



Webinar | IMI2 – Call 14 Rules and procedures

11 April 2018

Agenda

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



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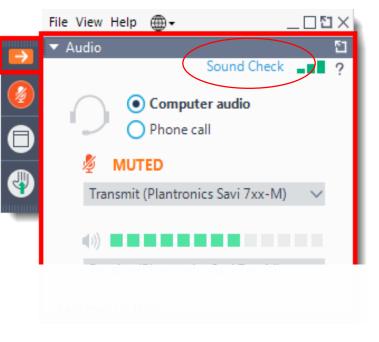
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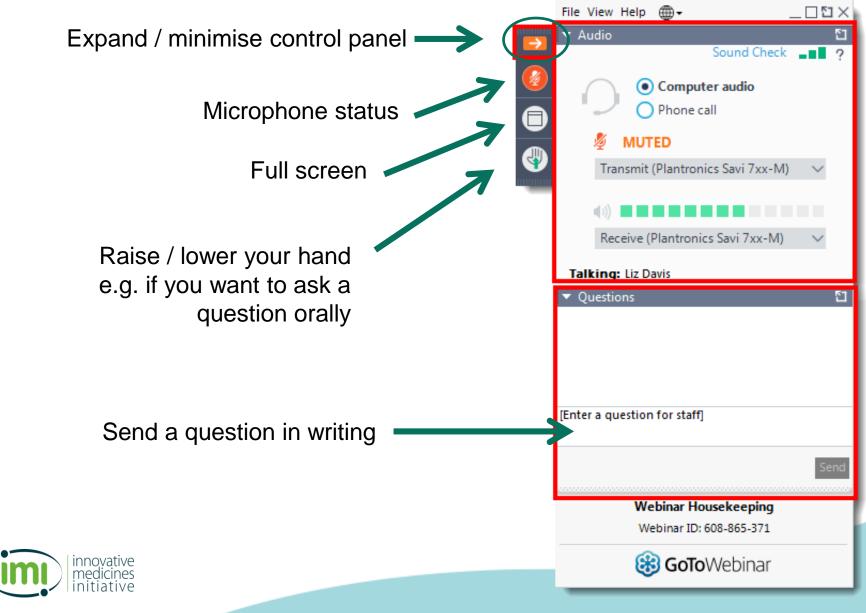
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How to use GoToWebinar



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 published on the website
- IMI2 Call 14 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

