

# Rules and Procedures for IMI Calls for proposals

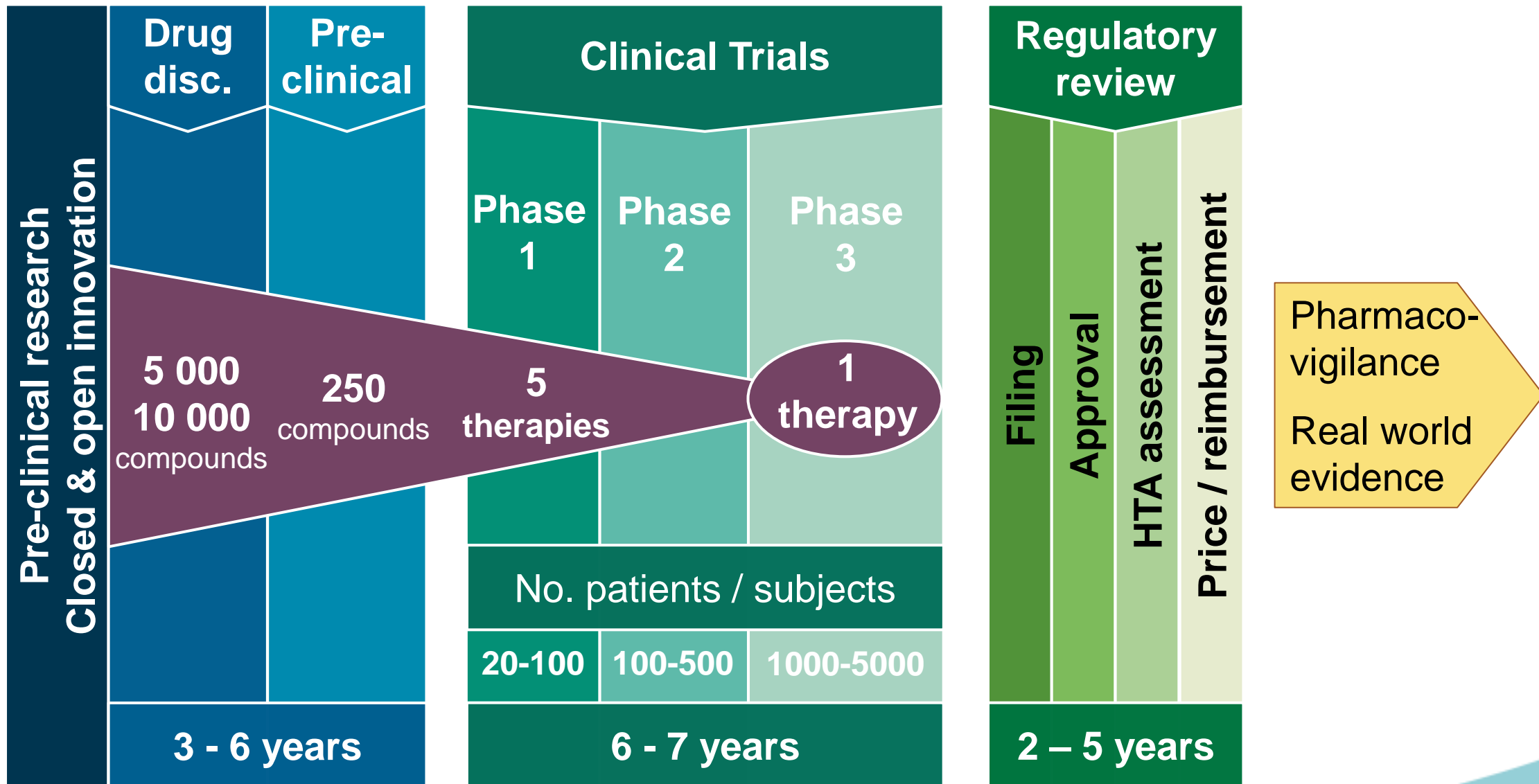
# Outline

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 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



# An international, cross-sector community



**Over 9 000 researchers** working for:

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

*Figures from June 2016*



# Introduction to IMI 2 – Call 10

# 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>
- **Deadline for short proposal submission: 28 March 2017**
- Deadline for Full proposal submission: 14 September 2017
- Webinar topic presentations and recordings: <http://bit.ly/1RSPiTC>

# Call 10 – **NEW!**

- Use of the electronic submission service of the **Horizon 2020 Participant Portal**:  
<https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/calls/h2020-jti-imi2-2016-10-two-stage.html>
- 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.

