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SEVENTH FRAMEWORK PROGRAMME

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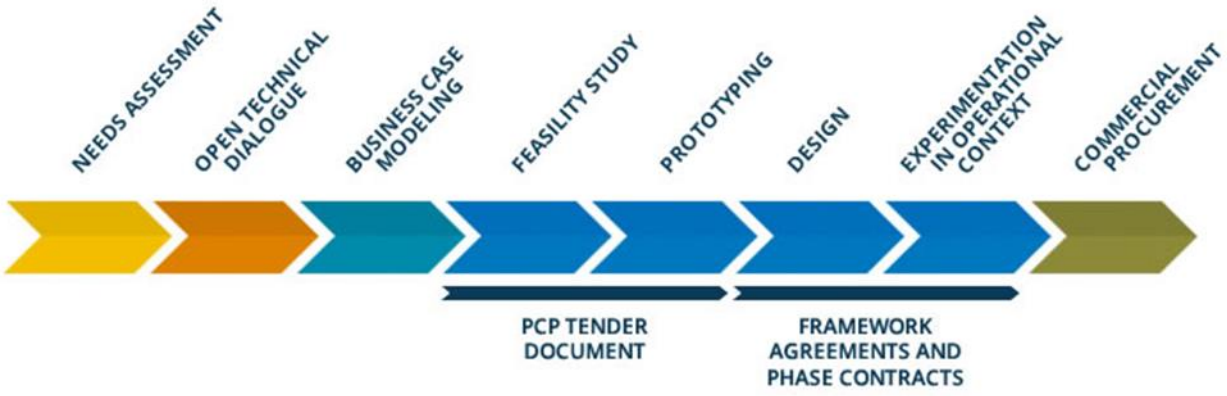
Executive Summary

This guide aims to introduce, step-by-step, the main relevant aspects when procuring innovation and the kind of problems that a careful procurement design and management could solve.

To explain “how” to approach the main steps of the end-to-end procurement process, this guide provide real-life examples, that couldn’t be assumed as “standard terms”.



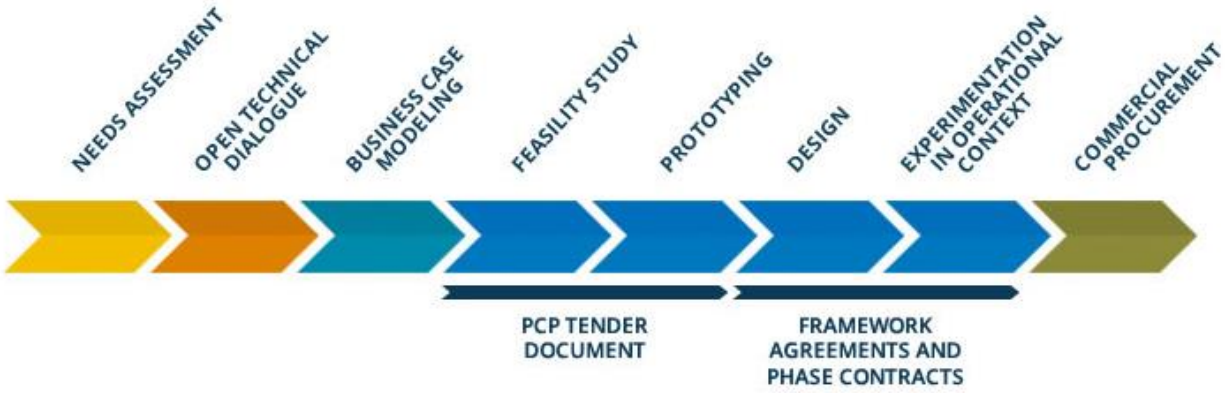
Setting the scene

The European legal framework for public procurement is defined by the provisions of the Treaty for the Functioning of the European Union ("TFEU") and by the EU Procurement Directives, namely the Directive 2004/18/EC of the European Parliament and of the Council on the coordination of procedures for the award of public works contracts, public supply contracts and public services contracts ("Old Procurement Directive") and the Directive 2004/17/EC of the European Parliament and of the Council coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sector ("Old Utilities Directive'). From an international perspective, European Union is also bound by the provisions of the General Procurement Agreement ("GPA") of the World Trade Organization ("WTO").

More recently, a new procurement directive was passed, namely the Directive 2014/24/EU of the European Parliament and of the Council on public procurement and repealing Directive 2004/18/EC ("New Procurement Directive"). Also, the Old Utilities Directive has been replaced by the new Directive 2014/25/EU of the European Parliament and of the Council on procurement by entities operating in the water, energy, transport and postal services sectors ("New Utilities Directive"). The New Procurement Directives have entered into force on 17th April 2014, and the Member States will have two years as of this date to fully implement the provisions thereof into national legislations.

Concerning PCP, in addition to the main legislative acts mentioned above, several policy related documents are also taken into consideration, including the COM (2007) 799 and subsequent documents from the European Union (Opinion of the Regions Committee 2008/C 325/06 relative to COM(2007)799, Opinion of the European Economic and Social Committee 2009/C 100/02, Resolution of the European Parliament of 3 February 2009 A6-0018/2009),

Nevertheless, in the scope of this deliverable, we will only look into the Old and New Procurement Directives and relevant soft regulation sources. Our aim is to provide a practical tool and ready to use resources to practitioner interested to undertake PCP and PPI actions.



1 Need assessment

The procurement, meaning the public procurer's act of obtaining works, supplies or services required to perform its functions and in the exercise of its duties, has to start from a genuine and real need that concern the public service delivered. If there isn't a real demand inherent to the procurer mission and activity, we are not configuring a procurement action but a measure for promoting innovation driven by public demand.

STARTING FROM A GENUINE, CONCRETE NEED, CHALLENGE OR PROBLEM, THAT IMPACT NEGATIVELY ON THE QUALITY AND/OR COST OF PUBLIC SERVICES OFFERED

TARGET INVOLVED:
THOSE RESPOSIBLE FOR OR WORKING WITHIN THE PUBLIC SERVICE DELIVERY AND, ULTIMATELY, USERS OF THE DESIRED INNOVATION

There are multiple method to identify and assess a need, but based on the premise that those who are best-placed to see the problems or the inefficiencies with a process or a service are those who work within the system delivering it on daily basis. The users and civil servants involved in delivering the service are typically too busy to consciously consider how the service could be transformed or could benefit from innovation, but they are skilled and perfectly prepared to do it. Therefore it is necessary to make time to take them out of their usual working environment to participate to a brainstorming session.

A very effective method to assess an innovation need is called **WIBGI**[1], being a collective exercise to complete the sentence "Wouldn't be great/good if….".

[1] The methodology has been defined by NHS (UK)

BOX 1. An example of structured WIBGI workshop comes from the EU project Ambulance SOCN aimed to design the ambulance of the future.

(1) Wouldn't It Be Great If ……

there was a new device to move patients with a fractured neck of femur/fractured shaft of femur

Background

The existing splint is too complicated to use, there are too many straps and bits go missing. If all the pieces are there and we can get it to fit properly it does little to stabilise the patient over rough terrain or when moving them. If we can't get it to work in 10 seconds we won't use it, especially in emergencies. There is recognition that getting granny down three flights of stairs in a cluttered house with no working lights is exactly why a better splint is needed especially when you combine this with the existing carry chair which does little to help the situation.

Clinical Need

A new easy to use/re-use mechanism to move patients with a fractured shaft of femur/fractured neck of femur which must fit the 10 second rule and be able to self regulate compression in transit.

…

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BOX 2. An example of one such session comes from health and social care workers at Niguarda Hospital (Lombardy Region, Italy), who were responsible to move, via manual pushing and pulling, the hospital beds. They produced the sentence "**Wouldn't be great/good if**…we could avoid collateral effect, in the form of accidents and functional limitations, affecting nursing personnel and socio-health operators when dedicated to move hospital beds". This lead to the detailed request to develop a new and cost-effective automated universal medical device for moving hospital beds, that is easy to use for a single operator, equipped with all anti-collision and safety systems, as described in box 5.

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other ROLES INVOLVED:

FACILITATOR

THEMATIC DOMAIN EXPERT

In conducting such session it has been found useful to involve simultaneously similar staff groups from multiple locations. Perceived inefficiency or need rarely relate to only one local operator. This type of pooling of demand also secures economies of scale that are the basis of the procurement. It is also a good practice to have an experienced facilitator to conduct the session, to draw out the issues and ideas, as well as a thematic domain expert who can guide the facilitator with respect to the specialist technicalities.

MEASURING KPI REFERRED TO THE SITUATION AS USUAL AND CONSIDERING TRENDS TO FIX THE KPI TO BE ACHIEVED WITH THE INNOVATION

Usually the brainstorming step leads to the identification of a list of needs, which have to be validated in comparative terms and put in order of priority, on the basis of their expected impacts and trends.

