

# H2020 Programme

# Proposal template 2016-2017

Administrative forms (Part A)
Project proposal (Part B)

SME instrument Phase 1

Version 3.1 21 February 2017

#### 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.

#### **HISTORY OF CHANGES Publication** Version Change **Page Date** 11.12.2013 Initial version 1.0 1.1 27.02.2014 Information on Evaluation added - scoring of proposals as 1 they were submitted, rather than on their potential if certain changes to be made (Part B) 1.2 10.03.2014 Part A added 7 2.0 new links added to WP16-17 General Annexes 2 28.01.2016 sentence inserted in instruction page: "The page limit will be 1 applied automatically, therefore you must remove this instruction page before submitting." + page numbers starting at cover page 6 subtitles "Tables for section 3.n" added in the tables section 7 explanations on third party parties and subcontracts have been added to section 4.1 3.0 21.12.2016 Part A In ethics issues table: Sub-question on 'destruction of Human embryos' added (S1) 9 Questions on 'Dual use' and 'Misuse' redrafted (S8, S10) 11 'Exclusive focus on civil applications' added (S9) 11 • SME-status updated calculation method: the system reads now the closing date of the accounts for the financial year on which the assessment of the SME status was based. The confirmation of the SME status applies for two years. Part B new instructions added cover small correction in paragraph numbering "4.1" par.4 replacement of "malevolent use" by "misuse" par.5.1 reference to ethics guidance on the Participant Portal par.5.1 removal of the security paragraph 5.2 since it is not par.5.2 applicable to this type of action 3.1 21.02.2017 additional bullet point under expected impacts: addressing par. climate change or the environment, or bringing other 2.1.a important benefits to society

## **Horizon 2020**

**Topic:** 

Type of action:

**Proposal number:** 

Proposal acronym:

Deadline Id:

Table of contents

Section	Title	Action
1	General information	
2	Participants & contacts	
3	Budget	
4	Ethics	
5	Call-specific questions	

## How to fill in the forms

The administrative forms must be filled in for each proposal using the templates available in the submission system. Some data fields in the administrative forms are pre-filled based on the previous steps in the submission wizard.

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Proposal ID

Acronym

## 1 - General information

Proposal title\*

Max 200 characters (with spaces). Must be understandable for non-specialists in your field.

Note that for technical reasons, the following characters are not accepted in the Proposal Title and will be removed: < > " &

Duration in months

Estimated duration of the project in full months.

Free keywords

Enter any words you think give extra detail of the scope of your proposal (max 200 characters with spaces).

#### **Abstract**

Short summary (max. 2,000 characters, with spaces) to clearly explain:

- Your project and intended business concept highlight the technical and/or innovative achievements and future challenges.
- Describe the expected product/solutions and the commercial potential. Please highlight clearly the innovation content of the envisaged concept.
- Describe the potential users/customers and their needs and how these needs are met through the outcome of the project.
- Describe the feasibility assessment intended to be undertaken under Phase 1 and, where appropriate, your intentions regarding potential Phase 2 funding.
- Include in the description also the expected European/global dimension in terms of addressing European/global challenges and markets.

Will be used as the short description of the proposal in the evaluation process and in communications with the programme management committees and other interested third parties.

Do not include any confidential information.

Use plain typed text, avoiding formulae and other special characters.

For the European/international dimension of the action, it is common practice to submit proposals in English. If the proposal is written in another language than English, please include an English version of this abstract in the "Technical Annex" section.

Remaining characters

2000

Has this proposal (or a very similar one) been submitted in the past 2 years in response to a call for proposals under the 7th Framework Programme, Horizon 2020 or any other EU programme(s)?

