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, 3rd of March 2020	Questions numbered 1 to 15
2	Monday, 9th of March 2020	Additional questions numbered 16 to 21
3	Monday, 16th of March, 2020	Additional questions numbered 22 to 27
4	Monday, 23rd 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 green and underlined.
5	Friday, 27th of March, 2020	Additional questions marked 35 to 45
6	Tuesday, 31st of March, 2020	Clarifications on Question 45

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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. EFPIA[1] 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[2]
- Parts A, B and C of the General Annexes to the H2020 Work Programme 2018-2020[3]
- IMI2 JU Commission Delegated Regulation[4]
- IMI2 JU Manual for submission, evaluation, and grant award[5]
- IMI2 JU Research and Innovation Actions Evaluation criteria[5]
- IMI2 JU Research and Innovation Actions (RIA/IA) Proposal template[6]

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
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[4] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2014_174_R_0003
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[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 of contributing partners.

The proposals will be evaluated by independent experts, and the results of this evaluation will be communicated to the consortia. Successful consortia will be invited to prepare a Grant Agreement following the required 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[7].

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[8] 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 Partners[9].

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 Statutes[10].

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 [11], 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 infrastructures[5]) 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[12] 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 29.3of 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.pdfhttps://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 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 need to 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.

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.

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

35. If Call 21 requires open access and data sharing within 30 days, how do we ensure IP protection as we likely will not be able to file patents so quickly?

We envision the project generating significant amount of 'digital research data'.

We further understand that beneficiaries may seek to utilise this research data outside the project, in support of patent applications or other IPR related/commercial activities.

For clarity, IMI2 JU Annotated grant agreement (hereafter IMI2 JU AGA) define digital research data as follows: information in digital form (in particular facts or numbers), collected to be examined and used as a basis for reasoning, discussion or calculation. This includes statistics, results of experiments, measurements, observations resulting from fieldwork, survey results, interview recordings and images. Only data that are generated by beneficiaries in the course of the action are concerned.

Conditions related to data sharing in Part L of General annexes to the H2020 Work programme are applicable mutatis mutandis to IMI2 JU actions. According to the text, open access to digital research data (or data sharing) means making possible for end-users via a repository and free-of-charge to access, mine, exploit, reproduce and disseminate the data concerned.

In general terms, the participants in IMI2 JU actions engage in data sharing as defined in Article 29.3.1a AGA. The text applies to two types of digital research data:

- the data needed to validate the results presented in scientific publications and associated metadata (i.e. data describing the deposited research data) and
- other data and associated metadata, as specified by the beneficiaries in their data management plan (DMP).

Data management plan is a deliverable of the project which is drafted by the consortium and submitted for acceptance by IMI2 JU.

In addition to obligations Article 29.3.1a, the grant agreements signed following the IMI2 - Call 21 will also contain specific obligations on data sharing arising from Article 29.3.1c AGA for health actions targeting public

health emergencies. The text requires data sharing of any type of quality controlled digital research data and associated metadata at the latest within 30 days after it has been generated.

As an exceptional measure, the beneficiaries might replace the open access obligation of Article 29.3.1c AGA by specific access rights to third parties that need the research data to address the public health emergency. Such limitation would be granted by IMI2 JU or the Commission, upon request from the grant beneficiary.

Public health emergencies are those declared under the international rules, EU rules such as Decision 1082/2013 or under the applicable national framework.

It should be noted that the data sharing obligation of Article 29.3 AGA does not apply to specific categories of data, subject to distinct legal rules. These are, inter alia, personal data, subject to Article 39 AGA, data covered by confidentiality obligation and subject to Article 36 AGA or by obligation to protect results, subject to Article 27 AGA.

Besides, the data generated during the project and falling under the definition of 'results' as defined by Article 26 AGA is comprehensively subject to IMI2 IPR rules. For results which can be expected to be commercially or industrially exploitable, the conditions of Article 27 AGA to examine and possibly seek an appropriate form of protection, such as patent, trademark, copyrights, trade-secret or confidentiality agreements, will be relevant. Understandably, the specific requirements of granting access rights to results for other consortium partners, IMI2 JU and third parties as laid out in Article 26, 31 AGA would then be applicable.

