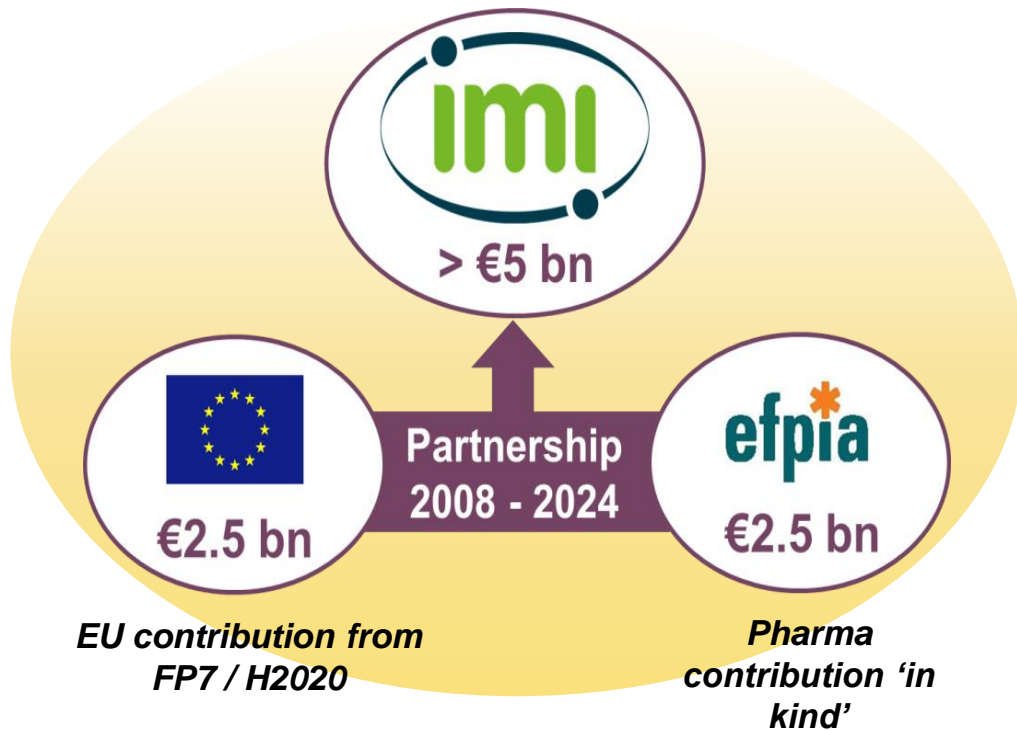


Webinar | IMI2 - Call 11 'Exploitation of IMI Project Results'

26.07.2016

Innovative Medicines Initiative: Europe's partnership for health



Focus on unmet needs

Non-competitive collaborative research

Competitive Calls for proposals

Open collaboration in public-private consortia

Data sharing, dissemination of results...

Industry contribution is in kind

Engagement with other sectors

A partnership between EU
Commission and the European
Federation of Pharmaceutical
Industries and Association
(EFPIA)

