

Rules and Procedures for IMI Calls for proposals

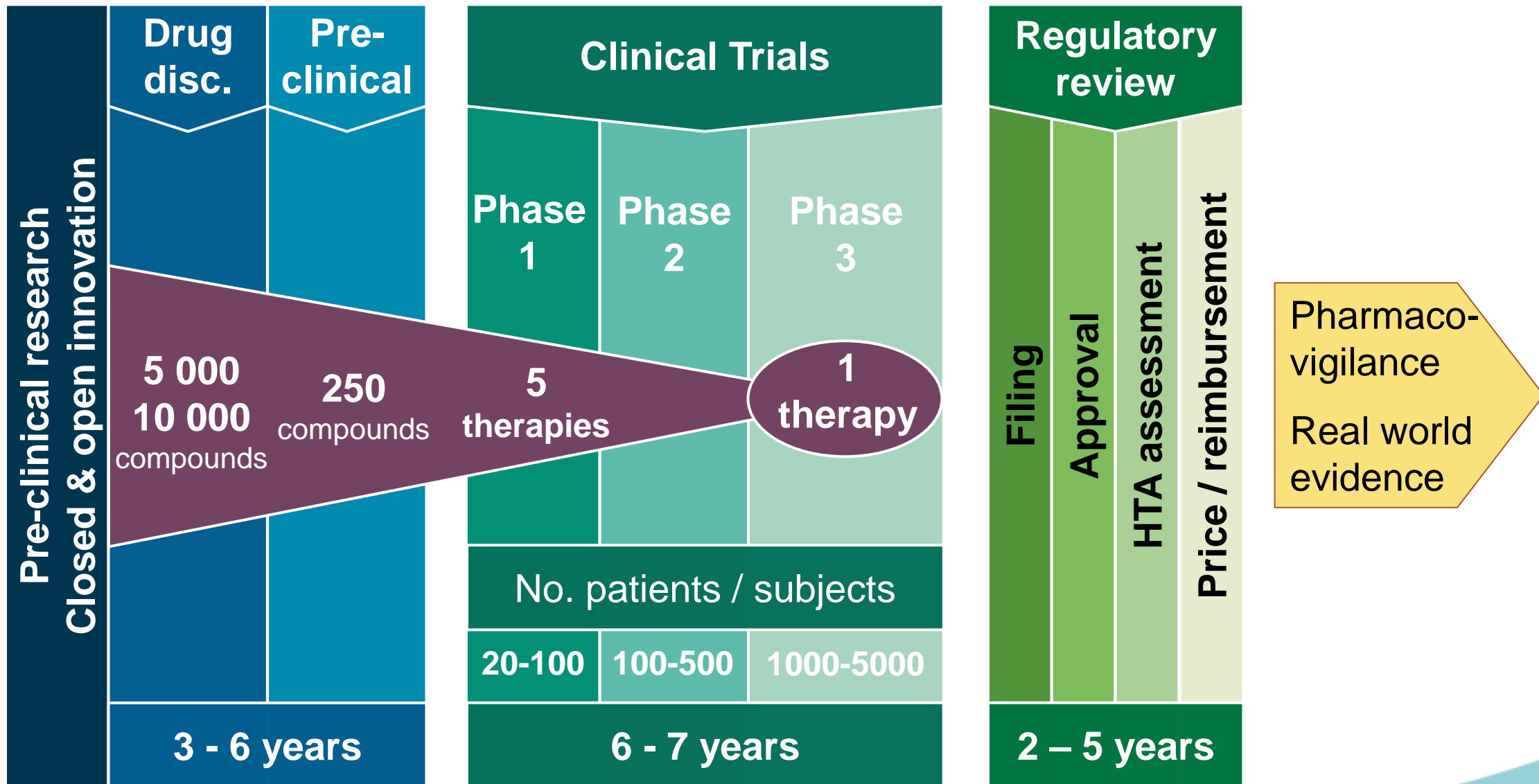
Outline

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 12

IMI2 Call 12 - topics

- **Topic 1:** Development and validation of technology enabled, quantitative and sensitive measures of functional decline in people with early stage Alzheimer's disease (RADAR-AD)
- **Topic 2:** FAIRification of IMI and EFPIA data
- **Topic 3:** Development of sensitive and validated clinical endpoints in primary Sjögren's Syndrome (pSS)
- **Topic 4:** European Health Data Network (EHDN)
- **Topic 5:** Analysing the infectious disease burden and the use of vaccines to improve healthy years in aging populations
- **Topic 6:** Discovery and characterisation of blood-brain barrier targets and transport mechanisms for brain delivery of therapeutics to treat neurodegenerative & metabolic diseases
- **Topic 7:** European Screening Centre: unique library for attractive biology (ESCulab)

