IMI 2
8th Call for proposals

C O R R I G E N D U M

- **Revision of Call conditions to indicate the change of the submission tool – page 13**
- **Update of the clinical trial template – page 13**

Document version 2.1

Last update: 14.06.2017

Reference Number: IMI2/INT/2015-02127

Contents

Introduction

The Innovative Medicines Initiative 2 (IMI2) Joint Undertaking is a public-private partnership between the European Union (European Commission) and EFPIA (the European Federation of Pharmaceutical Industry and Associations), implemented through public-private consortia to carry out research or other actions, where the EU provides funding and EFPIA and other members matching the EU funding with their own contributions (in kind and in cash). IMI2 has been set up[1] following the principles below:

- Research related to the future of medicine should be undertaken in areas where goals for societal need, public health and biomedical industry competitiveness are aligned. They require the pooling of resources and large-scale 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 .

IMI2 operates under the general rules of participation of the H2020 programme. A number of derogations however apply to these rules[2] due to the special characteristics of a public-private partnership.

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. The scientific priorities for 2015 for IMI2 have been prepared based on the SRA.

Applicant consortia are invited to submit a full proposal under this Call for proposals. These proposals should address all aspects of the Call. The size and composition of each consortium should be adapted so as to respond to the scientific goals and the expected key deliverables.

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 maximize European added value in health research. Where appropriate, the involvement of regulators is also strongly encouraged.

Before submitting a proposal, applicant consortia should familiarise themselves with all Call documents such as the IMI2 Manual for evaluation, submission and grant award[5], and the IMI2 evaluation criteria. Applicants should refer to the specific templates and evaluation procedures associated with Research and Innovation Actionsss (RIAs).

[1] The Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking.
[2] Regulation (EU) No 1290/2013 laying down the rules for Participation and dissemination in “Horizon 2020”; and Commission Delegated Regulation (EU) No 622/2014 establishing derogation from Regulation EU No 1290/2013 with regards to the Innovative Medicines Initiative 2 Joint Undertaking.
[3] Under the IMI2 JU, mid-sized companies having an annual turnover of EUR 500 million or less, 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] http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/IMI2_SubmissionManual_Dec2015.pdf

Ebola and other filoviral haemorrhagic fevers (Ebola+) programme: future outbreaks

Topic details

Topic code	IMI2-2015-08
Action type	Research and Innovation Actions (RIA)
Submission & evaluation process	Single stage

Background and problem statement

Viruses in the Ebolavirus and Marburg virus genera (family Filoviridae) have been associated with large outbreaks of haemorrhagic fever in human and nonhuman primates with high case fatality. Filovirus transmission among humans occurs through direct human-to-human contact or contact with their infectious bodily fluids, particularly in the late stages of infection, when viral loads are highest.

The recent outbreak of Ebola virus disease (EVD) in West Africa has reached historic proportions and underscores the vulnerability of populations worldwide to pathogens. Outbreaks of EVD have occurred in Africa in the past [1], however the current epidemic caused by Zaire Ebola virus [Guinea-Zaire Ebola virus H.sapiens-tc/GIN/2014/Gueckedou-C] (ZEBOV) [2], has been characterised by greater breadth and rapid spread.

Currently, there are no vaccines or antiviral drugs approved for prevention or treatment of filoviral infections in humans. However, the severity of the recent Ebola outbreak and failure of the health care system to contain the infection rates in West Africa underscore the need for the rapid development of safe and effective vaccines, treatments, and diagnostic tests that can be readily deployed in the field.

Recently, the G7 summit of 7-8 June 2015 reiterated the high-level political commitment to mobilise and disburse appropriate response capacities in a timely manner in order to prevent future outbreaks of EVD [3].

Need and opportunity for public-private collaborative research

Ebola and other filoviral haemorrhagic fevers is an area for which the expected return on investment into drug and vaccine development is low for a pharmaceutical company. At the same time, these diseases represent a great threat to nations worldwide. In case of an outbreak, diagnosis and deployment of the right measures to contain the outbreak is challenging in countries where the infrastructure may be limited. It is therefore an area where collaboration between different stakeholders, such as academic experts, the private industry, international aid organisations experienced in collaborations with countries at highest risk of being affected, regulatory agencies, and public health institutes, is a necessity.

