



Webinar | IMI2 - Call 13 Rules and procedures

7 December 2017 • 15:00 CET

Agenda

- How to use GoToWebinar Catherine Brett, IMI
- IMI rules and procedures Hugh Laverty,
 Fabrizio Federici, Desmond Barry, IMI
- Questions & answers



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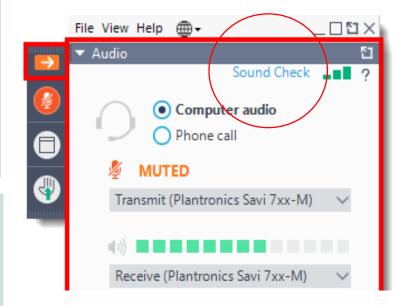
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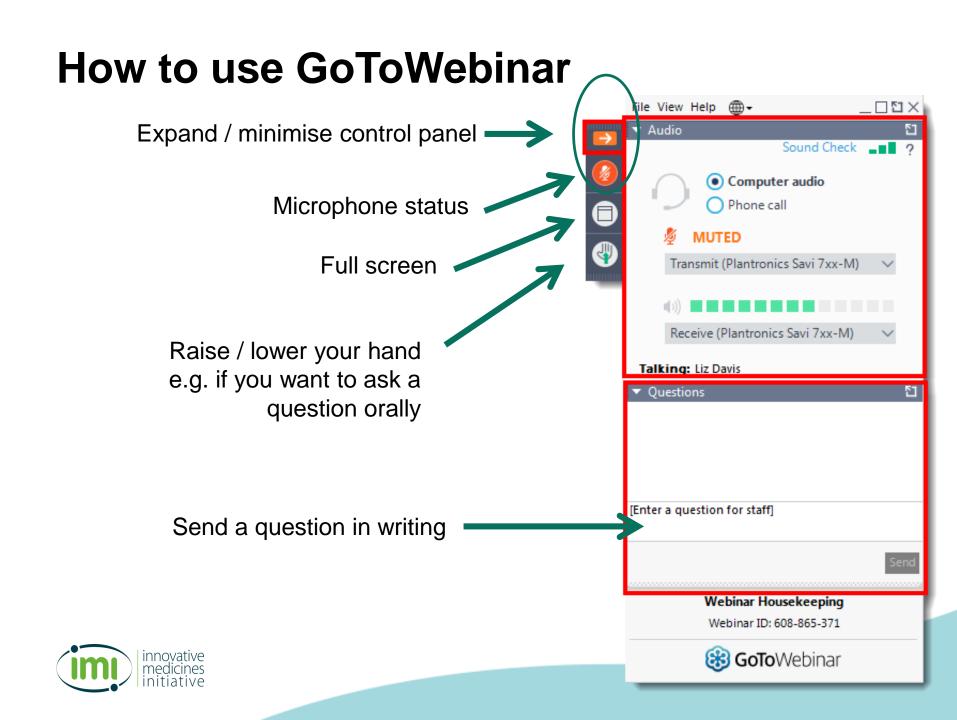
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Before we start...

- This webinar is being recorded and will be published on the IMI website and / or IMI YouTube channel
- Presentation slides will be published on the webinar web page
- A participant list will be circulated
- IMI2 Call 13 has been launched and all Call documents & details of how to apply can be found on the IMI website







