

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.

Version	Date	Comments
1	Tuesday, 3 rd of March 2020	Questions numbered 1 to 15
2	Monday, 9 th of March 2020	Additional questions numbered 16 to 21
3	Monday, 16 th of March, 2020	Additional questions numbered 22 to 27
4	Monday, 23 rd of March, 2020	Additional questions numbered 28 to 34 Additional clarifications and information for Q&As (19, 25, and 26) already included in previous version of this document, are presented in <u>green and underlined</u> .

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Part A: Questions and answers drafted by IMI2 JU

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. EFPIA¹ 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 Participation²
- Parts A, B and C of the General Annexes to the H2020 Work Programme 2018-2020³
- IMI2 JU Commission Delegated Regulation⁴
- IMI2 JU Manual for submission, evaluation, and grant award⁵
- IMI2 JU Research and Innovation Actions Evaluation criteria⁵
- IMI2 JU Research and Innovation Actions (RIA/IA) Proposal template⁶

For further questions, applicants may contact IMI2 JU at applicants@imi.europa.eu

¹ EFPIA is the European Federation of Pharmaceutical Industries and Associations www.efpia.eu

² http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf

³ https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2018-2020/annexes/h2020-wp1820-annex-ga_en.pdf

⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2014_174_R_0003

⁵ https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/IMI2_EvaluationForm_RIA-IA_v1.5_EN.pdf

⁶ 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

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 2018-2020⁷.

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 associated⁸ to H2020.

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.

⁷ See footnote 2

⁸ https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/3cpart/h2020-hi-list-ac_en.pdf

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.

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 Partners⁹.

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.

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 Statutes¹⁰.

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 million¹¹, hospitals, healthcare organisations, regulatory

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

¹⁰ 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

¹¹ 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.

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 infrastructures⁵) 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 Agreement¹² will apply.

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

¹² See: https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/h2020-mga-imi_en_v5.pdf

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.

Part B: Questions received by applicants and answered by IMI2 JU

15. Is the development of a COVID 19 test and POC system eligible for an IMI grant application?

Please refer to the Scope section (page 6) of the [Call text](#), where diagnostics is specified:

- Development of diagnostics, ensuring rapid evaluation of candidates based on existing technologies. Diagnostic tests will be essential for clinical trials of new or repurposed drugs, to help stratify patients and assess treatment efficiency (surrogate endpoint such as viral clearance).
- 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. These are essential and of utmost importance to manage the outbreak, isolate patients at risk, and treat people accordingly. It is crucial to differentiate and identify respiratory pathogens with similar clinical symptoms (e.g. flu, respiratory syncytial virus, other viruses or bacteria) and/or detect emerging pathogens such as SARS-CoV-2. This can be achieved through point-of-care (POC) testing or centralised testing.

16. Is there a submission template for Call 21?

This is the [template](#) for Call 21, which can be downloaded from the [Call documents section](#) on IMI's website.

17. Are US universities eligible for Call 21?

As the US is a 'Third Country', a university from the US is eligible to participate in IMI projects. This participation however is separate from its eligibility for funding from IMI (see below). If participation is planned, the US participant should satisfy itself that it will be able to sign and abide by the provisions of the IMI2 Grant Agreement ([link below](#)) and the project consortium agreement (which will be prepared by the applicant consortium themselves).

US University eligibility for funding:

The conditions of Call 21 specify that participants established in a third country are eligible to take part in IMI actions but are not automatically eligible for funding. They may exceptionally receive funding from the IMI2 JU provided that their participation is deemed 'essential' by the IMI2 JU to carry out the action.

This essentiality should be of such a character that the given IMI2 JU project would be unable to achieve its objectives without the inclusion of that entity, e.g. a similar expertise is not available within the EU or H2020 associated countries.

Thus, to be eligible for funding, such entities from third countries must demonstrate that their contribution is essential to the project. Such essentiality can be defined as provision of the following:

- outstanding competence/expertise;
- access to research infrastructure;
- access to particular geographical environments;
- access to data.

The relevance/essentiality of the above is usually established with the other applicants when an applicant consortium is being formed and confirmed by the independent experts evaluating the submitted proposal.