It is very important to evaluate the historic past-performance of the process or service under consideration, using key performance indicators (KPI) as a measure (cost, headcount, time, outcomes…). These KPIs have to be, then, extrapolated the future based on predictive data such as cost escalation, drawn from authoritative sources in order to fix the improvements and KPIs to be achieved (Bedin, 2014).

BOX 3. In the case of Lombardy Region, for example, the need for moving beds has been selected (out of 10 identified problems) due to the expected improvements in productivity, the possible reduction of dedicated personnel for carry out bed movements (personnel is below strength for the needs of Italian hospitals), the reduction of the total cost of the public services offered as well as the improvement of patient comfort and safety when moved.

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THE VALUE OF ANCHORING THE INNOVATION WITHIN THE PUBLIC SERVICES ORGANIZATION, ASSURING THE INVOLVEMENT OF USER GROUPS

Once selected and confirmed, the procurement need should be described in detail to ensure, when published, a full understanding and comparability of the competing solutions proposed by the market in view of potential conversion into permanent services. The description of the need involves, again, those are daily involved within the public service delivery chain and, ultimately, the final users of the innovation.

The brainstorming and focus group sessions are effective ways to ask focus groups to define their needs for innovation in terms of functional and performance requirements, without identifying a specific solution. This encourages the market to the active generation of application ideas and technological choices, including divergent and alternative ones, though equivalent from the point of view of performance and expected outcome.

The opportunity not to pre-define the technical solution and to be open to alternative technical ways to address the needs expressed in functional and performance based requirements does not mean that needs definition should be short and very general.

BOX 4. For example, for the description of the desired automated universal medical device for moving hospital beds, Lombardy Region has formulated in total 32 (minimum) requirements, all directed to assure a full scalability and wide adoption of the solutions.

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ASSURING AN UNAMBIGUOUS UNDERSTANDING OF THE (STRICTLY NECESSARY) REQUIREMENTS AND A FULL COMPARABILITY OF THE SOLUTIONS/SERVICES PROCURED, CONSIDERING ALSO THE FUTURE SCALABILITY and INTEROPERABILITY

This is a crucial point, as the only way in which solutions will meet their performance targets and expected outcome/impact is for them to be specified upfront, clearly and unambiguously. It is a simple fact that if functions and performances are not a stated criterion of the solution requirements then the product/service designers will generally not consider (strictly) performance issues.
At the same time, in order to pre-determine a wide potential market (public and private) for the new solutions developed or acquired and to enable the desired economies of scale and cost savings, it is important:

- not to fall into the hyper-description of the desired solution, i.e. excess customization and personalization and
- support scalability through requests for interoperability and open standards.

To describe a need in functional and performance terms, we have many methodologies and approaches.

Assuming that innovation procurement is about the total cost of ownership and not the lowest price, it is extremely crucial to direct innovation towards the entire life-cycle of the solution.

The method **TLC-PE**[2] (total life-cycle functional and performance description) creates associations between descriptive functions and quantified performance targets, categorizing functions and related performances along the solution life-cycle phases: production, delivery, installation, use, management, maintenance and disposal (Bedin, 2012).

One methodology used to elicit the functional specifications is called **FAST**[3] (Functional Analysis System Technique). According to this methodology the basic element of a system is the Function that describes the original intent or purpose that a product, process or service expected to be performed. The description of a Function is restricted to a two words format: Active Verb + Measurable Name. The Verb is used to answer to the question: What does it do? While the Name is used to answer to the question: What does the Verb apply to?

Oslo Medtech has developed a method for user involvement called "**I wish I had**". Oslo Medtech and the Geriatric Resource Center of the Municipality of Oslo in conjunction with users and other stakeholders, organized a dialogue/workshop on the topic "How to stay longer at home with high quality of life". The meeting mapped different situations that can cause insecurity. During the workshop, different solutions were discussed to meet the challenges.

BOX 5. Synthesis, that combine the TLC-PE and FAST methods, has been developed and implemented in Lombardy Region to conduct the PCP pilot, as represented by the example below:

Life cycle 1 – Installation, Start-up and management

1. The device must comply with general and design requirements set out in current regulations regarding safety at work and comply with current regulations as regards medical devices … such that there is no need for any modifications in order to obtain EC certification.
2. It must be very easy for operators to quickly learn how to use the device.
3. The device must be easy to install and use (with no need for calibration and adaptation).
4. The device must be provided with a utilization data registration system (meters travelled, date and time of start and end of use ...)

…

Life cycle 2 – Use and operation

….The “Innovative Solution” proposed by the bidder must have the following minimum functional and performance requirements relative to the use and operation of the same:

1. The device must permit the movement of hospital beds, both those with electrical or mechanical movements…
2. The device must not require any modification of the beds (i.e. the assembly of fixed parts and/or interfaces)…
3. The device must intrinsically able to be adapted to all models of hospital beds in use at AO

[2] Sara Bedin (TEHA), 2012, method developed and implemented in Lombardy Region (for more info: sara.bedin@ambrosetti.eu)

[3] AQuAS, 2014, method developed and implemented in DECIPHER

Niguarda and to the large number of hospital beds commercialized in Europe …
4. The device must be resistant to liquids.

Life cycle 3 - Maintenance

As regards maintenance, the "Innovative Solution" must satisfy the following minimum requirements:

1. The device must have self-diagnosis systems and must manage/produce an automated daily check-list.
2. The system must permit remote control and assistance (tele diagnosis).

…

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BOX 6. Functional requirements for Lot1 of HAPPI project (PPI)

Functions

- Detect falls by persons/residents/patients
- Alert in the event of actual fall
- Make it possible to ensure that the alert is noticed (acknowledgment)
- Trace alerts (be able to access a history to permit optimized fall management)

Requirements

The detection device must:

- Not change the nature of the living space of the patient or resident (be discreet and as small as possible)
- Be neutral for the patient/resident, not require the wearing of a device
- Respect the person's privacy
- Allow parameterization according to different fall contexts

Alerts generated by a fall must be able to be transmitted:

- Inside and outside the institution
- To the staff of the institution (health care, administrative and management staff)
- On a variety of media

Alerts (aside from audible alerts) must at a minimum contain the following information:

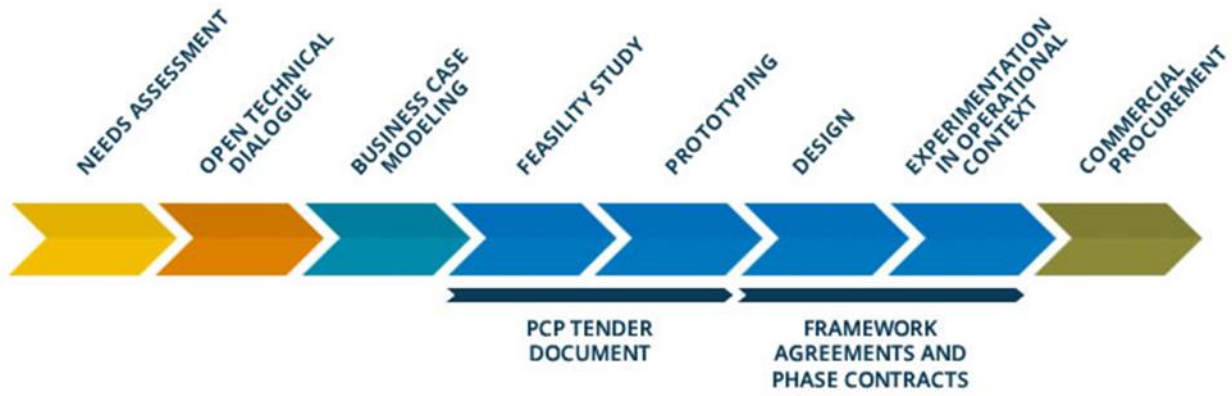
- The place of the fall
- The time of the alert

To describe needs from different vantage points, it makes sense to begin with the identification of the various user groups and their requirements. This can be done by documenting different scenarios, as illustrated in the example below.

BOX 7. Example: User needs in Lyngbakken Nursing house

In the report "New Warning Systems in Tomorrow's Nursing house" you can read about the survey made on the needs in Skien, Norway as a part of a plan to construct the new nursing in Lyngbakken. The report describes both the problems regarding nursing homes and the survey's methodology. (Downloading link is www.sintef.no/velferdsteknologi)

For (others) examples and templates please see the Attachment 1



2 Open technical dialogue

As part of the preparation for a call for tenders, public purchasers may be interested to consult companies first. Market consultation is a powerful instrument that helps bridging the gap between supply and demand and is vital as means to create and increase awareness of the market relating to the needs of public authorities.

It has lately become a common practice among public authorities in Europe to undertake more in-depth dialogue with suppliers of products / solutions / services, publishing and advertising a PIN (Prior Information Notice).

