IMI2
22nd Call for proposals

Annex III to the 3rd Amended IMI2 JU Annual Work Plan and Budget for 2020 approved by the IMI2 JU Governing Board on 19 June 2020 per Decision n° IMI2-GB-DEC-2020-20

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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 fulfilling the specific eligibility criteria (see Conditions for this Call) are invited to submit a research and innovation action proposal to the topic of this Call and address all its aspects. The size and composition of each consortium should be adapted so 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. Involvement of patients, where appropriate, 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 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 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/calldocuments/imi2/IMI2_ManualForSubmission_v1.7_November2018.pdf

Restricted Call to maximise impact of IMI2 JU objectives and scientific priorities

Topic details

Topic code	IMI2-2020-22-01
Action type	Research and Innovation Action (RIA)
Submission and evaluation process	single stage
IMI2 Strategic Research Agenda - Axis of Research	Not applicable
IMI2 Strategic Research Agenda - Health Priority	Not applicable

Specific challenges to be addressed by public-private collaborative research

Major challenges in life sciences, in particular within the medicines development process, are the scale of the investment required, the stepwise approach, very long development timelines and the successful involvement of relevant stakeholders. A platform to facilitate close collaboration is necessary to bring together the critical mass of expertise, knowledge and resources to address these challenges.

The Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU) provides the unique framework required to drive major and fundamental new innovations by enabling unique collaborative partnerships among public and private stakeholders. Such partnerships have the potential to deliver well beyond the initially expected outputs. The efficient harnessing of such unique outcomes would be extremely valuable for the achievement of the IMI2 JU objectives, as well for the benefit of citizens and public health.

Certain IMI2 JU topics, launched under IMI2 JU Calls for proposals that are now closed, anticipated in their corresponding Annual Work Plans the need for a stepwise approach. Thus, these Annual Work Plans informed potential applicants that IMI2 JU could at a later stage publish a subsequent, restricted Call for proposals, addressing the consortia selected under initial topics.

Scope, key deliverables and applicant consortium

The scope of the restricted Call will be to support further research activities in those exceptional cases where it is necessary to enable successful consortia to build on the achievements of their initial action and move onto the next step of the challenge.

Proposals will be evaluated by experts on the basis of the award criteria ‘excellence’, ‘impact’ and ‘quality and efficiency of the implementation’, in line with Article 15 of the Horizon 2020 Rules for Participation (Regulation No 1290/2013). Within these criteria, the experts will focus on the points listed below and the proposals should therefore address them in detail:

- The scientific relevance for successfully addressing the IMI2 JU objectives;
- How the proposed activities relate to an area with a high-unmet need from the public health perspective and having industrial challenges (where relevant). This should also include a landscaping exercise to demonstrate that no similar initiative of the same extent is already ongoing at national, European or global level;
- The need for the proposed activities to (in a timely fashion) seamlessly build on and add value to the already remarkable results achieved in the initial action, as demonstrated and documented by the applicant consortium;
- The scope of proposed activities must fall beyond the scope of the initial action (e.g. initial objectives and its financial and temporal framework). In the event that the new action and the initial one will be running in

parallel, measures should be proposed to ensure the achievement of the respective objectives and to ensure that there is no double funding between the initial action and the new action;

- The specific circumstances justifying that only the initial consortium can carry out the follow-up activities successfully. For instance, the initial consortium represents a unique and effective partnership with the expertise, equipment, methodologies, or access to unique resources and IP rights, that are not available from another consortium; if, to cover the expertise for the newly proposed activities, some modifications of the initial partnership is needed, this would have to be justified;
- How the proposed activities build on and benefit from the strong foundations as public-private partnership established in the initial action, e.g. governance, workflows, procedures.

The applicants will also need to justify why the proposed research activities can only be carried out in public private collaboration, including substantial contributions in the project activities of i.e. EFPIA constituents and affiliated entities and, where relevant, by IMI2 JU Associated Partners[10].

Applicants should define key specific deliverables that address the challenges identified by their proposal and enable the achievement of its objectives. They should also define deliverables that would be sustained beyond the duration of the funded action, and how this would be achieved along with any key results that would be expected to be made openly accessible.

Additional condition for participation[11]

This Call is:

- Restricted to the initial consortia of actions funded under topics published in the IMI2 JU Annual Work Plans of 2014, 2015 and 2016 since only these actions are sufficiently advanced in their implementation to be considered for follow-up activities, and;
- Limited to those actions derived from topics where the corresponding work plan already informed potential applicants about the possibility of a later restricted Call (see list of eligible actions under the Call conditions).

