

IMI2 Call 8 – Ebola and other filoviral haemorrhagic fevers (Ebola+) programme: future outbreaks

Frequently asked questions (FAQ)

The call text provides the overall principles, expectations and requirements to be followed respectively by the applicants in the preparation of their proposals and by the panel of experts in the evaluation of the submitted proposals. This Q&A document aims at merely explaining some aspects in more detail, but is by no means intended to be exhaustive nor should it differ from anything stated in the Call text.

1. What is the current Call for proposals about?

The current open and competitive call for proposals¹ is part of the Innovative Medicines Initiative 2 (IMI2) Ebola and other filoviral haemorrhagic fevers programme, the Ebola+ programme. Ebola + is a multi-company, cross-sector and multi-stakeholder programmatic approach to address the challenges of Ebola virus disease (EVD) and other filoviral haemorrhagic fevers. This is the second Call under the Ebola+ programme and falls under the same broad scope, including discovery, pre-clinical and clinical development and/or validation of both treatments and vaccines, diagnostics, tools and innovative solutions for adherence and deployment, stability of vaccines during transport and storage. This Call presents a continuous opportunity offered by IMI2 to support efforts that will ensure fast development and validation of innovative solutions that will result in an increased readiness to respond to future outbreaks. Applicants must pay particular attention to exploiting support from different stakeholders, as the expected impact of this call includes the mobilisation of funds through the inclusion of contributing partners under the IMI scheme of public-private consortia (see also answer to question No.12).

In addition, proposals for the development of adaptable platforms, which can address multiple other priority pathogens in addition to filoviruses are also eligible.

2. How will the funding be allocated?

The funding will be allocated throughout a series of cut-off dates (approximately every 6 months).

The first cut-off date for the submission of full proposals is 16 March 2016. The entire budget (EUR 70 million) will be available as from the first cut-off date. Proposals received by the first cut-off date will be evaluated by a panel of independent experts and ranked in one single list. Proposals that scored above threshold will be invited in ranked order to prepare a Grant Agreement, within the budget availability. Depending on the number of proposals that scored above threshold and the budgets asked for, there might or might not be sufficient budget available to fund all proposals that scored above threshold. Proposals positively evaluated but falling outside the budget availability will have to be rejected. The budget remaining after the first cut-off date will be moved to the next cut-off date, and so on. Three months prior to each subsequent cut-off date, the amount of the remaining budget will be published on the IMI website.

3. What is the total budget of the Ebola+ programme?

This is the second Call for proposals under the Ebola+ programme. As a result of the first Call for proposals, eight Ebola+ projects are now up and running with a total budget of EUR 215 million, of which EUR 114

¹ http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/C8_TOPICTEXTIMI2CALL8_EN.pdf

million is IMI2 JU financial contribution and EUR 101 million consists of EFPIA in-kind contribution. The maximum total IMI2 JU contribution to this second Call for proposals is EUR 70 million. This will be complemented by the expected contribution of contributing partners under the IMI scheme of public-private consortia (e.g. EFPIA companies or affiliated entities, IMI2 Associated Partners). The final budget of the entire programme will therefore depend on the projects resulting from this second Call for proposals.

4. What is the duration of the Ebola+ programme?

The current Call for proposals is open for a duration of 2 years, with cut-off dates for the submission of proposals approximately every six months. The duration of the projects to be funded has not been pre-determined, rather, applicants are invited to align the duration of their proposed project in relation to the activities and objectives.

5. How can I apply?

Each IMI call is published on the H2020 Participant Portal² and the IMI2 JU website.

The first deadline for the submission of proposals under the current call is 16 March, 2016, by which all required documents described in the call should be submitted via the IMI2 JU electronic submission tool SOFIA (Submission OF Information Application). To access the IMI2 JU electronic submission tool SOFIA, applicants wishing to submit a proposal will need to complete a request for access to the tool³. Organisations willing to participate in a project proposal must be registered with the Commission services and have obtained a 9-digit Participant Identification Code (PIC)⁴.

For any successful proposal, all participants' information provided at the time of the registration needs to be validated by the Commission service. It is important to note that a Grant Agreement cannot be signed until all participants have been validated.

Proposals may be finalised and re-opened online until the 'Submit' button is pressed. You have submitted your proposal when you have clicked both 'Finalise' and 'Submit' in SOFIA by the call submission deadline.

6. Who can participate in the current Call for proposals?

Legal entities established in EU as well as non-EU countries⁵ as long as the remaining admissibility and eligibility criteria of the Call for proposals are fulfilled (see questions No.10&11; in addition, see also answer to question 15 for eligibility to receive funding).

Applicant consortia need to fulfil the criteria as described in the rules for participation applicable to the IMI2 JU actions⁶. In particular, for Research and Innovation actions, the following minimum conditions shall apply:

- (a) at least three legal entities shall participate in an action;
- (b) three legal entities shall each be established in a different Member State or Associated Country.

