

Call for expressions of interest for the Innovative Medicines Initiative 2 JU pool of patient experts

1. About the Innovative Medicines Initiative

The Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU) 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, including universities, the pharmaceutical and other industries, small and medium-sized enterprises (SMEs), patient organisations, and medicines regulators. IMI2 JU is a partnership between the European Union and the European pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

IMI2 JU is a **neutral platform** where everyone involved in drug development can engage in open collaboration on shared challenges. With a €3.3 billion budget for the period 2014-2020, IMI2 JU is the world's biggest public-private partnership (PPP) in the life sciences. Half of the IMI2 JU budget (€1.638 billion) comes from Horizon 2020, the EU's framework programme for research and innovation; This will match €1.425 billion committed to the programme by EFPIA companies, plus up to €213 million committed by other life science industries or organisations that decide to contribute to IMI2 JU as members or associated partners in individual projects.

2. The IMI2 JU call process: From topic development to project launch

IMI 2 JU works by funding projects through competitive Calls for proposals. For most IMI 2 JU projects, the process of topic definition, Call launch, and project development is as follows.

Firstly, a consortium of EFPIA companies and, in some cases, <u>IMI JU Associated Partners</u>, agree on the need to work together and with other stakeholders on a specific issue/topic. These issues must be aligned with IMI's objectives and the IMI Strategic Research Agenda.

The topic text is drafted by the EFPIA/Associated Partner consortium and, following extensive discussion with the European Commission and consultation with various groups (including the IMI Scientific Committee and the States Representatives Group), the Call text is sent to the IMI Governing Board for approval.

Once the Governing Board has given its green light, the Call for proposals is published on the <u>IMI website</u> and the <u>Funding & Tenders Portal</u>. All interested parties from academia, SMEs, mid-sized companies, patient organisations, regulatory agencies, health technology assessment bodies, etc. are invited to form consortia and submit a short proposal, via the Funding & Tenders Portal, in response to the Call.

All eligible proposals are evaluated **by independent experts**, who score them based on three top-level criteria: excellence; impact; and quality and efficiency of the implementation. The applicant consortium that submitted the top-ranked application is then invited to proceed to the next stage.

The top-ranked applicant consortium and the EFPIA/Associated Partner consortium behind the topic join together to form a full consortium and submit a full proposal. The full proposal is also evaluated by independent experts. Once the results of this evaluation have been approved by the Governing Board, the consortium can start preparations to launch the project.





Once the Grant Agreement (which governs the relationship between the project and IMI), and the Consortium Agreement (which governs the relationship between the project partners.) have been signed, the project can officially start

For more information, please visit the IMI2 JU website: www.imi.europa.eu.

3. Background

IMI2 JU has involved patients in its projects and other activities since the beginning, in developing its engagement strategy and in training patients in order for them to engage in research and drug development activities as equal partners with researchers and clinicians from the public and private sectors. IMI2 JU has listened to the needs expressed by patients and will now create an IMI patient expert pool to provide patients' perspectives within IMI2 JU activities, both at strategic and operational levels.

4. Purpose of the call

IMI is launching a call for expressions of interest to identify expert patients / patient carers (hereafter 'experts') with a strong interest in fostering patient-centred innovation, to create a patient expert pool (hereafter 'the pool') that may be invited by the IMI Programme Office, in their personal capacity, on an *ad hoc* basis to:

- contribute to shaping the IMI2 JU portfolio and improving the quality of IMI2 JU projects from the patient perspective through early & meaningful engagement;
- support and enhance patient involvement in IMI2 JU projects;
- support the identification of patient relevant results and, where appropriate, provide input on their implementation in research, regulatory and medical practice.

Specifically, the experts may be invited to provide input to the IMI Programme Office and/or IMI2 JU advisory bodies, when relevant, for example through:

- input on scientific portfolio strategy, annual scientific priorities, strategic topic development;
- participation in early consultations/workshops aiming to identify research areas for future call topics;
- participation in panels evaluating applicant proposals submitted following IMI Calls for proposals, or reviewing ongoing and closed projects;
- participation in panels/workshops that review the content of documents prepared for patients and the general public;
- participation in IMI2 JU events, e.g. Stakeholder Forum.

The aim of their participation is to bring a unique perspective which only patients / informal carers can bring, based on their real-life experience with a disease.

5. Profile of participants

Expressions of interest (EoIs) may be submitted by individuals who meet all of the following minimum criteria:

- Individuals must be either
 - a patient with a chronic and/or lifelong illness/condition, or
 - a family member/informal carer of a patient with a chronic and/or lifelong illness/condition
- Applicants must also indicate which of the following disease areas is most relevant to them. These areas are based on the IMI Strategic Research Agenda:



- neuro-psychiatric disorders and brain diseases including pain
- inflammatory and immune-mediated diseases
- cancer
- metabolic diseases including cardiovascular diseases
- infectious diseases
- rare/orphan diseases
- neurodegenerative diseases.
- **Be resident of one the following groups of countries**: ¹ a) Member States of the European Union, b) Countries associated with the EU's research framework programmes.

