Innovative Medicines Initiative	**FULL PROJECT PROPOSAL SUBMISSION:** **Template** **Scientific Section** **Proposal Acronym:** **Proposal Full name:**

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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 Work-Package Number		Start Month		End Month	
Work Work-Package Title					
Activity Type					
Participant No. / Short name	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 hECSs 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		

Guidelines for Completing the Scientific Section

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 the 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 than6 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.

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 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'**.