

## IMI2 JU Call 21 – Development of therapeutics and diagnostics combatting coronavirus infections

### Questions and answers

The Call text provides the overall principles, expectations and requirements to be followed by applicants in the preparation of their proposals and by the panel of experts in the evaluation of the submitted proposals. This Q&A document aims 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.

#### 1. What is the current Call for proposals about?

Considering the public health and humanitarian implications of the COVID-19 outbreak, there is a need for all stakeholders across the public and private sectors to collaborate in global efforts to care for those affected, contain the outbreak, and develop the much-needed resources to prepare for the future. This Call presents an opportunity offered by the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU) to support collaborations of private companies, academia, international organisations, public bodies etc. to accelerate the development of therapeutics and diagnostics to tackle the current and future outbreaks.

In order to avoid duplication with other initiatives and due to several recent announcements regarding novel coronavirus vaccine development, IMI2 JU has decided to exclude vaccine development from the scope of this Call.

#### 2. What is the total budget of the IMI2 JU Call 21?

Applicant consortia will be competing for the maximum total financial contribution from IMI2 JU of 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<sup>1</sup> constituents or affiliated entities and/or, when relevant, IMI2 Associated Partners (see question 9 on the IM2 JU Associated Partners).

#### 3. All proposals submitted under this Call and evaluated above the threshold will be ranked in one single list. Proposals will be invited in order of ranking to prepare a Grant Agreement within the limits of the available overall budget. What are the reference documents for this Call for proposals?

Applicants are encouraged to study in detail the Call text as well as the following documents:

- H2020 Rules for Participation<sup>2</sup>
- Parts A, B and C of the General Annexes to the H2020 Work Programme 2018-2020<sup>3</sup>

<sup>1</sup> EFPIA is the European Federation of Pharmaceutical Industries and Associations [www.efpia.eu](http://www.efpia.eu)

<sup>2</sup> [http://ec.europa.eu/research/participants/data/ref/h2020/legal\\_basis/rules\\_participation/h2020-rules-participation\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf)

<sup>3</sup> [https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2018-2020/annexes/h2020-wp1820-annex-ga\\_en.pdf](https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2018-2020/annexes/h2020-wp1820-annex-ga_en.pdf)

- IMI2 JU Commission Delegated Regulation<sup>4</sup>
- IMI2 JU Manual for submission, evaluation, and grant award<sup>5</sup>
- IMI2 JU Research and Innovation Actions Evaluation criteria<sup>6</sup>
- IMI2 JU Research and Innovation Actions (RIA/IA) Proposal template<sup>7</sup>

For further questions, applicants may contact IMI2 JU at [applicants@imi.europa.eu](mailto:applicants@imi.europa.eu)

## 4. What is the single-stage process?

The single-stage submission scheme requires that applicants submit a proposal (max. 70 pages – see IMI2 RIA/IA Proposal Template) for the one and only evaluation stage. Proposals will be submitted by consortia composed of applicants requesting IMI2 JU funding and contributing partners.

The proposals will be evaluated by independent experts, and the results will be communicated to the applicant consortia. Successful consortia will be invited to prepare a Grant Agreement following the necessary modalities.

Applicants should be aware that under the single-stage submission procedure the threshold for the individual criteria (excellence, impact and quality and efficiency of the implementation) is 4 and the overall threshold is 12. It is important that applicant consortia read the evaluation criteria carefully.

For this Call, IMI2 JU will not organise hearings with applicants.

## 5. What are the admissibility criteria for the proposals?

To be considered admissible, a proposal must comply with the admissibility criteria set out in part B of the General Annexes of the H2020 Work Programme 2018-2020<sup>8</sup>.

Incomplete proposals may be considered inadmissible. In case of an 'obvious clerical error' (e.g. omission to submit evidence or information on a non-substantial element of the proposal), IMI2 JU may first ask applicants to provide the missing information or supporting documents.

## 6. What are the eligibility criteria for the proposals?

To be considered eligible, a proposal must comply with the eligibility criteria set out in part C of the General Annexes of the H2020 Work Programme 2018-2020.

In all cases: a minimum of three independent legal entities established in different Member States or countries associated<sup>9</sup> to H2020.

