

IMI2 PROPOSAL TEMPLATE

FIRST STAGE PROPOSAL IN TWO-STAGE PROCEDURE

(TECHNICAL ANNEX)

RESEARCH AND INNOVATION ACTIONS & INNOVATION ACTIONS

Note: This is for information only. The definitive template for your call will be available in the submission system, which you can then use when writing your proposal.

Please follow the structure of this template 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 short proposal.

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. There will be no possibility for significant changes to content, budget and consortium composition during stage two other than changes resulting from the merger with the industry consortium.

⚠ Page limit: For first stage proposals, the cover page, and sections 1, 2, 3 and 4 together should not be longer than 30 pages, with no more than 5 pages for section 4 (Participants). All tables in these sections must be included within this limit. The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers).

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.

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

Your proposal must address an IMI2 JU Annual Work Plan topic for this call for proposals.

⚠ This section of your proposal will be assessed only to the extent that it is relevant to that topic.

1.1 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).

1.2 Relation to the call topic text.

Indicate the call topic to which your proposal relates, and explain how your proposal addresses the specific challenge and scope of that topic; meet all key objectives as set out in the topic text.

1.3 Concept and approach

- Describe and explain the overall concept underpinning the project. Describe the main ideas, models or assumptions involved. Identify any trans-disciplinary considerations. 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 access), the contribution to the IMI2 JU objectives;
- 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;
- Describe and explain the overall approach and methodology, distinguishing, as appropriate, activities indicated in the relevant section of the IMI2 JU Annual Work Plan, e.g. for research, demonstration, piloting, first market replication, etc. Describe how the necessary expertise have been mobilised to achieve the objectives of the topic, to ensure engagement of all relevant key stakeholders and to complement the industry consortium. Where relevant, describe how sex and/or gender analysis is taken into account in the project's content. When relevant elaborate on any ethics strategy that may be linked to the credibility of the proposed approach.

⚠ Sex and gender refer 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/science-society/gendered-innovations/index_en.cfm

1.4 Ambition

- Describe the advance your proposal would provide beyond the state-of-the-art, and to what extent the proposed work is ambitious. Your answer could refer to the ground-breaking nature of the objectives, concepts involved, issues and problems to be addressed, and approaches and methods to be used.
- Describe the innovation potential which the proposal represents on how this could translate to the advantage of patients. 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

1 Expected impacts

- ⚠** *Please be specific, and provide only information that applies to the proposal and its objectives. Wherever possible, use quantified indicators and targets.*
- Describe how your project will contribute to:
 - the expected impacts of the proposed approach as indicated in the Call text and in relation to the problem statement and objectives; if relevant describe the expected impact to advance regulatory, clinical and healthcare practice;
 - achieving a greater impact with respect to research and innovation by combining Horizon 2020 and private sector funds in a public-private partnership.
 - strengthening the competitiveness and industrial leadership or addressing specific societal challenges;
 - improving European citizens' health and wellbeing and contribute to the IMI2 JU objectives;
 - Describe 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.

3. IMPLEMENTATION

3.1 Outline of project plan — Work packages, and major deliverables

Please provide the following:

- Brief presentation of the overall structure of the project 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 approximate use of the IMI budget;
 - a proposed list of major deliverables;
 - the roles and contribution of the partners;
 - How it is envisaged the collaboration with industrial partners, in particular how the integration of their expertise and assets, as described in the call text, will happen in the future public-private consortium which will be established under this topic.
- ⚠** *Base your account on the logical structure of the project and the stages in which it is to be carried out. Include preliminary resource allocation to each work package. 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) and to give due visibility in the project plan to 'data management', dissemination and exploitation' and 'communication activities', either with distinct tasks or distinct workpackages.*
- ⚠** *If relevant consider including strategy for:*

Please refer to submission system for the definitive template for your call

- implementation of the projects results in the drug development, regulatory setting, clinical and healthcare practices and/or decision making processes;
- interaction with regulators/HTA bodies (e.g through Qualification advice /opinion, etc..) to achieve the uptake of these results;
- engagement with other relevant stakeholders (e.g patients, prescribers, payers etc..) that would need to be involved in translation process.

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.

3.2 Management structure and procedures

- Outline the organisational, the decision-making structures and partnership with industry. Explain why the organisational structure and decision-making mechanisms are appropriate to the complexity and scale of the project as well as the manageability of the consortium.
- Describe, where relevant, how effective innovation management will be addressed in the management structure and project plan.
- ⚠ *Innovation management is a process which requires an understanding of both market and technical problems, with a goal of successfully implementing appropriate creative ideas. A new or improved product, service or process is its typical output. It also allows a consortium to respond to an external or internal opportunity.*

3.3 Consortium as a whole

- ⚠ *The individual members of the consortium are described in a separate section 4. There is no need to repeat that information here.*
- Describe the consortium. How will it match the project's objectives? How do the members complement one another (and cover the value chain, where appropriate)? In what way does each of them contribute to the project? How will they be able to work effectively together? How is the partnership with the industry consortium envisaged?

3.4 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

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4. PARTICIPANTS

4.1. 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.