Yes No

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#### **Declarations**

1) The coordinator or sole applicant declares to have the explicit consent of all applicants on their participation and on the content of this proposal.	
2) The information contained in this proposal is correct and complete.	
3) This proposal complies with ethical principles (including the highest standards of research integrity — as set out, for instance, in the <u>European Code of Conduct for Research Integrity</u> — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct).	
4) The coordinator or sole applicant confirms:	
- to have carried out the self-check of the financial capacity of the organisation on <a href="https://ec.europa.eu/research/participants/portal/desktop/en/organisations/lfv.html">https://ec.europa.eu/research/participants/portal/desktop/en/organisations/lfv.html</a> . Where the result was "weak" or "insufficient", the coordinator confirms being aware of the measures that may be imposed in accordance with the H2020 Grants Manual (Chapter on Financial capacity check); or	0
- is exempt from the financial capacity check being a public body including international organisations, higher or secondary education establishment or a legal entity, whose viability is guaranteed by a Member State or associated country, as defined in the H2020 Grants Manual (Chapter on Financial capacity check); or	0
- as sole participant in the proposal is exempt from the financial capacity check.	0
5) The coordinator or sole applicant hereby declares that each applicant has confirmed:	
- they are fully eligible in accordance with the criteria set out in the specific call for proposals; and	
- they have the financial and operational capacity to carry out the proposed action.	
The coordinator is only responsible for the correctness of the information relating to his/her own organisation. I applicant remains responsible for the correctness of the information related to him and declared above. Where to be retained for EU funding, the coordinator and each beneficiary applicant will be required to present a form declaration in this respect.	the proposal

According to Article 131 of the Financial Regulation of 25 October 2012 on the financial rules applicable to the general budget of the Union (Official Journal L 298 of 26.10.2012, p. 1) and Article 145 of its Rules of Application (Official Journal L 362, 31.12.2012, p. 1) applicants found guilty of misrepresentation may be subject to administrative and financial penalties under certain conditions.

#### Personal data protection

Your reply to the grant application will involve the recording and processing of personal data (such as your name, address and CV), which will be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Unless indicated otherwise, your replies to the questions in this form and any personal data requested are required to assess your grant application in accordance with the specifications of the call for proposals and will be processed solely for that purpose. Details concerning the processing of your personal data are available on the <u>privacy statement</u>. Applicants may lodge a complaint about the processing of their personal data with the European Data Protection Supervisor at any time.

Your personal data may be registered in the Early Warning System (EWS) only or both in the EWS and Central Exclusion Database (CED) by the Accounting Officer of the Commission, should you be in one of the situations mentioned in:

- -the Commission Decision 2008/969 of 16.12.2008 on the Early Warning System (for more information see the Privacy Statement), or
- -the Commission Regulation 2008/1302 of 17.12.2008 on the Central Exclusion Database

(for more information see the  $\underline{\text{Privacy Statement}})$  .

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# List of participants

#	Participant Legal Name	Country
1		

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Proposal ID Acronym Short name

## 2 - Administrative data of participating organisations

PIC	Legal name
Short name:	
Address of the organ	nisation
Street	
Town	
Postcode	
Country	
Webpage	
Legal Status of y	your organisation
Research and Inn	novation legal statuses
Public body	unknown Legal personunknown
Non-profit	unknown
International organis	ationunknown
International organis	ation of European interestunknown
Secondary or Higher	r education establishment unknown
Research organisation	onunknown
Enterprise Data	
SME self-declared st	tatusunknown
SME self-assessmer	nt unknown
SME validation sme.	unknown
Based on the above d	letails of the Beneficiary Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.
NACE Code: -	

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Department 1		
Department name		not applicable
	Same as organisation address	
Street	Please enter street name and number.	
Town		
Postcode		
Country		

7***, F	European Commission Research & Innovation - Participan Proposal Submission For	20 10		
Proposal ID	Acronym	Short name		
Person in char	ge of the proposal			
	ail of contact persons are read-only in stact details of contact persons, please			
Title		Sex	○Male	○ Female
First name		Last name		
E-Mail				
Position in org.	Please indicate the position of the	e Contact Point above in the organ	nisation.	
Department	Please indicate the department of	f the Contact Point above in the or	rganisati <mark>q</mark>	Same as organisation
	☐ Same as organisation address	;		
Street				
Town		Post code		
Country				

+XXX XXXXXXXXX

Phone 2

Website

+XXX XXXXXXXXX

Phone 1

Fax

+XXX XXXXXXXXX



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# 3 - Budget for the proposal

	Estimated eligible* costs (per budget category)		EU contribution		
	A. Costs of the feasibility study/Direct and indirect costs of the action	Total costs	Reimbursement rate %	Maximum EU contribution	Maximum grant amount
Form of costs	Lump sum				
Consortium/Beneficiary	50.000	71.429	70	50.000	50.000



