IMI2

11th Call for proposals

Annex to the Annual Work Plan approved on 11.07.2017 by Decision of the IMI2 JU Governing Board with no. IMI2-GB-DEC-2017-13

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Contents

Introduction

The Innovative Medicines Initiative is a jointly funded partnership between the European Union, represented by the European Commission, and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU) has been created[1] following the principles below:

- Research related to the future of medicine should be undertaken in areas where societal, public health and biomedical industry competitiveness goals are aligned and require the pooling of resources and greater collaboration between the public and private sectors, with the involvement of small and medium-sized enterprises (SMEs).
- The scope of the initiative should be expanded to all areas of life science research and innovation.
- The areas should be of public health interest, as identified by the World Health Organisation (WHO) report on priority medicines for Europe and the World[2].

The IMI2 JU objectives are usually implemented through Research and Innovation Actions (RIAs), and Coordination and Support Actions (CSAs) where public and private partners collaborate, joining their expertise, knowledge and resources.

The initiative should therefore seek to involve a broader range of partners, including mid-sized companies[3], from different sectors e.g. biomedical imaging, medical information technology, diagnostic and/or animal health industries. Involving the wider community in this way should help to advance the development of new approaches and technologies for the prevention, diagnosis and treatment of diseases with high impact on public health.

The IMI2 Strategic Research Agenda (SRA)[4] is the main reference for the implementation of research priorities for IMI2 JU. The scientific priorities for 2017 for IMI2 JU have been prepared based on the SRA.

Applicant consortia are invited to submit a proposal for each of the topics that are relevant for them. These proposals should address all aspects of the topic to which the applicant consortia are applying. The size and composition of each consortium should be adapted so as to respond to the scientific goals and the expected key deliverables.

Applicants consortia, during all stages of the evaluation process, must consider the nature and dimension of the IMI2 JU programme as a public-private collaboration.

While preparing their proposals, applicant consortia should ensure that the needs of patients are adequately addressed and, where appropriate, patient involvement is encouraged. Applicants should ensure that gender dimensions are also considered. Synergies and complementarities with other national and international projects and initiatives should be explored in order to avoid duplication of efforts and to create collaboration at a global level to maximise European added value in health research. Where appropriate, the involvement of regulators is also strongly encouraged.

Applicant consortia shall ensure that where relevant their proposals abide by the EU legal framework on data protection[5].

Before submitting a proposal, applicant consortia should familiarise themselves with all Call documents such as the IMI2 Manual for evaluation, submission and grant award[6], and the IMI2 evaluation criteria. Applicants should refer to the specific templates and evaluation procedures associated with the topic type: Research and Innovation Actions (RIA), Coordination and Support Action (CSA).

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[1] Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU).
[2] http://www.who.int/medicines/areas/priority_medicines/en/
[3] Under IMI2 JU, mid-sized companies having an annual turnover of EUR 500 million or less not being affiliated entities of companies with an annual turnover of more than 500 million; the definition of 'affiliated entities' within the meaning of Article 2(1)(2) of Regulation (EU) No 1290/2013 applies mutatis mutandis. Where established in an EU Member State or an associated country, are eligible for funding.
[4] http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_SRA_March2014.pdf
[5] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and the free movement of such data and implementing national laws: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31995L0046
[6] http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/IMI2_ManualForSubmission_v1.5_July2017.pdf

Exploitation of IMI project results

Topic details

Topic code	IMI2-2017-11-01
Action type	Research and Innovation Actions (RIA)
Submission & evaluation process	Single stage

Background and problem statement

A key challenge of any research funding scheme is to ensure that significant results, outputs and/or data generated during the lifetime of a project remain available and can be further exploited and valorised for maximum and long-term impact after the project finishes. Often, important scientific results reach the public domain via publication in relevant scientific journals. However, for some important results, the route to becoming available to the wider scientific community, or being fully exploited, remains a difficult path. Important results are defined as those with maximum potential long-term impacts on research and development, as well as on regulatory, clinical and healthcare practice.

Realising the full potential of project results within the timeframe available to the project is not always possible and sometimes may only be achieved through the involvement of additional expertise beyond the project.

In order for important results[7] from IMI JU projects to be integrated into general research and medical practice, significant outputs, important samples and/or data that have been generated by the large public-private investments need to be maintained and made available for future research by the whole scientific community. This might mean that new solutions paving the way to long term sustainability have to be identified.

This Call for proposals aims to provide initial/short term support so that significant results from IMI JU projects that have finished or are nearing completion become fully exploitable, available to all relevant end users, and fully sustainable.