As a conclusion, the data sharing obligation under IMI2 - Call 21 will apply according to conditions set in Articles 29.3.1a and 29.3.1c AGA and is relevant to data falling under the AGA definition of digital research data. Such data will be described in the Data management plan (DMP), provided preferably with the proposal or at the latest before the grant signature. DMP will indicate details on what data the project will generate, how it will be curated, exploited, made accessible for verification and re-use. DMP will be subject to IMI2 JU scrutiny and also to further modifications according to the project execution path. The data sharing does not change the obligation to protect specific data, such as personal, confidential data or those necessary to protect results. As an exception, beneficiary might request replacing the general data sharing obligation by specific rights granted to third parties that need the research data in order to address the public health emergency. Such request must be agreed upon by IMI2 JU or the Commission and include rights to access, mine, exploit and reproduce the data free of charge.

36. Can an institution participate in 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, being a call for proposals 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.

37. As I understand after reading all the information, we need to submit only the application through the Funding and Tenders portal with no additional documents. Do we need to provide at this stage (with the proposal) a collaboration agreement?

The requirement for a submission in response to this single stage IMI2 Call 21 is the electronic submission of the proposal in the Funding & and Tenders portal. The proposals are submitted by the coordinator.

A collaboration agreement is only required in case your proposal will be successful. In such a case, your consortium will have to agree a collaboration agreement with the other consortia selected under this call 21 since all grant agreements signed under this call will be complementary grants. The collaboration agreement must ensure all consortia to 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.

38. I am a bit unsure which template to use for this application as it is single stage and involves a clinical trial in our case. Could you please advise?

The template used for submission in a single stage call for proposals is the same as the template for the second stage in a two stage procedure.
For this reason, you will find it on the webpage dedicated to essential IMI2 Call documents (link below), under the heading:
'Research and Innovation Actions - second stage proposal in a two-stage procedure and single-stage procedure.'
https://www.imi.europa.eu/apply-funding/call-documents/imi2-call-documents

The template for essential information for proposals including clinical trials / studies / investigations can be found under the link below:
https://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/h2020_tmpl-clinical-studies_2018-2020_en.pdf
This guide provides detailed explanations on the required information, the word version of the template is then available in the submission environment.

In addition, you will find detailed information on submission of proposals in the IMI2 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

39. I am working on a proposal for IMI-2 call 21, but in order to make my project more complete I would like to perform some regulatory preclinical test. Could you please be so kind to let me know if this contribution could be performed by sub-contractors, and if yes what is the maximum admissible cost for a subcontractor?

According to Article 13 of IMI2 JU Annotated grant agreement (AGA), subcontracts concern the implementation of action specific tasks, which are described in the Description of action (DoA). The subcontracted tasks may only cover a limited part of the action; there is no financial limit.

Any task necessary for the action can be subcontracted, if the required expertise is not available within the consortium. Additionally, the beneficiaries receiving IMI2 funding must ensure meeting all conditions established in Article 13 IMI2 JU MGA, such as the competitive selection of subcontractor, ensuring best value for money and respecting rules on conflict of interest.

Consequently, if the pre-clinical study is part of the project, described in DoA and no other participant and carry-out the task, it can be performed by a subcontractor.
Please note that, subcontracted activities, as any other of the proposed activities will be subject to the evaluation of the panel of expert according to the applicable evaluation criteria.
For further information, you may also consult the relevant annotations in the IMI2 JU Annotated Grant Agreement.

40. I have read that the minimum requirement is three partners from 3 different EU member states or H2020 Associated countries. How are the requirements in regards to numbers of partners from the same country, is there a limit?

The minimum eligibility condition for participation in a Research & innovation action (RIA) under this call is indeed at least three legal entities. Each of the three entities must be established in a different EU member state or H2020 associated country. All three entities must be independent of each other.

On the other hand, there are no maximum limits on number of participants based in the same country as far as the minimum eligibility condition is fulfilled. In fact these parameters should match up to the capacities and excellence brought to the consortium and also to the operational capacity to carry-out tasks foreseen in the proposals.

41. Data sharing versus intellectual property (IP) rights protection Within publicized documentation it is stated that beneficiaries in grants awarded under this topic must make available their research data, at the latest within 30 days after it has been generated. What kind of data the beneficiary is obligate to publicize and is it up to beneficiary decision which data cannot be shared due to IP rights protection? How, with the abovementioned obligation, we can keep our know-how within the company?

Concerning your question on the interplay between the data-sharing obligation and intellectual property rights (IPR) protection, we envision the project generating significant amount of ‘digital research data’.

We further understand that beneficiaries may seek to utilise this research data outside the project, in support of protecting their technical know-how, such as patent applications, business secret or protection of other IP

rights.