---

<sup>4</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL\\_2014\\_174\\_R\\_0003](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2014_174_R_0003)

<sup>5</sup> [https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/IMI2\\_ManualForSubmission\\_v1.7\\_November2018.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/IMI2_ManualForSubmission_v1.7_November2018.pdf)

<sup>6</sup> [https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/IMI2\\_EvaluationForm\\_RIA-IA\\_v1.5\\_EN.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/IMI2_EvaluationForm_RIA-IA_v1.5_EN.pdf)

<sup>7</sup> [https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/IMI2\\_ProposalTemplate\\_RIA-IA\\_SingleStage\\_Stage2of2\\_v1.5\\_Word.docx](https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/IMI2_ProposalTemplate_RIA-IA_SingleStage_Stage2of2_v1.5_Word.docx)

<sup>8</sup> See footnote 2

<sup>9</sup> [https://ec.europa.eu/research/participants/data/ref/h2020/grants\\_manual/hi/3cpart/h2020-hi-list-ac\\_en.pdf](https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/3cpart/h2020-hi-list-ac_en.pdf)

## 7. Do I need a contributing partner, i.e. providing an in-kind contribution, in my consortium? Can beneficiaries eligible to receive funding instead reduce the funding requested and contribute to the total project cost themselves?

It is not an eligibility criterion to have a contributing partner, i.e. an EFPIA company or affiliated entity, or an IMI2 JU Associate Partner contributing in-kind as part of your consortium.

However, a key element of the expected impact of this Call for proposals is that applicants must maximise the value of the IMI2 JU public-private partnership by harnessing support from different stakeholders. This includes the mobilisation of resources through the inclusion of contributing partners (e.g. an EFPIA company or affiliated entity, or an IMI2 JU Associated Partner), providing contributions (in kind and/or financial), to reflect the public-private character of IMI2 JU actions.

In that respect, it is important to understand that under one of the evaluation criteria (published at: <http://www.imi.europa.eu/content/overview-imis-calls-how-participate>), the expected impact of your proposal will be assessed based on what is listed under the section "Expected impact" in the Call text.

This means that your proposal will only score highly under the evaluation criterion 'Impact' if the experts consider that it meets those expectations. Please also note that the threshold for the evaluation criterion 'Impact' is 4 in a single-stage Call process. It is therefore highly unlikely if not impossible, that your proposal will score above threshold if no contributing partner under the IMI2 JU scheme of public-private consortia is included.

The intention is not to reduce the funding available to public partners by revisiting the applicable funding rate as established for this Call (100% of the total eligible costs), but to mobilise investments by other stakeholders, e.g. private investments, as part of a public-private partnership (PPP).

## 8. What type of contribution could contributing partners bring to the project?

Contributing partners are usually industry companies that are constituent entities of EFPIA or their affiliated entities and/or IMI2 JU Associated Partners which contribute with either in kind or financial contributions. The in-kind contribution consists of costs incurred for project implementation which are not reimbursed by IMI2 JU. This will typically be human resources (which may be determined in "full-time equivalents" (FTEs)), consumables, work outsourced to contract research organisations (CROs) or other service providers, etc. Some in-kind resources can originate from non-EU or associated countries (i.e. in practice: work can be carried out in these countries).

The in-kind contribution that contributing partners could bring may include the following (this list is not exhaustive):

Scientific knowledge; drug discovery and development expertise; assay development activities; preclinical activities (in vitro/in vivo, toxicology); chemistry, manufacturing and controls (CMC) activities; identification of new molecular entities (incl. medicinal chemistry); sample collection; development of diagnostics; clinical trials (biostatistics, data-management, clinical supplies, regulatory support).

In that respect, a number of companies have already expressed their interest to join an applicant consortium (this list is not exhaustive):

- Abbvie
- Astellas
- Bayer
- Boehringer Ingelheim

- E-Pharma
- Enyo Pharma
- IDbyDNA
- Janssen
- Merck
- Novartis
- Pfizer
- Special Product's Line S.p.A.
- Takeda

Potential applicants are invited to interact with the above mentioned company(ies), using the general mailbox set up by EFPIA: [covid19@efpia.eu](mailto:covid19@efpia.eu).

Any other companies 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.

As from the launch of the IMI2 JU Call 21, potential applicants are also encouraged to upload their contact details on the [SEDIA portal](#).

