Information Guide

For

IMI2 Associated Partners

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History of changes

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1.3	21 March 2017	First version	
2.0	23 April 2018	Update of IMI and EFPIA web links	Entire document
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Foreword

The Innovative Medicines Initiative (IMI)[1] is working to improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need.

Within this context, the scope of IMI2 covers all areas of life science research and innovation of public health interest. Research related to the future of medicine should:

- be undertaken in areas where combination of societal, public health and biomedical industry competitiveness goals requires the pooling of resources between the public and private sectors;
- foster collaboration between the key players involved in healthcare research, including universities, the pharmaceutical and other industries, small and medium-sized enterprises (SMEs), patient organisations, and medicines regulators.

IMI2 should consequently seek to involve a broader range of partners from different sectors, such as biomedical imaging, medical information technology, diagnostic and animal health industries. A wider participation would help:

- to further develop the IMI2 objectives;
- to advance the development of new approaches and technologies for the prevention, diagnosis and treatment of diseases with high impact on public health;
- but also to maximise the pooling of resources and amplify scientific and financial investments.

Therefore the IMI2 membership is open to any legal entities interesting in supporting the IMI2 objectives in their specific areas of research by offering the possibility to become an Associated Partner.

This Guide aims to streamline and facilitate the discussions on Associated Partners (or 'Associated Partner status') with interested entities.

It provides comprehensive and practical information on:

- The rationale for establishing and developing close and long-term cooperation with other stakeholders at a more horizontal level;
- An overview of the IMI2 framework IMI2: mission, objectives, legal status, Members and Associated Partners of IMI2, funding model, activities supported by IMI2, summary of IMI2 evaluation and selection process, intellectual property provisions.
- Routes for participation in IMI2 activities.
- How to join IMI2 as an Associated Partner: Legal framework, Scope of the association, Application process including template application letters, Contributions; Contractual obligations, Role within the IMI2 governance structure.

For any questions, contact the IMI Programme Office.

[1] IMI was launched in 2008 (IMI1) and is currently in its second phase (IMI2 from 2014)

The IMI2 mission and objectives

The goal of the Innovative Medicines Initiative 2 (IMI2) programme is to support the development of better and safer medicines and treatments for patients.

In particular, IMI2 aims to:

- 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 products;
- develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators;
- where possible, reduce the time to reach clinical proof of concept in medicine development, such as for cancer, immunological, respiratory, neurological and neurodegenerative diseases;
- increase the success rate in clinical trials of priority medicines identified by the World Health Organisation;
- develop new therapies for diseases for which there is a high unmet need: such as Alzheimer's disease and limited market incentives: such as antimicrobial resistance;
- reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks.

Built on the successes and lessons learnt under IMI's first phase, it does this by bringing together companies, universities, public laboratories, innovative small and medium-sized enterprises (SMEs), patient groups and regulators in collaborative projects that will pave the way for breakthrough vaccines, medicines and treatments to tackle Europe's growing health challenges, and secure the future international competitiveness of Europe's pharmaceutical industry. Cost savings will ease the burden on public healthcare systems and greater coordination across industry sectors will result in more reliable and faster clinical trials, and better regulation.

IMI2 research and innovation efforts will also open new commercial possibilities based on new services and products. The research, industry and societal sectors involved in IMI2 programmes will benefit from the cooperation and knowledge sharing which take place in these projects.

1 LEGAL BASIS AND STRUCTURE

1.1 Legal status of IMI2

IMI2 is a partnership between the European Union (represented by the European Commission) and the European pharmaceutical industry (represented by EFPIA -the European Federation of Pharmaceutical Industries and Associations).

IMI2 derives its legal basis, and much of its structure and modalities from the EU's Horizon 2020 Research and Innovation programme. It runs between 2014 and 2020 and is directing nearly €80 billion of public funding towards critical areas of research and development whilst marshalling unparalleled levels of private investment and resources.

IMI2 is formally established by Council Regulation (EU) 557/2014 wherein the JU's form, objectives, and modalities are defined. By European Commission Delegated Regulation (EU) 622/2014 a number of provisions of the Horizon 2020 EU funding model were modified to better reflect IMI2's role in fostering research and technological development. These legal structures are further underpinned by the application of the European Union's Financial Regulations throughout the entire project cycle.

1.2 Members and Associated Partners of IMI2

The Members of IMI2 are:

- the European Union represented by the Commission, and
- the European Federation of Pharmaceutical Industries and Associations (EFPIA).

