**First stage proposal in two-stage procedure**

**IMI2 PROPOSAL TEMPLATE**

(TECHNICAL ANNEX)

**Research and Innovation Actions**

**&**

**Innovation Actions**

|  |
| --- |
| This template is to be used at the 1st stage of a two-stage submission procedure. The structure of this template must be followed when preparing your proposal. It has been designed to ensure that the important aspects of your planned work are presented in a way that will enable the experts to make an effective assessment against the evaluation criteria. Sections 1, 2 and 3 each correspond to an evaluation criterion for a 1st stage proposal in a two-stage submission procedure. Please be aware that proposals will be evaluated as they were submitted, rather than on their potential if certain changes were to be made. This means that only proposals that successfully address all the required aspects will have a chance of being funded. * **Page limit**: For first stage proposals, the cover page, and sections 1, 2, 3 and 4 together should not be longer than 30 pages.

The page limit will be applied automatically; therefore you must remove this instruction page before submitting.If you attempt to upload a proposal longer than the specified limit before the deadline, you will receive an automatic warning and will be advised to shorten and re-upload the proposal. After the deadline, excess pages (in over-long proposals/applications) will be automatically made invisible, and will not be taken into consideration by the experts. The proposal is a self-contained document. Experts will be instructed to ignore hyperlinks to information that is specifically designed to expand the proposal, thus circumventing the page limit.Please, do not consider the page limit as a target! It is in your interest to keep your text as concise as possible, since experts rarely view unnecessarily long proposals in a positive light. * The following formatting conditions apply.

The reference font for the body text of IMI2 proposals is Times New Roman (Windows platforms), Times/Times New Roman (Apple platforms) or Nimbus Roman No. 9 L (Linux distributions). The use of a different font for the body text is not advised and is subject to the cumulative conditions that the font is legible and that its use does not significantly shorten the representation of the proposal in number of pages compared to using the reference font (for example with a view to bypass the page limit). The minimum font size allowed is 11 points. Standard character spacing and a minimum of single line spacing is to be used. Text elements other than the body text, such as headers, foot/end notes, captions, formula's, may deviate, but must be legible. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers). |

**COVER PAGE**

**Title of Proposal**

**List of participants**

|  |  |  |
| --- | --- | --- |
| **Participant No \*** | **Participant organisation name** | **Country** |
| 1 (Coordinator) |  |  |
| 2 |  |  |
| 3 |  |  |

\* Please use the same participant numbering as that used in the administrative proposal forms.

### Table of Contents

**1. EXCELLENCE**

### Objectives

* + - Describe the specific objectives for the project, which should be clear, measurable, realistic and achievable within the duration of the project. Objectives should be consistent with the expected exploitation and impact of the project (see section 2).
		- Explain how your proposal addresses the specific challenge and scope of the call topic text, as set out in the relevant IMI2 Annual Work Plan.

### Concept and methodology

### (a) Concept

* + - Describe and explain the overall concept underpinning the project. Describe the main ideas, models or assumptions involved. Identify any inter-disciplinary approaches and use of relevant stakeholder knowledge. Where relevant, include measures taken for public/societal engagement on issues related to the project. Describe the positioning of the project e.g. the unmet medical need addressed, where it is situated in the medicines development cycle (from early discovery to patient access). Refer to Technology Readiness Levels (TRLs) where relevant (see [General Annex G of the Work Programme](http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2018-2020/annexes/h2020-wp1820-annex-g-trl_en.pdf));
		- Describe any national or international research and innovation activities which will be linked with the project, especially where the outputs from these will feed into the project;

### (b) Methodology

* + - Describe and explain the overall methodology, distinguishing, as appropriate, activities indicated in the relevant section of the call topic text, e.g. for research, demonstration, piloting, first market replication, etc.
		- Where relevant, describe how *the gender dimension, i.e.* sex and/or gender analysis is taken into account in the project’s content.

* Please note that this question does not refer to gender balance in the teams in charge of carrying out the project but to the content of the planned research and innovation activities . Sex and gender analysis refers to biological characteristics and social/cultural factors respectively. For guidance on methods of sex / gender analysis and the issues to be taken into account, please refer to* [*http://ec.europa.eu/research/swafs/gendered-innovations/index\_en.cfm?pg=home*](http://ec.europa.eu/research/swafs/gendered-innovations/index_en.cfm?pg=home)

### Ambition

* + - Describe the advance your proposal would provide beyond the state-of-the-art, and the extent the proposed work is ambitious.
		- Describe the innovation potential which the proposal represents on how this could translate to the advantage of patients. (**e.g. novel concepts and approaches, new products, services or business and organisational models.)** Where relevant, refer to products and services already available on the market. Please refer to the results of any patent search carried out.

