

Webinar | IMI2 JU - Call 21

Development of therapeutics and diagnostics combatting coronavirus infections

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Introduction

IMI – Europe's partnership for health

IMI mission

IMI facilitates open collaboration in research to advance the development of, and accelerate patient access to, personalised medicines for the health and wellbeing of all, especially in areas of unmet medical need.

IMI – Ecosystem for innovative collaborations

- Allow engagement in a cross-sector, multi-disciplinary consortium at the forefront of cutting-edge research
- Provide the necessary scale by combining funding, expertise, knowledge, skills and resources
- Build a collaboration based on trust, creativity and innovative and critical thinking
- Learn from each other - new knowledge, skills, ways of working
- Take part in transformative research that will make a difference in drug development and ultimately patients' lives

IMI is a **neutral platform** where **all involved** in drug development can engage in **open collaboration** on **shared challenges**.

IMI 2 budget (2014 – 2024)

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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Development of therapeutics and diagnostics combatting coronavirus infections

Challenges

- COVID-19 outbreak declared by WHO as a Public Health Emergency of International Concern according to the International Health Regulation.
- Collaboration between public partners and private companies has potential to accelerate the development of therapeutics and diagnostics to tackle the current and future outbreaks.
- IMI contribution to the pan-European efforts responding to this Public Health Emergency and addressing one of the eight immediate research actions agreed at the WHO global research and innovation forum held on 11-12 February 2020.

Scope

Scope broad but proposals must address at least one of the defined objectives

- 1. Development of antivirals and other types of therapeutics to address a rapid response to the current COVID-19 outbreak**
Relevant “clinical ready”-assets e.g approved therapies or compounds in development. If repurposing proposed, need for preliminary rationale of the compound’s potential efficacy against COVID-19.
- 2. Development of therapeutics to address the current and/or future coronavirus outbreaks**
Identification of new potential assets and approaches including preventive strategies and combination approaches, addressing also potential resistance, optimisation of promising treatments used in rapid response (e.g. reformulation).

Scope

3. Development of diagnostics, ensuring rapid evaluation of candidates based on existing technologies.

Essential for clinical trials of new or repurposed drugs, to help stratify patients and assess treatment efficiency (surrogate endpoint such as viral clearance).

4. Development of fast and reliable tools that go beyond the state of the art for detection of COVID-19 carriers and symptomatic individuals suspected of COVID-19 infection

Essential to manage the outbreak, isolate patients at risk and treat people accordingly. Differentiation and identification of respiratory pathogens with similar clinical symptoms (e.g. flu, respiratory syncytial virus, other viruses or bacteria) and/or detection of emerging pathogens such as SARS-CoV-2 crucial. This can be achieved through point-of-care (POC) testing or centralised testing.

Scope

- Focus – development of therapeutics and diagnostics to address the current COVID-19 outbreak and/or future coronavirus outbreaks
- Preventive vaccines specifically excluded from the scope
- Overall proposals expected advance knowledge of SARS-CoV-2 specifically and the wider coronavirus family in general with the aim of contributing to an efficient patient management and/or public health preparedness and response to current and future outbreaks of coronavirus infection.

Scope

- For increased impact, proposals should build on promising avenues from previous or ongoing research, taking into account the recommendations from the WHO and ensuring complementarity and ideally synergy with the work carried out under the auspices of CEPI, Wellcome, BARDA, the Bill and Melinda Gates Foundation, GloPID-R and H2020 Call SC1-PHE-CORONAVIRUS-2020.
- EMA has activated its plan for emerging health threats, which includes the possibility for fast-tracked Scientific Advice. Proposals covering investigation of a therapeutic should engage with the EMA to ensure adequacy from a regulatory point of view.

Expected deliverables

- antivirals and other types of therapeutics to be used in the current outbreak, including preventive and symptomatic treatments;
- novel therapeutics including combination treatments to ensure appropriate treatment for current and/or future outbreaks and/or to prevent resistance;
- diagnostics.

it is recognised that to achieve the above deliverables studies related to the understanding of the mechanism of action will generate new knowledge on the virology, immunology and pathogenesis of the coronavirus, and that new analytical technologies and reagents may be developed.

