IMI2 PROPOSAL TEMPLATE

SECOND STAGE PROPOSAL

IN TWO-STAGE PROCEDURE

& SINGLE STAGE PROPOSAL

(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 full 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 grant preparation other than changes resulting from the merger with the industry consortium.

⚠ **Page limit:** For full proposals, the cover page, and sections 1, 2 and 3, together should not be longer than 70 pages. 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).

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.

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

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.

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

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1. EXCELLENCE

Your proposal must address a 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 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 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 the 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

2.1 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 objectives;

  - any other environmental and socially important impacts (if not already covered above).

- 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. (This should not include any risk factors concerning implementation, as covered in section 3.2.)

2.2 Measures to maximise impact

a) Dissemination and exploitation of results

- When stated in the work plan, provide a draft 'plan for the dissemination and exploitation of the project's results'.

  ⚠️ *Dissemination and exploitation measures should address the full range of potential users and uses including research, commercial, investment, social, environmental, policy making, setting standards, skills and educational training.*

  ⚠️ *The approach to innovation should be as comprehensive as possible, and must be tailored to the specific technical, market and organisational issues to be addressed.* Explain how the proposed measures will help to achieve the expected impact of the project. Include a business plan where relevant.

- Where relevant, include information on how the participants will manage the research data generated and/or collected during the project, in particular addressing the following issues:

  - What types of data will the project generate/collect?What standards will be used?

  - How will this data be exploited and/or shared/made accessible for verification and re-use? If data cannot be made available, explain why.

  o How will this data be curated and preserved?

⚠️ *You will need an appropriate consortium agreement to manage (amongst other things) the ownership and access to key knowledge (IPR, data etc.). Where relevant, these will allow you, collectively and individually, to pursue market opportunities arising from the project's results.*

⚠️ *The appropriate structure of the consortium to support exploitation is addressed in section 3.3.*

- Outline the strategy for knowledge management and protection. Include measures to provide open access (free on-line access, such as the 'green' or 'gold' model) to peer-reviewed scientific publications which might result from the project[1].

⚠️ *Open access publishing (also called 'gold' open access) means that an article is immediately provided in open access mode by the scientific publisher. The associated costs are usually shifted away from readers, and instead (for example) to the university or research institute to which the researcher is affiliated, or to the funding agency supporting the research.*

⚠️ *Self-archiving (also called 'green' open access) means that the published article or the final peer-reviewed manuscript is archived by the researcher - or a representative - in an online repository before, after or alongside its publication. Access to this article is often - but not necessarily - delayed ('embargo period'), as some scientific publishers may wish to recoup their investment by selling subscriptions and charging pay-per-download/view fees during an exclusivity period.*

b) Communication activities

Describe the proposed communication measures for promoting the project and its findings during the period of the grant. Measures should be proportionate to the scale of the project, with clear objectives. They should be tailored to the needs of various audiences, including groups beyond the project's own community. Where relevant, include measures for public/societal engagement on issues related to the project as well as a plan for interactions with stakeholders in particular with Regulatory Agencies/health technology assessment bodies (This should be further detailed and reflected in section 3.1 Project plan with proper resouces allocated)

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3. IMPLEMENTATION

3.1 Project plan — Work packages, deliverables and milestones

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);

- detailed work description, i.e.:

  o a description of each work package (table 3.1a);

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[1] Open access must be granted to all scientific publications resulting from Horizon 2020 actions. Further guidance on open access is available in the H2020 Online Manual on the Participant Portal.

[PROPOSAL ACRONYM]

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- o a list of work packages (table 3.1b);
- o a list of major deliverables (table 3.1c);
  - graphical presentation of the components showing how they inter-relate (Pert chart or similar).

⚠ *Give full details. Base your account on the logical structure of the project and the stages in which it is to be carried out. Include details of the resources to be allocated to each work package. The number of work packages should be proportionate to the scale and complexity of the project.*

⚠ *You should give enough detail in each work package to justify the proposed resources to be allocated and also quantified information so that progress can be monitored, including by the Commission.*

⚠ *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 work packages.*

⚠ *You will be required to include an updated (or confirmed) 'plan for the dissemination and exploitation of results' in both the periodic and final reports. (This does not apply to topics where a draft plan was not required in the relevant work plan) This should include a record of activities related to dissemination and exploitation that have been undertaken and those still planned. A report of completed and planned communication activities will also be required.*

⚠ *If relevant consider including strategy for:*

- *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.*

⚠ *The expected deliverables and milestones should also be sufficiently broken down to allow, as far as possible, for the annual reporting and monitoring of the progress and outputs of the project.*

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.

'Milestones' means control points in the project that help to chart progress. Milestones may correspond to the completion of a key deliverable, allowing the next phase of the work to begin. They may also be needed at intermediary points so that, if problems have arisen, corrective measures can be taken. A milestone may be a critical decision point in the project where, for example, the consortium must decide which of several technologies to adopt for further development. They can also be divided into meaningful interim milestones in order to be able to report annually on progress against these control points.

3.2 Management structure and procedures

- Describe the organisational structure and the decision-making (including a list of milestones (table 3.2a)).

- Explain why the organisational structure and decision-making mechanisms are appropriate to the complexity and scale of the project.

- 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.*

- Describe any critical risks, relating to project implementation, that the stated project's objectives may not be achieved. Detail any risk mitigation measures. Please provide a table with critical risks identified and mitigating actions (table 3.2b).

- Describe a sustainability plan beyond the end of the grant agreement.

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 do the industrial partners contribute to the project? (where relevant);

- If applicable, describe the industrial/commercial involvement in the project to ensure exploitation of the results and explain why this is consistent with and will help to achieve the specific measures which are proposed for exploitation of the results of the project (see section 2.2).