If the action selected under this Call starts before the end date of the initial Grant Agreement, the applicants must demonstrate in their proposal how proper collaboration between the two actions will be ensured.

Expected impact

Applicants should describe the significant impacts of their proposed activities, taking into consideration the points below. Applicants should include baseline, targets and, where relevant, metrics for measuring them:

- Improve the current drug development process by providing support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health product;
- Benefit public health and improve the health and well-being of European citizens;
- Contribute to the EU's industrial leadership, including in relation to small and medium-sized enterprises (SMEs);
- Have an impact on regulatory and/or health technology assessment, and healthcare practices, where relevant;

[10] 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.

[11] Article 9(5) 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.

- Further maximise the value of the IMI2 JU public-private partnership by harnessing support from different stakeholders, including the substantial mobilisation of funds through contributing partners (i.e. EFPIA constituents and affiliated entities and, where relevant, by IMI2 JU Associated Partners)[12], not necessarily involved in the initial project. Reflecting the public-private character of IMI2 JU actions, applicants should demonstrate that the mobilised contributions are in addition to those already committed by any contributing partners in the initial project(s).

Indicative duration of the action

The indicative duration of the action is 24 months.

However, the consortium may propose a different duration if properly justified.

Indicative budget

Applicant consortia will be competing for a maximum total financial contribution from IMI2 JU of EUR 11 427 098.

Within this budgetary envelope, each proposal must include a sound justification of the budget requested, taking into account the proposed in-kind contributions from contributing partners, i.e. EFPIA constituents or affiliated entities and/or, when relevant, IMI2 JU Associated Partners.

Proposals above the threshold will be invited in order of ranking to prepare a Grant Agreement within the limits of the available overall budget.

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].

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 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.

[12] 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.
[13] Guidance on data management is available at http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/openaccess-data-management/data-management_en.htm
[14] As an additional dissemination obligation under Article 29.1 of the IMI2 JU Grant Agreement will apply.

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.

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.

Synergies

Applicants should briefly present an environment scan of relevant existing initiatives to ensure synergies and complementarities, and avoid unnecessary overlap and duplication of efforts and include a plan on how they propose to synergise with these initiatives.

Regulatory strategy

Applicants are expected to have a strategy for the translation of the relevant outputs into the 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.

Note on the template for preparing your proposal

When using the IMI2 JU single-stage proposal template, applicants should ensure that in addition to all the information to be provided as standard in the relevant sections of the template, they also address the following points specific to this restricted Call for proposals:

Under the section **Excellence**:

Section 1.1 Objectives

- Indicate the initial action (acronym - Grant Agreement number) and the related Call topic published in the IMI2 JU Annual Work Plan of 2014, 2015 or 2016 to which their proposal relates.
- Explain how the proposal addresses the specific challenge and scope of the restricted Call for proposals (i.e. the topic text) and meet all key objectives as set out in the topic text.

Under this point, applicants should address the following:

- The scientific relevance for successfully addressing the IMI2 JU objectives;
- How the proposed activities relate to an area with a high unmet need in the context of public health and having industrial challenges (where relevant). This should also include a landscaping exercise to

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

demonstrate that no similar initiative of the same extent is already ongoing at national, European or global level;

- The need for the proposed activities to (in a timely fashion) seamlessly build on and add value to the already remarkable results achieved in the initial action as demonstrated by the applicants. Applicants may wish to further document in an optional annex the results on which they are building the proposed activities. The annex will need to be uploaded as a separate document. There is no specific template for the annex.
- the scope of proposed activities must fall beyond the scope of the initial action (e.g. initial objectives and its financial and temporal framework);
- the specific circumstances justifying the fact that only the initial consortium can carry out the follow-up activities successfully. For instance, the initial consortium represents a unique and effective partnership with the expertise, equipment, methodologies, or access to unique resources and IP rights, that are not available from another consortium; if some modifications of the initial partnership are needed to cover the expertise for the newly proposed activities this would have to be justified;
- how the proposed activities build on and benefit from the strong foundations as public-private partnership established in the initial action, e.g. governance, workflows, procedures.

The applicants will also need to justify why the proposed research activities can only be carried out in public private collaboration, including substantial contributions in the project activities of i.e. EFPIA constituents and affiliated entities and, where relevant, by IMI2 JU Associated Partners.

Section 1.2 Concept and methodology

Define specific, important key deliverables addressing the challenges identified by their proposal and enabling the achievement of its objectives. This should include consideration for sustainability beyond the duration of the funded action and how this would be achieved, along with any key results expected to be made openly accessible.