Convergence between innovative small and medium-sized enterprises (SMEs), industries, and academic institutions will ensure that the best approaches are further exploited. International collaboration will bring together competences and facilities which are not available on a national level, and will contribute to maintaining European competitiveness in the field of biomedical research and innovation.

Scope

A programmatic approach addressing different challenges across the entire innovation cycle and leveraging input and multidisciplinary expertise across stakeholders was launched with the Ebola+ programme under IMI2 Call 2 in November 2014. As a result of this first Call, eight projects were funded and are now up and running, supporting different aspects of vaccine development, deployment, and rapid diagnostic tests[6]

This Call is the second Call under the Ebola+ programme and falls under the same broad scope. It provides an opportunity to capture emerging scientific advances and to progress those rapidly into health care interventions. Projects funded under this Call should ensure fast development, uptake and/or wide deployment of sustainable 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, including the mobilization of funds through the inclusion of contributing partners under the IMI programme of public-private consortia, as requested under 'Expected Impact'.

Proposals may address aspects of pre-clinical development and/or Phase 1, 2, and 3 clinical developments of vaccines (in particular multivalent), treatments and diagnosis of Ebola or other filovirus infections. Manufacturing strategies, vaccine stability during transport and storage, and/or deployment of vaccines and treatments are also in scope. Proposals for the development of adaptable platforms, which can address multiple other priority pathogens in addition to filoviruses are also eligible.

Proposals should clearly demonstrate that the latest knowledge and learning from the current epidemic are being taken into consideration and that work proposed is novel and innovative and expected to deliver clear added value. Applicants are encouraged to develop proposals that build on outcomes of research stemming from other programmes in this general area of research and innovation, national or international. In writing the proposal, applicants are invited to consider recommendations from the WHO (e.g. High-Level-Panel Health and Global Observatory for Health R&D). The partners in a proposed consortium must have the capability and capacity to broaden and fast-forward the results into validated treatments, preventive measures or accurate and fast diagnosis that will result in increased preparedness in case of future outbreaks. Collaboration with international organisations that were involved in the management of the 2014/2015 Ebola epidemic is encouraged.

Particular attention needs to be paid to ensure compliance with all ethical rules, notably those related to the conduct of clinical investigations and clinical trials.

Expected key deliverables

The key deliverables of projects funded under the Ebola+ programme must be outputs that will increase our preparedness to react to future outbreaks of Ebola and other filoviral haemorrhagic fevers. Key deliverables might include (but are not limited to) the following:

- the progression of a novel vaccine candidate, diagnostic or treatment up to a stage ready for testing in an outbreak setting;
- the development of tools to help with pre-clinical and clinical development of vaccine candidates and treatments (incl. Proof of Concept testing of existing platforms for screening compounds for Ebola and other filoviruses);
- the development and/or validation of a novel diagnostic test that is sufficiently sensitive, rapid, user-friendly, cheap, and usable in resource-limited settings;
- the development of novel strategies to improve the stability of vaccines against Ebola and other filoviral infections during transport and storage, e.g. which would allow storage at 8°C or ambient temperatures for prolonged durations;

[6] http://www.imi.europa.eu/content/ebola-programme

- the development of novel manufacturing and delivery strategies;
- the development of learning and strategies for optimal deployment and adherence to vaccination programmes;
- the facilitation of the exploitation of recent advances in our understanding of Ebola and other filoviral infections and the acceleration of their development into health care interventions.

Proposals might include a combination of the key deliverables, if warranted, for a positive impact on our readiness to react to future outbreaks of Ebola or other filoviral haemorrhagic fevers.

Every proposal should plan for a clearly defined strategy on how to ensure translation of the relevant project outputs into regulatory, clinical and healthcare practices, and ultimately into value for people in countries at risk of future outbreaks of filoviral haemorrhagic fevers. Activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem should take into account the country-level pharmacovigilance systems.

In that respect, a plan for interactions with regulatory agencies/health technology assessment bodies including relevant milestones and allocated resources should be proposed (e.g. qualification advice on the proposed methods for novel methodologies for drug development, qualification opinion).

A plan for aspects related to sustainability, facilitating continuation beyond the duration of the project, should also be proposed.