Rules and Procedures for IMI2 JU Calls for proposals

IMI Webinar • 7 December 2017

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

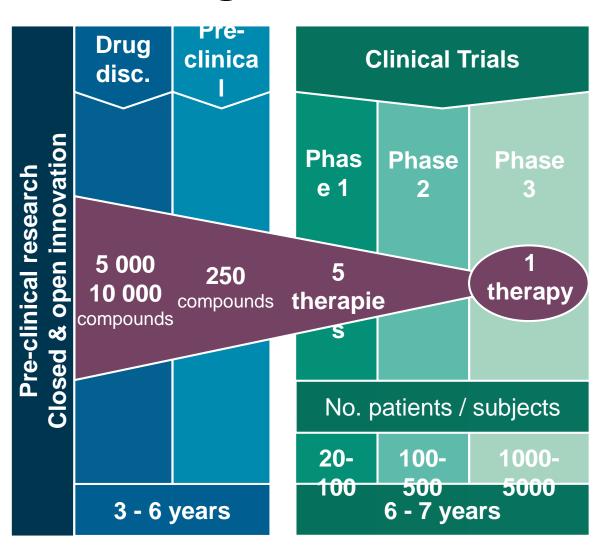


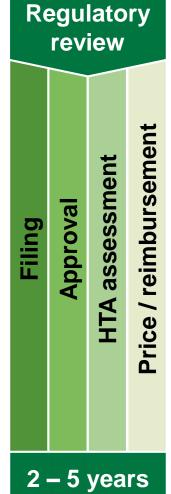




Introducing IMI

Challenges in medicines development





Pharmaco vigilance

Real world evidence



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





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

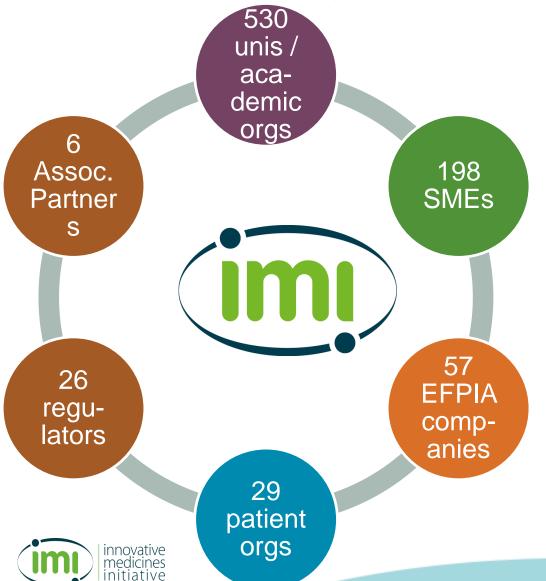


A typical IMI consortium





An international, cross-sector community



Over 11 500 researchers working for:

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

Figures as of end 2016





Introduction to IMI 2 – Call 13

IMI2 Call 13 - topics

- TOPIC 1: ASSESSMENT OF THE UNIQUENESS OF DIABETIC CARDIOMYOPATHY RELATIVE TO OTHER FORMS OF HEART FAILURE USING UNBIASED PHENO-MAPPING APPROACHES
- TOPIC 2: GENOME-ENVIRONMENT INTERACTIONS IN INFLAMMATORY SKIN DISEASE
- TOPIC 3: THE VALUE OF DIAGNOSTICS TO COMBAT ANTIMICROBIAL RESISTANCE BY OPTIMISING ANTIBIOTIC USE
- TOPIC 4: MITOCHONDRIAL DYSFUNCTION IN NEURODEGENERATION
- TOPIC 5: SUPPORT AND COORDINATION ACTION FOR THE PROJECTS
 IN THE NEURODEGENERATION AREA OF THE INNOVATIVE
 MEDICINES INITIATIVE
- TOPIC 6: A SUSTAINABLE EUROPEAN INDUCED PLURIPOTENT STEM CELL PLATFORM
- TOPIC 7: LINKING DIGITAL ASSESSMENT OF MOBILITY TO CLINICAL ENDPOINTS TO SUPPORT REGULATORY ACCEPTANCE AND CLINICAL PRACTICE
- TOPIC 8: HUMAN TUMOUR MICROENVIRONMENT IMMUNOPROFILING



IMI2 Call 13 - topics

- TOPIC 10: IMPROVING THE PRECLINICAL PREDICTION OF ADVERSE EFFECTS OF PHARMACEUTICALS ON THE NERVOUS SYSTEM
- TOPIC 11: TRANSLATIONAL SAFETY BIOMARKER PIPELINE (TRANSBIOLINE): ENABLING DEVELOPMENT AND IMPLEMENTATION OF NOVEL SAFETY BIOMARKERS IN CLINICAL TRIALS AND DIAGNOSIS OF DISEASE

PILOT PROGRAMME ON A CLINICAL COMPOUND BANK FOR REPURPOSING

- TOPIC 12: CARDIOVASCULAR DISEASES AND DIABETES
- TOPIC 13: RESPIRATORY DISEASES
- TOPIC 14: NEURODEGENERATIVE DISEASES
- TOPIC 15: RARE/ORPHAN DISEASES

IMI 2 - Call 13

- Date of Call launch: 30 November 2017
- Calls text and documents are published on the:
 IMI2 JU website
- Deadline for Short Proposal submission: 28 February 2018
- Deadline for Full Proposal submission: 6 September 2018
- Webinar topic presentations and recordings: http://bit.ly/1RSPiTC



Call 13 – NEW!

- As of IMI2 JU call 10, 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 13 – 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	nt Country	(A) Direct personnel costs/€	(B) Other direct costsÆ	(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*!)	(K) Requested EU Contribution/ €
		0	0	0	0	0	0,00	0	0,00	100	0,00	0,00
Tota	1	0	0	0	0	0	0,00	0	0,00		0,00	0,00







Participation rules

A single set of rules



etc.

