IMI2 - 3rd and 4th Calls for proposals
Advice to potential applicants for meaningful patient engagement in IMI projects

The Innovative Medicines Initiative (IMI) is a public-private partnership between the European Union (represented by the European Commission) and the European pharmaceutical industry (represented by the pharmaceutical industry association EFPIA). IMI 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. It does this by facilitating collaboration between the key players involved in healthcare research, and it is in this spirit that IMI is keen to promote the involvement of patients in its projects and activities. This work is also in line with the broader realisation that patients have a unique and essential role to play in medical research and drug development.

This document provides practical advice for:

- **patient groups** on **how to get involved in IMI** projects;
- **other applicants** on **how best to involve patients** when preparing and implementing projects.

It also highlights specific ideas as to how **patients** can get involved in the topics launched under **IMI 2 – Calls 3 and 4**, which were launched in December 2014.

More information on IMI: **www.imi.europa.eu**

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Patient involvement in IMI projects – ideas for patient groups and other applicants

	For patient advocacy groups	For Applicant Consortia
Development of Short Proposals	Patient groups are strongly advised to **advertise** their willingness to be partners on IMI projects. You can do this by: ▪ using your **existing contacts** in academia and other patient groups ▪ registering via the **IMI Partner Search Tool** ▪ actively participating in the **IMI LinkedIn Group** ▪ actively participating in the IMI Call **webinars** ▪ highlighting your interest in specific topics via your own organisation's **website** and other communication channels. For further advice, consult with patient groups already participating in IMI projects.	Applicant consortia are encouraged to **consider whether their proposal could benefit from patient involvement**. Very often, the **Call text** itself will highlight areas where patient involvement would be beneficial to the project. However, applicants should also think about **other areas** where patients could contribute to the project. Examples of successful collaboration with patient experts already exist in previous IMI projects – these could provide **inspiration** on how to involve patients in your project. When starting to work on a proposal, explore which patient advocacy groups will be able to provide knowledge / experience / perspective on the topic. Patient groups do not necessarily need to have research experience, although they should have an affinity with the subject matter. Patient partners might be identified via **IMI Partner Search Tool** or the **IMI LinkedIn Group**. In addition, the IMI Programme Office may be able to provide assistance. Moreover, thanks to the **EUPATI** project, a number of trained, certified Patient Experts will be available to engage in projects.
Project scoping & structuring – proposal stage	There are a number of ways for patients to get involved in IMI projects – as **full project partners**; or as members of **advisory committees**; for example. Experience has shown that the best approach is to be clear from the outset on **what you can offer** and **what you want to get out of the project**, and use this as your starting point.	Preparing a project proposal is a lengthy, time-consuming process, and you should consider the **different resources** which will be needed during the project scoping phase and ensure that you have properly taken these into account from your patient group partners' perspective. These can include, but are not limited to: ▪ **Travel and accommodation costs** for patient groups to participate in partner meetings whilst drafting the proposal. This

For patient advocacy groups

As a full project partner

You may wish to be considered as a full project partner, a role which brings both rights and obligations.

Your rights:

To be heard as an equal partner in terms of project scope. As a full project partner, you are in an equal position to all other partners in terms of the knowledge and expertise you bring to the consortium. Your input could include information on:

- What research outcomes would be useful from a patient perspective?
- Is it really novel therapeutic research which is necessary? Or is it more about mitigating (lowering) the risk?
- What about benefit-risk considerations?
- How will patients be involved in project governance?

Funding. As long as you fulfil the eligibility criteria, you will receive funding from IMI.

Your obligations

All project partners, including patient groups, have **contractual obligations** to one another and to IMI. Before engaging yourself and your organisation, make sure you understand IMI's rules and your obligations as a project partner. When planning the project, you should think about the following points:

- What are the current and potential **capacities** of your group? Don't over-promise!
- How will you **communicate** internally about the project amongst your constituencies? Bear in mind that IMI only co-

For Applicant Consortia

is outside the remit of IMI funding, but a practical consideration you may wish to consider when partnering with patient organisations to develop proposals.
- Resources necessary for **building capacity** within the patient advocacy groups to ensure parity of quality of contributions across sites once the project is up and running.
- **Translation costs** for multi-site research programmes.