To conclude, in order for a third country legal entity to be funded in the IMI2 JU context, it has to fulfil the conditions for funding applying to organisations from EU and H2020 associated countries, as defined in Article 1 of Regulation 622/2014.

18. Is a consortium made of research institutions, SMEs and medical centres belonging to three different EU member states eligible?

Regulation (EU) 1290/2013 ('The H2020 Rules of Participation' or 'ROP') state that the following minimum conditions shall apply:

- a. At least three legal entities shall participate in an action;
- b. three legal entities shall each be established in a different Member State or associated country; and
- c. the three legal entities referred to in point (b) shall be independent of each other within the meaning of Article 8.

A 'legal entity' is any natural person, or any legal person created and recognised as such under national law, Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations (ROP, Article 2: 'Definitions')

Article 8 of the ROP lays out the conditions under which legal entities can be considered to under the direct/indirect control of another legal entity (this may be of relevance).

We would therefore suggest that the prospective participants satisfy the eligibility criteria.

19. Who is expected to drive the process of assembling a consortium and an application for the single-stage call?

Will the reference person be a Coordinator, academic or SME, let's say in the "public" side, or a project Leader in the EFPIA/private domain? An entity willing to participate as a beneficiary, to whom has to address its contribution offer? One in the public domain possibly acting as a coordinator, or and EFPIA partner?

IMI does not mandate how applicant consortia organise themselves. The task of assembling a consortium (and then preparing an application) is solely in the hands of the applicants themselves. You may find [further information under #6, #7 and #11 of this Questions and Answers document, as well on the IMI page on 'Finding Partners' useful:](#)

https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/open-calls/Call21_QandA_FINAL.pdf<https://www.imi.europa.eu/apply-funding/general-overview/finding-partners>

20. Is there a fixed duration for Call 21 projects?

The call text includes no fixed duration for the project, this is left to applicants whereby the duration should accurately reflect the approach set out in the applicant proposal. We would refer you to the topic text (link below), specifically to 'Indicative duration of the action' (page 8).

https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/open-calls/IMI2Call%2021_Coronavirus_CallText.pdf

21. Is there a functional mailbox for the applicants to contact companies interested in joining an applicant consortium?

EFPIA has set up this functional mailbox covid19@efpia.eu in order to facilitate the communication between applicants and the companies interested in joining an applicant consortium.

22. How many proposals will be funded?

There is no set number. This will depend upon the funding utilised by the top ranked proposal(s) and outlined in the(ir) budget(s).

23. How many companies can be part of a consortium?

IMI2 JU sets no guidelines for the maximum size of a consortium. However, IMI2 JU requires that a Consortium contains a minimum of three independent legal entities established in different Member States or Associated Countries.

24. We are preparing a consortium for the coronavirus IMI call, and are wondering about the budget, could you give us any range of budget we should aim at?

"According to the Innovative Medicines Initiative 2 Joint Undertaking (IMI 2 JU)-Call 21 text, the applicant consortia are expected to address at least one of the objectives of the topic. These consortia will be competing for the maximum total financial contribution from IMI2 JU 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.

The indicative budget must be drafted as close as possible to the real estimated costs, taking into account the tasks foreseen and cost efficiency considerations. Please bear in mind that according to the IMI2 JU "Manual for submission, evaluation and grant award", proposals with an inflated budget are likely to receive a lower score.

Award of the grants will be made on the basis of this ranking, subject to the availability of budget.

You will find more information under the links below.

IMI 2 JU-Call 21:

https://www.imi.europa.eu/sites/default/files/IMI2%20Call%2021%20Coronavirus%20-%20Call%20text_final.pdf

IMI 2 JU-Manual for submission, evaluation and grant award:

https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/IMI2_ManualForSubmission_v1.7_November2018.pdf

25. Should I contact EFPIA during the drafting phase of the proposal?

Being a single-stage call, the submission scheme requires that a proposal (max. 70 pages) is submitted by a consortium composed of applicants requesting IMI2 JU funding, and contributing partners, e.g. EFPIA companies and/or an IMI2 JU Associated Partner. Therefore, you must reach out and integrate the contributing partners in your consortium before the submission of your proposal. Please refer to #7 for further information on the involvement of 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.

