

Rules and Procedures for IMI Calls for proposals

IMI2 Calls 7 and 8

- Calls for proposals launched on 18 December 2015
- Calls text and documents available at <http://bit.ly/IMI2Call7> and <http://bit.ly/IMI2Call8>
- **Deadline for short proposal submission for Call 7:** 17 March 2016, 17:00 Brussels time. **For Open Call 8:** 16 March 2016, 15 September 2016, 16 March 2017, 14 September 2017, 15 March 2018 – 17:00 Brussels time.

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

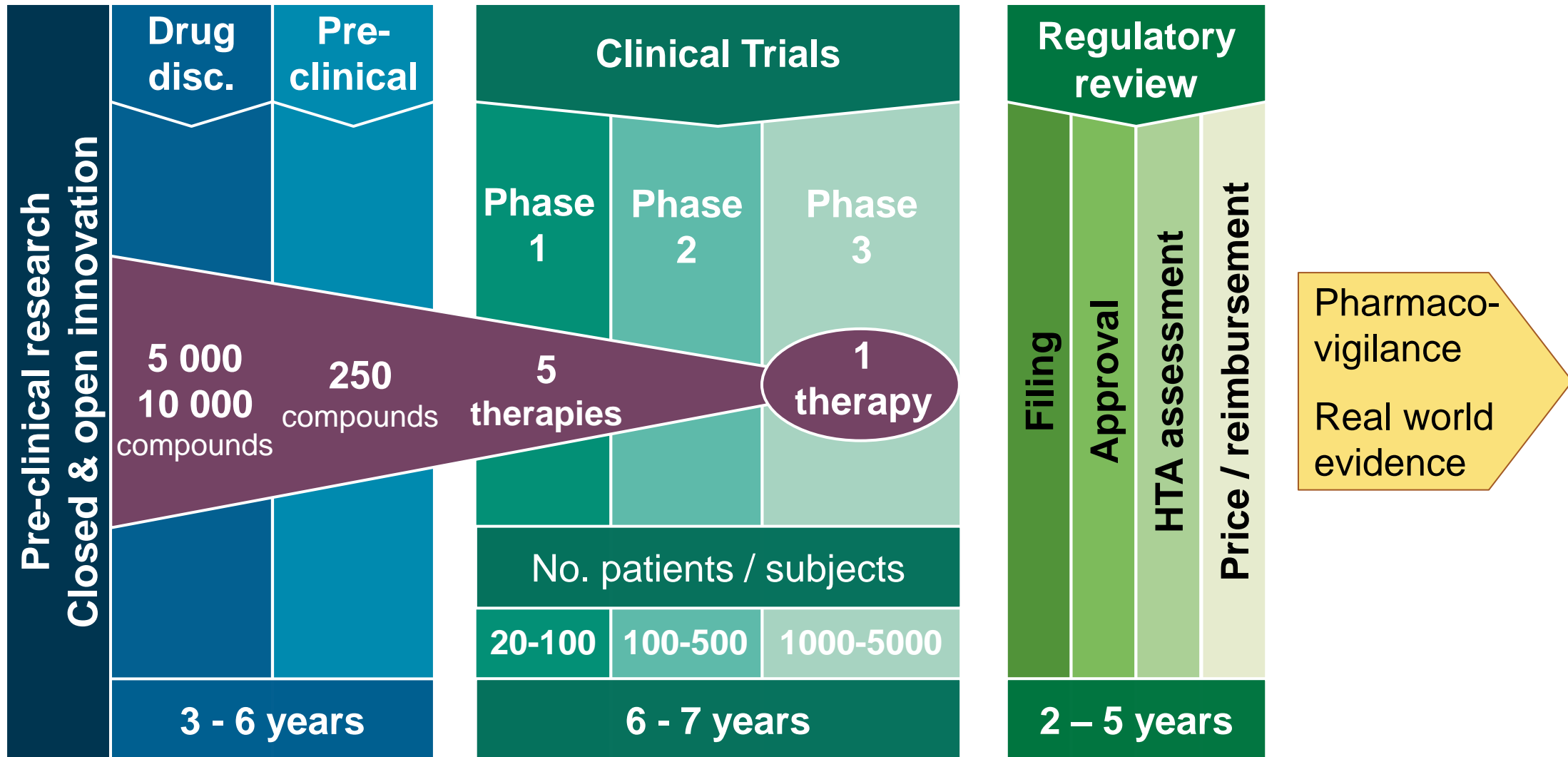
Outline

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



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...