In order for the public authority/ies involved in the procurement project to be able to understand the state of the art and, at the same time, to provide a coherent incentive towards innovation for the market, the needs and the desired solutions should be openly and clearly communicated.

Also, the preparatory PIN (Prior Information Notice), as well as the tender documentation, has to specifically mention the desire for a sustainable and innovative outcome, as perceived by the demand side.

THE SUCCESS OF A MARKET CONSULTATION IS ENHANCED WHEN ITS GOALS and the PUBLIC NEED ARE SET CLEARLY.

Highlighting specific solutions that the public authority/ies have become aware of (by means of evidences provided in the open technical dialogue) and the use, consistently during the entire preparatory and procurement process and in all documents addressed to the market, of performance/output based specifications is advisable and could have a positive impact on the final result of the tender procedure.

A more detailed analysis regarding the definition of the subject matter of the contract and of setting specific requirements has been provided in the previous section of this material.

IT IS FUNDAMENTAL TO PROVIDE A CLEAR STATEMENT OF THE PROBLEM AND MEASUREMENT OF ACTUAL SERVICE PERFORMANCE

The principal thing to keep in mind when preparing a market consultation is the need to provide a clear description of the context where innovation will be used and a clear statement of the problem and need, clearly conceived within the public sector.

At the same time, it's important to have clear and objective understanding (based on data/measurement if possible) of actual performance and the business as usual situation. The dialogue with the market should be well planned with the aim to be able to evaluate the innovation gap to be solved and the technology state-of-the art (meaning whether a specific product/technology is ready available on the market or still needs to undertake development or whether a product requires customization which has not been previously performed).

Furthermore, the market consultation gives the necessary input to decide what the most suitable procurement procedure is.

One other important thing to keep in mind when working with the market is the need to provide sufficient time to prepare for the tender.

The Old Procurement Directive was rather scarce in providing guidance on the opportunity / the need for public authorities to conduct market consultations. The New Procurement Directive however, contains specific provisions regarding the conduct of market consultations. The article 40 of the New Procurement Directive states: "Before launching a procurement procedure, contracting authorities may conduct market consultations in view of preparing the procurement and informing economic operators of their procurement plans and requirements. For this purpose, contracting authorities may for example seek or accept advice from independent experts or authorities or from market participants. This advice may be used in the planning and conduct of the procurement procedure, provided that such advice does not have the effect of distorting competition and does not result in a violation of the principles of non-discrimination and transparency."

Special attention must be paid to the possibility that such consultations do not lead to situations that favor the companies involved in the market consultations, thus distorting competition. These consultations seem to be better regulated under the New Procurement Directive and the public purchasers should keep in mind the following:

- *The contracting authority should take the necessary steps to ensure that the participation of a previously consulted company does not affect competition within the tender procedure concerned;*
- *Any information to which the company may be party as a result of its prior involvement must be transparently published or sent to the other participating companies;*
- *When conducting an early market engagement processes, legal assurances must be put in place that suppliers' intellectual property rights (IPRs) will be protected;*
- *Any early market engagement needs to be undertaken with due regard to the principles of openness, transparency, non-discrimination and equal treatment, in line with European procurement law;*
- *No advantage or disadvantage should be given to any supplier / group of suppliers to the detriment of others;*
- *It is paramount that suppliers understand that the competitive phase of the public procurement procedure shall be conducted separately and all supplier shall be treated equally; it is recommended to include such a statement in any invitations to open discussions.*
- *A market consultation couldn't be used to pre-select the market operators for the procurement phase and fair chances in the subsequent procurement have to be assured*[4]*.*

Whereas various methods to engage the market exist, including market survey, "open meet the buyer" events or industry days, the organization of a technical dialogue, anticipated by a PIN, could be a good solution in most cases.

The market consultation can be divided into the following stages:
- Define the PIN, market consultation agenda and materials;
- Publish the PIN and promote the event;
- Conduct the consultation, possibly assuring a web streaming or recording;
- Formulate a report of the consultation;
- Publish the report of the consultations;
- Process gathered intelligence into the procurement decisions.

The market consultation document should clearly describe the goals of the market consultation, the form and planning of the consultation, the characteristics of the organizations that are expected to participate etc. An indicative structure of a market consultation document is outlined below:
- Reasons for holding a market consultation and project background

[4] Bedin and Corvers, 2014 – Legal study for PROBIS project.

- Goals of the market consultation
- Targeted participants/selection
- Approach
- Planning
- Expected input (including specific questions)
- Procedural steps following the market consultation
- Communication around the market consultation
- Legal framework for the market consultation.[5]

The outcomes of the technical dialogue, concerning the level of innovation necessary to solve the problem identified, should be expressed and returned to the market, through the conscious decision to procure via ordinary procurement or PCP or alternatively via PPI.

For each identified need, the technology state of the art assessment might result in three possible alternatives:

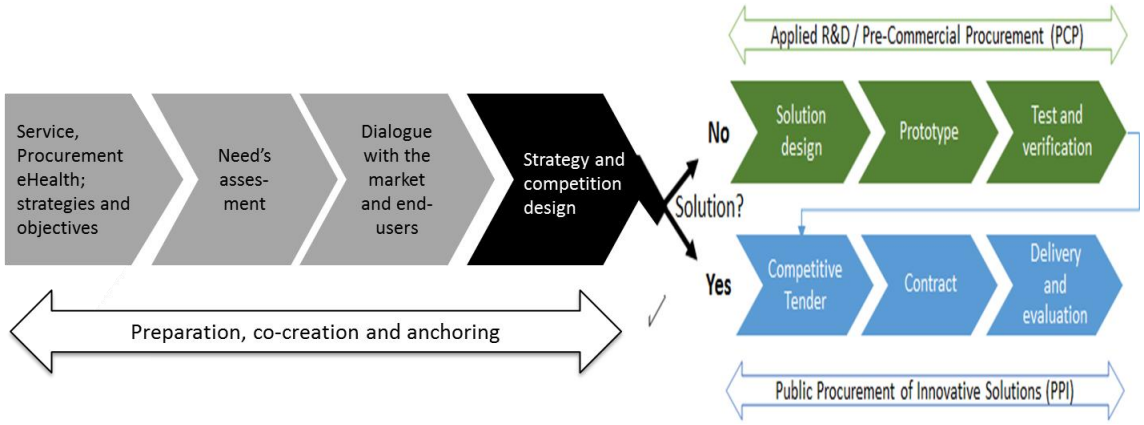
i. There is technology already available in the market that can meet the need. In this case traditional off-the-shelf procurement is used.

ii. There is no technology available yet in the market that can meet the need, but the Contracting Authority's horizon scanning activities generates evidence that it is likely that there will be soon or that it could be soon if industry were aware of this requirement and aware that there is a substantial public sector customer base that is interested to start procuring those products. In this case, the Contracting Authority may choose not engage in a PCP competition, but rather publicize the need to enable the current market to respond with commercial offers. In addition, the Contracting Authority may wish to further strengthen market pull by deploying a Forward Commitment Procurement exercise. This type of procurement commits the Contracting Authority to purchase innovative solutions if the market can deliver a new innovative solution against clearly defined requirements in a specified time frame (typically 6 months to 1 year).

iii. There is no technology available yet in the market that can meet the need, and the Contracting Authority horizon scanning activities do not generate any evidence to indicate that there will be soon or that it could be soon if industry where aware of this requirement, but the horizon scanning activities indicate that there is still R&D needed to define/experiment with the technological and financial viability of various solution approaches that could potentially be used to address the need. In this case, where innovations can only be expected in the mid- to-long term and experimentation is still

[5] *Bedin and Corvers, 2014 Legal study for PROBIS project.*

needed to check in how far the Contracting Authority's functional/performance requirements can realistically be met by solution providers, the Contracting Authority may choose to engage in a PCP competition to procure the R&D needed to get the desired innovative solutions developed and compare alternative solution approaches on their merits.



BOX 8. In Lombardy Region, the structured technological analysis – carried out via technical dialogue, collective discussions and on line forums with the market, explorative calls for tender, patents analysis etc – has confirmed the basis for using a pre-commercial contract, as set out in article 19, section 1 letter f) of Legislative Decree no. 163/2006 and Commission communication no. 799 (07). As a result of the same activities the following has emerged:

i) Existence of a market and innovation gap displaying deficiencies that require further R&D activity;

ii) Non-existence on the market of commercialised products complying with the requirements (expressed in terms of functional and performance needs) of universality, ease of use, safety and cost effectiveness of the devices;

iii) The need, in the light of the above points, to promote a significant advance in terms of technology and performance, able to satisfy the requirements of universality, ease of use, safety and cost effectiveness of the devices.