IMI 2 - Call 12

- Date of Call launch: 19 July 2017
- Calls text and documents are published on the:
IMI website
- **Deadline for Short Proposal submission: 24 October 2017**
- Deadline for Full Proposal submission: 16 May 2018
- Webinar topic presentations and recordings: <http://bit.ly/1RSPiTC>

Call 12 – **NEW!**

- Use of the electronic submission service of the **Horizon 2020 Participant Portal**:
<https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020>

- 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

Call 12 – **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 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

- **Two-stages**

Stage 1 SPs from applicants requesting JU funding

Stage 2 merging 1stranked SPs with industry consortia

- **Evaluation criteria**

At stage 1, all 3 criteria are evaluated (including budget)

- **Page-limits**

SP 30 pp, FP 70 pp

Conditions for this Call for proposals

- **NEW: Submission tool**

As of call 10, 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, 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

- **Information on the outcome of the evaluation:**

Information to the applicants - max 5 months from submission deadline

- **Financial Support to Third Parties**

Where relevant, applicants should develop in FPs open, transparent, objective processes and criteria for the allocation of financial support in accordance to Annex K of the H2020 WP, and article 15 of the IMI2 MGA

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

Expected consortia

Stage 1 of two stage - Short Proposals

- **Consortia consisting of:**
 - IMI2 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 - IMI2 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 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)

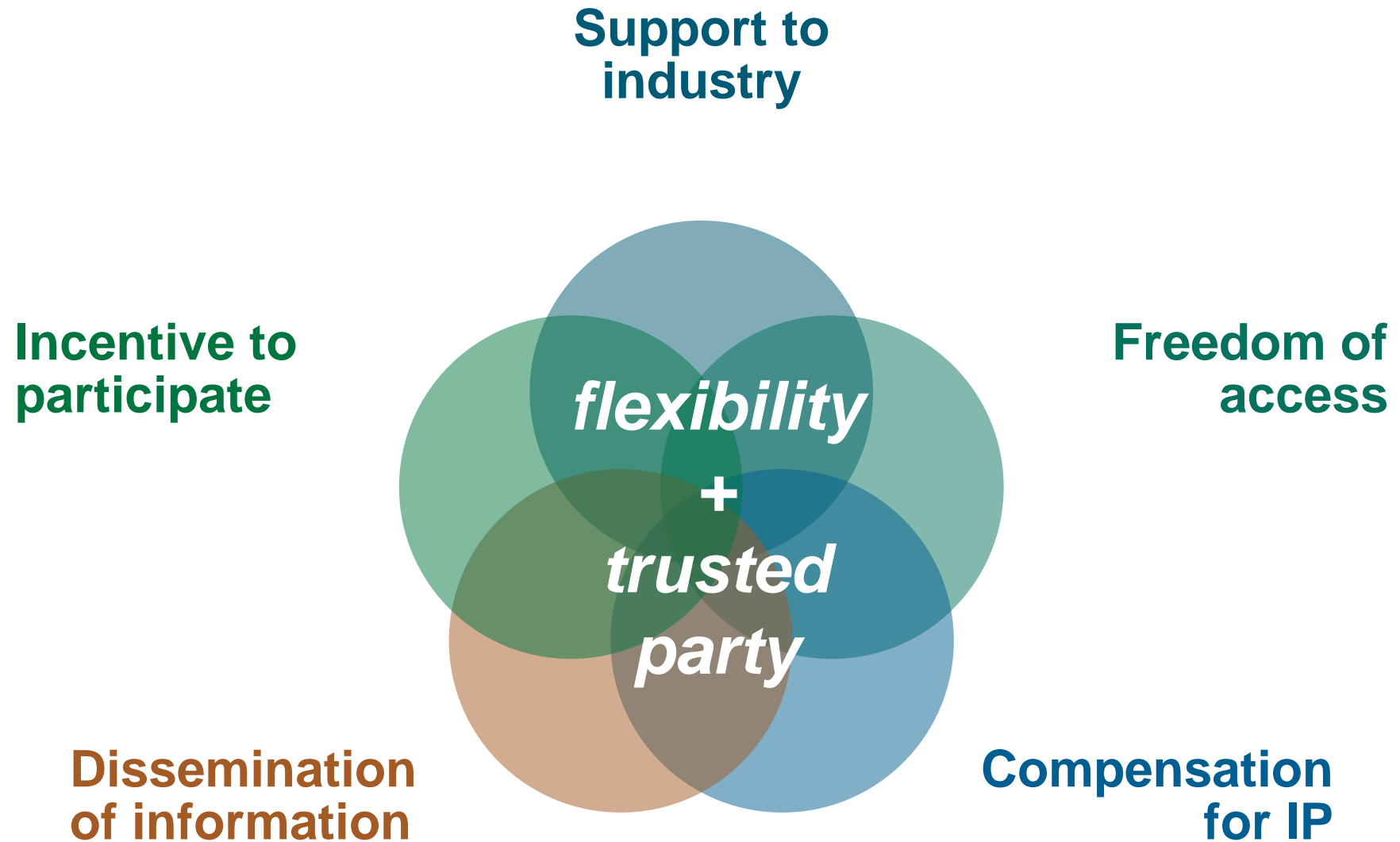
Annual financial reporting is disconnected from GA periodic reports