More information: [http://ec.europa.eu/research/participants/docs/h2020-funding-guide/user-account-and-roles/ecas-login\\_en.htm](http://ec.europa.eu/research/participants/docs/h2020-funding-guide/user-account-and-roles/ecas-login_en.htm)

# 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

Participant	Country	(A) Direct personnel costs/€	(B) Other direct costs/€	(C) Direct costs of sub- contracting/€	(D) Direct costs of providing financial support to third parties/€	(E) Costs of inkind contributions not used on the beneficiary's premises/€	(F) Indirect Costs / € (=0.25(A+B-E))	(G) Special unit costs covering direct & indirect costs / €	(H) Total estimated eligible costs / € (=A+B+C+D+F +G)	(I) Reimburse- ment rate (%)	(J) Max.EU Contribution / € (=H*I)	(K) Requested EU Contribution/ €
		?	?	?	?	?	?	?	?	?	?	?
		0	0	0	0	0	0,00	0	0,00	100	0,00	0,00
Total		0	0	0	0	0	0,00	0	0,00		0,00	0,00



# 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 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 1<sup>st</sup>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 1<sup>st</sup> 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 ( $\leq$  €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:**
  - 1<sup>st</sup> ranked SP consortium - IMI fundable legal entities/additional legal entities
  - ☞ **Under Topic 3 - 1<sup>st</sup> ranked consortium selected under each (of 3) sub-topic are merged**
  - 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 **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