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

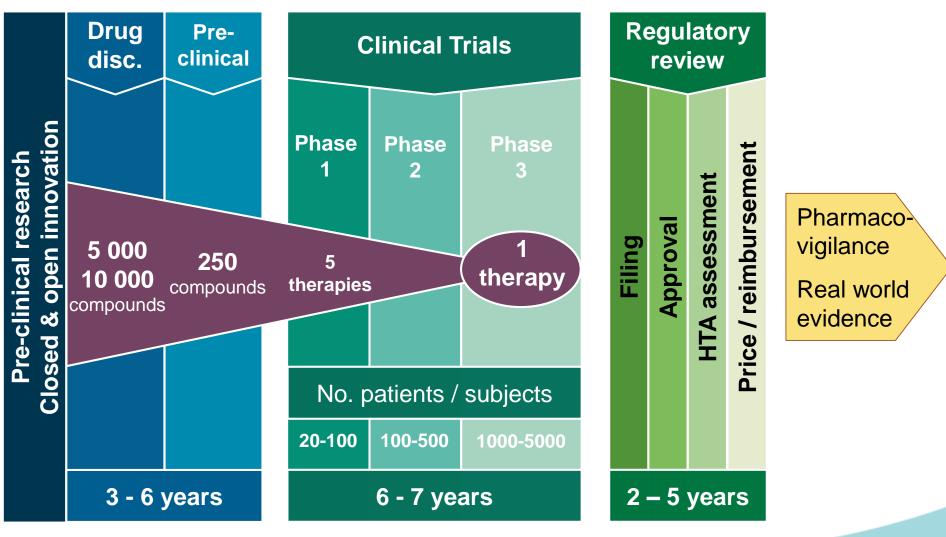






Introducing IMI

Challenges in medicines development





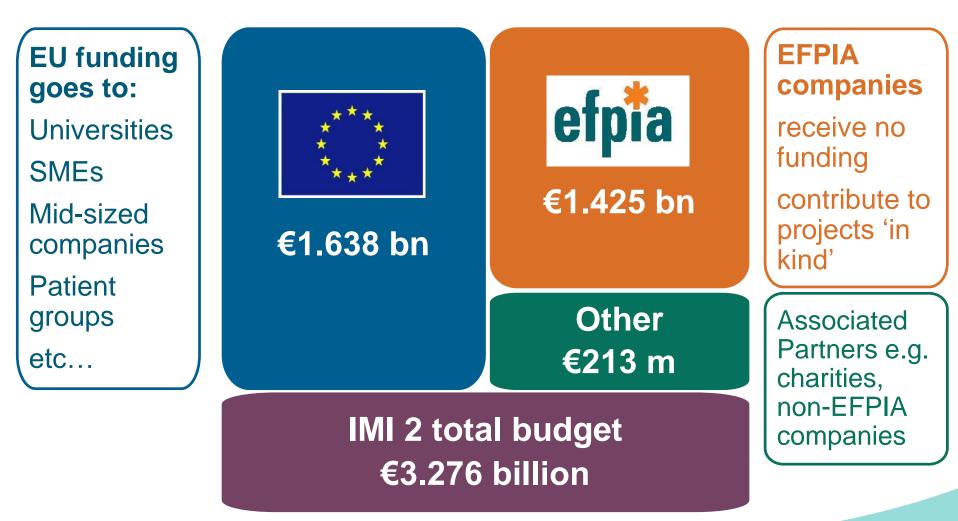
IMI – key concepts

- Non-competitive collaborative research
- Competitive Calls for proposals
- Open collaboration in public-private consortia
 - Data sharing, dissemination of results...
- Industry contribution is in kind





IMI2 budget (2014 – 2020)





IMI2 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

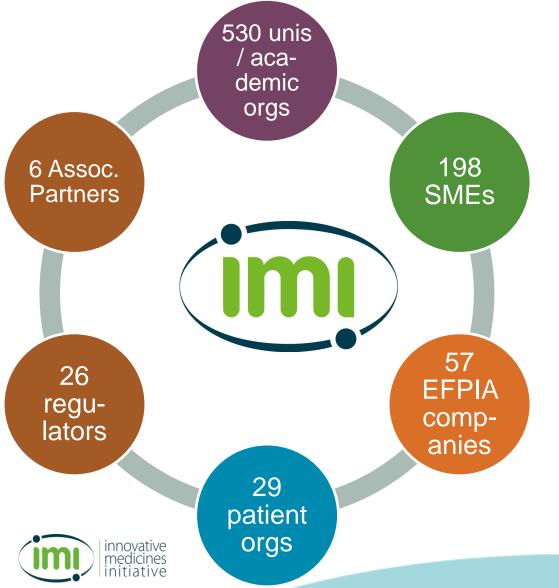
Scale is a key to success and is provided by IMI funding and the outcomes should be transformative for the industry as well as having a clear "public" value



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 IMI2 JU – Call 14

IMI2 JU Call 14 - topics

- Topic 1: Targeted immune intervention for the management of nonresponse and relapse
- Topic 2: Non-invasive clinical molecular imaging of immune cells
- Topic 3: Development of a platform for federated and privacy-preserving machine learning in support of drug discovery
- Topic 4: Centre of excellence remote decentralised clinical trials



IMI 2 JU - Call 14

- Date of Call launch: 15 March 2018
- Calls text and documents are published on the: IMI2 JU website
- **Deadline for Short Proposal submission**: 14 June 2018
- Deadline for Full Proposal submission: 11 December 2018
- Webinar topic presentations and recordings: http://bit.ly/1RSPiTC



Call 14 – 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/h2 020

- 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: <u>http://ec.europa.eu/research/participants/docs/h2020-</u> funding-guide/user-account-and-roles/ecas-login_en.htm



Call 14 – 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/t	(F) Indirect Costs /€ (=0.25(A+8-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	0	0	0	0	0
		0	0	0	0	0	0,00	0	0,00	100	0,00	0,00
Tota	I	0	0	0	0	0	0,00	0	0,00		0,00	0,00