€1.638 bn



€1.425 bn

Other
€213 m

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

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

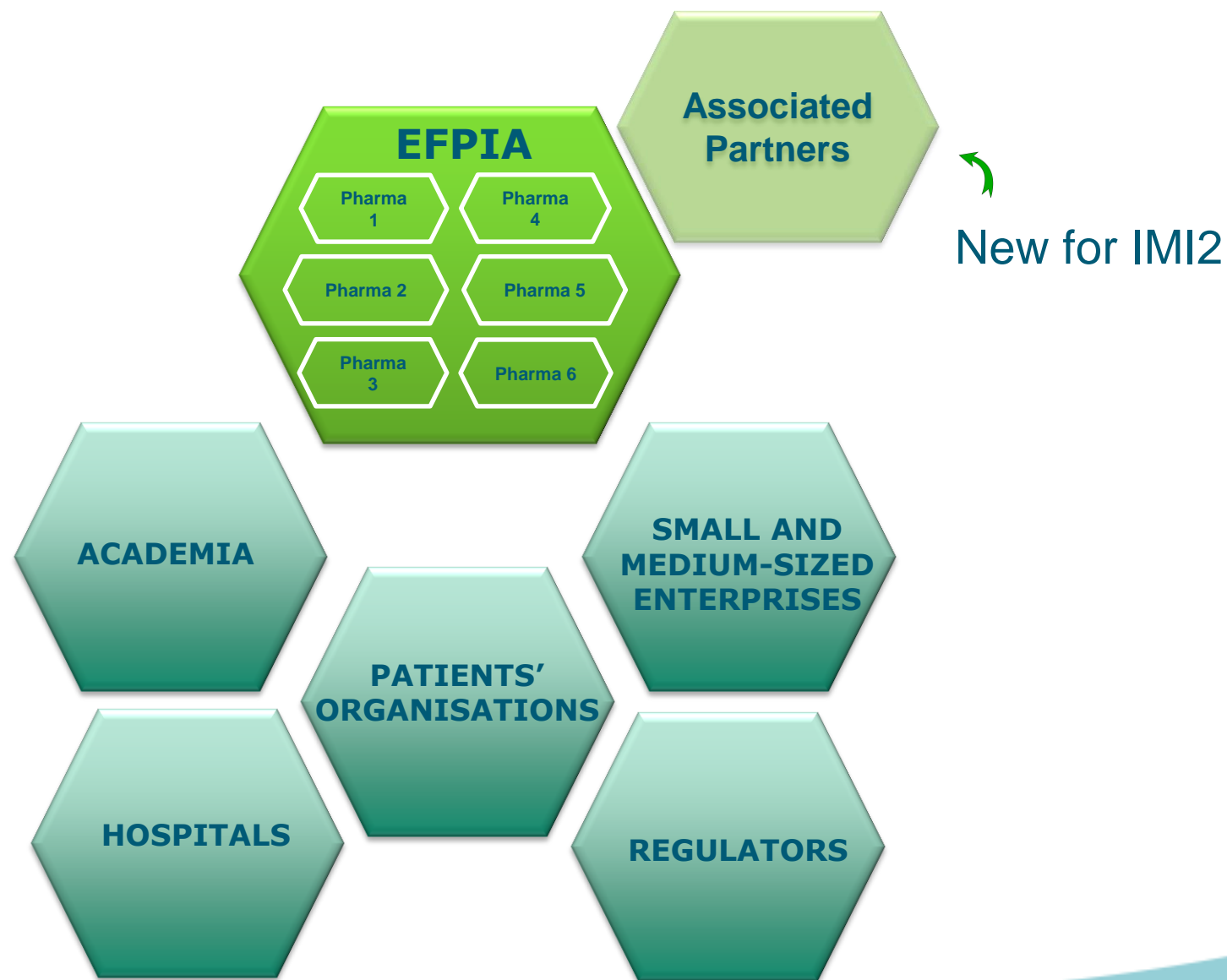
1. Imaging
2. ICT
3. Medical devices....