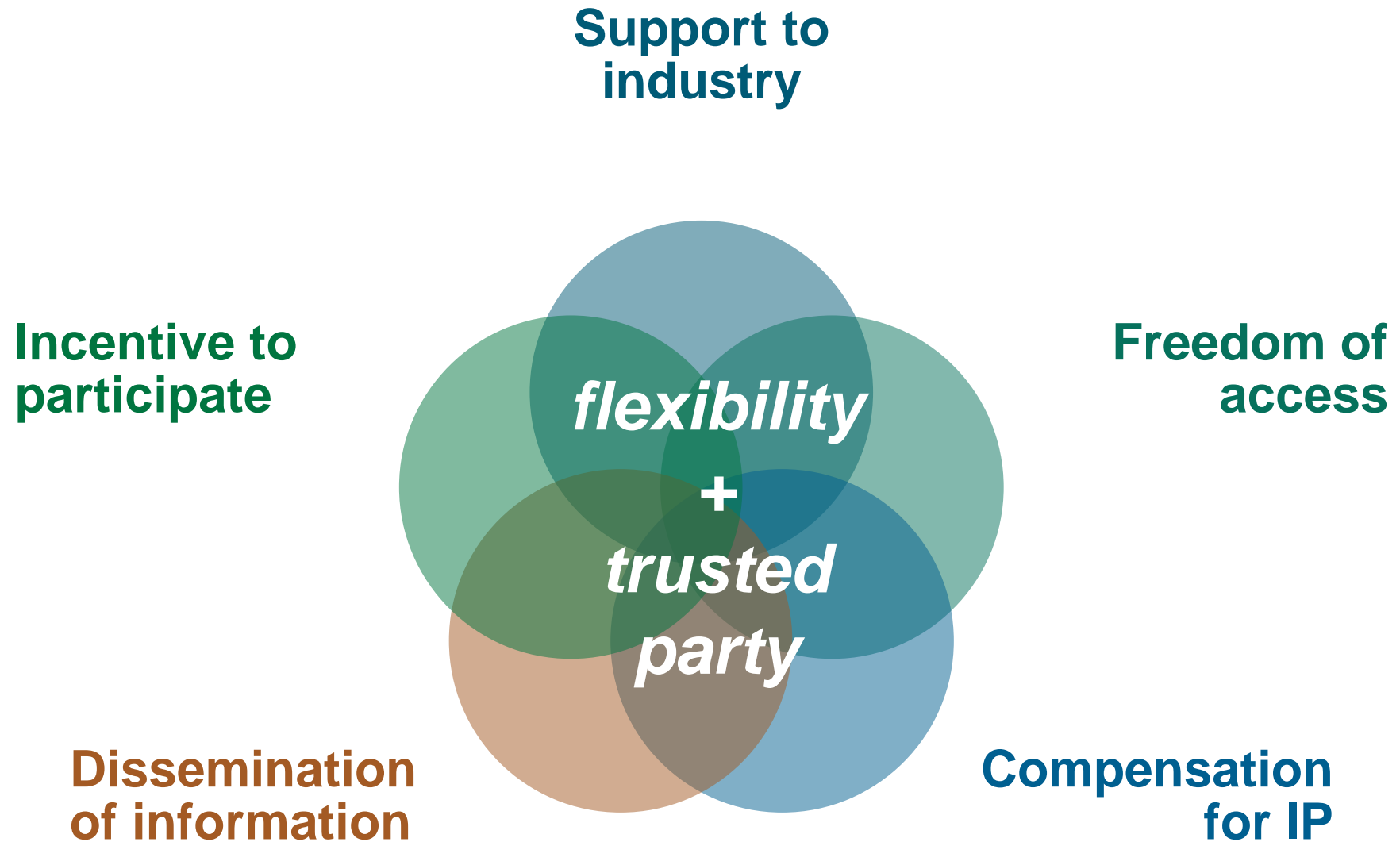
# Deadlines for reporting

- 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

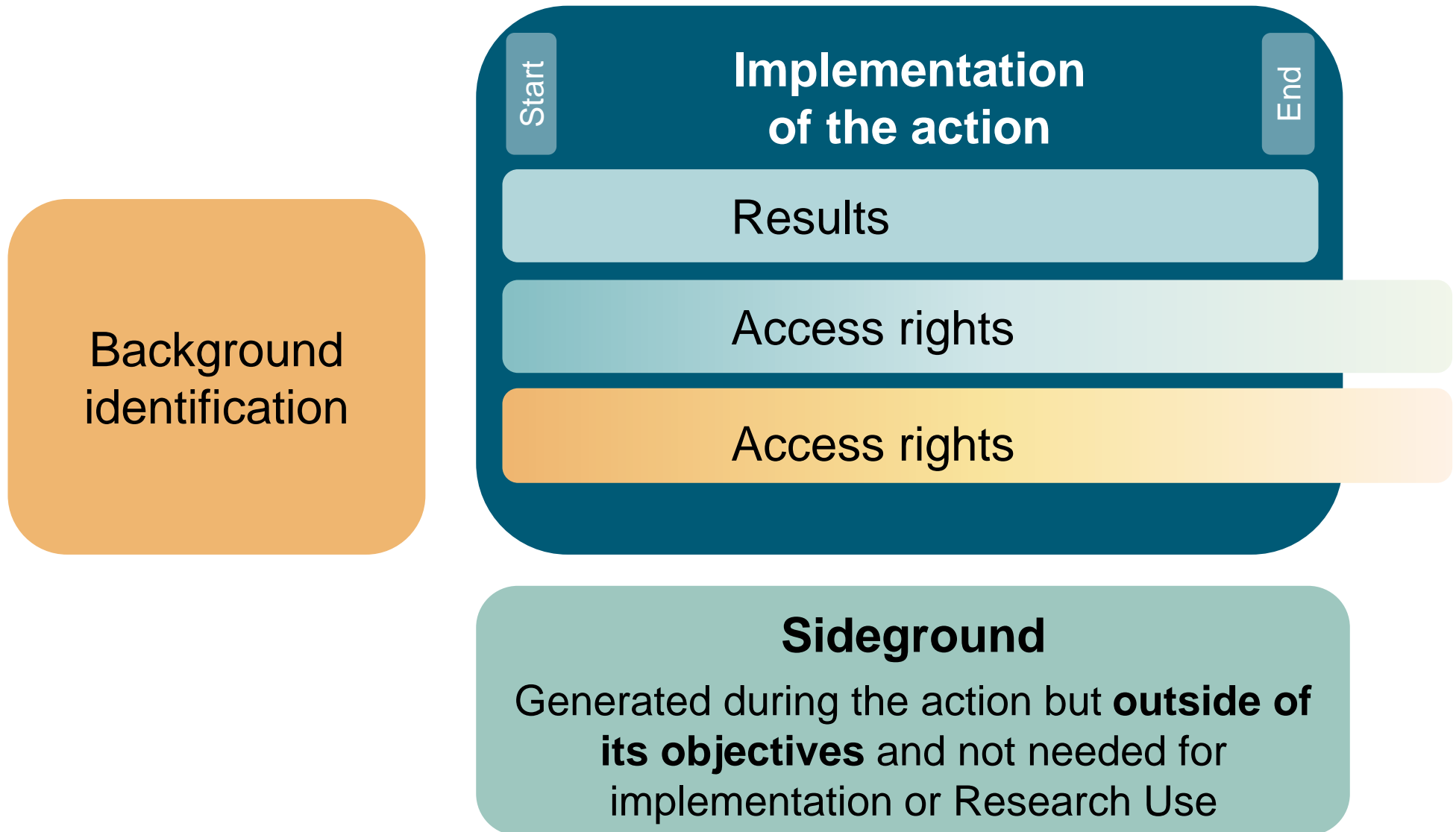
# IMI's Intellectual Property (IP) rules