Under this Call, applicant consortia may intend to develop pre-existing product candidates (such as vaccines, medicines or diagnostics) owned by one of the beneficiaries. Under IMI2 rules, results generated are owned by the generating beneficiary. To encourage public and private partners to bring valuable proprietary assets to the IMI projects, the H2020/IMI2 rules allow the consortium to establish that the ownership of such results, when solely owned by a specific generating beneficiary, can be transferred to the owner of the initial background / asset. When the initial background owner would request such transfer, and to ensure the viability of the action, the applicant consortium shall try to do the necessary to accommodate such a request and indicate in the proposal how the request would be accommodated.

Expected impact

Proposals must contribute to the objectives of IMI2 and in particular to the goals of the Ebola+ programme which is a programmatic approach addressing different challenges across the entire innovation cycle and aims at leveraging input and multi-disciplinary expertise across stakeholders. IMI2 offers a unique opportunity to complement the ongoing European and international efforts by offering a multi-company, cross-sector and multi-stakeholder programmatic approach to address the various challenges of Ebola virus disease and other filoviral haemorrhagic fevers.

Specifically, proposals must increase the readiness to respond to future outbreaks of Ebola and other filoviral haemorrhagic fevers.

An important expected impact of projects funded under this Call and the Ebola+ programme in general must be to maximise the benefit to the people in the countries at risk from future outbreaks of filoviral haemorrhagic fevers. In order to achieve this, successful applicant consortia should have the capability to accelerate their project results into health care interventions.

Furthermore, proposals are expected to take advantage of and exploit support from different stakeholders with the necessary expertise, including the mobilization of funds through the inclusion of contributing partners under the IMI scheme of public-private consortia. Such contributing partners might include EFPIA companies or organizations associated to EFPIA, and Associated Partners to IMI2 JU[7]. The budgeted cost for the participation of such partners is expected to account for at least 40% of the total project cost.

[7] 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

Projects are expected to have a significant impact on global health, both at the individual and the public health level by leading to results that have a direct impact for persons at risk of exposure to filoviral diseases or for patients suffering from filoviral disease.

Potential synergies with existing consortia

Successful projects will be part of the Ebola+ programme, launched in the IMI2 2nd Call for proposal on 6 November 2014. Any project funded under the Ebola+ programme is expected to interact with other projects funded under the programme, and to adhere to the Ebola+ joint Scientific Advisory Board (established under the leadership of the EBOVAC 1 project[8]) and Ethics Board (established under the leadership of the EBOVAC2 project[9]). Projects are also expected to liaise with the Central Information Repository established under the leadership of the EBOVAC 1 project and to explore ways to share and make available data and learning as much as possible, both with participants in the various Ebola+ projects and with the scientific community in general.

In addition, any project funded under the Ebola+ programme is expected to synergise with the other EU-funded projects addressing the 2014/15 Ebola outbreak in West Africa that were recently launched under Horizon 2020 through a fast-track exceptional procedure [4].

In general, synergies and complementarities with other national and international projects, initiatives and international organisations involved in the management of the current Ebola epidemic 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.

Potential synergies with the IMI project ADVANCE[10] Accelerated development of vaccine benefit-risk collaboration in Europe should also be explored.

Indicative duration of the Call

This call for proposals is continuously open for a period of two years with the following cut-off dates for submission of proposals:

16 March 2016, 15 September 2016, 16 March 2017, 14 September 2017, 15 March 2018.

Indicative duration of the actions

Proposals should include a proposed duration for the action in relation to the activities and action work plan.

Indicative budget

The indicative financial contribution from the IMI2 JU for the entire period of 2 years will be a maximum of EUR 70 000 000.

The entire budget for this call will be available as from the first cut-off date. Three months prior to each subsequent cut-off date, the amount of the remaining budget will be published on the IMI2 website.

Following each cut-off date, all proposals received will be reviewed by a panel of independent experts according to the IMI2 Manual for submission, evaluation and grant award, and will be ranked in one single list. Proposals above threshold and within the available budget will be invited in ranked order to prepare a Grant

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.

[8] http://www.ebovac.org/

[9] http://www.ebovac2.com/

[10] http://www.advance-vaccines.eu/

Agreement. Therefore, proposals positively evaluated but falling outside the budget availability will be rejected.

Applicant consortium

Applicant consortia are expected to address all of the formulated objectives of the proposal and should cover the necessary expertise to meet the deliverables and ensure the expected impact.