IMI – Europe's partnership for health

IMI mission

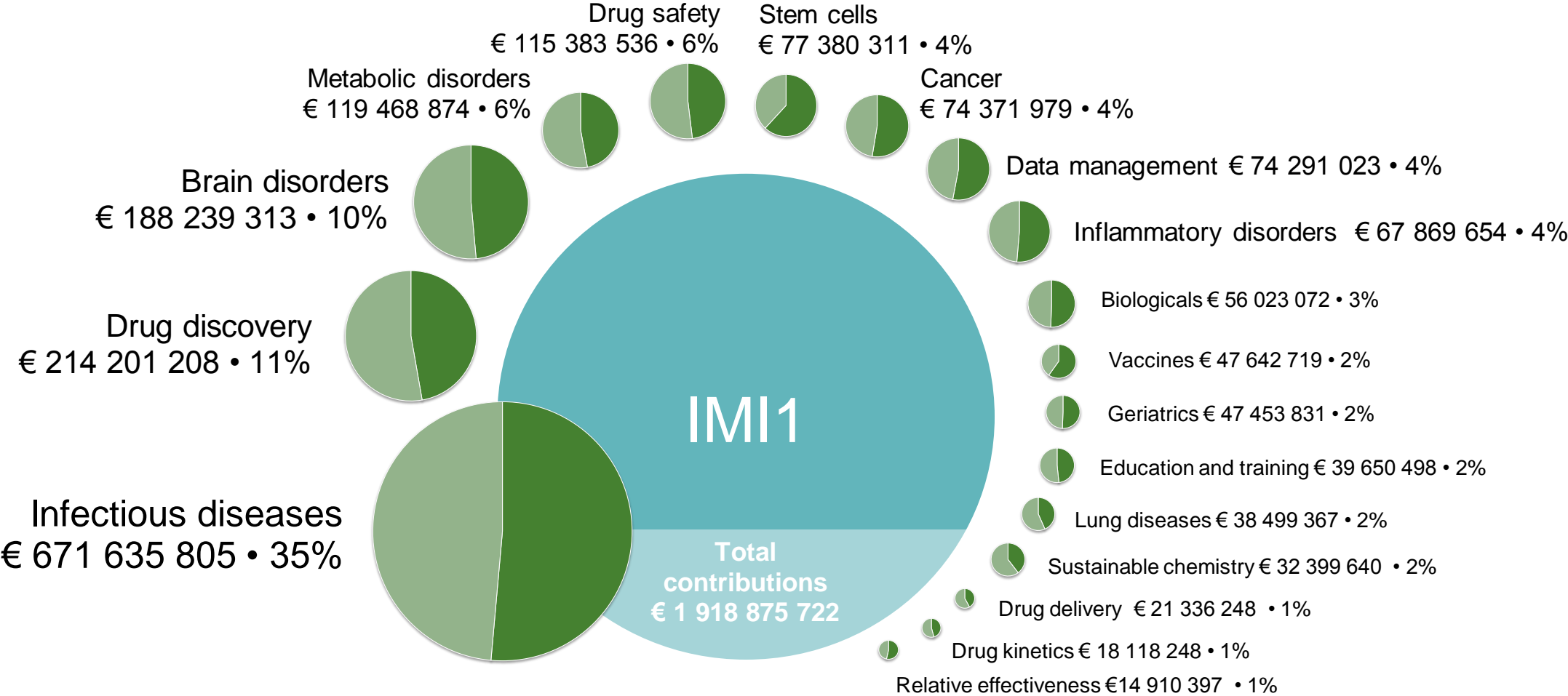
IMI facilitates open collaboration in research to advance the development of, and accelerate patient access to, personalised medicines for the health and wellbeing of all, especially in areas of unmet medical need.

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**.

Distribution of funding per scientific area – IMI1

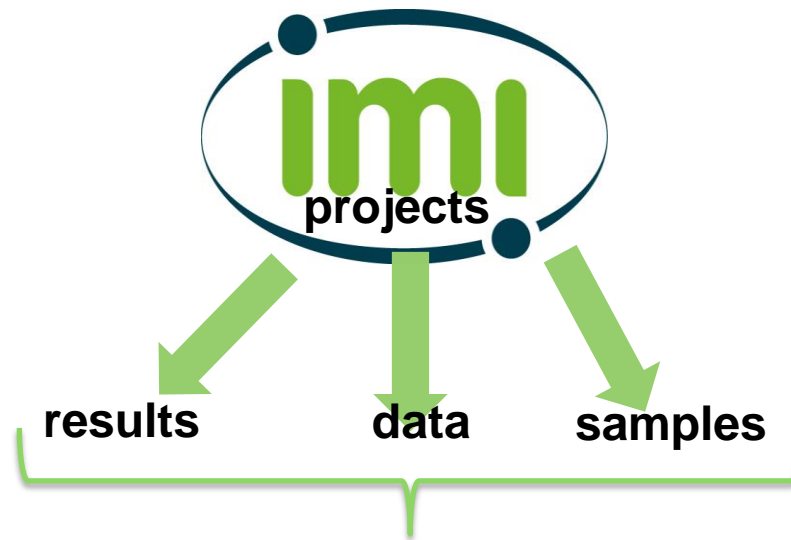


 EFPIA contributions
  IMI contributions

Webinar | IMI2 - Call 11 'Exploitation of IMI Project Results'