# One set of rules for multiple interests



# 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 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)

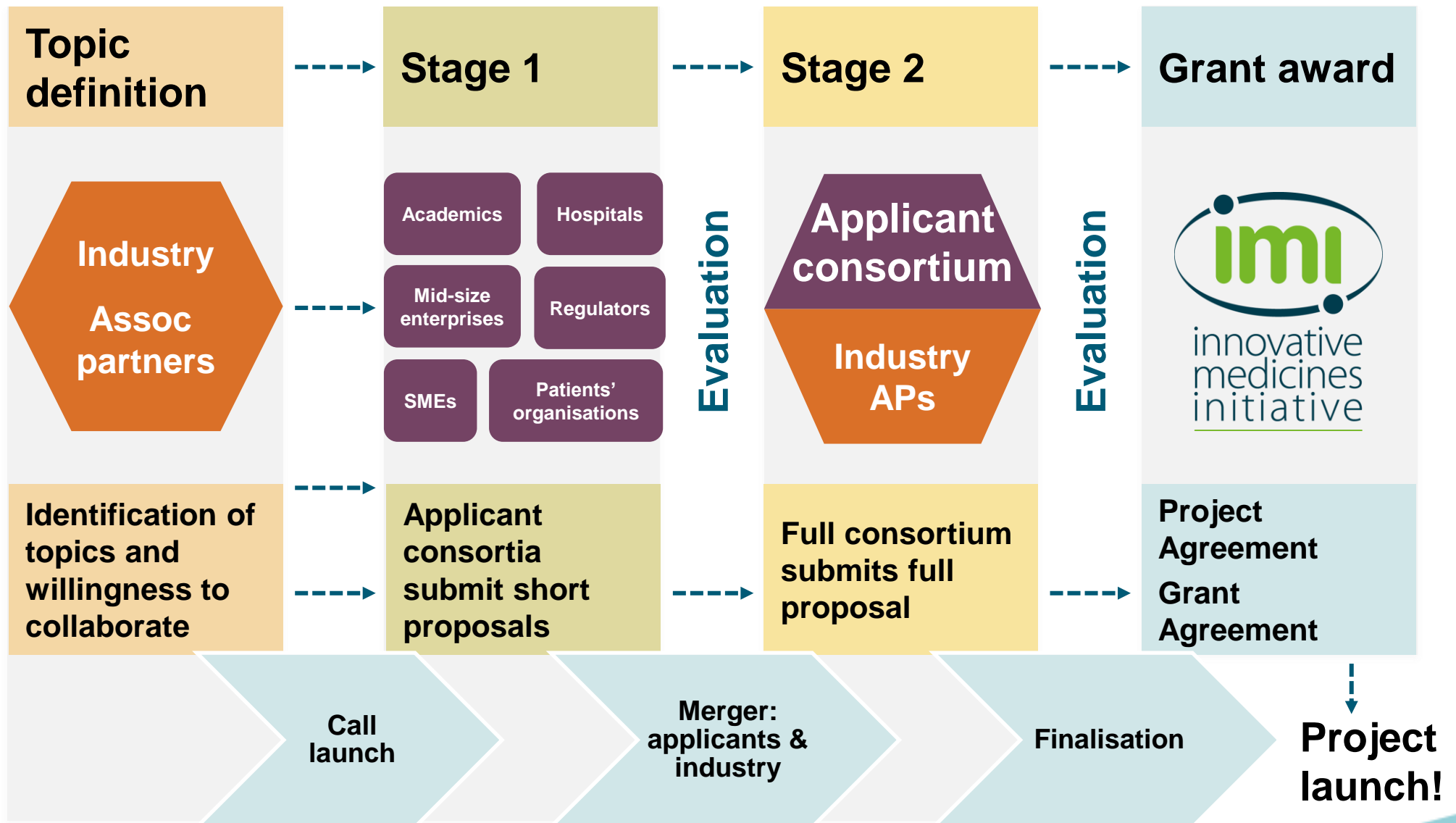
[www.imi.europa.eu/content/documents](http://www.imi.europa.eu/content/documents)