Participation rules

A single set of rules



- 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 JU Call for Proposals and Actions except where specifically derogated

Minimum conditions

RIA: at least three independent legal entities, each established in adifferentEU Member State or H2020 associated countryCSA: one legal entity established in EU Member State or H2020
associatedassociatedcountry

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



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



	CHARACTERISTICS										
ТҮРЕ	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				
Contractor (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 participat action as		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

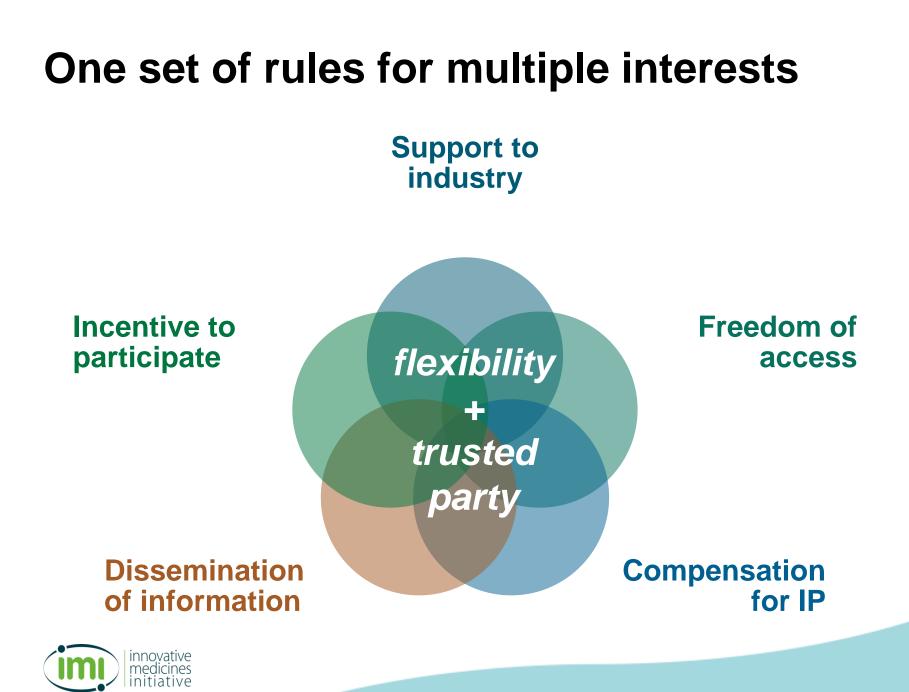
- Financial reporting for:
 - Beneficiaries receiving JU funding, due at project deadlines (i.e.GA)
 - CFS: >EUR 325k at project end
 - Beneficiaries Not receiving funding (e.g. EFPIA companies and APs),
 - due by 31 Jan certification by 30 April covering previous calendar year



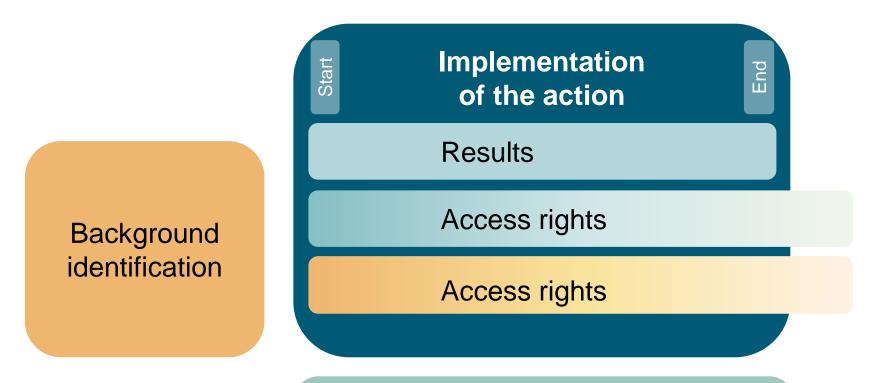




IMI2 JU's Intellectual Property (IP) rules



Background vs. Results



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

<u>Results</u>

- 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 are owned by the beneficiary that generates them

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



Open Access in IMI2 Projects

Open Access to Publications

(Article 29.2 GA)

Deposit in repositories and publishing in Open Access (OA) both encouraged.

