



Research and Innovation Actions (RIA) Innovation Actions (IA)

IMI2 Proposal template Second stage proposal in two-stage submission procedure & Single stage proposal

Version 1.5 9 April 2019

Disclaimer

This document is aimed at informing potential applicants for Horizon 2020 funding. It serves only as an example. The actual Web forms and templates, provided in the online proposal submission system under the Participant Portal, might differ from this example. Proposals must be prepared and submitted .via the online proposal submission system under the Participant Portal.

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History of changes

Version	Date	Change	Page
1.0	30 June 2014	First version	
1.1	3 November 2014	Clarified page limit text	3
1.2	10 March 2016	Updated according the revision of the evaluation criteria in Annual Work Plan 2016	All
1.3	14 April 2016	Modification on criteria two-stage evaluation procedure	all
1.4	23 October 2017	Updated information on proposal page limit	3
1.5	9 April 2019	Updated according the revision of the evaluation criteria in Annual Work Plan 2019	all



IMI2 PROPOSAL TEMPLATE

SECOND STAGE PROPOSAL IN TWO-STAGE PROCEDURE & SINGLE STAGE PROPOSAL

(TECHNICAL ANNEX)

RESEARCH AND INNOVATION ACTIONS

&

INNOVATION ACTIONS

This template is to be used in a single- stage submission procedure or at the 2nd 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.

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.

Page limit: The title, list of participants and sections 1, 2 and 3, together, should not be longer than 70 pages. All tables, figures, references and any other element pertaining to these sections must be included as an integral part of these sections and are thus counted against this page limit.

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 H2020 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

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).
- 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.

1.2 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);
- 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

1.3 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

- A 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;
 - Demonstrate 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;
 - 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.);
 - Describe how the project will impact on competitiveness and growth of companies including SMEs.

2.2 Measures to maximise impact

a) Dissemination, exploitation and sustainability of results

• Provide a draft 'plan for the dissemination and exploitation' including sustainability of the project's results. Please note that such a draft plan is an <u>admissibility condition</u>, unless the call topic text explicitly states that such a plan is not required.

Explain how the proposed measures will help to achieve the expected impact of the project.

The plan, should be proportionate to the scale of the project, and should contain measures to be implemented both during and after the end of the project.

- A Your 'plan for the dissemination and exploitation' including sustainability of the project's results is key to maximising their impact. This plan should describe, in a concrete and comprehensive manner, the area in which you expect to make an impact and who are the potential users of your results.
- 4 Your plan should also describe how you intend to use the appropriate channels of dissemination and interaction with potential users
- Consider the full range of potential users and applications including research, commercial, investment, social, environmental, policy making, setting standards, skills and educational training where relevant.
- Your plan should give due consideration to the possible follow-up of your project, once it is finished. Its exploitation could require additional investments, wider testing or scaling up. Its exploitation could also require other pre-conditions like regulation to be adapted, or value chains to adopt the results, or the public at large being receptive to your results.
- 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 reuse? If data cannot be made available, explain why.
- o How will this data be curated and preserved?
- o How will the costs for data curation and preservation be covered?
- All IMI2 JU actions participate in the extended 'Pilot on Open Research Data in Horizon 2020 ('open research data by default'), except if they indicate otherwise ('opt-out'.)¹
- 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 project².
 - ⚠ 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.

[PROPOSAL ACRONYM]

Opting out of the Open Research Data Pilot is possible, both before and after the grant signature. For further guidance on open research data and data management, please refer to the <u>H2020 Online Manual</u> on the Participant Portal.

² 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.

3. IMPLEMENTATION

3.1 Project work plan — Work packages, deliverables and milestones

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);
- detailed work description, i.e.:
 - o a list of work packages (table 3.1a);
 - a description of each work package (table 3.1b);
 - 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. The number of work packages should be proportionate to the scale and complexity of the project.
- 4 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 IMI2 JU.
- A Resources assigned to work packages should be in line with their objectives and deliverables. You are advised to include a distinct work package on 'management' (see section 3.2) and to give due visibility in the project work plan to 'data management', 'dissemination, exploitation and sustainability of results' and 'communication activities', either with distinct tasks or distinct work packages.
- You will be required to propose a 'plan for the dissemination and exploitation' including sustainability of results in the full proposal. This must also be a captured in your work plan as a dedicated deliverable within the first 6 months of the project. An updated plan will also be required in both the periodic and final reports. This should include a record of activities related to dissemination, exploitation and sustainability that have been undertaken and those still planned. A report of completed and planned communication activities will also be required.
- 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 <u>H2020 Online Manual</u>. This deliverable will evolve during the lifetime of the project in order to present the status of the project's reflections on data management.

Definitions:

'Work package' means a major sub-division of the proposed project.

'<u>Deliverable</u>' 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.

3.2 Management structure, milestones 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).

Definition

'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.

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, 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.
 - Clearly describe the contribution of the industrial partners and their effective integration to the project?
 - Describe engagement and input of relevant stakeholders (e.g. patients, health-care professionals, regulators, HTA bodies, payers etc..) that would need to be involved to meet the project's objectives
 - Other countries and international organisations: If one or more of the participants requesting JU funding (or receiving financial contribution from EFPIA partners or IMI2 JU Associated Partners) 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 are automatically eligible for JU funding) explain why the participation of the entity(ies) in question is essential to carrying out the project.