A range of organisations had already become Associated Partners. They are listed on the IMI website.

The Council Regulation establishing the Innovative Medicines Initiative 2 Joint Undertaking (EU) No 557/2014 provides the legal basis for the participation and contributions of IMI2 Members and Associated Partners.

Annex to IMI2 Regulation – Statutes: Article 2 Members and Associated Partners

1. The Members of the IMI2 Joint Undertaking shall be:

(a) the Union, represented by the Commission;

(b) upon acceptance of these Statutes by means of a letter of endorsement, the European Federation of Pharmaceutical Industries and Associations ('EFPIA').

2. Provided that it contributes to the funding referred to in Article 13 of these Statutes to achieve the objectives of the IMI2 Joint Undertaking set out in Article 2 of this Regulation and accepts these Statutes, any legal entity that directly or indirectly supports research and innovation in a Member State or in a country associated with Horizon 2020 may apply to become a Member of the IMI2 Joint Undertaking.

3. Constituent entities of a Member are the entities that constitute each Member of the IMI2 Joint Undertaking other than the Union, according to that Member's Statutes.

4. Upon acceptance of these Statutes by means of a letter of endorsement, any legal entity other than a Member or a constituent entity of a Member or any affiliated entity of either, supporting the objectives of the IMI2 Joint Undertaking in its specific area of research, in a Member State or in a country associated with Horizon 2020, may apply to become an Associated Partner of the IMI2 Joint Undertaking. The letter of endorsement shall detail the scope of the association in terms of content, activities and duration.

5. Associated Partners shall contribute in the same manner as Members other than the Union to the IMI2 Joint Undertaking's operational costs, in accordance with Article 13 of these Statutes.

The letter of endorsement shall detail the Associated Partners' contribution to IMI2 Joint Undertaking, that the Union will match, in accordance with Articles 3 and 4 of this Regulation.

IMI2 Regulation: Article 4 - Contributions of Members other than the Union and of Associated Partners

1. Associated Partners shall make, or arrange for their constituent entities or their affiliated entities to make, the contributions corresponding to the amounts they have committed when becoming a Member or an Associated Partner.

2. The contributions referred to in paragraph 1 of this Article shall consist of contributions to the IMI2 Joint Undertaking as set out in Article 13(2), point (b) of Article 13(3) and point (c) of Article 13(3) of the Statutes. In-kind contributions consisting of costs incurred in third countries other than countries associated to Horizon 2020 shall be justified and relevant to the objectives set out in Article 2 of this Regulation, and shall not exceed 30 % of the eligible costs at the level of the IMI2 programme, incurred by the Members other than the Union and by the Associated Partners.

3. The Members other than the Union and Associated Partners shall report each year by 31 January to the Governing Board of the IMI2 Joint Undertaking on the value of the contributions referred to in paragraph 2

made in each of the previous financial years. The States Representatives Group shall also be informed thereof in a timely manner.

4. For the purpose of valuing the contributions referred to in point (b) of Article 13(3) of the Statutes, the costs shall be determined in accordance with the usual cost accounting practices of the entities concerned, to the applicable accounting standards of the country where the entity is established, and to the applicable International Accounting Standards and International Financial Reporting Standards. The costs shall be certified by an independent external auditor appointed by the entity concerned. The valuation method may be verified by the IMI2 Joint Undertaking should there be any uncertainty arising from the certification. In case of remaining uncertainties, it may be audited by the IMI2 Joint Undertaking.

5. The Commission may terminate, proportionally reduce or suspend the Union financial contribution to the IMI2 Joint Undertaking or trigger the winding up procedure referred to in Article 21(2) of the Statutes if those Members and Associated Partners, their constituent entities or their affiliated entities do not contribute, contribute only partially or contribute late with regard to the contributions referred to in paragraph 2 of this Article.

Annex to IMI2 Regulation – Statutes: Article 13 - Sources of financing

[…] 3. The operational costs of the IMI2 Joint Undertaking shall be covered through the following contributions:

[…] (b) in kind contributions by the Members other than the Union and the Associated Partners, or their constituent entities or their affiliated entities, consisting of the costs incurred by them in implementing indirect actions, and in relation to advisory groups, if foreseen in the annual work plan, less the contribution of the IMI2 Joint Undertaking and any other Union financial contribution to those costs;

(c) financial contributions by the Members other than the Union and the Associated Partners, or their constituent entities or their affiliated entities, which may be made in addition to, or instead of point (b). […]

1.3 The IMI2 funding model

IMI is funded jointly by the European Union (represented by the European Commission) and the European pharmaceutical industry (represented by EFPIA, the European Federation of Pharmaceutical Industries and Associations).