Need and opportunity for public-private collaborative research

IMI JU projects are public-private partnerships between industrial members of EFPIA and other private and public stakeholders with a focus on tackling challenging bottlenecks in pharmaceutical research and development (R&D) and improving the delivery of healthcare to patients. Important project results have been developed based upon collaboration between public and private stakeholders. In order to ensure that these results are exploited fully and eventually benefit end users, the collaboration of public and private stakeholders and additional public and private support may be necessary to ensure that:

- the results are available to the wider scientific community and other relevant end users, and/or
- key industry and societal challenges can be tackled.

Exploitation might often be most successfully achieved via integration in healthcare systems and public research infrastructures.

To enable this exploitation, collaboration between private industries (especially EFPIA members), and different stakeholders such as academic experts, small and medium-sized enterprises (SMEs), regulatory agencies, patient organisations, public health institutes, and potentially public research infrastructures, is necessary. Convergence between innovative SMEs, larger companies, and academic institutions will ensure

[7] For the purposes of this Call, results are defined as that foreground generated under a IMI project from IMI Calls launched between 2008-2013.

that the best approaches are sought to ensure the IMI JU results are further exploited in line with IMI2 JU objectives. Cross-country collaboration will bring together competences and facilities which are not available on a national level, avoid dispersion of the results, and contribute to maintaining European competitiveness in the field of biomedical research and innovation.

Scope

The objective is to ensure the optimal exploitation and sustainability of key results from IMI projects that have finished or are nearing completion, and where relevant activities had not been already included as a funded activity of the project. Results should be those with the greatest chance of significant impact, beyond the original project lifetime. In some cases, this might be best achieved by finding solutions that can be applied to results generated across more than one project, to avoid dispersion and duplication of efforts.

Proposals must be in line with the objectives of IMI2 JU[8], particularly by aiming at sustaining and exploiting key results of previous projects to improve processes for the development of new medicines and/or lead to an improvement of individual and public health.

It is essential that applicants demonstrate that the funding sought will facilitate and foster the exploitation and sustainability of results beyond the original objectives of the project(s) by providing the necessary intermediate solutions and funding for a maximum of two years. It is expected that at the end of this period, further exploitation and sustainability will be achievable.

Thus commercial exploitation is outside the scope of this Call.

Applicants should be aware that only the project results identified in **Table A** annexed to the Topic Text are within the scope of this Call. As such, applicants must clearly indicate through their proposals which results they are utilising. In furtherance of the Call objectives, in line with Article II.30 and II.31 of the relevant IMI JU Model grant agreement[9], participants from the listed IMI JU projects have formally undertaken to grant potential applicants access to appropriate information in order to enable them to draft a proposal. Furthermore, access to appropriate information for successful applicants will be addressed on a case by case basis in line with Article II.30 and II.31 of the relevant IMI JU Model grant agreement.

The work to be supported will consist mainly of activities and measures to make the results available to the broader scientific community and as such may include measures to enable technology transfer and the analysis of regulatory aspects, as well as the standardisation and transfer of samples, databases, tools, etc. to sustainable infrastructures. In addition, the work may also encompass further activities should novel solutions/tools/methods be required to achieve the objectives of sustaining the results and ensuring their full impact. These could include adaptation of technologies to enable wider engagement, development of novel standardisation and/or interoperability measures, further development of scientific and business solutions, etc., as appropriate.

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[8] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.169.01.0054.01.ENG
The IMI2 Joint Undertaking shall have the following objectives:
(a) to support, in accordance with Article 25 of Regulation (EU) No 1291/2013, the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership or to address specific societal challenges in particular as described in parts II and III of Annex I to Decision 2013/743/EU, and in particular the challenge to improve European citizens' health and well-being;
(b) to contribute to the objectives of the Joint Technology Initiative on Innovative Medicines, in particular to:
(i) increase the success rate in clinical trials of priority medicines identified by the World Health Organisation;
(ii) where possible, reduce the time to reach clinical proof of concept in medicine development, such as for cancer, immunological, respiratory, neurological and neurodegenerative diseases;
(iii) 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;
(iv) develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators;
(v) reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks;
(vi) 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.

[9] http://www.imi.europa.eu/sites/default/files/uploads/documents/Rev_Grant_Agreement_2011/1_WP_2013_GA_Annex%20II_2013%2003%2013.pdf

The applicants must demonstrate that the results to be exploited and sustained are viable for exploitation. A justification has to be included of the importance and value of sustaining these results for biomedical research and/or the delivery of healthcare, and to fulfil an unmet need of the end users, e.g. researchers or patients.

