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D2.5 Innovative Procurement delivery

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Abstract

This document, developed in the framework of T2.5 Innovative Procurement Phases Delivery, lays the foundations for the creation and implementation of a strategy to promote public procurement of AI-based solutions with the aim to improve delivery of care in European hospitals in Europe. We have analysed the European and national legal frameworks that apply in this regard, the types of public procurement models, the processes that apply in each hospital and/or region of the ODIN consortium, the stakeholders involved in the hospitals and the best practices and pain points identified by these institutions.

The conclusions drawn from the work presented in this document, will serve as a basis for collaboratively working with the Demand Sides (hospitals) and the Supply Sides (medical technology suppliers) in focus groups, for co-creation workshops in the framework of tasks T10.2 and T10.3 and for defining guidelines and the framework for the procurement of solutions promoted in the ODIN project.

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation, or both.

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1 About this deliverable

This document is developed for WP2 – DEMAND AND SUPPLY COCREATION: Smart Hospital Needs, Reference Use Cases and Catalogue Specifications in Task 2.5 Innovative Procurement Phases Delivery. The main objective of this Task is to design and implement the overall procedure for innovative procurement of the outcomes of the ODIN project.

This will be done by developing the following activities:

- Analysis of the status of the EU Public Procurement of Innovation (PPI) in healthcare
- Analysis of the status of Public Procurement in Hospitals
- Barriers and best practices for the implementation of PPIs in Hospitals
- Value-based healthcare paradigm and its impact in procurement
- Definition of a common methodology and guideline for the procurement of ODIN solutions

Public Procurement of Innovation is one of the pillars of the ODIN exploitation and sustainability because the acquisition of the ODIN services and solutions by public Health & Care Agencies, such as hospitals and regional authorities, can only be done following the country legal regulations of public procurement.

The scope of this deliverable is to analyse the current state of the art of the Public Procurement of Innovation in Europe taking in consideration the current legislation, ongoing initiatives, and examples of published PPIs. This analysis will be combined with the feedback received from the healthcare authorities involved in the ODIN project. Their experience in such procurement-related activities will form the basis for the ultimate task goal which is represented by the definition of PPI guidelines for the procurement of the ODIN solutions. This task will involve the preparation of focus groups and the co-creation of a workshop.

In this document, we focus on the analysis of the current situation of public procurement in the countries where ODIN is developing pilot sites. This selection has been done since, as members of the ODIN project, hospitals will be the first users of ODIN services and solutions. These hospitals are the so-called early adopters. Therefore, by adopting a hand-to-hand approach, we will be able to analyse how they are currently purchasing these innovative solutions, which are the barriers and the current best practices that we can incorporate to the guidelines developed during the execution of Task 2.5.

The work has been done in relation with Task 2.1 Co-creation strategy, stakeholders' definition and mapping, Task 2.2 Hospital requirements specification. Apart from that, the outcomes of T2.5 will be further developed in D10.2 Demand Open Innovation and D10.3 Supply Open Innovation and consider in Task 9.4 Exploitation Report and Business Models

1.1 Deliverable context

Table 1. Deliverable context

PROJECT ITEM	RELATIONSHIP
Objectives	This deliverable is directly contributing to meet O2: Build a dynamic and collaborative co-creation mechanism for Innovative Procurement Journey and O4: set up an exploitation strategy to reach a critical mass, to allow the ODIN solutions to be delivered, as this document is setting the basis of the public procurement framework for the acquisition of the ODIN services and solutions from the HC authorities.
Exploitable results	This deliverable is going to contribute to develop a methodology for the overall procedure and reference regulation for the innovation procurement of ODIN solutions.
Workplan	D2.5 is attributed to the WP2 DEMAND AND SUPPLY COCREATION: Smart Hospital Needs, Reference Use Cases and Catalogue Specifications. The task involved in the preparation of this deliverable is T2.5 Innovative Procurement Phases Delivery.
Milestones	D2.5 is contributing to the overall ODIN sustainability that will be one of the key activities to be achieved on MS2 (Procurement procedure simulation) for Designing Solution Intervention Phase and MS4 (Pre-commercial Procurement) for Innovative Procurement & Product Packaging phase of the project.
Deliverables	D2.5 is performing an analysis of the status of the EU PPI in Healthcare, identifying its barriers, best practices, and framework for the definition of ODIN solutions procurement.
Risks	There is no foreseen related risk to this deliverable/task.

2 European Reference Regulation for Innovative Procurements

Regarding Public Procurement (acquisition of works, goods, and services by Public Administrations), we can find an important legislative framework that defines the procedures to carry out and materials to be used in these initiatives. This chapter will describe the European Directive on Public Procurement and its transposition in each of the EU member countries present in ODIN. Likewise, the most frequent models of public procurement nowadays will be commented.

2.1 European Directives in Public Procurement

The first European rules dealing with public procurement are:

- Directive 2004/18/EC of the European Parliament and European Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts and;
- Directive 89/665/EEC of the European Council 21 December 1989 on the coordination of the laws, regulations and administrative provisions relating to the application of review procedures to the award of public supply and public works contracts

In 2014, the European Parliament and European Council adopted Directive 2014/24/EU on public procurement, transposed into national law in the EU member states.

This Directive created a more flexible framework for public procurement with the aim of using instruments that enable smart, sustainable, and inclusive growth, ensuring the most efficient use of public funds. In addition, it positions research and innovation as one of the main drivers of future growth [1] .

In this respect, one concept included in this Directive was the European "most economically advantageous tender" (MEAT) principle. The European Union legislation promotes a methodological framework for making use of the Best Price to Quality Ratio (BPQR), with which to boost innovation, while taking into account the costs including the price of procured goods, services and solutions [2].

On the other hand, an important element of Directive 2014/24/EU is the defence of the SME sector. Contracting Authorities are encouraged to make use of the "European Code of Best Practices Facilitating Access by SMEs to Public Procurement Contracts" and to divide large contracts into lots to improve competition in two areas: (i) quantitatively, to match the size of the contract to the operational capacity of SMEs; and (ii) qualitatively, so that lots are tailored to SMEs specialised sector [1].

Also, in this Directive there are concepts indicated such as Joint Procurement, the process by which different buyers from different Member States join together, in a single process, with the objective of increasing volume and obtaining better prices or access to [2].

In addition, the EU promotes the adoption of Artificial Intelligence in the public sector, by preparing an "Adopt AI programme". This and other actions in order to boost AI can be found in the White Paper On Artificial Intelligence - A European approach to Excellence and trust [3].

Finally, this Directive should consider the United Nations Convention on the Rights of Persons with Disabilities when choosing means of communication, technical specifications, award criteria and contract conditions. In fact, contracting authorities have the possibility to exclude economic operators which violate rules on accessibility for disable people [1].

2.1.1 Transposition of the Directives across Europe

The European Directives in Public Procurement have different transpositions on the different countries. Hence, under the following subsections, we have done a first analysis about the Public Procurement policies and its process in the different countries where ODIN is developing its use cases. The selected countries are members of the ODIN project; thus they will represent the first users of ODIN services and solutions (the early adopters). Therefore, a state-of-the-art overview of the procurement landscape will help us to understand how their situation can foster or not the acquisition of those services and solutions, in their corresponding organisations and regions.

2.1.1.1 Spain

European Directive 2014/24/EU is mainly transposed in Law 9/2017, of 8 November, on Public Sector Contracts, which replaced Royal Decree-law 3/2011, of 14 November, approving the Consolidated Text of the Public Sector Contracts. Two other important laws concerning public procurement in Spain are: Law 14/2011, of 1 June, on Science, Technology and Innovation; and Royal Decree 3/2020, of 4 February, on urgent measures transposing into Spanish law various European Union directives in the field of public procurement in certain sectors; private insurance; pension plans and funds; taxation and tax litigation. Following Royal Legislative Decree 3/2011, the MEAT criterion was established. However, the basic and sole award criterion was usually based exclusively on the price. For this reason, Law 9/2017 introduced the reference to the best Price-quality ratio, emphasizing the conceptual swift.

This national legislation is further developed at regional level, as the Spanish public procurement system is decentralized among 17 regions and 2 autonomous cities with contracting authorities at all levels. However, Ministry of Science and Innovation, through the General Secretariat for Innovation, is the body responsible for the provision of funding for innovation procurement projects under the European Structural and Investment Funds (ESIF). The Centre for the Development of Industrial Technology (CDTI) is the national competence centre for public procurement of innovation, together with Carlos III Health Institute (ISCIII) and the National Institute for Aerospace Technology (INTA). Although the public bodies do not usually consider allocation of resources for public procurement of innovation as part of their budgets, they work on different public procurement of innovation projects funded by the European Regional Development Funds (ERDF).