For the IMI2 programme (2014-2020), the total budget is €3.276 billion.

- Up to €1.638 billion (half the budget) comes from the Health, Demographic Change and Wellbeing Societal Challenge of Horizon 2020, the EU's framework programme for research and innovation.
- At least €1.425 billion comes from the in-kind contribution of EFPIA, or its constituent entities[2] or their affiliated entities[3].
- Up to €213 million comes from in-kind contribution of other Members, Associated Partners, or from their constituent entities or their affiliated entities.

[2] Constituent entities of an EFPIA company or Associated Partner are the entities constituting them according to that Member's own statutes.

[3] Affiliated entities' means any legal entity that is under the direct control or indirect control of a beneficiary, or under the same direct or indirect control as the participant, or that is directly or indirectly controlling a participant. Control may take any of the forms set out in Article 8(2) of Regulation 1290/2013 laying down the rules for participation and dissemination in Horizon 2020.

The EU funding supports the participation in its projects of organisations eligible to receive IMI2 funds, like universities, research organisations, patient organisations, small and medium-sized enterprises, mid-sized companies, patient organisations, regulators.[4]

IMI2 funds only go to the selected legal entities that are eligible to receive them.

In IMI2 projects, EFPIA, Associated Partners, as well as their constituent entities or their affiliated entities, do not receive EU funding through IMI2, but contribute to the projects 'in kind', for example through their researchers' time, and by providing other resources to the projects.

2 ROUTES FOR PARTICIPATION IN IMI2 ACTIVITIES

IMI2 owes its success to the involvement in its activities of people from the pharmaceutical and other industries, universities, small and medium-sized enterprises, patient groups, regulatory authorities, and others.

Several routes exist for getting involved with IMI2 activities.

2.1 Participant in IMI2 projects[5]

Any legal entity carrying out activities relevant to the IMI2 and project's objectives may participate in IMI2 projects.

Participants may be either beneficiaries receiving funding (such as public organisation, SME's, mid-sized companies, etc. eligible to receive funding) or beneficiaries not receiving funding (such as EFPIA members and Associated Partners). They all shall adhere to the grant agreement[6] with IMI2 and sign the consortium agreement between the participants.

2.2 IMI2 Member

Any legal entity that directly or indirectly supports research and innovation in an EU Member State or in a country associated with Horizon 2020 and is willing to contribute to the IMI2 funding and accept the IMI2 Statutes may apply to become a Member of IMI2.

Members have voting rights in the IMI2 Governing Board, contribute to the administrative costs of IMI2, and co-finance IMI2 actions.

So far, the IMI2 Members are the European Union represented by the Commission, and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

2.3 IMI2 Associated Partner

Any legal entity, other than a Member or a constituent/affiliated entity of a Member, may apply to join IMI2 as an Associated Partner provided that they:

[4] Article 1 of the Commission Delegated Regulation No 622/2014 of 14 February 2014 and Article 10 of H2020 Regulation (EU) No 1290/2013

[5] Note that according to H2020, participants are referred as to beneficiaries and projects as actions.

[6] IMI2 model grant agreement http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/jtis/h2020-mga-imi_en.pdf

- support the objectives of IMI2 in its specific area of research in a member State or in a country associated with Horizon 2020;
- submit a written application for the approval of the IMI2 Governing Board that:
    - Endorses the IMI2 JU Statutes;
    - Details the scope of the association in terms of contribution (in-kind or cash), activities, and duration.

A template for this application can be found in the annexes of this document.

Like EFPIA members participating in and contributing to IMI2 projects, Associated Partners (and their constituent or affiliated entities) do not receive any funding from IMI2. The contribution is usually through in-kind contributions (such as their experts' time, access to resources / equipment). Any resources they put into a project may be equally matched by IMI2 funds, making this a good way of leveraging precious resources.

As contributors to the project, Associated Partners are involved in the definition of the said project (this might be via participation to relevant Strategic Governing Groups for example), and could participate as observers in IMI2 Governing Board meetings during discussions relating to the projects they are involved in.

