

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

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

Topic details

| | |
|-----------------------------------|--------------------------------------|
| Action type | Research and Innovation Action (RIA) |
| Submission and evaluation process | single stage |

Specific challenges to be addressed by public-private collaborative research

A major challenge in life sciences, in particular within the medicines development process, is the scale of the investment required, the stepwise approach, very long development timelines and the successful involvement of relevant stakeholders. They are, through close collaboration, in a position to bring the critical mass of expertise, knowledge and resources to address the vast challenges ahead.

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, move onto the next step of the challenge, and maximise the impacts of the initial action results.

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 the 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 very high relevance for successfully addressing the IMI2 JU objectives and scientific priorities;
- how the proposed activities relate to an area with a high unmet need in the context of public health and industrial challenges as relevant. This should also include a landscaping exercise to demonstrate that no similar effort 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 by the applicant consortium in the initial action, which may include intellectual properties (IP) and ethical constraints as relevant;
- 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 (with some justified modifications of the partners list, if any, to cover the expertise needed for the newly proposed

activities) 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;

- how the proposed activities build on and benefit from the strong foundations established in the initial action, e.g. governance, workflows, procedures;
- the applicants will also need to justify how the proposed activities are needed to further maximise the public-private partnership value of IMI2 JU as demonstrated both by: 1) the success of the initial public private partnership; and 2) a substantial amount of in-kind and financial contributions brought to the action by contributing partners, i.e EFPIA constituents and affiliated entities and, when relevant, by IMI2 JU Associated Partners¹.

Accordingly, applicants should define key specific deliverables addressing the challenges identified by their proposal and enabling 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 participation²

This Call is:

- restricted to the initial consortia of actions funded under topics published in the IMI2 JU Annual Work Plans of 2014 and of 2015, 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 how their proposal will uniquely contribute to the following impacts and include baseline, targets and metrics to measure impact.

Funded actions are expected to significantly:

- enhance the impacts already delivered by the consortium in the initial action;
- improve the drug development process;
- have public health benefits and improve European citizens' health and well-being;
- contribute to the EU's industrial leadership including small and medium-sized enterprises (SMEs);
- have an impact on regulatory, health technology assessment, and healthcare practices, if relevant;
- further maximise the IMI2 JU public-private partnership value by harnessing support from different stakeholders, including the mobilisation of funds through the inclusion of contributing partners – not necessarily involved in the initial project – to reflect the public-private character of IMI2 JU actions. These mobilised contributions must be in addition to those already committed by any contributing partners when the initial project(s) began.

¹ 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.

² 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.

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 the maximum total financial contribution from IMI2 JU of EUR 20 000 000.

Within this budgetary envelope, each proposal must include a sound justification of the budget requested, taking into account the proposed in-kind contributions from contributing partners, i.e. EFPIA constituents or affiliated entities and/or, when relevant, IMI2 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.³

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.⁴ 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.

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).⁵

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.

³ Guidance on data management is available at http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/data-management_en.htm

⁴ As an additional dissemination obligation under Article 29.1 of the IMI2 JU Grant Agreement will apply

⁵ <http://www.corbel-project.eu/about-corbel/research-infrastructures.html>

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, they also address the following points specific to this restricted Call for proposals:

Under the section **Excellence**:

Section 1.1 Objectives

- Explain how the proposal addresses the specific challenge and scope of the topic text of the restricted Call for proposals to maximise the impact of IMI2 JU objectives and scientific priorities, as set out in the relevant IMI2 Annual Work Plan;
- Indicate the initial action (acronym - Grant Agreement number) and the related Call topic published in the IMI2 JU Annual Work Plan of 2014 or of 2015 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.

In particular, applicants should address the following points:

- the very high relevance for addressing successfully the IMI2 JU objectives and scientific priorities;
- how the proposed follow up activities relate to an area with a high unmet need in the context of public health and industrial challenges as relevant. This should also include demonstration that no similar effort of the same extent is already ongoing at national, European or global level;
- the need for the proposed follow up activities to seamlessly build on and add value to the already remarkable results achieved by the applicant consortium in the initial action in a timely fashion; this may include intellectual properties (IP) and ethical constraints as relevant;
- the scope of proposed follow up activities must fall beyond the scope of the initial action (e.g. initial objectives and financial and temporal framework);
- the specific circumstances, justifying the fact that only the initial consortium (with some justified modifications to the list of partners, if any, to cover the expertise needed for the new proposed activities) can carry out follow up activities successfully. For instance, the initial consortium represents a unique and effective partnership as expertise, equipment or methodologies, or access to unique resources and IP rights are not available from another consortium;
- how the proposed follow up activities build upon and benefit from the strong foundations established in the initial action, e.g. governance, workflows, procedures, success in completing all planned relevant deliverables.

In addition, applicants should justify that the proposed follow up activities are needed to further maximise the public-private partnership value of IMI2 JU as demonstrated by both: 1) the success of the initial public private partnership; and 2) by a substantial amount of in-kind and financial contributions brought to this new action by contributing partners, i.e. EFPIA constituents and affiliated entities and, when 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 relevant Call topic text; in particular how it will enhance the impacts already delivered by the consortium in the initial action.

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.

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-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 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 and of 2015, 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/ |

| AWP year | Call | Topic number | Topic title | Project acronym | Project number | Project website |
|----------|------|--------------|--|-----------------|----------------|---|
| 2015 | 3 | 3 | Linking clinical neuropsychiatry and quantitative neurobiology | PRISM | 115916 | https://prism-project.eu/en/prism-study/ |
| 2015 | 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/ |
| 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 | http://bd4bo.eu/index.php/portfolio/do-it/ |