Under the section **Impact**:

Section 2.1 Expected impact

Demonstrate how the outputs of the project will contribute to each of the expected impacts mentioned in the topic text.

Under the section **Implementation**:

Section 3.1 Project work plan — Work packages, deliverables and milestones

Provide a brief presentation of the overall structure of the project work plan; including a sound justification for the budget requested together with the contribution from EFPIA/Associated Partners. Applicants should justify the proposed total duration of the action.

Section 3.2 Management structure, milestones and procedures

If the start of the proposed action overlaps with the duration of the initial Grant Agreement, explain how the collaboration between the two actions would be ensured. In addition, in the event that the new action and the initial one will be running in parallel, measures should be proposed to ensure the proper achievement of the respective objectives;

Section 3.3 Consortium as a whole

Provide a justification in case of modifications to the initial consortium. If new members are included, applicants should justify how they bring expertise needed for the new proposed follow-up activities.

Conditions for this Call for proposals

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-rulesparticipation_oj_en.pdf) and the Commission Delegated Regulation with regard to IMI2 JU http://eurlex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0622&from=EN.

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

- The Call is restricted to the initial consortia of actions funded under topics published in the IMI2 JU Annual Work Plans (AWPs) of 2014, 2015 and 2016, since only these actions are sufficiently advanced in their implementation to be considered for follow-up research activities.
- In addition, it is limited to those actions derived from topics where the corresponding work plan already informed potential applicants about the possibility of a later restricted Call as listed below.

AWP year	Call	Topic number	Topic title	Project acronym	Project number	Project website
2014	1	1	Translational approaches to disease modifying therapy of type 1 diabetes Mellitus (T1DM)	INNODIA	115797	https://www.innodia.eu/
2015	3	1	RADAR-CNS	RADAR-CNS	115902	https://www.radar-cns.org/
2015	3	2	Assessing risk and progression of prediabetes and type 2 diabetes to enable disease modification	RHAPSODY	115881	https://imi-rhapsody.eu/
2015	3	3	Linking clinical neuropsychiatry and quantitative neurobiology	PRISM	115916	https://prism-project.eu/en/prism-study/
2014	4	1	Enabling platform on medicines adaptive pathways to patients	ADAPT-SMART	115890	https://www.infographic.adaptsmart.eu/
2015	5	2	Diabetic Kidney Disease Biomarkers (DKD-BM)	BEAt-DKD	115974	https://www.beat-dkd.eu/
2015	5	5	Evolving models of patient engagement and access for earlier identification of Alzheimer's disease: Phased expansion study	MOPEAD	115985	https://www.mopead.eu/
2015	6	1	Development of Quantitative System Toxicology (QST) approaches to improve the understanding of the safety of new medicines	TransQST	116030	http://transqst.org/

AWP year	Call	Topic number	Topic title	Project acronym	Project number	Project website
2015	6	2	Establishing impact of RSV infection, resultant disease and public health approach to reducing the consequences	RESCEU	116019	http://resc-eu.org/
2015	6	4	Development of an outcomes-focused data platform to empower policy makers and clinicians to optimize care for patients with hematologic malignancies	HARMONY	116026	https://www.harmony-alliance.eu/
2015	7	3	Pathological neuron-glia interactions in neuropathic pain	NGN-PET	116072	http://ngn-pet.com/
2015	7	5	A comprehensive 'paediatric preclinical POC platform' to enable clinical molecule development for children with cancer	ITCC-P4	116064	https://www.itccp4.eu/
2015	7	6	Coordination and Support Actions (CSA) for the Big Data for Better Outcomes programme	DO-IT	116055	https://bd4bo.org/
2016	9	1	Addressing the clinical burden of Clostridium difficile infection (CDI): Evaluation of the burden, current practices and set-up of a European research platform	COMBACTE-CDI	777362	https://www.combacte.com/about/combacte-cdi-understanding-of-the-epidemiology-and-clinical-impact-of-clostridium-difficile-infection/
2016	9	5	Identification and validation of biomarkers for nonalcoholic steatohepatitis (NASH) and across the spectrum of non-alcoholic fatty liver disease (NAFLD)	LITMUS	777377	https://litmus-project.eu/
2016	10	1	Understanding hypoglycaemia: the underlying mechanisms and addressing clinical determinants as well as consequences for people with diabetes by combining databases from clinical trials	Hypo-RESOLVE	777460	https://hypo-resolve.eu/
2016	10	2	How Big Data could support better diagnosis and	PIONEER	777492	https://prostate-pioneer.eu/