The size and composition of each consortium should be adapted so as to respond to the scientific goals and the key deliverables.

In accordance with the Horizon 2020 Rules for Participation in order to be eligible, a proposal must be made by a consortium of at least three independent legal entities, each established in a different Member State or associated country.

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

Governance

In the spirit of the partnership, and to reflect that IMI2 call topics are built upon identified scientific priorities agreed together with EFPIA beneficiaries/large industrial beneficiaries, it is envisaged that IMI2 proposals and projects may allocate a leading role within the consortium to an EFPIA beneficiary/large industrial beneficiary. Within an applicant consortium it is expected that one of the EFPIA beneficiaries/large industrial beneficiaries may elect to become the coordinator or the project leader. Therefore to facilitate the formation of the final consortium, all beneficiaries are encouraged to discuss the weighting of responsibilities and priorities therein. Until the roles are formally appointed through a consortium agreement the proposed project leader shall facilitate an efficient negotiation of project content and required agreements.

References

[1] http://www.cdc.gov/vhf/ebola/outbreaks/history/chronology.html

[2] Baize, S. et al. Emergence of Zaire Ebola Virus Disease in Guinea. N. Engl. J. Med. (2014), 371, 15.

[3] http://www.state.gov/r/pa/prs/ps/2014/09/232122.htm#

[4] http://ec.europa.eu/research/health/infectious-diseases/emerging-epidemics/ebola-projects_en.html

Conditions for this Call for proposals

All proposals must conform to the conditions set out in the H2020 Rules for Participation (http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf) and the Commission Delegated Regulation with regard to IMI2 JU (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0622&from=EN)

The following general conditions shall apply to this IMI2 Call for proposals:

Applicants intending to submit a full proposal in response to this Call for proposals should read this topic text, the IMI2 Manual for submission, evaluation and grant award, the IMI2 RIA-IA evaluation form and other relevant documents (e.g. IMI2 model Grant Agreement).

Call Identifier	H2020-JTI-IMI2-2015-08-single-stage
Type of action	Research and Innovation Actions
Publication date	18 December 2015
Submission start date	18 December 2015
Submission deadlines (cut-off dates)	16 March 2016 – 17:00:00 Brussels time 15 September 2016 – 17:00:00 Brussels time 16 March 2017 – 17:00:00 Brussels time 14 September 2017 – 17:00:00 Brussels time 15 March 2018 – 17:00:00 Brussels time
Indicative budget	
From the IMI2 JU	a maximum of EUR 70 000 000

Call Topic

IMI2-2015-08	The total indicative financial contribution from the IMI2 JU for the entire period of 2 years is a maximum of EUR 70 000 000. The entire budget for this Call will be available as from the first cut-off-date. Three months prior to each subsequent cut-off date the amount of the remaining budget will be published on the IMI2 website.	Research and Innovation Actions. Single-stage submission and evaluation process. Proposals submitted at each cut-off date will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget availability and their ranking.

The following general conditions shall apply to this IMI2 Call 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 IMI2 JU:

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

In accordance with Article 10(2) point (a) of the Regulation (EU) No 1290/2013, in case of participating legal entity established in a third country, that is not eligible for funding according to point (a) above, funding from the IMI2 JU may be granted provided the participation is deemed essential for carrying out the action by the IMI2 JU.

Admissibility conditions for grant proposals and related requirements

Part B of the General Annexes[12] to the H2020 Work Programme shall apply *mutatis mutandis* for the actions covered by this Call for proposals.

Eligibility criteria

Part C of the General Annexes to the H2020 Work Programme 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 H2020 Work Programme shall apply *mutatis mutandis* for the actions covered by this Call for proposals.

[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

[12] http://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-ga_en.pdf

Technology Readiness Levels (TRL)

Part G of the General Annexes to the H2020 Work Programme shall apply *mutatis mutandis* for the actions covered by this Call for proposals.

Evaluation

Part H of the General Annexes to the H2020 Work Programme shall apply *mutatis mutandis* for the actions covered by this Call with the following exceptions:

The proposals are evaluated against the specific IMI2 evaluation criteria (Excellence, Impact and Quality and efficiency of the implementation)[13].