Elisabetta Vaudano 26.07.2016

Background and problem statement



IMPORTANT RESULTS

with potential long-term impacts on R&D, regulatory, clinical and healthcare practice

- Facilitate the integration of important results into general research and medical practice
- New solutions towards long-term sustainability may have to be identified

Scope of the call

- Foster the exploitation and sustainability of results from IMI JU projects that have finished or are nearing completion. by providing the necessary intermediate solutions and funding for a maximum of two years.
- It is expected that at the end of the funding period, further exploitation and sustainability will be achievable, so that significant results become fully exploitable, available to all relevant end users, and fully sustainable.
- The work to be supported will consist of activities and measures to make the results available to the broader (scientific) community, beyond original project objectives.
- Only the project results identified in Table A annexed to the Topic Text are within the scope of this Call.
- In some cases, solutions may be applied to results generated across more than one project, to avoid dispersion and duplication of efforts.

Need and opportunity for public-private collaborative research

- Important project results have been generated based upon collaboration between public and private stakeholders
- Collaboration between private industries (especially EFPIA members), and different stakeholders (e.g. academic experts, SMEs, regulatory agencies, patient organisations, public health institutes, potentially public research infrastructures) is necessary to achieve the expected impact of the call
- Convergence between innovative SMEs, larger companies, and academic institutions will ensure that the best approaches are sought to ensure the IMI results are further exploited in line with IMI2 objectives.
- Cross-country collaboration will bring together competences and facilities which are not available on a national level, avoid dispersion of the results, and contribute to maintaining European competitiveness in the field of biomedical research and innovation.

IMI Project results in the scope of the call

* more information in Table A annexed to the Topic Text

Project acronym & number	Foreground type
EMTRAIN (115015)	<ul style="list-style-type: none"> • Databases • Learning platforms
EUPATI (115334)	<ul style="list-style-type: none"> • Educational material on seven-language toolbox website and on EUPATI Moodle e-learning system • Guidance documents on interaction of patient organisations with 4 stakeholder groups, text • Pan-European network of key contacts in advocacy and PPI, database • Patients involved platform, website
PharmaTrain (115013)	<ul style="list-style-type: none"> • Course Handbook for post-graduate diploma and Master programmes in pharmaceutical medicine and regulatory affairs • Standard operating procedures (SOPs) and charters for national implementation of the post-graduate certification programme 'Specialist in Medicines Development' • Position paper with syllabus and learning outcomes for the three levels investigator training in clinical trial management
Open PHACTS (115191)	<ul style="list-style-type: none"> • Semantically integrated life science data
RAPP-ID (115153)	<ul style="list-style-type: none"> • Prototype
WEB-RADR (115632)	<ul style="list-style-type: none"> • Databases • Technology platform
GetReal (115546)	<ul style="list-style-type: none"> • Website • Software tools • Online education and Training programme

Activities to be supported

- Activities may include:
 - Development of measures to enable technology transfer
 - Analysis of regulatory aspects
 - Standardisation and transfer of samples, databases, tools, etc. to sustainable infrastructures
 - Adaptation of technologies to enable wider engagement
 - Transfer to sustainable infrastructure
 - Standardisation and/or interoperability measures
 - Further development of scientific and business solutions
 - Other activities necessary to the achievements of the key deliverables and impact
 - **Commercial exploitation is outside the scope of this Call.**

Expected key deliverables

- Plans for the further exploitation and sustainability of results of IMI projects (i.e. transfer to a sustainable infrastructure, technology transfer, etc).
- A clear value proposition for the end users to be targeted.
- Convincing scientific and business solution that sustains key IMI project results without the need for further IMI funding.
- Measures to make the results available to the broader scientific community (public and private) beyond the duration of the sustainability funding to maximise impact on biomedical research and delivery of healthcare.

