



FULL PROJECT PROPOSAL

Guidance Notes for Submission and Preparation

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Guidelines for Coordinators – How to Prepare the Full Project Proposal submission

These guidelines do not replace the IMI Submission Rules and requirements which are published on the IMI web site: www.imi.europa.eu

For the Stage 2 of the Call for Proposals, each Consortium will have to submit a **Full Project Proposal**:

The Full Project Proposal must contain the necessary information for the Innovative Medicines Initiative Joint Undertaking (IMI JU) to perform its administrative and evaluation obligations.

The Actors for a Full Project Proposal Submission:

The Coordinator: the EFPIA Member Company acting as overall scientific project coordinator. The Coordinator's responsibilities include:

- the scientific content of the Full Project Proposal
- the formal submission and finalisation of the Consortium's Full Project Proposal to IMI via the electronic submission tool

The Managing Entity: the legal entity representing the Applicant Consortium from Stage 1 or any other entity eligible to receive IMI JU funding.

The Participants: all entities taking part to the Full Project Proposal. The Coordinator and the Managing Entity are also Participants.

The Full Project Proposal Submission:

The submission will be via the IMI electronic submission tool. Access to the IMI electronic submission tool will be open for a minimum of 1 month before the deadline for submission. The opening and closing dates for Full Project Proposal submissions are published on the IMI website on the relevant Call pages.

The Full Project Proposal will consist of two sections:

Administrative Section: It captures the information about the legal status of each Participant, as well as an overview of the eligible project costs, the IMI JU contribution requested by entities eligible to receive IMI JU funding and the in-kind contributions to be provided by the European Federation of Pharmaceutical Industries and Associations (EFPIA) Member Companies participating to the Full Project Proposal.

Scientific Section: It captures the project scientific description and objectives, the overall project implementation plan, description of Work-Packages, deliverables and milestones, and ethical issues.

Information contained in the administrative and scientific Sections will be used and/or included in the Grant Agreement signed between the Consortium and the IMI JU (subject to a positive peer-review evaluation of the Full Project Proposal).

Guidelines for Completing the Administrative Section

(See appended specimen template forms)

The administration section has to be filled in primarily by the 'Coordinator' and the 'Managing Entity of the IMI JU funding'. Some information shall be filled directly by the participants (see below) under guidance of the Coordinator. The different forms need to be completed on-line using the IMI submission tool (SOFIA).

By default, the '**Coordinator**' will always be identified as '**Participant 1**', and the '**Managing Entity of the IMI JU funding**' will always be identified as '**Participant 2**'.

The Coordinator is responsible for:

- the completion of administrative forms **A1** and **A2.6**;

The Managing Entity is responsible for:

- The completion of administrative forms **A2.7** and **A4** (banking form for the 'Managing Entity of the IMI JU funding').

The Coordinator together with the Managing Entity of the IMI JU funding are requested to fill in the administrative forms **A3.2** and **A5**.

Each participant, in the consortium (including the Coordinator and managing Entity), must complete the following administrative forms: **A2.1, A2.2, A2.3, A2.4 and A3.1**. In order to help the Consortium to fill in all the forms, Explanatory notes are provided on the last pages of these guidance notes. Please read them carefully.

Administrative forms A2.6, A2.7 and A4, requiring signatures, are to be uploaded. All other **administrative** forms need to be completed on-line using the electronic tool.

Invitation to Participants – Submitting Data

The IMI electronic submission tool has a function for the Coordinator to invite the consortium participants to enter their **OWN institution-specific** data (corresponding to the administrative forms **A2.1, A2.2, A2.3, A2.4 and A3.1**) into the system.

An invitation e-mail is sent to all participants requesting them to enter their respective **institution-specific** data directly into the IMI electronic submission tool.

The Coordinator should inform Participants that they will receive an invitation by email from the sender: noreply@imi-europe.org. **Participants should ensure that email spam filters do not block this mail.**

Important information:

Information provided within the administrative form **A2.1** will allow the IMI JU to perform a legal assessment to verify the existence and status of the legal Entity.

Coordinators are advised to start collecting the following administrative information as soon as possible:

For completion of administrative form **A2.1**:

- Full legal names for the Managing Entity and all of the Participants in the consortium

- Full details of all key contacts for the Managing Entity and all Participants' e-mail addresses
- For the purpose of this legal assessment, each project participant will also need a **Participant Identity Code (PIC)**. This PIC will serve as a customer number and will be needed for the preparation of the Grant Agreement to be signed between the IMI Consortium and the IMI JU. Participants that are already participating in FP7-supported projects will already have a PIC assigned. If a participant does not have a PIC, they must request one. The required procedure and forms and a more detailed explanation can be found at <http://ec.europa.eu/research/participants/portal/page/myorganisations#>
- The Legal Entity Appointed Representative (**LEAR**) for each Participant. This is the contact person for all legal information. If the Participant has not yet appointed a LEAR, the required procedure and forms and a more detailed explanation can be found at http://cordis.europa.eu/fp7/urf-lear_en.html)

For instructions on the PIC and the LEAR, please see the explanatory notes to the administrative form A2.1.

