Webinar | IMI2 – Call 18
Rules and procedures

18.06.2019

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

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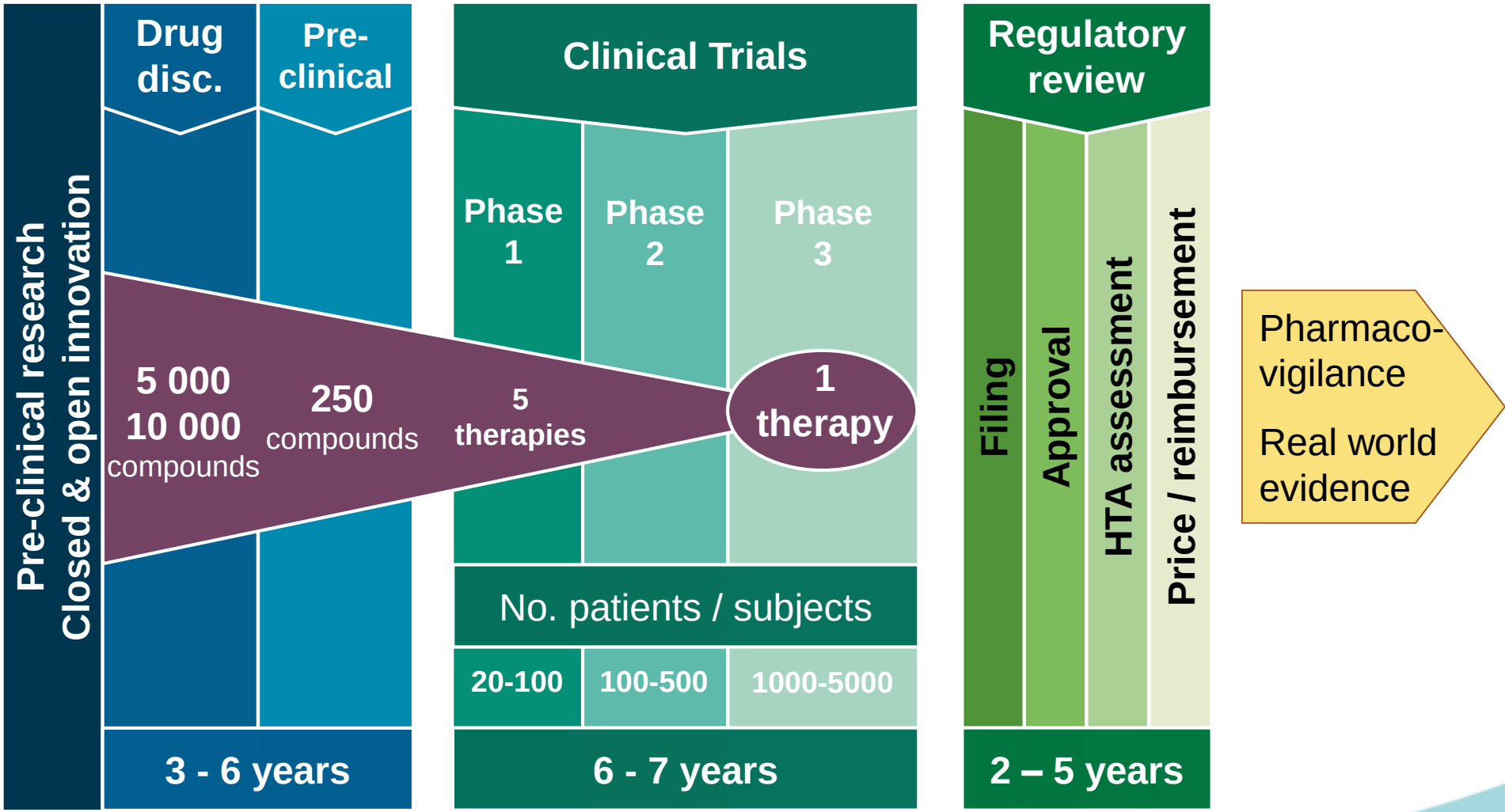
Introducing IMI

Challenges in medicines development



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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

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IMI2 budget (2014 – 2020)

EU funding goes to:

Universities

SMEs

Mid-sized companies

Patient groups

etc…

€1.638 bn

€1.425 bn

EFPIA companies

receive no funding

contribute to projects ‘in kind’

Other
€213 m

Associated Partners e.g. charities, non-EFPIA companies

IMI 2 total budget
€3.276 billion

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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

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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

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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