2.1.1.2 France

EU Directive 2014/24, Article 82 obliges contracting authorities to award public contracts to the 'most economically advantageous' bids. This provision has been transposed into French law (Article 52 of the 2015 Decree and Article 62 of the 2016 Decree).

The following types of public contracts are used under Article 4 and 5 of the 2015 Decree:

- Public contract
- Public supply contract
- Public service contract
- Public works contract
- Framework agreement
- Partnership contract

Article 42 of the 2015 Decree defines the following competitive bidding procedures:

Formalised procedures

- Open or restricted tendering procedure, whereby the buyer chooses the most economically advantageous tender based on objective criteria communicated to the candidates in advance (without negotiation).
- Competitive procedure with negotiation, whereby a contracting authority negotiates the terms of a public contract with one or more economic operators.
- Negotiated procedure with prior call for competition, whereby a contracting entity negotiates the terms of a public contract with one or more economic operators.
- Competitive dialogue, in which the buyer discusses with a select group of candidates in order to define or develop solutions that meet their need(s).

Adapted procedure

- Defined by the buyer in line with public procurement principles for purchases below the formalised procedure thresholds and involving the public procurement of social services and other specific services.
- Negotiated procedure without publication or competitive bidding (Article 30).

French contracting authorities can award public contracts with values below €25,000 (excluding VAT) without prior advertising or competition. Fostering innovative purchasing, the Ministry of the Economy has raised the threshold for public procurement contracts for innovative products, services or works from SMEs that can be concluded without prior notice/publication or competitive bidding from €25,000.00 to €100,000.00.

The legislation allows certain types of organisations to apply special rules: "National public administration institutions with a statutory research mission can apply special rules for research related purchases [which applies to non-state purchasers and public entities that are not industrial or commercial organisations, as well as local authorities, their public institutions and groups]" (Article 2 of the Decree). Such rules establish some exemptions from the threshold values that usually require tenders to be advertised nationally:

- The publication/advertising threshold for 'adapted' procedures32 is set as below €144,000.00, replacing the intermediate €90,000.00 threshold specified in the general law (Article 34 I 2)
- Buyers are only required to advertise the tender and publish the award notice in the Official Journal of the European Union for formalised procedures, whereas national legislation requires additional publication in the Official Bulletin of Public Procurement Announcements (BOAMP) (Article 33 I 2).

Article 14 3 of the 2015 Decree exempts "Public procurement of R&D services for which the buyer does not acquire exclusive ownership of the results or does not fully fund the service. [...]" (for example, research partnership contracts) from its scope. - Article 30 of the 2016 Decree states that "II. - Contracting authorities may also negotiate public supply contracts for the purchase of products manufactured solely for the purposes of research, experimentation, study or development, and with no profitability or amortization of research and development costs objectives, without advertising or issuing a prior call for competition." - Innovation partnerships (Article 93) covering R&D for innovative goods, services or works [...] and the acquisition of goods, services or works responding to a need that cannot be satisfied by solutions already available on the market. - Public contracts under publicly funded programmes (Article 97) and that support national public research, testing and experimentation programmes.

The French public procurement system is characterised by a large number of contracting authorities and oversight institutions due to the size of the country and its semi-decentralised political structure. This results in methods that are not fully standardised, and therefore the outcomes vary. In addition, its relatively complex structure can be burdensome for suppliers [4].

The French Public Procurement Code applies to all public-private contracts, public concessions as well as partnership contracts are derived from EU Directives 2014/24/EU and 2014/25/EU. Some of the general principles from the Code are the equal treatment, the open access to public procurement, transparency, the streamlining of public procurement and the proper use of public funds. On the other hand, the Code adapts some rules to Research and Development contracts, as well as innovative procurement (after an experimental period, contracting authorities can award a contract of 100,000 without prior advertising or competitive tendering, in accordance with Decree nº2021-1636) [5].

2.1.1.3 Germany

The regulation 2014/24/EU has been legally implemented in Germany by changing the national law **"Gesetzes gegen Wettbewerbsbeschränkungen"** (GWB) and by adding a number of additional / supplemental law regulations. For the medical field, especially the additional regulations **"Verordnung über die Vergabe öffentlicher Aufträge"**(Vergabeverordnung – VgV) and the regulation **"Verordnung über die Vergabe von Konzessionen"** (Konzessionsvergabeverordnung – KonzVgV) are of high relevance. The law changes were set in power on 18. April 2016.

The new regulations define the principles for procurement "Grundsätze der Vergabe" which are: competition, transparency, economically sensible, relativity, equality. Beside these general guidelines, after the new law was set in power, the general aspects of quality and innovation as well as social and environmental aspects needed to be included (§ 97 Abs. 3 GBW). These conditions are described in more detail in the different steps of the stepwise procurement (performance description, criteria for accepting the tender, execution regulations).

Important instruments for innovative public tenders in Germany:

- Functional performance description

  In case of a functional performance description the seeking party does not require a detailed description of the envisaged solution. The involved parties can prepare the solutions for the required project themselves and together.

- To allow and evaluate supplemental tenders

  To allow supplemental tenders enables public entities with a relatively low additional administrative burden to see and evaluate innovative solution tenders which were not known previously.

- Negotiation procedures

  Negotiation procedures can add and incorporate new and innovative aspects, which become visible only during the negotiation phase with the tenders. This allows to correct deficits during the process of negotiations and allows to find an optimal and most efficient solution.

- Competitional dialogue

  The competitional dialogue is mostly recommended if it is not known what the market has available in terms of technical, financial, or legal solutions. This is especially useful in

innovative projects, in realizing large traffic infrastructure projects, or in case of large computer network projects.

- Innovation partnership

  The innovation partnership enables the public entity to acquire products and services, which are simply not available on the market. This procedure is only possible for complex products and services because both sides (partners) need to invest resources and the multi-step procedure of this kind of procurement is very time consuming.

- Pre-Commercial Procurement (PCP)

  Public entities can reduce risks in procurement by asking several tenders to prepare a solution and then, with several interim steps with competitions between them, filtering out the best tender. The development costs for the interim steps are not necessarily higher than financing just one developer, because the developers pay a large proportion of their costs themselves, because they receive the right to use the developed solutions otherwise, if they do not win the final competition. Since the developers pay a large proportion of their costs and they receive the right to use their own developed solutions (if they do not win the final competition), the development costs for the interim steps do not need to be higher than the costs needed for financing just one developer.

These legal regulations are supplemented by additional supportive actions given by the Federal government of Germany, by the federal states, and by the regional authorities.

2.1.1.4 Netherlands

The Public Procurement Act applies to all types of public procurement contracts in The Netherlands. This amended Act enters into force on 1 July 2016 as the transposition of the latest EU Procurement Directives (2014/23/EU on the award of concession contracts, 2014/25/EU on public procurement and 2014/25/EU on procurement by entities operating in the water, energy, transport, and postal services sectors). This Act is described in detail in the Public Procurement Decree.

As part of this Decree, the Proportionality Guide (Proportionaliteitsgids), the Works Procurement Regulation 2016 (Aanbestedingsreglement Werken 2016) and the European Single Procurement Document (Uniform Europees Aanbestedingsdocument) can be found.

- Proportionality Guide: aims to ensure that the requirements imposed by the contracting authority are proportionate to the subject matter and scope of the public contract. This Guide helps to improve the position of SMEs in procurement procedures.
- Works Procurement Regulation 2016: aims to describe the procedures to be used for awarding contracts.
- European Single Procurement Document (ESPD): this document, signed by the tenderers, indicates that they comply with the tender requirements, and only must be submitted by the winner. The ESPD replaced the Dutch Self-Declaration[6].

2.1.1.5 Italy, Lazio

European Directive 2014/24/EU was transposed in Italy in Legislative Decree (D. Lgs.) 50/2016 of April 18, on Public Sector Procurement, which replaced D. Lgs 163/2006 of April 12, approving the Consolidated Text of the Public Sector Contracts. The D. Lgs. has been amended twice in

2017, firstly by D. Lgs. 56/2017 (“decreto correttivo”, i.e., corrective decree) and then by Law 96/2017. The most recent amendments, following the economic and pandemic crisis, were Law 55/2019 (also known as “Sblocca cantieri”) and Law Decree 76/2020 (“decreto semplificazione”, i.e., simplification decree) converted in Law 120/2020. The amendments were introduced with the aim of simplifying and speeding up an overall complex tender process and of supporting and favouring the participation of SMEs to public tenders. The most recent modification, dictated by the Italian Recovery and Resilience Plan, has been introduced in February 2022 with Law 238/2021 (also called “European law”).