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## 4 - Ethics issues table

1. HUMAN EMBRYOS/FOETUSES			Page
Does your research involve <u>Human Embryonic Stem Cells (hESCs)</u> ?	<ul><li>Yes</li></ul>	○ No	
Will they be directly derived from embryos within this project?	○Yes	No     No     No	
Are they previously established cells lines?	○Yes	No     No	
Does your research involve the use of human embryos?	<ul><li>Yes</li></ul>	○ No	
Can you confirm that your research will not destroy those embryos?	() Yes	No	
Does your research involve the use of human foetal tissues / cells?	() Yes	<ul><li>No</li></ul>	
2. HUMANS			Page
Does your research involve human participants?	<ul><li>Yes</li></ul>	○No	
Are they volunteers for social or human sciences research?	○ Yes	<ul><li>No</li></ul>	
Are they persons unable to give informed consent?	○ Yes	<ul><li>No</li></ul>	
Are they vulnerable individuals or groups?	○ Yes	<ul><li>No</li></ul>	
Are they children/minors?	○Yes	<ul><li>No</li></ul>	
Are they patients?	○Yes	<ul><li>No</li></ul>	
Are they healthy volunteers for medical studies?	○Yes	<ul><li>No</li></ul>	
Does your research involve physical interventions on the study participants?	<ul><li>Yes</li></ul>	○No	
Does it involve invasive techniques?	⊖Yes	<ul><li>No</li></ul>	
Does it involve collection of biological samples?	⊖Yes	<ul><li>No</li></ul>	
If your research involves processing of genetic information, see also section 4.			
3. HUMAN CELLS / TISSUES			Page
Does your research involve human cells or tissues (other than from Human Embryos/Foetuses, i.e. section 1)?	<ul><li>Yes</li></ul>	○ No	
Are they available commercially?	○Yes	● No	
Are they obtained within this project?	○ Yes	<ul><li>No</li></ul>	



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Are they obtained from another project, laboratory or institution?	○ Yes	No     No	
Are they obtained from biobank?	○Yes	No     No	
PERSONAL DATA			Page
oes your research involve personal data collection and/or processing?	<ul><li>Yes</li></ul>	○ No	
Does it involve the collection and/or processing of sensitive personal data (e.g.: health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	○Yes	No     No	
Does it involve processing of genetic information?	○Yes	No     No	
Does it involve tracking or observation of participants?	○ Yes	No     No	
oes your research involve further processing of previously collected personal data econdary use)?	○Yes	● No	
ANIMALS			Page
pes your research involve animals?	<ul><li>Yes</li></ul>	○ No	
Are they vertebrates?	○Yes	No     No	
Are they non-human primates?	○ Yes	No     No	
Are they genetically modified?	○ Yes	No     No	
Are they cloned farm animals?	○Yes	No     No	
Are they endangered species?	○ Yes	No     No	
lease indicate the species involved(Maximum number of characters allowed: 1000)			
THIRD COUNTRIES			Page
case non-EU countries are involved, do the research related activities undertaken in ese countries raise potential ethics issues?	<ul><li>Yes</li></ul>	○ No	
pecify the countries involved:(Maximum number of characters allowed: 1000)		l .	



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	es (e.g. animal and/or human tissue samples, geneticains, materials of historical value, endangered fauna or		<b>●</b> No	
Do you plan to import any material the EU?	- including personal data - from non-EU countries into	Yes	○No	
Specify material and countries inve	olved: (Maximum number of characters allowed: 1000)			
Do you plan to export any materia	al - including personal data - from the EU to non-EU	○ Yes	● No	
	olved: (Maximum number of characters allowed: 1000)			
If your research involves low and/o actions planned?	or lower middle income countries, are benefits-sharing	○Yes	<ul><li>No</li></ul>	
Could the situation in the country p	out the individuals taking part in the research at risk?	○Yes	<ul><li>No</li></ul>	
7. ENVIRONMENT & HEALTH and	SAFETY			Page
Does your research involve the environment, to animals or plants?	e use of elements that may cause harm to the	Yes	<ul><li>No</li></ul>	
	angered fauna and/or flora and/or protected areas?	○ Yes	<ul><li>No</li></ul>	
Does your research involve the including research staff?	use of elements that may cause harm to humans,	○ Yes	No     No     No	
8. DUAL USE				Page
Does your research involve dual-us or other items for which an authoris	se items in the sense of Regulations 428/2009, sation is required?	○ Yes	No	
9. EXCLUSIVE FOCUS ON CIVIL	APPLICATIONS			Page
Could your research raise concern	s regarding the exclusive focus on civil applications?	○Yes	No	
10. MISUSE				Page
Does your research have the pote	ntial for misuse of research results?	○ Yes	<ul><li>No</li></ul>	

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11. OTHER ETHICS ISSUE	S			Page
Are there any other ethics is	sues that should be taken into con	sideration? Please specify	● Yes ○ No	
Please specify: (Maximum I	number of characters allowed: 100	0)		
	nto account all ethics issues descri hics self-assessment and attach th		ethics issues	

How to Complete your Ethics Self-Assessment

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# 3 - Call specific questions

## Call specific declaration(s)

I declare on my honour that: Neither I nor any of the members of the consortium (if relevant) are involved in concurrent submission or implementation with another SME instrument Phase 1 or Phase 2 project.

