Platform for Innovation of Procurement and Procurement of Innovation

PiPPi
Horizon 2020 GA project No 826157

Deliverable 5.3 – Project plan template

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Contents

1 Template overview

1.1 Introduction

Procurement of innovation differs fundamentally from procurement of existing solutions/products: in innovation procurement, a need is shared for which a solution that meets the required outcomes does not exist or an innovative solution is not (yet) available on the market.

If no solution exists nor is soon commercially available in the market, research and development (R&D) efforts can be employed to reach prototype solutions. The EU Directive 2014/24/EU allows for procurement procedures to obtain these prototype solutions first, thereafter Public Procurement of Innovation (PPI) process can be started. This procurement of prototypes is called "pre-commercial procurement (PCP)".

From a project management perspective, concerned with projects with a deliverable and end-time, project planning and management is also critical. This is important for these type of projects to achieve the results on-time, and within budget and available resources. Innovation procurement projects in general are more time consuming and require specific skill and competencies compared to regular procurement projects.

A project plan must be set-up to prepare for an innovation procurement project. This should be based on the demand/unmet need that has been identified by the PiPPi Community of Practice "general process", please see below:

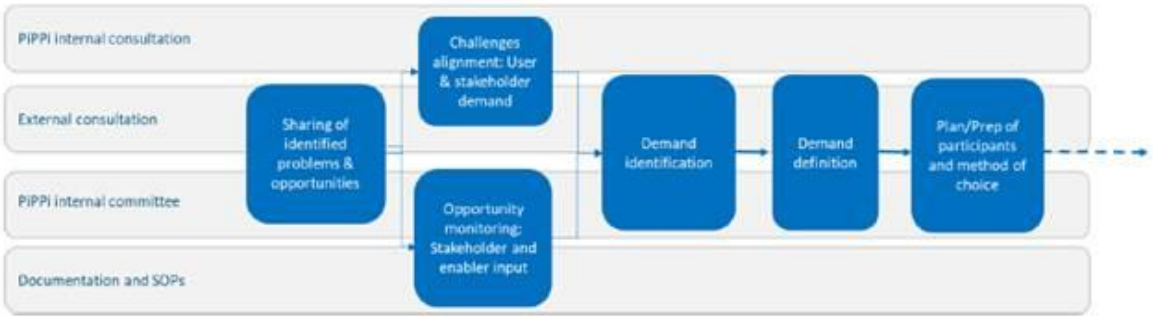

Fig 9 – The general process

In any case, the innovation procurement process covers the following phases that must be planned for in the project plan:

- **Alignment on challenge** – summary of unmet identification and validation based on stakeholder (e.g. clinician and patient) needs
- Set-up of project execution and (continuous) **stakeholder management and engagement**
- Sign-off by **sponsors/champion** of the challenge
- **Market consultation and availability** (in parallel)
    - Open focused market consultation with possible selection for 1-on-1 dialogue (on feedback only)
    - Market scouting of solutions
    - Based on lessons learned within the PiPPi Community of Practice, an open market consultation and solutions availability assessment are regarded as crucial to determine the availability and

quality of solutions for the defined (unmet) need, and if PCP is to be preferred over PPI.
    - This consultation of market parties, stakeholders and other experts should also result in an overview of requirement and barriers to be considered in the next stage (e.g. setting-up solution criteria)
- **Business case & procurement strategy**: development first (PCP) or direct procurement of innovation (PPI); estimation of costs/benefits/support; estimate contract value for each participant; execution plan for development phase and final procurement; estimate budget for solutions; cost/benefits/value and support of strategy for each participant
- Sign-off and **go-ahead** for proposed strategy
- **Execute PCP or PPI**
    - PCP: selection, contracting for R&D / prototype development, contracting (PPI thereafter)
    - Direct PPI: selection, dialogue, offer, award and contracting
- **Implementation** of solution
- **After-care and contract management** through life cycle of solution

1.2 Generic template

This document is the template that should be used for any (future) planning plan for any type of joint and cross-border project that deals with the procurement of innovation as described above. Particularly research and development (pre-commercial procurement and/or procurement of innovation) for which a go-ahead has been given by participating (university) medical centres based on an initial project proposal and high-level business case.

It is assumed that the participating institutions have assessed their organisational readiness and budget availability, in particular also covering the implementation of these type of contracts and contract management thereof.

This template does not cover the planning for the local actions at a participating university medical centre. For this, local templates must be adhered to. This template does also not provide the template on how to report on progress when projects are actually executed.