The public sector legislation applies to public work contracts, public service contracts, public supply contracts and public-private partnership contracts, which include public works, public service concessions, availability contracts and financial lease contracts. Quantitative thresholds for tenders on the aforementioned processes are defined within art 35 of the D. Lgs 50/2016.

The procedures for provider selections, established in D. Lgs 50/2016, can be split into two categories: traditional procedures (open and restricted procedures, competitive dialogue and negotiated procedure) and new procedures (competitive procedure with negotiation, and partnership for innovation). Moreover, outside D. Lgs 50/2016, two additional procedures for providers selection were introduced to comply with the need to purchase innovative solutions: pre-commercial contract and R&D supply contract.

To support and harmonize the procurement process at national level, a key role is played by Consip S.P.A. (inhouse of the Italian Ministry of Economy and Finance). It is the central procurement body that defines specific agreements (framework agreements, dynamic purchasing system, electronic marketplace, etc.) to support single Public Administrations (PAs) in the transversal procurement process within any purchasing area (automotive, infrastructures, IT solutions, services, healthcare devices and instrumentations, etc.) for any goods and services.

At regional level, most of the procurement activities are managed by Consip S.P.A. due to the geographic location in Rome. Nonetheless, Regione Lazio has additional dedicated inhouse companies. The most important one for the innovation procurement is Lazio Innova, which represents the main link between the Region and the European programs for innovation. It manages the analysis and the implementation of services and activities beneficial for the Lazio innovation system.

The Ministry for Innovation and Digital Transaction and the Agency for Digital Italy (AgID), the technical agency of the Presidency of the Council of Ministers, are responsible for the strategic definition and coordination of Italian innovations. Most specifically, AgID main purpose is to guarantee the achievement of the objectives set by the Italian digital agenda and to contribute to the spread of ICT to ultimately foster innovation and economic growth.

Italy brought its domestic procurement laws into compliance with EU Procurement Directives (2014/24/EU, 2014/25/EU, 2009/81/EC). Italy has more than 22,000 contracting authorities at both central and local level. At the local level, the main agencies include regions, provinces, and municipalities, including local health authorities, in charge of hospital administration, among other things. Efforts are being made to reduce contracting authorities and streamline procurement protocols and processes [7].

In addition to this, from 2020 onwards, the COVID-19 pandemic has affected the public procurement sector. Emergency measures were adopted by the government to contain the negative impact of the restrictions and to support the economic operators most affected by the crisis. Therefore, the Public Contracts Code has been significantly amended by decree laws [8].

2.1.1.6 Poland

The provisions on the implementation of public procurement are regulated in the Act - Public Procurement Law (Journal of Laws of 2021, item 1129, as amended). It is a new legal act prepared in 2019, adjusting Polish regulations to the provisions of Directive 2014/24 / EU of the European Parliament and of the Council on public procurement. The provisions of the Act apply to the award of classic and sectoral contracts by public and sectoral awarding entities throughout the country.

Detailed regulations of the above-mentioned Act were included in the Regulations to the Act.

The act regulates the rules of purchasing goods, services or construction works above the amount of PLN 130,000 net (approx.29,000 EUR). Below this amount, the rules are set out in the internal University Regulation entitled 'Regulations on application of public contracts' to which the Act - Public Procurement Law does not apply. In addition, the procedure for submitting applications and awarding contracts in the field of science or cultural activity at the University with an estimated value equal to or exceeding PLN 130,000 net (approx.29,000 EUR) was also regulated.

3 Public Procurement in Hospitals

3.1 Types of Procurements

Public procurement is the purchase by governments or public entities of a country of goods and services. Innovation and public procurement are closely linked.

The most common public procurement models include the following ones:

- Open tender: it is the main tendering procedure; it allows to submit a tender to supply the required goods or services and offers an equal opportunity to any organization to submit a tender. The main requirements are: be open to all interested bidders, advertised at an appropriate level, clear technical specifications and clear evaluation criteria [9].
- Low-value contracts: it occurs when a procurement does not exceed a certain quantity (established usually by each national regulation), thus simplified rules apply. Based on EU, the tender should not be valued more than between €15,000.00 and €144,000.00.
- Negotiated purchase: it occurs when a contracting authority approaches a single supplier based on their track-record or a previous relationship. The terms of the contract are then negotiated [10].
- Accelerated public tender: it is considered as an Open Tender, but with accelerated timeframes, used in states of urgency [11].

According to the Organisation for Economic Co-operation and Development (OECD), innovation has become a recurrent strategy pursued by public authorities. Moreover, between 2010 and 2012, between 14% and 36% of companies that had participated in public procurement processes reported having included innovation elements in their procurement strategies.

Despite this, and according to the OECD, public procurement and innovation are not fully aligned at the moment, although it is recognised that Contracting Authorities are gradually including more strategies and initiatives to boost innovation and SMEs' participation, as indicated in section 2.1 of this [12].

In this regard, the European Commission's vision for innovation procurement includes two different initiatives, as detailed below (see

Table 2):

- Pre-Commercial Procurement – PCPs: the co-development of innovative solutions through the procurement of research and development services. PCP is used when there are not solutions that meet the needs and requirements of the payers nor close to be launched to the market, so R&D alternatives have to be developed. One of the benefits of PCPs is the reduction of the risk of acquiring innovative solutions, as they are designed, prototyped and developed in real time [13] [14].
- Public Procurement of Innovative solutions – PPIs: the procurement of innovative solutions that do exist and are in their final stages of creation but are not yet widely available on the market. This initiative is undertaken when there is evidence that there are early adopters willing to purchase the innovative solution [15] [16].

Below is a table comparing the two procurement of innovation frameworks [13]:

Table 2. Comparative table between PCP and PPI

	PCP vs PPI	
	PCP	PPI
What?	Public Administrations buy R&D according to their needs	Public Administrations act as an early adopter or first buyer of solutions that are very close to the market or have just arrived
When?	The problem is clearly defined, but the pros and cons have not been compared or validated	There is no R&D involved and a solution is required around market entry without large-scale implementation
How?	R&D is purchased from several suppliers, to compare their performance and impact	Public sector acts as a facilitator for the industry to scale up its production.

3.2 The procurement process of innovation in the ODIN hospitals

3.2.1 SERMAS, Madrid (Spain)

The Spanish national public procurement system is decentralized among 17 regions and 2 autonomous cities. One of these regions, the Community of Madrid, is committed to the Public Procurement of Innovation (PPI) as one of their strategic lines. The Regional Ministry of Health specifically contemplates the implementation of PPI procedures to develop and incorporate new products and services to improve the quality of care.

The *Consejería de Sanidad de la Comunidad de Madrid*, through the *Dirección General de Investigación, Docencia y Documentación*, is in charge of promoting and leading the PPI in the healthcare sector, developing innovative projects to achieve new products and services that increase the efficiency and effectiveness of healthcare services.

With this aim, the Community of Madrid envisions the PPI as a strategic instrument to cover 5 main objectives:

1. **Development of the business sector:** the procurement mainly aimed at fostering the participation of companies in the bidding process, especially SMEs and innovative start-ups.
2. **Attraction of investment and large companies:** the procurement encourages reference large companies in their sector to participate and commit investments in the Community of Madrid.
3. **Cultural change of the Public Sector:** the aim is to integrate innovation into the daily dynamics of public administrations.

4. **Procurement of goods and services**: the procurement is focused on meeting the needs of the public administrations at the best cost/benefit ratio.
5. **Innovation in Public Service:** the procurement seeks to incorporate innovations that improve service delivery, even though this may entail a higher initial investment.

The PPI is conceived as a cycle that goes from the definition of the strategy to the execution of the project; aligned with the international best practices fostered by the European Commission [17].

This model is defined in 6 different steps and responds to the need of sequencing the necessary actions to get from the design of the intervention to its implementation. Furthermore, it solves potential successive problems, faced by the different agents involved: the political decision-maker, the technical manager of a public service (who is the "owner of the need), the project's financier (often an innovation agency different than the procuring entity), the contracting manager, the contracting officer (accompanied by the legal and budgetary controller) and the potential supplier companies. Hereby, we describe the 6 steps depicted in Figure 1.