2.4 EFPIA member

EFPIA members refers to corporate members of EFPIA, affiliated entities of an EFPIA corporate member, EFPIA specialised group (e.g. Vaccines Europe, EBE) members of national EFPIA associations, and EFPIA 'Partners in Research'. So-called "EFPIA Partners in research" are non-pharmaceutical companies, e.g. imaging, medical information technology, diagnostic, animal health industries, etc.

For details of the different categories of EFPIA membership, contact EFPIA.

EFPIA members, or their constituent or affiliated entities, usually all contribute to IMI2 projects mainly through in-kind contributions (which is then matched by the IMI2 funds).

They are fully represented through the EFPIA participation in the IMI2 Governing Board, and can contribute to EFPIA's broader research policies.

2.5 Member of advisory bodies of IMI2 (part of the governance structure of IMI2)

The IMI2 Scientific Committee is made up of scientific experts from diverse fields and provides high-level recommendations to the IMI2 Governing Board.

The IMI2 States Representatives Group (SRG) consists of representatives of the EU Member States and the countries associated to the EU's research programmes. It provides strategic opinions to the IMI2 Governing Board.

The Strategic Governing Groups (SGG) comprise representatives of pharmaceutical companies as well as people from the European Commission and the IMI2 Scientific Committee. They ensure the coordination of IMI2 projects in key areas and with the European Commission's wider research programmes.

2.6 Member of scientific advisory boards of IMI2 projects

IMI2 projects might benefit from the insight and advice from other organisations or individuals and these parties, working from their own roles, objectives, and mandates s, might want to take up an advisory role to contribute to specific IMI2 projects.

2.7 Third party ideas

In addition to the formal routes outlined herein, anyone is invited to submit your ideas and suggestions for IMI2 call topics / projects that will be directed to the appropriate Strategic Governance Group(s) to be discussed and further matured.

There might be an opportunity for organisations that are not IMI2 Members or Associated Partners to get invited on an ad hoc basis to relevant SGG meetings, subject to confidentiality obligations and non-conflict of interest.

3 JOINING IMI2 AS AN ASSOCIATED PARTNER

3.1 Applying as an Associated Partner

Any legal entity, other than a Member or a constituent/affiliated entity of a Member, may apply to join IMI2 as an Associated Partner provided that they:

- support the objectives of IMI2 in its specific area of research in a Member State or a country associated with Horizon 2020;
- Submit a written application for the approval of the IMI2 Governing Board that:
  - Endorses the IMI2 JU Statutes;
  - Details the scope of the association in terms of contribution (in-kind) or cash, activities, and duration.

Because of IMI's option to match additional JU funds to those contributions by APs, prospective APs should be confident in their ability to meet the obligations as laid out in their commitment letter over the lifetime of the project. In the event that an application is accepted, IMI will proceed on the basis that all commitments will be met over the lifetime of the project.

Therefore, both public and private organisations of various natures may be considered to become an Associated Partner of IMI2.

Examples of organisations that could become IMI2 Associated Partners include philanthropic organisations and charities that run their own health research programmes, as well as organisations working in sectors related to healthcare such as ICT, imaging, diagnostics, animal health, etc.

Importantly, their association must relate to an overlap of their objectives and IMI2 JU's objectives. Also, the association must clearly result in an increase in the expected impact of the action and provide for added value for the achievement of the objectives of IMI2 in addition of also for the project(s) concerned. The association must be relevant / needed for achieving the expected impact.

Legal entities wishing to become Associated Partners must apply to the IMI2 Governing Board with a letter of application stating endorsement of IMI2 Statutes, and detailing the scope of the association in terms of:

- contribution (in-kind or cash),
- activities, and
- duration.

A template letter of association can be found in the annexes to this guide.

3.2 Scope of the association

The Associated Partner's association with IMI2 shall be compatible with IMI2's strategic objectives and those programmatic goals determined by the IMI2 Strategic Research Agenda.

Associated Partners usually engage with IMI2 on a project-by-project basis. However, Associated Partners may also decide engaging on a more strategic programme basis.

There is no limitation on the number of projects that interested Partners can contribute to. Existing Associated Partners are already engaged in multiple projects across IMI2's research spectrum. A template letter of association for an additional project can be found in the annex to this guide.

Of note is also the possibility to become an Associated Partner in one specific project or scientific area and apply as beneficiary eligible to receive IMI2 funds in another specific project or scientific area.