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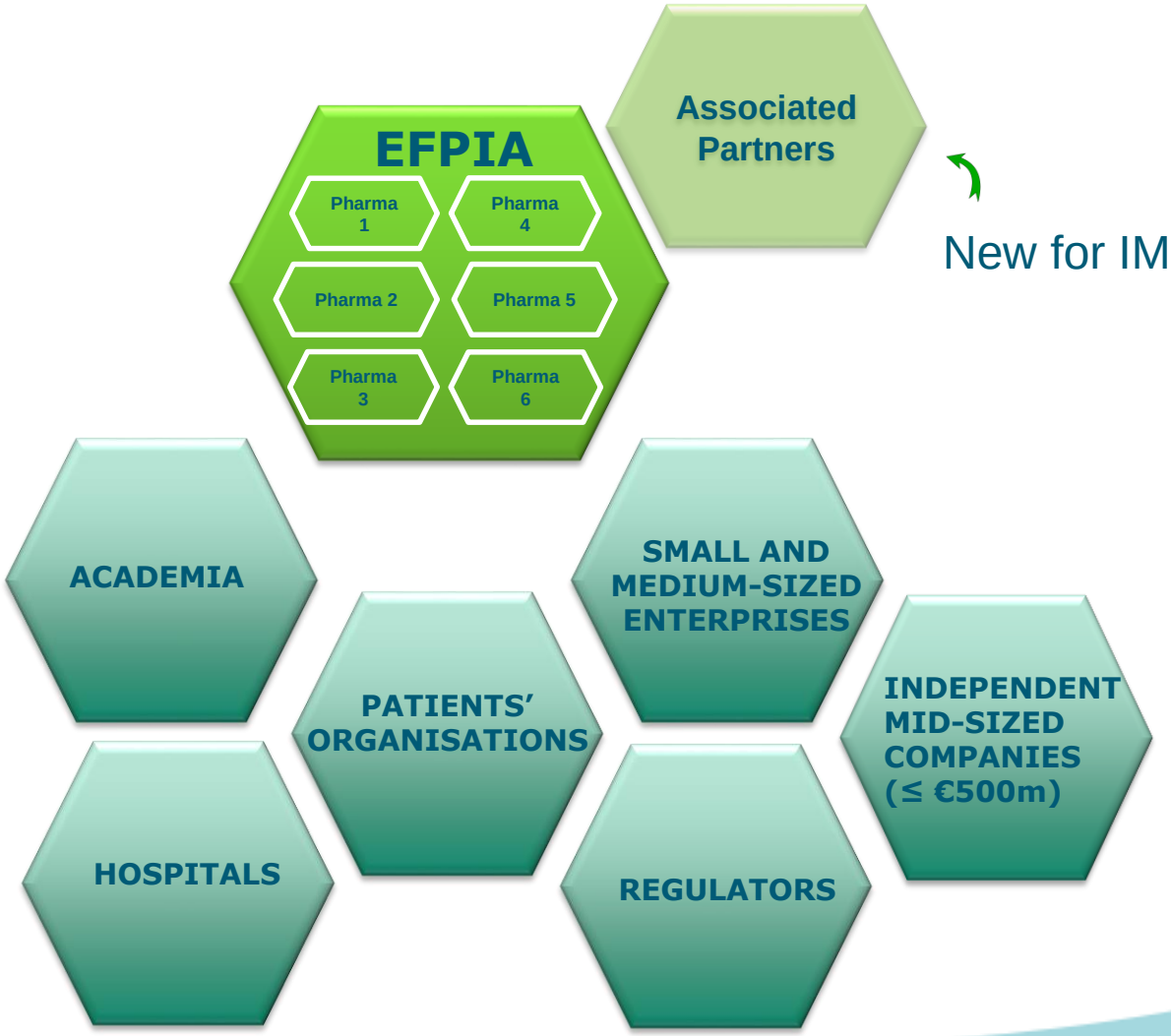
A typical IMI consortium