Residents from the broader_European Region as defined by the World Health Organisation can also submit an Eol.

Please note that we expect most of the experts selected to come from Member States of the EU and Countries associated with the EU's research framework programmes.

Possess a working knowledge of English. A working knowledge of English, at least at an upper intermediate level or B2 (based on the <u>Common European Framework of References for Languages</u>), is necessary.

In addition to the eligibility criteria, applicants have to state in the application form if they possess any of the following knowledge and/or experience related to IMI activities.

- a) knowledge and/or experience of research and innovation activities;
- b) knowledge and/or experience of the pharmaceutical sector / the medicines development cycle, ethics;
- c) knowledge and /or experience of IMI2 JU and public-private partnerships;
- d) experience of working/interacting with different stakeholders in medicines development such as health technology assessment (HTA) bodies, regulators, payers, medical practitioners, etc.

This will enable the IMI programme office to identify the experts with the most suitable profile for every task assigned.

Motivation for applying.

In the application form, all applicants will be asked to state their reasons for applying to this call and participating in IMI2 JU activities.

¹ List of eligible countries:

Albania, Andorra, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Faroe Islands, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Luxembourg, Malta, Moldova, Monaco, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russian Federation, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Tajikistan, Tunisia, Turkey, Turkmenistan, Ukraine, United Kingdom, Uzbekistan.



6. Identification procedure

All EoIs received by the deadline will first undergo a check to make sure all the minimum criteria listed in Section 5 of this call are fulfilled.

All applicants who meet the eligibility criteria will be part of this pool.

From this pool, IMI2 JU will draw individual experts for specific assignments/activities as and when needed.

7. Reimbursement/allowances

Invited experts will be entitled to reimbursement and allowances only for the activities they are requested to perform. The reimbursement and allowances will depend on the nature of the task each expert is requested to perform.

For instance, they may be invited to speak at an IMI2 JU event, in which case they will be entitled to reimbursement of travel, accommodation and subsistence expenses in line with the applicable IMI2 JU rules.

Alternatively, they may be appointed to perform specific work assignments, based upon a standard expert contract, in which case they will be entitled to a fixed fee of €450 (four hundred and fifty euro) per working day, plus the reimbursement of travel, accommodation and subsistence expenses.

Allowances may be increased for experts with disabilities. (See 7.1 below)

7.1 Experts with disabilities.

If an expert's disability requires that a person accompany him/her when travelling, then the travel expenses of that person will also be refunded upon prior request. IMI2 JU will also pay accommodation allowances and daily allowances to the accompanying person.

8. Transparency

Experts who are invited to perform tasks and roles associated with the evaluation of project proposals and/or the monitoring of projects **will be requested** to register in the European Commission Register of experts. Additionally, the names of experts who have been assigned to such tasks **will be published** on the general H2020 'Funding and Tenders Portal'.

9. Rules of engagement

Once invited to contribute to a task, patients will provide input based on the real-life experience of those affected by a disease and its current therapeutic environment. Their role will be for short-term assignments on an occasional basis. There is no guarantee of a minimum assignment of tasks/activities for each expert. Furthermore, at this stage, no indication can be provided about when and how often individual patients experts will be invited to perform activities/tasks for IMI2 JU. IMI2 JU will strive to involve experts in its activities whenever it would be of added value. Whenever a need for a patient expert arises, the IMI Programme Office will assess the profiles of the experts in the pool to identify the most suitable expert(s) for the task. All experts should enjoy their full legal capacity in order to participate in IMI2 JU activities/tasks.

Tasks/activities assigned may be carried out at the IMI2 JU premises in Brussels, at any other premises where an IMI2 JU event is taking place, or remotely, using electronic communication tools.



Experts will be required to abide by the rules of procedure of any IMI2 JU bodies / groups they participate in.

Experts will act in their personal capacity. They must respect the confidential character of the proceedings in which they participate and protect any information whose disclosure could damage the interests of IMI2 JU.

All experts who are part of the pool will be requested to sign a declaration of interests form.

Experts assigned to certain tasks may be required to sign a declaration of non-conflict of interest for that specific task.

The pool will remain active until 31 December 2021, subject to possible explicit renewal by IMI2 JU.

10. Application procedure

Interested individuals are invited to submit their EoI to IMI2 JU via this website: https://www.imi.europa.eu

Eols must be completed in English.

The online application form must be filled in, documenting how the individual fulfils the criteria listed above. All applicants will be requested to submit a declaration of honour, certifying that the information contained in their application is correct and complete.

11. Deadline for application

EoIs must be submitted by 16 July 2019, 17:00 CEST / Brussels time.

12. Data protection

All personal data provided by individuals who have submitted their EoI will be dealt with in compliance with the Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.

For any further information, please contact the IMI2 JU Programme office: Patients@imi.europa.eu