Because IMI's unique model allows the enactment of research at very large scales, the impact of IMI2 projects can be more easily discerned. To encourage such scales, and the benefits that this produces, IMI2 has the ability to match the committed resources from Associated Partners with further funds (i.e. association at programme level). This funding synergy would enable IMI2 projects to be comprehensively resourced, thereby optimising the opportunities for cutting edge scientific research and development.

3.3 Assessment of the application by the IMI2 Governing Board[7]

Upon receipt of the letter of application, the IMI2 office will first assess the letter to ensure that it details the scope of the association in terms of amount of contribution (in-kind or cash), activities, and duration and the applying entity is committed to endorse the IMI2 Statutes. If this is confirmed, the letter is forwarded to the IMI2 Governing Board that shall decide on the application.

The IMI2 Governing Board shall assess the application taking into account the relevance, the expected impact of the proposed association and the added value of the association for the achievement of the objectives of IMI2 and also for the project(s) concerned. In case of engagement on a project basis, the IMI2 Governing Board will also assess the committed contribution in the light of both IMI2's aims and the objectives of the project(s) that the applicant is intending on contributing to.

The IMI2 Governing Board will then issue a written decision. This result will be promptly communicated to the applicant.

3.4 Role of the Associated Partners in the IMI2 governance structure

Associated Partners:

- are involved in the definition of the scientific topics to which they contribute;
- are invited by the IMI2 Governing Board to take part in deliberation of the Governing Board for those points on the agenda that concern the association of the Associated Partner, but have no voting rights;
- may be involved in the discussions of the relevant Strategic Governing Group.

[7] Article 3.2 of the Statutes annexed to the Council Regulation establishing the Innovative Medicines Initiative 2 Joint Undertaking (EU) No 557/2014

3.5 Contributions from an Associated Partner in IMI2 projects[8]

IMI has issued guidelines to provide a framework for the valuation and reporting activities of EFPIA members and Associated Partners (or their constituent or affiliated entities).

Like EFPIA members participating in IMI2 projects and contributing in-kind to the IMI2 projects, Associated Partners (and their constituent/affiliated entities) contribute to the projects mainly through in-kind contributions and do not receive any funding from IMI2.

When establishing the value of in kind and financial contributions to the IMI2 JU projects, EFPIA members and Associated Partners must comply with:

- their usual cost accounting practices of the entities concerned,
- the applicable accounting standards of the country where the entity is established and
- the applicable International Accounting Standards and International Financial Reporting Standards.

In kind contributions are the contributions by the Associated Partners, or their constituent entities or their affiliated entities, consisting of the costs incurred by them (and as such recorded in their accounting system) in implementing the project activities. These contributions are mostly in the form of:

- Personnel - the time of staff employed by an Associated Partner directly working on IMI projects. This is important because IMI's success is based on the way it brings together the expertise of people working in the relevant partner organisations with the expertise found in other organisations, like universities, SMEs, and patient groups.
- Other direct costs - consumables, equipment depreciation, samples, compounds.
- Subcontracting - e.g. for clinical trials, subcontracting to Clinical Research Organisations, subcontracting to data management companies, lab services, communication, project management support, etc.
- Financial contribution - a transfer of funds from an Associated Partner to another participants eligible to receive IMI2 funding in complement to the IMI2 support (e.g. an academic institution or a small and medium sized enterprise) within the same project/consortium. This financial contribution is used by the recipients to hire researchers during the lifetime of the IMI2 project or to buy consumables or equipment.

In-kind contributions consisting of costs incurred in third countries other than countries associated to Horizon 2020 shall be justified and relevant to the objectives of the IMI2. It shall not exceed 30% at the level of the IMI2 programme of the eligible costs incurred by the Members other than the Union and the Associated Partners.[9]

As mentioned above, resources contributed to a project may be matched by IMI2 funds, making this a good way of leveraging precious resources. IMI2 has made available a total of €213M for such matching over the duration of the initiative. Because of this, and in keeping with section 3.1 above, Associated Partners must be confident of their ability to meet the commitments as outlined in their application letter as the IMI Programme Office will commit its own funds on this basis and regard these commitments as the basis of the APs participation going forward.

[8] Article 4 of the Council Regulation establishing the Innovative Medicines Initiative 2 Joint Undertaking (EU) No 557/2014 and Article 13 of the annexed Statutes

[9] Such costs shall be deemed to be incurred in third countries (other than EU/H2020 associated countries) if the underlying activities (e.g. provision of services) are carried out in third countries (other than EU/H2020 associated countries). This rule should be applied irrespective of the place where the Associated Partners are established. The same principle applies to subcontracting.