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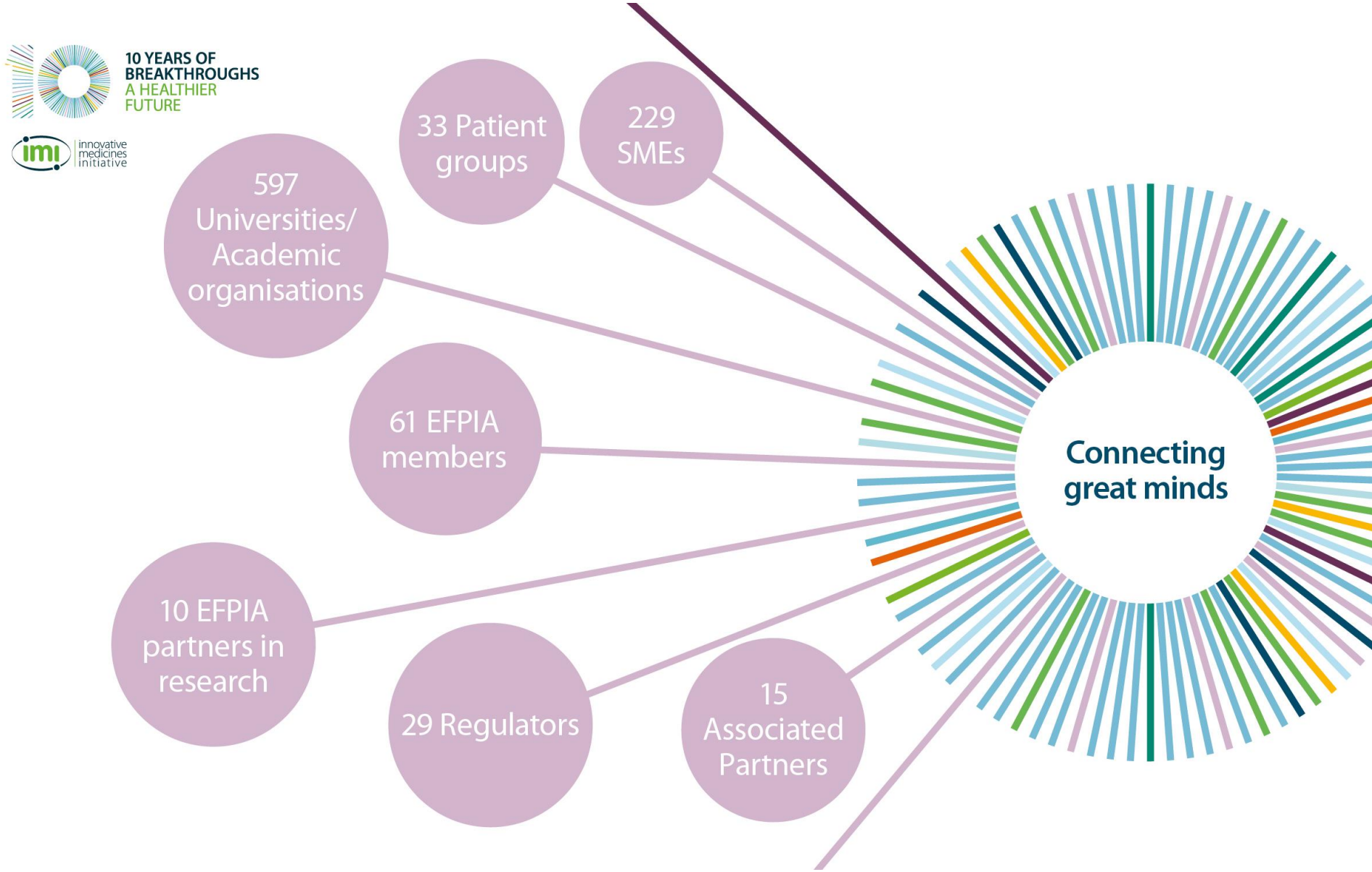
An international, cross-sector community



Introduction to IMI2 JU – Call 18

IMI2 JU Call 18 - topics

- **Topic 1:Central repository of digital pathology slides to support the development of artificial intelligence tools**
- **Topic 2:Health Outcomes Observatories - empower patients with tools to measure their outcomes in a standardised manner creating transparency of health outcomes**
- **Topic 3: Improving patient access, understanding and adherence to healthcare information: an integrated digital health information project**
- **Topic 4:Establishing international standards in the analysis of patient reported outcomes and health-related quality of life data in cancer clinical trials**
- **Topic 5: Accelerating research & innovation for advanced therapy medicinal products**
- **Topic 6: Supporting the development of engineered T cells**

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IMI 2 JU - Call 18 two stages

- Date of Call launch: 26 June 2019
- Calls text and documents are published on the:
  IMI2 JU website and the **new** Funding and Tenders Portal
- **Deadline for Short Proposal submission**: 26 September 2019 (17:00:00 Brussels time)
- Deadline for Full Proposal submission: 26 March 2020 (17:00:00 Brussels time)
- Webinar topic presentations and recordings will be available from the IMI website.

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Call 18 – two stages

- 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

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Call 18

As of IMI2 JU Call 10, use the electronic submission service which is now under the **new** **Funding and Tenders Portal**:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home

- 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 Funding and Tenders 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

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Participation rules

A single set of rules

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

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Conditions for Call 18 two-stages

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

- **Two-stages - C18**

  Stage 1 SPs from applicants requesting JU funding

  Stage 2 merging 1st ranked SPs with industry consortia

- **New Evaluation criteria**

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

Evaluation criteria, thresholds and Proposal templates have been revised as of Call18

- Threshold is 3 for each of the evaluation criteria 'excellence', 'impact' and 'quality and efficiency of the implementation'
- the overall threshold is 10

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Conditions for Call 18 two-stages

- **Submission tool**

  (As of Call10) SPs/FPs to be submitted through the

  Electronic Submission Service of the new Funding and Tenders 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 hold hearings with applicants during panel meetings. After submission deadline, coordinators will be informed about the possible date for the hearing (☞ **check SP details!**)

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Conditions for Call 18 two-stages

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

  Information to the applicants - max 5 months from submission deadline

  N.B. GA signature is expected by September/October 2020, specific timelines are provided after stage 2.

- **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 JU MGA

- **Plan for exploitation and dissemination**

  It must be included in 2nd stage Full proposals

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.