² <http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/calls/h2020-jti-imi2-2015-08-single-stage.html#c,topics=callIdentifier/t/H2020-JTI-IMI2-2015-08-single-stage/1/1/1/default-group&callStatus/t/Forthcoming/1/1/0/default-group&callStatus/t/Open/1/1/0/default-group&callStatus/t/Closed/1/1/0/default-group&+identifier/desc>

³ <https://sofia.imi.europa.eu/Pages/RequestAccess.aspx>

⁴ <http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html>

⁵ Please see 'List of countries and applicable rules for funding' as established in the Call conditions of this IMI2 Call 8:

http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/C8_TOPICTEXTIMI2CALL8_EN.pdf

⁶ http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/IMI2_provisions_for_participating_in_IMI2_actions.pdf

It is to be noted that all proposals will be subject to peer-review evaluation and it is up to the evaluation experts to assess the proposals. This includes the composition of the consortium.

7. What are the reference documents for this Call for proposals?

Applicants are encouraged to study in detail the Call text, the Call conditions as well as the following documents:

- H2020 Rules for Participation⁷
- Parts B, C, D, G and H of the General Annexes to the H2020 general work programme 2014-2015⁸
- IMI2 JU Commission Delegated Regulation⁹
- IMI2 JU Manual for submission, evaluation, and grant award¹⁰
- IMI2 JU Research and Innovation Actions Evaluation criteria¹¹
- IMI2 JU Research and Innovation Actions (RIA/IA) Proposal template¹²

8. What other documentation must be submitted with the project proposal by the set deadline?

Applicants shall submit a full proposal using the aforementioned proposal template by the set deadline.

9. What is the single-stage process?

The single-stage submission scheme requires that applicants submit a full proposal (max. 70 pages – see IMI2 RIA/IA Template Proposal) for the one and only evaluation stage. The full proposals shall be subject to remote and in-house evaluation, results of which will be communicated to the applicant consortia. The successful consortia will be invited to prepare a Grant Agreement following the necessary modalities.

10. What are the admissibility criteria for the proposals?

To be considered admissible, a proposal must comply with the admissibility criteria set out in part B of the General Annexes of the H2020 Work Programme 2014-2015¹³.

Incomplete proposals may be considered inadmissible.

In case of an 'obvious clerical error' (e.g. omission to submit evidence or information on a non-substantial element of the proposal), IMI2 JU may first ask applicants to provide the missing information or supporting documents.

7 http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf

8 http://ec.europa.eu/research/participants/portal/doc/call/h2020/common/1587809-18._general_annexes_wp2014-2015_en.pdf

9 <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0622;>

10 http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/IMI2_SubmissionManual_Dec2015.pdf

11 http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/IMI2_Evaluation-Form_RIA-IA_en.pdf

12 http://www.imi.europa.eu/webfm_send/1464

13 See footnote 1

11. What are the eligibility criteria for the proposals?

To be considered eligible, a proposal must comply with the eligibility criteria set out in part C of the General Annexes of the H2020 Work Programme 2014-2015 and:

In all cases: a minimum of three independent legal entities established in different Member States or countries associated to H2020 (please also see answer to question No. 6).

12. Do I need an EFPIA company contributing in-kind in my consortium? Can beneficiaries eligible to receive IMI2 JU funding instead reduce the funding requested and self-contribute 40% of the total project cost?

It is not an eligibility criterion to have an EFPIA company (or affiliated entity) or Associate Partner contributing in-kind as part of your consortium. However, a key element of the expected impact of this Call for proposals is that support from different stakeholders should be exploited, and this includes the mobilisation of funds through the inclusion of contributing partners under the IMI scheme of public-private consortia (e.g. EFPIA company or affiliated entity, IMI2 Associated Partner). In that respect, it is important to understand that under one of the evaluation criteria (published here: <http://www.imi.europa.eu/content/overview-imis-calls-how-participate>), the expected impact of your proposal will be assessed based on what is listed under the section “Expected impact” in the Call text. This means that your proposal will only score high under the evaluation criterion ‘Impact’ if the experts consider that it meets those expectations. Please also note that the threshold for evaluation criterion ‘Impact’ is 4 in a single-stage Call process. It is therefore considered highly unlikely if not impossible for your proposal to score above threshold if no contributing partner under the IMI scheme of public-private consortia is included.

The intention is not to reduce the funding available to public partners by revisiting the applicable funding rate as established for this call (100% of the total eligible costs) but to mobilise investments by other stakeholders, e.g. private investment, as part of a PPP.

13. What is an Associated Partner and what organisations can become Associated Partners? Can the process of becoming an Associated Partner be concluded AFTER submission of a proposal, e.g. only once evaluated positively?

Under the IMI 2 programme, organisations other than EFPIA companies can become IMI2 Associated Partners. 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, normally the resources they put into a project are matched by IMI, making this a good way of leveraging precious resources.