Proposals should clearly demonstrate that the solutions selected for achieving exploitation and sustainability of the results are fit for purpose, including when relevant attention to standardisation and interoperability, and leveraging the latest knowledge and learning, allowing the results to enable further research beyond the state of the art.

Expected key deliverables

- At the end of the action, plans for the further exploitation and sustainability of results of IMI JU projects will have to be in place. Plans should include a clear value proposition for the end users to be targeted, for example: transfer to a sustainable infrastructure, technology transfer, etc.
- A convincing scientific and business solution that sustains key IMI JU project results without the need for further IMI JU funding beyond the duration of the funding of this Call.
- Measures to make the results available to the broader scientific community (public and private) beyond the duration of the sustainability funding to maximise the impact of the results on biomedical research and/or the delivery of healthcare.

Expected impact

It is expected that proposals selected for award under this Call will result in the future full exploitation of key project results in the scope of this Call (**Table A**, annexed) and their sustainability, which will stimulate the development of an open innovation model in biopharmaceutical research and contribute to the achievement of the objectives of IMI2 JU.

To ensure the expected impact, it is necessary that the most valuable solutions with maximum potential long-term impacts on research and development, as well as on regulatory, clinical and healthcare practice be identified. Some examples can be, among others, integrated and interlinked (translational) databases linked to biobanks that, when relevant, enable the sustainability of results from multiple projects. Other examples are well validated targets, assays, tools, biomarkers and models that require only limited further refinement for practical applications in drug development, regulatory and healthcare practices.

Thus to ensure the expected impact, applicants should seek out the best solutions to achieve the exploitation and long-term sustainability of the result, and identify relevant end users. Proposals have to include a clear argumentation of how the sustained assets will be effectively applied in future activities that will significantly move the field forward, create socio-economic impact, and bring significant benefits to the wider scientific and R&D community.

Where appropriate, the activities funded should prove the viability of the findings, methodologies, processes, prototypes, models, technologies, clinical trials etc., developed with a potential for application.

Overall, proposals should demonstrate an appreciation of the impact of exploiting the results with respect to:

- their long-term sustainability as a result of the exploitation activities;
- an impact on R&D, regulatory, clinical and healthcare practice as relevant;
- a strengthening of the competitiveness and industrial leadership (demonstrated by the ability to mobilise relevant industrial contributions) and/or addressing specific societal challenges, improving European citizens' health and wellbeing.

The impact of the IMI2 JU action is expected to be generated via mobilizing resources and relevant expertise from the members of the consortium of the IMI2 JU action[10] significant enough to ensure meeting the proposal specific objectives and contribute to the IMI2 JU objectives as a public-private partnership.

Potential synergies with existing consortia

While proposals must be based on results included in the table presented in **Table A** annexed to the Topic Text, synergies with existing initiatives should be considered in order to favour solutions maximising the impact while avoiding duplication and fragmentation.

Consortia have to demonstrate that they have developed their proposal taking into consideration and leveraging already available and relevant research infrastructures in Europe.

Indicative duration of the action

Proposals should include an appropriate duration for the action in relation to the activities and action work plan but should be no longer than 24 months.

Indicative budget

The financial contribution from the IMI2 JU will be a maximum of EUR 5 000 000 globally for all selected actions. Within this budgetary envelope it is expected that each proposal will include a sound justification of the budget requested.

Applicant consortium

Applicant consortia are expected to address all of the objectives and have the necessary expertise to produce the deliverables and ensure the expected impact as outlined in the Call text.

The size and composition of each consortium should be adapted so as to respond to the goals and the key deliverables. The consortium participants need to include participants as appropriate to exploit the targeted results in the most logical and efficacious manner.

While preparing their proposals, applicant consortia should ensure that all relevant stakeholders are engaged appropriately and that the needs of patients are adequately addressed and, where appropriate, patient involvement is encouraged.

Applicant consortia will also be required to establish a robust legal/IPR apparatus that can facilitate the management and transfer of project results and sustainability efforts, including relevant ethical considerations, whilst remaining cognisant of, and consistent with, the IMI legal framework and associated project consortium agreements.

Applicants must pay particular attention to harnessing support from different stakeholders, including the mobilisation of funds through the inclusion of contributing partners – not necessarily involved in the original project – to reflect the public-private character of IMI actions. These mobilised contributions must be in addition to those already committed by any contributing partners when the original project(s) began.

[10] Including 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.

