

# Complete Project Specification

The purpose of this document is to allow IVCC to determine if they will support this project. The contents of this document will be reviewed by the External Scientific Advisory Committee (ESAC) and the IVCC Management Committee. When the project is reviewed and approved by these bodies project teams will be invited to complete a Complete Project Specification which will detail the project plan and budget.

For each new opportunity, a fresh document should be initiated and named according to IVCC project naming convention and saved to the active proposals folder on SharePoint: **active opportunities**

# Section 1: Initial Project Proposal

## Working Project Title:

IVCC Strategic Fit [IVCC to complete]

Product Need:

TPP

What is the need for IVCC to make this investment?

Is this a good approach to best address the strategic need?

## Project Background

Explain the project background including any work that has been done so far and results. Describe the product you plan to develop and outline why there is a need for the new product, how it will fit against existing interventions and who is going to purchase it.

## Project Purpose

Explain the goal of this project

## Project Scope

Explain which technologies will be used, range of approaches to be investigated, breadth of target product, it can also be useful to describe things which are not in scope

## Project Objectives:

SMART: Specific, Measurable, Achievable, Relevant, Timebound

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## Project Outputs:

The project outputs are deliverables which are of significance towards product development, e.g. product specification, or proof of concept; an end point at which a clear case for the next stage is reached, with all factors for product development addressed, these will be addressed in more detail in the TPP in Section 2.

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*The project management terminology referenced in the above section is defined in Annex 1.*

## Collaborating Organisation Details

Organisation Name:

Lead Contact Name:

Job Title:

Email:

Phone:

## Other Collaborating Party Details

Organisation Name:

Lead Contact Name:

Job Title:

Email:

Phone:

# Section 2: Full Project Proposal

## Target Product Profile

State if this is based on a reference TPP or whether it has been created *de novo*

Criteria: each section will a specification of the criteria for the targeted product.	Minimal requirements	Current Project Status / Evidence
<b>Efficacy</b>		
<b>Formulation</b>		
<b>End User Acceptability</b>		
<b>Product Safety</b>		
<b>Shelf Life &amp; Storage</b>		

**Market and Competition****Resistance Management****Delivery and Implementation****Economics****Manufacturing****Policy/Strategy****Freedom to Operate**

## Project Description

The purpose of this section is to define the tasks needed to deliver the project, who is responsible for them, how long they will take and how much it will cost. Please describe all aspects including technology development, evaluations, manufacturing development and regulatory studies and submissions; referring to the project objectives and describing how they and the TPP will be addressed.

## Project Fit against Product Development Stage Plan

The purpose of this section is to define how the project once complete is envisaged to progress towards product launch. This needs to include for example whether a manufacturing partner and/or marketing partner needs to be sought, how long it will take for the product to be available to deliver impact. What is the likely onward cost of investment, who will lead the product development, how much it will cost and what risks are associated with the project?

Rationale for getting from current product component(s)/hypothesis to final product specification:

Describe the key steps and sequence of tasks required to achieve start of product development or to complete product development:

## Project Plan

Please attach a project plan to this document, ideally in MS Project, otherwise with a similar approach

### Planning Assumptions and Project Dependencies:

List any event, schedule, budgetary, resource or technical factor you have assumed to exist, or not exist and upon which you have based the project and product.

Assumption	Description

### Task Table

Complete the table with the key tasks, showing their Gantt chart Task number.

Task number	Task	Responsible person	Start date	End date	Cost

### Milestones and Deliverables Overview

Complete the table of milestones/deliverables, referring to the Gantt chart Task number.

Milestone number	Deliverable description	Responsible person	Due date

## Project Stop/Go Decision Points:

[Define the key points during the project where a decision to proceed or not will be made. Please specify what data will be available at each of these points and what the decision will be based upon.]