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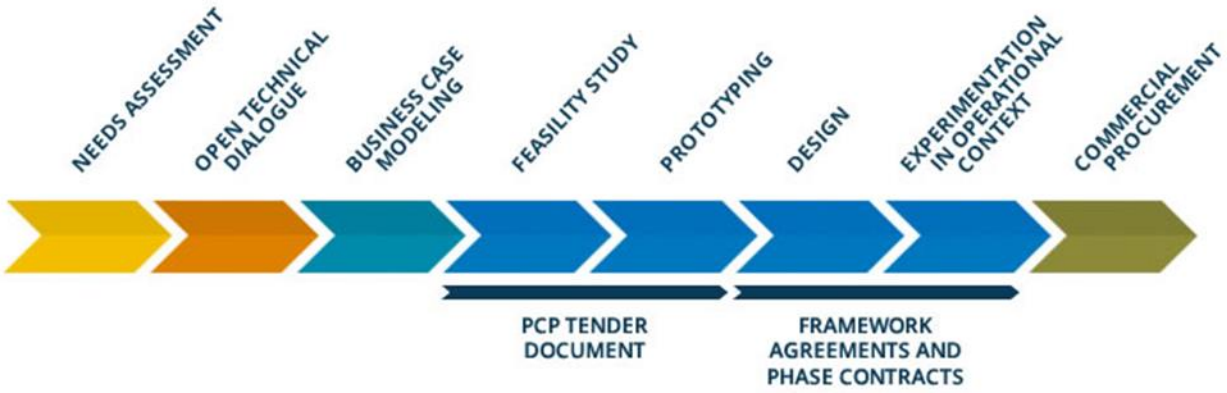
For examples and templates please see the Attachment 2



3 Business case modeling

A business case is an argument, usually documented, that is intended to convince a decision maker to approve some kind of action. The document itself is sometimes referred to as "the Business Case". As a rule, a business case has to articulate a clear path to an attractive return on investment (ROI) in either financial or social benefit terms, or preferably both. Because the business case for many projects is not immediately clear, documentation can be essential for their approval.

There is no fixed format for the creation of a Business Case and it maybe that the Public Procurer's own organization provides its own guidance and format. One format that has been found to be useful can be located at: http://inspirecampus.eu/wp-content/uploads/2014/02/Business-Case-Template.pdf

As a minimum, the Business Case should clearly articulate the current situation and an extrapolation of the current situation, e.g. 5 years into the future. This gives the 'do nothing' baseline against which the envisaged future (achieved by enacting the PCP or PPI) can be compared.

CONSIDER THE IMPACT OF NOT INNOVATING AND THE EXTRAPOLATION OF BUSINESS AS USUAL for 5 years into the future

Ultimately, it is the analysis of the difference in social (system level) outcomes and operating costs between the 'do-nothing' case and the PCP/PPI-enabled improved performance case which should clearly depict the economic drivers for conducting the innovation procurement.

BOX 9. Extract from the initial business case of Lombardy Region PCP

… At the present time moving hospital beds, be they gurneys or mechanical or electrical movement hospital beds, is carried out by pushing or pulling by at least 2 socio-health operators (OSS), with a high rate of accidents and long transport times.

With reference to AO Niguarda, where experimentation of the innovative solution will be carried out, overall some ten accidents and collateral effects have been registered per year affecting nursing personnel and socio-health operators. Such accidents lead to 15-20% invalidity and/or functional limitation in those who carry out bed movements. The economic impact for the administration could be estimated in ….€…

…At the present time AO Niguarda has an overall number of 24 gurneys and 1160 hospital beds, produced by approx. 9 different manufacturers (relative to 14 different electro-commanded beds for intensive therapy or reanimation and 5 different models of electrified beds for patients), as set out in paragraph 5 below. It is estimated that 40% of beds could need a universal movement device….

BOX 10. Extract from the initial/final business case of ”Zero waste mattress” PPI project

Business Opportunities	Revised infrastructure. Very large scale = risk	Supplier collaboration. Multiple skills needed	Risk of litigation	Clear spec from NHS and quantities	Define benefit to end user	Doctors surgery	Saves time and money for NHS. Cost increases benefit also increases?	Cost of manufacture	How many units?	Global?	Number of systems
	Service contract?	Charge NHS for data transfer?	DHL model tracking system	Patient specific - disposable	Collaboration of system (service opportunity)	Training requirements	Training aid using logged data	Run training courses-site CBT value here?			
	NHS intra-hospital transfer-ITU	Markets beyond ambulance	Bundle with other products	Market information about patient weight BMI etc	Used on normal bed care home-extend market	Linking family of products and not interop?	Link to other equipment in the hospital 'Total solution'	Budget?	How much profit?	Time to generate ROI	How does …compare with current arrangements?

Historically, the majority of waste mattresses and pillows from Her Majesty's Prison Service (HMPS) were sent to landfill or incinerated as clinical waste. The increasing costs of disposal together with a drive to reduce volumes of waste to landfill driven by the SOGE (Sustainable Operations on the Government Estate) targets brought this problem into focus.

This led to a fundamental shift in the procurement approach and, after trials, the procurement in March 2009 of a fully managed Zero Waste Mattress system.

Outcomes? A zero waste mattress and pillows solution, sooner than expected and with significant cost savings – estimated to be in the region of £5 million over the life of the contract.

The results speak for themselves: innovative new covers will reduce turnover, and all but eliminate the need for clinical waste disposal; no end-of-life mattresses will be sent to landfill, but instead will be recycled into useful products. HMPS are committed to auditing the zero waste outcomes of the contract, and will look to continual improvement in performance all aspects of the contract

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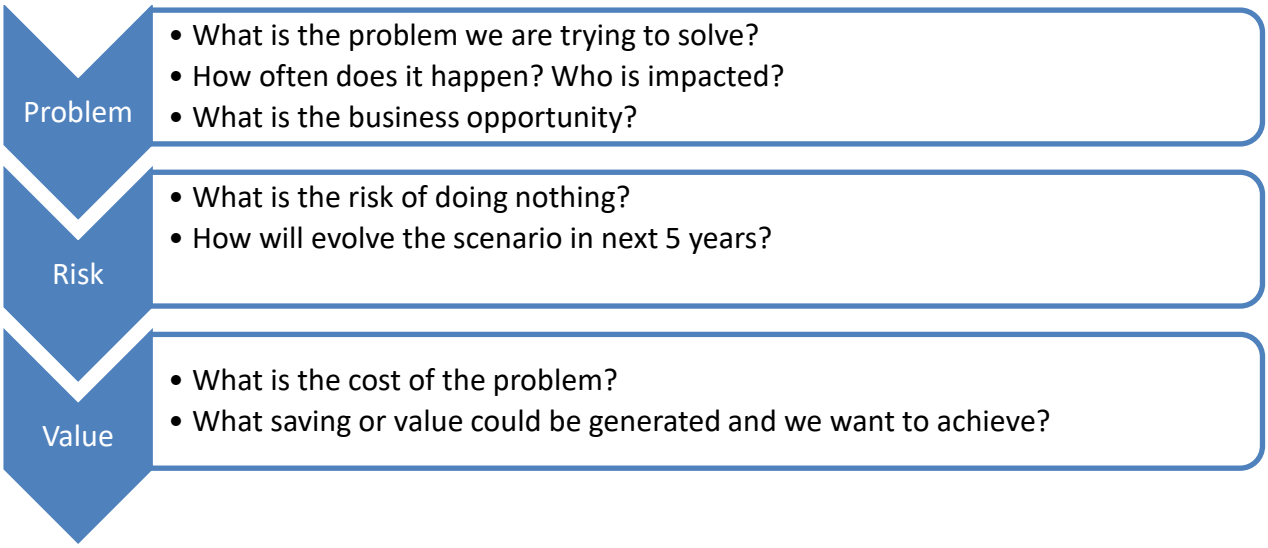
Typically, the phases of developing and modelling the business case are as shown in the following diagram.



It is important to evidence the problem i.e. to show proof that there is a real problem that needs to be resolved. A weakness here will undermine the whole business case. It is of extreme importance to check that:

- That the described 'problem' is not a just a symptom of a more fundamental issue
- That others agree the problem is real
- That the problem is 'big' enough to justify devoting resources to solve it
- That the data that demonstrates the problem is not itself dubious or questionable

A successful Business Case will:

- **State and articulate the problem** that the innovation is supposed to solve, identifying the area or areas where there are issues that need to be addressed, such as inefficiencies, missed opportunities, unacceptable market performance or unfavorable consumer response to a product or service.
- **Quantify that the problem is (or will be) real**, providing metrics and evidences of the situation behind the problem, general projections about potential events if the current situation continues, as well as the potential replicability and scalability of the solution.
- (if relevant, as it is in PPI) **Explore and analyze options** to solve the problem and describe their pros and cons,
- **Examine costs/benefits**, with particular attention to the total cost of ownership (TCO). Cost/ benefits should be optimized for all those who pay, not only for the hospital. Crucial for value creation in healthcare is thus a focus on: the patients' needs and main patient

types, the interlinked challenges for the providing organizations (or the areas wherein there lies a solution opportunity) and ways to get the total costs down for the entire community.

