IMI2

21st Call for proposals

Version 1.1, dated 05/03/2020, addressing a clerical error on page 12 of this document and further confirming that applicants should submit a proposal and that the page limit for proposals is 70 pages

Annex II to the Decision of the IMI2 JU Governing Board No. IMI2-GB-DEC-2020-08 adopted on 28/02/2020

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Contents

Introduction

The Innovative Medicines Initiative is a jointly funded partnership between the European Union, represented by the European Commission, and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU) has been created[1] following the principles below:

Research related to the future of medicine should be undertaken in areas where societal, public health and biomedical industry competitiveness goals are aligned and require the pooling of resources and greater collaboration between the public and private sectors, with the involvement of small and medium-sized enterprises (SMEs).

The scope of the initiative should be expanded to all areas of life science research and innovation.

The areas should be of public health interest, as identified by the World Health Organisation (WHO) report on priority medicines for Europe and the World[2].

The IMI2 JU objectives are usually implemented through Research and Innovation Actions (RIAs), and Coordination and Support Actions (CSAs) where public and private partners collaborate, joining their expertise, knowledge and resources.

The initiative should therefore seek to involve a broader range of partners, including mid-sized companies[3], from different sectors e.g. biomedical imaging, medical information technology, diagnostic and/or animal health industries. Involving the wider community in this way should help to advance the development of new approaches and technologies for the prevention, diagnosis and treatment of diseases with high impact on public health.

The IMI2 Strategic Research Agenda (SRA)[4] is the main reference for the implementation of research priorities for IMI2 JU. The scientific priorities for 2020 for IMI2 JU have been prepared based on the SRA.

Applicant consortia are invited to submit a proposal which should address at least one of the objectives of the topic. The size and composition of each consortium should be adapted so as to respond to the scientific goals and the expected key deliverables.

Applicant consortia, during all stages of the evaluation process, must consider the nature and dimension of the IMI2 JU programme as a public-private collaboration.

While preparing their proposals, applicant consortia should ensure that the needs of patients are adequately addressed and, where appropriate, patient involvement is encouraged. Applicants should ensure that gender dimensions are also considered. Synergies and complementarities with other national and international projects and initiatives should be explored in order to avoid duplication of efforts and to create collaboration at a global level to maximise European added value in health research. Where appropriate, the involvement of regulators is also strongly encouraged.

[1] Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU), OJ L 169, 7.6.2014, p. 54–76.
[2] http://www.who.int/medicines/areas/priority_medicines/en/
[3] Under IMI2 JU, mid-sized companies having an annual turnover of E
UR 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 applies mutatis mutandis. Where established in an EU Member State or an associated country, are eligible for funding.
[4] http://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/research-agenda/IMI2_SRA_March2014.pdf

Applicant consortia shall ensure that where relevant their proposals are in compliance with the General Data Protection Regulation (EU) 2016/679[5] and Clinical Trial Regulation (EU) 536/2014[6] (and/or Directive 2001/20/EC[7)] and any relevant legislation[8].

Before submitting a proposal, applicant consortia should familiarise themselves with all Call documents such as the IMI2 JU Manual for submission, evaluation and grant award[9], and the IMI2 evaluation criteria. Applicants should refer to the specific templates and evaluation procedures associated with the topic type Research and Innovation Actions (RIA).

[5] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1–88.
[6] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ L 158, 27.5.2014, p. 1-76.
[7] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (the "Clinical Trials Directive), OJ L 121, 1.5.2001, p. 34.
8 Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and the free movement of such data and implementing national laws, OJ L 281, 23.11.1995, p. 31–50.
[9] https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/IMI2_ManualForSubmission_v1.7_November2018.pdf

Development of therapeutics and diagnostics combatting coronavirus infections

Topic details

Topic code	IMI2-2020-21-01
Action type	Research and Innovation Action (RIA)
Submission and evaluation process	Single stage
IMI2 Strategic Research Agenda - Axis of Research	Adoption of innovative clinical trial paradigms
IMI2 Strategic Research Agenda - Health Priority	Other

Specific challenges to be addressed by public-private collaborative research

Coronaviruses (CoV) are a large family of enveloped positive-stranded RNA viruses that typically result in respiratory and enteric infections. CoV are zoonotic in origin, but they can evolve into a strain that can infect human beings leading to fatal illness. Typically, CoV infections were considered relatively benign to humans before the severe acute respiratory syndrome (SARS-CoV) outbreak in 2002/2003 in China, and the Middle East respiratory syndrome coronavirus (MERS-CoV) outbreak in 2012 in the Middle Eastern countries.