- **Other countries**: If one or more of the participants requesting EU funding is based in a country that is not automatically eligible for such funding , explain why the participation of the entity(ies) in question is essential to carrying out the project

3.4 Resources to be committed

⚠ *Please make sure the information in this section matches the costs as stated in the budget table in section 3 of the administrative proposal forms, and the number of person/months, shown in the detailed work package descriptions.*

Please provide the following:

- a table showing number of person/months required (table 3.4a)

- a table showing 'other direct costs' (table 3.4b) for participants where those costs exceed 15% of the personnel costs (according to the budget table in section 3 of the administrative proposal forms)

- For Industry participants, in cases of non-EU in kind contribution, please specify the amount and related activities.

Table 3.1a: Work package description

For each work package:

Work package number		Start Date or Starting Event					
Work package title							
Participant number							
Short name of participant							
Person/months per participant:							

Objectives

Description of work (where appropriate, broken down into tasks), lead partner and role of participants

Deliverables (brief description and month of delivery)

Table 3.1b: **List of work packages**

Work package No	Work Package Title	Lead Participant No	Lead Participant Short Name	Person-Months	Start Month	End month
				Total months		

Table 3.1b: **List of work packages**

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Table 3.1c: List of Deliverables

Deliverable (number)	Deliverable name	Work package number	Short name of lead participant	Type	Dissemination level	Delivery date

KEY

Deliverable numbers in order of delivery dates. Please use the numbering convention <WP number>.<number of deliverable within that WP>.

For example, deliverable 4.2 would be the second deliverable from work package 4.

Type:
Use one of the following codes:
 R: Document, report (excluding the periodic and final reports)
 DEM: Demonstrator, pilot, prototype, plan designs
 DEC: Websites, patents filing,   press & media actions, videos, etc.
 OTHER: Software, technical diagram, etc.

Dissemination level:
Use one of the following codes:
 PU = Public, fully open, e.g. web
 CO = Confidential, restricted under conditions set out in Model Grant Agreement
 CI = Classified, information as referred to in Commission Decision 2001/844/EC.

Delivery date
Measured in months from the project start date (month 1)

Table 3.2a: List of milestones

Milestone number	Milestone name	Related work package(s)	Estimated date	Means of verification

KEY

Estimated date
Measured in months from the project start date (month 1)

Means of verification
Show how you will confirm that the milestone has been attained. Refer to indicators if appropriate. For example: a laboratory prototype that is 'up and running'; software released and validated by a user group; field survey complete and data quality validated.

Table 3.2b: Critical risks for implementation

Description of risk	Work package(s) involved	Proposed risk-mitigation measures

Table 3.4a: Summary of staff effort

Please indicate the number of person/months over the whole duration of the planned work, for each work package, for each participant. Identify the work-package leader for each WP by showing the relevant person-month figure in bold.

	WPn	WPn+1	WPn+2	Total Person/ Months per Participant
Participant Number/Short Name				
ParticipantNumber/ Short Name				
Participant Number/ Short Name				
Total Person/Months				

Table 3.4b: 'Other direct cost' items (travel, equipment, other goods and services, large research infrastructure)

Please complete the table below for each participant if the sum of the costs for' travel', 'equipment', and 'goods and services' exceeds 15% of the personnel costs for that participant (according to the budget table in section 3 of the proposal administrative forms).

Participant Number/Short Name	**Cost (€)**	**Justification**
Travel		
Equipment		
Other goods and services		
Total		

Please complete the table below for all participants that would like to declare costs of large research infrastructure under Article 6.2 of the General Model Agreement[2], irrespective of the percentage of personnel costs. Please indicate (in the justification) if the beneficiary's methodology for declaring the costs for large research infrastructure has already been positively assessed by the Commission.

Participant Number/Short Name	**Cost (€)**	**Justification**
Large research infrastructure		

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[2]   Large research infrastructure means research infrastructure of a total value of at least EUR 20 million, for a beneficiary. More information and further guidance on the direct costing for the large research infrastructure is available in the H2020 Online Manual on the Participant Portal.

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4.	MEMBERS OF THE CONSORTIUM

⚠️ *This section is not covered by the page limit.*

⚠️ *The information provided here will be used to judge the operational capacity.*

4.1. Participants (applicants)

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

- a 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 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 work plan for this call.]

4.2. Third parties involved in the project (including use of third party resources)

Please complete, for each participant, the following table (or simply state "No third parties involved", if applicable):

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y/N
If yes, please describe and justify the tasks to be subcontracted	
Does the participant envisage that part of its work is performed by linked third parties[3]	Y/N
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	Y/N
If yes, please describe the third party and their contributions	

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[3] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

5.	ETHICS

⚠️ *This section is not covered by the page limit.*

If you have entered any ethics issues in the ethical issue table in the administrative proposal forms, you must:

- submit an ethics self-assessment, which:

  o describes how the proposal meets the national legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out;

  o explains in detail how you intend to address the issues in the ethical issues table, in particular as regards:

    - research objectives (e.g. study of vulnerable populations, dual use, etc.)

    - research methodology (e.g. clinical trials, involvement of children and related consent procedures, protection of any data collected, etc.)

    - the potential impact of the research (e.g. dual use issues, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing, malevolent use , etc.).

- provide the documents that you need under national law(if you already have them), e.g.:

  o an ethics committee opinion;

  o the document notifying activities raising ethical issues or authorising such activities

  ⚠️ *If these documents are not in English, you must also submit an English summary of them (containing, if available, the conclusions of the committee or authority concerned).*

  ⚠️ *If you plan to request these documents specifically for the project you are proposing, your request must contain an explicit reference to the project title.*