Deadlines for reporting

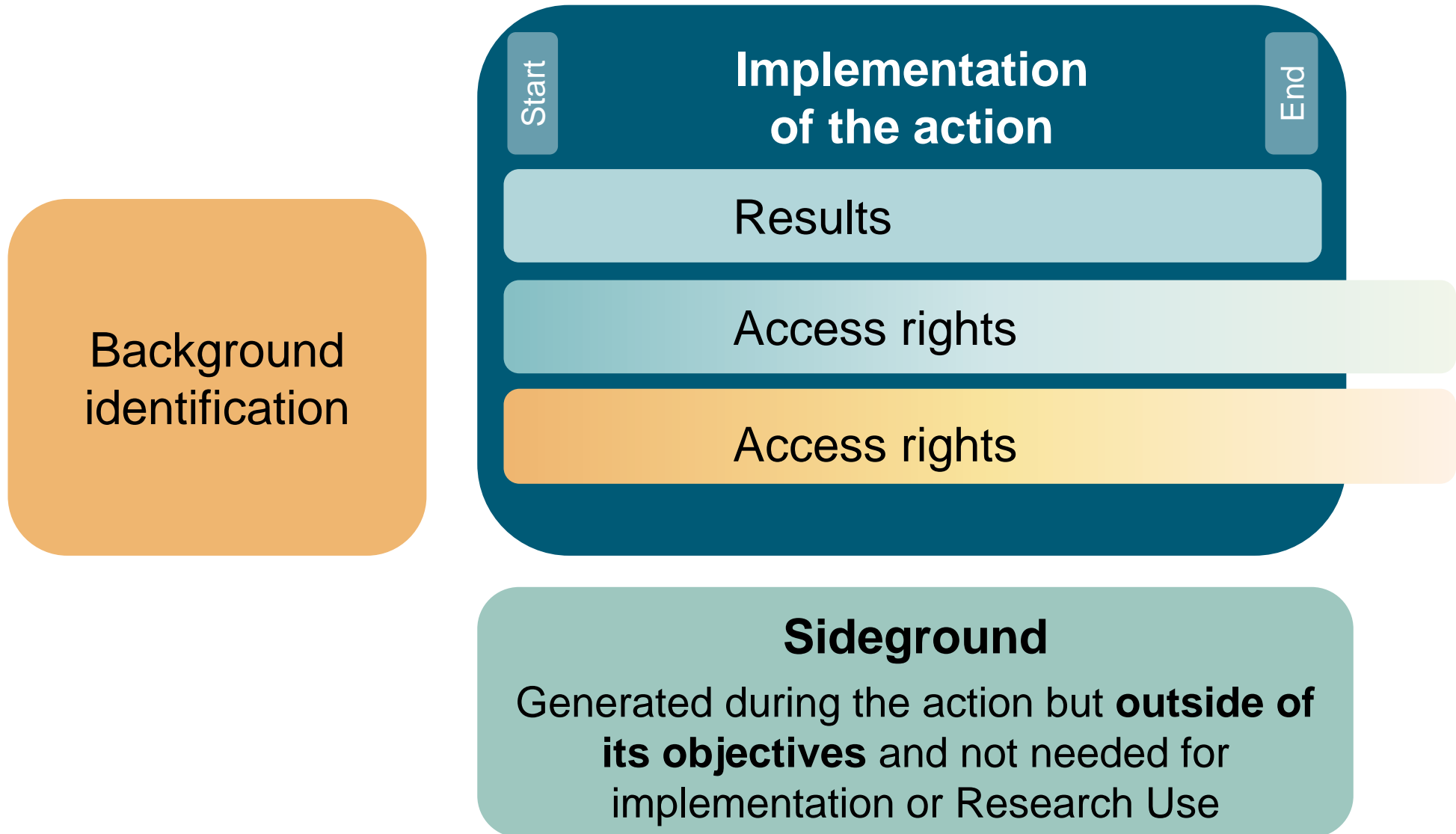
- Scientific reporting (full consortium) due at project deadlines (i.e.GA),
duration reporting period: 12 months
- Financial reporting for:
 - Beneficiaries receiving JU funding, due at project deadlines (i.e.GA)
 - CFS: >EUR 325k at project end
 - Beneficiaries Not receiving funding (e.g. EFPIA companies and APs),
 - due by 31 Jan - certification by 30 April - covering previous calendar year