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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

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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

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Expected consortia – Call 18

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 Call 18

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

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Funding rules

IMI2 JU Funding model

- **IMI2 JU is a PPP, actions are normally co-funded by:**
  - JU funding to BRFs (**b**eneficiaries **r**eceiving **f**unding = legal entities eligible for funding)
  - In-kind/cash contribution from BNRFs (**b**eneficiaries **n**ot **r**eceiving **f**unding):
    - EFPIA constituents and affiliates
    - IMI2 JU Associated Partner
    - (future other IMI2 members)

Other legal entities may also participate as BNRFs at their own cost

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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**

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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

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IMI2 JU GA: third parties

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

Overview different types of third parties

TYPE	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 and be eligible for funding	Article 14
International 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[31]	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

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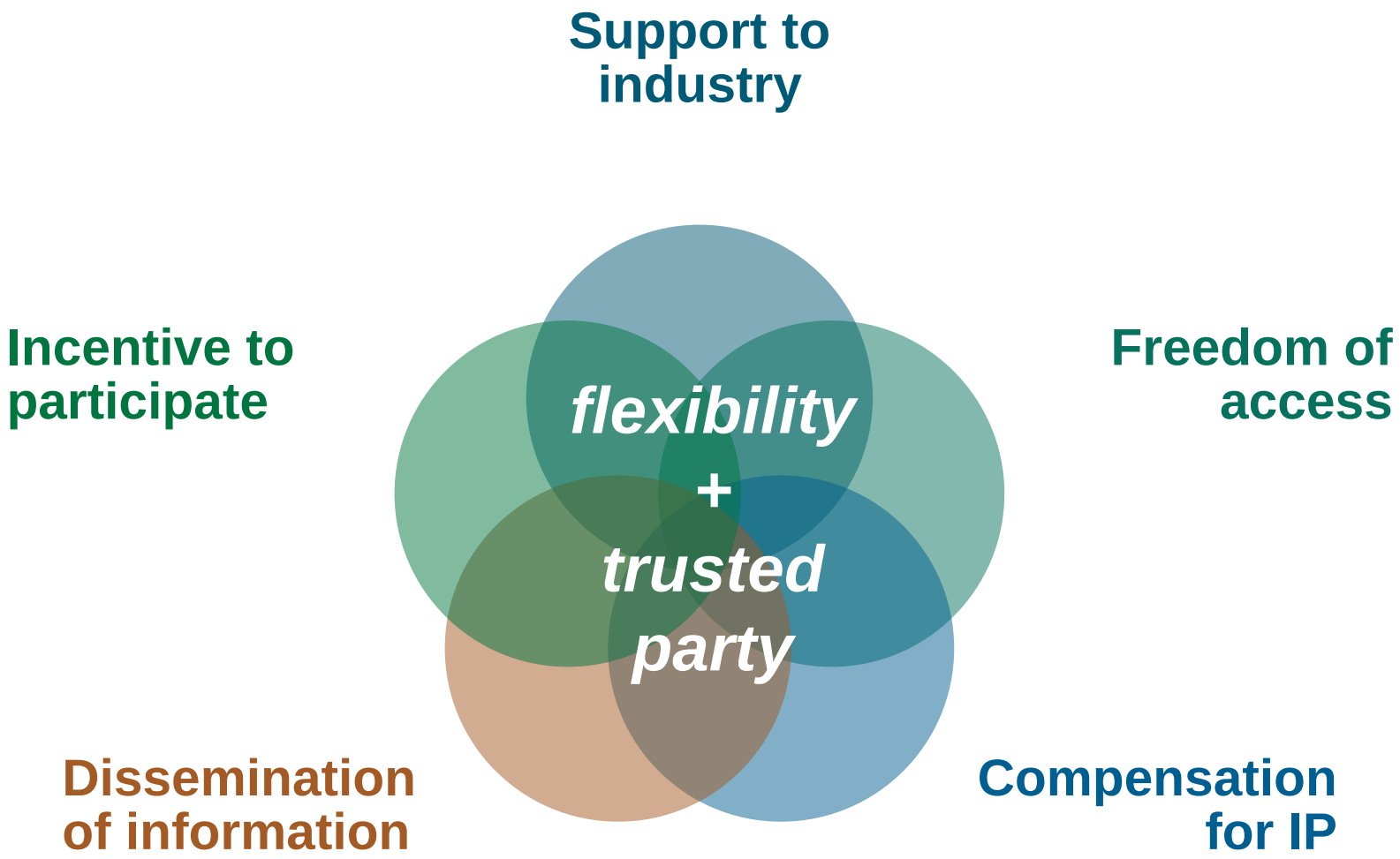
Deadlines for reporting