## **9. What is an IMI2 JU Associated Partner and what organisations can become Associated Partners? Can the process of becoming an IMI2 JU Associated Partner be concluded AFTER submission of a proposal, e.g. only once evaluated positively?**

Under the IMI2 JU programme, organisations other than EFPIA companies can become IMI2 JU Associated Partners. Like EFPIA partners in IMI2 JU projects, Associated Partners do not receive any funding from IMI2 JU, but contribute to the projects, mainly through in-kind contributions (such as their experts' time, access to resources / equipment). In addition, normally the resources they put into a project are matched by IMI2 JU, making this a good way of leveraging precious resources.

Examples of organisations that could become IMI2 JU Associated Partners include philanthropic organisations and charities that run their own health research programmes, as well as organisations working in sectors related to healthcare such as ICT, imaging, diagnostics, animal health, etc.

So far, among others, the Bill and Melinda Gates Foundation and Wellcome have become Associated Partners<sup>10</sup>.

Organisations wishing to become IMI2 JU Associated Partners must apply to the IMI2 JU Governing Board with a letter of endorsement setting out their acceptance of the IMI2 JU Statutes as well as the details of their proposed contribution to IMI2 JU (e.g. in-kind/cash contributions, activities, duration, etc.).

With reference to the IMI2 JU Call 21, proposals are expected to exploit support from different stakeholders, including the mobilisation of funds through the inclusion of contributing partners under the IMI scheme of public-private consortia (e.g. an EFPIA company or affiliated entity, or an IMI2 JU Associated Partner).

In that respect, a contributing partner in a proposal selected for funding under the present Call which is not an affiliate or a constituent entity of EFPIA, or an IMI2 JU Associated Partner at the time of the proposal submission, is invited to become an affiliate or a constituent entity of EFPIA, or an IMI2 JU Associated Partner in accordance with the IMI2 JU Statutes prior to the signature of the relevant Grant Agreement.

---

<sup>10</sup> <https://www.imi.europa.eu/get-involved/associated-partners>

In practical terms, contributing partners may decide to apply for such affiliations when and if the proposal where they are participating is selected for funding.

Where a contributing partner becomes an affiliate or a constituent entity of EFPIA or an IMI2 JU Associated Partners, it will have to report annually its contribution to the project in accordance to the IMI2 JU Statutes<sup>11</sup>.

## 10. Is my organisation eligible to receive funding?

Universities and other public research institutions, small- and medium-sized enterprises (SMEs), other companies having an annual turnover up to EUR 500 million <sup>12</sup>, hospitals, healthcare organisations, regulatory agencies, public health authorities, no-profit patients organisations, and others no profit organisations are eligible to receive IMI2 JU financial contribution, in accordance with the applicable rules.

Specifically, legal entities established in a Member State or country associated to H2020 are eligible to receive IMI2 JU financial contribution.

Under exceptional circumstances, legal entities from countries other than those set out above (i.e. third countries), such as the People's Republic of China might also be eligible for IMI2 JU funding should their participation be evaluated as essential for the realisation of the project's objectives.

Proposals should justify the need for IMI2 JU funding for organisations in third countries.

## 11. Is cooperation with other organisations or on-going projects envisaged?

Considering the public health and humanitarian implications, synergies and complementarities with ongoing efforts in the COVID-19 field are expected to maximise impact.

Therefore synergies and complementarities are expected with relevant national, European and non-European initiatives (including suitable biological and medical sciences research infrastructures<sup>5</sup>) in order to incorporate past achievements, available data and lessons learnt where possible, thus avoiding unnecessary overlap, and duplication of efforts and funding. In particular, applicants are expected to collaborate with any relevant project or initiative targeting the current COVID-19 outbreak supported by the European Commission, CEPI, Wellcome, BARDA, The Bill and Melinda Gates Foundation and others.

Where relevant, applicants might 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

Proposals covering investigations of therapeutic should consider engaging with the European Medicines Agency (EMA) which has activated its plan for emerging health threats. The latter includes the possibility for fast-tracked Scientific Advice [3].

