Webinar | IMI2 - Call 10
Topic 4 Creation of a pan-European paediatric clinical trials network

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Today’s webinar

- Will cover all aspects of the Call topic
  - Objectives of the project
  - Need for public-private collaborative research
  - Structure of the project
  - Expected contribution of the applicants
  - Contribution of industry consortium
  - Key deliverables

- Will not cover rules and procedures
  - A webinar on rules and procedures will take place on 09.01.2017 at 14:00.
  - Register at bit.ly/IMI2C10webinars
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 – 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.
Typical IMI project life cycle

1. Topic definition
2. Identification of topics and willingness to collaborate
3. Call launch

Industry
Typical IMI project life cycle

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

**Evaluation**
- Academics
- Hospitals
- Mid-size enterprises
- Regulators
- SMEs
- Patients' organisations

**Call launch**

**Topic definition**
- Industry
**Typical IMI project life cycle**

1. **Topic definition**
   - Identification of topics and willingness to collaborate
   - **Stage 1**
     - Applicant consortia submit short proposals
   - **Stage 2**
     - Full consortium submits full proposal

2. **Evaluation**
   - Applicant consortium
   - Industry

3. **Call launch**
   - Merger: applicants & industry

Participating entities:
- Academics
- Hospitals
- Mid-size enterprises
- Regulators
- SMEs
- Patients’ organisations
- Industry
- Manufacturers
- Mid-size enterprises
- Regulators


Typical IMI project life cycle

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

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

**Identification of topics and willingness to collaborate**

**Call launch**

**Merger: applicants & industry**
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

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

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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 EFPIA 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** 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.

In particular, in this topic, SMEs can participate providing expertise and experience in paediatric drug development but also clinical network, data and knowledge management, project management and professional communication among others.
Patient Participation

Inclusion of patients and parent organisations is encouraged. There are many ways you can improve project performance by working with your patient partners e.g:

- Input to development and standardisation of study procedures and processes (e.g. creation of study documents, patient/parent information)
- Input in assessments of feasibility clinical protocols, clinically meaningful endpoints, and risk-benefit assessment
- Input into operationalisation & monitoring of patient recruitment for clinical trials
- Input into the wording of informed consents
- Community outreach and dissemination

“The patient, doctor and researcher – each is a different kind of expert.”
Contact IMI

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www.imi.europa.eu

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