IMI2 JU'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

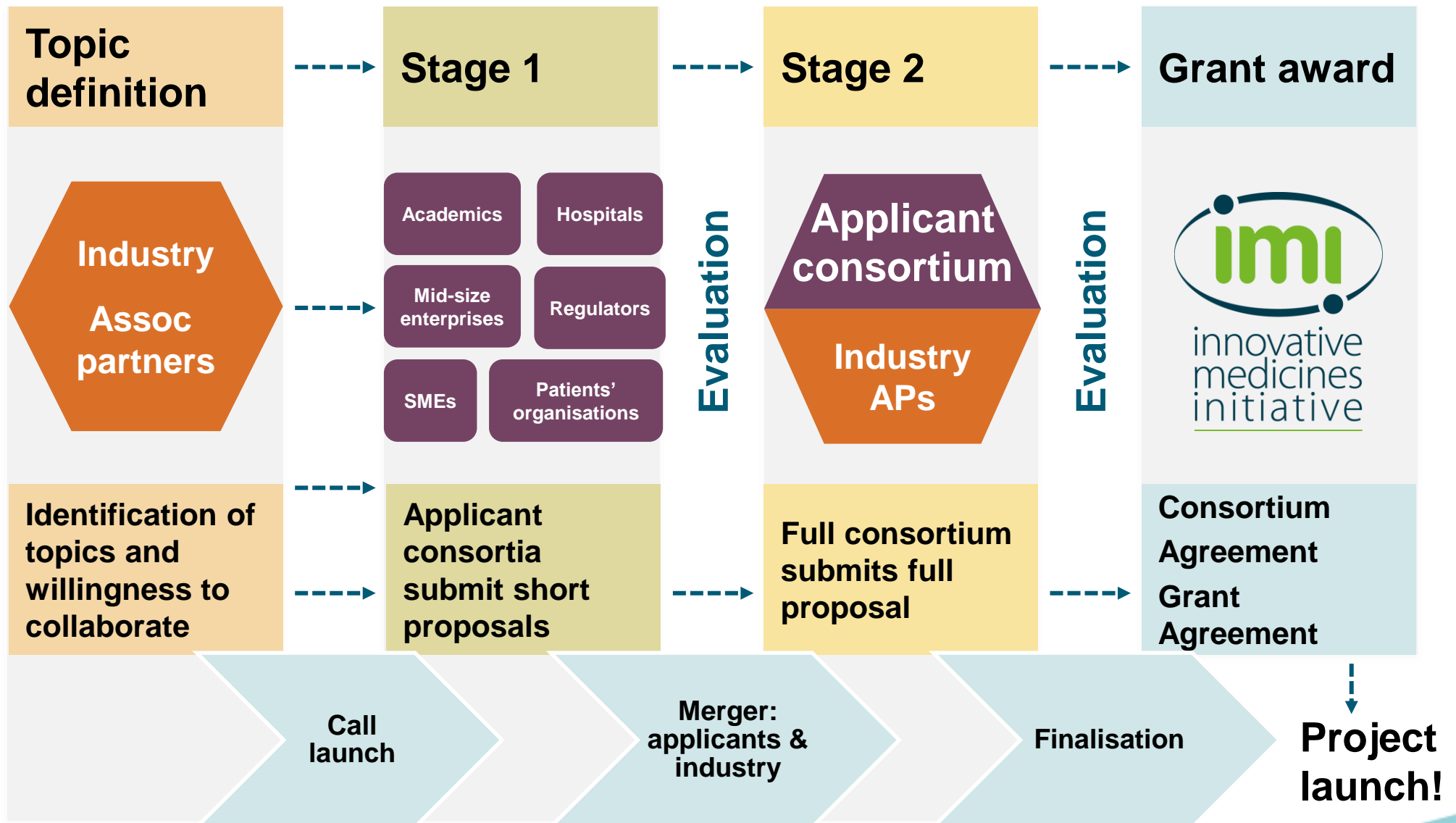
Reference documents

- **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

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
- 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.4) will apply to Call 12
- 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.

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
- 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

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' section and a 'Call updates' box with a '+ More' link. 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, each with an 'Open' status and specific dates for action, deadline, and opening.

European Commission Participant Portal

European Commission > Research & Innovation > Participant Portal > Opportunities

HOME FUNDING OPPORTUNITIES HOW TO PARTICIPATE EXPERTS SUPPORT Search LOGIN REGISTER

EU Programmes 2014-2020

Search Topics

Updates

Calls

H2020

3rd Health Programme

Asylum, Migration and Integration Fund

Consumer Programme

COSME

Internal Security Fund - Borders

Internal Security Fund - Police

Justice Programme

Promotion of Agricultural Products

Research Fund for Coal & Steel

Rights, Equality and Citizenship Programme