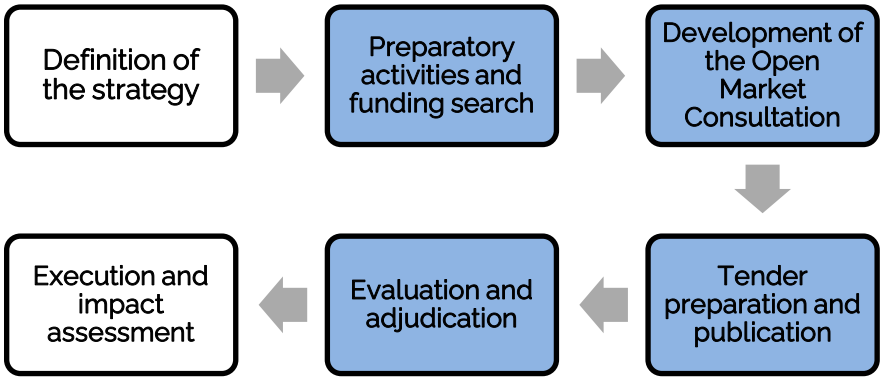

Figure 1. PPI model in Madrid Region (Spain) based on 6 steps

1. **Definition of the strategy:** the first step is to define the objectives in order to accordingly design the instruments. It is also understood that the nature of the "owner" of the policy determines to a large extent the strategy.
2. **Preparatory activities and funding search:** this step refers to all the related and necessary activities prior to starting the project. The most important activity is **training**. Before undertaking new procurements, a training program has to be performed to cover the legal and budget control services. These trainings not only set the basis for future projects, it is also essential for cultural change and to overcome prejudices. Another key activity in this step is to **define the unmet challenges** and create a list of potential projects. There are various techniques and approaches., The most recommended approach is involving the "need owners" and, when possible, the citizens who are users of public services.

3. Open Market Consultation: in this process the procurer dialogues with the market, starting from the identified challenge. The goal is to obtain the necessary information for the procurement process in an efficient way, by balancing the interests of the institution with potential suppliers.
4. Tender preparation and publication: one of the key aspects of this step is the validation of the tender by the legal services. Madrid City Council has created PPI tender templates covering key recurrent aspects such as IP management, that have been validated and approved by their legal teams. These templates enable to speed up the process of the PPI tender publication, making possible to publish 8 PPI tenders in 2018.
5. Evaluation and adjudication: for this step, it is crucial to ensure transparency before the submission of tenders indicating the timeline and awarding criteria.
6. Execution and impact assessment: in the case of PPIs, provider company must develop a hand-in-hand solution with the public procurer, who is the real owner of the project, under the provisions of contracting law. These PPIs tend to be long period contracts, between 1 and 4 years. Then, robust management methodologies have to be applied.

Some of the examples of PPIs initiatives carried out in Madrid Region and Spain can be found in following tables (Tables 3-9):

Table 3. INFOCANBANCO: Example of PPI process in Madrid Region

NAME OF THE PPI			
INFOBANCO			
Country	Spain	Procuring Agency	Comunidad de Madrid
Budget	2,5 M€	Duration	3 years
Stage of the procurement		Preliminary Open Market Consultation	
Unmet need			
Spanish national solutions for clinical data does not necessarily consider standardized data model or interoperability requirements.			
What is being requested?			
To develop a regional health data network architecture, conceived as a standardized repository of health data, by combining information generated from different sources, both clinical and administrative and research systems. INFOBANCO aims for this architecture to work as a platform that provides services to clinicians, managers and researchers, and is intended to be equipped with governance tools as well as tools for obtaining, transforming, interrogating, visualizing and analysing data in order to obtain knowledge and support decision making.			
How is being requested?			
- To design a functional and technological architecture, based on the state of the art, that will allow to meet the proposed objectives. - Implement the designed architecture in one or more SERMAS hospitals that meet the requirements established in the project. - Evaluate the health data platform for general quality dimensions: uniqueness, completeness, consistency, multi-origin stability and accuracy. - Determine the validity of the human health data platform against the manual registry taken as "gold standard". - To quantify the usefulness of the health data platform in research, knowledge generation and care improvement.			
Project KPIs			
- Population covered by basic NHS eHealth services. - Population benefiting from chronic disease management or other specific services in the area of health and active and healthy aging. - Number of tele-transferable procedures that are created or improve operations. - Number of people impacted by dissemination, awareness and dynamization actions aimed at promoting the use and demand for ICT networks, products and services. - Population covered by health services.			
Expected output			
- A more accurate identification of the different procedures operating in the health and social care sector by having better information available. - A reduction in the duplication of unnecessary tests through the information obtained from the exploitation of large databases with information from the real world. - Improved diagnostic accuracy with the consequent improvement in efficiency in the provision of health services.			

- Increased quantity and quality of information will result in more efficient treatments with a consequent reduction in hospitalizations and improved efficiency in the sector.
- Increased real-time visibility of operations, patient experience, patient opinions and behaviour of the different agents.
- It will improve system intelligence and, therefore, also the quality and accuracy of the decisions to be made.
- It will improve the user experience: greater availability of medical assistance, access to history, analysis and test results, possibility of early diagnosis and treatment of diseases, etc.
- Healthcare professionals will be able to better detect, better predict, better alert, better relate and better catalogue information.

The Procurement Process

1 - Preparatory activities and funding search
2 - Market Consultation
3 - Tender publication
4 - Evaluation and adjudication

Technological requirements

- ETL tools from architecture components as external systems.
- Tools for the extraction of structured data from unstructured text using NLP technologies.
- Data Lake with different processing areas as a core element of the architecture.
- Model and terminology server (SNOMED-CT).
- Standardized repository for secondary use (RWD) based on ISO 13606/openEHR/i2B2, OMOP standards).
- Platform for the elaboration of data collection notebooks.
- Standards-based interfaces (FHIR, CDISC) for the integration of decision support and AI systems
- Business intelligence tools.
- Tools for data quality evaluation.
- Tools to ensure data security and confidentiality.

Related Links

https://cpisanidadcm.org/infobanco/

Table 4. Medigenomics: example of PPI process in Madrid Region

NAME OF THE PPI			
Genomisation and digitisation of Medicine (Medigenomics)			
Country	SPAIN	Procuring Agency	Comunidad de Madrid
Budget	2,5 M€	Duration	3 years
Stage of the procurement		Preliminary Open Market Consultation	
Unmet need			
There is a very important deficit of standardisation in the custody, storage, access and the custody, storage, access and updating of patients' and citizens' genomic information of patients and citizens. Expert systems based on machine learning, big data in healthcare and artificial intelligence applied to clinical processes are a scientific reality that requires early implementation in healthcare systems.			
What is being requested?			
To design, build and develop an integrated genetic service that combines in a single platform the entire process of genomic study of an individual, in a simple and automated way, with continuous updating in real time. The aim is to optimise the overall process of genetic diagnosis for the patient/citizen, improve the diagnostic tools for genetic diseases, and improve the information available to the administrations.			
How is being requested?			
Develop more efficient genomic diagnostic tools that are integrated into clinical management processes. To develop a high-performance computerised genomic analysis system capable of integrating and standardising patient genomic information in a centralised expert system, with future interaction with patients/individuals.			
Project KPIs			
- Improved diagnostics and clinical reporting from raw genomic data. - Replacing a static report versus real-time updated Genomic Medicine information in real time, i.e. keeping the database updated as knowledge and information emerges in the medical literature. - Integration of patients' genomic information in a centralised expert system within the regional health system (in centralised EHR). - Computerisation using identical standards (FASTQ, BAM and VCF files) of genomic information and standardisation of clinical (HPO, MEDDRA) and disease coding (ICD11, Orpha, MONDO, SNOMED-CT, Malacard, etc.). - Responsible and personal decision making for each patient/citizen through gradual or "layered" access to genetic information.			
Expected outputs			

The added value of this project can be summarised as follows:

1. it would allow the integration of patients' genomic information in a centralised expert system, within the NHS (regional, national, supranational, etc.)

2. it facilitates the standardisation of genomic information (health/disease) of patients or individuals within the NHS, and the possibility of sharing it with other health systems, by computerising genomic information with identical standards (FASTQ, BAM and VCF files).

3. it enables interaction, updating and decision making between patients/individuals and health professionals

4. it optimises health information systems, electronic health records and patient management systems, improving the efficiency of healthcare big data and international EHR coding languages such as SNOMED-CT, HPO, etc.