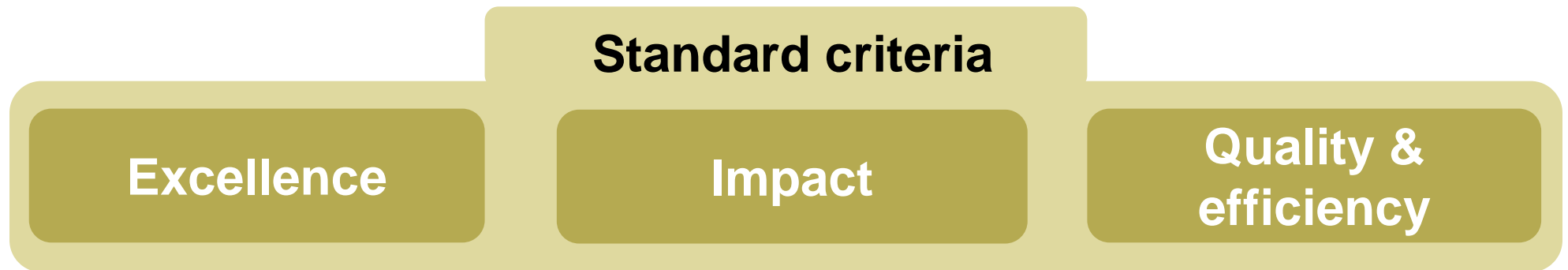


# From Call to grant award

# Typical IMI project life cycle



# 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

# IMI2 Grant Agreement



- 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



# 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.

# 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](http://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](http://www.imi.europa.eu/content/tips-applicants)