NOTE: ensure within the project team that the right existing methodologies and tools are selected which are either already in use at different sites in different public procurement of innovation procedures or made available in the PiPPi CoP.

1.3 Structure of the template

This chapter provides a short scope of this document. The second chapter deals with the actual challenge in more details for which a specific procurement process is followed. The third chapter provides the actual planning items that must be covered and filled, and references to key mandatory attachments.

2 Project guidance

2.1 Demand identification & definition

Please describe in more detail the unmet need that has been identified and defined within the PiPPi community of practice and ensure that all project team members understand the key outcomes that solutions need to fulfil:

- Desired outcomes (functionally described)
- Explain and quantify potential societal value / impact
- Short explanation why the unmet need has not been met so far
- Indication of impact if the challenge is not solved
- Specify locally required outcomes (on top of basis cross-country)

2.2 Stakeholder management

Please describe how the team will address the following:

- Identify relevant stakeholders within each organisation, include stakeholders to take away potential barriers (IP-rules, tender law etc.)
- Check with all (local) organisations if it is understood what must be provided for in terms of delivering and what is required in development and implementation
- Check with stakeholders if they understand the length of the complete tender process
- Create commitment and support for the fact that solving the problem requires investment and dedication
- Project team composition for the PCP/PPI project is key: Select the team based on competences and experience, not on the basis of availability; Triple leadership of the project: patient, clinician and project leader; Create a role and allocate time availability for clinicians during the execution of the PCP/PPI project
- Communicate the above early in the process

2.3 Market interest and feasibility findings

Please summarize the findings of (earlier) interest and feasibility assessments done within the PiPPi CoP; describe the interest of the market actors, users and internal stakeholders as well as external stakeholders.

Pay special attention to findings with regards to industry feedback on their experience with R&D. Also test organisational readiness

2.4 Expected method of choice

It is assumed that for the findings above, a broad consultation took place. Although a dedicated market availability assessment and consultation must be prepared and executed to decide on the method of choice (PCP or PPI), the project team should already indicate here what method is expected based on challenge requirements and

availability of possible solutions.

2.5 Key learnings / checklist

Based on PIPPI member experiences, a focused questionnaire was developed to find the key learnings that need to be considered for any innovation procurement project. Ensure to check whether developed project plans adhere to these lessons / best-practices. The lessons can be categorised in four sections:

Problem definition:

- Define clearly what the problem is: specific, include a time-horizon, measurable, bold
- Bring in different experts for defining the problem (e.g. designers)
- Define clearly what the impact of the problem is when it is not solved (vis-a-vis solved), in positive and negative terms, preferably with key output parameters
- Identify who is benefitting from the status quo, and who is interested to have it changed (to have the problem solved)
- Raise interest in a solution (e.g. show market potential), do not focus on the actual procurement process in this phase
- Include stakeholders to take away potential barriers (IP-rules, tender law etc.)
- The business case is the main driver for a successful tender

Internal support creation / commitment building:

- Understanding of the societal value / impact
- Communicate the length of the complete tender process
- Create commitment and support for the fact that solving the problem requires investment and dedication
- Team composition for the PCP/PPI project is key: Select the team based on competences and experience, not on the basis of availability
- Triple leadership of the project: patient, clinician and project leader
- Create a role and allocated time for clinicians to be available during the execution of the PCP/PPI project
- Communicate the above early and clearly in the process

Solutions assessment:

- Do not neglect the assessment on how suited a solution is for implementation
- Assess the capability of the own (buying) organisation in terms of delivering what is required in development and implementation
- Functional and outcome-oriented specifications for the solution. Refrain from stipulating how suppliers should solve the challenge, only focus on overall goals (e.g. sustainability).
- Be open to alternative solutions that differ from what is expected, but have a substantial impact on solving the challenge
- Also assess a supplier's organisation on R&D capabilities and commitment to dialogue. However, consider the maturity and learning capabilities of firms, to not discourage / negatively assess SMEs.
- Involve stakeholders, business expertise and technical expertise in assessment. Create feedback loops to bidders (also losing bidders) to promote continuous improvement.

Development and procurement:

- Have clear decision and communication guidelines beforehand. Communicate these as early as possible to suppliers
- Let suppliers interact with R&D experts / designers & problem owners (clinicians, patients etc.). Set-up dialogue options for all suppliers equally.

- This can help SME's specifically, who now have a problem in competing against bigger firms and incumbent suppliers
- Also include experts on the procurement process / business cases in the design phase
- Ensure contracts for R&D that are fit for purpose

2.6 Conditions and (inter)dependencies

Please describe following:

In order to successfully manage and execute the project the following boundary conditions need to be met: e.g. users are willing to let project members represent their expertise or clinical specialist, and staff are willing to come to prioritisation in consensus on requirements and wishes (as these may be conflicting); budget must be made available for project purposes and procurement.