On 31 December 2019, the local authorities of Wuhan, Hubei province, China, reported a cluster of pneumonia cases of unknown origin. On 9 January 2020, the China Centre for Disease Control reported a novel coronavirus - now referred as SARS-CoV-2 to be the causative agent.

As of 24 February 2020, 79 360 cases of novel coronavirus infection COVID-19 (in accordance with the applied case definitions in the affected countries) have been reported, including 2 618 deaths. The disease has already spread to 31 countries outside China, with new cases continuing to emerge daily [1]. The COVID-19 outbreak has been declared by WHO as a Public Health Emergency of International Concern according to the International Health Regulation [2].

Bearing in mind that the SARS-CoV epidemic in 2003 resulted in over 8 000 cases reported (and a 10% fatality ratio), it is crucial to rapidly gain a better understanding of the newly-identified virus and the virus family that it represents, especially in relation to potential clinical and public health measures that can be put to immediate use to improve patients' health and/or contain the spread of COVID-19.

Considering the public health and humanitarian implications, 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. A collaboration of private companies, academia, international organisations, public bodies etc. has the potential to accelerate the development of therapeutics and diagnostics to tackle the current and future outbreaks. The actions resulting from this Call will contribute to the pan-European efforts responding to this Public Health Emergency and address one of the eight immediate research actions agreed at the WHO global research and innovation forum held on 11-12 February 2020 [3].

Scope

Proposals submitted under this topic are expected to advance our knowledge of SARS-CoV-2 specifically and the wider coronavirus family in general with the aim of contributing to an efficient patient management and/or public health preparedness and response to current and future outbreaks of coronavirus infection.

Considering that this is a newly-identified virus, the scope of this topic remains broad and must address at least one of the following objectives:

- **Development of antivirals as well as other types of therapeutics to address a rapid response to the current COVID-19 outbreak**
  Relevant "clinical ready"-assets include approved therapies or compounds in development, which could be repurposed for use in treating patients with the coronavirus. For example, this could include (but is not limited to), angiotensin-converting-enzyme (ACE) inhibitors, protease inhibitors or immunotherapies (for example antibodies/antibody-like molecules) that could be relevant in the context of CoV. If repurposing is proposed, this should be supported by a preliminary rationale of the compound's potential efficacy against COVID-19. Where relevant, evidence of regulatory and ethics approvals for the investigational products included in the study(ies) must be presented.

- **Development of therapeutics to address the current and/or future coronavirus outbreaks** Identification of new potential assets and approaches that could be utilised including preventive strategies and combination approaches, and that could also address potential resistance. This may also include the optimisation of promising treatments used in rapid response (e.g. reformulation).

- **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.

Preventive vaccines are specifically excluded from the scope of the Call.

For increased impact, proposals should build on promising avenues from previous or ongoing research, taking into account the recommendations from the WHO and ensuring complementarity and ideally synergy with the work carried out under the auspices of Coalition for Epidemic Preparedness Innovations (CEPI), Wellcome, Biomedical Advanced Research and Development Authority (*BARDA*), the Bill and Melinda Gates Foundation, Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) and H2020 Call SC1-PHE-CORONAVIRUS-2020.

The European Medicines Agency (EMA) has activated its plan for emerging health threats, which includes the possibility for fast-tracked Scientific Advice [4]. Proposals covering investigation of a therapeutic should engage with the EMA to ensure adequacy from a regulatory point of view.

Collaboration agreement(s)

To ensure the interactions between actions funded under this Call, the selected consortia are expected 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. Therefore, all grants awarded under this Call will be complementary grants. The respective options under Article 2, Article 31.6 and Article 41.4 of the IMI2 JU Model Grant Agreement[10] 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.

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

Expected key deliverables

Each proposal must include at least one of the following key deliverables:

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

In the context of achieving the above deliverables, i.e. development of therapeutics and diagnostics, it is recognised that studies related to the understanding of the mechanism of action will generate new knowledge on the virology, immunology and pathogenesis of the coronavirus, and that new analytical technologies and reagents may be developed.

When relevant, deliverables should include:

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

  For the clinical studies applicants should consider the Therapeutic Trial Synopsis in the WHO's Global Research and Innovation Blueprint on the novel Coronavirus COVID-19 [3].
- Diagnostics and associated enablers (e.g. production of antibodies and viral proteins); characterisation of nCoV strains and evolution; sustainability plans for data repositories, sample repositories etc.; documentation supporting regulatory submission.