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



An international, cross-sector community



Over 7 000 researchers working for:

- open collaboration
- improved R&D productivity
- innovative approaches to unmet medical needs

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 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 1stranked 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 (\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 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 (**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 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

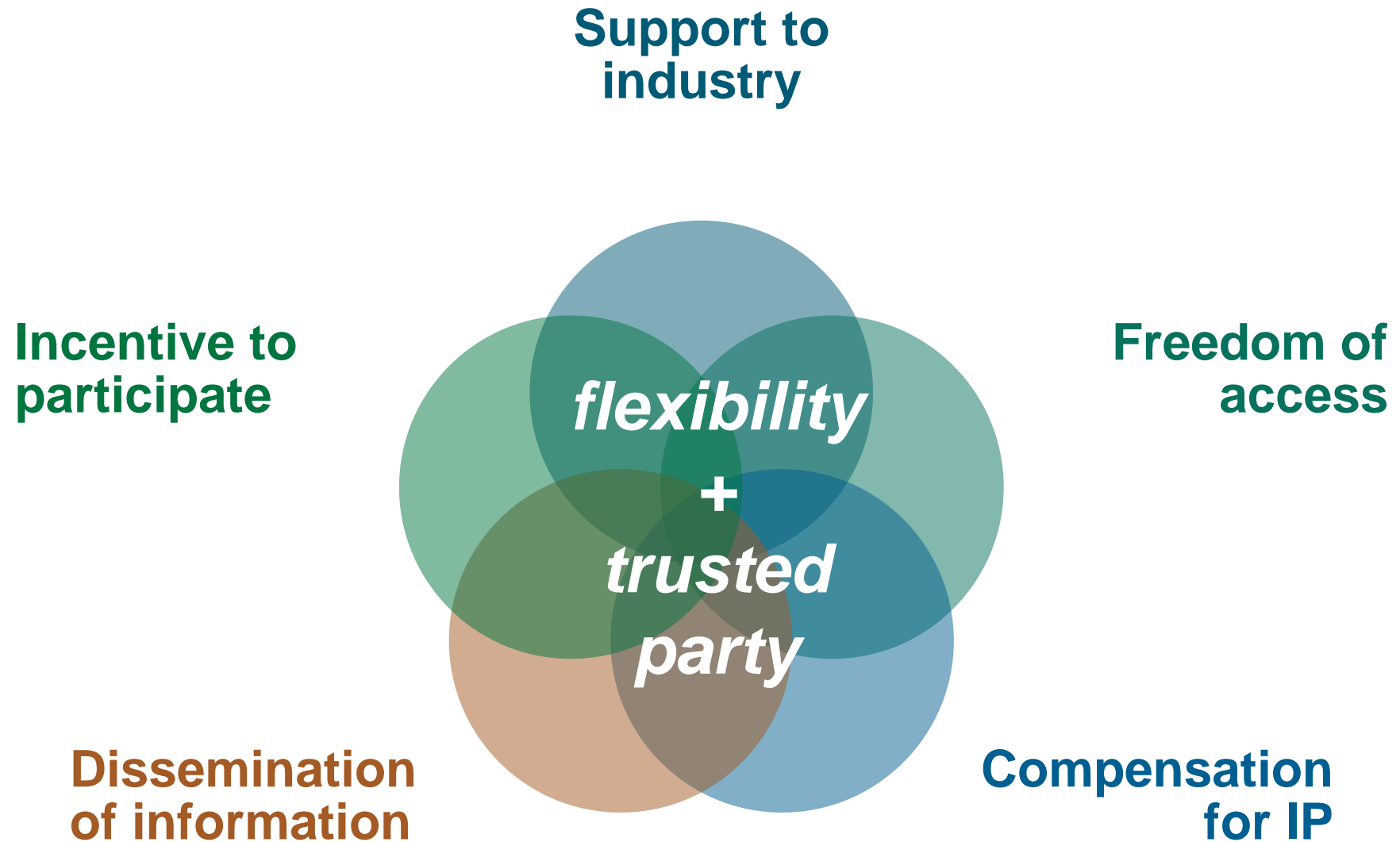
Annual financial reporting is disconnected from GA periodic reports