Examples of organisations that could become IMI 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.

So far, diabetes charity JDRF, the Leona M. and Harry B. Helmsley Charitable Trust and the Bill and Melinda Gates Foundation have become Associated Partners.

Organisations wishing to become Associated Partners must apply to the IMI Governing Board with a letter of endorsement setting out their acceptance of the IMI2 statutes as well as details of their proposed contribution to IMI.

With reference to the IMI2 Call 8, submitted proposals are expected to exploit support from different stakeholders, including the mobilisation of funds through the inclusion of contributing partners under the IMI scheme of public-private consortia (e.g. EFPIA company or affiliated entity, IMI2 Associated Partner).

In that respect, a contributing partner in a proposal selected for funding under the present call which 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, 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.

In practical terms, contributing partners may decide to apply for such affiliations when and if the proposal where they are participating has been selected for funding.

Where a contributing partner becomes an affiliate or a constituent entity of EFPIA or an IMI2 Associated Partners, it will have to report annually its contribution to the project in accordance to the IMI2 Statutes.

14. How can consortia be built for a single-stage process? How do I find partners?

To facilitate setting up consortia, the IMI2 Programme Office offers a partner search tool on the IMI website¹⁴. Applicants interested in joining a consortium, are further encouraged to use the IMI LinkedIn group for partnering activities.

EFPIA companies or Associated Partners interested in participating in an applicant consortium are expected to sign up in the IMI partner search tool.

15. Is my organisation eligible to receive funding?

Universities and other public research institutions, small- and medium-sized enterprises (SMEs), larger mid-sized companies¹⁵, hospitals, healthcare organisations, regulatory agencies, public health authorities, and others are eligible to receive IMI2 JU financial contribution, in accordance with the applicable rules. Specifically, legal entities established in a Member State or country associated¹⁶ to H2020 are eligible to receive IMI2 JU financial contribution.

Under exceptional circumstances, legal entities from countries other than the aforementioned might also be eligible for IMI2 JU funding should their participation be evaluated by the IMI2 JU as essential for the realisation of the project's objectives.

16. What type of contribution could my organisation bring to the project?

Industry companies that are constituent entities of EFPIA or their affiliated entities, IMI2 JU Associated Partners and/or any other contributing partner can contribute with either in kind or financial contributions. The in kind contribution is the non-reimbursed cost that a company incurs supporting the project. This will typically be human resources (which may be determined in "full-time equivalents", FTEs), consumables, work outsourced to contract research organisations (CROs) or other service providers, etc. Some in kind resources can originate from non-EU or associated countries (in practice: work can be carried out in these countries).

¹⁴ <http://www.imi.europa.eu/content/partner-search>

¹⁵ Independent legal entities having an annual turnover of EUR 500 million or less which are established in a EU Member States or H2020 Associated Countries (http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/3cpart/h2020-hi-list-ac_en.pdf).

¹⁶ http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/3cpart/h2020-hi-list-ac_en.pdf

17. Is cooperation with other organisations or on-going projects envisaged?

In view of the many projects and efforts that were supported by us and many others during the course of the recent Ebola outbreak, it is of particular interest to ensure that projects selected for funding build on outcomes of research from other programmes and initiatives, national or international. The partners in a proposed consortium must have the capacity and expertise needed to fast-forward results into validated health interventions that will result in increased preparedness in case of future outbreaks. Collaboration with international organisations that were involved in the 2014/2015 Ebola outbreak is encouraged. Hence also the expectation under “Expected impact” to take advantage of and exploit support by different stakeholders through the inclusion of contributing partners (see also answer to question 13).

In addition, any project funded under this Call for proposals will be part of the Ebola+ family of projects. This offers opportunity for close interaction and collaboration with other Ebola+ projects. For example, Ebola+ projects share an Ethics Board and a Scientific Advisory Board. Also, a Joint Information Repository is put in place under the leadership of the EBOVAC1 project, with the goal to share and make available data and learnings as much as possible, both within the Ebola+ community and with the scientific community in general. Projects funded under this Call for proposal are expected to explore adhering to those structures, and to contribute to and make use of the Joint Information Repository.

Where applicable, consortia are expected to interact with the European Medicines Agency for advice on the conduct of clinical trials and manufacturing-related questions or with African regulatory bodies.

18. Who do I contact if I encounter problems during the submission process for troubleshooting purposes? Who manages the Call process? Is there a helpline available for other administrative/procedural inquiries?

Contact the IMI2 JU Programme Office. E-mail: Infodesk@imi.europa.eu. Tel.: +32 2 221 8181.

IT Helpdesk - contact the SOFIA IT helpdesk for questions such as forgotten passwords, access rights and roles, technical aspects of submission of proposals, etc.

IMI2 JU States Representative Group (SRG)¹⁷ – contact you SRG member for assistance.

¹⁷ <http://www.imi.europa.eu/content/states-representatives-groups>