Proposal preparation

Given the specific scope of this Call, when preparing their proposals, applicants must ensure the following points are covered in the relevant section of the proposal template:

- Result(s) chosen from those listed as in the scope of this Call have to be highlighted in the section of the proposal '1.2 Relation to the Call topic text'.
- A justification of the need and importance of further exploiting these results and expected value to be created, as well as how the funding under the present Call will trigger further long-term, self-standing sustainability. These activities should be confirmed as not being part of the funded activities of the original IMI JU project(s).
- A clear justification of the contributions mobilised to achieve the objectives.
- A description of the intended end-users and how they would benefit from the proposed exploitation and sustainability solution.
- All elements listed in the 'Expected Impact' section have to be addressed.
- A detailed explanation of the resources required and alignment with the budget requested.
- For entities that intend to contribute by becoming an Associated Partner of IMI2 JU, a request letter (http://www.imi.europa.eu/content/get-involved) has to be provided as an appendix to the proposal (this letter is not to be counted in the maximum number of pages).

Conditions for this Call for proposals

All proposals must conform to the conditions set out in the H2020 Rules for Participation (https://ec.europa.eu/research/participants/portal/doc/call/h2020/common/1595113-h2020-rules-participation_oj_en.pdf),the Commission Delegated Regulation with regard to IMI2 JU (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0622&from=EN) and the relevant general conditions of the IMI2 JU AWP2017.

Applicants intending to submit a proposal in response to this Call for proposals should read in particular this topic text, the IMI 2 JU Annual Work Plan, the IMI2 Manual for submission, evaluation and grant award, the IMI2 RIA evaluation criteria and other relevant documents (e.g. IMI2 model Grant Agreement).

Call Identifier	**H2020-JTI-IMI2-2017-11-single-stage**
Type of action	**Research and Innovation Action (RIA)**
Publication Date	**19 July 2017**
Submission start date	**19 July 2017**
Submission deadline	**24 October 2017 (17:00:00 Brussels time)**
Indicative budget	
From the IMI2 JU	A maximum of EUR 5 000 000

Call Topic

IMI2-2017-11-01	The total financial contribution from the IMI2 JU is a maximum of EUR 5 000 000.	Research and Innovation Actions. Single-stage submission and evaluation process. Proposals submitted will be evalutated and ranked in one sigle list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.

The following general conditions shall apply to the IMI2 JU Calls for Proposals:

List of countries and applicable rules for funding

By way of derogation[11] from Article 10(1) of Regulation (EU) No 1290/2013, only the following participants shall be eligible for funding from the Innovative Medicines Initiative 2 Joint Undertaking:

(a) legal entities established in a Member State or an associated country, or created under Union law; and

[11] Pursuant to the Commission Delegated Regulation (EU) No 622/2014 of 14 February 2014 establishing a derogation from 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)' with regard to the Innovative Medicines Initiative 2 Joint Undertaking

(b) which fall within one of the following categories:

(i) micro, small and medium-sized enterprises and other companies with an annual turnover of EUR 500 million or less, the latter not being affiliated entities of companies with an annual turnover of more than 500 million; the definition of 'affiliated entities' within the meaning of Article 2(1)(2) of Regulation (EU) No 1290/2013 shall apply *mutatis mutandis*;

(ii) secondary and higher education establishments;

(iii) non-profit organisations, including those carrying out research or technological development as one of their main objectives or those that are patient organisations.

(c) the Joint Research Centre;

(d) international European interest organisations.

Participating legal entities listed in (b) above established in a third country may receive funding from the IMI 2 JU provided their participation is deemed essential for carrying out the action by the IMI 2 JU or when such funding is provided for under a bilateral scientific and technological agreement or any other arrangement between the Union and the country in which the legal entity is established[12].

Standard admissibility conditions and related requirements

Part B of the General Annexes[13] to the Horizon 2020 – Work Programme 2016 – 2017 shall apply mutatis mutandis for the actions covered by this Call for proposals.

In addition, page limits will apply to proposals as follows:

For a single stage call the limit for full proposals is 70 pages.

Eligibility conditions

Part C of the General Annexes to the Horizon 2020 – Work Programme 2016 – 2017 shall apply mutatis mutandis for the actions covered by this Call for proposals.

Types of action : Specific provisions and funding rates

Part D of the General Annexes to the Horizon 2020 – Work Programme 2016 – 2017 shall apply mutatis mutandis for the actions covered by this Call for proposals.

Techonolgy Readiness Levels (TRL)

Part G of the General Annexes to Horizon 2020 – Work Programme 2016 – 2017 shall apply mutatis mutandis for the actions covered by this Call for proposals.