How best to involve patients in your project

There are a number of ways for patients to get involved in IMI projects – as **full project partners** or as members of **advisory committees** (such as ethics boards), for example. You should discuss these options thoroughly with your patient partners. Bear in mind that if you choose to involve patient groups that are not formal project partners, you will need to ensure you set aside sufficient **budget** to support their participation in meetings (i.e. travel and accommodation costs).

It might be interesting to set up a **Patient Advisory Platform / Group**, which would be relevant all the way through the project and through to the sustainability elements post-IMI funding. An example of such an initiative exists in the U-BIOPRED project. The Patient advisory group / platform can be integrally involved in setting the research questions and could include both patient groups that are full project partners as well as patient groups that are not official project partners. Depending on the project, the group's role can be to ensure inclusion of the patient perspective horizontally and within each individual work package.

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	funds the project and the other half is funded through industry contributions. ▪ What are your organisation's **strong points**? Is it dissemination? Is it an ability to mobilise patients at grass roots level? Is it patient-led research/ training? **As a member of an advisory board** Many projects involve patients through **advisory boards**, including through dedicated patient input platforms and ethics boards. If this is your chosen route, you should think about points outlined above under 'planning', as well as the following: ▪ What will your organisation's **workload** be as a result of this project, and do you have sufficient capacity to take it on? ▪ Will the project bear the **costs** involved in attending advisory board meetings (travel, accommodation, etc.)? ▪ Are the project's **governance structures** and mechanisms clear, so that recommendations from advisory boards are taken up and considered by the project leaders and implemented where appropriate?	
Project implementation – Governance	When patient groups are project partners it would be advisable to include at least one **patient representative on the Steering Group** of the project. This would help ensure that the patient perspective is embedded across all key decisions made for the project. Think about nominating steering group members who have a **background in management and / or research** themselves.	Ensure that the **patient participants are well integrated** into the project at both project coordination and research site level. Patient participants should have the opportunity to participate in **project meetings**. **Strong leadership** needs to be shown by the overall consortium coordinator. Be prepared to educate researchers who are new to working with patients in a partnership. You might want to consider conducting a **workshop** to this effect or adapt one from initiatives such as EUPATI in collaboration with your patient project partners.

	For patient advocacy groups	For Applicant Consortia
Project implementation - Research	There are many ways in which you can proactively improve the performance of an IMI project. : ▪ Get involved in the actual scoping of the **research questions**. ▪ Design of **patient reported outcomes** and establishing the project research **protocols**. ▪ Leverage your experiences in setting up of the **clinical studies/ trials**. Be sure to actively participate in the operations scoping of the project once approved. What time of day is it best for the clinical study/ trial to take place for patients? What has been your personal experience that you can convey to other potential patient participants at site level? ▪ **Patient recruitment** – you have access to networks that researchers do not at local site level. You can leverage them for the purposes of the clinical studies conducted during IMI-funded projects. ▪ You can guide the researchers from the consortium as to **benefit-risk considerations** and how to express these properly in the context of patient recruitment. ▪ **Dissemination** of project results (particularly from the patient perspective) and sharing of best practice.	There are many ways you can improve project performance by working with your patient partners. These include: ▪ input into operationalisation and monitoring of **patient recruitment** for clinical trials ▪ **co-designing** the value proposition for patients taking part in the study/ trial ▪ development of **materials** to encourage patient recruitment ▪ input into the wording of informed **consents** ▪ input into **Patient Reported Outcomes** tools ▪ input into **benefit risk** discussions ▪ community **outreach and dissemination**, especially from the patient perspective.
Sustainability planning	You may want to consider participating in the **sustainability** tasks in terms of valorisation of the research results and their eventual **implementation** in the healthcare setting.	Patient organisations are your **gateway to real life implementation**. This is an excellent opportunity to involve them in the sustainability of the project when thinking of uptake of the research

