deliverables

- **Public Screening Centre**
  - The screening centre will host the compound library and manage the logistic processes around the library to support compound logistic processes for up to 37 HTS projects per year.
  - Responsible for public programmes* from Assay Development to Hits providing a list of confirmed hits constituting the QHL which requires medicinal chemistry expertise.

- **Sustainability plan**
  - A business model based on fee-for-service and milestone-based income to ensure self-sustainability at the end of the ESCulab period.
  - Establishing the maintenance of the compound library beyond the lifetime of the ESCulab project.

* + 5 EFPIA AP programmes
Thank you

Contact the IMI Programme Office
infodesk@imi.europa.eu • www.imi.europa.eu
SME & patient involvement

Salome Koussoroplis, IMI
IMI webinar • 14.07.2017
SME Participation

IMI encourages the participation of SMEs in applicant consortia as they can offer a complementary perspective to other organisations.

In particular, in this topic, SMEs can participate by providing:

- A centralised facility for carrying out the HTS screening operations
- Professional, industry-like management of HTS library logistics
- Strong experience in assay development, miniaturisation, validation for HTS
Patient Participation

While there is little opportunity for patients to get involved in the ESCulab consortium itself, one of the objectives is to significantly lower the hurdles for patient foundations that want to initiate drug discovery in their specific field of interest. Therefore, once the project is ongoing, patient organisations could submit targets for screening.

“The patient, doctor and researcher – each is a different kind of expert.”
Questions & answers