Evaluation rules

Part H of the General Annexes to the Horizon 2020 - Work Programme 2016– 2017 shall apply *mutatis mutandis* for the actions covered by this Call for proposals.

[12] In accordance with Article 10(2) of the Regulation (EU) No 1290/2013 and Article 1 of Commission Delegated Regulation (EU) No 622/2014

[13] http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016-2017/annexes/h2020-wp1617-annex-ga_en.pdf

Award criteria and scores:

Experts will evaluate the proposals on the basis of criteria of "Excellence", "Impact" and "Quality and efficiency of the implementation", as follows:

Type of action	Excellence	Impact	Quality and efficiency of the implementation[14]
RIA and IA **Single stage, and 2nd stage evaluation**	The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the call for proposals and referred to in the IMI2 annual work plan and is consistent with the stage 1 proposal: Clarity and pertinence of the proposal to meet all key objectives of the topic; Credibility of the proposed approach; Soundness of the concept, including trans-disciplinary considerations, where relevant; Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art; Mobilisation of the necessary expertise to achieve the objectives of the topic, ensure engagement of all relevant key stakeholders.	The following aspects will be taken into account, to the extent to which the outputs of the project should contribute at the European and/or International level: The expected impacts of the proposed approach as mentioned in the call for proposals; Added value from the public private partnership approach on R&D, regulatory, clinical and healthcare practice as relevant; Enhancing innovation capacity and integration of new knowledge; Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges; Improving European citizens' health and wellbeing and contribute to the IMI2 objectives;[15] Any other environmental and socially important impacts; Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant.	The following aspects will be taken into account: Coherence and effectiveness of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and budget; Complementarity of the participants within the consortium (where relevant); Clearly defined contribution to the project plan of the industrial partners (where relevant); Appropriateness of the management structures and procedures, including manageability of the consortium, risk and innovation management and sustainability plan.

These evaluation criteria include scores and thresholds. Evaluation scores will be awarded for the criteria, and not for the different aspects listed in the above table. For all evaluated proposals, each criterion will be scored out of 5. Half marks may be given.

[14] In a single-stage, or in the second-stage of a two-stage evaluation procedure, experts will also be asked to assess the operational capacity of applicants to carry out the proposed work.
[15] Article 2 of the Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (O.J. L169 of 7.6.2014)

For the evaluation of proposals under a single-stage submission procedure, the threshold for individual criteria is 3. The overall threshold, applying to the sum of the three individual scores, is 10.

Following the evaluation, applicants will receive an ESR (Evaluation Summary Report) regarding the respective evaluated proposal.

The full evaluation procedure is described in the IMI2 JU Manual for submission, evaluation and grant award in line with the H2020 Rules for Participation.[16]

Under the single-stage evaluation process, evaluated proposals will be ranked in one single list. The best-ranked proposals, in the framework of the available budget, will be invited to prepare a Grant Agreement.

As part of the panel deliberations, the IMI2 JU may organise hearings with the applicants to:

clarify the proposals and help the panel establish their final assessment and scores, or

improve the experts' understanding of the proposal.

Indicative timetable for evaluation and grant agreement

	Information on the outcome of the evaluation (single stage, or first stage of a two-stages)	Information on the outcome of the evaluation (second stage of a two stages)	Indicative date for the signing of grant agreement
Single-stage	Maximum 5 months from the submission deadline at the single stage.	N/A	Maximum 8 months from the submission deadline.

Budget flexibility

Part I of the General Annexes to the Horizon 2020 – Work Programme 2016 – 2017 shall apply mutatis mutandis for the actions covered by this Call for proposals.

Actions involving financial support to third parties

Part K of the General Annexes to the Horizon 2020 – Work Programme 2016 – 2017 shall apply mutatis mutandis for the actions selected under topics covered by this Call for proposals.

Conditions related to open access to research data

Part L of the General Annexes to the Horizon 2020 – Work Programme 2016 – 2017 shall apply mutatis mutandis for the actions covered by this Call for proposals.

However, should a project "opt-out" of these provisions, a Data Management Plan must still be prepared. A template for the Data Management Plan is available on the IMI website.

[16] http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/IMI2_ManualForSubmission_v1.5_July2017.pdf

Submission tool

Proposals in response to this call for proposals must be submitted on-line, before the call deadline, by the coordinator via the Electronic Submission Service of the Participant Portal:

http://ec.europa.eu/research/participants/portal/desktop/en/home.html

No other means of submission will be accepted.