Deadlines for reporting

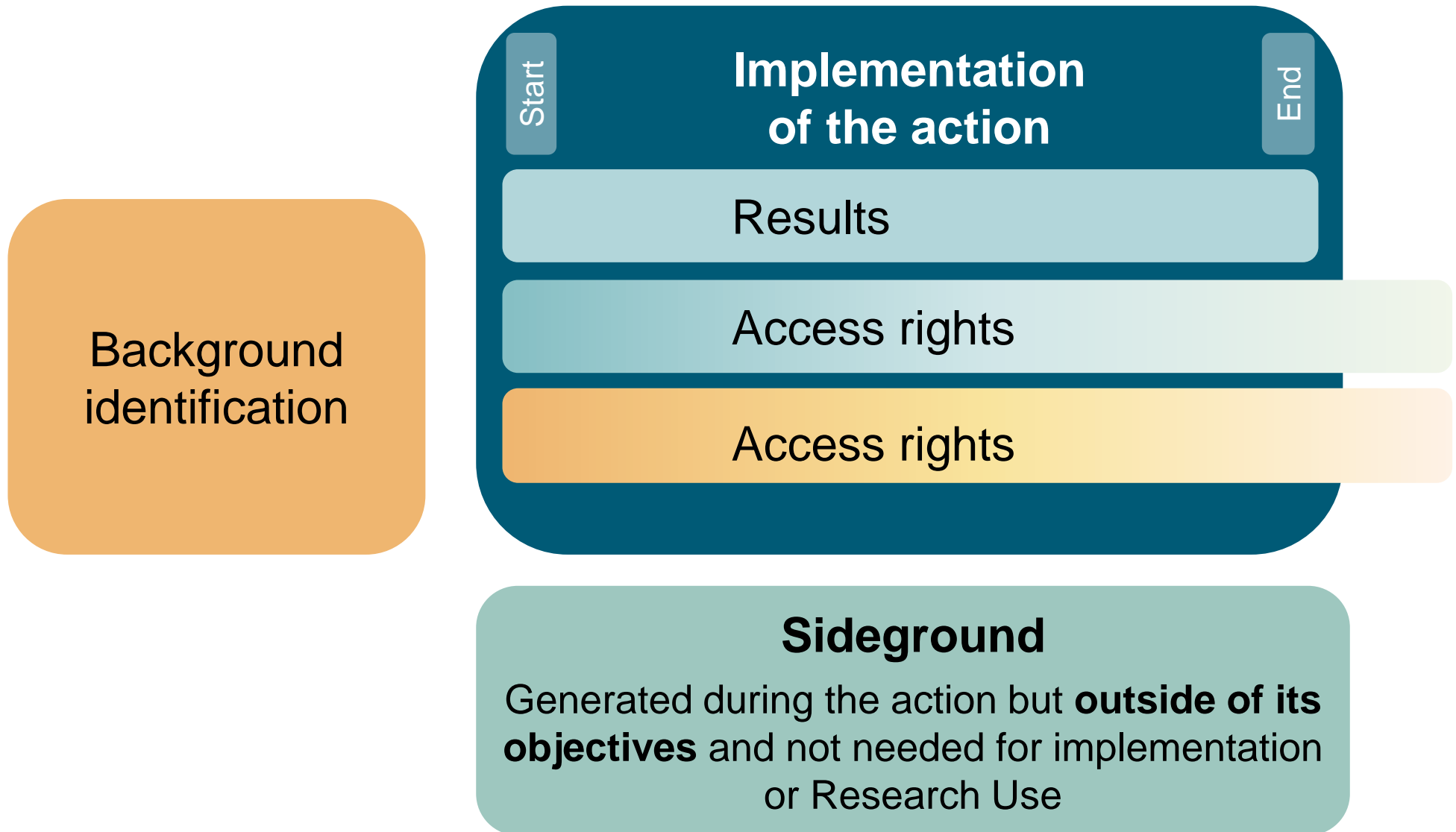
- Scientific reporting (full consortium) due at project deadlines (i.e.GA), duration reporting period: 12 months
- Financial reporting for:
 - Beneficiaries receiving JU funding, due at project deadlines (i.e.GA)
CFS: >EUR 325k at project end
 - Beneficiaries Not receiving funding (e.g. EFPIA companies 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



Background vs. Results



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 terms for background needed for using the results	Fair & reasonable terms	N.A.
Third Parties for Research Use after the action	Fair & reasonable terms for background needed for using the results	Fair & reasonable terms	N.A.
Beneficiaries and affiliates or Third Parties for Direct Exploitation	To be negotiated	To be negotiated	N.A.