Further also the below information will be needed:

- The authorised representatives for the project for each Participant (administrative **form A2.3**)
- The contact people for this project for each Participant (administrative **form A2.4**)

Explanatory notes for Administrative Forms

1. Project Number

The project number will be assigned by the IMI JU as the unique identifier for your project.

2. Project acronym

The Project Consortium should agree on a project acronym.

3. Project Title

It should be no longer than 200 characters. The title should be understandable to the non-specialist.

4. Starting date

Insert the planned starting date of the project. The coordinator should present during the negotiations a written justification for the requested starting date. This starting date must be after the submission of the proposal and normally after the end of the negotiations.

5. Duration

Insert the estimated duration of the project in full months.

6. IMI Call (part) identifier

The IMI Call (part) identifier is the reference number given in the call or part of the call you were addressing, as indicated in the publication of the call.

7. Keywords

Maximum 100 characters including spaces, commas etc.

8. Executive Summary

The executive summary should be entered in administrative form A1 and it should not use more than 2,000 characters.

It should, at a glance, provide the reader with a clear understanding of the objectives of the project and how the objectives will be achieved, and their relevance in the context of the objectives of the call and the specific topic. This summary will be used as the short description of the project for the public following signature of the grant agreement. It must therefore be short and precise and should not contain confidential information.

Please use plain typed text, avoiding formulae and other special characters.

9. Participant number

The number allocated by the Consortium to the participant for this project. The scientific coordinator of a project is Participant No.1, the Managing Entity of IMI JU funding is No. 2. This latter participant holds a specific role of receiving and distributing the IMI JU funding allocated to the project.

10. Participant short name

The short name chosen by each participant. This should normally not be more than 20 characters and the same short name should be used for the participant in all documents relating to the project.

11. Participant identity code (PIC)

The code provided for each FP7 validated legal Entity in the Unique Registration Facility. The Legal Entity Appointed Representative (LEAR) of the legal Entity will distribute this code to participants within the Entity. If a participant does not have a PIC, they need to register for one at <https://ec.europa.eu/research/participants/urf/>.

12. Participant legal name

The official name of the participant's organisation. If applicable, the name under which the participant is registered in the official trade registers. This name should be identical to the one given by the PIC.

13. Address data

The complete postal address should be provided. This data should be identical to those associated with the corresponding PIC. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

14. Country

The name of the country as commonly used. For the legal address of the participant, this data should be identical to those associated with the corresponding PIC. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

15. Legal registration number, place and date of registration

This data should be identical to those associated with the corresponding PIC. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

16. VAT number

This data should be identical to those associated with the corresponding PIC. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

17. Legal form

This data should be identical to those associated with the corresponding PIC. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

18. Legal Entity Appointed Representative Contact person for legal information (LEAR)

This data should be identical to those associated with the corresponding PIC. If no LEAR has been appointed, you should introduce a separate request for appointment of a LEAR. Forms for the appointment of LEARs are available at http://cordis.europa.eu/fp7/urf-lear_en.html.

19. Phone and fax numbers

Please insert the full numbers including country and city/area code.

Example +32-2-29911111.

20. Legal person or Natural person

This data should be identical to those associated with the corresponding PIC. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

21. Research organisation

This data should be identical to those associated with the corresponding PIC. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

22. Non-profit qualified patient organisations

Non-profit patient organisations as referred to in the IMI Council Regulation and the IMI JU Rules for participation.

23. Public body

This data should be identical to those associated with the corresponding PIC. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

24. International organisation

This data should be identical to those associated with the corresponding PIC. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

25. Secondary and higher education establishment

This data should be identical to those associated with the corresponding PIC. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

26. Enterprise

This data should be identical to those associated with the corresponding PIC. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

27. SME

This data should be identical to those associated with the corresponding PIC. If necessary, requests for changes have to be introduced via the Unique Registration Facility.

28. EFPIA member companies

Research-based pharmaceutical companies that are members of EFPIA

29. Non-SME and non-EFPIA member company

It is an enterprise falling neither into the category of SME, nor into the category of EFPIA member companies.

30. Dependencies between participants

Two participants (legal entities) are dependent on each other where there is a controlling relationship between them:

- A legal Entity is under the same direct or indirect control as another legal Entity, or
- A legal Entity directly or indirectly controls another legal Entity, or
- A legal Entity is directly or indirectly controlled by another legal Entity.

Control:

Legal Entity A controls legal Entity B if:

- A, directly or indirectly, holds more than 50% of the share capital or a majority of voting rights of the shareholders or associates of B, or
- A, directly or indirectly, holds in fact or in law the decision-making power in B

Direct or indirect holding of more than 50% of the nominal value of the issued share capital in a legal Entity or a majority of voting rights of the shareholders or associates of the said Entity by public investment corporations, institutional investors or venture-capital companies and funds shall not in itself constitute a controlling relationship.