FP7 & CIP Programmes 2007-2013

Calls

Other Funding Opportunities

CALL: H2020-JTI-IMI2-2016-10-TWO-STAGE [Call budget overview](#)
Call identifier: H2020-JTI-IMI2-2016-10-TWO-STAGE
Publication date: 21 December 2016

Horizon 2020

Call updates [+ More](#)

- 04 January 2017 10:24** The submission session is now available for: IMI2-2016-10-01(IMI2-RIA), IMI2-2016-10-04(IMI2-RIA), IMI2-2016-10-03(IMI2-RIA), IMI2-2016-10-08(IMI2-RIA), IMI2-2016-10-07(IMI2-RIA), IMI2-2016-10-05(IMI2-RIA), IMI2-2016-10-02(IMI2-RIA), IMI2-2016-10-06(IMI2-RIA).

Topics and submission service

To access the **Submission Service**, please **select the TOPIC** of your interest and then open the Submission Service tab.
To access **existing draft proposals**, please login to the portal and select My Proposals from the My Area menu.

Status Forthcoming Open Closed

Sort by (Planned) opening date Deadline Topic title Topic identifier

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 [Open](#)
Publication date: 21 December 2016

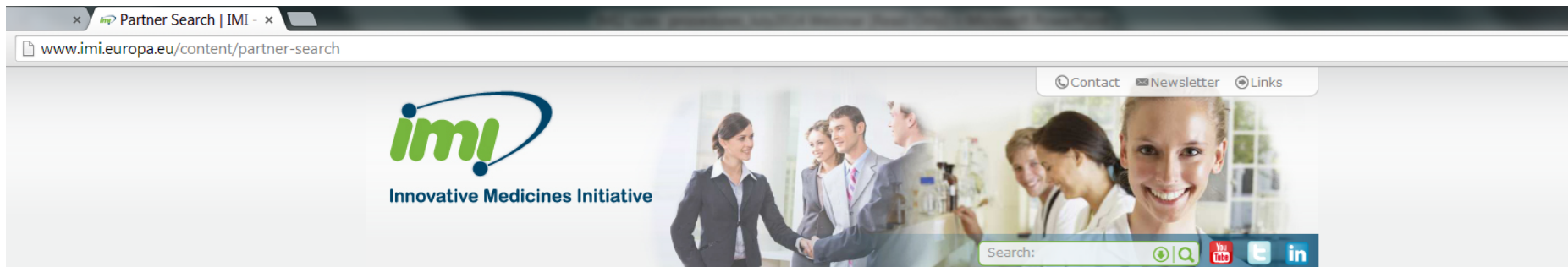
Types of action: IMI2-RIA Research and Innovation action
DeadlineModel: two-stage **Deadline:** 28 March 2017 17:00:00
Opening date: 04 January 2017 **2nd stage Deadline:** 14 September 2017 17:00:00
Time Zone : (Brussels time)