- 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



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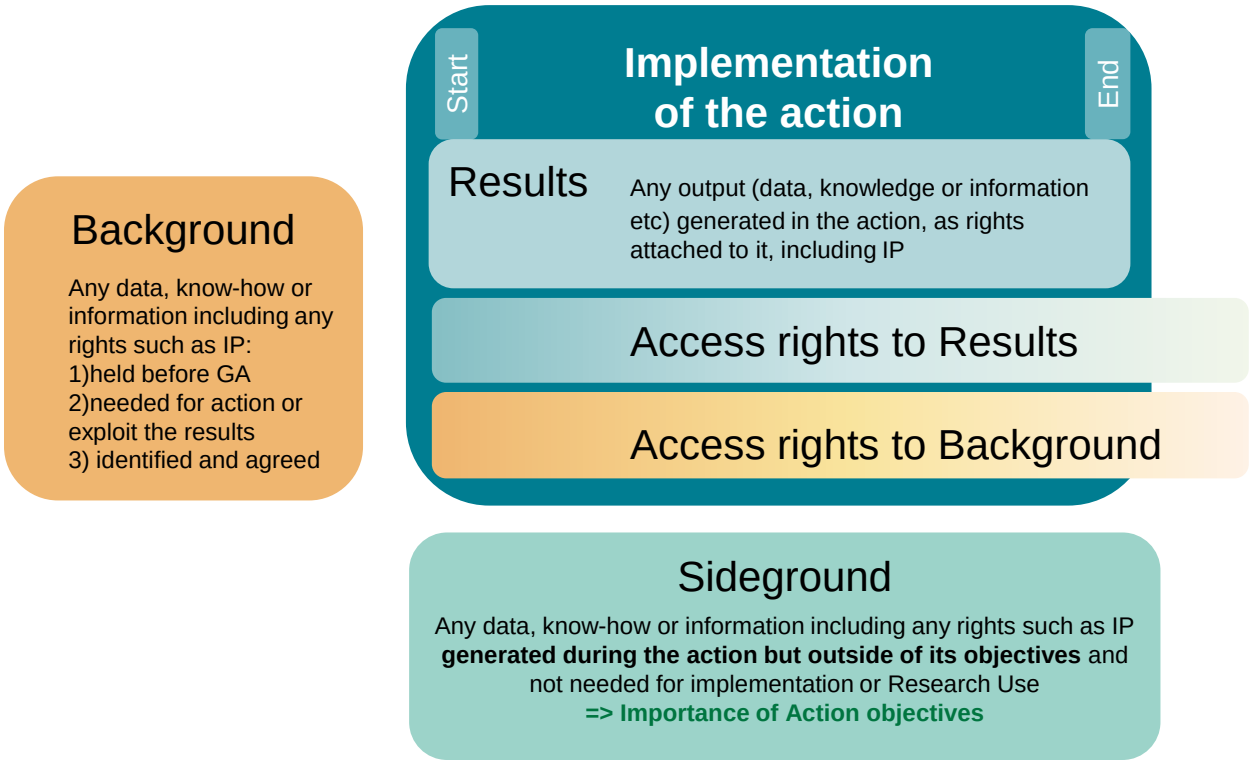
Background vs. Results



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Ownership of results

Results are owned by the beneficiary that generates them

Possible transfer of ownership of Results only after their generation:

- Pre-allocation of ownership NO
- Prior agreement on transfer after generation YES

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Protection of results

Mandatory for beneficiaries receiving funding

- lies with the owner(s) in adequate and effective manner based on relevant (national) legal provisions, action peculiarities, type of result and legitimate interests
- Type of protection to be reported to the JU
- if valuable results left unprotected, to be discussed within the consortium and inform JU

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Access Rights

Articles 25 IMI2 MGA (to background) and 31 IMI2 MGA (to results)

- Access rights = rights to use
- Mandatory written request
- Access rights are in principle not sub licensable but beneficiaries may agree in the consortium agreement to define certain situations where sublicense apply **=> Traceability**
- Time limit to request access rights
  - No minimum/maximum
  - Consistent with particular project/results/background

Mandatory access rights: right to use

Background

Access rights to beneficiaries

- for action implementation (including to affiliated entities)
- If needed for research use of results

Results

Access rights to beneficiaries:

- for action implementation (including to affiliated entities)
- For research use of results

Background

Access rights to third parties:

- after completion of the action
- if needed for research use of results
- possibility to exclude certain elements

Results

Access rights to third parties:

- after completion of the action
-within established time limits
- for research use of results

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Purposes of Access Rights: 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
- The application of results (like an animal model or a biomarker) as a tool for research and clinical research in the discovery or development (as the case may be for commercialisation) of pharmaceutical products by for-profit institutions and organisations

Direct Exploitation

- Development for commercialisation or to commercialise the results
- Commercialisation of such biomarker itself as a diagnostic kit would be direct exploitation

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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.

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Dissemination modalities

Each beneficiary has the obligation to disseminate its own results

- As soon as reasonably practicable
- For publications: Open access is mandatory
- Mandatory to mention IMI support & EFPIA in-kind contribution in patent applications / all communications

IMI2 JU Communication guide:
https://www.imi.europa.eu/apply-funding/call-documents/imi2-call-documents

Open Access in IMI2 JU Projects

Open Access to Publications

(Article 29.2 GA)

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

OA charges may be considered eligible costs.

Open Research Data (ORDP)

(Article 29.3 GA)

IMI2 projects are part of the ORDP:

- 'underlying data to published results' generated in the project, and any other data.