Expected impact

- Long term sustainability as a result of the exploitation activities.
- Impact on R&D, regulatory, clinical and healthcare practice as relevant.
- Strengthening of the competitiveness and industrial leadership and/or addressing specific societal challenges, improving European citizens' health and wellbeing
 - Demonstrated by the capacity of mobilizing relevant industrial resources from contributing partners (e.g. EFPIA and IMI2 Associated Partners)

Impact is expected to be generated via mobilisation of resources and relevant expertise to ensure meeting the proposal specific objectives and contribute to the IMI2 JU objectives as a public-private partnership.

Potential synergies with existing consortia

- Synergies with any relevant initiative should be considered in order to favour solutions maximising the impact while avoiding duplication and fragmentation
- Leveraging on relevant research infrastructures in Europe already available
- However please notice that only results in Table A are in the scope

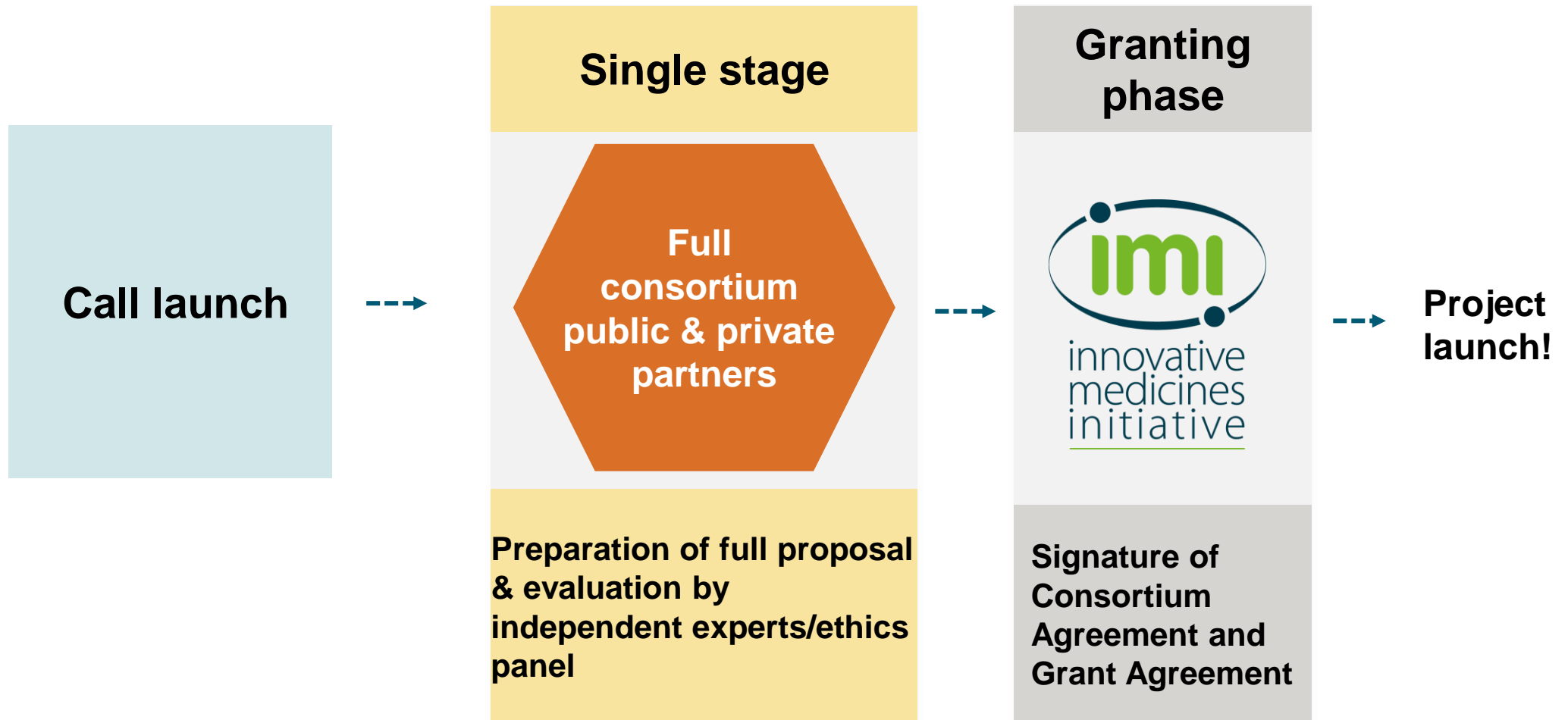
Applicant consortium

- The size and composition of each consortium should be adapted to respond to the goals and the key deliverables.
- Relevant stakeholders should be appropriately engaged and the needs of patients adequately considered (where appropriate, patient involvement is encouraged).
- Robust legal/IPR apparatus and associated project consortium agreements to facilitate the management and transfer of project results and sustainability efforts (including relevant ethical considerations) should be established.
- Consortia may be partially/wholly composed of:
 - beneficiaries of the original IMI projects generating the results, and/or
 - partners not involved in the original project.
- Harnessing support from different stakeholders, including the mobilisation of funds through the inclusion of contributing partners – not necessarily involved in the original project – to reflect the public-private character of IMI actions.

Key facts

- **Duration of selected actions:** max 24 months
- **Total budget available** for the Call: EUR 5 000 000 to fund all selected proposals based on the ranking list
- **Publication Date:** 19 July 2017
- **Submission start date:** 19 July 2017
- **Submission deadline:** 24 October 2017 (17:00:00 Brussels time)

IMI2 Call 11: a single-stage Call process



Proposal preparation

- Result(s) chosen from those listed in Table A annexed to the Topic Text have to be highlighted in the section '1.2 Relation to the Call topic text'.
- Justification for the need to further exploit results and expected value to be created - how the proposal trigger long term self-standing sustainability?