Expected Deliverables

When relevant, deliverables should include:

- **Hit identification of suitable assets against SARS-CoV-2 and/or pan-coronavirus**
e.g. existing libraries, approved drugs/assets that have passed phase 1 for repurposing; implementation of high-throughput screening assays in collaboration with Europe-based centres of excellence.
- **Lead optimisation**
initiating target-based discovery programmes based e.g on literature for identification of promising approaches. Proof of Concept: pre-clinical animal studies and clinical studies including at least first in human and phase 2A and/or 2B studies.

For clinical studies consider the Therapeutic Trial Synopsis in the WHO's Global Research and Innovation Blueprint on the novel Coronavirus COVID-19.

- **Diagnostics and associated enablers** (e.g. production of antibodies and viral proteins)
characterisation of nCoV strains and evolution; sustainability plans for data repositories, sample repositories etc.; documentation for regulatory submission

Expected impact

Proposals must be timely, with rapid activation, to enable early and valuable outcomes to be established.

- fast-track development and availability of therapeutics and/or diagnostics to be used in the clinical management of patients infected by COVID-19 and/or future outbreaks of coronaviruses, and to ensure that a variety of drugs are available for patients, including tackling resistance, and combination therapy;
- contribution to public health preparedness and response in the context of the ongoing epidemic of COVID-19 and/or future outbreaks of pan-coronaviruses;
- significant impact on global health, both at individual and public health level by leading to results that have a direct impact on people at risk of exposure to coronavirus or on patients suffering from coronavirus disease.

Expected impact

- To ensure maximum impact for patients, applicants should demonstrate their operational capacity as well as their readiness and access to asset(s) to progress through clinical development and reach patients as rapidly as possible
- Although actions to be funded should be centred around SARS-CoV-2 and CoV, applicants should explain how the knowledge and new concepts arising from the action can be applied in more general terms to the preparedness strategy that could be applied to new outbreaks as a rapid response.
- Considering the unknown evolution of this COVID-19 outbreak, applicants should develop strategies on how to develop their proposals and continuity plans, allocate their funds and implement sustainability measures in the different scenarios that could occur: 1) rapid regression of the epidemic with no patients left for clinical trials, 2) pandemic, 3) seasonal reoccurrence as typically seen with influenza.

Expected impact

- Maximise the IMI2 JU PPP value, including the mobilisation of resources through the inclusion of contributing partners (i.e. EFPIA constituents or affiliated entities and/or, when relevant, IMI2 JU Associated Partners) providing in kind and/or financial contributions
- Maximise the potential for public health impact, by outlining a strategy for engagement with patients, healthcare professional associations, healthcare providers, and public health bodies where relevant
- Maximise impact by making available research data, at the latest within 30 days after it has been generated, through open access or, if agreed by the IMI2 JU or the EC, by giving access rights to those third parties that need the research data to address the public health emergency (option (1c) of Article 29.3 of the GA).

Collaboration agreement(s)

- To ensure the interactions between actions funded under this single Call, all grants awarded will be complementary grants (Article 2, Article 31.6 and Article 41.4 of the IMI2 JU Model Grant Agreement)

This is to ensure that the selected consortia cooperate with each other and share their learnings for the purpose of achieving the objectives of their respective actions, in order to maximise the impact.

Accordingly, the relevant consortia will conclude collaboration agreement(s) to ensure the exchange of relevant information, exploration of synergies, and collaboration where appropriate.

- See:

https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/h2020-mga-imi_en_v5.pdf

Potential synergies with existing consortia

- Applicants expected to collaborate with any relevant project or initiative targeting the current COVID-19 outbreak supported by, including but not restricting to, the European Commission (H2020 call SC1-PHE-CORONAVIRUS-2020), CEPI, Wellcome, BARDA, The Bill and Melinda Gates Foundation, GloPID-R, and others.
- Consider also building on achievements of relevant IMI projects such as the COMBACTE projects, ZAPI, and the European Lead Factory (ELF/ESCU LAB).
- Where relevant consider the advantages of the use of the European supercomputing centres (PRACE network) to accelerate the process of diagnosis and therapeutics research, using the exiting high-end computing, data and simulation resources.

Key points

Indicative duration of the action

To be proposed in relation to the activities and expected impact.

Possibility to have starting date prior the entry into force of the GA, but no earlier than the date of grant proposal submission.

Indicative budget

- Total IMI2 JU financial contribution up to EUR 45 000 000.
- Within this budgetary envelope, each proposal must include a sound justification of the requested IMI2 JU financial contribution. This should take into account the proposed in-kind contributions from contributing partners that will complement the IMI2 JU financial contribution, i.e. EFPIA constituents or affiliated entities and/or, when relevant, IMI2 JU Associated Partners.