Others

For proposals including clinical trials/studies/investigations, a specific template to help applicants to provide essential information on clinical studies in a standardised format is available under:

http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/h2020_tmpl-clinical-studies_en.pdf

In a single-stage evaluation procedure involving clinical studies, the use of this template is mandatory in order to provide experts with the necessary information to evaluate the proposals. The template may be submitted as a separate document.

Ethical issues should be duly addressed in each submitted proposal to ensure that the proposed activities comply with ethical principles and relevant national, Union and international legislation. Any proposal that contravenes ethical principles or which does not fulfil the conditions set out in the H2020 Rules for Participation, or in the Annual Work Plan shall not be selected.[17]

In order to ensure excellence in data and knowledge management consortia will be requested to Disseminate scientific publications on the basis of open access[18] (see “Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020”).

Full proposals must contain a draft plan for the exploitation and dissemination of the results.

Applicants intending to submit a proposal in response to the IMI2 JU Calls should also read the topic text, the IMI2 JU Manual for submission, evaluation and grant award, and other relevant documents[19] (e.g. IMI2 JU model Grant Agreement).

Consortium agreements

In line with the Rules for Participation and Dissemination applicable to IMI2 actions[20] and the IMI2 model grant agreement, participants in IMI2 actions are required to conclude a consortium agreement prior to grant agreement.

[17] Article 19 of Horizon 2020 Framework Programme, and Articles 13 and 14 of the Horizon 2020 Rules for Participation.
[18] Article 43.2 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
[19] http://www.imi.europa.eu/content/documents#calls_for_proposals_-_imi_2_programme
[20] Regulation (EU) No 1290/2013 of 11 December 2013 and Commission Delegated Regulation (EU) No 622/2014 of 14 February 2014.

ANNEX : Table A of project results

Project acronym, title and number	Project results (IMI1 project foreground)	Foreground type	Reference to scientific publications / other public sources	Project website and contacts
EMTRAIN **European Medicines Research Training Network** **115015**	▪ on-course®: a unique, independent, searchable, postgraduate course database containing over 7 600 courses for Masters, short courses and PhD programmes with >100 000 users. Now also used for research purposes. ▪ LifeTrain: established the principles for mutually-recognised lifelong learning and developed competency profiles, assessment of competencies and recognition / implementation processes - now part of the European Molecular Biology Laboratory (EMBL) conference series. ▪ Public-private partner (PPP) PhD workshops to increase industry awareness and support the acquisition of critical transferable skills. ▪ Toolkit for trainers: teaching methods for course developers. ▪ Extensive pan-European network including hundreds of thousands of biomedical scientists.	▪ Databases ▪ Learning platforms	1. Payton A, Janko C, Renn O, Hardman M. on-course(®) portal: a tool for in-service training and career development for biomedical scientists. Drug Discovery Today 2013; 18: 803-806. 2. Payton A, Dallakian P, Fitton A, Payton A, Hardman H, Yuille M. Course fees and academic ranking: insights from the IMI EMTRAIN on-course® database. Drug Discovery Today 2013; 19 (7): 830 – 833. 3. Hardman M, Brooksbank C, Johnson C, Janko C, See W, et al. LifeTrain: towards a European framework for continuing professional development in biomedical sciences. Nature Reviews Drug Discovery 2013; 12: 407-408. 4. Aperia A, Dirach J, Hardman M, et al. It pays to promote joint PhD programmes between academia and the private sector. Journal of Medicines Development Sciences 2015; 1 (2): 37–40. 5. Klech H, Brooksbank C, Price S, Verpillat P, Bühler FR, et al. European initiative towards quality standards in education and training for discovery, development and use of medicines. European Journal of Pharmaceutical Sciences 2012; 45: 515-520. 6. www.on-course.eu 7. www.lifetrain.eu	www.emtrain.eu michael.wolzt@meduniwien.ac.at
EUPATI **European Patients' Academy on**	▪ Certificate Patient Expert Training Course on medicines research and development (R&D). ▪ 98 certified Patient Experts in two course cycles.	▪ Educational material on seven-language toolbox website and on EUPATI Moodle e-learning system	1. Pavitt S. EUPATI: An initiative to provide expertise in patient advocacy and in medicines development processes. Regulatory Rapporteur 2013; 10 (9).	www.eupati.eu jan@patientsacademy.eu