3.4 Resources to be committed

A 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).
- In cases where EFPIA and IMI2 Associated Partners are providing non-EU in kind contributions, please specify the amount and related activities (table 3.4c).

- In cases where EFPIA and IMI2 Associated Partners (Beneficiaries Not Receiving Funding, BNRFs) are providing financial contributions to Beneficiaries Receiving Funding (BRFs), please specify the amount, the recipient and related activities (table 3.4d).
- In cases where EFPIA and IMI2 Associated Partners are carrying out scientifically relevant activities for generating data / collecting samples in prospective activities, please specify the cost and provide a description of samples/data and rationale for inclusion (table 3.4e).

Tables for section 3.1

Table 3.1a: List of work packages

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

Table 3.1b: Work package description

For each work package:

Work package number	Lead	Beneficia	ry		
Work package title					
Participant number					
Short name of participant					
Person months per participant:					
participant.					
Start month			End		
			month		

Objectives			

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

Deliverables (brief description and month of delivery)	

Table 3.1c: List of Deliverables³

Deliverable (number)	Deliverable name	Work package number	Short name of lead participant	Туре	Dissemination level	Delivery date (in months)

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)

³ You must include a data management plan as a distinct deliverable within the first 6 months of the project. This deliverable will evolve during the lifetime of the project in order to present the status of the project's reflections on data management. A template for such a plan is available in the H2020 Online Manual on the Participant Portal. [PROPOSAL ACRONYM]

Tables for section 3.2

Table 3.2a: List of milestones

Milestone number	Milestone name	Related work package(s)	Due date (in months)	Means of verification

KEY

Due 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 (indicate level of likelihood: Low/Medium/High)	Work package(s) involved	Proposed risk-mitigation measures

Definition critical risk:

A critical risk is a plausible event or issue that could have a high adverse impact on the ability of the project to achieve its objectives.

Level of likelihood to occur: Low/medium/high

The likelihood is the estimated probability that the risk will materialise even after taking account of the mitigating measures put in place.

Tables for section 3.4

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 personmonth 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	Cost	Justification
Number/Short Name	(€)	
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 Agreement⁴, 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	Cost	Justification
Number/Short Name	(€)	
Large research		
infrastructure		

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.
[PROPOSAL ACRONYM]

Table 3.4c: EFPIA and IMI2 Associated Partners non-EU in kind contributions.

Please complete the table below with a separate row for each EFPIA and IMI2 Associated Partner bringing non-EU contributions

	Non-EU activities and justification
Participant Number/Short Name	

Table 3.4d: Financial contributions (FCs) provided by EFPIA and IMI2 Associated Partners (BNRFs) to beneficiaries receiving funding

For each financial contribution provided by EFPIA and IMI2 Associated Partners (BNRFs) to beneficiaries receiving funding (BRFs), please complete the table below.

FC provided	FC received	Amount (€)	Related activities
BNRF Number/Short	BRF Number/Short		
Name	Name		

Table 3.4e: Scientifically relevant activities of EFPIA and IMI2 Associated Partners for generating data / collecting samples in prospective activities

Where EFPIA and IMI2 Associated Partners are carrying out scientifically relevant activities for generating data / collecting samples in prospective activities that are part of broader clinical studies independent from, but carried out in connection with the action and necessary for achieving its objectives, please complete the following table. Include numbers and all data types where available. Full details of the samples and data from the broader clinical studies must be provided as a distinct deliverable during the project.

	Cost (€)	Description of samples/data and rationale for inclusion
Participant Number/Short Name		
Total		

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;
- If operational capacity cannot be demonstrated at the time of submitting the proposal, describe the concrete measures that will be taken to obtain it by the time of the implementation of the task
- [Any other supporting documents specified in the IMI2 JU Annual 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 ⁵	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		
Does the participant envisage that part of the work is performed by	Y/N	

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).

[PROPOSAL ACRONYM]

International Partners ⁶ (Article 14a of the General Model Grant Agreement)?	
If yes, please describe the International Partner(s) and their contributions	

⁶ 'International Partner' is any legal entity established in a non-associated third country which is not eligible for funding under Article 10 of the Rules for Participation Regulation No 1290/2013.
[PROPOSAL ACRONYM]

5. ETHICS AND SECURITY

⚠ This section is not covered by the page limit.

5.1 Ethics

▲ For more guidance, see the document "How to complete your ethics self-assessment".

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:
 - Obscribes 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;
 - 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.:
 - An ethics committee opinion;
 - 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.

5.2 Security⁷

Please indicate if your project will involve:

- o activities or results raising security issues: (YES/NO)
- 'EU-classified information' as background or results: (YES/NO)

⁷ See article 37 of the IMI2 <u>Model Grant Agreement</u>. For more information on the classification of Information, please refer to the Horizon 2020 guidance: https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/secur/h2020-hi-guide-classif_en.pdf