

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
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;
- 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 Partners¹.

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 participation²

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;

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.

- 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)³, 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.

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 lifetime⁴.

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 project⁵. 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).⁶

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 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.

⁴ 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

⁵ As an additional dissemination obligation under Article 29.1 of the IMI2 JU Grant Agreement will apply.

⁶ <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 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 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 is 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

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	RHAPSODY	115881	https://imi-rhapsody.eu/

AWP year	Call	Topic number	Topic title	Project acronym	Project number	Project website
			diabetes to enable disease modification			
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.mothead.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	https://bd4bo.org/

AWP year	Call	Topic number	Topic title	Project acronym	Project number	Project website
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 treatment outcomes for Prostate Cancer	PIONEER	777492	https://prostate-pioneer.eu/
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/