Project acronym, title and number	Project results (IMI1 project foreground)	Foreground type	Reference to scientific publications / other public sources	Project website and contacts
Therapeutic Innovation **115334**	▪ Pan-European workshop series on patient involvement in R&D. ▪ 'EUPATI Toolbox' and 'Internet Library' on medicines R&D in 7 languages, more than 50 000 users, add-on 'mini-course starter-kits' for short–courses. ▪ ~18 supported EUPATI National Platforms: launched: AT, FR, DE, IE, IT, MT, ES, CH, UK, PL; emerging: DK, SL, SR, NL, PT, GR; under construction: BE, LU. ▪ Guidance documents for interaction of patients/patient organisations with industry, regulators, health technology assessment (HTA) and ethics committees. ▪ Spearheaded public debate on patient and public involvement (PPI) in R&D.	▪ Guidance documents on interaction of patient organisations with 4 stakeholder groups, text ▪ Pan-European network of key contacts in advocacy and PPI, database ▪ Patients involved platform, website	2. Chakradhar S. Training on trials: Patients taught the language of drug development. Nature Medicine 2015; 21 (3): 209-210. 3. Parsons S, Starling B, Mullan-Jensen C, et al. What the public knows and wants to know about medicines research and development: a survey of the general public in six European countries. BMJ Open 2015; 5: e006420. doi: 10.1136/bmjopen-2014-006420. 4. Pushparajah DS, Geissler J, Westergaard N. EUPATI: Collaboration between patients, academia and industry to champion the informed patient in the research and development of medicines. Journal of Medicines Development Sciences 2015; 1(1): 74–80. 5. Parsons S, Starling B, Mullan-Jensen C, et al. What do pharmaceutical industry professionals in Europe believe about involving patients and the public in research and development of medicines? A qualitative interview study. BMJ Open 2016; 6: e008928. doi: 10.1136/bmjopen-2015-008928. 6. Korieth, K. (2016) Three resonating patient-centric initiatives. The CenterWatch Monthly 2016; 23 (7). 7. Organisation for Economic Co-operation and Development (OECD) Global Science Forum. Facilitating international cooperation in non-commercial clinical trials. 2011.	walter.atzori@eu-patient.eu
PharmaTrain **Pharmaceutical Medicine Training Programmes** **115013**	▪ Shared content and quality standards for post-graduate diploma and Master programmes in medicines development + implemented course recognition procedure + implementation of post-graduate certification as 'Specialist in Medicines Development'	▪ Course Handbook for post-graduate diploma and Master programmes in pharmaceutical medicine and regulatory affairs	1. Klech H, Brooksbank C, Price S, Verpillat P, Bühler FR, Dubois D, et al. European initiative towards quality standards in education and training for discovery, development and use of medicines. European Journal of Pharmaceutical Sciences 2012; 45: 515-520.	www.pharmatrain.eu ingrid.klingmann@pharmatrain.eu

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	presented in the 'PharmaTrain Manual, Curriculum Standards and Best Practices'. ▪ Shared content and quality standards for post-graduate Master programmes in regulatory affairs. Clinical investigator certificate (CLIC) position paper on development of a responsibility-based clinical trial management training programme for clinical investigators and their staff.	▪ Standard operating procedures (SOPs) and charters for national implementation of the post-graduate certification programme 'Specialist in Medicines Development' ▪ Position paper with syllabus and learning outcomes for the three levels investigator training in clinical trial management	2. Boeynaems J-M, Canivet C, Chan A, Clarke MJ, Cornu C, Daemen E, et al. A European approach to clinical investigator training. Frontiers in Pharmacology 2013; 4: 112.	
Open PHACTS **The Open Pharmacological Concepts Triple Store** **115191**	The Open PHACTS Discovery Platform offers semantically integrated life science data allowing to query across the concepts compounds - targets - pathways - diseases. A well-structured application programming interface (API) allows standardised access and data retrieval.	▪ Semantically integrated life science data	1. Williams AJ, Harland L, Groth P, Pettifer S, Chichester C, Willighagen EL, et al. Open PHACTS: Semantic interoperability for drug discovery. Drug Discovery Today 2012; 17: 1188-98. doi: 10.1016/j.drudis.2012.05.016. 2. www.openphacts.org/news-and-events/publications	www.openphacts.org gerhard.f.ecker@univie.ac.at stefan.x.senger@gsk.com
RAPP-ID **Development of RApid Point-of-Care test Platforms for Infectious Diseases** **115153**	Breath sample technology: this technology is intended for capturing non-volatile components of exhaled breath for patient diagnostic purposes. The device, labelled BESS (Breath ElectroStatic Sampler), is based on electrostatic capture of microbe-containing aerosols present in exhaled breath. The BESS features a liquid capture interface, allowing collection of exhaled breath particles directly	▪ Prototype	1. Ladhani L, Pardon G, van der Wijngaart W. A 3D microfluidic cage collector for airborne particles. 19th International Conference on Miniaturized Systems for Chemistry and Life Sciences, October 25-29 2015, Gyeongju, South Korea. www.rsc.org/images/LOC/2015/PDFs/Papers/0079_1B3-4.pdf	www.rapp-id.eu jvillaci@its.jnj.com herman.goossens@uza.be pieter.moons@uantwerpen.be