The Procurement Process

1 - Preparatory activities and funding search
2 - Market Consultation
3 - Tender publication
4 - Evaluation and adjudication

Technological requirements

1. System for automatic data collection (voice/text).

2 System for tertiary analysis of genomic information.

3 Storage and restricted/controlled access to genomic information.

4 Automatic updating of the medical information associated with the genomic information.

5 Updating of the information in the patient's medical history in the health system and alerts on each patient's personal device.

6. Alerts on each person's personal device.

7. Patient access to their medical records.

Related Links

https://cpisanidadcm.org/medigenomics/

Table 5. MedP Bigdata: example of PPI process in Spain

NAME OF THE PPI			
Personalized Big Data Medicine (MedP Bigdata)			
Country	Spain	Procuring Agency	▪ Servicio Canario de Salud ▪ Conselleria de Sanitat Universal i Salut Pública de la Generalitat Valenciana
Budget	4M€	Duration	4 years
Stage of the procurement		Tender preparation	
Unmet need			
Inefficiencies in providing care due to a lack of personalization in prevention, early detection, diagnosis, prognosis and integrated care.			
What is being requested?			
Technology platform to support multiple tools that operationalize the available data into useful functionalities for patient care during diagnosis, treatment and research on chronic, degenerative and rare disease; and cancer.			
How is being requested?			
Two different challenges to be addressed: - Development of a tool based on dialogue techniques supported by artificial intelligence, capable of mediating the flow of information between citizen, patient and HIS/EHR. - Clinical decision support tools for chronic patients.			
Project KPIs			
- Reduction in pharmacy spending / year. - Reduction of avoidable admissions for more effective treatments. - Reduction of avoided complementary tests by more powerful and selective data processing in the evaluation of their demand.			
Expected outputs			
- Increase treatments effectiveness. - Reduce the adverse effects of treatments. - Increase knowledge of individual determinants of treatment efficacy. - Increase adherence to treatment for complex chronic patients. - Improve the planning and coordination of the different devices for the care of chronic patients. - Obtain objective and reliable measures of the evaluation of chronic patient care . - Identify and detect the risk of progression to frailty. - Improve training and information on personalized treatments for associations and professionals in the care settings.			
The Procurement Process			
1 - Preparatory activities and funding search 2 - Market Consultation 3 - Tender publication 4 - Evaluation and adjudication			
Technological requirements			

- Allow pairing with sensors, smartwatches and other fitness devices or specific apps. Even automated diagnostic devices, such as auto-analysers or automatic sphygmomanometers.
- Facilitate PREMS and PROMS.
- Multi-channel accessible by screens or voice, including technologies such as VR or AR.
- Accessibility strategies for people with functional and language diversity.
- Empathy with the user in order to maintain attention and trust.
- Open to interoperability with other healthcare applications.
- Bidirectionality, including data capture and access by patients.

Related Links

https://contrataciondelestado.es/wps/portal/!ut/p/b0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOKdgi0sHJ0MHQ0szJ1cDBzNXI3NTAMNjQycjfULsh0VAXlVzSI!/pw/Z7_BS88AB1A0GIL20AMMG1VR100L7/ren/p=CTX=QCPPLACE_esQCPNoticiasQCASiteQCPNoticiasQCPCPMQCADireccionQCAdelQCAServicioQCACanarioQCAdeQCASaludQCA-QCAMedP-BigD/-/?param1=MenuHistorico

3.2.2 France

Table 6. example of Public Procurement process in France

Country	FRANCE	Procuring Agency	UNIHA
Budget	-	Duration	
Stage of the procurement		Notification	
Unmet needs			
- Access to surgical robots. - Improve the utilization rate and the ROI of robotic surgery. - Use Data as a enabler to improve physician's training, practices and optimize the usage of the robots.			
What is being requested?			
The tender requires the provider to deliver a global solution for robotic surgery. The solution needs to be composed of an advanced surgical robots and innovative services to optimize the care pathway, the usage of the equipment and use the data as an enabler to reduce surgical variabilities and improve surgical outcomes.			
How is being requested?			
- Setup, training, and maintenance of the robot. - Operational support on site to facilitate the utilization of the robot and its integration in a care pathway. - Data collection, mining, and implementation of specific actions to improve the usage of the robots.			
The Procurement Process			
- Scouting of the potential providers. - Exploration of their services' offering. - Tender's preparation. - Publication. - Proposal's evaluation. - Rounds of discussion and negotiation. - Selection of the best provider. - Notification.			
Related Links			
https://www.francemarches.com/appel-offre/3boamp21146090-2021-uniha-fourniture-robots			

3.2.3 Germany

The Master template for procurement of innovations in Germany is shown in the following table. Depending on the specific project it is possible that some of the steps mentioned below can be skipped.

Table 7. Phases for processes in procurement of innovation in Germany

1.	Identification of needs	Identification of user needs.
2.	Project planning	Compilation of a team with the relevant interdisciplinary capabilities and experiences.
3.	Consolidation of goals and duties	Interviews with all relevant groups of interest and first market analysis. Course functional definitions of demands and goals.
4.	Preliminary information of market	Early market information about the planned procurement activities, in order to give potential tenders enough time for their planning and preparation of tender submissions.
5.	Market exploration and market research	Intense exchange of information between potential tenders and procurers, evaluation of potential solutions and future developments.
6.	Selection of the procurement procedure	Selection of the specific procurement procedure (open procurement, negotiation procurement, competing dialog procurement, innovation partnership procurement, or pre-commercial tender procurement).
7.	Preparation of the procedure, publication of this	Preparation of the exact functional requirements and procurement criteria, inclusion of contract contents which promote innovations.
8.	Procedure execution and process management	Electronic procurement, evaluation of incoming tenders, if needed then negotiations or discussions, checking of quality and performance criteria.
9.	Finalizing the project	Procurement execution, if needed signing of additional agreements, implementation of the cooperation.

In the following table, THALEA and THALEA II PPIs processes can be found:

Table 8. THALEA and THALEA II: Examples of PPI processes in Germany

NAME OF THE PPI			
THALEA und THALEA II			
Country	Germany	Procuring Agency	University Hospital RWTH Aachen
Budget	THALEA - 1,8 Mio. EUR THALEA II - 0,8 Mio. EU	Duration	THALEA - January 2015 - October 2016 THALEA II - June 2016 - May 2019
Stage of the procurement	The project has already been completed.		
Unmet need			
THALEA stands for "Telemonitoring and Telemedicine System for the demand of Hospitals need in Early Warning of Live Threatening Conditions Assisted by innovative ICT for Life saving co-morbid patients in Europe as part of a Patient personalised care programme of the EU". The projects aim to make patient care in the ICU (intensive care unit) even safer through additional, computer-assisted monitoring.			
What is being requested?			
In order to secure the best possible patient care, all data concerning a patient's condition are to be brought together by means of a software solution, the "cockpit". The data agglomerated with the help of intelligent software tools allow dual control from two perspectives: attending physician at the patient's bed and attending physician on patient monitoring on a screen.			
How is being requested?			
THALEA and THALEA II are the first project tandem in the area of innovative public procurement where, building on the results of pre-commercial procurement (PCP), in the first step, software products are purchased; and in a second step, in the framework of public procurement of innovative solutions (PPI).			
The Procurement Process			
Thanks to two EU-funded projects coordinated by Aachen Telemedicine Centre at University Hospital RWTH Aachen, it has been possible in recent years to develop solutions that are now to be established in the marketplace. **PCP – Pre-Commercial Procurement:** From January 2015 to October 2016, three different prototypes for telemonitoring and telemedicine systems were developed in the framework of the THALEA project and tested and evaluated in practice. The project was funded under the EU's 7th Framework Programme for Research and Technological Development. **PPI – Public Procurement of Innovative Solutions:** THALEA II, the successor project, started in June 2016, with the purpose of purchasing such innovative telemonitoring and telemedicine systems. The project is funded under Horizon 2020, the current EU Framework Programme for Research and Innovation. Procurement phases: Phase 0 (project idea) Phase 1 (solution exploration) Phase 2 (prototype development) Phase 3 (testing) Phase 4 (Marketing and Commercial Procurement).			
Related Links			
https://www.rwth-aachen.de/go/id/smme?lidx=1 https://www.koinno-bmwi.de/en/eu-funding/best-practices/pcp-and-ppi-thalea/			

3.2.4 Netherlands

3.2.5 Lazio (Italy)

The Public Procurement of Innovation process in Italy and Lazio follows the same rules provided at national level. In the framework of innovative procurement, there are multiple available solutions, each one with a complex set of formal steps that PAs are required to rigorously follow, including:

- Open procedure;
- Competitive dialogue;
- Competitive procedure with negotiation;
- Partnership for innovation;
- Pre-commercial contract;
- R&D supply contract.

