

## GENERAL CONDITIONS FOR THE CALL FOR PROPOSALS

### LIST OF COUNTRIES AND APPLICABLE RULES FOR FUNDING

By way of derogation<sup>1</sup> 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:

- 1) Legal entities established in a Member State or an associated country, or created under Union law; and
- 2) which fall within one of the following categories:
  - 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*;
  - secondary and higher education establishments;
  - non-profit organisations, including those carrying out research or technological development as one of their main objectives or those that are patient organisations.
- 3) The Joint Research Centre;
- 4) International European interest organisations.

### ADMISSIBILITY CONDITIONS FOR GRANT PROPOSALS, AND RELATED REQUIREMENTS

Part B of the General Annexes<sup>2</sup> to the EC Work Programme shall apply *mutatis mutandis* for the actions covered by this Call for Proposal.

### ELIGIBILITY CRITERIA

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

### TYPES OF ACTION: SPECIFIC PROVISIONS AND FUNDING RATES

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

### TECHNOLOGY READINESS LEVELS (TRL)

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

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<sup>1</sup> 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

<sup>2</sup> [http://ec.europa.eu/research/participants/data/ref/h2020/wp/2014\\_2015/annexes/h2020-wp1415-annex-ga\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-ga_en.pdf)

## EVALUATION

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

The criteria, scoring and threshold are described in the IMI2 Evaluation Criteria<sup>3</sup>, with the following exception: 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.

The full evaluation procedure is described in the IMI2 Manual for submission, evaluation and grant award.<sup>4</sup>

The proposals will be evaluated against the evaluation criteria (including scoring and threshold) and according to the evaluation procedure described in the Call text.

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 (first stage)	Information on the outcome of the evaluation (second stage)	Indicative date for the signing of grant agreements
Maximum 5 months from the date of submission to the first stage.	Maximum 5 months from the date of submission to the second stage.	Maximum 3 months from the date of informing the applicants following the second stage evaluation.

Where appropriate and duly justified, IMI 2 JU calls for proposals may follow a single or a two-stage process.

Under the single-stage process, all 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 the two-stage evaluation procedure, the applicant consortium of the highest ranked short proposal (stage 1) for each topic will be invited to discuss with the relevant industry consortium the feasibility of jointly developing a full proposal (stage 2). The applicant consortia of the second and third-ranked short proposals (stage 1) for each topic may be invited for preliminary discussions with the industry consortium if the preliminary discussions with the higher ranked proposal and the industry consortium fail. Such contacts should be done in priority order, i.e. the second ranked proposal should be contacted only after failure of pre-discussions with the first ranked, and the third after the second ranked.

<sup>3</sup> For Research and Innovation Actions, and Innovation Actions:

[http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2\\_Call1/IMI2\\_C1\\_S0\\_Evaluation\\_form.pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_Call1/IMI2_C1_S0_Evaluation_form.pdf)

For Coordination and Support Actions: [link to be added once published]

<sup>4</sup>[http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2\\_Call1/Manual\\_for\\_submission\\_evaluation\\_grant%20award\\_2014.06.26.pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_Call1/Manual_for_submission_evaluation_grant%20award_2014.06.26.pdf)

## BUDGET FLEXIBILITY

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

## FINANCIAL SUPPORT TO THIRD PARTIES

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

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.

## SUBMISSION TOOL

Unless otherwise stipulated in the relevant Call Conditions of the specific Call, the IMI electronic submission tool **SOFIA** (Submission OF Information Application) is to be used for submitting a proposal in response to a topic of the IMI2 Call; no other means of submission will be accepted. Updates of the proposals may be submitted online until the Call submission deadline. Proposals need to be formally submitted in the tool indicated in the Call text to trigger the admissibility and eligibility checks, and the peer review evaluation.

Access to the IMI electronic submission tool SOFIA first requires a request to access to the tool.

## 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/portal/doc/call/h2020/h2020-phc-2014-single-stage/1600139-essential\\_information\\_for\\_clinical\\_studies\\_en.pdf](http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-phc-2014-single-stage/1600139-essential_information_for_clinical_studies_en.pdf)

Ethical issues should be paid due attention for each of the submitted proposals.

In order to ensure excellence in Data and Knowledge Management, consortia will be requested to:

- 1) Disseminate scientific publications and research data on the basis of open access. Collection, processing and generation of research data is to follow documented data management procedures (see "[Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020](#)" and "[Guidelines on Data Management in Horizon 2020](#) "). 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.
- 2) 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 organization (e.g. CDISC).
- 3) In order to make the resources included and generated by the IMI Actions discoverable for metrics and re-use, consortia will be required to disseminate a description of resources<sup>5</sup> according to well-established metadata standards such as the Dublin Core (ISO15836). Proposals shall contain a draft plan for the exploitation and dissemination of the results.

Potential applicants must be aware that the Innovative Medicines Initiative 2 (IMI2) Joint Undertaking, if so foreseen in the relevant Call documents, may publish at a later stage another call for proposals restricted to those projects already selected under that call, if exceptionally needed to enhance their results and achievements and facilitate the delivery of new treatments to patients, by extending their duration and funding. Consortia would then be entitled to open to other beneficiaries as they see fit.

<sup>5</sup> Examples of Resources are (a collection of) biosamples, datasets, images, publications etc.