EU Financial Regulation
Specific rules for participatio

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



F

Conditions for this Call for proposals

H2020 Rules for participation apply to IMI2 JU Call for Proposals and Actions except where specifically derogated

Minimum conditions

RIA: at least three independent legal entities, each established in a different EU Member State or H2020 associated country

CSA: one <u>legal entity</u> established in 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)



Conditions for this Call for proposals

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, the maximum JU contribution and the estimated industry contributions are set in the call text

Hearings

Panels may decide at stage 1 to held hearings with applicants during panel meetings. After submission deadline, coordinators will be informed about the possible date for the hearing (** check SP details!)



Conditions for this Call for proposals

- 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
- Plan for exploitation and dissemination
 It must be included in FPs

NB: Contacts/discussions about a given topic between potential applicant consortia and members of the industry consortium are prohibited throughout the procedure until the results of the first stage evaluation.



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 (≤ €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

Art.1 Commission Delegated Regulation (EU) No 622/2014



Expected consortia

Stage 1 of two stage - Short Proposals

Consortia consisting of:

- IMI2 JU 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 JU fundable legal entities/additional legal entities
 - Industry consortium (EFPIA companies and IMI2 JU 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 (beneficiaries receiving funding = legal entities eligible for funding)
 - In-kind/cash contribution from BNRFs (beneficiaries not receiving funding):
 - EFPIA constituents and affiliates
 - IMI2 JU 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 direct 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



IMI2 JU Grant Agreement

Third party is a legal entity which carries out work of the action, supplies goods or provide services for the action, but which did not sign the grant agreement

Types of third parties:

- 1. Third parties directly carrying out part of the work described in Annex 1
- 2. Other third parties: providing resources, goods or services to beneficiaries carrying out the work described in Annex 1
- 3. Third parties receiving financial support (money) from the beneficiary as part of the action, subject to specific conditions,
- i.e. Annex K H2020 WP



ТҮРЕ	CHARACTERISTICS							
	Works on action tasks?	Provides resources or services for action?	What is eligible?	Must be indicated in Annex 1?	Indirect costs?	Selecting the third party	GA articles	
Linked third party	YES	NO	Costs	YES	YES	Must be affiliated or have a legal link	Article 14	
Int. Partners	YES	NO	N/A	YES	N/A	Must not be eligible for funding	Article 14a	
Subcontractor	YES	NO	Price	YES	NO	Must be best value for money, avoid conflict of interest	Article 13	
Third party providing in-kind contribution	NO	YES	Costs	YES	YES	May not be used to circumvent the rules	Articles 11 and 12	
(selling, equipment, good or service)	NO	YES	Price	NO	YES	Must be best value for money, avoid conflict of interest	Article 10	
Third parties receiving financial support ⁵¹	The third parties participate in the action as recipients.		Amount of support given	YES	NO	According to the conditions in Annex 1	Article 15	



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 financial contributions (FC)*
 - Based on the usual management principles and accounting practices
 - Contributions from affiliated entities as part of in-kind
 - * Recipient of FC must be BRFs, i.e. eligible for JU funding

When relevant to IMI2 JU 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







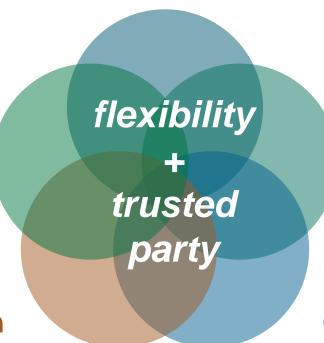
IMI2 JU's Intellectual Property (IP) rules

One set of rules for multiple interests

Support to industry

Incentive to participate

Dissemination of information



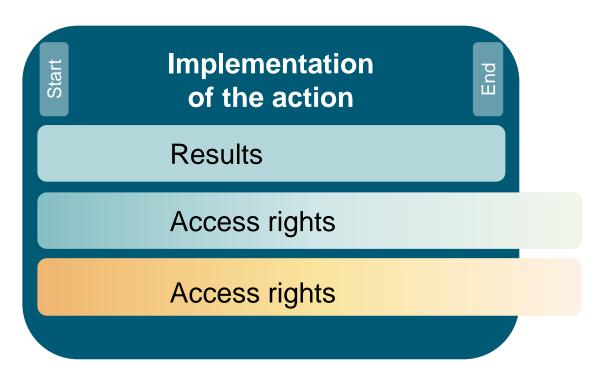
Freedom of access

Compensation for IP



Background vs. Results

Background identification



Sideground

Generated during the action but **outside of its objectives** and not needed for
implementation or Research Use



Background vs. Results

Background

- Any data, know-how or information whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights that:
 - is held by the beneficiaries before they acceded to the Agreement,
 - is needed to implement the action or exploit the results, and
 - which is identified and agreed by the Beneficiaries.