The PAs select the most suitable solution based on two aspects (see Figure 2): (i) the degree of technical knowledge of the product/service; and (ii) the availability on the market of the requested product/service.

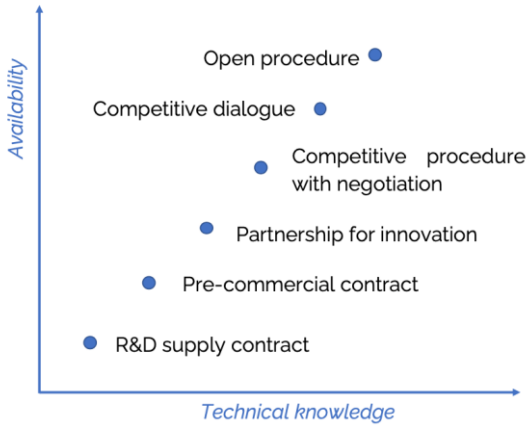

Figure 2. Diagram of Public Procurement models considering technical knowledge and availabity

In Italy, issuing a public tender is extremely risky, complex and time consuming. This consideration does not encourage the PAs to search for solutions with innovative contents and it explains the widespread preference towards more traditional technologies, which are purchased by means of simpler procurement procedures.

Moreover, to further simply and speed up the procurement process and reducing the risks of procedural errors, many PAs prioritize the use of pre-defined instruments provided by *Consip S.P.A.,* typically following the guidelines defined by the *Programme for the rationalization of public spending of the PA*. This programme supports PAs with innovative e-procurement solutions within all the economic fields (e.g., ICT, biomedical devices, drugs, etc). The process is based on the following steps:

- Regardless of the nature of the product/service, the *Ministry of Economy and Finance*, through *Consip S.P.A.*, defines the guidelines of the programme;
- PAs cooperate to define the procurement needs;

- Economic providers contribute to the definition of market analysis;
- *Consip S.P.A.* publishes tender procedures according to the defined needs and market analysis;
- Economic providers participate to the tender procedures;
- *Consip S.P.A.* activates the procurement initiatives (e.g., but not limited to, in the form of Framework agreement or SDA (Dynamic Purchasing System);
- PAs procure goods and services.

The process is innovative itself since is totally digitalized.

If the solution is not fully traditional and not technically well-defined nor available off- the-shelf on the market, each PA (either local or national) will pursue available innovative procedures depending on the specific needs.

Several procedures can be adopted with extremely heterogenous needs and operative conditions. In the following, the innovation partnership, as one representative examples, will be briefly described. The innovation partnership is a specific procurement procedure which responds to specific needs that cannot be met by solutions already available on the market, and it aims, at: i) developing innovative products, services and works and ii) purchasing the resulting supplies, services or works.

The innovation partnership consists mainly of the following steps:

- Selection of private providers. Those who have applied to the procedure and who owns the general, technical-professional and economic-financial skills indicated in the Tender Regulations;
- Proposal submission. Providers who have passed phase 1 submit the project proposal for their solution. They are assessed according to the degree of innovation and adherence to the need of the PA. At the end of this phase, 3 providers are selected;
- Presentation of offers. This phase includes: initial offers (technical and economic), negotiation process and presentation of final offers. At this stage, the technical offer includes a proof of concept. At the end of this phase, the providers are invited to present their own final offers (technical and economic), which are evaluated according to the procedures and selection criteria set in the invitation letter referred to in phase 2.
- Selection of the provider and prototyping. Award, stipulation, and execution of the partnership contract with the winning economic operator are pursued within this phase. Furthermore, during this phase, the delivery of the solution is pursued with a step- wise advancement of activities based on intermediate objectives. The main activities include *solution design* (during which the partner collaborates with the client) and *solution prototyping* (during which the partner develops the first working prototype).
- Finalization of developments. Later stages of development are pursued, and they consist of development and release of modular components by the partner.

It is worth noticing that, if the design and deployment activities are not properly executed, the PAs have the legal power of end any partnership with providers

Given the complexity of Italian procedures, as also reported in the AgID official webpage for innovative procurement (http://www.appaltinnovativi.gov.it), the PPI is often not adopted and most advanced procedures are detrimental for both the PAs (who perceive them at high risk of

procedural errors) and for the private providers (who are in the position to accept an extremely high level of risk, for example in developing solutions from scratch).

Table 9. Example of an Open Tender in Italy

Country	Italy	Procuring Agency	Consip S.P.A.
Budget	540 M€	Duration	3 years
Stage of the procurement		Open tender procedure	
What is being requested?			
Coherently with mission 6 of Italian Recovery and Resilience Plan (healthcare), the tender requests the following services: application services for healthcare central booking services, interoperability of healthcare data, application platforms for healthcare structures, support services.			
How is being requested?			
• Development of ex-novo software applications Green Field. • Development of evolutionary maintenance of existing applications. • Cloud application migration. • Development of improvement of software in co-working with PA. • Customization and adaptation of open-source solutions.			
Expected outputs			
• Evolutionary, Corrective and Adaptive Maintenance. • Application management and databases. • Digital front management services. • Publishing and website content. • Specialized support. • Handover. • Know-how transfer/data exit strategy. • Technical management.			
The Procurement Process			
• Tender publication. • Evaluation. • Tender adjudication and award.			
Related Links			
https://www.consip.it/bandi-di-gara/gare-e-avvisi/gara-sanit-digitale-sistemi-informativi-sanitari-e-servizi-al-cittadino-per-le-pubbliche-amministrazioni-del-snn			

3.2.6 Medical University of Lodz, Lodz (Poland)

For a long time, The Public Procurement Law has contained a number of elements and instruments conducive to the implementation of public procurement for innovation. The new Public Procurement Law links the procurement of innovations by public entities with a broader perspective of the national policy and strategy in this area. According to the act, it is necessary to develop a separate government document, which is the state purchasing policy. Pursuant to Art. 21 of the Public Procurement Law, the state purchasing policy defines the priority activities of the Republic of Poland in the field of public procurement, as well as the desired direction of the contracting authority's activities in the field of contracts awarded, which includes the purchase of innovative or sustainable products and services, taking into account:

1. standardization aspects;
2. cost calculation in the life cycle of products;
3. corporate social responsibility;
4. disseminating good practices and purchasing tools;
5. applying social aspects.

The state purchasing policy is adopted by the Council of Ministers, as a resolution, at the request of the minister responsible for economy, whose task is to prepare a draft document as well as to coordinate the implementation of the policy. The document is prepared every 4 years, specifying the planned activities of the government administration while taking into account the goals and directions set out in the country's medium-term development strategy.

Pursuant to Article 22 of the Public Procurement Law, awarding entities, being central government administration bodies, are required to prepare their own management strategies for individual purchasing categories, consistent with the state purchasing policy. Such strategies define orders of a key nature for the implementation of the state's purchasing policy.

The new act introduced a number of new instruments of importance from the perspective of Public Procurement for innovation, including:

1. Analysis of the client's needs and requirements. Such analysis includes, inter alia, market research in terms of alternative means of satisfying the identified needs or in terms of possible variants of the contract. Market research in terms of alternatives and variants may lead to the decision to include innovative solutions in the next steps as best suited to the needs of the contracting authority.

2. Initial market consultations. The contracting authority, prior to commencing the procurement procedure, may conduct preliminary market consultations in order prepare the procedure and inform contractors of your procurement plans and requirements. When conducting market consultations, the contracting authority may, use the advice of experts, public authorities or contractors. This advice may be used in planning, preparing or conducting a procurement procedure, provided that it does not distort competition or infringe the principles of equal treatment of economic operators and transparency.

3. Requirements related to the execution of the order. The contracting authority may specify in the contract notice or procurement documents, the requirements related to the performance of the contract, which may include aspects related to innovation. If the contracting authority provides such requirements, the procurement documents shall specify the manner of documenting the requirement fulfilment by the contractor, and the contracting authority's powers in the scope of control of the contractor's compliance with the requirements and sanctions for failure to meet them.

4. Innovation-friendly public procurement modes:

a) Negotiation with publication

b) Competitive dialogue

c) Innovation partnership

d) Negotiated without publication

e) Competition

5. Exclusions from the act - exclusion from the public procurement regime of supplies and services for research and development purposes. Pursuant to the Act, it does not apply to contracts with a value lower than the EU thresholds. Their subject are supplies or services used solely for the purposes of research, experimental, scientific or development works, which are not aimed at mass production by the ordering party aimed at achieving market profitability or covering the costs of research or development.