26. What is the required TRL (**Technology Readiness Level**) to enter the proposal? Is there a start TRL level and/or a level that needs to be reached during the project?

It is up to the applicants to show how they will address at least one of the objectives of the call topic and achieve at least one of the key deliverables listed and therefore demonstrate their capacity as well as the readiness to progress as rapidly as possible to ensure maximum impact.

27. Are private companies financed at 100% of the total cost of the project?

The IMI2 JU rules and conditions of Call 21 specify that only certain types of legal entities are eligible for IMI JU funding.

Concerning private companies based in EU and H2020 associated countries, those defined in Article 1 of Regulation 622/2014 will be eligible to receive funding:

- (i) micro, small and medium-sized enterprises and other companies with an annual turnover of EUR 500 million or less, the latter 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;
- (ii) non-profit organisations, including those carrying out research or technological development as one of their main objectives or those that are patient organizations.

If eligible for receiving IMI2 JU funding, the direct costs incurred during execution of project tasks will be reimbursed at 100% rate, increased by 25% indirect costs.

You can refer to the IMI 2 JU-Call 21 topic text under the link below,

https://www.imi.europa.eu/sites/default/files/IMI2%20Call%2021%20Coronavirus%20-%20Call%20text_final.pdf

and to IMI2 JU Call 21 – Development of therapeutics and diagnostics combatting coronavirus infections Questions and answers:

https://www.imi.europa.eu/sites/default/files/Call21_QandA_FINAL.pdf

28. Is it up to the consortium to decide how to split the grant between partners or are there any limitations?

According to the Innovative Medicines Initiative 2 Joint Undertaking (IMI 2 JU)-Call 21 text, the applicant consortia are expected to address at least one of the objectives of the topic. These consortia will be competing for the maximum total financial contribution from IMI2 JU 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 (i.e. EFPIA constituents or affiliated entities and/or, when relevant, IMI2 JU Associated Partners) that will complement the IMI2 JU financial contribution

The proposal estimated budget should be drafted in line with the proposal objectives and activities, and cost efficiency considerations. It should present the estimated costs and requested JU contribution for applicant requesting JU funding, plus the estimated costs for contributing partners not receiving JU funding. The proposal estimated budget has to be broken-down for each member of the consortium, both receiving and not receiving JU funding. This budget will be reviewed, as part of your proposal, by the panel of experts during the evaluation.

Please note that the IMI2 JU funding will eventually only reimburse eligible costs incurred in the implementation of the funded project.

Thus, the consortium is responsible to decide about the allocation of the grant within its members. Nevertheless, the IMI2 JU will only accept and reimburse eligible costs actually incurred during the project which pertain to project tasks and activities necessary to achieve the project objectives.

29. Are non-EU in-kind-contributions allowed in Call 21? If yes, is there a maximum per project? Will it affect negatively the evaluation score if the project includes a high number of non-EU in-kind-contributions?

Under the IMI2 JU legal framework, in accordance with article 3 of the IMI2 JU Regulation EU 557/2014, the IMI2 JU funding is matching in-kind (i.e. costs incurred by contributing partner for project implementation) and financial contributions which are normally provided by EFPIA constituent or affiliated entities and/or IMI2 JU Associated Partners.

In relation to in-kind contribution consisting of costs incurred in third countries, i.e. other than EU Member states or H2020 Associated countries, these must meet specific conditions established under Article 4 of the IMI2 JU Regulation, EU 557/2014:

- they must be justified and relevant to the IMI2 JU objectives and
- they shall not exceed 30% of the total eligible costs incurred by all contributing partners at the level of the IMI2 JU programme.

Please note that costs for in-kind contribution shall be deemed to be incurred in third countries (i.e. non-EU in-kind-contribution) if the underlying activities are carried out in third countries irrespective of the place where the contributing partner is established.

More information regarding the contributing partners' contributions and reporting obligations can be found in the following document:

[IMI2 JU guidelines for reporting in kind and financial contributions by Members other than the Union and Associated Partners](#)

In-kind contributions must be relevant for achieving proposal objectives under the IMI2 JU Call 21. They will be assessed, as any other proposed activity, against the evaluation criteria of excellence, expected impact and quality and efficiency of implementation. Thus, in principle, relevant and justified in-kind contributions should not be negatively evaluated for being provided by third countries. At the same time, there is no maximum amount of non EU in-kind contribution established for this Call21.