Processing charges can be considered eligible costs but:

- Must be budgeted before project start

- Publications must be placed in repository

- Provision of OA is a requirement

Open Research Data (ORDP)

(Article 29.3 GA)

From Call 11, all IMI2 projects are automatically part of the ORDP.

The ORDP covers 'underlying data' generated in the project, but can be extended to other types of data.

The ORD balances openness with protection of scientific information, commercialisation and IPR and embraces a flexible approach; allowing projects varying degrees of engagement with the ORDP.

Data Management Plan (DMP)

(AWP)

All projects need to:

- Develop and update a DMP*.

- Deposit their data.

DMPs should aim to produce 'FAIR' data:

<u>F</u>indable

<u>A</u>ccessible

<u>Interoperable</u>

<u>R</u>e-usable

Note: All IMI Projects are required to provide a Data Management Plan (DMP) regardless of the project's engagement with the ORDP.



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

www.imi.europa.eu/apply-funding/call-documents/imi2-calldocuments

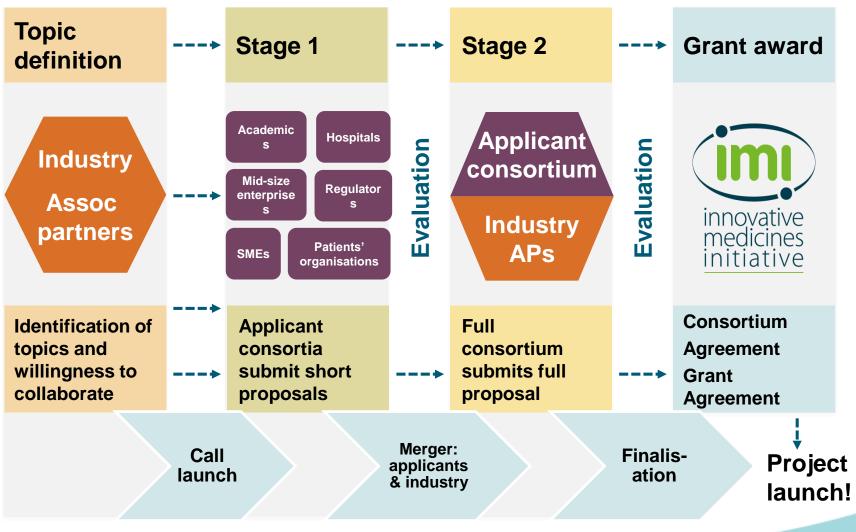






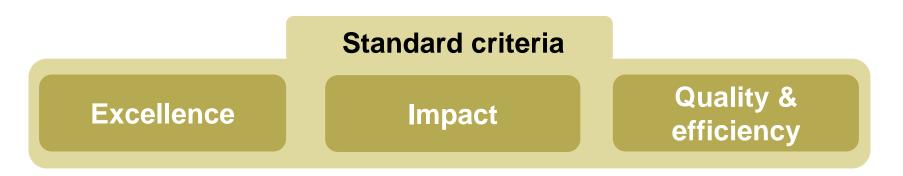
From Call to grant award

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 JU MGA (v.5) will apply to Call 14
- It follows H2020 Model Grant Agreement (v.5) with IMI2 specificities.
- IMI2 JU Annotated Model Grant Agreement (v1 based uponH2020 AGA v4.1) NEW
- 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, for more info please consult '*IMI2 JU guidelines for reporting in kind and financial contributions by Members other than the Union and Associated Partners*' NEW



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 <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)

IMI2 specificities are presented in the IMI2 JU AGA



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 IMI 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