Based on previous experience

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)

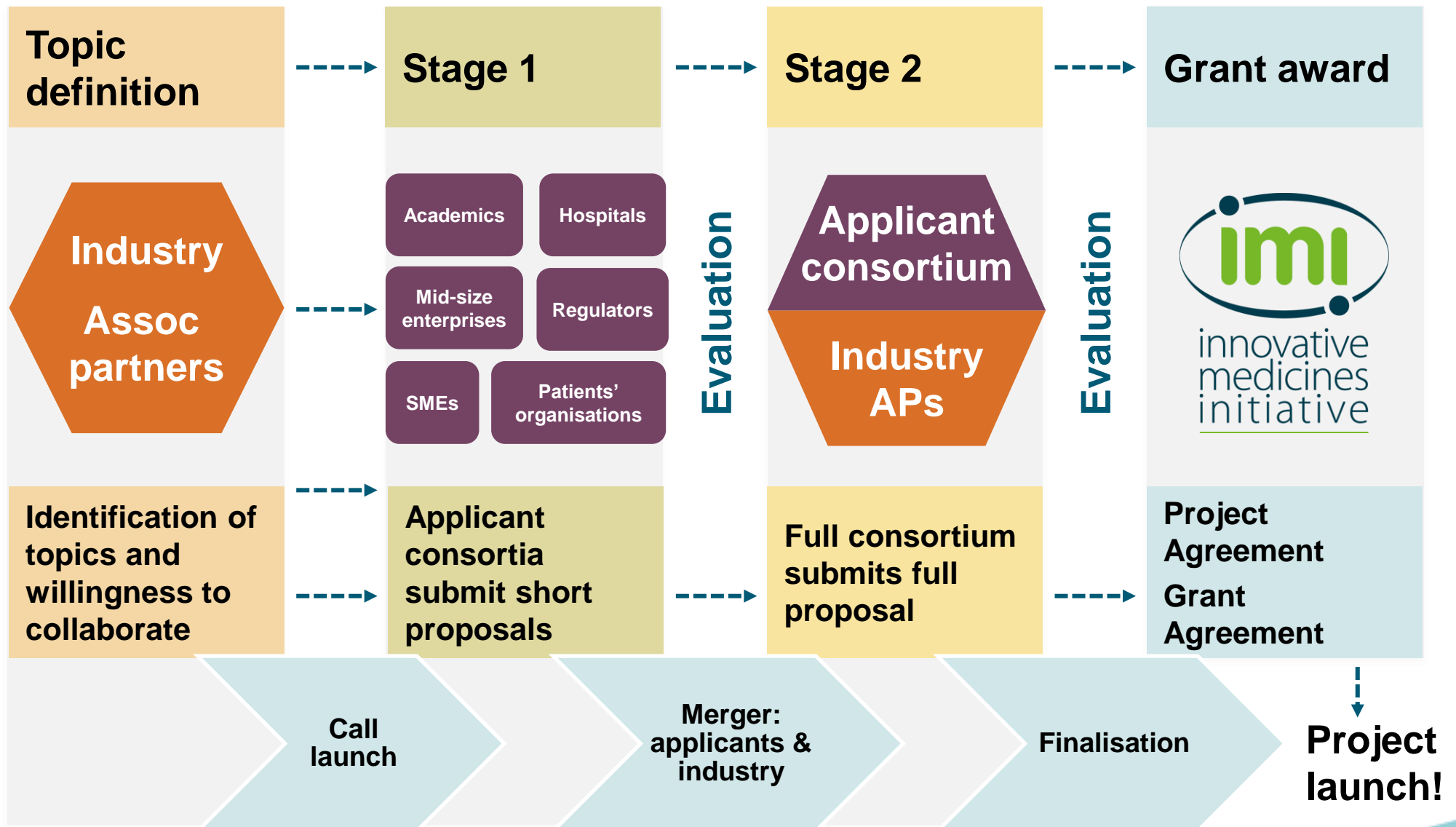
www.imi.europa.eu/content/documents

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



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

[Innovative Medicines Initiative \[BE\]](https://sofia.imi.europa.eu/Pages/Login.aspx) [Request Access](#) [Forgot your password?](#) [Log In]

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Innovative Medicines Initiative

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RESEARCH & INNOVATION
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HOME | **FUNDING OPPORTUNITIES** | HOW TO PARTICIPATE | EXPERTS | SUPPORT

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The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of

[Specific Privacy Statement](#) [SOFIA: Submission OF Information Application](#) Copyright © 2013 IMI.