Furthermore, please refer to the IMI 2 JU-Call 21 (Coronavirus) Questions and Answers:

https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/open-calls/Call21_QandA_FINAL.v.3.pdf

30. Do you have a suggestion on how to join to other forming consortia?

With regards to forming consortia, you may find the following resources useful:

<https://www.imi.europa.eu/apply-funding/general-overview/finding-partners>

31. Is it possible to participate to more than one consortia?

There is no legal rule preventing a partner from participating in two (or more) proposals from competing consortia, provided that the entity meets all requirements to participate in an IMI2 JU call for proposals.

However, a call for proposals being a competitive process, please be aware that multiple participations might raise concerns within the competing consortia, mainly on matters of confidentiality and exchange of information useful to build the consortium.

32. Are clinical trials a pre-requisite for Call 21?

Clinical Trials are not considered a prerequisite for this call.

33. My proposal covers the development of a potential therapeutic against the novel coronavirus disease (COVID-19). Do I need to contact the European Medicines Agency (EMA)?

As per the call topic text, proposals covering investigation of a therapeutic should engage with the EMA to ensure adequacy from a regulatory point of view.

The EMA has recently announced that they provide full fee waivers for [scientific advice](#) applications from developers of potential therapeutics (to treat the disease) against the novel coronavirus disease (COVID-19). Developers of potential therapeutics against COVID-19 should contact EMA as soon as possible with information about their proposed development, by emailing 2019-ncov@ema.europa.eu. In a first round of discussions, EMA can provide preliminary informal comments and feedback on the development. This will then allow EMA to identify the products which are mature enough to benefit from fast-track [scientific advice](#), to guarantee best use of this tool. In the context of the COVID-19 pandemic, with this fast-track [scientific advice](#), EMA can give developers prompt guidance and direction on the best methods and study designs to generate robust information on how well a medicine works and how safe it is. More information can be found on the [EMA webpage](#).

Therefore in your proposal, you should provide information on any interaction that may have already occurred, or propose a plan for such interaction.

34. Can management companies be involved in IMI projects?

According to Article 41.2 (b)(i) 'Internal roles and responsibilities' of the IMI2 JU Model grant agreement (MGA), the coordinator:

- monitors that the action is implemented properly. The requirements of proper implementation are defined in Article 7 of the IMI2 JU Annotated GA and consist of obligation to carry out the action, especially the research work, as described in Annex I to GA, and to comply with all the other provisions of the GA and all the applicable provisions of EU, international and national law;
- acts as the intermediary for all communications between the beneficiaries and the JU;
- requests and review any documents or information required by the JU and verify their completeness and correctness before passing them on to the JU;
- submits the deliverables and reports to the JU;

- ensures that all payments are made to the other beneficiaries without unjustified delay;
- informs the JU of the amounts paid to each beneficiary.

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party. Exceptionally, coordinators that are secondary or higher education establishments or public bodies may delegate the administration of the payments to another legal entity.

In other words, the responsibility for carrying-out the tasks described above is exclusively in hands of the coordinator. Nevertheless, if there is a management company participating in such consortium, it will be able to assist and support the coordinator with the administrative and other tasks. This separation of duties should be clearly described in the Annex I to GA, and in particular in the dedicated management work package. Please also note that under IMI2 JU there is the possibility to identify, besides the coordinator, a project leader. This is explained in the IMI2 JU Annotated grant agreement, particularly in the introduction (IV.D -Partnering with EFPIA beneficiaries/other large industrial beneficiaries not receiving JU funding: project scientific governance and leadership) and in annotations of article 41.3 par. 2. 'The coordinator's roles and responsibilities'.

As a conclusion, a member of consortium (e.g. a management company) can collaborate on execution of exclusive coordinator's management tasks, in a way as described in the Annex I. But only the coordinator shall be responsible and accountable for those tasks.

You can refer to the IMI 2 JU IMI2 JU Annotated grant agreement:

https://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2%20Annotated%20Model%20Grant%20Agreement%20AGA_v2.2_updated.pdf