3.6 Contractual obligations of an Associated Partner

Associated Partners (and where relevant their constituent or affiliated entities) shall:

- Adhere to the grant agreement[10] signed between IMI2 and the project coordinator. Therefore Associated Partners shall notably comply with the IMI2 financial and Intellectual Property rules. The tasks and estimated costs of the Associated Partners will be laid out in an annex to the grant agreement; and
- Sign the consortium agreement. All project partners must sign a consortium agreement that sets out participants' rights and obligations and addresses issues like governance, liability and intellectual property rights. The agreement should be adapted to the needs of each project. A template prepared by EFPIA shows what a consortium agreement might look like. Consortia may also use alternative templates if they wish.

Within the IMI2 grant agreement, like EFPIA members contributing in-kind in IMI2 projects, Associated Partners (and where relevant their constituent or affiliated entities) are considered as beneficiary not receiving IMI2 funding.

3.7 Reporting the contributions from the Associated Partners[11]

In-kind or cash contributions from Associated Partners, and where relevant their constituent or affiliated entities, (like for EFPIA members) are reported yearly outside the grant agreement (by 31 January each year).

Each Associated Partner (and where relevant their participating constituent or affiliated entities) submits one report covering their contributions to all the IMI2 JU projects they participate in. Such a contribution has to be in line with the initial estimation made in the letter of association and relevant Grant Agreement(s).

The reporting follows the usual management principles and accounting practices. The total reported costs must be certified by an independent external auditor appointed by the respective organization and submitted to the IMI office by 30 April each year.

This only covers the financial reporting obligations, while scientific reporting obligations are the same for the Associated Partner as for the entire consortium of the relevant project/s.

4 HOW IMI2 WORKS

4.1 Activities supported by IMI2

IMI2 supports the development and implementation of pre-competitive research and innovation actions and any relevant accompanying measures to improve European citizens' health and well-being:

- The research and innovation actions (RIA) primarily consist of activities aiming to establish new knowledge and/or to explore the feasibility of a new or improved technology, product, process, service or solution. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment. Such projects may contain closely connected but limited demonstration or pilot activities aiming to show technical feasibility in a near to operational environment.

[10] http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/jtis/h2020-mga-imi_en.pdf

[11] Article 4 of the Council Regulation establishing the Innovative Medicines Initiative 2 Joint Undertaking (EU) No 557/2014 and Article 13.3 (b) and (c) of the annexed Statutes

- Coordination and support actions (CSA) primarily consist of accompanying measures such as standardisation, dissemination, awareness raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure and may also include complementary activities of networking and coordination between programmes in different countries.

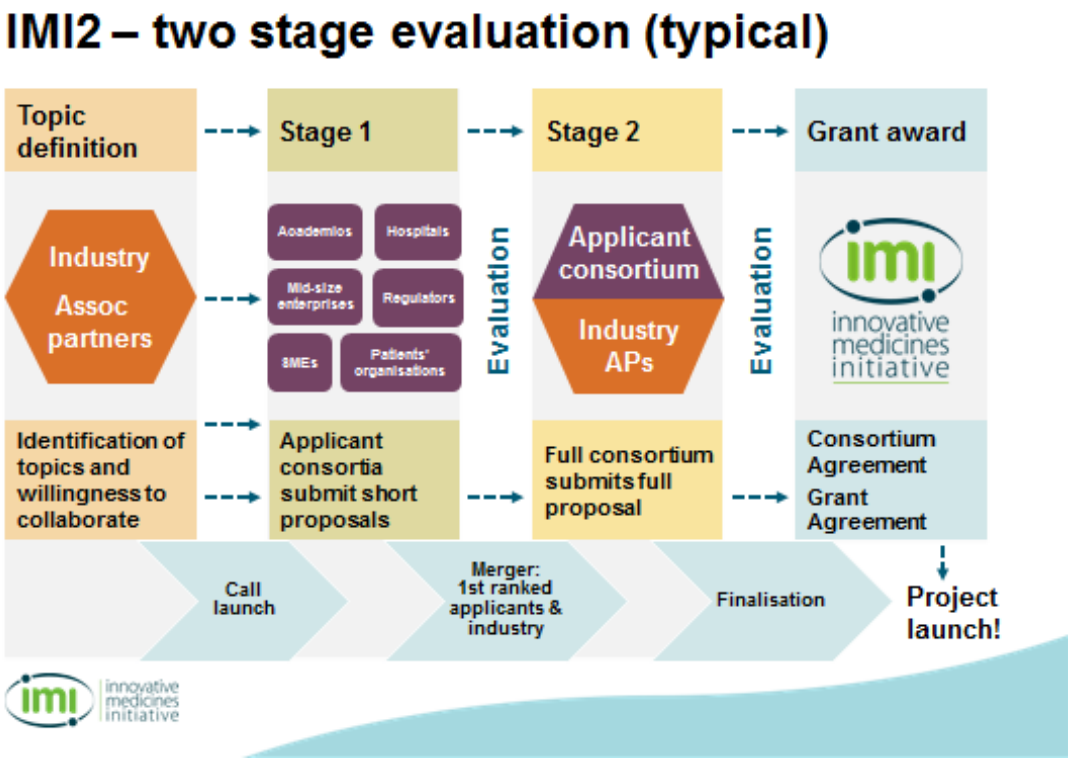
IMI2 initiates competitive calls for proposals and any other necessary procedure for funding, evaluates proposals, awards funding to projects according to the applicable rules, within the limits of available funds. The relevant IMI2 Annual Work Plan and/or the Call for Proposals specify the type of action and the applicable process.