Welcome to the Research and Innovation Participant Portal

About the Participant Portal:

The Participant Portal is your entry point for the electronic administration of EU-funded research and innovation projects. It hosts services for managing proposals and projects throughout their lifecycle.

The Participant Portal supports activities funded mainly by the following EU programmes:

- 7th Framework Programme for Research and Technological Development (FP7)
- Competitiveness and Innovation Framework Programme (CIP)

Using the Participant Portal:

As a guest user, browse the public pages to:

- search for funding opportunities
- download guidance and legal documents
- search for the participant identification code (PIC) of an organisation
- contact the FP7 support services and browse the FAQ for guidance on the Participant Portal tools

As a registered user, benefit from personalised services for proposal submission, negotiation, and project management.

WHAT'S NEW | **FUNDING OPPORTUNITIES** | **HOW TO PARTICIPATE?** | **WORK AS AN EXPERT** | **ACCESS MY PERSONAL AREA** | **INFORMATION AND SUPPORT**

Partner Search Tool

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

Contact Newsletter Links

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Innovative Medicines Initiative

Search: [input] [magnifying glass] [YouTube] [Twitter] [LinkedIn]

- Home
- About IMI
- Ongoing projects
- Calls for proposals
- News, Events & Media
- Reference documents

Partner search

IMI provides an online **partner search tool** for people, organisations and enterprises interested in participating in future IMI projects.

The tool facilitates the search for potential partners for an Expression of Interest in response to an IMI Call for proposals.

- The Partner Search Tool is accessible through [this link](#)
- Full lists of **key words** has been included for the **IMI 2 Call 1 Call** for proposals.
- The Partner Search Tool was improved, updated and moved to a new location in June 2012. If you were already registered in the previous version of the tool, your profile is automatically included in the new tool, but you will need to **reset your password**, by going to 'Login with an existing account' on the login page.
- People who used the partner search tool for IMI's previous Calls for proposals are advised to update their profiles to reflect the new topics that they are interested in.

If you have any difficulties using the partner search tool, contact pst@imi.europa.eu

LATEST NEWS

11/07/2014 : RT @EFPIA: Friday means a FRESH EFPIA Newsletter! Highlight of the week @IMI_JU @innovationunion #horizon2020 #JTICalls2014 READ <http://t.c...>

10/07/2014 : RT @MichelGoldman: @IMI_JU future: we are very proud to welcome @JDRF to co-drive the type1 #diabetes topic of IMI2: #patients will be at the...

UPCOMING EVENTS

- 30/09/2014** - IMI 2 Open Info Day 2014 IMI will hold an Open Info Day on its

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

<http://www.fitforhealth.eu/>



More information

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- PARTNER SEARCH
- EDUCATION & TRAINING
- SMALL & MEDIUM-SIZED ENTERPRISES
- INTELLECTUAL PROPERTY

THE INNOVATIVE MEDICINES INITIATIVE
The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients.
IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.
IMI is a joint undertaking between the European Union and the pharmaceutical industry association EFPIA.

IMI NEWSFLASH
10/11/2014 : Got questions about IMI's #Ebola programme? Check the FAQs and sign up to our webinars on 12/11 and 17/11 <http://t.co/gaZFmWZk1a>
06/11/2014 : IMI #Ebola Topic 5: rapid #diagnostic tests that work in the real world <http://t.co/gaZFmWZk1a>
06/11/2014 : IMI #Ebola Topic 4: using technology to promote #vaccine compliance <http://t.co/gaZFmWZk1a>

IMI LAUNCHES EBOLA+ PROGRAMME
IMI has launched an ambitious programme to accelerate the development of **vaccines and treatments against Ebola and related diseases**. The first Call under the Ebola+ programme has a total budget of €280m.

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AGENDA
• 03/12/2014 - C-Path and IMI 2nd Annual Meet...
• 26/11/2014 - Bringing health-related life s...
• 18 - 18/11/2014 - Financial Management Workshop ...



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

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