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	into microliters of buffer, the latter being adaptable to any biological assay of interest. The BESS has been designed with disposability in mind, using cost-saving plastics, along with one-time-use collectors to eliminate cross contamination between patients and saving time. Early-stage studies with influenza-infected patients of the usage of BESS versus swab sampling indicate a strong preference for BESS-collected samples, rather than the standard nasopharyngeal swab collection.			
WEB-RADR **Recognising Adverse Drug Reactions** **115632**	WEB-RADR has delivered a mobile app for adverse drug reaction (ADR) reporting, regulatory news and ADR data. WEB-RADR can make available software code, images, and databases developed through the project. Additionally, the backend connections and rules between the World Health Organization Uppsala Monitoring Centre (WHO-UMC), national authorities and the apps are a shared resource, developed through WEB-RADR. The foreground can be described in sufficient detail to provide a sense of the capabilities. However, data security is paramount because a too detailed public description could expose systems to outside malicious actors. Therefore, the level of information that is transferred must meet the security requirements of each existing country using the app.	▪ Databases ▪ Technology platform	1. https://itunes.apple.com/gb/app/yellow-card-mhra/id990237487?mt=8 2. https://itunes.apple.com/mg/app/bijwerking/id1060529495?mt=8 3. https://itunes.apple.com/us/app/halmed/id1080314179?mt=8 4. https://play.google.com/store/apps/details?id=uk.org.mhra.yellowcard&hl=en_GB 5. https://play.google.com/store/apps/details?id=nl.lareb&hl=en_GB 6. https://play.google.com/store/apps/details?id=hr.halmed&hl=en_GB	www.web-radr.eu phil.tregunno@mhra.gsi.gov.uk

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GetReal **Incorporating real-life clinical data into drug development** **115546**	▪ The web-based navigator tool has been designed to: a. guide medicine development/evidence generation strategy: b. provide a methodological platform to provide options for study designs and analytical approaches; c. guide users towards more detailed material, publications and case studies reported by each GetReal work package (WP); d. direct users to authoritative external guidance and sources. ▪ Research and policy recommendations on the use of real world evidence (RWE) in drug development and stakeholder decision making in addition to recommendations around the use of the research tools, key outputs of simulation studies and methodological recommendations generated in GetReal. ▪ PragMagic: a decision support tool for pragmatic trial design aimed at facilitating the design & planning of pragmatic trials, by providing insights into the consequences of design choices & possible operational challenges to maximise the generalisability of trial findings while ensuring validity and operational feasibility. ▪ ADDIS software: a system that allowed us structured clinical trials data. We support the automated discovery and (meta-) analysis of trial data, as well as benefit-risk assessment. ▪ Education and training materials on a remote e-learning platform intended to simultaneously	▪ Website ▪ Software tools ▪ Online education and Training programme	Information on all aspects of the project foreground included in this call are publically available at the following sources: 1. General information about GetReal and all relevant publications can be found on the GetReal website https://www.imi-getreal.eu 2. The Navigator can be accessed via: http://rwe-navigator.nice.org.uk 3. Details of the all the deliverables described in this Call can be can be found at: https://www.imi-getreal.eu/Events/Stakeholder-Conference Additional information regarding all key foreground listed are available via the GetReal website (slides and materials shown at stakeholder meeting of 24 November 2016, Brussels).	www.imi-getreal.eu elaine.a.irving@gsk.com d.e.grobbee@umcutrecht.nl p.stolk@umcutrecht.nl

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	discover the possibilities of, and the requirements on, a database of ▪ Increase knowledge and skills about topics that are at the core of the GetReal project, with a particular emphasis on the connection between methodology development and its practical applications within companies, regulatory agencies and HTA bodies. ▪ GetReal platform for the engagement of key stakeholders.			

Glossary

CSA	Coordination and Support Action
EFPIA	European Federation of Pharmaceutical Industries and Associations
IMI	Innovative Medicines Initiative
IP	Intellectual Property
R&D	Research and development
RIA	Research and Innovation Action
SMEs	Small and medium-sized enterprises
SRA	IMI2 Strategic Research Agenda
WHO	World Health Organisation