Ownership or supervision of legal entities by the same public body shall not in itself give rise to a controlling relationship between them.

31. Character of dependence

Insert the appropriate abbreviation according to the list below to characterise the relation between your organisation and the other participant(s) you are related with:

- SG: Same group: if your organisation and the other participant are controlled by the same third party;
- CLS: Controls: if your organisation controls the other participant;
- CLB: Controlled by: if your organisation is controlled by the other participant.

32. Title

Please choose one of the following: Prof., Dr., Mr., Ms.

33. Gender

This information is required for statistical purposes. Please indicate with an F for female or an M for male as appropriate.

34. Position

Please indicate the position in your organisation e.g. Rector, President, Chief Executive Officer, Director etc.

35. Department/faculty/institute/laboratory name/...

Please indicate here the postal address for contact purposes.

36. Coordinator

The Coordinator will be the Consortium's main contact to the IMI JU. The Coordinator must be an EFPIA member company, unless otherwise agreed by the Consortium.

37. Managing Entity of the IMI JU Funding

The coordinator of the former Expression of Interest's Applicant Consortium, unless otherwise agreed by the Consortium.

38. Eligibility to receive IMI JU funding

See the 'IMI JU Rules for Participation' downloadable on the IMI website.

39. Funding rate

For participants eligible to receive IMI JU funding, the funding rate for research and technological development activities performed in European Member States and countries associated to Framework programme (FP) 7 may reach a maximum of 75% of the total eligible costs; for management and other activities, the funding rate may be up to 100%.

40. Indirect costs

Indirect costs are all those eligible costs which cannot be identified by the beneficiary as being directly attributed to the project, but which can be identified and justified by its accounting system as being incurred in direct relationship with the eligible direct costs attributed to the project. They may not include any direct costs.

41. Standard flat rate for indirect costs, or actual indirect costs

According to the IMI JU rules, coverage of indirect costs shall be done

- in a form of a flat rate of up to a maximum of 20% of the participant's total eligible costs, excluding costs for subcontracting and the costs of resources made available by third parties that are not used on the premises of the participant, or
- as actual indirect costs

42. Account name

The name or title under which the account has been opened and not the name of the authorised agent.

43. IBAN

If the IBAN code (International Bank Account Number) is applied in the country where your bank is situated.

44. Bank stamp + signature bank representative

The bank stamp and signature of its representative are not required if this form is accompanied by a copy of a bank statement.

Guidelines for Completing the Scientific Section

(See appended specimen template form)

The scientific section is a downloadable word document to be prepared 'off-line' and then uploaded as a pdf file via the IMI electronic submission tool. (pdf <10MB, graphics 300dpi, avoid colour, Calibri, 11 point).

All the following fields have to be included:

Front Page

Please complete with the Full Project Proposal acronym and title. The information has to be the same as in administrative section.

1. List of Abbreviations

This Section should include a full list of all abbreviations used in the Full Project Proposal.

2. Scientific case

It consists of two sub-sections:

2.1 Concept and Objectives

Section 2.1 should be **no longer than 12 pages**.

Please use the section to explain the concept of your project and the rationale for proposing this project plan. Please also describe the objectives of your project and demonstrate how these objectives are aligned with the Call topic. You should describe the methodologies to be applied, and the advances that the proposed project would bring about. Include descriptions of the innovative approaches you intend to use to fulfill the proposed objectives. Briefly describe the potential impact of the results of your project.

Please refer also on the Stage 2 Evaluation Form (available on-line on the IMI website) that will be used by the independent experts to evaluate your proposal, and ensure that your proposal addresses the Evaluation criteria: criteria 1 (scientific and/or technological excellence); 2 (excellence of the project implementation plan), 3 (consistency with Call Topic and stage 1) & 4 (potential impact of project results).

2.2 References List

This refers to all the scientific and reference material cited in the Full Project Proposal.

3. Project Plan

A project plan should be presented broken down into individual Work-Packages (WPs) that will implement the objectives of the project. The proposed Work-Packages should cover all project activities including management, training and communication.

It consists of the following subsections:

3.1 Overall Descriptions of Structure and Timelines of the Project

Section 3.1 should be **no longer than 1 page**.

The description should include a high-level description of the Work-Packages and how they interconnect. Please provide an overall description of the structure and timelines of the project, including a schematic representation (e.g. Gantt chart).

3.2 Work-Package list

The table should provide a list of the required details about each Work-Package.

3.3 Staff Effort

The table should provide details of the overall staff commitment per participant for each Work-Package in person months for the duration of the entire project.

3.4 Work-Package Description

Each Work-Package description should be **no longer than 6 pages (excluding tables)**.

Please provide detailed information about each Work-Package, including objectives of each Work-Package and a description of each task with its own timeline and justification of resources requested.

For activity type, please indicate one activity per Work-Package, using the following:

RTD – Research **MGT** – Management **TRA** – Training **OTHER** – Please describe.

List of Work-Package Participants: Please insert the Work-Package Leader in first position, highlighted in **bold**.