## Budget:

Please provide a budget using a spreadsheet format to show a detailed breakdown of how much will be spent against activities in by time, e.g. month/quarter by technical resource and link to project plan milestones described earlier. Please include all resources necessary including those of Third Parties and IVCC. The budget should be outlined according to personnel, fringe, travel, consultants, supply, assets, overheads, specifying inflation rate assumptions. USD is preferred currency (but not essential). Please also indicate if there are necessary costs to complete the project which are provided by other parties, such as public grants or industrial funding.

# Section 3: Complete Project Specification

## Payment Schedule

Schedule for payments (either regular and/or against milestones)	Payment
[Contract Signature]	[set out sum or %]
[Insert details]	[Insert details]
[Insert details]	[Insert details]
[Insert details]	[Insert details]
[Acceptance of final report]	[set out sum or %]

## Project Reporting

The Project Steering Committee will consist of an equal number of representatives from each party and is responsible for managing the performance and progress of the project. The nominated committee members for each party are:

IVCC	Partner

The Project Steering Committee will meet at least three times a year to approve all formal technical and progress reports, and to ensure the project is managed in accordance with IVCC's Charitable Objectives.

The project team will meet once a month to provide updates on project progress or will meet as when milestones are completed.

An External Scientific Advisory Committee (ESAC), which has been formed by IVCC, will host a meeting twice a year that project partners are expected to attend and present their project(s).

Partners will submit formal project reports prior to ESAC meetings and Project Steering Committee meetings.

### **Reporting Schedule**

Report	Due date
Project Steering Committee	
ESAC	
Project Steering Committee	
ESAC	
Project Steering Committee	

## Project Organisation and Governance

Describe the makeup of the project team by workstream, including IVCC staff, indicating each person's specific responsibility and the person with overall project management responsibility for the project.

Name	Responsibility	Expertise	Contact
<i>Partner lead</i>			
<i>IVCC Project Manager</i>			

## Project Risks

List the risks to the project and suggest ways to mitigate these risks. Example table below:

ID	Risk	Probability	Impact	Mitigating Actions
1		1	5	
2				
3				
4				

## Stakeholder Involvement

[The purpose of this section is to provide a summary of who the stakeholders are and how they will be consulted, engaged and informed during the project]

## Product Specification

[The purpose of this section is to clearly define the characteristics of the final product that will be developed and how it will be used in the market. Define how the product will be marketed and distributed in the DEC's]

## Global Access Commitment Agreement (GACA)

Confirm that the project partners have understood and agreed to comply with the principles of Global Access.

## Acceptance

Signature page to confirm that all project partners have reviewed, agreed upon and approved the project outline specification document

# Annex 1. Glossary of project management terminology

**Milestone** - Milestones indicate specific progress points or events in project timelines. They mark progress needed to complete projects successfully.

**Objective** - A clear, concise statement about what an activity is meant to accomplish. Objectives are written to be SMART: specific, measurable, achievable, relevant, and timebound. A successful project meets all its stated objectives.

**Output** - In project management, an output is the (usually physical) end product of a process.

**Scope** - The scope of a project constitutes everything it is supposed to accomplish in order to be deemed successful. It can additionally be helpful to outline topics which are 'out of scope'

Project Roles and Responsibilities:

**Project Owner:** The Project Owner is responsible for a programme of projects. They should have strategic oversight of the portfolio and understand how each project fits within IVCC's objectives and that each project has goals which fit IVCC's strategy and are aligned with the product development mission (SR or DN).

**Project Manager:** The (IVCC) Project Manager is responsible for ensuring the project stays on track, updating the rest of the IVCC R&D team and reporting achievements (the PM is an IVCC staff member).

**Technical Lead:** The Technical Lead will provide scientific oversight of the project, will ensure the know that technical tasks are carried out to address the goals of the project in a timely manner and provide advice and guidance to the R&D team.

**Project Leader:** The Project Leader leads a multi-disciplinary team, whose members may be affiliated to different organisations, and is responsible for ensuring the project delivers on its' objectives as agreed with the Project Owner

**Project Team Member:** one of several Subject Matter Experts who work as part of the team to design, plan and carry out technical work packages to address the project objectives in a timely manner. They will report data and provide interpretation and guidance to the rest of project team.