IMI2-2016-10-02: How Big Data could support better diagnosis and treatment outcomes for Prostate Cancer [Open](#)
Publication date: 21 December 2016

Types of action: IMI2-RIA Research and Innovation action
DeadlineModel: two-stage **Deadline:** 28 March 2017 17:00:00
Opening date: 04 January 2017 **2nd stage Deadline:** 14 September 2017 17:00:00
Time Zone : (Brussels time)

<https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020>

Partner Search Tool



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

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

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

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

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



More information

Stay in touch

- Visit our website
www.imi.europa.eu
- Sign up to our newsletter
bit.ly/IMInewsletter
- Follow us on Twitter
[@IMI_JU](https://twitter.com/IMI_JU)
- Join our LinkedIn group
bit.ly/LinkedInIMI
- E-mail us
infodesk@imi.europa.eu



- Home
- About IMI
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- Reference documents

- 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 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.

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/gaZFnWZk1a>

06/11/2014 : IMI #Ebola Topic 5: rapid #diagnostic tests that work in the real world <http://t.co/gaZFnWZk1a>

06/11/2014 : IMI #Ebola Topic 4: using technology to promote #vaccine compliance <http://t.co/gaZFnWZk1a>

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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 ...

more



Your contact points

At the IMI Programme Office

- General queries: infodesk@imi.europa.eu
- IP queries: IMI-IP-Helpdesk@imi.europa.eu

Local contacts

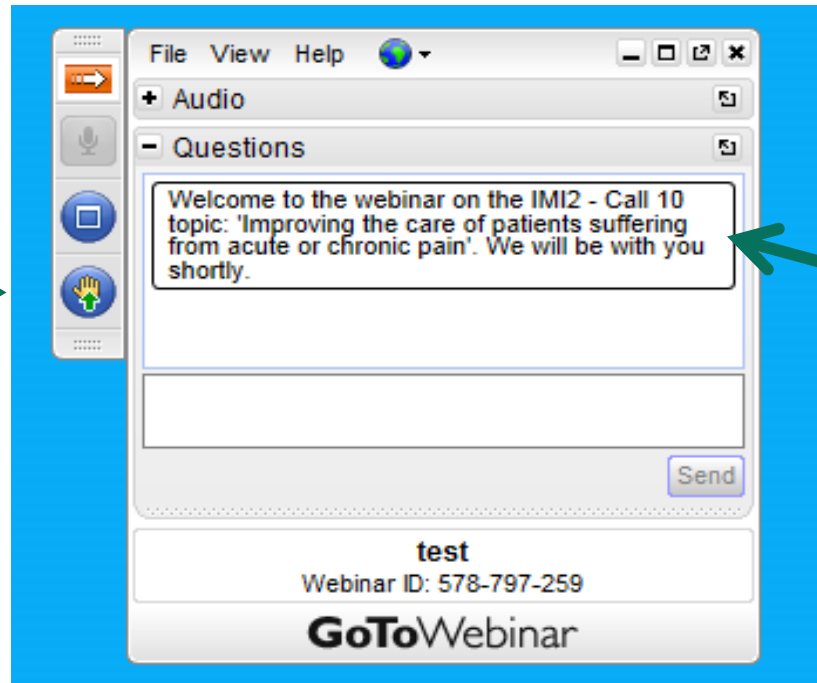
- IMI States Representatives Group: bit.ly/IMISRG
- Horizon 2020 Health National Contact Points: bit.ly/H2020_NCPs

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

www.imi.europa.eu

 [@IMI_JU](https://twitter.com/IMI_JU)