Person-months: The total number of person-months allocated to each WP. (1 person-month = 1 person working full time for one month, or two people working for two weeks or one person working at 50 % for 2 months, etc.).

If a participant is providing significant resources other than person-months, please indicate this with a **YES** and describe how these resources are allocated and integrated into the Work-Package. Please indicate if the participant is claiming funding (**F**) or providing contributions in kind (**IK**). If the participant is not contributing in kind and is ineligible to receive IMI funding, please indicate none (**N**).

Objectives, tasks, milestones, deliverables, resources and subcontracting:

Please provide details of the objectives of the Work-Package and a description of tasks to be undertaken in this Work-Package. The information provided should be concise but sufficient for the reviewers to evaluate the scientific and technological soundness, the feasibility of the proposed work in the timeline of the project, and the alignment with the requested budget per participant.

Specific descriptions of milestones and deliverables are required for first 2 years. For the remaining period only titles of milestones and deliverables are required.

The delivery date is measured in months from the project start date (month 0).

Milestones are check points where decisions are needed with regard to the next stage of the project. Show how you will confirm that the milestones have been attained. Refer to indicators if appropriate.

For deliverables, please indicate the nature of the deliverable using the following:

R – Report **P** – Prototype **O** – Other

Please provide **per participant** a description of the use of resources including personnel, equipment, consumables etc: an estimated description for the whole duration of the project and a more detailed description for the first 2 years.

For EFPIA participants, in cases of non-EU in kind contributions (as stated in the administrative form 3.1), please specify the amount and related activities.

If any subcontracting of tasks is foreseen, please provide a brief explanation about the work involved (including an estimation of costs), and the need for it.

3.5 Summary Deliverables list for all Work-Packages for the whole project

The Table should include a summary of all deliverables for all the Work-Packages during the duration of the project.

3.6 Summary Milestone list for all Work-Packages for the whole project

The Table should include a summary of all milestones for all the Work-Packages during the duration of the project.

3.7 Communication and dissemination strategy

This section should be no longer than 1 page. Describe the overall strategy for project communication and dissemination.

Details should be presented as part of a work-package (e.g. work-package on management) in section 3.4 including as early deliverable (6-12 months) a communication plan.

4. Partnership case

The section includes the following subsections:

4.1 Individual Participants: Short Profile of key staff members undertaking the work

For each participant please provide information about the legal entity (role within the consortium, department involved etc.) as well as the key individual staff members who will be allocated to the project. Explain how the tasks allocated match their experience. Complete one table for each participant.

4.2 Third Parties

This section should be **no longer than one** page.

Please provide information on all third parties involved in the project and the reason for their inclusion. Please also identify the activities where they would be involved together with the related financial implication. The definition of 'third parties' for these purposes is the one mentioned in the IMI Financial Guidelines:

http://www.imi.europa.eu/sites/default/files/uploads/documents/Rev_Grant_Agreement_2011/IMI_Financial_Guidelines_rev2012.pdf .

4.3 Consortium as a whole

This section should be **no longer than one and half** pages.

Please provide details of the complementarity of consortium partners. Mention any unique features of the consortium. Please explain how the public and SME applicant partners will work with the EFPIA partners and how all partners will work together.

Please refer also on the Stage 2 Evaluation Form (available on-line on the IMI website) that will be used by the independent experts to evaluate your proposal, and ensure that your proposal addresses in particular criterion 2, bullet point 1 & 3.

5. Implementation

The section includes the following subsections:

5.1 Governance of the Consortium and Management procedures

This section should be **no longer than two and half** pages.

Please provide information on how the project will be implemented, including decision-making mechanisms, responsibilities, governance and the management plan. Provide details of how the organizational structure is matched to the scale and complexity of the project. Describe means to monitor progress and mitigate risk (e.g. contingency plans).

Please refer also on the Stage 2 Evaluation Form (available on-line on the IMI website) that will be used by the independent experts to evaluate your proposal, and ensure that your proposal addresses in particular criterion 2, bullet point 4.

5.2 Summary Table of Staff Effort and subcontracting (per Work package & per participant)

The Table should present an overview of all staff efforts (in man-months) and subcontracting (in k€) broken down per Work-Package and per participant.

6. Ethics

This section should be **no longer than 5** pages.

Please provide:

- a description of the potential ethical aspects of the proposed research regarding its objectives including a justification based on the expected potential impact;
- the methodology and the possible implications of the results;
- a justification of the design of the research project;
- an explanation on how the ethical requirements set out in the work programme will be fulfilled;
- a strategy for the management and monitoring of all ethical issues that may arise during the course of the project;
- an indication on how the proposal meets the national legal and ethical requirements of the country where the research is performed;
- a demonstration that the workplan has taken into consideration the timing for approval by any relevant authority at national level;
- a description of the tasks, milestones, deliverables and resources as part of the relevant work package(s).

Take into account issues like:

Informed consent: Illustrate an appropriate level of ethical sensitivity, considering issues of insurance, incidental findings and consequences of leaving the study. Include a strategy for collecting, storing informed consents, and for re-use of data.