Include “touchpoints” with other projects and/or initiatives. Also during and after development of solutions. This can help solve the challenge “bottom-up” from several angles.

3 Plan/prep participants method of choice

3.1 Timing (phasing / milestones / decision moments)

	Start date	**End date**
Throughput time full project	Mm yyyy	Mm yyyy
Phase 1: Definition		
Milestones and/or decision moments		
Set-up project team • Team • Tools/work • Governance/DMU • Work streams: legal/IP/procurement, solution, communication, change management and project reporting Interviews and desk research for project plan, specific attention to: • Summary of demand i.e. challenge (see chapter • Internal stakeholder management and engagement • Challenge sign-off sponsors/champion		
Set up and determine detailed project plan including project organisation Prepare document for approval from all participating parties		
Set up and determine first version of Business case (high level), in particular: • Estimation of Cost/benefits • Estimate contract value for each participant, development phase and final procurement • Estimate budget for solutions • Cost/benefits/value and support of strategy of each participant		
Phase 2: Design		
Milestones and/or decision moments		
Conduct open focused market consultation		
Conduct solution availability assessment		
Phase 3: Preparation & Tender		
Milestones and/or decision moments		
Propose procurement strategy and tender procedure: development first (PCP) or direct procurement of innovation (PPI)?		
2nd version of Business case (incl. market feedback)		
Determine procurement strategy and procedure		
Obtain approval from Procurement Board(s)		
Prepare the choosen procedure		
Execute PCP or PPI:		

• PCP: selection, contracting for R&D / prototype development, contracting (PPI thereafter) • Direct PPI: selection, dialogue, offer, award and contracting Special focus required on (from lessons learned): • Contractual approach: local versus cross-border and IP • Tender law in relation to innovation: local versus cross-border and dialogue or partnership • Communication platform for tender and 1-on-1 dialogue		
Phase 4: Implementation		
Milestones and/or decision moments		
Detail implementation plan (with suppliers)		
Phase 5: Aftercare and evaluation		
Milestones and/or decision moments		
Evaluation with project team and sponsor(s), focus on (promised) impact versus actual impact realized!		

3.2 Project cost/benefits

Total

Costs/Benefits	**Investments**	**Exploitation incidental**	**Exploitation structural**	**Scale**	**FTE**
People internal	€ /hours	€/hours	€		
People external	€ /hours	€	€		
Resources	€ xx	€ yy	€ zz		
Benefits (in EUR)	€	€	€		
Project management		€ xx			
Total	€ pp	€ qq	€ rr		

Fill in the above, include below:

Estimation based on figures and information available at the time of planning.

A detailed overview of the project costs must be attached.

3.3 Quality

Provide insight in how the quality of work is assured, e.g. how involvement and content from key representatives is delivered and how a project driven approach is followed and adhered to, e.g. decision making is agreed within a decision making structure embedded in the existing and participating hospitals.

3.4 Communication

Target group	Frequency	Goal	Means
E.g users	1x per phase	Inform	*Web and internal*

3.5 Project organisation

Include graphic display of organisation

Role	Name	Function	Tasks & responsibility
Sponsor			*End responsibility*
Projectleader			*Delivery of project*
Projectmember (core team)			*Set-up, lead and advice*
Steering group			*Decision making on content and direction*
Workstream / group	**Representation**[1]		Wishes, outcomes, functional requirements Assessments
Stakeholders general		IT Patient groups Medical devices Quality assurance Medical technology Clinician stafconvent	Inform and assess (interim) results

Meeting structure

Meeting	Frequency	Participants	Goal

3.6 Resources

Competencie(s) required	Period	# hours
Projectleader	mmyyyy - mmyyyy	xx

[1] E.g. MDR

Projectmembers	mmyyyy - mmyyyy	yy hour per week
Workstream members, e.g. legal/IP, communication, change management, solution delivery, reporting	mmyyyy - mmyyyy	Zz hour per workstream
Expertise externally required Market availability assessment Others…		

3.7 Risk management

Risk-name	**Mitigation**	**Chance**	**Impact**	**Risk**
1. Risk xx	•	3	3	9
2. yy	•	2	3	6
3. zz	•	2	2	4

1 = small chance or impact
2 = medium chance or impact
3 = high chance or impact
Risk = Chance * impact

4 APPENDIX

Appendix 1: Detailed project costing