**2. IMPACT**

### 2.1 Expected impacts

* *Please address all bullet points. Please be specific, and provide only information that applies to the proposal and its objectives. Wherever possible, include baseline, targets and metrics to measure impact.*
* Demonstrate how the outputs of the project will contribute to each of the expected impacts mentioned in the relevant Call topic text;
* Outline how the project plans to leverage the public private partnership model to achieve greater impact on innovation within R&D, regulatory, clinical and healthcare practices, as relevant;
* Outline any barriers/obstacles, and any framework conditions (such as regulation and standards), that may determine whether and to what extent the expected impacts will be achieved;
* Outline how the project will impact on competitiveness and growth of companies including SMEs.

### 2.2 Outline Measures to maximise impact

* *Please address all bullet points. Please be specific, and provide only information that applies to the proposal and its objectives.*
* Dissemination, exploitation and sustainability of the project results;
* Management of research data;
* Communication measures for promoting the project to relevant target audiences.

**3. IMPLEMENTATION**

* 1. **Outline of project work plan — Work packages, and major deliverables**

Please provide the following:

* + - brief presentation of the overall structure of the project work plan;
		- timing of the different work packages and their components (Gantt chart or similar);
		- brief work description, i.e.:
			* a brief description of each work package, including contributing partners and approximate use of the resources;
			* a proposed list of deliverables.
* *Base your account on the logical structure of the project and the stages in which it is to be carried out. The number of work packages should be proportionate to the scale and complexity of the project.*
* *You are advised to include a distinct work package on ‘management’ (see section 3.2)*
* *Give due visibility in the project work plan to ‘data management’, ‘dissemination, exploitation and sustainability’ and ‘communication activities’, either with distinct tasks or distinct work packages.*
* *You must include a dedicated deliverable for a ‘plan for the dissemination and exploitation’ including sustainability of results within the first 6 months of the project.*
* *You must include a 'data management plan' as a distinct deliverable within the first 6 months of the project. A template for such a plan is given in the guidelines on data management in the* [*H2020 Online Manual*](http://ec.europa.eu/research/participants/docs/h2020-funding-guide/index_en.htm)*.*
* *Consider including a strategy for ensuring the translation of the projects results to drug development, regulatory/ Health Technology Assessment (HTA) settings (e.g. through scientific advice/ qualification advice /opinion, etc.), clinical and healthcare practices and/or decision making processes.*

#### Definitions:

*‘Work package’ means a major sub-division of the proposed project.*

*‘Deliverable’ means a distinct output of the project, meaningful in terms of the project's overall objectives and constituted by a report, a document, a technical diagram, a software etc. These can be further divided into meaningful interim outputs, particularly if the final deliverables are few and can only be achieved over several years.*

### Management structure and procedures

* + - Outline the organisational and decision-making structures;
		- Explain why the organisational structure and decision-making mechanisms are appropriate to the complexity and scale of the project;

### Consortium as a whole

* *The individual members of the consortium are described in a separate section 4. There is no need to repeat the same information here.*
* Describe the consortium. How will it match the project’s objectives, and bring together the necessary expertise? How do the members complement one another (and cover the value chain, where appropriate)?
* How does each member contribute to the project? Show that each has a valid role, and adequate resources in the project to fulfil that role;
* Describe engagement and input of relevant stakeholders (e.g. patients, health-care professionals, regulators, payers etc.) that would need to be involved to meet the project’s objectives;
* Describe a strategy to create a successful partnership with the industry consortium as mentioned in the Call topic text;
* **Other countries and international organisations**: if one or more of the participants requesting EU funding is based in a country or is an international organisation that is not automatically eligible for such funding (entities from Member States of the EU, from Associated Countries and from one of the countries in the exhaustive list included in General Annex A of the Work Programme are automatically eligible for EU funding), explain why the participation of the entity in question is essential to carrying out the project

### Table 3.4a: List of work packages

|  |  |  |
| --- | --- | --- |
| **Work package number** | **Work Package Title** | **Participants involved (Short Names)** |
|  |  |  |
|  |  |  |

 **Table 3.4b: List of Deliverables**

|  |  |  |
| --- | --- | --- |
|  **Work package number** | **Deliverable (number)** | **Deliverable name** |
|  |  |  |
|  |  |  |

**4. PARTICIPANTS**

* 1. **Participants (applicants)**

Please provide, for each participant, the following (if available):

* + - A brief description of the legal entity and its main tasks, with an explanation of how its profile matches the tasks in the proposal;
		- A brief curriculum vitae or description of the profile of the persons, including their gender who will be primarily responsible for carrying out the proposed research and/or innovation activities;
		- A list of up to 5 relevant publications, and/or products, services (including widely-used datasets or software), or other achievements relevant to the call content;
		- A list of up to 5 relevant previous projects or activities, connected to the subject of this proposal;
		- A brief description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work;
		- Any other supporting documents specified in the IMI2 JU Annual Work Plan for this call.