Data protection issues: Avoid unnecessary collection/use of personal data, how it is used and protected and consider issues of informed consent. Identify the source of data as being from previous studies, or generated as part of the on-going research.

Use of animals: Where animals are used, consider and address convincingly the 3Rs (Replace, Reduce, Refine), specifying numbers of animals used.

Human embryonic stem cells: Research proposals that will involve human embryonic stem cells (hESC) should address the following:

- How the project serves important research aims to advance scientific knowledge and to increase medical knowledge for development of diagnostic, preventative or therapeutic methods to be applied to humans.
- Why it is necessary to use hESC to achieve the scientific objectives in the proposal and why appropriate validated alternatives (in particular stem cells from other sources or origins) are not suitable and/or available to achieve expected goals. This latter provision does not apply to research comparing hESC with other human stem cells.
- Take into account the relevant legislation, regulations, ethical rules and/or codes of conduct in place in the countries where research using hESC is to take place, including the procedures for obtaining informed consent.
- Assurance that for all hESC lines to be used, they were derived from embryos:
- Donor express, written and informed consent is provided freely in accordance with national legislation prior to the procurement of the cells
- Result from medically-assisted *in vitro* fertilization designed to induce pregnancy and were no longer to be used for that purpose
- Measures are in place to ensure protection of personal data (including genetic) and privacy of donors during the procurement of hESC and for any use thereafter. All data should be presented in a form to ensure donor anonymity.
- The conditions for donation are adequate and no pressure or financial inducement was used to procure the hESC lines and that infertility and research activities were kept appropriately separate.
- Identify which ethical committees and regulatory organizations in the countries of research need to be approached during the life of the project.

More information and guidance on ethics can be found here: <http://www.healthncpnet.eu/jahia/Jahia/pid/23>.


6.1 Ethical Issues Table

Please complete the Ethical issues table 6.1 in order for the Ethics experts to decide if an ethical review is required. If there are no ethical issues for your proposal, please indicate this in the final square of the table by ticking 'YES'.

Appendix 1 Full Project Proposal Submission: Administrative Section-Specimen Administrative (A) Forms

A1 OUR PROJECT :

Project number	
Project Acronym	<input type="text"/>

General Information	
Call Identifier	IMI_JU_
Topic Code	IMI_JU_
Topic Title	
Project Title	<input type="text"/>
Foreseen Starting date	<input type="text"/> 
Duration in Month	<input type="text"/>
Keywords	<input type="text"/>
Executive Summary (maximum 8000 characters)	
<input type="text"/>	
Part B - Scientific Case	
Current FPP Document	
FPP Document (PDF, Max. 10MB)	<input type="button" value="Choose File"/> No file chosen

A2.1 WHO WE ARE - LEGAL DATA

Project Number
Project Acronym
Created at 09/08/2012 by

Legal Data	
If your organisation has already registered for FP7, enter your Participant Identity Code (PIC)	
Participant Identity Code (PIC)	<input type="text"/>
	<input type="button" value="Retrieve"/> (This will load the most recent data entered for that PIC)
Participant Legal name	<input type="text"/>
Participant Short name	<input type="text"/>

Legal Address	
Legal Address	
Street name	<input type="text"/>
	Number <input type="text"/>
Town	<input type="text"/>
Postal Code / Cedex	<input type="text"/>
Country	<input type="text" value="Select country"/>
Internet homepage	<input type="text"/>

Registration data of the participant	
Legal registration number	<input type="text"/>
Place of registration	<input type="text"/>
Date of registration	<input type="text"/>
	dd/mm/yyyy
VAT Number	<input type="text"/>
Legal form	<input type="text"/>

Contact person for legal information		
Family Name	<input type="text"/>	
First Name(s)	<input type="text"/>	
Phone 1	<input type="text"/>	Phone 2 <input type="text"/>
E-Mail	<input type="text"/>	Fax <input type="text"/>

A2.2 WHO WE ARE - STATUS OF YOUR ORGANISATION

Project Number
Project Acronym
Participant Short Name
PIC
Created at 09/08/2012 by

Status of the applicant organisation [0]	
<input type="checkbox"/> Natural person	
<input type="checkbox"/> Legal person	
<input type="checkbox"/> Non-profit	
<input type="checkbox"/> Non-profit research organisation	
<input type="checkbox"/> Non-profit qualified patients organisation	
<input type="checkbox"/> Public body	
<input type="checkbox"/> International organisation	
<input type="checkbox"/> Secondary and higher education establishment	
<input type="checkbox"/> Enterprise	
<input type="checkbox"/> SME	
<input type="checkbox"/> EFPIA member company	
<input type="checkbox"/> Non SME and non EFPIA member company	
<input type="checkbox"/> Not Eligible and non EFPIA member company (participant special clause 11)	
<input type="checkbox"/> None of the above	<input type="text"/>

(For non-EFPIA members) Dependencies with EFPIA member companies [0]
If you are not an EFPIA member, please indicate eventual dependencies with EFPIA member companies:
No <input type="text"/>