- Clear explanation of the contributions mobilised.
- Description of the intended end-users - how they would benefit from the proposed exploitation/sustainability solution?
- All elements listed in the 'Expected Impact' section have to be addressed.
- Detailed explanation of the resources required and alignment with the budget requested.
- For entities that intend to contribute by becoming an Associated Partner of IMI2 JU, a request letter (<http://www.imi.europa.eu/content/get-involved>) has to be provided as an appendix to the proposal

IMI2 Evaluation criteria

- **Excellence – threshold of 3**

Please note sub-criteria listed in evaluation form,

- **Impact – threshold of 3**

Please note sub-criteria listed in evaluation form,

- **Quality and efficiency of the implementation – threshold of 3**

Please note sub-criteria listed in evaluation form

Overall threshold is 10

Submitting a proposal – tips

- **Read** all the relevant material on the IMI2 website **evaluation criteria + Call text !**
- **Understand** the **IMI 2 rules** and respect them
- **Provide all information** the reviewers will need to evaluate your proposal
- **Start working early** (pre-materials available before Call launch)
- **Finalise your submission on time:**

Deadline **24 October 2017**, 17:00:00 CET / Brussels time

- **Contact** the IMI Programme Office if you have any questions

Submitting a proposal – common mistakes

Admissibility / Eligibility criteria not met:

- Missed deadline
- Proposal out of scope
- Submitted text does not respect the proposal template
- Minimum number of independent eligible legal entities

Other:

- All objectives not addressed
- Redundancy between partners
- Limited impact of the proposal, despite scientific excellence
- Ethical issues not addressed

Webinar | IMI2 - Call 11

Rules and procedures

Desmond Barry 26.07.2016

Participation rules

A single set of rules



EU Financial
Regulation
Specific rules for
participation

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

Conditions for this Call for proposals

H2020 Rules for participation apply to IMI2 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

- **Single-stage**

Full proposals combining the public (JU funded) and private applicants

- **Evaluation criteria**

3 criteria (Excellence, Impact, and Quality and efficiency of the implementation)

- **Page-limit**

Conditions for this Call for proposals

- **Submission tool**

FPs to be submitted through the
Electronic Submission Service of the H2020 Participant Portal

- **Submission deadlines**

Established in the Call topic text

- **JU contribution**

The maximum JU contribution is set in the call text.