'*As open as possible as closed as necessary*': balance between openness and protection of scientif… information and IP…

Data Management Plan (DMP)

(AWP)

All projects need to develop and update a DMP, even if opted out.

DMPs should aim to produce 'FAIR' data:

Findable

Accessible

Interoperable

Re-usable

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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-call-documents

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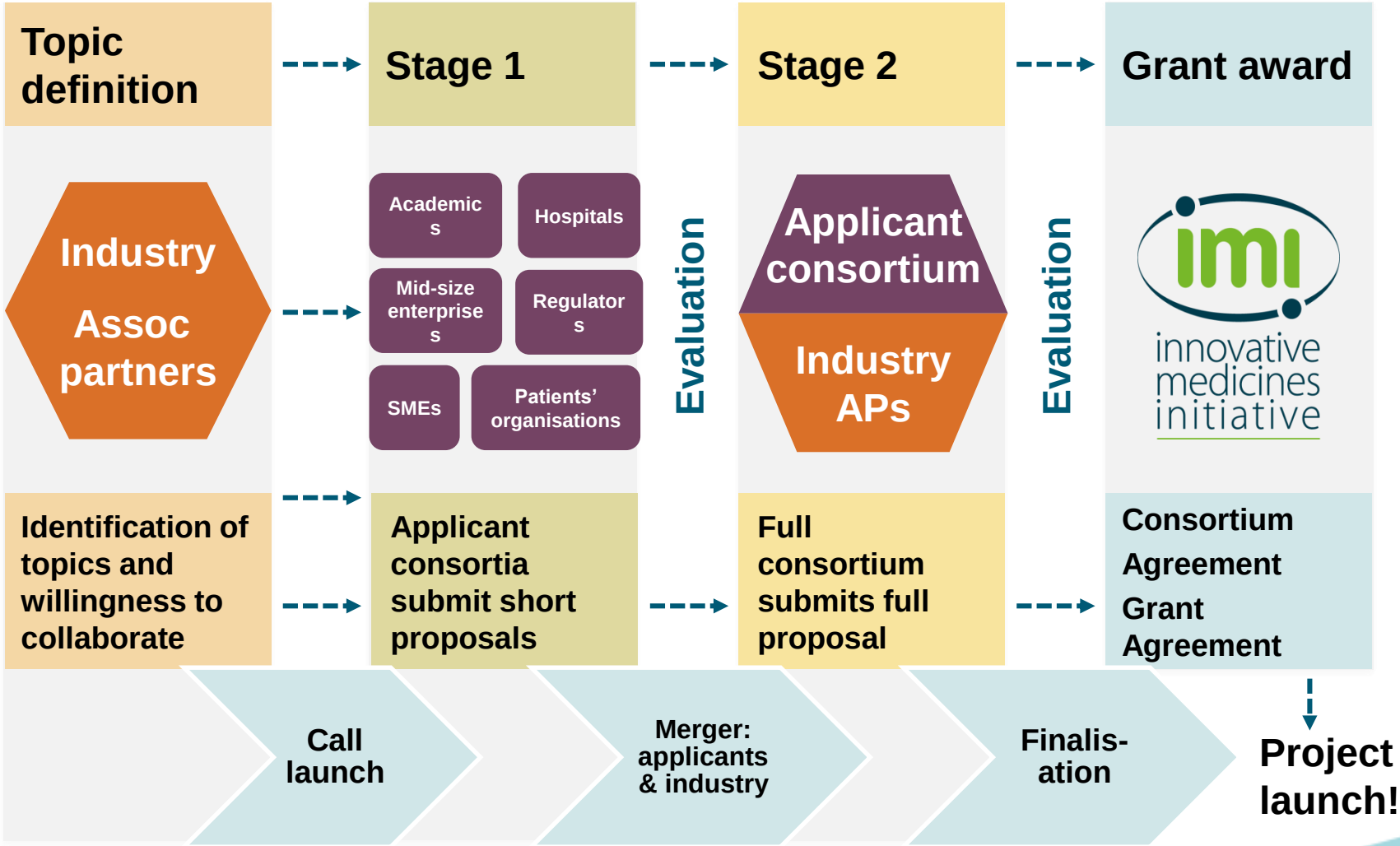
From Call to grant award

IMI2 JU Call 18 two-stages



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A single set of evaluation criteria

- As of Call 18 the evaluation criteria, thresholds and proposal templates have been revised
- Two-stage evaluation: all three criteria considered at both stages
- Thresholds and weighting in the **Call documents** depending two-stages/single stage
- Minimum of **3 independent experts**

Each proposal **evaluated 'as it is'**, not as 'what could be'

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Keeping the momentum

Maximum Time To Grant: 8 months from submission of full proposal:

N.B. Call 18 GAs expected to be signed by September/October 2020

5 months
for informing applicants of scientific evaluation

3 months
for signature of grant agreement

NEW Legal entity validated in parallel

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IMI2 Grant Agreement

- The new IMI2 JU MGA (v.5) will apply to Call 18
- It follows H2020 Model Grant Agreement (v.5) with IMI2 specificities.
- IMI2 JU Annotated Model Grant Agreement v.2.1 (based upon H2020 AGA v.5.1)
- 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*'

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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)

IMI2 specificities are presented in the IMI2 JU AGA

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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.