Like any other participants in an IMI2 project, Associated Partners (and where relevant their constituent or affiliated entities) will have to comply with the IMI2 rules and procedures, submit one report covering their contributions to all the IMI2 projects they participate in, adhere to the grant agreement with IMI2 and sign a consortium agreement with the other participants.

4.2 Summary of the IMI2 evaluation and selection process[12]

Every year IMI2 launches a number of projects (research and innovation actions or coordination and support actions). Proposals are selected through open and competitive Calls for proposals, based on independent peer review.

Most IMI2 Calls for proposals follow this two-stage approach.



[12] http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/IMI2_Manual_submission_evaluation_grant_v1.3_April2016.pdf

Before the Call launch: For a given topic, a consortia of EFPIA members and/or Associated Partners agrees on the need to work together and with other stakeholders on a specific issue, and to contribute in-kind. The topic text is drafted and, following consultation with various groups (including the IMI2 Scientific Committee and the States Representatives Group), the Call text is sent to the IMI2 Governing Board for approval.

Stage 1: Once the IMI2 Governing Board has given its green light, the Call for proposals is published on the IMI website and the Horizon 2020 Participant Portal. All interested parties from academia, small- and medium-sized enterprises (SMEs), patient organisations, regulatory agencies, etc. are invited to form consortia and to submit a proposal in response to the Call. Following the submission deadline, the proposals are screened for eligibility and reviewed by independent experts. The experts rank the applications per topic, and the consortium that submitted the top-ranked application for a given topic is invited to proceed to Stage 2.

Stage 2: In Stage 2, the top-ranked applicant consortium, the participating EFPIA members and where relevant the participating Associated Partners are invited to form a full consortium and submit a full proposal. The full proposal is also reviewed by independent experts.

Proposals are evaluated considering the following elements:

- Excellence. Projects must demonstrate high quality in relation to the topics and criteria set out in the call.
- Transparency. Funding decisions must be based on clearly described rules and procedures, and applicants should receive adequate feedback on the outcome of the evaluation.
- Fairness and impartiality. All proposals submitted in response to a call are treated equally and evaluated impartially on their merits, irrespective of their origin or the identity of the applicants.
- Efficiency and speed. Evaluation, award and grant preparation should be done as quickly as possible without compromising quality or neglecting the rules.
- Ethics and security. Proposals must not contravene fundamental ethical principles or relevant security procedures.

Project launch: If the full proposal receives a positive review, the full project consortium is invited to conclude a grant agreement governing the relationship between the consortium and IMI2. All the project participants must also sign a consortium agreement dealing with issues such as project governance and intellectual property.

IMI2 also launches other types of Calls for proposals (for example through a single stage procedure). The details of the process for each Call are always described in the Call documents, and potential applicants are advised to read these carefully.

4.3 Summary of the IMI2 intellectual property rules[13]

The IMI2 Intellectual Property (IP) provisions govern the IP regime of all projects supported by IMI2 and apply equally to all partners in the projects. The guiding principle behind provisions is IMI2 objective of making a very practical contribution to improving the efficiency of drug development. The IP provisions are therefore designed to promote the creation and exploitation of knowledge generated and reward innovation, while respecting the assets and interests of all project partners.