3.2.7 Overview

According to section *3.2 The procurement process of innovation in the ODIN hospitals*, the hospitals and/or regions from ODIN project follow similar public procurement schemes. This is understandable, considering that the national and regional laws of the European Union countries are transpositions of the European Directives explained in section 2. European Reference Regulation for Innovative Procurements.

As a result, the procurement processes follow similar phases that can be established as follows:

1. Identification of needs within the organization or region.
2. Market consultations to dialogue with suppliers in the market and obtain the information necessary to subsequently detail the tender.
3. Selection of the most appropriate procurement model, preparation of the tender and publication. The proposed procurement models are similar in all cases: open procedure, competitive dialogue, procedure with negotiation, PPI, PCPs, etc.
4. Submission of offers by economic operators
5. Evaluation and selection of the provider
6. Execution and impact assessment

4 Value-based healthcare paradigm

Value-based Healthcare (VBHC) is understood as the need to provide clinical results with minimum costs [18]. VBHC is based on Lean thinking approach, which aims to create value as defined by the client. The approach changes from an individual perspective of improvement to an improvement in the flow of products and services from the supplier to the customer.

In healthcare, the clients are the patients. In a traditional approach, patients are aware that processes are not created for their benefit, but that the benefits accrue for the convenience of the health service provider or health institution. In addition, this fact discourages healthcare providers since they have to force patients through inefficient processes, resulting in a poor and uncoordinated healthcare system. In this way, healthcare, by its nature, must be focused on patients' health, resulting in a patient-centred, and therefore in a value-based approach [19].

This way of managing healthcare systems is based on the major transformations that are being experienced due to the ageing of population, the increase in chronic diseases and the introduction of new technologies. Patients with complex needs (e.g. patients with multiple chronic diseases) are characterised by high resource consumption, which compromises the economic state of Health Systems [20]. As a result, costs in Health Systems are skyrocketing due to this ageing and the new medical advances, which are costly [21].

VBHC emerges in America to resolve an unsustainable USA Health System trajectory [8]. In the traditional fee-for-service model, service providers are paid on the basis of services provided, whether or not they are medically necessary. This may encourage some healthcare providers to schedule healthcare to an excessive number of patients so that they provide services simply to receive reimbursement [22].

In contrast to other sectors, the actors involved in the health sector generally have different and often contradictory objectives. This results in different approaches and mismanagement of changes within organisations [18]. Costs are managed by moving from one place to another: one actor loses and another wins, so care is not focused on welfare of the patient and maximizing value throughout the cycle of care, but on minimizing the costs of each intervention and limiting the services provided [21] [23].

Actions are paid for the volume of work and not for the value provided to patients, which should be the primary objective of a Health System. In this way, obtaining value in the healthcare of patients can be an element that benefits everyone and improves the sustainability of the system. To do so, indicators must be established to measure the value of a patient's health caring during the entire healthcare cycle. This will allow studies to be carried out on the effectiveness and evaluation of health services which will help to use this knowledge to make future decisions. Furthermore, a fact to be taken into account is that there is a false belief in cost reduction in a fee-for-service model. However, the results achieved are not considered, leading to consider "false savings" and limitations that may then have a negative impact on the economic efficiency of the system. The responsibility must lie with all the stakeholders in the environment and achieve an integrated clinical practice centred on the patient and his or her environment [20], where both the results and the costs associated with the services received by the patient are tracked over time [18].

Due to strategies focused on preventing the development of diseases and promoting a better health status, a lower expenditure in healthcare will be achieved. This will imply reduction of resources, causing a decrease in the cost associated to them. Moreover, although initial investment is needed to tackle prevention, control of chronic diseases will be better and more efficient. Finally, providers will benefit from their capacity to align their portfolio of products and services with positive results for patients [18].

In addition, the use of new technologies can play a very important role in the paradigm shift, as they can facilitate the management of different care processes, integrated care, communication between professionals in the sector, knowledge management and patient empowerment. The challenge is to find a management model that allows us to advance towards a coordinated technological innovation in order to obtain a greater benefit from the services [18].

However, some restrictions found in this model are a perfect coordination between primary care and specialized care is needed. A structure is needed to provide specific prevention and wellness services, by not overloading Primary Care professionals and not involving them in disparate services with limited staff attempting to cover a wide range of patients. Furthermore, an effective exchange of information through computer systems would reduce redundant care and associated costs [18] [21].

This paradigm shift also means that companies face a number of challenges. Firstly, business models must be changed, as reimbursements made for different reasons. Also, the performance of the system must be measured in order to improve the final results of the patients. This means developing data management capabilities. On the other hand, the value-based model advocates comprehensive and coordinated patient care where all stakeholders need to communicate effectively, which also has an impact on companies. Finally, a VBHC model implies a financial risk that is shared since the final results of the patient depend on the joint actions of all parties involved [24].

5 Initial analysis of the status in the adoption of PPI in the ODIN hospitals: best practices and barriers

The first stage for establishing the basis and framework for the implementation of PPI in hospitals, is to understand the current situation regarding the adoption of this type of public procurement models. Therefore, this situation has been analysed in the hospitals that are part of the ODIN consortium.

The first results show the low penetration of these innovative models in these hospitals, as only Amiens Hospital and Utrecht Hospital indicate that they have worked on PPIs, while PCPs have only been carried out in SERMAS and Utrecht.

In general, all stakeholders (Regional authorities, Hospital manager, Chief Medical Officer (CMO)/Chief Nursing Officer (CNO), Economy Director, Chief Information Officer, Innovation units and Head of departments) are involved either in the prescription, development, approval, or execution of public procurement investment plans by these hospitals. This demonstrates the multidisciplinary character of these processes. In case of UCBM as a private healthcare provider, it should be noted that profiles such as Operations Manager and CEO are particularly relevant.

As for the support of other teams within the organisation in carrying out public procurement processes, more than half of the ODIN hospitals have a technology assessment group in their organisations. Therefore, they are supported in the evaluation of existing technologies, their added value, their user experience, and the possible gaps that may exist in their organisations. In addition, entities such as SERMAS and UMC Utrecht report that there are specific stakeholders and bodies that participate in public procurement processes for innovation: Innovation Units, Biomedical Research Foundation of the Hospital; and Technology Transfer Office and a specific PPP-office, respectively. On the other hand, the legal support services provide support for any type of procurement process, whether it involves procurement of innovation or not.

Finally, the success points those hospitals highlight about public procurement of innovation are getting the innovation to the market faster, considering a multidisciplinary approach to succeed in project management, support from top managers, having an open-minded spirit to discover new approaches and solutions, carefully consider the weights for technical and economic aspects in the final decision, fair and constructive competition and transparency in the process. On the other hand, the pain points are lack of internalization by some health authorities, which lengthens the process of public procurement of innovation, causing solutions to lose their innovative value proposition; and difficulty in accessing funds to finance this innovation. It is noteworthy to mention that UCBM as private healthcare service provider does not usually rely on public procurement.

The inputs provided by each hospital in the ODIN consortium can be found in the following sections (Tables 10-15).

5.1.1 Hospital Clínico San Carlos – SERMAS (Spain)

Table 10. Inputs for PPI processes provided by Hospital Clínico San Carlos (SERMAS)

	HOSPITAL CLÍNICO SAN CARLO - SERMAS		
Type of entity	Public healthcare service provider		
Procurement models	Open Tender (>50) Direct Purchase (>50) Negotiated purchase (>50)	Accelerated public tender (>50) Pre-Commercial Procurement (>50)	
Prescriber of solutions	Regional authorities Hospital manager	Economy director Head of departments	There are 4 levels of requests for procurement. • The first level is given by the Regional Health Agency, *Consejería de Sanidad*, the 34 public hospitals in Madrid follow the general guidelines set by it. • The second level is set by the hospital management. • The third level comes from the procurement department. •The fourth level comes from the Heads of the departments: clinical and non-clinical departments. For certain items, it is the clinical specialists themselves who indicate the need for procurement.
Stakeholders in development of investment plan	Regional authorities Hospital manager CMO/CNO	Economy director Head of department Clinician staff	Similar to the previous questions. For certain items/services the research strategy lines and its Principal Investigators are the promoters
Stakeholders approve investment plan	Regional authorities	Economy director	The approval of the budget dedicated to the purchasing chapter is given by the economic director. This in turn follows the guidelines set by the Regional Health Agency. The margin of decision for each public hospital of the Madrid network (SERMAS) is limited. Each year the procurement process is audited by the Regional Economic Agency of Madrid.
Stakeholders execute investment plan	Head of department	Clinician staff	The Heads of every department of the Hospital are the responsible of the execution.
Technology assessment group	Yes		
Stakeholders in PPI	Innovation Unit	Biomedical Research Foundation of the Hospital	Each public hospital in the Madrid hospital network has or belongs to a biomedical research foundation. These foundations are the managing bodies of the research activities carried out in the hospitals. Therefore, the foundations are in charge of all procurement processes related to research activities. Innovative