Applicant consortium

- Applicants are expected to address at least one of the objectives of the call topic and demonstrate the necessary expertise and access to facilities to meet the relevant key deliverables and ensure the expected impact.
- Size and composition of consortium to be adapted so as to respond to the objectives and the key deliverables of the Call while ensuring its manageability.
- To be eligible, a consortium should have at least three independent legal entities, each established in a different Member State or associated country.
- Applicants should ensure that needs of patients are adequately addressed and, where appropriate, patient involvement is encouraged.

Single stage proposal (1/2)

- **Data management**
 - Due visibility to data management including use of the data standards
 - Full 'data management plan' (DMP) as a distinct deliverable due within the first 6 months of the action. DMP needed to be updated during the lifetime of the action
 - Data must be deposited in a relevant established international data platform, such as the one by WHO and/or European Molecular Biology Laboratory (EMBL)
 - Because of the Public Health Emergency, beneficiaries must make available their research data (option 1c Article 29.3 MGA): not possible to opt out from the Open Access to Research Data
- **Dissemination, exploitation and communication**
 - Draft plan for the exploitation and dissemination of results
 - Full plan as a distinct deliverable due within the first 6 months of the project
 - Applicants should be aware that beneficiaries in grants awarded in this Call for proposals are expected to apply the principles established in the [Statement on Data Sharing in Public Health Emergency](#)

Single stage proposal (2/2)

- **Sustainability**

- Sustainability plan beyond the end of the GA (may be updated during the action lifetime)
- Proposed plan should also ensure that the new concepts for rapid response developed in the projects can be applied to new outbreak situations.

👉 Allocate sufficient resources to the sustainability plan.

- **Patient and healthcare provider engagement**

- Strategy to engage with patients, learned societies and healthcare providers as relevant encouraged to ensure the project results impact on healthcare practices.

- **Regulatory strategy**

- Strategy for the translation of the relevant outputs into the regulatory practice to promote the uptake of the results e.g. qualification advice, qualification opinion when relevant expected (plan for interactions with regulatory agencies/health technology assessment bodies /payers, with relevant milestones and sufficient resources).

Submitting a proposal

Via the **new** Funding and Tenders Portal

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

The screenshot shows the 'Funding & tender opportunities' portal. At the top, there is the European Commission logo and the text 'Single Electronic Data Interchange Area (SEDIA)'. On the right, there are 'English EN', 'Register', and 'Login' buttons. Below this is a dark blue navigation bar with a home icon and menu items: 'SEARCH FUNDING & TENDERS', 'HOW TO PARTICIPATE', 'PROJECTS & RESULTS', 'WORK AS AN EXPERT', and 'SUPPORT'. A 'select programme' dropdown is also present.

A light blue banner contains the text: 'The Funding & Tenders Portal is the entry point (the Single Electronic Data Interchange Area) for participants and experts in funding programmes and tenders managed by the European Commission and other EU bodies.' A 'Feedback' button is on the right.

Below the banner is a search section titled 'Find calls for proposals and tenders' with a search input field and a 'Search' button.

The main content area is titled 'Calls for proposals by EU Programme' and features a grid of programme cards. The 'Horizon 2020 Framework Programme (H2020)' card is circled in red.

Calls for proposals by EU Programme							
3rd Health Programme (3HP)	Asylum, Migration and Integration Fund (AMIF)	Consumer Programme (CP)	Creative Europe (CREA)	Erasmus+ Programme (EPLUS)	European Maritime and Fisheries Fund (EMFF)	HERCULE III (HERC)	Horizon 2020 Framework Programme (H2020)
Internal Security Fund Borders and Visa (ISFB)	Internal Security Fund Police (ISFP)	Justice Programme (JUST)	Pilot Projects and Preparatory Actions (PPPA)	Programme for the Competitiveness of	Promotion of Agricultural Products (AGRIP)	Research Fund for Coal & Steel (RFCS)	Rights, Equality and Citizenship Programme (REACT)

Proposal Template

- Available on IMI website & H2020 submission tool
- For the proposals, the page limit is **70 pages** (for sections 1-3)

Please do not consider the page limit as a target. It is in your interest to keep your text as concise as possible, since experts rarely view unnecessarily long proposals in a positive light.