The consortia selected through this Call are expected to cooperate with each other and share their learnings for the purpose of achieving the objectives of their respective actions, and to maximise their impact. Therefore, all grants awarded under this Call will be complementary grants. Consequently, the respective options under Article 2, Article 31.6 and Article 41.4 of the IMI2 JU Model Grant Agreement<sup>13</sup> will apply.

<sup>11</sup> Please consult the IMI2 JU guidelines for reporting in kind and financial contributions by Members other than the Union and Associated Partners: [https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/IMI2\\_JU\\_Guidelines\\_for\\_reporting\\_in\\_kind\\_and\\_financial\\_contributions\\_by\\_%20Members\\_other\\_%20than\\_the\\_%20Union\\_%20and\\_%20Associated\\_Partners\\_0.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/IMI2_JU_Guidelines_for_reporting_in_kind_and_financial_contributions_by_%20Members_other_%20than_the_%20Union_%20and_%20Associated_Partners_0.pdf)

<sup>12</sup> Independent legal entities having an annual turnover of EUR 500 million or less, not being affiliated entities of companies with an annual turnover of more than 500 million; the definition of 'affiliated entities' within the meaning of Article 2(1)(2) of Regulation (EU) No 1290/2013 shall apply mutatis mutandis.

<sup>13</sup> See: [https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/h2020-mgaimi\\_en\\_v5.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/h2020-mgaimi_en_v5.pdf)

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

## **12. Are there any special provisions regarding the intellectual property (IP) regime under the IMI2 JU Call 21?**

Where relevant under this Call, applicant consortia are expected to bring into the project assets which are owned by one of the beneficiaries participating in the proposal, for use in the treatment of patients diagnosed with COVID-19. These assets could include approved therapies or compounds in development or for repurposing. Clinical results that are generated from the assets tested will be owned by the generating beneficiary(ies). However, these results may be improvements (or directly related) to the assets.

The consortium should recognise the requirements of Article 26.2 of the IMI2 JU Model Grant Agreement with respect to jointly generated results. All beneficiaries should be aware that when negotiating the consortium agreement each beneficiary may propose all possible safeguarding provisions with respect to the rights to results generated from their assets. For instance in the consortium agreement, the relevant beneficiaries may agree that, when requested by a beneficiary (e.g. an EFPIA partner) that is the owner of a pre-existing asset (i.e. background of the project), the ownership of results (including clinical results) generated by any other beneficiary, relating to the pre-existing background – when and only where not jointly owned according to Article 26.2 of the IMI2 JU Model Grant Agreement – will be transferred under the terms of the consortium agreement to the owner of the pre-existing asset. Such contractual arrangements may state that, e.g. such a transfer would be at no cost, if so requested by the owner of the pre-existing asset.

## **13. Are there any conditions on data management and dissemination within the IMI2 JU Call 21?**

In the context of a Public Health Emergency, grant beneficiaries will be subject to additional requirements with respect to the timely sharing of data. Beneficiaries in grants awarded under this Call for proposals must make available their research data, at the latest within 30 days after it has been generated, through open access or, if agreed by IMI2 JU or the European Commission, by giving access rights to those third parties that need the research data to address the public health emergency. Therefore, the relevant option of Article 29.3 of the IMI2 JU model Grant Agreement will be applied.

Applicants should be aware that data must be deposited in a relevant established international data platform, such as those of the WHO, or the European Molecular Biology Laboratory (EMBL).

In addition, applicants should be aware that beneficiaries in grants awarded in this Call are expected to apply the principles established in [the Statement on Data Sharing in Public Health Emergency](#)

## **14. Which rules apply to the UK legal entities joining a proposal under the IMI2 JU Call 21?**

The Withdrawal Agreement as agreed between the European Union and the United Kingdom entered into force on 1 February 2020. In overall terms, on the basis of the Withdrawal Agreement, UK-based legal entities will continue to be fully eligible to participate and receive funding in the current 2014-2020 EU programmes, including Horizon 2020 and IMI2 JU, as if the UK were a Member State until the closure of these programmes, unless security considerations apply. This means that UK beneficiaries can continue – without interruption – to receive grants awarded under the current and previous multiannual financial frameworks (MFFs) until their end dates, even if these are after 2020. Accordingly, UK-based legal entities will be fully eligible to apply, participate and receive JU funding under the IMI2 JU Call 21.