Dependencies with other participant(s) than EFPIA member companies [0]
Are there dependencies between your organisation and other participant(s) in this proposal?
No <input type="text"/>

A2.3 AUTHORISED REPRESENTATIVES

Project Number
Project Acronym
Participant Short Name
PIC
Created at 09/08/2012 by

Authorised representative to sign the grant agreement or to commit the organisation for this project		[0]
Family Name	<input type="text"/>	
First Name(s)	<input type="text"/>	
Legal name of organisation	<input type="text"/>	
Title	Gender (M/F)	<input type="radio"/> M <input type="radio"/> F
Position in the Organisation	<input type="text"/>	
Address		
Street name	Number	<input type="text"/>
Town	<input type="text"/>	
Postal Code / Cedex	<input type="text"/>	
Country	Select country <input type="text"/>	
Phone 1	Phone 2	<input type="text"/>
E-Mail	Fax	<input type="text"/>

Second authorised representative to sign the grant agreement or to commit the organisation for this project		[0]
Family Name	<input type="text"/>	
First Name(s)	<input type="text"/>	
Legal name of organisation	<input type="text"/>	
Title	Gender (M/F)	<input type="radio"/> M <input type="radio"/> F
Position in the Organisation	<input type="text"/>	
Address		
Street name	Number	<input type="text"/>
Town	<input type="text"/>	
Postal Code / Cedex	<input type="text"/>	
Country	Select country <input type="text"/>	
Phone 1	Phone 2	<input type="text"/>
E-Mail	Fax	<input type="text"/>

A2.4 HOW TO CONTACT US

Project Number
Project Acronym
Participant Short Name
PIC
Created at 09/08/2012 by

Person in charge of administrative, legal and financial aspects in this project		[1]
Family Name	<input type="text"/>	
First Name(s)	<input type="text"/>	
Legal name of organisation	<input type="text"/>	
Title	Gender (MF)	<input type="radio"/> M <input type="radio"/> F
Position in the Organisation	<input type="text"/>	
Address		
Street name	Number	<input type="text"/>
Town	<input type="text"/>	
Postal Code / Cedex	<input type="text"/>	
Country	Select country <input type="text"/>	
Phone 1	Phone 2	<input type="text"/>
E-Mail	Fax	<input type="text"/>

Person in charge of scientific and technical/technological aspects in this project		[1]
Family Name	<input type="text"/>	
First Name(s)	<input type="text"/>	
Legal name of organisation	<input type="text"/>	
Title	Gender (MF)	<input type="radio"/> M <input type="radio"/> F
Position in the Organisation	<input type="text"/>	
Address		
Street name	Number	<input type="text"/>
Town	<input type="text"/>	
Postal Code / Cedex	<input type="text"/>	
Country	Select country <input type="text"/>	
Phone 1	Phone 2	<input type="text"/>
E-Mail	Fax	<input type="text"/>

Submission Forms

	IMI Joint Undertaking	Full Project Proposal	A2.6: Data protection & coordination role
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Project Number	Project Acronym	Participant number in this project	Participant short name
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SIGNED ONLY BY THE COORDINATOR – PARTICIPANT N° 1

Certified Declaration

As Coordinator on behalf of all project participants I take note of the following statement:


"All personal data (such as names, addresses, CVs, etc.) will be processed in accordance with Regulation (EC) No. 45/2001 of the European Parliament and of the Council of 18 December 2000 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 (Official Journal L 8, 12.01.2001). Such data will be processed solely in connection with the assessment of the project by the IMI Joint Undertaking. On request, proposers may obtain access to their personal data and correct or complete them. Any questions relating to the processing of these data can be addressed to the project officer. Proposers may lodge a complaint against the processing of their personal data with the European Data Protection Supervisor at any time."

I also certify that our organisation is committed to act as the coordinator of this project.



Legal Name of participant n° 1 – the Coordinator			
Family name of <u>authorised</u> representative		First Name(s)	
Date DD/MM/YYYY	Signature of the <u>authorised</u> representative to sign the grant agreement or to commit the <u>organisation</u>		
Family name of <u>authorised</u> representative		First Name(s)	
Date DD/MM/YYYY	Signature of the <u>authorised</u> representative to sign the grant agreement or to commit the <u>organisation</u>		

Submission Forms

	IMI Joint Undertaking	Full Project Proposal	A2.7: Data protection & financial management role
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Project Number	Project Acronym	Participant number in this project	Participant short name
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SIGNED ONLY BY THE "MANAGING ENTITY OF THE IMI JU FUNDING" – PARTICIPANT N° 2

Certified Declaration

As the "Managing Entity of the IMI JU funding" on behalf of all participants I take note of the following statement:

"All personal data (such as names, addresses, CVs, etc.) will be processed in accordance with Regulation (EC) No. 45/2001 of the European Parliament and of the Council of 18 December 2000 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 (Official Journal L 8, 12.01.2001). Such data will be processed solely in connection with the assessment of the project by the IMI Joint Undertaking. On request, proposers may obtain access to their personal data and correct or complete them. Any questions relating to the processing of these data can be addressed to the project officer. Proposers may lodge a complaint against the processing of their personal data with the European Data Protection Supervisor at any time."