Evaluated proposals will be ranked in one single list. The best-ranked proposals within available budget will be retained and invited to Grant Agreement preparation.

Conditions for this Call for proposals

- **Plan for exploitation and dissemination**

It must be included in proposals

- **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 (\leq €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 IMI2 JU for carrying out the action

Applicant consortia

Single stage – Full Proposals

- **One Full Consortium consisting of:**
 - IMI fundable legal entities carrying out activities relevant for achieving the project objectives

and

 - legal entities carrying out activities relevant for achieving the project objectives not requesting JU funding which are
 - EFPIA companies
 - IMI2 Associated Partners
 - or any contributing organization

NB: Consortia and beneficiaries not originally involved in the generation of those results annexed to this Call will also be eligible to apply

Funding rules

IMI2 Funding model

- **IMI2 JU is a PPP, actions are normally co-funded by:**
 - JU funding to BRFs (**b**eneficiaries receiving funding = legal entities eligible for funding)
 - In-kind/cash contribution from BNRFs (**b**eneficiaries **n**ot 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 (only) 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)

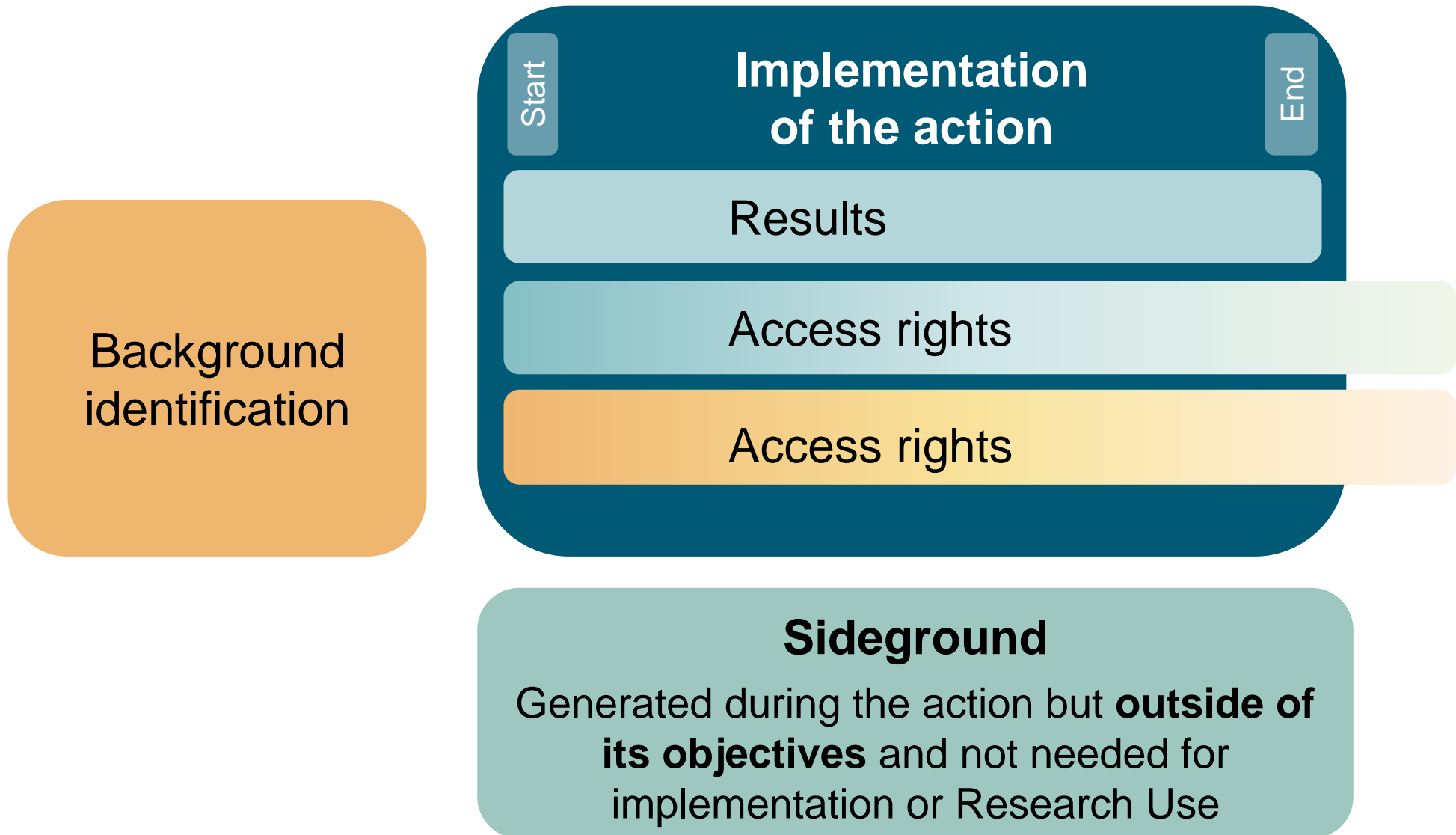
Annual financial reporting is disconnected from GA periodic reports