#### **Excluded Reviewers**

You can provide up to three names of persons that should not act as an evaluator in the evaluation of the proposal for potential competitive reasons.

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# Validation result

Show Error

The red 'Show Error' button indicates an error due to a missing or incorrect value related to the call eligibility criteria. The submission of the proposal will be blocked unless that specific field is corrected!

Show Warning

The yellow 'Show Warning' button indicates a warning due to a missing or incorrect value related to the call eligibility criteria. The submission of the proposal **will not be blocked** (proposal will be submitted with the missing or incorrect value).

Section

Description

The form has not yet been validated, click "Validate Form" to do so!



# **Proposal template** (technical annex)

## SME instrument – phase 1

#### The application shall provide

- 1) an outline of the envisaged overall innovation project, its intended scope, merits, risks and state of development to allow for an assessment of the business idea as well as an initial business plan based on the proposed idea/concept
- 2) a description of the activities to be undertaken during phase 1 that shall result in a comprehensive feasibility report, including the specifications of the elaborated business plan, which is to be the outcome of the project (for more details refer to the Work Programme and the Guidance documentation).

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 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.

Page limit: The cover page and sections 1, 2 and 3, together should not be longer than 10 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, any excess pages will be overprinted with a 'watermark', indicating to evaluators that these pages must be disregarded.

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	

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

#### **Table of Contents**

#### 1. Excellence

Your proposal must address a work programme 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.

⚠ Applicants are expected to address the points relevant to their overall innovation project and to provide information available at this stage. They should clearly explain which aspects will be further explored in the feasibility study.

#### 1.1 Objectives

- Describe the objectives of your overall innovation project ant the subsequently expected outcome. Describe the industrial/economic/social problem to be solved and/or business opportunity you intend to address.
- Describe the specific objectives for the feasibility study, including the elaboration of a business plan, 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 work programme

• Indicate the work programme topic to which your proposal relates.

## 1.3 Concept and methodology

(a) concept

- Explain how your innovative solution will solve the problem and/or use the business opportunity.
- Describe the current stage of development of the innovation. Where appropriate, mention key milestones that led to the current stage (e.g. prototype, field trials, pilot studies with intended end-users and/or potential clients).
- Describe the positioning of the business innovation project, e.g. where it is situated in the spectrum from 'idea to application', or from 'lab to market'. Refer to Technology Readiness Levels where relevant. (See General Annex G of the work programme).

#### (b) methodology

- Describe what you want to achieve in the feasibility assessment. Explain the methodology, distinguishing, as appropriate, activities linked to assess the technological/technical/practical feasibility and economic viability (e.g. market studies, customer survey, etc.).
- Describe how your project intends to develop something new to Europe that addresses EUwide/global challenges
- Where relevant, describe how sex and/or gender analysis is taken into account in the project's content.

⚠ 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

- Explain the novelty of your innovation business project. What do you envisage as key market application of the innovation project result?
- Explain the envisaged solution (products, processes, services etc.) and highlight the advantage of your (expected) solution with respect to competing solutions; how does it provide more added value to potential customers? Provide a preliminary comparison with alternatives solving the same or similar problems. If appropriate, compare to state-of-the-art research and known commercial initiatives. This could include costs, environmental benefits, ease-of-use or other features.
- Describe intended improvement potential over time also compared to existing solutions. Why is it worth to develop / or to invest in it?

## 2. Impact

⚠ Applicants are expected to address the points relevant to their overall innovation project and to provide information available at this stage. They should clearly explain which aspects will be further explored in the feasibility study.