# Submitting a proposal

The screenshot displays the 'Participant Portal' for the European Commission. The main navigation bar includes 'HOME', 'FUNDING OPPORTUNITIES', 'HOW TO PARTICIPATE', 'EXPERTS', and 'SUPPORT'. A search bar and 'LOGIN'/'REGISTER' buttons are also present. The left sidebar lists various EU programmes from 2014-2020 and FP7 & CIP programmes from 2007-2013. The main content area features a call for proposals: 'CALL: H2020-JTI-IMI2-2016-10-TWO-STAGE', published on 21 December 2016. Below this, there is a 'Horizon 2020' banner and a 'Call updates' section with a '+ More' button. A 'Topics and submission service' section provides instructions on how to access the submission service and existing draft proposals. At the bottom, there are two detailed topic cards. The first topic is 'IMI2-2016-10-01: Understanding hypoglycaemia: the underlying mechanisms and addressing clinical determinants as well as consequences for people with diabetes by combining databases from clinical trials', published on 21 December 2016. It is a two-stage IMI2-RIA action with an opening date of 04 January 2017, a deadline of 28 March 2017 17:00:00, and a 2nd stage deadline of 14 September 2017 17:00:00. The second topic is 'IMI2-2016-10-02: How Big Data could support better diagnosis and treatment outcomes for Prostate Cancer', also published on 21 December 2016, with identical submission details.

<https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/calls/h2020-jti-imi2-2016-10-two-stage.html>

# Partner Search Tool

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

Contact Newsletter Links

**imi**  
Innovative Medicines Initiative

Search: [input] [button] [button] [button] [button]

- 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](mailto: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.imi.europa.eu/content/partner-search)

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





**More information**

# Stay in touch

- Visit our website  
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- Sign up to our newsletter  
[bit.ly/IMInewsletter](http://bit.ly/IMInewsletter)
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- Join our LinkedIn group  
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- E-mail us  
[infodesk@imi.europa.eu](mailto:infodesk@imi.europa.eu)



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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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**NEWSLETTER**  
Read & subscribe more  
**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](mailto:infodesk@imi.europa.eu)
- IP queries: [IMI-IP-Helpdesk@imi.europa.eu](mailto:IMI-IP-Helpdesk@imi.europa.eu)

## Local contacts

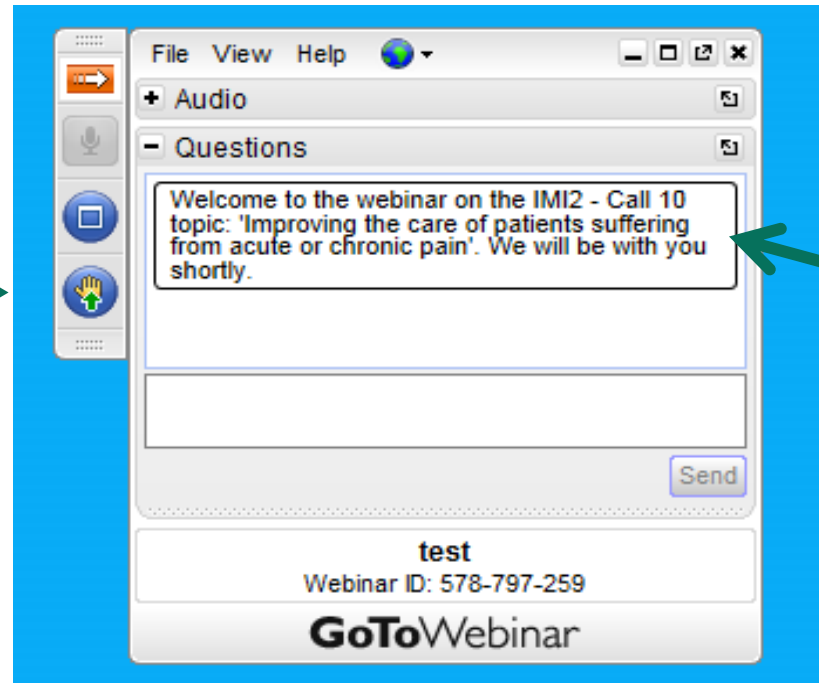
- IMI States Representatives Group: [bit.ly/IMISRG](http://bit.ly/IMISRG)
- Horizon 2020 Health National Contact Points: [bit.ly/H2020\\_NCPs](http://bit.ly/H2020_NCPs)

# 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!**

[Infodesk@imi.europa.eu](mailto:Infodesk@imi.europa.eu)

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