Expected impact

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

On the basis of the proposed activities, applicants should describe how the outputs of the project will contribute to the following impacts and include wherever possible targets and metrics to measure them:

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

To ensure maximum impact for patients, applicants should demonstrate their operational capacity as well as their readiness and access to asset(s) to progress through clinical development and reach patients as rapidly as possible.

Although actions to be funded should be centred around SARS-CoV-2 and CoV, applicants should explain how the knowledge and new concepts arising from the action can be applied in more general terms to the preparedness strategy that could be applied to new outbreaks as a rapid response.

In addition, considering the unknown evolution of this COVID-19 outbreak, applicants should develop strategies on how to develop their proposals and continuity plans, allocate their funds and implement sustainability measures in the different scenarios that could occur: 1) rapid regression of the epidemic with no patients left for clinical trials, 2) pandemic, 3) seasonal reoccurrence as typically seen with influenza.

Applicants must maximise the IMI2 JU public-private partnership value by harnessing support from different stakeholders, including the mobilisation of resources through the inclusion of contributing partners[11], providing contributions (in kind and/or financial), to reflect the public-private character of IMI2 JU actions.

To maximise the potential for public health impact, applicants should outline in their proposals a strategy for engagement with patients, healthcare professional associations, healthcare providers, and public health bodies where relevant

Beneficiaries in grants awarded under this topic must make available their research data, at the latest within 30 days after it has been generated, through open access or, if agreed by the IMI2 JU or the European Commission, by giving access rights to those third parties that need the research data to address the public health emergency. Therefore, the relevant option (1c) of Article 29.3 of the Grant Agreement shall apply.

Potential synergies with existing consortia

Synergies and complementarities are expected with relevant national, European and non-European initiatives (including suitable biological and medical sciences research infrastructures[12]) 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, including but not restricting to, the European Commission (H2020 call SC1-PHE-CORONAVIRUS-2020), CEPI, Wellcome, BARDA, The Bill and Melinda Gates Foundation, GloPID-R, and others.

Applicants should also consider building on achievements of relevant IMI projects such as the COMBACTE projects, ZAPI, and the European Lead Factory (ELF/ESCULAB).

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.

Indicative duration of the action

Proposals should include a proposed duration for the action in relation to the activities and expected impact.

Successful applicants may request a starting date prior the entry into force of the GA, but no earlier than the date of grant proposal submission.

[11] Contributing partners: EFPIA companies or organisations associated to EFPIA, and Associated Partners to IMI2 JU contributing resources to the action may report it as their in-kind or financial contribution to the IMI2 JU. If the contributing entity is not yet an affiliate or a constituent entity of an IMI2 Member other than the Union (i.e. EFPIA), or an Associated Partner at the time of the proposal submission, and the proposal is selected for funding, such a legal entity is invited to become an affiliate or a constituent entity of an IMI2 Member, other than the Union, or an Associated Partner in accordance with the IMI2 JU Statutes prior to the signature of the relevant Grant Agreement.
[12] http://www.corbel-project.eu/about-corbel/research-infrastructures.html

Indicative budget

Applicant 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.

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.

Applicant consortium

Applicant consortia are expected to address at least one of the objectives of the topic and demonstrate the necessary expertise and access to facilities to meet the relevant key deliverables and ensure the expected impact.

The size and composition of each consortium should be adapted so as to respond to the objectives and the key deliverables of the Call while ensuring its manageability.

In accordance with the Horizon 2020 Rules for Participation, in order to be eligible, a proposal must be made by a consortium of at least three independent legal entities, each established in a different Member State or associated country.

While preparing their proposals, applicant consortia should ensure that needs of patients are adequately addressed and, where appropriate, patient involvement is encouraged.

Single stage proposal

While preparing their proposal, applicants are requested to pay due attention to all the following points.

Data management

In their proposal, applicants should give due visibility to data management including use of the data standards. A full 'data management plan' (DMP) as a distinct deliverable must be delivered within the first 6 months of the action. The DMP needs to be kept up to date with the needs of the action and as such be updated as necessary during its lifetime.[13]

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

Dissemination, exploitation and communication

In their proposal, applicants must provide a draft plan for the exploitation and dissemination of results. A full plan as a distinct deliverable must be delivered within the first 6 months of the project.[14] The proposed communication

[13] Guidance on data management is available at https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/data-management_en.htm

[14] As an additional dissemination obligation under Article 29.1 of the IMI2 JU Grant Agreement will apply

measures for promoting the action and its findings during the period of the grant should also be described and could include a possible public event to showcase the results of the action.