- **Examine risks and establish a plan for how to handle different possible risks** and incidents, being aware of cultural issues and address them as part of risk profile documentation.
- **Make Recommendations** on how the procurement is to be designed and conducted, providing a final statement that you believe the project should go ahead.

Source: VALUE BASED PROCUREMENT MANUAL – A ROAD MAP TO RADICAL INNOVATION
REPORT ON DISRUPTIVE BUSINESS MODEL CASES IN HEALTHCARE
SUNDHEDSINNOVATION SJÆLLAND –REGION SJÆLLAND

The ability to analyze and understand the existence of the preconditions for innovation diffusion appears to be a particular requirement for exploiting PPI and PCP to generate extensive economic and social impact. Consideration should be given to both supply-and demand-side characteristics: the replicability and scalability of the product, capacity of the firm to reach out to other markets, and the absorptive capacity of the market targeted for diffusion.

For a detailed explanation of PCP business case development please refer to INSPIRE deliverable D3.1 - Economic Determinants of PCP and Attachment 3

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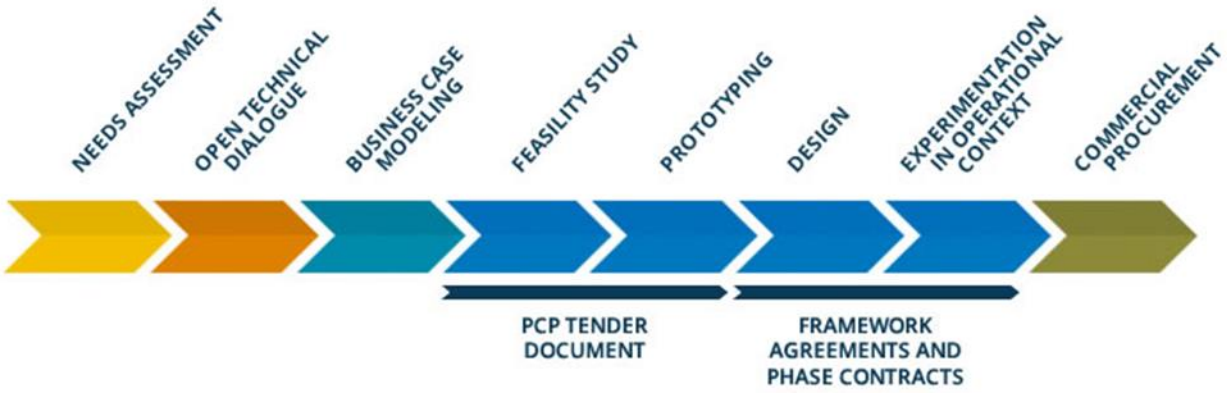

4 PCP and

5 PPI tender documentation and contractual agreement definition

Object of the contract definition and description

In essence innovation procurement unlocks the stalemate by providing the missing demand – or 'market-pull' – for new products and services. Whereas PCP targets the development of innovative solutions that are not yet available on the market, PPI involves the early adoption of innovative solutions that are new arrivals on the market but not yet available on a large-scale basis due to a lack of market commitment to deploy.

When a public entity implements a procurement of something which does not yet exist in the market or intends to purchase a novel product not yet tested by other users, the procurer needs a confirmation that the solutions functions as intended and delivers the expected performance.

The first information that a tender document should provide is a clear description of the need to be fulfilled, in other words the problem statement and description. The aim is to make the market aware of needs, not in vague, general terms but in the context of a credible public service delivery and procurement process that offers to buy solutions that meet those needs once they're available at the right price and fit into the overall service delivery context.

PROVIDE A CLEAR PROBLEM STATEMENT

When being advertised the procurer may include in the advertisement of the tender a section that explains to bidding suppliers the advantages of participating to the PCP or PPI process in view of getting compelling offers. The advertisement can also contain reference of the estimated potential size of the total market for the products to be developed through the PCP process. These references has to be based on authoritative sources and on concrete plans so that the market opportunities for suppliers are clear and the participation to the PCP process is win-win to both parties.

PROVIDE A DETAILED (NOT VAGUE) DESCRIPTION OF THE NEED

It should be noted that innovation procurement looks for unexpected solutions. Specifying requirements in functional and performance terms and not prescribing particular technical solutions leaves room for suppliers to suggest alternative technological solutions.

It has been argued that purchasing authorities/entities need to have considerable technical expertise in order to specify functional requirements. However this expertise could also be provided by other experts in the public administration and also by clinicians and other practitioners, involved in the public service delivery. All key actors that share the commitment to renew the services in question should be involved in need assessment and definition phase, including the final end-users (care professionals, patients etc) of the final solutions.

Users have the best knowledge about their real needs and can therefore contribute most to a supplier's innovation. In some cases, particularly when the procuring unit is the actual user of the acquired product, users can be engaged at low additional cost. In other instances, particularly when end users are citizens consuming contracted-out public services, engaging users requires specific efforts and may incur significant extra costs. Designated user engagement practices need to be set in place. *We refer to section 1 "Need Assessment" for more details*.

Reconciling expectations and needs from a large number of users, especially among a heterogeneous set of users, may require a considerable amount of time and effort, we can say not less than 3-4 months.

SET-UP AND DESCRIBE THE OPERATIONAL CONTEXT TO TEST THE SOLUTIONS

Testing arrangements in a real-life context are also needed to be put in place. Mere technical testing is often not enough to ensure the effectiveness of technology adoption. A change of organizational practices is needed because technology seldom fits the user environment in a seamless fashion (Leonard-Barton, 1988).

At the same time, innovations need to adapt to existing organizational arrangements. The mutual adaptation of innovation and user organization leads to a process of 'inno-fusion' (Fleck, 1993).

BOX 11. Prior inspections in Lombardy Region. …."The context for experimentation in a real environment focuses on hospital rooms, corridors, lifts, areas in diagnostic wards for the preparation of patients located in the South block of Niguarda Cà Granda Hospital.

Prior to the deadline for submission of the offers, those competitors who request the same can carry out a prior inspection of the experimentation context, as set out in the definitions, where prototype experimentation for bed movement will be carried out. Each competitor interested in taking part in the inspection activity must state their interest in participating in the said activity by communicating the same not later than …."

extract from the Lombardy Region call for tender, for more info: sara.bedin@ambrosetti.eu

Concerning the object of PCP, it has to be noted that a double level of description is required: on one hand, the description of the challenge / need (as discussed before) and on the other hand, the description of the R&D services and deliverables required.

Selecting the suppliers

As the European purpose of the procedures for award of public contracts is to eliminate barriers to the freedom to provide services and goods and therefore to protect the interest of traders established in a Member State who wish to offer goods or services to contracting authorities established in another Member State, no quantitative or qualitative restrictions are admitted on geographical or dimensional basis. Indeed, innovation procurement, and in particular PCP, looks for unexpected solutions. The range of suppliers potentially interested in undertaking the R&D activity in a PCP is normally very wide and unpredictable. Ensuring that all potential bidders have equal chances to bid also implies that the procurement process, including IPR arrangements, does not discriminate against any potential supplierr.

BOX 12. To encourage the participation of SMEs and assure in its own right the possibility of purchasing the solutions arising from the R&D, despite the well-established practice, Lombardy Region has not used stringent qualification requirements as in procurements for large scale deployment (e.g. minimum qualification requirements and financial guarantees proof, customer reference, provisional deposit…) but forward looking criteria which are objective and relevant in view of the subject-matter of the PCP and in particular a declaration of the ability to carry out all contractual activities and to have accounting and organizational structures to ensure the

management, exploitation and / or transfer of IPRs arising from the research.

for more info: sara.bedin@ambrosetti.eu

Derogations to the principle of equal treatment in EU law are not admitted, unless for order or security reasons. It shall also fulfil the criteria of proportionality according to which the measure must be apt to pursue the objective at stake and not go beyond what is necessary to obtain it.
In any case, the requisite relative to suppliers' personal situation should be set out in the call for tender, presenting relevant regulations.

BOX 13. ….The requisite relative to personal situation as set out in point III.2.1) of the call for tender must be declared, subject to exclusion from the procedure, in Annex 1 to the present regulations indicating: a) entry, if needed, in the companies register or in one of the professional or commercial registers of the state of residency if a member state of the European Union is involved, in compliance with what is set out in article 39, Legislative Decree no. 163/2006, with the exception of non-economic public bodies; b) the non-existence of reasons for exclusion as set out in article 38, Legislative Decree no. 163/2006.

extract from the Lombardy Region call for tender for more info: sara.bedin@ambrosetti.eu

Selecting the most advantageous offer/offers

Transparency requires rule-based decision-making in awarding tenders. The underlying principle is that the impartiality of the contracting authorities' decision can be reviewed. Rule-based decision-making is designed to limit discretion and concealed discrimination. Transparency also requires the selection and award processes are based on known and beforehand advertised criteria. This means that the criteria for assessing the tenders in order to award a contract must form part of the minimum information contained in the call for tender or contract notice.