I also certify that our organisation is committed to act as the "Managing Entity of the IMI JU funding" of this project.

Legal Name of participant n°2 - the Managing Entity of the IMI JU funding			
Family name of authorised representative		First Name(s)	
Date DD/MM/YYYY		Signature of the authorised representative to sign the grant agreement or to commit the organisation	
Family name of authorised representative		First Name(s)	
Date DD/MM/YYYY		Signature of the authorised representative to sign the grant agreement or to commit the organisation	

Form A3.1 non-EFPIA organisation

A3.1 WHAT IT COSTS

Project Number
 Project Acronym
 Participant Short Name
 PIC
 Created at 09/08/2012 by

What it costs					
If your organisation is an enterprise, please indicate here your enterprise organisation status <input type="checkbox"/> SME <input type="checkbox"/> EFPIA member company <input type="checkbox"/> Non SME and non EFPIA member company					
For participants eligible to receive IMI JU funding, the funding rate for: Research activities (A) is 75 % Management, Training and other activities (B, C, D) is 100 %					
(d) Indirect cost method: <input type="radio"/> Flat rate 20% <input checked="" type="radio"/> Actual indirect costs as per analytical accounting system					
	Type of Activity				Total A+B+C+D (€)
	Research activities (A) (€)	Management activities (B) (€)	Training activities (C) (€)	Other (D) (€)	
Personnel costs (a)	0	0	0	0	0
Subcontracting (b)	0	0	0	0	0
Other direct costs (c)	0	0	0	0	0
Indirect costs (d)	0	0	0	0	0
Total costs (e)	0	0	0	0	0
Maximum IMI JU financial contribution (f)	0	0	0	0	0
Does your organisation receive financial contribution from EFPIA participant? <input type="radio"/> Yes <input checked="" type="radio"/> No					
Among Total costs (e)					
Financial contribution requested to IMI JU (g)	0	0	0	0	0

Form A3.1 – EFPIA company

A3.1 WHAT IT COSTS

Project Number
 Project Acronym
 Participant Short Name
 PIC
 Created at 14/06/2011

What it costs

If your organisation is an enterprise, please indicate here your enterprise organisation status

SME
 EFPIA member company
 Non SME and non EFPIA member company

For participants eligible to receive IMI JU funding, the funding rate for:
 Research activities (A) is 75 %
 Management, Training and other activities (B, C, D) is 100 %

(d) Indirect cost method:

Flat rate 20%
 Actual indirect costs as per analytical accounting system

	Type of Activity				Total A+B+C+D (€)
	Research activities (A) (€)	Management activities (B) (€)	Training activities (C) (€)	Other (D) (€)	
Personnel costs (a)	0	0	0	0	0
Subcontracting (b)	0	0	0	0	0
Other direct costs (c)	0	0	0	0	0
Indirect costs (d)	0	0	0	0	0
Total costs (e)	0	0	0	0	0
Financial contribution to IMI JU-funded beneficiaries (h)	0	0	0	0	0
IN KIND contribution (w)	0	0	0	0	0
Does your company provide resources from countries outside the EU or any FP7 associated countries? <input checked="" type="radio"/> Yes <input type="radio"/> No					
Non-EU IN KIND contribution (x)	0	0	0	0	0
	>	>	>	>	

A3.2 WHAT IT COSTS

Project Number
Project Acronym
Participant Short Name
PIC
Created at 09/08/2012 by

What it costs										
For project participants eligible to receive IMI JU funding, please fill the sum of estimated costs in the row "Total eligible cost for IMI JU contribution"; in the column "Requested IMI JU contribution" please fill the corresponding costs requested. For EFPIA project participants please fill the sum of estimated costs in the row/column "Total/EFPIA in-kind contribution".										
Participant number in this project	Participant short name	Estimated eligible costs (full duration of project) in euros				Total A+B+C+D (€)	Non EFPIA		EFPIA	
		Research activities (A) (€)	Management activities (B) (€)	Training activities (C) (€)	Other (D) (€)		Receipts as financial contribution from EFPIA participant (€)	Requested IMI JU financial contribution (€)	Financial contribution to IMI JU-funded beneficiaries (€)	IN KIND contribution (€)
1										
2										
3										
4										
5										
6										
Total project eligible costs (j)										
Non-EFPIA total costs (j)										
EFPIA total costs (m)										
							0		0	

Submission Forms



IMI Joint Undertaking

A4:

Bank account

Participant number in this project ³	Participant short name ¹⁰
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Project Number ¹	Project Acronym ²
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BANKING INFORMATION OF THE MANAGING ENTITY OF THE IMI JU FUNDING – PARTICIPANT N° 2

Account name⁴² _____

Full address of account _____

PO Box¹² _____ Postal Code/Cedex¹² _____

Street name and number¹³ _____

Town _____ Country¹⁴ _____

Contact person for the account _____

Name _____ First name(s) _____

Phone¹⁴ _____ Fax¹⁴ _____

e-mail _____

Bank name _____

Branch address (full address – PO box not accepted) _____

Postal Code/Cedex¹³ _____

Street name and number¹³ _____

Town _____ Country¹⁴ _____

Details of bank account

IBAN⁴³ _____

or

ACCOUNT NUMBER _____

Remarks:	
-----------------	--


We certify that above information declared is complete and true.