#### 2.1 Expected Impacts

#### a) Users/Market

- Which user needs have been identified and will be met upon completion of the project?
- Describe the main *economic* benefits for the users that, compared to current state of the art, will make the users buy or invest in the innovation. What are you planning to use as unique selling points?
- Describe how your innovation will contribute to any substantial impact addressing issues related to climate change or the environment, or bring other important benefits to society.
- Describe the type of market, e.g. a niche market or high volume market. What is the estimation of total available market size and growth rate (mature or growing market)?
   What are the market trends? Describe if and how your project addresses European and/or global markets.
- List main competitors and competitive solutions.
- Indicate the most relevant market segments for initial introduction of the new solution.
- Indicate the most important market barriers to be overcome to realise commercialization.
- Describe the targeted users of the final solution; in which market segment/geographical areas do you see these potential users, and how do you intend to reach them?
- List key stakeholders to get involved for making a successful commercial exploitation.

#### b) Company

- How does the innovation project fit with the strategy of the participating SME(s)
- What is the relevance and rationale of the innovation project for the management team of the SME (or lead SME(s) in a consortium)
- What is the expected growth potential of your solution in terms of turnover, employment, market seize, IP management, sales, return on investment and profit etc.

#### 2.2 Measures to maximise impact

#### a) Dissemination and exploitation of results

- Explain an initial plan for full commercialisation of the project results, i.e. own commercialisation or licensing? Need of cooperation with third parties for own commercialisation? Estimate of the total funding requirements? Approximate time to first sales/employment?
- How does the proposed work in Phase 1 of the SME instrument fit into the overall plan to reach market?

#### b) Intellectual Property, knowledge protection and regulatory issues

- Explain key knowledge (IPR) items and who owns them. Refer to the results of any patent search carried out. Have you conducted a "freedom to operate analysis", and if "yes" what has been the result?
- Outline the status and the strategy for knowledge protection. If by patent, has a patent application already been filed or is there potential for patent application?
- If regulatory and/or standard requirements are to be fulfilled for the exploitation of the innovation, please list them, and what are the plans to meet these regulatory and/or standard requirements? Indicate if and how they will be addressed in the feasibility assessment. Are you seeing any new market opportunity through regulatory requirements?

#### 3. Implementation

#### 3.1 Work plan – Work package and deliverable

Please provide the project plan comprising one work package with one deliverable (i.e. elaboration of the feasibility report including a business plan) – see Table 3.1 a

#### Definitions:

'<u>Work package'</u> means a major sub-division of the proposed project. In the case of the SME instrument – phase 1, there is only one work package describing the work to be done for the feasibility assessment.

4

'<u>Deliverable</u>' means a distinct output of the project. In the case of the SME instrument – phase 1 the output is the feasibility report, including a business plan.

# 3.2 Management structure and procedures (only to the extent relevant in single entity proposals)

• Describe the organisational structure and the decision-making

### 3.3 Consortium as a whole (if applicable)

⚠ 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?

#### 3.4 Resources to be committed

△ Include the following budget table; no modification is possible¹. The description of work (feasibility study) in table 3.1 a must demonstrate that it corresponds to the total costs (in EUR).

	A. Costs of the feasibility study/Direct and indirect costs of the action	Total costs	Reimbursement rate %	Maximum EU contribution	Maximum grant amount
Form of costs	Lump sum				
	50 000	71 429	70 %	50 000	50 000

<sup>&</sup>lt;sup>1</sup> Commission Decision C(2013)8198 authorising the reimbursement on the basis of a lump sum for SME instrument phase 1 actions under the Horizon 2020

## Table 3.1 a: Work package description

Work Package Title	Feasibility Study
Objectives	
	.0
Description of work (where	e appropriate, broken down into tasks), lead partner and role of
participants	e appropriate, oroxen down into tasks), lead partner and role of
Deliverable:	
Feasibility report, including	g a business plan (brief description and month of delivery)

#### **Section 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.

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

- a description of the legal entity and, in case of consortia, its main tasks, with an explanation of how its profile matches the tasks in the proposal;
- a curriculum vitae or description of the profile of the persons, including their gender, who will be primarily responsible for carrying out the proposed 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;
- in case of a newly created company, explain the purpose of the company creation.

## 4.1. Third parties involved in the project

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	Y/N
If yes, describe and justify the tasks to be subcontracted	

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#### **Section 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
  - 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:
    - o research objectives (e.g. study of vulnerable populations, dual use, etc.)
    - o research methodology (e.g. clinical trials, involvement of children and related consent procedures, protection of any data collected, etc.)
    - o the potential impact of the research (e.g. dual use issues, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing, misuse, etc.).
- provide the documents that you need under national law (if you already have them) e.g.
  - o 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.

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