ASSURE THAT THE CRITERIA ARE UNDERSTANDABLE, QUANTIFIABLE AND VERIFIABLE

It also means that, when the award is made to the most economically advantageous tender, all criteria the contracting authority is intending to apply must be stipulated, where possible, in descending order of importance.
All offers will be evaluated according to the same objective criteria regardless of the nationality of the bidder and these criteria will be understandable, quantifiable and verifiable.

BOX 14. Example 1 – Lombardy Region PCP – Awarding criteria (and scoring system for Phase 1)

CODE	SUB-CRITERION	DESCRIPTION	MAXIMUM TECHNICAL SCORE	MINIMUM TECHNICAL SCORE
1	Ability to satisfy requirements	Level of solution satisfaction (in terms of quality and completeness) of functional and performance requisites.	25.00	12.50
2	Level of innovation	Ability of the solution to innovate and significantly improve the operational context in which the same is to be introduced.	22.00	11.00
3	Industrialisation and technical feasibility	Realisability and reproducibility of the solution in accordance with an industrial process that is appropriate relative to the reference market.	20.00	10.00
4	Reduction of overall cost	Improvements adopted to limit the costs of the solution throughout its entire life cycle (production, delivery, installation, use, maintenance, management and disposal).	15.00	7.50
5	Reduction of environmental impact	Improvements and measures adopted to ensure the environmental sustainability of the solution throughout the entire life cycle (production, delivery, installation, use, maintenance, management and disposal).	10.00	5.00
6	Quality of project organisation	Coherence and quality of the organisation of work relative to the technical-scientific objectives and competences of the research team effectively committed to the project.	8.00	4.00

for more info: sara.bedin@ambrosetti.eu

BOX 15. Example 2 – DECIPHER PCP Project – Awarding criteria

		Score*	Max. Points	Min. Points Exclusión Criteria	Score*	Max. Points	Min. Points Exclusión Criteria	Score*	Max. Points	Min. Points Exclusión Criteria
I	**FUNCTIONALITY**		**25**	**10**		**21**	**10**		**20**	**10**
	Basic functions		***20***			***16***			***16***	
	Secure Access tp PA-PHR-S	10	5		10	4		10	4	
	Share information	10	5		10	4		10	4	
	Manage treatments	10	5		10	4		10	4	
	Inform in Emergency Situations	10	5		10	4		10	4	
	Design functions		***5***			***5***			***4***	
	Provide User interface accessibility	10	1		10	1		10	1	
	Provide Data availability and redundancy	10	2		10	2		10	1	
	Satisfy Technical design requirements	10	1		10	1		10	1	
	Satisfy Business Model Design requirements	10	1		10	1		10	1	
II	**INNOVATION**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**
III	**IMPACT OF INNOVATION**	**10**	**5**	**2**	**10**	**5**	**2**	**10**	**5**	**2**
IV	**QUALITY**		**15**	**8**		**15**	**8**		**15**	**8**
	Quality in Management	10	8		10	8		10	8	

		Score*	Max. Points	Min. Points Exclusión Criteria	Score*	Max. Points	Min. Points Exclusión Criteria	Score*	Max. Points	Min. Points Exclusión Criteria
	Quality of Risk Management	10	7		10	7		10	7	
V	**TECHNICAL FEASIBILITY**	**10**	**20**	**8**	**10**	**20**	**12**	**10**	**20**	**16**
VI	**COMMERCIAL FEASIBILITY**	**10**	**20**	**8**	**10**	**20**	**12**	**10**	**20**	**16**
VII	**FINANCIAL FEASIBILITY**	**10**	**9**	**5**	**10**	**8**	**5**	**10**	**4**	**2**
VIII	**PRICE**		**5**			**10**			**15**	

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Excluding the presence of State Aid when implementing PCP

Under competition rules, Contracting Authorities must pay no more than the market price for the R&D services procured. A financial compensation for leaving IPR ownership rights compared to exclusive development price that is either non-existent or too low would contravene State Aid law.

There are at least three options available and these include:

I. discount on the R&D price (compared to exclusive development price) for doing the research, and/or
II. share of equity stake with the Contracting Authority and/or
III. Royalty payment to the Contracting Authority.

The setting of the exact value for the above three options is best achieved through the competitive process. As part of the tendering process, bidders compete to win a contract to deliver R&D services. It is in the tender publication that the Contracting Authority indicates which of the above options it accepts, and it is in their submission that the bidder states (in case of option 1) the amount of money they require to deliver the R&D (indicating the size of the offered reduction in the R&D price) and/or the price for doing the R&D services in the case of a specific percentage of sales/profits as royalty payment and/or the equity stake back to the Contracting Authority.

On receipt and evaluation of the bids, the Contracting Authority either accepts or rejects each offer against criteria stated in the PCP Call for Tender. In addition, in order to make sure that the presence of State Aid is excluded, procurers should observe the requirements of the EC as laid out in the Commission's working paper SEC (2007) 1668

Risk management

Pre-commercial procurement is characterized by following three aspects:
Risk-benefit sharing according to market conditions
Competitive development in phases
Separation of the R&D phase from deployment of commercial products

Introducing explicit objectives to promote innovation through procurement implies to manage the associated risk. PCP is based on contractual and structured process based risk management. PCP is both a risk-managed and a stage-gated process, i.e. PCP as a stepwise process does balances risk & investment.

Basic risks connected to PCP approach include; 1. No automatic purchase/commercialization of the developed product/service, 2. The risk of supplier exclusion, 3. State aid infringements, 4. Non-completion of the PCP – process.

The potential of PCP must be seen in the light of the gains. Investing in the PCP phase can mean de-risking while;

- Significant post-commercial procurement adjustments often imply additional work time and financial investments which are not included in the original procurement budget and thus not even considered in the procurement and selection process
- The procured solution is likely to be better real needs adopted from the start, than when acquired traditionally through commercial procurement.
- The solution is likely to fit the service environment more rapidly, fluently and in a more secure manner (also reduced technology risk). This implies also e.g. better user-acceptance, fluency of clinician work, better patient satisfaction and patient security (less error in the care delivery).
- Risk of buying yesterday's product diminished
- Pooling of demand diminishes the risk carried by single procurer / contracting authority
- PCP should be seen as an investment in a learning process where public sector capabilities are strengthened delivering gains even in future.

PCP process can naturally also materialize risks such as a situation where PCP has led to very customized non-scalable products without commercial procurement by the PCP Contracting Authority. (However, even in this case the supplier has been paid for the R&D).

Expected efficiency and effectiveness gains from PPI cannot be guaranteed due to the inherent risks involved with any innovation. Technological risks may lead to non-completion, underperformance or false performance of the procured service or product (Edler and Georghiou, 2007, Tsipouri et al., 2010). However, this same applies often to other forms of demanding and challenging procurements.

For a complete guide on risk management we refer also to: ”Introduction to Risk Management in the Public Procurement of Innovation” Download the link from: www.innovation-procurement.org.

Intellectual Property Rights (IPRs) management

To introduce this topic, we reproduce (and we refer to) the “Introduction to intellectual property rights in Public Procurement of Innovation” published by ICLEI on Procurement of Innovation Platform[6].

“…*When procuring innovation, new findings, insights, and potentially new technology are possible - and indeed expected outcomes. As a result, determining who owns the Intellectual Property (IP) Rights to these outcomes can be very important.*

If a public authority retains the intellectual property rights, the involved companies' incentive to innovate and search for new solutions can be too limited. It can also result in a public authority paying too much for intellectual property rights that it does not (or cannot) exploit.

If a public authority leaves the intellectual property rights with the involved economic operator, vendor lock in looms: the authority is tied to the vendor for a specific service or product it has paid to develop.

ASSURE THE INCENTIVE TO INNOVATE and PREVENT the LOCK-IN

https://www.innovation-procurement.org

Among different forms of intellectual property rights three types are most relevant in the public procurement of innovation: patent rights, protection of trade secrets and copyrights.
A patent is a common method of legally protecting inventions (products or processes). In Europe it is regulated by European patent law. It is an exclusive right to make, use, import and sell an invention. It is granted for a limited time. A result of a patent is that the exact details of the invention are disclosed to the general public. An innovation can only be patented if it is new and non-obvious to an expert.

A more common method of intellectual property is trade secrets. The innovation is protected by keeping it a secret, which can be legally supported through a Non-Disclosure Agreement (NDA) between the public authority and the supplier. Trade secrets lend themselves specifically to processes that are applied in a 'closed' environment. Maybe the best known trade secret is the recipe for Coca Cola. Trade secrets are not disclosed publically, and can last indefinitely, unlike patents which have an expiry date.
Intellectual property rights provide the supplier with no additional protection once the information of the trade secret is uncovered, such as through the reverse engineering of an innovation.