Title of proposal

List of participants

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4. MEMBERS OF THE CONSORTIUM

4.1 Participants

4.2 Third parties involved in the project

5. ETHICS

Tips for writing a successful proposal

- Read **all the call-relevant material**:
www.imi.europa.eu
- Q&A document developed to explain some aspects in more detail, but is by no means intended to be exhaustive, nor should it differ from anything stated in the Call text.
- Begin forming your consortium **early**
Partner search tools & networking events
- Provide **reviewers** with all the information requested to allow them to evaluate your proposal
- **Finalise and submit your proposal early**
- Contact the **IMI Office** infodesk@imi.europa.eu

Common mistakes

- Admissibility/Eligibility criteria not met:
 - submission **deadline** missed
 - minimum of **3 legal entities** from **3 member states & H2020 associated countries** not met
- The proposal does **not address the objectives** of the topic
- A proposal is **scientifically excellent** but will have **limited impact**
- **Complementarity** among partners, including industry partners not well described.

Find project partners

- Network with **your contacts**
- **Network** with fellow webinar participants
- Use **Partner Search Tools**:
 - Funding & tender opportunities portal under this IMI call topic, there is a specific tab **Partner Search**

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/imi2-2020-21-01>

- Funding & tender opportunities portal partner search (more general)

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/partner-search>

- German NCP partner search tool: www.imi-partnering.eu
- Get in touch with your **local IMI contact point**: www.imi.europa.eu/about-imi/governance/states-representatives-group
- Talk to your **Health National Contact Point (NCP)**
- Network on **social media** (e.g. IMI LinkedIn group)

Find contributing partners

- Companies that expressed particular interest are listed in the Questions and answers document (see question 8) together with a not exhaustive list of possible in-kind contribution.
- Potential applicants are invited to interact with the above mentioned company(ies), using the general mailbox set up by EFPIA: covid19@efpia.eu.
- Any other company interested in contributing with in-kind should also contact EFPIA, using the same mailbox.
- Note that no confidential or sensitive information should be included in the messages sent to this email address.
- Potential applicants are also encouraged to upload their contact details on the Funding & tender opportunities portal under this IMI call topic, there is a specific tab **Partner Search** <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/imi2-2020-21-01>

Participation of SMEs, patient groups, regulators

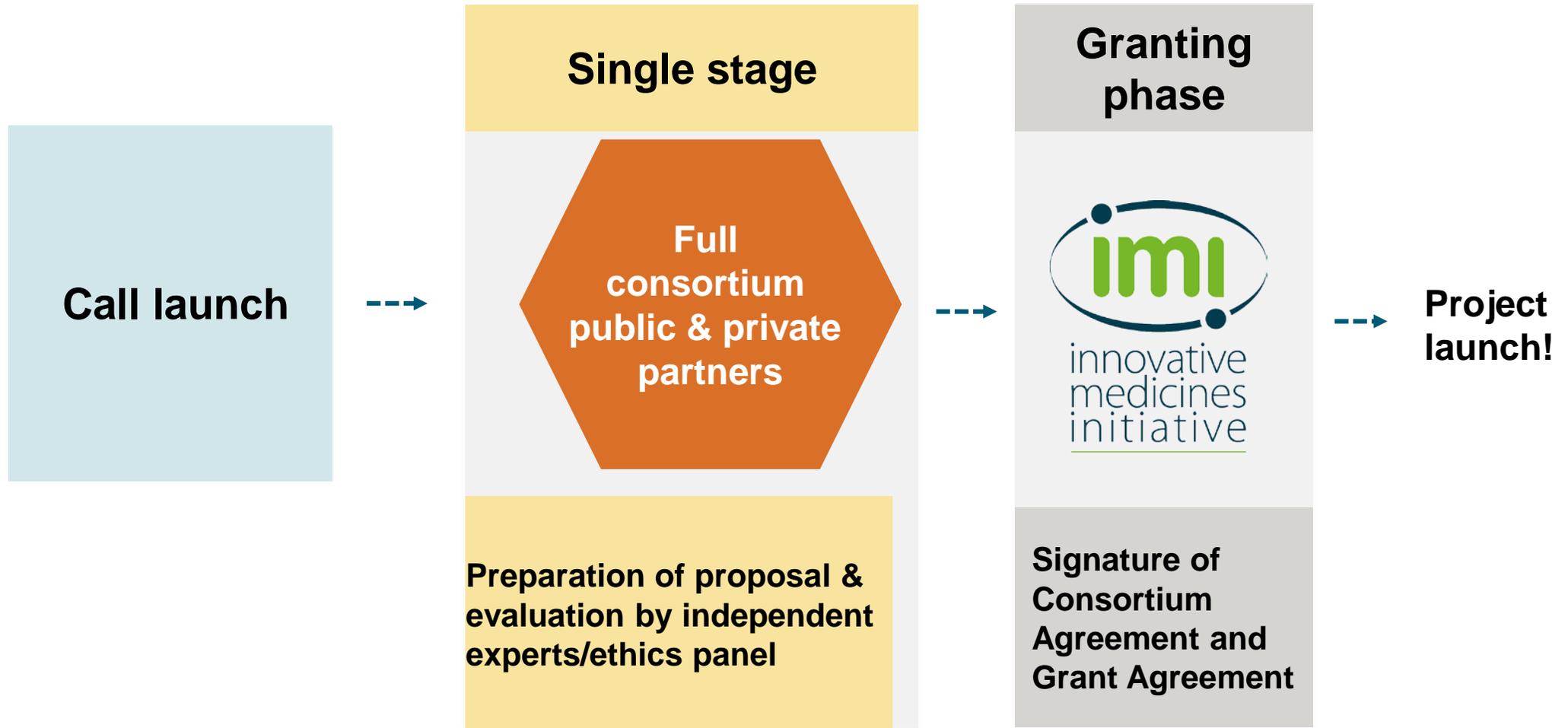
We encourage the participation of a wide range of health research and drug development stakeholders in our projects.

