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

<table>
<thead>
<tr>
<th>Action type</th>
<th>Research and Innovation Action (RIA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submission and evaluation process</td>
<td>single stages</td>
</tr>
</tbody>
</table>

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 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 benefits of the citizens and the public health.

Certain IMI2 JU topics, launched under now closed IMI2 JU Calls for proposals, anticipated in their corresponding Work Plans the need for the stepwise approach. Thus, these Work Plans included the information for potential applicants that the 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 activities in those exceptional cases where it is necessary to enable successful consortia to build upon the achievements of their initial action, seamlessly 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 those criteria, the experts will focus on the points listed below and thus the proposals should address them in detail:
the very high relevance for addressing successfully 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 timely and 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 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 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 upon and benefit from the strong foundations established in the initial action, e.g. as governance, workflows, procedures;
the applicants will also need to justify that proposed activities are needed to further maximise the public-private partnership value of IMI2 JU as demonstrated both 1) by the success of the initial public private partnership and 2) by a substantial amount of in-kind and financial contributions brought to the action by EFPIA constituent and affiliated entities and when relevant by IMI2 JU Associated Partners.

Accordingly, applicants should define specific, important 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 participation\(^1\)

This Call is:

- restricted to the initial consortia of actions funded under topics published in the IMI2 JU Annual Work Plan of 2014 and of 2015, since only these actions are sufficiently advanced in their implementation to be considered for further activities, and;
- limited to those topics where the corresponding Work Plan already pre-informed potential applicants about the possibility of a later restricted Call.

In case 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 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.

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.

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.²

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.³ 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.


³ As an additional dissemination obligation under Article 29.1 of the IMI2 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
- proposed sustainability roadmap

Sufficient resources should be foreseen for activities related to the sustainability of the project results. This may involve engaging with suitable biological and medical sciences Research Infrastructures (RIs).

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

A specific template has to be used by applicants to submit the proposal to this restricted Call. This proposal template is available in the submission tool.

Please read carefully the instructions and ensure all information is included in the relevant sections.

* http://www.corbel-project.eu/about-corbel/research-infrastructures.html