BANK STAMP + SIGNATURE BANK REPRESENTATIVE ⁴⁴ (both obligatory)	DATE + SIGNATURE ACCOUNT HOLDER (Obligatory)

A5 REPORTING PERIODS

Project Number						
Project Acronym						
Reporting periods						
Period	From month	To month	Total estimated eligible cost (€)	Total requested IMI JU contribution (€)	Total EFPIA in-kind contribution (€)	<input type="button" value="Add Period"/>
1	1	12				<input type="button" value="Edit"/> <input type="button" value="Delete"/>
Total						
Total Available Costs						

Appendix 2 Full Project Proposal Submission: Scientific Section–Specimen Form

 <p>imi Innovative Medicines Initiative</p>	<p>FULL PROJECT PROPOSAL SUBMISSION: Template Scientific Section Proposal Acronym: Proposal Full name:</p>
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1. List of Abbreviations

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2. Scientific case

2.1 Concept and Objectives

2.2 References List

3. Project Plan

3.1 Overall description of the structure and timelines of the project

--

3.2 Work-packages List

Work-package No.	Work-package title	Type of activity	Lead part. No.	Person-months	Start month	End month
WP1						
WP2						
...						

3.3 Staff Effort

Participant No. / Short name	WP1	WP2	WP3	WP..	WP..	WP..	WP..	WP..	Total person months
Part.1/									
Part.2/									
....									
Total person months									

3.4 Work-package Description

Work-Package Number		Start Month		End Month	
Work-Package Title					
Activity Type					
Participant No. / Short	Person-months per participant full project duration	Person-months per participant (first 2 years)*	Other resources (YES/NO)*	Funding claimed (F/ IK / N) *	Subcontracting (k€)

Objectives of the work-package

--

Work-package Tasks

Task. No.	Task Title / Description

Work-package Milestones

Milestone No.	Milestone Description	Expected delivery date	Means of verification

Work-package Deliverables

Deliverable No.	Deliverable description	Nature (R, P or O)	Expected delivery date

Description of use of resources for participant no x

--

Subcontracting

--

3.5 Summary Deliverable list for all work-packages for the entire project

Del. No.	Deliverable name	WP No.	Nature	Delivery date

3.6 Summary Milestone list for all work-packages for the entire project

Milestone	Milestone name	WPs involved	Expected delivery date	Means of verification

3.7 Communication and dissemination strategy

--

4. Partnership case

4.1 Individual Participants

Participant no x

- Short description of legal entity and its role within the consortium
- Short profile of the key staff members undertaking the work

Name	Sex	Job title and role in the project	Mini-CV including 3 most relevant publications/patents

4.2 Third Parties

4.3 Consortium as a whole

5. Implementation

5.1 Governance of the consortium and management procedures

--

5.2 Summary tables of Staff effort and subcontracting (per Work package & per participant)

Work-package Number:	Person-months per participant over duration of project:	Subcontracting (k€)
Participant 1/Short Name		
Participant 2/Short Name		
Total		

6. Ethics

- 6.1 Ethical Issues Table

Ethical Issues Table:	YES	PAGE
Research on Humans:		
Does the proposed research involve children?		
Does the proposed research involve patients?		
Does the proposed research involve patients or persons not able to give consent?		
Does the proposed research involve adult healthy volunteers?		
Does the proposed research involve Human Genetic Material?		
Does the proposed research involve Human biological samples?		
Does the proposed research involve Human data collection?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		
Research on Human embryo/foetus:		
Does the proposed research involve Human embryos?		
Does the proposed research involve Human Foetal Tissue/Cells?		
Does the proposed research involve Embryonic Stem Cells? (hESCs)		
Does the proposed research on hESCs involve cells in culture?		
Does the proposed research involve the derivation of cells from Embryos?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		
Privacy:		
Does the proposed research involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?		
Does the proposed research involve tracking the location or observation of people?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		
Research on Animals:		
Does the proposed research involve research on animals?		
Are those animals transgenic small laboratory animals?		
Are those animals transgenic non-rodents?		
Are those animals transgenic farm animals?		
Are those animals cloned farm animals?		
Are those animals non-human primates?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		
Research Involving Developing Countries:		
Does the proposed research involve the use of local resources (genetic, animal, plant etc.)		
Is the proposed research of benefit to local communities (e.g. capacity building, access to healthcare, education, etc.)?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		
Dual Use:		
Research having direct military application		
Research having the potential for terrorist abuse		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		