- SMEs and mid-sized companies
- not-for profit profit patient organisations
- Regulatory bodies
- Companies / organisations from related fields (e.g. diagnostics, animal health, IT, imaging etc...)



From Call to grant award

IMI2 Call 21: a single-stage Call process



Note:

- Considering the emergency, this is a fast-track Call for proposals
- There will be no hearing with Applicants.

Conditions for Call 21 single-stage

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

- **Submission deadlines**

Deadline Proposal submission: 31 March 2020

- **Minimum conditions**

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

- **Single-stage - C21**

Proposals submitted by consortium combining applicants requesting JU funding and contributing partners providing in kind and/or financial contributions.

All evaluated proposals will be ranked in one single list.

Proposals above the threshold will be invited in order of ranking to prepare a Grant Agreement within the limits of the available overall budget.

A single set of evaluation criteria



- Thresholds and weighting in the **Call documents**
- Minimum of **3 independent experts**

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

IMI2 JU Evaluation criteria

Single stage call

- **Excellence – threshold of 4**

Please note sub-criteria listed in evaluation form,

- **Impact – threshold of 4**

Please note sub-criteria listed in evaluation form,

- **Quality and efficiency of the implementation – threshold of 4**

Please note sub-criteria listed in evaluation form

Overall threshold is 12

Fast track Call for Proposal

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

BUT, because this is a fast-track Call for proposals

Call 21 GAs are expected to be signed and to start by Q2/2020

IMI2 JU Grant Agreement



- The IMI2 JU MGA (v.5) will apply to Call 21
- It follows H2020 Model Grant Agreement (v.5) with IMI2 JU 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*'

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 IMI2 JU 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.

Reference legal documents

- **H2020 Rules for Participation**
- **EC Delegated Regulation for IMI2 JU**
- **IMI2 JU model Grant Agreement**
- **IMI2 JU annotated Grant Agreement**

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

Funding rules

IMI2 JU 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

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**, or
- **H2020 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

One single funding rate per project – Beneficiaries receiving funding

One project = One rate

For all beneficiaries and all activities

- 100% of the eligible costs
- Indirect costs: **25% flat rate**

Contributing partners

- EFPIA companies/organisations associated to EFPIA, and/or
- Associated Partners (AP) to IMI2 JU

Contribution as **in-kind** or **financial contribution** to the IMI2 JU

If the contributing entity is **not** yet an EFPIA member (or affiliate) or an IMI2 JU AP at the time of the proposal submission, and the proposal is selected for funding, such a legal entity is invited to become an EFPIA member (or affiliate) or an IMI2 JU AP

prior to the signature of the relevant Grant Agreement



Questions & answers