All conditions have to be met to be considered background and be subject to specific rights & obligations

Results

- Any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not
 - that is generated in the action, as well as any rights attached to it, including intellectual property rights
 - excluded Sideground output generated by a beneficiary under the action but outside of the action objectives as defined in the Grant Agreement
 - => Importance of Action objectives



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



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 and third parties

- Only after the end of the action for research use purposes
- Time-limits to be agreed
- Possibility to exclude specific elements of background (only for existing background) under exceptional circumstances and after a reasoned request

Based on IMI1 experience



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 2017)
 - IPR section: Articles 23a to 31
- IMI2 annotated Grant Agreement (soon)

www.imi.europa.eu/content/documents

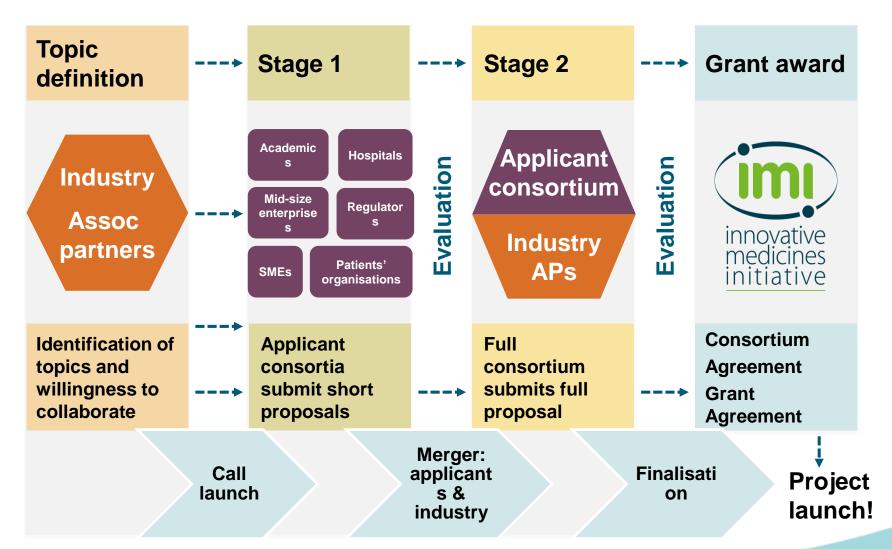






From Call to grant award

Typical IMI project life cycle





A single set of evaluation criteria

Standard criteria

Excellence Impact Quality & efficiency

- 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 JU MGA (v.5) will apply to Call 13
- It follows H2020 Model Grant Agreement (v.5) with IMI2 specificities.
- IMI2 JU Annotated Model Grant Agreement for 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, <u>including allocation of scientific tasks among beneficiaries</u>

Scientific Project Leadership

Scientific Project Leader may be different from Coordinator to:

- reflect the <u>spirit of industrial co-leadership</u> in call topics built upon EFPIA/industry scientific priorities
- address the need for <u>strong scientific coordination and collaboration</u> 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 JU 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 independent legal entities (RIA) from three different MS/AC



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
- Budget, either over-estimated or not fully justified
- Ethical issues not addressed

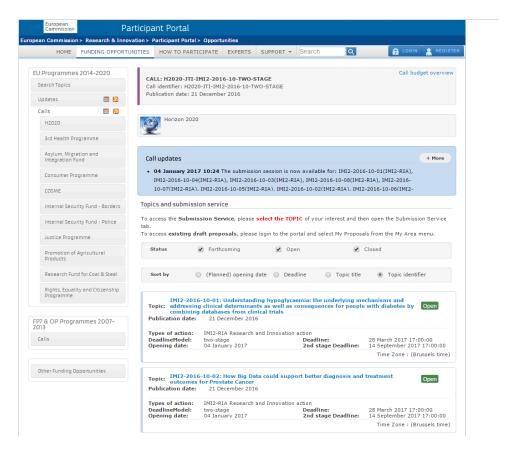


Tips

- Read all the Call-relevant material that is provided on the IMI2 JU website – www.imi.europa.eu
- Understand IMI2 JU rules and respect them
- Consider the PPP dimension of the action (e.g. Governance, industry contribution vs IMI2 JU 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



https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h 2020







More information

Stay in touch

- Visit our new website www.imi.europa.eu
- Sign up to our newsletter via the website
- Follow us on Twitter@IMI_JU
- Join our LinkedIn group bit.ly/LinkedInIMI
- E-mail us infodesk@imi.europa.eu







Your contact points

At the IMI Programme Office

- General queries: <u>infodesk@imi.europa.eu</u>
- IP queries: <u>IMI-IP-Helpdesk@imi.europa.eu</u>

Local contacts

- IMI2 JU States Representatives Group: bit.ly/IMISRG
- Horizon 2020 Health National Contact Points: bit.ly/H2020_NCPs







Questions



Raise your hand if you want to ask a question orally

Send a question in writing

After the webinar, send any questions to the **IMI Programme Office**

infodesk@imi.europa.eu