A copyright gives the creator of original work exclusive rights to it, usually for a limited time. Copyright may apply to a wide range of creative, intellectual, or artistic forms or "works". Copyright does not cover information and ideas themselves, only the form or manner in which they are expressed.

In procurement, the following options are open when it comes to intellectual property rights:

- *Claim the full rights to new intellectual property*
- *Claim no rights to new intellectual property*
- *Share intellectual property rights between public authority and supplier.*

Based on needs and risks, the public authority decides on the best strategy to follow.

In general:

- *The more innovation and investment expected from the market, the more intellectual property rights should be left with the market.*
- *The more opportunities for commercialization of the intellectual property rights by the market, the more intellectual property rights should be left with the market.*
- *The more 'after-sales' improvement and development are expected on the innovation, the more reason there is to leave the intellectual property rights with the market. For example,*

companies selling standardized software packages typically provide regular updates and develop improvements for groups of customers.

- *The larger the risk of vendor lock-in, the larger the necessity to retain intellectual property rights (e.g. through a license-structure).*
- *The more uncertain the future is, the larger the necessity to retain intellectual property.*

In most cases the adverse of the above statements is true as well. For example, when only limited investment for innovation is necessary, there is limited opportunity in the market for commercial exploitation, and/or the product or service concerned is a specific one-off solution, the public authority should claim intellectual property rights.

In general term, we have to underline that the ultimate innovation policy goal for PCP and PPI is that new products and services also diffuse to other government users, private users and export markets. Poor diffusion of innovation can undermine higher investments in procurement. Understanding the preconditions for a diffusion process is an essential function for innovation procurement (Rothwell, 1982; Rolfstam et al., 2011).
Consideration should be given to the real operational and technical possibility to manage IPRs and assuring their allocation to those who can effectively exploit".

The types of issues which must be addressed by contracting authorities differ according to whether the instrument used is PPI or PCP, as described below (Bedin and Corvers, 2014).

- In the case of PPI, a contracting authority often plays the role of a first-purchaser or early-adopter of existing technology on the market. The technology is often characterized as pioneering or cutting edge and may also be high-risk/high impact, so may as yet have only limited market share. The purpose of PPI is to help 'pull' the technology towards successful widespread commercialization, by the contracting authority taking on some of the risks by acting as first customer.
  In most cases, when the contracting authority engages in PPI, the private party has already successfully performed all R&D and will have prototypes, beta-testers, or even first commercial volumes available. In such a case, the IP is generally the property of the private party since it has performed the entire R&D itself without public support. From an IP perspective, the instrument of PPI is therefore a contractual arrangement which aims to provide the contracting authority with licensing rights to the IP contained in the technology.

It is essential that the license rights should reflect all of the uses to which the contracting authority wishes to put the technology.

- Unlike PPI, the instrument of PCP involves the contracting authority actually "sponsoring" the generation of R&D outputs. In so far as the R&D outputs also give rise to IP, this IP is allocated to the private party, who may also be required to compensate the contracting authority for the market value of the IP, according to State Aid rules. The contracting authority will generally be granted a 'free use' license to the generated IP, as well as a right to sublicense the IP to third parties on non-exclusive, market-based terms and conditions.

CALL BACK CLAUSE IN PCP SHOULD BE ACTIVATED AFTER A PRE-DEFINED AND CONGRUOUS TIME-FRAME STIPULATED IN THE CONTRACT

The scope of the 'free use' license is generally limited to internal use only within the contracting authority, and only extends to the IP embodied in the 'pre commercial' R&D outputs. If the contracting authority wishes to also implement the technology once it has been developed commercially, then a separate procurement- often in the form of a PPI- is necessary.

In order to ensure that the private party has sufficient incentives to actually commercialize the results at the end of the PCP, PCP contracts may also contain an IP 'call back clause'. Such clauses obligate the private party to transfer the ownership of the IP generated under PCP to the contracting authority in case of failure to commercialize within a certain time-frame stipulated in the contract.

ASSURE A WIN-WIN IPRs ALLOCATION and AVOID CUT AND PASTE OF DEFAULT CLAUSES

As standard clauses for terms and conditions may not exist, it is important to design the IPRs allocation assuring a win-win situation, avoiding uncritical adoption of default clauses.

We provide one examples of IPRs clauses as defined by DECIPHER PCP tendering & contracting documents.

- … Risks and benefits of the IPRs shall be shared between the Bidders and the Procuring Authorities, according to market conditions and the principles of the Treaties of the European Union (free movement of goods, the free movement of workers, the freedom to provide services, the freedom of establishment and the free movement of capital, as well as the principles deriving therefrom, such as the principles of non-discrimination, transparency and equal treatment) and pursuant to the provisions of this clause.

- According to the principles established by the European Commission in the Communication on Pre-commercial Procurement "in pre-commercial procurement the contracting authority does not assume all the results and benefits of the R&D services performed in the contract exclusively for itself for use in the conduct of its own affairs, but shares them with others", the regulation of the

IPRs generated in the framework of this project will be as follows:

- Ownership of IPRs generated by a Bidder during and in the framework of the Project will be assigned to such Bidder, and therefore the Procuring Entity hereto shall not have any ownership rights in connection with such IPRs;

- All background IPR ("Background IPRs") used or supplied for the purposes of this PCP shall remain the property of the Party introducing the same (or, where applicable, the third party from whom the right to use it has derived). On the submission of each phase of the procedure, and in any event as soon as practicable when there is a variation with respect to the notification which shall be done by the Bidders at the beginning of each phase, the Bidder shall notify in writing with full and complete information of any self or third party owned pre-existing or Background IPRs that may in any way affect any use or exploitation rights corresponding to the Procuring Authorities and/or the Procuring Entity as explained below. These notifications will be provided by the Bidders with the necessary authorizations at no cost for the Procuring Authorities and/or the Procuring Entity and, if necessary, the latters will be reinstated as legitimate users according to the terms below, including as the case may be, the substitution of equivalent solutions or products that do not infringe third party IPRs.

- In any case, the Procuring Authorities will be each individually assigned an irrevocable, unlimited, worldwide, fully paid-up, royalty-free, non-exclusive license until the expiry of the respective IPRs to use such IPRs, and if necessary the Background IPRs referred to in Section (ii) above -with protection of claims of third parties, but exclusively for internal purposes related to the possible implementation of new proofs of concept and the training of new users (both professionals and patients) in the solutions reached throughout this PCP, and just within the scope of the public provision of healthcare services or products within the health public sector organizations to which the Procuring Authorities are attached or linked.

    - The Bidders shall confirm that they have procured from the owner of any Background IPR owned by a third party the necessary license or the necessary variation to any pre-existing license required to allow the Procuring Authorities to use that Background IPR to the extent that it is supplied with or forms part of the Project and will be used by the Procuring Authorities according to the internal purpose referred to in the previous paragraph. The Bidders shall indemnify and hold the Procuring Authorities harmless from any claim exercised by any third party regarding an infringement due to their use of the Background IPRs.

    - The abovementioned license in favor of the Procuring Authorities shall be deemed to have been granted to the Procuring Authorities or to any other entity, which may in the future carry out the objectives and functions that may have been vested to them. Should the Procuring Authorities become subject to a merger, split, or other restructuring measure, the license shall automatically – without any consent from the Bidders being required – transfer to the new (where this is the case) legal entity that is to continue the activities encompassed by this PCP.

    - The license in favor of the Procuring Authorities shall include, as far as it is related to software, a right to immediate access to and to the development, modification, transformation or adaptation of the up-to-date source code.

    - As an exception, in the particular case of the license granted to TicSalut as Procuring Authority such license shall further include the right to issue a sublicense on the same terms, and subject to the same limitations, as the one granted to TicSalut, in favor of the Procuring Entity for its internal use or to any other entity, which may in the future carry out

the objectives and functions that may have been vested to the Procuring Entity. Should the Procuring Entity become subject to a merger, split, or other restructuring measure, the sub-license shall automatically – without any consent from the Bidders being required – transfer to the new (where this is the case) legal entity that is to continue the activities encompassed by this PCP. For clarification purposes, the Procuring Entity shall also be indemnified and held harmless by the Bidders in case of any claim exercised by any third party regarding and infringement due to their use of the Background IPRs.

- In addition, upon request of any Procuring Authority, the Bidders shall offer to such Procuring Authority a non-exclusive license to use or exploit for any purpose the Project IPRs, and/or the Results on significantly better terms and conditions than those prevailing on the market, reflecting the fact that such Procuring Authority partly funded the research having led to the Project IPRs.

- Upon request of the Procuring Authorities, the Bidders shall offer to any third party designated by the Procuring Authorities a non-exclusive licence to use the IPRs under fair and reasonable conditions with consideration of the rights of other third parties that do not accrue to such Bidders.