Becoming an IMI Associated Partner

Another option for patient organisations with their own research funding programmes is to become an Associated Partner of IMI. Associated Partners are typically involved in the development of new call topics from the very beginning, and as such they are able to influence the scope of project(s). Like EFPIA partners in IMI projects, Associated Partners do not receive any funding from IMI, but contribute to the projects, mainly through in kind contributions (such as their experts' time, access to resources / equipment). In addition, any resources they put into a project are matched by IMI, making this a good way of leveraging precious resources.

The Associated Partner status was introduced under the IMI 2 programme, which began in 2014. Diabetes charity JDRF has already joined IMI as an Associated Partner (as have some philanthropic organisations, such as the Helmsley Charitable Trust and the Bill and Melinda Gates Foundation).

Propose an idea for a project to EFPIA

Organisations with an idea for a project that do not wish to become Associated Partners can still suggest their idea by contacting EFPIA. Details of how to do this can be found at http://imi.efpia.eu/imi2/create-your-imi2

Organisations that choose this option should be aware that if their idea is adopted and ultimately used in an IMI Call for proposals, they will have to apply for funding like any other organisation. Their proposal would therefore be evaluated by independent experts alongside all other proposals received for the topic in question.

Ideas for patient involvement in IMI 2 – Calls 3 and 4

Topic	Scope for patient involvement?	Possible types of involvement	Possible contributions to the project
RADAR - CNS	Yes	▪ Patient representation as part of project steering group. ▪ Patient groups should not be restricted to only primary CNS therapeutic areas, but consortia should also think about related co-morbidities.	▪ Study design ▪ Scoping of research questions ▪ Ethics ▪ Benefit-risk considerations ▪ Work packages (WPs): Clinical studies, data analysis & bio signatures, healthcare pathways ▪ Patient recruitment ▪ Co-creation with patients of privacy and usability parameters
Assessing Risk and progression of pre-diabetes and Type 2 diabetes to enable disease modification	Yes	▪ Patient representation as part of project steering group. ▪ Ethics advisory group (e.g. benefit-risk, data privacy, informed consent).	▪ Innovative trial design ▪ WPs: 1, 5,6,7 ▪ Modelling of short and long term economic & public health benefit-risk assessments etc. (objective 3)
Linking clinical neuropsychiatry and quantitative neurobiology	Yes		▪ WPs: 1,2,4,5,6,7,8
The consistency approach to quality control in vaccine manufacture	Yes	▪ Patient representation as part of project steering group. ▪ Ethics advisory group (e.g. benefit-risk, data privacy, informed consent).	▪ WPs 6 & 7

Topic	Scope for patient involvement?	Possible types of involvement	Possible contributions to the project
Pertussis vaccination research	Yes	▪ Patient representation as part of project steering group. ▪ Ethics advisory group (e.g. benefit-risk, data privacy, informed consent). ▪ Internal as well as external communications.	▪ WPs 6 & 7
Knowledge repository to enable patient focussed medicine development	Yes	▪ Could be patient-led.	▪ All through the project
Enabling platform on medicines adaptive pathway to patients	Yes	▪ Patient representation as one of the key stakeholders. ▪ Patient groups should not be restricted to rare diseases, consortia should also think about common diseases where personalised medicine is of potential benefit (beyond cancer).	▪ Input into coordination of MAPPS activities in IMI 2 (e.g. adaptive clinical trials, benefit/risk considerations, HTA/pricing and reimbursement) ▪ Input into dialogue with all stakeholders as well as outreach and communication strategies to patients and general public.

More information on the Calls for proposals, including the **Call texts** and details of **how to apply**, can be found at:

IMI 2 – Call 3: http://www.imi.europa.eu/content/stage-1-14

IMI 2 – Call 4: http://www.imi.europa.eu/content/stage-1-15