Applicants should be aware that beneficiaries in grants awarded in this Call for proposals are expected to apply the principles established in the Statement on Data Sharing in Public Health Emergency.

Sustainability

In their proposal, applicants must describe a sustainability plan beyond the end of the Grant Agreement

This plan may be updated during the action lifetime and could include:

- identification of results that may need sustainability solutions;
- identification of potential end-users for these results;
- a proposed sustainability roadmap.

The proposed plan should also ensure that the new concepts for rapid response developed in the projects can be applied to new outbreak situations.

Sufficient resources should be set aside for activities related to the sustainability of the project results. This may involve engaging with suitable biological and medical sciences research infrastructures (RIs).[15]

Patient and healthcare provider engagement

Applicants are encouraged to include a strategy to engage with patients, learned societies and healthcare providers as relevant to ensure the project results impact on healthcare practices.

Regulatory strategy

Applicants are expected to have a strategy for the translation of the relevant outputs into regulatory practice to promote the uptake of the results, e.g. qualification advice, qualification opinion when relevant. A plan for interactions with regulatory agencies/health technology assessment bodies /payers, with relevant milestones and sufficient resources, should therefore be proposed.

[15] http://www.corbel-project.eu/about-corbel/research-infrastructures.html

References

[1] ECDC. Novel Coronavirus (COVID-19) Situation - Worldwide. 2020. https://www.ecdc.europa.eu/en/geographical-distribution-2019-ncov-cases

[2] World Health Organisation. Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (COVID-19). 2020. https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)

[3] World Health Organisation. 2019 Novel Coronavirus: Global Research and Innovation Blueprint**.** 2020. https://www.who.int/blueprint/priority-diseases/key-action/novel-coronavirus/en/

[4] EMA to support development of vaccines and treatments for novel coronavirus https://www.ema.europa.eu/en/news/ema-support-development-vaccines-treatments-novel-coronavirus

Conditions for this Call for proposal

All proposals must conform to the conditions set out in the H2020 Rules for Participation (https://ec.europa.eu/research/participants/portal/doc/call/h2020/common/1595113-h2020-rules-participation_oj_en.pdf) and the Commission Delegated Regulation with regard to IMI2 JU http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0622&from=EN.

The following conditions shall apply to this IMI2 JU Call for Proposals:

Applicants intending to submit a proposal in response to the IMI2 Call 21 should read this topics text, the IMI2 JU Manual for submission, evaluation and grant award and other relevant documents (e.g. IMI2 JU Model Grant Agreement).

Call Identifier	**H2020-JTI-IMI2-2020-21-single-stage**
Type of actions	**Research and Innovation Action (RIA)**
Publication Date	**3 March 2020**
Submission start date	**3 March 2020**
Submission deadline	**31 March 2020**
Indicative Budget	
From EFPIA companies and IMI2 JU Associated Partners	to be defined based upon selected proposals
From the IMI2 JU	EUR 45 000 000

Call Topic

IMI2-2020-21-1 Development of therapeutics and diagnostics combatting coronaviruses infections	The indicative contribution from EFPIA companies is to be defined based upon selected proposals. The financial contribution from IMI2 JU is a maximum of EUR 45 000 000	Research and Innovation Action (RIA) Single stage submission and evaluation process. Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.

The following general conditions shall apply to the IMI2 JU Calls for Proposals. They are based on the General Annexes to the Horizon 2020 Work Programme 2018-2020[16].

LIST OF COUNTRIES AND APPLICABLE RULES FOR FUNDING

By way of derogation[17] from Article 10(1) of Regulation (EU) No 1290/2013, only the following participants shall be eligible for funding from the Innovative Medicines Initiative 2 Joint Undertaking:

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

(b) which fall within one of the following categories:

(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) secondary and higher education establishments,

(iii) non-profit organisations, including those carrying out research or technological development as one of their main objectives or those that are patient organisations;

(c) the Joint Research Centre;

(d) international European interest organisations.

Participating legal entities listed in (b) above established in a third country may receive funding from the IMI2 JU provided their participation is deemed essential for carrying out the action by the IMI2 JU or when such funding is provided for under a bilateral scientific and technological agreement or any other arrangement between the Union and the country in which the legal entity is established[18].