- All contracts will include a call-back provision to ensure that IPRs from Bidders that do not succeed to exploit the IPRs by themselves, or are using them to the detriment of the public interest behind the DECIPHER PCP, are returned back to the Procuring Authorities, which shall pay the corresponding compensation for the background IPRs referred to in Section (ii) above. The call-back provision will be invoked only if the Bidders are not progressing with the exploitation within a maximum of three-year period after the end of the Framework Agreement or are used to the detriment of the public interest behind the DECIPHER PCP at any time,. In this regard, both Procuring Entity as well as Procuring Authorities may request information from Bidders in order to confirm the effective and adequate exploitation of the IPRs by Bidders. In any case, the Bidders have the right to apply for and maintain any IPRs which may derive from the Project and, in the event the Bidders wishes to waive this right, shall notify the Procuring Entity at least six (6) months prior to expiration of the IPR title. The Bidder shall transfer the IPR in question to the designee of the Procuring Authorities.

- Bidders shall use their best efforts to promote the dissemination of the Results of the Project and therefore, shall be obliged to work with other contracting or public authorities or Standard Development Organizations ("SDO") that show interest in making any use of the solutions or experiences found or lived in this PCP guaranteeing thus a European wide exploitability or the expansion of the knowledge in PCPs.

- The Bidders shall inform the Procuring Authorities of any Results which are suitable for the exploitation whether patentable or not within one (1) month from its obtaining. Both the Bidders and the Procuring Authorities shall refrain from doing any publication that may prejudice to their registration.

- While the Bidders maintain the ownership of the IPRs:

  - They shall at their own expense be responsible for the application, examination, grant, maintenance, management and protection of the IPRs and in particular, but without limitation, they shall ensure that: the Results of the Project are identified, recorded and carefully distinguished from the outputs of other research and development activities not covered by the Project; prior to any publication on the Project, patentable inventions arising from the Project are identified, duly considered for patentability and, where it is reasonable to do so, patent applications in respect thereof are filed at the relevant Member State or European Patent Office; and all such patent applications are diligently executed and prosecuted having regard to all relevant circumstances.

- If any Bidder becomes aware of any product or activity of any third party that involves or may involve infringement or other violation of any IPRs, it shall promptly notify the Procuring Authorities of the infringement or violation.
- They shall take all appropriate measures to protect or defend said IPRs.
- They shall permit the Procuring Authorities to monitor the operation and effectiveness of the Bidders' procedures for the management of IPRs in such a way as the Procuring Authorities consider reasonably necessary.

for more info: jpmathieu@gencat.cat

For what concern the general framework agreements and contracts

we refer to the examples provided in attachment (annex 4 and 5).

Attachments:

Annex 1

Wouldn't It Be Great If… (WIBGI)

(1) Wouldn't It Be Great If ……

……e.g. there was a new device to move patients with a fractured neck of femur/fractured shaft of femur

Background

....e.g. *The existing splint is too complicated to use, there are too many straps and bits go missing. If all the pieces are there and we can get it to fit properly it does little to stabilise the patient over rough terrain or when moving them. If we can't get it to work in 10 seconds we won't use it, especially in emergencies. There is recognition that getting granny down three flights of stairs in a cluttered house with no working lights is exactly why a better splint is needed especially when you combine this with the existing carry chair which does little to help the situation....*

Clinical Need

...e.g. A new easy to use/re-use mechanism to move patients with a fractured shaft of femur/fractured neck of femur which must fit the 10 second rule and be able to self regulate compression in transit.....

(2) Wouldn't It Be Great If ……

....

Background

...

Clinical need

....

Annex 2

EXAMPLE OF A PIN (Prior Information Notice)

Formal notification of an Open Market Consultation (OMC) to canvass stakeholder feedback on procuring integrated diabetes care for the population of Eastern Cheshire.

This includes procuring technology enabled diabetes services for older people as a support to the EU policies on Active and Healthy Ageing. The intention of NHS Eastern Cheshire Clinical Commissioning Group is to procure services up to the value of 3 000 000 EUR.

http://ted.europa.eu/udl?uri=TED:NOTICE:285729-2015:TEXT:EN:HTML&tabId=1

Original language | Data

Display compact view

13/08/2015 S155 Member states - Service contract - Prior Information Notice - Not applicable

I.II.B.III.VI.

United Kingdom-Macclesfield: Health and social work services

2015/S 155-285729

Prior information notice

Services

Directive 2004/18/EC

Section I: Contracting authority

I.1) **Name, addresses and contact point(s)**
Eastern Cheshire CCG
1st Floor, West Wing, New Alderley House
Contact point(s): Senior Programme Manager
For the attention of: Hadleigh Stollar
SK10 3BL Macclesfield
UNITED KINGDOM
E-mail: hadleighstollar@nhs.net
Internet address(es):
General address of the contracting authority: https://www.easterncheshireccg.nhs.uk/
Address of the buyer profile: https://www.nhssourcing.co.uk/project_19991
Further information can be obtained from: The above mentioned contact point(s)

I.2) **Type of the contracting authority**
Regional or local authority

I.3) **Main activity**
Health

I.4) **Contract award on behalf of other contracting authorities**
The contracting authority is purchasing on behalf of other contracting authorities: no

Section II.B: Object of the contract (Supplies or services)

II.1) **Title attributed to the contract by the contracting authority:**
Formal notification of an Open Market Consultation (OMC) to canvass stakeholder feedback on procuring integrated diabetes care for the population of Eastern Cheshire. This includes procuring technology enabled diabetes services for older people as a support to the EU policies on Active and Healthy Ageing. The intention of NHS Eastern Cheshire Clinical Commissioning Group is to procure services up to the value of 3 000 000 EUR.

II.2) **Type of contract and place of delivery or of performance**
Service category No 25: Health and social services
Eastern Cheshire, Cheshire, United Kingdom.
NUTS code UK,UKD2

II.3) **Information on framework agreement**

Annex 3

(Business case modeling and challenge briefing)

Improving the Care of the Diabetic Foot Ulcer
– Better prevention, diagnosis, treatment

.pdf version downloaded here:

http://www.sbrihealthcare.co.uk/past-competitions/improving-the-care-of-the-diabetic-foot-ulcer-better-prevention-diagnosis-treatment/

Annex 4

DECIPHER PCP general Framework

DECIPHER PCP GENERAL FRAMEWORK

1. The Contractor agrees to provide research and development services to the Procuring Entity in the framework of a project entitled "*Distributed European Community Individual Patient Healthcare Electronic Record*" in accordance with the specifications detailed in the Tender documents (the "**Project**").

1.1 The Project is divided into four different stages:

1.1.1 **Phase 0 – Initial Selection**: In this Phase, any Bidder shall be entitled to submit a preliminary innovative solution, for which shall receive no payment (no budget nor payments at this stage). This Phase shall approximately last up to 4 calendar months, being regulated by the provisions contained in this DECIPHER PCP Invitation to Tender (ITT) as well as in the DECIPHER PCP Challenge Brief (CB).

1.1.2 **Phase 1 – Solution design Selection**: A maximum of 9 Bidders awarded with the Phase 1 shall be entitled to submit a final innovative solution, for which each Bidder shall receive a maximum payment of 25.000 EUR (VAT excluded). This Phase shall approximately last up to 5 calendar months, being regulated by the IT, the CB and, in addition, by two additional contractual documents to be signed by the Bidders when awarded with the Phase 1: a **Framework Agreement** (FA) with provisions related to the three remaining Phases and a Contract governing Phase 1.

1.1.3 **Phase 2 - Prototype Development Selection:** A maximum of 6 Bidders awarded with the Phase 2 shall be entitled to develop prototypes on the basis of the final innovative solutions selected at the end of Phase 1, for which each Bidder shall receive a maximum payment of 52.500 EUR (VAT excluded). This Phase shall approximately last up to 8 calendar months, being regulated by the IT, the CB and, in addition, by the Framework Agreement signed by the Bidder when awarded with Phase 1 and by a Contract governing Phase 2, to be signed by the Bidders when awarded with Phase 2.

1.1.4 **Phase 3: Proof of Concept.** A maximum of 3 Bidders awarded with the Phase 3 shall be entitled to produce and test a small scale of products on the basis of the prototypes finally selected at the end of Phase 2, for which each Bidder shall receive a maximum payment of 120.000 EUR (VAT excluded), which could be increased if there is a remained amount of Phases 0, 1 and 2. This Phase shall approximately last up to 9 calendar months, being regulated by the IT, the CB and, in addition, by the Framework Agreement signed by the Bidder when awarded with Phase 1 and by a Contract governing Phase 3, to be signed by the Bidders when awarded with Phase 3.

Annex 5

PPI tendering framework

HAPPI tender instructions – see separate pdf document