Type of action	Excellence	Impact	Quality and efficiency of the implementation
RIA and IA	The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the IMI2 annual work plan: clarity and pertinence of the objectives; 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 and to 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 listed in the IMI2 annual work plan under the relevant topic; 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;[14] 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 allocation of tasks and resources; 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 risk and innovation management and sustainability plan.

[13] http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/IMI2_Evaluation-Form_RIA-IA_en.pdf
[14] 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 the two first criteria, 'excellence' and 'impact' will be 4. The overall threshold, applying to the sum of the three individual scores, is 10.

These evaluation criteria include scores and thresholds. If a proposal fails to achieve the threshold for a criterion, the other criteria will not be assessed and the evaluation of the proposal will be discontinued.

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.

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

The full evaluation procedure is described in the IMI2 Manual for submission, evaluation and grant award in line with the H2020 Rules for Participation[15].

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

Under a continuous open call, a set of indicative cut-off dates (16 March 2016, 15 September 2016, 16 March 2017, 14 September 2017, 15 March 2018) are established.

Proposals will be evaluated and ranked by a panel of independent experts after the respective cut-off-dates.

The entire budget will be available as from the first cut-off-date.

Three months prior to each subsequent cut-off date the amount of the remaining budget will be published on the IMI2 website.

Eligibility criteria

Part C of the General Annexes to the H2020 Work Programme shall apply *mutatis mutandis* for the actions covered by this Call for Proposal with the following exception:

Types of action: specific provisions and funding rates

Part D of the General Annexes to the H2020 Work Programme shall apply *mutatis mutandis* for the actions covered by this Call for proposals.

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

Indicative timetable for evaluation and Grant Agreement

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

	Information on the outcome of the evaluation	**Indicative date for the signing of Grant Agreements**
IMI2-2015-08	Maximum 5 months from the submission deadline of the relevant cut-off date.	Maximum 8 months from the submission deadline of the relevant cut-off date.

Budget flexibility

Part I of the General Annexes to the H2020 Work Programme shall apply *mutatis mutandis* for the actions covered by this Call for proposals.

Financial support to third parties

Part K of the General Annexes to the H2020 Work Programme shall apply *mutatis mutandis* for the actions covered by this Call for proposals.

Submission tool

~~The IMI electronic submission tool **SOFIA** (Submission OF Information Application) is to be used for submitting a proposal in response to this Call; and **no other means of submission will be accepted**. Proposals may be finalised and re-opened online until the 'Submit' button is pressed. To trigger the admissibility check, eligibility check and the evaluation, firstly the 'Finalise' button and secondly the 'Submit' button must be pressed in SOFIA by the Call submission deadline.~~

~~Access to the IMI electronic submission tool SOFIA for the first time requires a request to access to the tool[16].~~

Starting from the fourth cut-off date, the H2020 Participant Portal submission tool is to be used for submitting a proposal in response to this Call; and **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:
~~http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-phc-2014-single-stage/1600139-essential_information_for_clinical_studies_en.pdf.~~

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

(link to template on IMI website will be available after Call publication)

~~[16] https://sofia.imi.europa.eu/Pages/RequestAccess.aspx~~

For proposals 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 proposals 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 IMI2 Call for proposals shall not be selected[17].

In order to ensure excellence in data and knowledge management, consortia will be requested to:

1. disseminate scientific publications on the basis of open access [18] (see Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020);
2. include a Data Management Plan outlining how research data will be handled during a research project, and after it is completed, as part of the full proposal. (see Guidelines on Data Management in Horizon 2020 providing guidance for the collection, processing and generation of research data). In order to ensure adherence to the legislation concerning protection of personal data, controlled access digital repositories and data governance will need to be considered;
3. use well-established data format and content standards in order to ensure interoperability to quality standards. Preferably existing standards should be adopted. Should no such standards exist, consideration should be given to adapt or develop novel standards in collaboration with a data standards organisation (e.g. CDISC);

disseminate a description of resources[19] according to well-established metadata standards such as the Dublin Core (ISO15836) in order to make the resources included and generated by IMI2 actions discoverable for metrics and re-use.

Proposals shall contain a draft plan for the exploitation and dissemination of the results.

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 signature of the 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] Examples of Resources are (a collection of) biosamples, datasets, images, publications etc.
[20] Regulation (EU) No 1290/2013 of 11 December 2013 and Commission Delegated Regulation (EU) No 622/2014 of 14 February 2014.