STANDARD ADMISSIBILITY CONDITIONS, PAGES LIMITS AND SUPPORTING DOCUMENTS

Part B of the General Annexes to the Horizon 2020 Work Programme 2018-2020 shall apply *mutatis mutandis* for the actions covered by this Call for proposals.

In addition, page limits will apply to proposals as follows:

- for a single-stage call the limit for RIA/IA full proposals is 70 pages.

STANDARD ELIGIBILITY CONDITIONS

Part C of the General Annexes to the Horizon 2020 Work Programme 2018-2020 shall *apply mutatis mutandis* for the actions covered by this Call for proposals.

[16] http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2018-2020/annexes/h2020-wp1820-annex-ga_en.pdf
[17] Pursuant to the Commission Delegated Regulation (EU) No 622/2014 of 14 February 2014 establishing a derogation from Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in 'Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020)' with regard to the Innovative Medicines Initiative 2 Joint Undertaking
[18] In accordance with Article 10(2) of the Regulation (EU) No 1290/2013 and Article 1 of Commission Delegated Regulation (EU) No 622/2014

TYPES OF ACTION: SPECIFIC PROVISIONS AND FUNDING RATES

Part D of the General Annexes to the Horizon 2020 Work Programme 2018-2020 shall apply *mutatis mutandis* for the actions covered by this Call for proposals.

TECHNOLOGY READINESS LEVELS (TRL)

Part G of the General Annexes to Horizon 2020 Work Programme 2018-2020 shall apply *mutatis mutandis* for the actions covered by this Call for proposals.

EVALUATION RULES

Part H of the General Annexes to the Horizon 2020 Work Programme 2018-2020 shall apply *mutatis mutandis* for the actions covered by this Call for proposals with the following additions:

Award criteria and scores:

Experts will evaluate the proposals on the basis of criteria of 'Excellence', 'Impact' and 'Quality and efficiency of the implementation' according to the submission stage and type of action, as follows:

Type of action	Excellence *The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the Call for proposals and referred to in the IMI2 JU annual work plan:*	Impact *The following aspects will be taken into account:*	Quality and efficiency of the implementation *The following aspects will be taken into account:*
RIA **Single stage evaluation**	▪ Level to which all the objectives of the Call topic text are addressed; ▪ Soundness of the concept and credibility of the proposed methodology; ▪ Extent that the proposed work is beyond the state of the art and demonstrates innovation potential; ▪ Appropriate consideration of interdisciplinary approaches and use of stakeholder knowledge.	▪ Demonstration of how the outputs of the project will contribute to each of the expected impacts mentioned in the relevant Call topic text; ▪ Demonstration of how the project plans to leverage the public-private partnership model to achieve greater impact on innovation within R&D, regulatory, clinical and healthcare practices, as relevant; ▪ Impacts on competitiveness and growth of companies including SMEs; ▪ Quality and effectiveness of the proposed measures to: ▪ Disseminate, exploit and sustain the project results; ▪ Manage research data; ▪ Communicate the project activities to relevant target audiences.	▪ Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables; ▪ Appropriateness of the management structures and procedures, including management of risk and innovation; ▪ Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role; ▪ Complementarity of the participants and extent to which the consortium as whole brings together the necessary expertise; ▪ Clearly defined contribution and effective integration of the industrial partners to the project.

These evaluation criteria include scores and thresholds. Evaluation scores will be awarded for the criteria, and not for the different aspects listed in the above table. For all evaluated proposals, each criterion will be scored out of 5. Half marks may be given.

For the evaluation of proposals under a single-stage submission procedure:

- the threshold for individual criteria will be 4;
- the overall threshold, applying to the sum of the three individual scores, will be 12.

Following each evaluation stage, applicants will receive an ESR (Evaluation Summary Report) regarding the respective evaluated proposal.

The full evaluation procedure is described in the IMI2 JU Manual for submission, evaluation and grant award in line with the Horizon 2020 Rules for Participation.[19]

Under the single-stage evaluation process, evaluated proposals will be ranked in one single list. The best-ranked proposals, in the framework of the available budget, will be invited to prepare a Grant Agreement.

Under the IMI2 JU Call 21, IMI2 JU will not organise hearings.

The IMI2 JU evaluation procedure is confidential. The members of the applicant consortia shall avoid taking any actions that could jeopardise confidentiality.