An important aspect of IMI2 IP provisions is their flexibility, which allows them to be adapted to the needs of the individual projects and their partners. Of significance here is the neutral role played by the IMI2 Office, which offers impartial advice to all partners during negotiations on IP, and ensures that the resulting agreement is in line with the IMI2 IP provisions and does not leave some project partners at a disadvantage. The flexibility of the provisions, coupled with IMI2 neutral role in negotiations, have allowed IMI2 project partners to share resources and knowledge in unprecedented ways and deliver results that would not have been possible otherwise.

[13] Articles 1.3 (c) and 41 to 49 of H2020 Regulation (EU) No 1290/2013 Articles 2 to 7 of the Commission Delegated Regulation N°622/2014 of 14 February 2014

Another key element of successful negotiations is that IP issues are agreed before the launch of the project. Project partners can therefore be confident that knowledge developed and shared within the project will be used appropriately.

In addition, open access must be granted to all scientific publications resulting from IMI2 actions and proposals must refer to measures envisaged. Where relevant, proposals should also provide information on how the participants will manage the research data generated and/or collected during the project, such as details on what types of data the project will generate, whether and how this data will be exploited or made accessible for verification and re-use, and how it will be curated and preserved.

For any questions:

- Visit http://www.imi.europa.eu/apply-funding/general-overview/intellectual-property
- Contact IMI-IP-Helpdesk@imi.europa.eu

ANNEXES

Template letter of association for new Associated Partner

Chair of the IMI2 JU Governing Board
c/o Pierre Meulien
Executive Director
Innovative Medicines Initiative
56 Avenue de la Toison d'Or
Brussels – 1060
Belgium
[Date]

Re: [IMI2 Topic]

Dear Mr Meulien,

On behalf of [Associated Partner] of [Registered Address] and in accordance with Articles 2 and 3 of the Statutes annexed to Council Regulation (EU) No. 557/2014 of 6th May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (O.J. L169 of 7.6.2014), we wish to apply to become an Associated Partner of the IMI2 Joint Undertaking.

[Introduction to Associated Partner]

[Aims/Ethos of the Associated Partner]

In support of our application, we hereby confirm our endorsement of the Statutes of the IMI2 Joint Undertaking in their entirety.

[How Associated Partner is to contribute to IMI2/What relevance and potential added value does the proposed association present for the achievement of the objectives of the IMI2 JU/ projected duration of association with IMI]

[Details of topic]

[Manner of Association with topic]

[Manner and specifics of Contribution to topic, in kind and/or in cash total equivalent amount (please specify currency)]

We confirm that we are confident of our ability to meet the above commitments over the lifetime of the project and further confirm our understanding that the IMI2 JU will allocate resources to the above topic based on these commitments.

[Additional Details as required]

Yours faithfully

Template letter of association for existing Associated Partners that want to apply to extend the scope of their association

Chair of the IMI2 JU Governing Board
c/o Pierre Meulien
Executive Director
Innovative Medicines Initiative
56 Avenue de la Toison d'Or
Brussels – 1060
Belgium
[Date]

Re: [IMI2 Topic]

Dear Mr Meulien,

My organisation, [Organisation Name], has the status as an Associated Partner of the Innovative Medicines Initiative pursuant to Articles 2 and 3 of the Statutes annexed to Council Regulation (EU) No. 557/2014 of 6th May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (O.J. L169 of 7.6.2014).

With reference to the [above topic currently under definition by the IMI2 JU] OR [on going action in the field of ( ) - PROJECT ACRONYM], we hereby propose to expand the scope of our association by contributing to [IMI2 Topic OR given action]. With the present letter we confirm our continuing willingness to observe in their entirety the Statutes of the IMI2 Joint Undertaking.

[How Associated Partner is to contribute to IMI2 for the new topic/What relevance and potential added value does the proposed association for the new topic present for the achievement of the objectives of the IMI2 JU/ projected duration of association with IMI]
[Details of topic]

[Manner of Association with topic]

[Manner and specifics of Contribution to topic, in kind and/or in cash total equivalent amount (please specify currency)]

We confirm that we are confident of our ability to meet the above commitments over the lifetime of the project and further confirm our understanding that the IMI2 JU will allocate resources to the above topic based on these commitments.

[Additional Details as required]

Yours faithfully

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