For clarity, IMI2 JU Annotated grant agreement (hereafter IMI2 JU AGA) define digital research data as follows: information in digital form (in particular facts or numbers), collected to be examined and used as a basis for reasoning, discussion or calculation. This includes statistics, results of experiments, measurements, observations resulting from fieldwork, survey results, interview recordings and images. Only data that are generated by beneficiaries in the course of the action are concerned.

Conditions related to data sharing in Part L of General annexes to the H2020 Work programme are applicable mutatis mutandis to IMI2 JU actions. According to the text, open access to digital research data (or data sharing) means making possible for end-users via a repository and free-of-charge to access, mine, exploit, reproduce and disseminate the data concerned.

In general terms, the participants in IMI2 JU actions engage in data sharing as defined in Article 29.3.1a of IMI2 JU Model grant agreement (MGA). The text applies to two types of digital research data:
- the data needed to validate the results presented in scientific publications and associated metadata (i.e. data describing the deposited research data) and
- other data and associated metadata, as specified by the beneficiaries in their data management plan (DMP). Data management plan is a deliverable of the project which is drafted by the consortium and submitted for acceptance by IMI2 JU.

In addition to obligations Article 29.3.1a, the grant agreements signed following the IMI2 - Call 21 will also contain specific obligations on data sharing arising from Article 29.3.1c MGA for health actions targeting public health emergencies. The text requires data sharing of any type of quality controlled digital research data and associated metadata at the latest within 30 days after it has been generated.

As an exceptional measure, the beneficiaries might replace the open access obligation of Article 29.3.1c MGA by specific access rights to third parties that need the research data to address the public health emergency. Such limitation would be granted by IMI2 JU or the Commission.

Nevertheless, it should be noted that the data-sharing obligation of Article 29.3a and c MGA does not apply to specific categories of data, subject to distinct legal rules. These are, inter alia, personal data, subject to Article 39 MGA, data covered by confidentiality obligation and subject to Article 36 MGA or by obligation to protect results (e.g. IP generated in the action) , subject to Article 27 MGA.

Besides, the data generated during the project and falling under the definition of ‘results’ as defined by Article 26 MGA is comprehensively subject to IMI2 IPR rules. For results which can be expected to be commercially or industrially exploitable, the conditions of Article 27 AGA to examine and possibly seek an appropriate form of protection, such as patent, trademark, copyrights, trade-secret or confidentiality agreements, will be relevant. Understandably, the specific requirements of granting access rights to results for other consortium partners, IMI2 JU and third parties as laid out in Article 26, 31 AGA would then become applicable.

As a conclusion, the data-sharing obligation under IMI2 - Call 21 will apply according to conditions set in Articles 29.3.1a and 29.3.1c MGA and is relevant to data falling under the AGA definition of digital research data. Such data will be described in the Data management plan (DMP), provided preferably with the proposal or at the latest before the grant signature. DMP will indicate details on what data the project will generate, how it will be curated, exploited, made accessible for verification and re-use. DMP will be subject to IMI2 JU scrutiny and also to further modifications according to the project execution path. The data sharing does not change the obligation to protect specific data, such as personal, confidential data or those necessary to protect results, by seeking for example IPR registration. As an exception, beneficiary might request replacing the general data-sharing obligation by specific rights granted to third parties that need the research data in order to address the public health emergency. Such request must be agreed upon by IMI2 JU or the Commission and include rights to access, mine, exploit and reproduce the data free of charge.

42. The applicants are expected 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 consortium. What percentage of the proposal estimated budget should be provided by contributing partners, in form of in-kind or financial contribution?

As you might know, the public-private partnership (PPP) principle attributes a significant role that EFPIA, other large industrial beneficiaries and IMI2 JU Associated Partners (AP) play in the implementation of the IMI2 JU actions.

The in-kind and financial contributions provided by EFPIA/AP beneficiaries are being matched, at IMI2 JU programme level, with the IMI2 JU funding provided to beneficiaries receiving funding.

In relation to your question, for IMI2 JU Call 21 there is no strict proportion in a consortium between the budget for participants receiving IMI2 JU funding and participants providing in-kind contribution. Nevertheless, the contributions from EFPIA/AP should be in line and proportioned to the scientific objectives and related activities described in the proposal. Additionally, the public-private partnership nature of the IMI2 JU should be taken into consideration when building the consortium and the proposal budget.