Work Pr	ogramme Veart H2020-JTI-IM ogramme Part: H2020-JTI-IM	(J-2018 J-2018	
Call updates			+ More
		sion is now available for: IMI2-2018-:	
2018-14-02(IM	I2-RIA), IMI2-2018-14-03(IA	(I2-RIA), IMI2-2018-14-04(IMI2-RIA	0
pics and submis	ision service		
b .		t the TOPIC of your interest and the	
access existing o	draft proposals, please logi	n to the portal and select My Proposal	s from the My Area menu.
Status	Forthcoming	🕑 Open 🕑	Closed
Sort by	(Planned) opening date	② Deadline ③ Topic title	e 🛞 Topic identifier
Topic: and relay Publication date Types of action: DeadlineModel: Opening date:	15 March 2018	ne intervention for the manageme novation action Deadline: 2nd stage Deadline:	14 June 2018 17:00:00 11 December 2018 17:00:00 Time Zone : (Brussels time
Topic: IMI2-20		inical molecular imaging of immu	
Types of action:		nnovation action	
DeadlineModel: Opening date:	two-stage 15 March 2018	Deadline: 2nd stage Deadline:	14 June 2018 17:00:00 11 December 2018 17:00:00 Time Zone : (Brussels time
Topic: IMI2-20 machine Publication date	learning in support of dru	a platform for federated and priv g discovery	acy-preserving Open

 The links to start the submission of a proposal are available on the Participant Portal.



Proposal Submission Form - Part A

Please indicate only one of the following options if applicable to your organisation	
Companies (including micro enterprises and SMEs) with an annual turnover up to EUR 500 millions which are not affiliated entities of companies with an annual turnover of more than EUR 500 millions	\bigcirc
Patients Organisation	0
Regulatory Agency	\bigcirc
Member of EFPIA not requesting funding	0
IMI2 Associated Partners to this topic not requesting funding	\bigcirc
Any other organisation not requesting funding	\bigcirc

Certain type of organisations are not covered by the above options, in that case none should be selected

- Where applicable, the organisation type has to be indicated (see above):
 - Applies apply to the 6 types of organisations identified in the form;
 - If none of the options is selected, the system generates a warning;
 - The warning is not blocking the submission of the proposal.



Proposal Submission Form - Part A

Validation result

Show Error	The red 'Show Error' button indicates an error due to a missing or incorrect value related to the call eligibility oriteria. The su of the proposal will be blocked unless that specific field is corrected!				
Show Warning	The yellow 'Show Warning' button indicates a warning due to a missing or incorrect value related to the call eligibility criteria. The submission of the proposal will not be blocked (proposal will be submitted with the missing or incorrect value).				
Section	Description				
Legal Entity	Please indicate if your organisation is one of the following legal entity.	Show Warning			
Legal Entity	Please indicate if your organisation is one of the following legal entity.	Show Warning			
Legal Entity	Please indicate if your organisation is one of the following legal entity.	Show Warning			
Legal Entity	Please indicate if your organisation is one of the following legal entity.	Show Warning			
Legal Entity	Please indicate if your organisation is one of the following legal entity.	Show Warning			
Legal Entity	Please indicate if your organisation is one of the following legal entity.	Show Warning			
Legal Entity	Please indicate if your organisation is one of the following legal entity.	Show Warning			
Legal Entity	Please indicate if your organisation is one of the following legal entity.	Show Warning			
Budget	The indirect cost (F) for the project is zero. Please check the budget columns (A),(B) and (E).	Show Warning			
Budget	The requested EU Contribution (K) value cannot be zero.	Show Warning			

- When validating the forms, different warnings appear (see above):
 - The yellow warnings don't block the submission of the proposal;
 - Only the warnings flagged in red will block the submission of the proposal.



Proposal Submission Form - Part A

4 - Call specific questions

Essential information to be provided for proposals including clinical Trials / studies / investigations

Applies to proposals including clinical trials / studies / investigations

Are clinical studies / trials / investigations included in the work plan of this project?

Please upload the dedicated annex 'Essential information for clinical studies / trials / investigations' (a Word template is provided under 'download templates' in the up-load section for Part B and Annexes).

This document should include the relevant information of <u>each</u> clinical study / trial / investigation included in the work plan of this project.

Please give a short title, an acronym or a unique identifier to each clinical study / trial / investigation, to be used as a reference/ identifier in the other parts of the proposal.

Give short title/acronym/unique identifier

- If the proposal includes clinical trials/studies/investigations, in stage one of twostages calls, the specific annex is not requested (see above the section):
 - In stage one relevant aspects should be integrated in part B of the proposal template;
 - The dedicated annex is compulsory in stage two (see *Clinical trial template*).







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: <u>bit.ly/IMISRG</u>
- Horizon 2020 Health National Contact Points: <u>bit.ly/H2020_NCPs</u>







Questions