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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)
  - Not involving at least **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

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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

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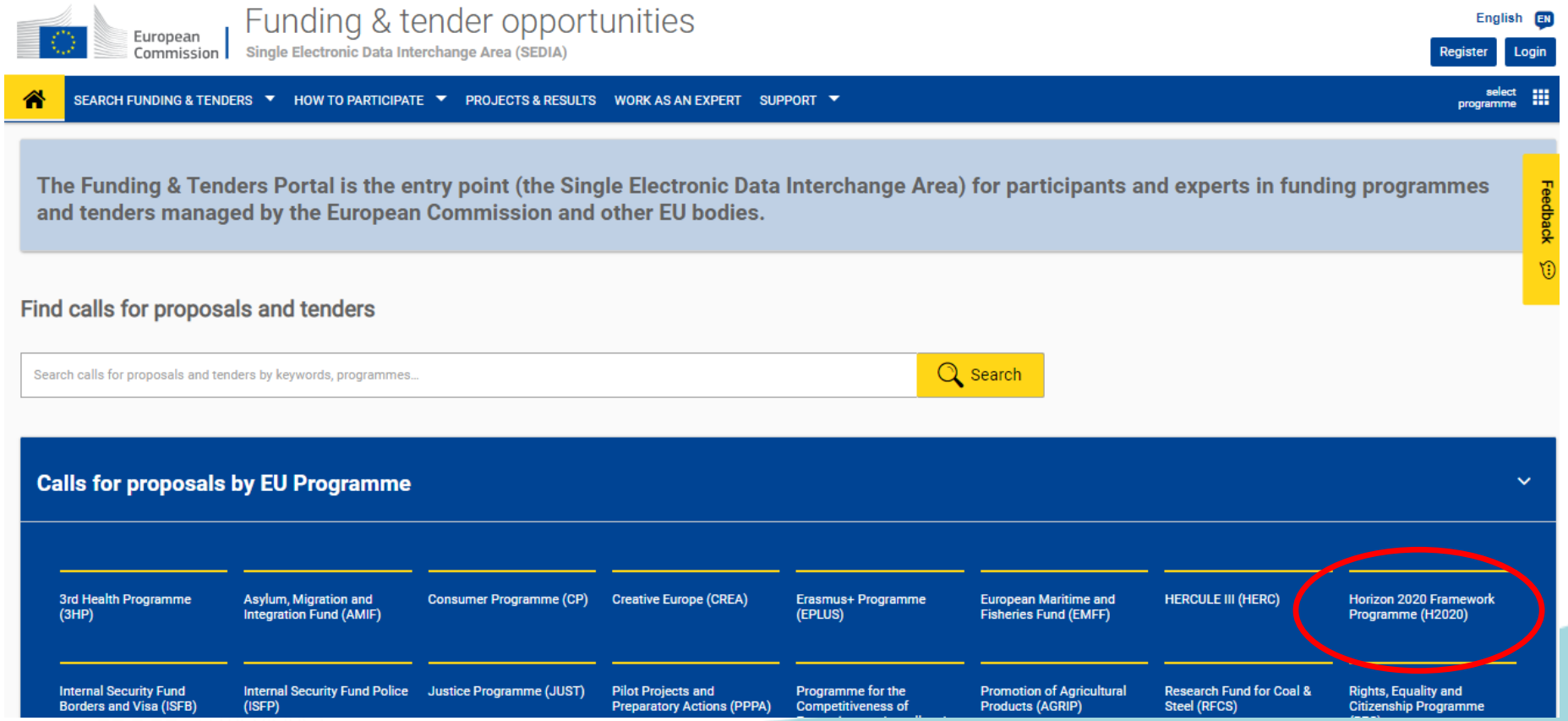
Submitting a proposal