43. I was wondering about the number of winning consortia (and their average expected budgets) in order to put together a consortium. It's not clear from the call whether there will be one or several winning proposals and whether the 45m euros will be granted to one or several consortia. This is will be critical in deciding whether to partner with a few or many partners.

As for your question on how many projects will be funded and what is the average expected budget, this depends on the content, quality and requested IMI2 contribution of the submitted proposals.

As you might know, the scope of the Innovative Medicines Initiative 2 Joint Undertaking (IMI 2 JU)-Call 21 is to advance knowledge of SARS-CoV-2 and is articulated around four objectives:

- Development of antivirals as well as other types of therapeutics,
- Development of therapeutics to address the current and/or future coronavirus outbreaks,
- Development of diagnostics,
- Development of fast and reliable tools that go beyond the state of the art for detection of COVID-19

According to the IMI2 Call 21 text, the applicant consortia are expected to address at least one of the objectives of the topic. Hence, when deciding on the composition of the consortium, it is critical that the participation of each partner, and the tasks attributed to it, must be efficient and necessary for the project objectives. In particular, the requested funding must correspond to the content of the tasks foreseen in the proposal and should also correspond to the extent of topic scope covered and number of objectives addressed.

The applicant consortia in this call 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 be drafted as close as possible to the real estimated costs and include a sound justification of the requested IMI2 JU financial contribution. In fact, IMI2 JU Manual for submission indicates that 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.
As a conclusion, the proposal budget should be based on the real estimated costs of the tasks described. The global envelope of EUR 45 000 000 will be awarded following the ranking order based on proposal(s)

requested funding, as evaluated by the panel. The number of proposals eventually funded will depend from the amount of JU funding requested by the highest ranked proposal(s).

44. Can commercial service providers in diagnostics also participate?

Concerning the eligibility to participate in the submission of a proposal, we refer to Article 7 of Regulation (EU) 1290/2013 (the H2020 Rules for participation). The text states that, any legal entity, regardless of its place of establishment, may participate in an action provided that the conditions laid down in this Regulation have been met, together with any conditions laid down in the relevant work plan.

However, the participation of each consortium partner, and the tasks attributed to it, must be necessary for the project objectives. In fact, the scope of the Innovative Medicines Initiative 2 Joint Undertaking (IMI 2 JU)-Call 21 is to advance knowledge of SARS-CoV-2, knowing that the proposals must address at least of the following objectives:

- Development of antivirals as well as other types of therapeutics,
- Development of therapeutics to address the current and/or future coronavirus outbreaks,
- Development of diagnostics,
- Development of fast and reliable tools that go beyond the state of the art for detection of COVID-19.

In addition, and concerning commercial companies, Article 1 of Regulation 622/2014 establishing IMI2 Rules for participation, declares that following entities will be eligible for IMI2 funding:

- legal entities established in a Member State or an associated country, or created under Union law; and
- 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.

If eligible for funding, the reimbursement rates are 100% of the direct eligible costs incurred (i.e. no business rate) during the project implementation, increased by 25% overheads.

As a conclusion, if the commercial services providers can provide tasks aligned with the research objectives of the proposal and necessary for this Research & innovation action, then they would be welcome to participate. If fulfilling the conditions of eligibility for funding, their costs could be reimbursed at the rates indicated above.

45. In the eForms the row of Partner 1 (Coordinator) is different from the other rows:
- in the column "I" the Reimbursement rate is "0" and it is not fillable
- the overheads are not calculated and so this cost remains "0"
- the total of the costs that I enter (Personnel and Other direct costs) automatically appears in the columns reserved for EFPIA and associated partners.

In the proposal e-forms, under ‘Administrative data of participating organisations’ for your entity, you probably selected “Member of EFPIA” or “IMI2 Associated partners”.

If so, the tool considers your organisations as a contributing partner and therefore its budget fall under in kind contribution with no indirect costs.

We advise to verify the Administrative data of your organisation and modify as necessary.

It is not possible to undo the selection in those fields, it is only possible to modify them.

Therefore, in the interest of time also considering that the submission deadline is on March 31, their advice is either:

a) to select one of the first three options that will configure the same type of budget table as the one needed for UNIFI. All first three options are for beneficiaries receiving funding, thus you can include UNIFI budget as relevant. These options are selected in red below. Any correction of the applicant status will be dealt during the Grant Agreement Preparation in case the proposal is successful, OR

b) to start the submission again, i.e. preparing a new application,

Please note that option a) is the less time consuming solution.