AWP year	Call	Topic number	Topic title	Project acronym	Project number	Project website
			treatment outcomes for Prostate Cancer			
2016	10	4	Creation of a pan-European paediatric clinical trials network	c4c	777389	https://conect4children.org/
2016	10	6	Unlocking the solute carrier gene-family for effective new therapies (unlock SLCs)	ReSOLUTE	777372	https://re-solute.eu/
2016	10	7	Patient perspectives in medicines lifecycle	PARADIGM	777450	https://imi-paradigm.eu/

Applicants intending to submit a proposal in response to the IMI2 Call 22 should read this topic 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-IMI2-2020-22-single-stage**
Type of actions	**Research and Innovation Action (RIA)**
Publication Date	**23 June 2020**
Submission start date	**23 June 2020**
Submission deadline	**29 September 2020 (17:00:00 Brussels time)**

Indicative Budget

From EFPIA companies and IMI2 JU Associated Partners
to be defined based upon selected proposals

From the IMI2 JU[16] **EUR 11 427 098**

Call Topic

IMI2-2020-22-01 **Restricted Call to maximise impact of IMI2 JU objectives and scientific priorities**	The indicative contribution from EFPIA companies and IMI2 JU Associated Partners is to be defined based upon selected proposals. The financial contribution from IMI2 JU is a maximum of EUR 11 427 098.	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.

[16] In case the budget of this given line cannot be consumed (totally or partially) the corresponding budget will be allocated to the topics under the other budget lines.

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[17].

LIST OF COUNTRIES AND APPLICABLE RULES FOR FUNDING

By way of derogation[18] 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[19].

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.

Furthermore, the IMI2 JU Call 22, single-stage submission procedure, will be launched under the scientific priority 'Restricted Call to maximise the impact of IMI2 JU objectives and scientific priorities'. This Call 22 intends to support further activities in those exceptional cases where it is necessary to enable successful consortia to build upon the achievements of their initial action in order to take full advantage of the impacts of the initial action results. In the context of the IMI2 JU Call 22, the following additional condition[20] applies:

- the IMI2 JU Call 22 is restricted to the original consortia of actions funded under topics published in the IMI2 JU Annual Work Plan of 2014, 2015 and 2016, since only these actions are sufficiently advanced in their implementation to be considered for follow-up activities, and;

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

[18] 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

[19] In accordance with Article 10(2) of the Regulation (EU) No 1290/2013 and Article 1 of Commission Delegated Regulation (EU) No 622/2014

[20] Article 9(5) of the Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020".

- the IMI2 JU Call 22 is limited to those topics which already pre-informed potential applicants about the possibility for a later restricted Call.

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 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** **IMI2 JU Call 22**	▪ 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.

The scheme above is applicable to a proposal in a single-stage submission procedure.

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.

Under IMI2 JU Call 22, 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.[21]

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.

As part of the panel deliberations, IMI2 JU may organise hearings with the applicants to:

- clarify the proposals and help the panel establish their final assessment and scores, or
- improve the experts' understanding of the proposal.

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.

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

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.[22]

All submitted proposals at single stage should be 'ethics ready'. The ethics self-assessment performed by applicants in their proposal must identify and deal correctly with any ethics issues that may arise from the research activities. Once submitted, all proposals recommended for funding will undergo an ethics review (screening) and in addition, a number of projects could be assessed for ethics compliance (ethics checks), if recommended by ethics experts.

In order to ensure excellence in data and knowledge management consortia will be requested to disseminate scientific publications on the basis of open access[23] (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[24] (e.g. IMI2 JU model Grant Agreement).

[22] Article 19 of Horizon 2020 Framework Programme and Articles 13 and 14 of the Horizon 2020 Rules for Participation.
[23] 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
[24] http://www.imi.europa.eu/apply-funding/call-documents/imi2-call-documents

LIST OF ACCRONYMS

Acronym	Meaning
AWPs	Annual Work Plans
CSA	Coordination and Support Actions
DKD-BM	Diabetic Kidney Disease Biomarkers
DMP	Data management plan
EFPIA	European Federation of Pharmaceutical Industries and Associations
IMI2 JU	Innovative Medicines Initiative 2 Joint Undertaking
IP	Intellectual properties
POC	Proof of concept
QST	Quantitative System Toxicology
RIA	Research and Innovation Action
RIs	Research infrastructures
RSV	Respiratory Syncytial virus
SMEs	Small And Medium-Sized Enterprises
SRA	Strategic Research Agenda
WHO	World Health Organisation
T1DM	Type 1 diabetes Mellitus
WP	Work package