INDICATIVE TIMETABLE FOR EVALUATION AND GRANT AGREEMENT

	Information on the outcome of the evaluation (single stage, or first stage of a two-stages)	Information on the outcome of the evaluation (second stage of a two stages)	Indicative date for the signing of grant agreement
Single-stage	Maximum 5 months from the submission deadline at the single stage.	N/A	Maximum 8 months from the submission deadline.

BUDGET FLEXIBILITY

Part I of the General Annexes to the Horizon 2020 Work Programme 2018-2020 shall apply mutatis mutandis for the actions covered by this Call for proposals.

ACTIONS INVOLVING FINANCIAL SUPPORT TO THIRD PARTIES

Part K of the General Annexes to the Horizon 2020 Work Programme 2018-2020 shall apply mutatis mutandis for the actions selected under topics covered by this Call for proposals.

CONDITIONS RELATED TO OPEN ACCESS TO RESEARCH DATA

Part L of the General Annexes to the Horizon 2020 Work Programme 2018-2020 shall apply mutatis mutandis for the actions covered by this Call for proposals.

However, should a project 'opt-out' of these provisions, a Data Management Plan must still be prepared. A template for the Data Management Plan is available on the IMI2 JU website.

IMI2 JU Call 21 - Public Health Emergency- Availability of research data

Beneficiaries in grants awarded under IMI2 JU Call 21 must make available their research data, at the latest within 30 days after it has been generated, through open access or, if agreed by the IMI2 JU or the European Commission, by giving access rights to those third parties that need the research data to address the Public Health

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

Emergency. Therefore, the relevant option of Article 29.3 (option 1c) of the IMI2 JU Model Grant Agreement[20] will apply. It is expected that quality-controlled data are shared in accordance with the FAIR principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose.

SUBMISSION TOOL

Proposals in response to a topic of the IMI2 JU Call for proposals must be submitted online, before the call deadline, by the coordinator via the Submission Service section of the relevant topic page available under Funding & tender opportunities - Single Electronic Data Interchange Area (SEDIA).

No other means of submission will be accepted.

OTHERS

For proposals including clinical trials/studies/investigations, a specific template to help applicants to provide essential information on clinical studies in a standardised format is available under: https://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/h2020_tmpl-clinical-studies_2018-2020_en.pdf.

In a single stage evaluation procedure involving clinical studies, the use of this template is mandatory in order to provide experts with the necessary information to evaluate the proposals. The template may be submitted as a separate document.

Ethical issues should be duly addressed in each submitted proposal to ensure that the proposed activities comply with ethical principles and relevant national, Union and international legislation. Any proposal that contravenes ethical principles or which does not fulfil the conditions set out in the H2020 Rules for Participation, or in the IMI2 JU Call for proposals shall not be selected. [21]

In order to ensure excellence in data and knowledge management consortia will be requested to disseminate scientific publications on the basis of open access[22] (see 'Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020').

To ensure actions are implemented properly, at the time of the signature of the grant agreement, each selected consortia must have agreed upon a consortium agreement, i.e. the internal arrangements regarding their operation and co-ordination.

Single-stage proposals must contain a draft plan for the exploitation and dissemination of the results.

Applicants intending to submit a proposal in response to the IMI2 JU Calls should also read the topic text, the IMI2 JU Manual for submission, evaluation and grant award, and other relevant documents[23] (e.g. IMI2 JU model Grant Agreement).

[20] https://ec.europa.eu/research/participants/data/ref/h2020/other/mga/jtis/h2020-mga-imi_en.pdf
[21] Article 19 of Horizon 2020 Framework Programme and Articles 13 and 14 of the Horizon 2020 Rules for Participation.
[22] Article 43.2 of Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006
[23] http://www.imi.europa.eu/apply-funding/call-documents/imi2-call-documents

List of Acronyms

Acronym	Meaning
CoV	Coronaviruses
COVID-19	Corona Virus Disease 2019
CSA	Research and Innovation Action
DMP	Data Management Plan
ECDC	European Centre for Disease Prevention and Control
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EMBL	European Molecular Biology Laboratory
IMI2 JU	Innovative Medicines Initiative 2 Joint Undertaking
MERS-CoV	Middle East respiratory syndrome coronavirus
REA	Research and Innovation Action
SARS-CoV	Severe acute respiratory syndrome –associated coronavirus disease
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SMEs	Small and medium-sized enterprises
SRA	Strategic Researvh Agenda
WHO	World Health Organisation
WP	Work Package