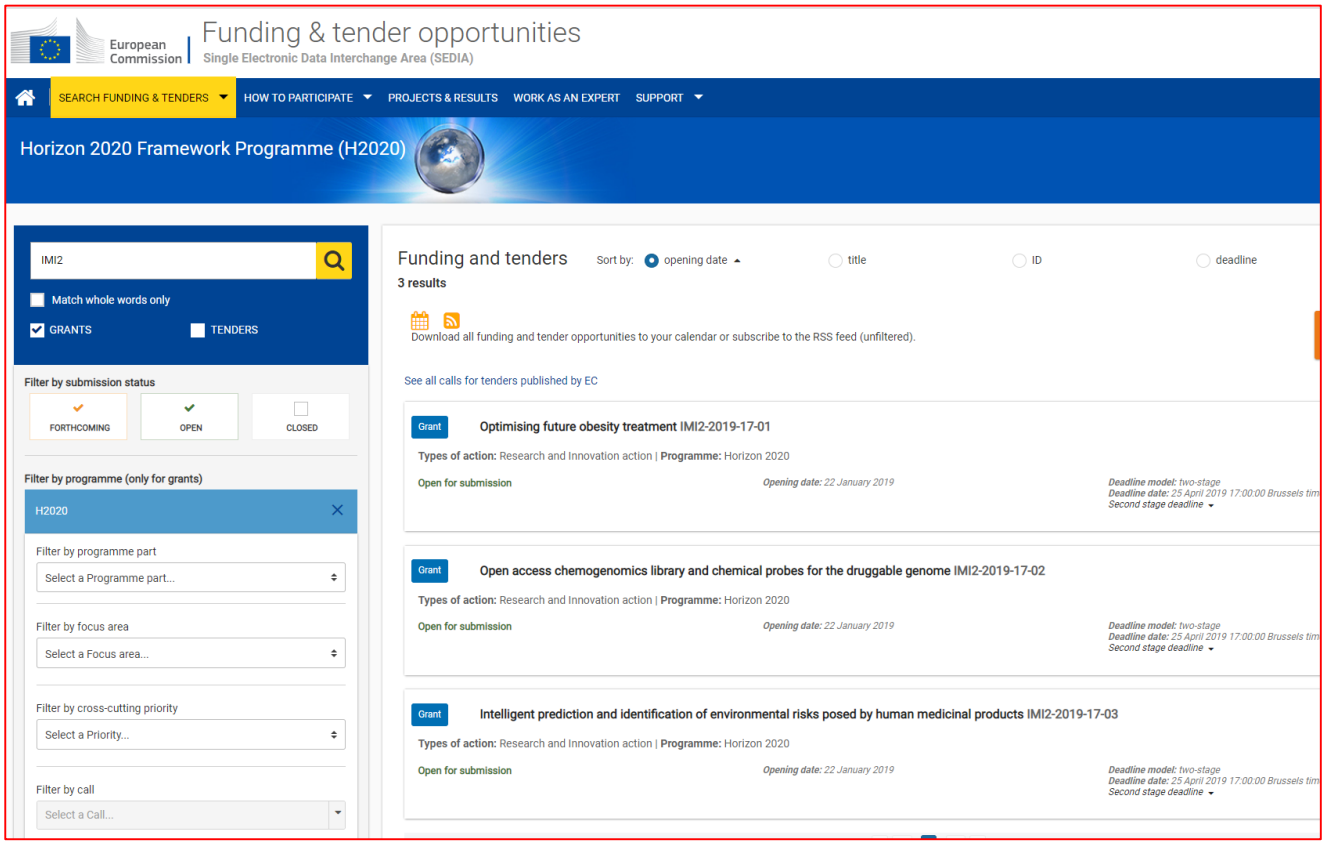
Via the **new** Funding and Tenders Portal

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home



Submitting a proposal

Look for IMI2 JU Calls, you will find the links to start the submission of a proposal:



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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	○
Patients Organisation	○
Regulatory Agency	○
Member of EFPIA not requesting funding	○
IMI2 Associated Partners to this topic not requesting funding	○
Any other organisation not requesting funding	○

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 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.

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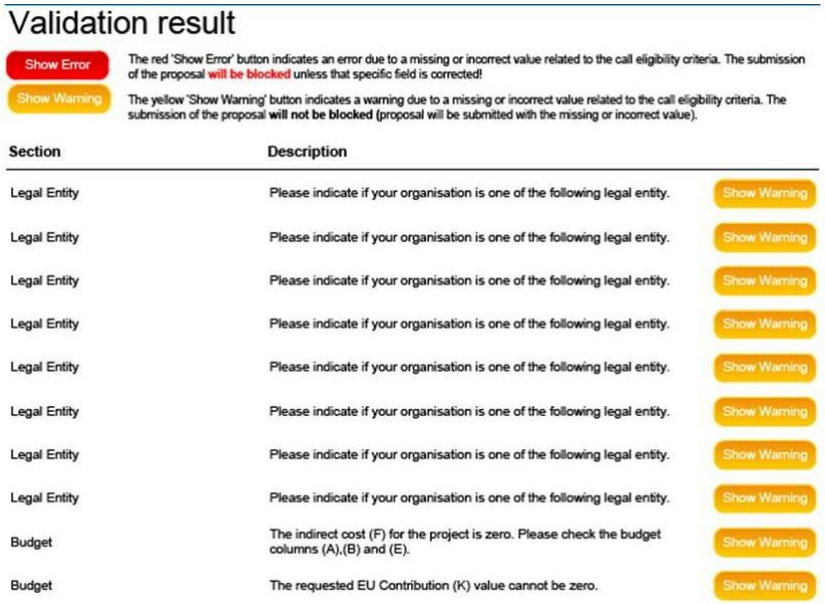
Proposal Submission Form - Part A



Validation result

Show Error — The red 'Show Error' button indicates an error due to a missing or incorrect value related to the call eligibility criteria. The submission 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.

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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?	(•) Yes	( ) No

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 each 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 two-stages 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).*

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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**

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Your contact points

At the IMI Programme Office

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

Local contacts

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

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Thank you