Deadlines for reporting

- Scientific reporting (full consortium) due at project deadlines (i.e.GA),
duration reporting period: to be adapted to action duration
- 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

IMI2 JU's Intellectual Property (IP) rules

Background vs. Results



How IMI1 Project Foreground is used in IMI2 Call 11



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

Based on previous experience

- **Direct exploitation**

- to develop for commercialisation or to commercialise the results

Access Rights conditions

Access rights granted by a beneficiary to/on	Background (necessary and identified)	Results	Sideground
Beneficiaries for completion of the action	Royalty-free	Royalty-free	N.A.
Beneficiaries and affiliates for Research Use	Fair & reasonable conditions (e.g. Royalty-free conditions)	Fair & reasonable conditions (e.g. Royalty-free conditions)	N.A.
Third Parties for Research Use after the action	Appropriate conditions	Appropriate conditions	N.A.
Beneficiaries and affiliates or Third Parties for Direct Exploitation	To be negotiated	To be negotiated	N.A.

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

A single set of evaluation criteria



- One-stage evaluation:
 - all three criteria considered
- Thresholds and weighting in the **Call documents**
- Minimum of **3 independent experts**

Each proposal **evaluated** 'as it is', not as 'what could be'

Ethics – Self Assessment

Guidance how to complete your ethics self-assessment

- http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf
- Designed to identify and deal correctly with any ethics issues that may arise & necessary to obtain satisfactory clearance by ethics reviewers and will allow avoiding additional delay for grant signature.
- This ethics self-assessment will become part of your grant agreement and may thus give rise to binding obligations.

Ethics Review: Screening

Ethics screening is performed by independent ethics reviewers appointed by the IMI. The proposal is evaluated against the ethics evaluation criteria and may result in the following outcomes:

Intermediate outcomes

- Additional information requested prior to the GA signature;
- Ethics assessment recommended

Final outcomes

- Ethics clearance: nothing to implement during grant preparation
- Conditional ethics clearance: 'Ethics requirements' to be included in the GA

Ethics Review: Assessment

When

- Proposals including human embryonic stem cells (hESC) are directly routed to ethics assessment
- Proposals with complex ethics issues can be routed to ethics assessment as a result of the screening phase

Outcome

- Ethics clearance;
- Conditional ethics clearance (ethics requirements to be implemented during the lifetime of the project);
- Second ethics assessment;
- No ethics clearance (proposal to be rejected).

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



- The new IMI2 MGA (v.4) will apply to Call 11
- It follows H2020 Model Grant Agreement (v.4) with IMI2 specificities.
- An Annotated Model Grant Agreement for IMI2 will soon be available, in the meantime please refer to H2020 AGA
- It is e-signed between IMI2 JU and Coordinator only. Other beneficiaries e-sign Accession Forms
- EFPIA and Associated Partners are beneficiaries not receiving funding (BNRFs, Art.9) - their financial report occurs outside the GA

IMI2 Grant Agreement

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:

<http://efpia.eu/documents/229/141/EFPIA-Consortium-Agreement-Template-for-IMI2-actions>

Consortia may also use alternative templates if they wish.

Questions & answers