IMI2 Call 21 – Development of therapeutics and diagnostics combating coronavirus infections

All information regarding future IMI Call topics is indicative and subject to change. Final information about future IMI Calls will be communicated after approval by the IMI Governing Board.

Frequently asked questions (FAQ)

The call text provides the overall principles, expectations and requirements to be followed respectively by the 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 at merely explaining 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 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 IMI2 to support collaboration of private companies, academia, international organisations, public bodies etc. to accelerate the development of therapeutics and diagnostics to tackle the current and future outbreaks.

2. What is the total budget of the COVID-19?

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 budget requested, taking into account the proposed in-kind contributions from contributing partners, i.e. EFPIA constituents or affiliated entities and/or, when relevant, IMI2 Associated Partners (see question xx on the IM2 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

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 Template Proposal) for the one and only evaluation stage. The proposals shall be subject to remote evaluation (and in-house where relevant), results of which will be communicated to the applicant consortia. The successful consortia will be invited to prepare a Grant Agreement following the necessary modalities.

Applicants should be aware that under single stage submission procedure the threshold for 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 carefully the evaluation criteria.

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.

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 to H2020.

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7 See footnote 2
7. Do I need an EFPIA company contributing in-kind in my consortium? Can beneficiaries eligible to receive funding instead reduce the funding requested and self-contribute to the total project cost?

It is not an eligibility criterion to have an EFPIA company (or affiliated entity) or 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 IMI2 JU public-private partnership value by harnessing support from different stakeholders. This includes the mobilisation of resources through the inclusion of contributing partners (e.g. EFPIA company or affiliated entity, IMI2 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 here: 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 high under the evaluation criterion ‘Impact’ if the experts consider that it meets those expectations. Please also note that the threshold for evaluation criterion ‘Impact’ is 4 in a single-stage Call process. It is therefore considered highly unlikely if not impossible for your proposal to score above threshold if no contributing partner under the IMI 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 investment, as part of a 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 the 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 (in practice: work can be carried out in these countries).

In that respect, a number of companies have already expressed their interest to join an applicant consortium. This list is not final and will be updated with additional information and details when the Call is launched.

- Janssen
- Takeda
- Roche
- Servier
- Astellas
- Covance
- Illumina

The in kind contribution that they could bring may include the following (list not exhaustive):
Scientific knowledge; Drug discovery and development expertise; Assay Development activities; Preclinical activities (in-vitro/in-vivo, toxicology); CMC-activities; Identification of new molecular entities (incl. medicinal
chemistry); Sample collection; Development of diagnostics; Clinical trials (biostatistics, data-management, clinical supplies, regulatory support).

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 Welcome Trust have become Associated Partners.

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 details of their proposed contribution to IMI2 JU (e.g. in-kind/cash contributions, activities, duration, etc.).

With reference to the IMI2 COVID-19 Call, 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. EFPIA company or affiliated entity, IMI2 Associated Partner).

In that respect, a contributing partner in a proposal selected for funding under the present call which is not yet an affiliate or a constituent entity of an IMI2 JU Member other than the Union (i.e. 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 an IMI2 JU Member, other than the Union, or an IMI2 JU Associated Partner in accordance with the IMI2 JU Statutes prior to the signature of the relevant Grant Agreement.

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 Associated Partners, it will have to report annually its contribution to the project in accordance to the IMI2 Statutes.

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,10 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.

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9 https://www.imi.europa.eu/get-involved/associated-partners

10 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.
Under exceptional circumstances, legal entities from countries other than the aforementioned (i.e. Third countries) such as 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 involving third countries organisations receiving IMI2 JU funding.

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) 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, proposals should consider the close collaboration with leading European supercomputing centres to use high-end computing, data and simulation resources in order to accelerate the processes of diagnosis and vaccine research and development. In this respect, the Supercomputing facilities in Barcelona (BSC) and Bologna (Cineca) are open to collaborate with any interested proposer or successful proposal. Other leading European supercomputer centres, such as the organisations hosting the PRACE Tier-0 supercomputers, may also be interested in such collaborations.

Proposals covering investigation of therapeutic should consider engaging with the European Medical Agency (EMA) to ensure adequacy of the proposals from a regulatory point of view, i.e. via the innovation task force, scientific advice or consultation in the context of the health threats interactions [3].

In addition to ensure the interactions between actions funded under this call, the selected consortia are expected to cooperate and share their learnings for the purpose of achieving the objectives of their respective actions, in order to maximise the impact. Therefore, all grants awarded under this call will be complementary grants 11.

12. Q: Are there any special provisions regarding the IP regime under COVID-19 Call?

Under this Call Topic when relevant, the applicant consortia are expected to bring assets (which may include approved therapies or compounds in development or repurposed) for use in treating patients diagnosed with COVID-19 owned by one of the beneficiaries participating in the proposal. 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 in respect to jointly generated results. All beneficiaries should be aware that when negotiating the consortium agreement each may propose all possible safeguarding provisions in respect to the rights to results generated from their assets. For instance in the consortium agreement, it may be agreed by the relevant beneficiaries that, when requested by one of the beneficiaries (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.

agreement to the owner of the pre-existing asset. Such contractual arrangements may state that, e.g., such transfer would be at no cost, if so requested by the owner of the pre-existing asset.

13. Q: Are there any conditions on data management and dissemination within COVID-19 Call

In the context of a public health emergency, grant beneficiaries will be subject to additional requirements with respect to 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 the 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 will be applied.

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

In addition, beneficiaries in grants awarded under this topic Call for proposals should be aware that the principles established in the Statement on Data Sharing in Public Health Emergency will be applied.