	HOSPITAL CLÍNICO SAN CARLO - SERMAS	
		public procurement procedures are managed through these foundations.
Legal services: advice on PPI	Yes	Biomedical research foundations have their own legal departments independent of the hospitals' legal departments. These departments are responsible for all innovative public procurement processes.
Points of success in PPI/PCP	The key to the success of innovative public procurement is the ability to bring innovative solutions to the market that are still in the development phase. These speeds up the time to market for these products.	
Pain points in PPI/PCP	Unfortunately, the Regional Health Agency of Madrid has not internalized innovative public procurement processes and execution times are extremely long, > 3 years. As a result, all the competitive advantages of this procedure are lost in this time. The solutions are no longer innovative after such a long time.	
Other observations	The lack of experience in the promotion and development of the PPI in the Regional Health Agency of Madrid has meant that the first PPI project has been immersed in administrative processes for more than 4 years. Having learned from previous mistakes, it can be concluded that the new INFOBANCO and Medigenomics projects are being managed in a more agile manner and their implementation is expected to be a milestone for the Madrid region. It should be added that the successful use of PPI in the Regional Health Agency of Madrid is due to the drive of the project managers who have a very advanced vision of data-driven healthcare management and are champions of digital transformation in the public hospital sector in the Madrid region.	

5.1.2 CHU Amiens – Picardie (France)

Table 11. Inputs for PPI processes provided by CHU Amiens

	CHU AMIENS – PICARDIE		
Type of entity	Public healthcare service provider		
Procurement models	Open Tender (weekly) Direct Purchase (monthly)	Negotiated purchase (monthly) PPI (Yearly)	
Prescriber of solutions	Hospital manager Economy director	Head of departments	The clinicians propose a medical project including innovative solutions. Then, the hospital managers are analysing the project regarding their strategic priorities and financial capabilities.
Stakeholders in development of investment plan	Hospital manager CMO/CNO Economy director CIO	Innovation Units Head of department	When we develop a new project, we are building up multidisciplinary team in order to cover all the potential topics of the project.
Stakeholders approve investment plan	Hospital manager Economy director	Head of department	The C-suits get the approval responsibility in collaboration with the end users, the physicians, in order to validate that the solution fits their needs and can be implemented without complex efforts or additional resources.
Stakeholders execute investment plan	Hospital manager	Head of department	HCP's are implemented those services with the support of transversal department when needed and external partners (industrial, start-ups...) to facilitate the integration of those new technologies in a care pathway
Technology assessment group	Yes		
Stakeholders in PPI	Hospital manager		
Legal services: advice on PPI	Yes		They are also discovering those new procurement models. they lack sometimes of knowledge, expertise and resources to dare publishing innovating tender.
Points of success in PPI/PCP	Engaged all the stakeholders in the organization: Multidisciplinary team to succeed the project management tasks. Support of the top managers and open-minded spirit in order to discover new approach and solutions to implement complex projects.		
Pain points in PPI/PCP	Not enough experienced and organized to deal with this kind of tenders. Difficulties to get access to specific innovation funds.		
Other observations			

5.1.3 Charité Universitätmedizin Berlin (Germany)

Table 12. Inputs for PPI processes provided by Charité Universitätmedizen Berlin

	CHARITÉ UNIVERSITÄTMEDIZIN BERLIN		
Type of entity	Public healthcare service provider		
Procurement models	Open Tender		
Prescriber of solutions	Economy director		
Stakeholders in development of investment plan	Regional authorities CMO/CNO Economy director	CIO Head of department	The administrative board of the university hospital makes the decision. It consists of the economy director, the medical director, and the nursing director. They together with the heads of all clinics decide.
Stakeholders approve investment plan	CMO/CNO Economy director	CIO Head of department	The administrative board of the university hospital makes the decision. It consists of the economy director, the medical director, and the nursing director. They together with the heads of all clinics decide.
Stakeholders execute investment plan	CMO/CNO Economy director	CIO Head of department	The administrative board of the university hospital makes the decision. It consists of the economy director, the medical director, and the nursing director. They together with the heads of all clinics decide.
Technology assessment group	No		
Stakeholders in PPI	CMO/CNO Economy director	CIO Head of department	
Legal services: advice on PPI	Yes		They provide their service for any contract they are asked for.
Points of success in PPI/PCP			
Pain points in PPI/PCP			
Other observations	All the tender, the procurement, the negotiations are done by the administration independent in order not to create a conflict of interest. PPI processes have never been carried out at our institution. This experience is missing at our institution.		

5.1.4 UMC Utrecht (Netherlands)

Table 13. Inputs for PPI processes provided by UMC Utrecht

	UMC UTRECHT		
Type of entity	Public healthcare service provider (semi-public, not 100% government funded)		
Procurement models	Open Tender (48) Direct purchase Negotiated purchase (30)	PCP PPI	
Prescriber of solutions	Hospital manager	Head of department	We have a decentralized governance structure where divisions negotiate management contracts with the board of directors. There is a lot of freedom for divisions to purchase whatever they want as long as they meet the financial deals they made with the board of directors. The board of directors is involved when it comes to overarching purchases like a new Hospital Information System or something (where they 100% involve the Chief Medical Information Officer).
Stakeholders in development of investment plan	Hospital manager CIO	Innovation Units Head of department	See above
Stakeholders approve investment plan	Hospital manager	CIO Head of department	See above
Stakeholders execute investment plan	Hospital manager	Head of department	See above
Technology assessment group	Yes		
Stakeholders in PPI	Other		We have a technology transfer office and a specific PPP-office that helps our departments to collaborate with commercial entities.
Legal services: advice on PPI	Yes		Yes, they provided legal input to come to the specific arrangements for the TTT and PPP offices
Points of success in PPI/PCP			
Pain points in PPI/PCP	Commercial businesses are not so interested in early-TRL procurement *Start-ups that invent expensive innovation have to take part in a formal tender which for them is impossible to win because of the requirements. Some innovation thus never makes it to the market.		
Other observations	We have several specific departments that deal with PPP and TTT. Our local PPP department has a specific approach that they are now expanding to the rest of the Netherlands, it deals with co-ownership, licensing deals and division of royalties.		

5.1.5 Università Campus Bio-Medico di Roma (Italy)

Table 14. Inputs for PPI processes provided by Università Campus Bio-Medico di Roma (Italy)

	UNIVERSITÀ CAMPUS BIO-MEDICO DI ROMA		
Type of entity	Private healthcare service provider		
Procurement models	Direct purchase	Negotiated purchase	
Prescriber of solutions	Operation manager		
Stakeholders in development of investment plan	CMO/CNO Economy director CIO	BOD and CEO Operations Manager	
Stakeholders approve investment plan	BOD and CEO	Operations Manager	Approval depends on amount of the expense. Below 100 k€ the cost is approved by the Operations Manager.
Stakeholders execute investment plan	Operations Manager	Procurement Area	The Procurement Are is under the responsibility of the Operations Manager. In this case the CEO is not involved.
Technology assessment group	Yes		
Stakeholders in PPI	Operations Manager	Procurement Area	
Legal services: advice on PPI	Yes		They do not provide advice on PPI because it does not fall within the assigned competences
Points of success in PPI/PCP	Good price/quality ratio. Normally is important to evaluate the technical and economic aspects of the offer and it is important to define the weights for a good balance in the final decision (weights are defined by the BOD). Fair and constructive competition. Transparency in the process.		
Pain points in PPI/PCP	Extended time with respect to direct purchase.		
Other observations	UCBM as a private healthcare service provider only seldom relies on public procurement. Addendum to point 1: In case of purchase the preliminary steps are: i) internal market analysis; ii) selection of short-list of potential provider companies (also based on previous experiences); iii) verification of solvency of companies; and iv) verification of reliability of the companies. This is made still taking into account the quality of the product/service. Addendum to point 2: procurement is under the responsibility of the Operations Director, who is under the supervision of the CEO. Addendum to point 6: HTA group is within the Clinical Engineering area.		

5.1.6 Medical University of Lodz (Poland)

Table 15. Inputs for PPI processes provided by Medical University of Lodz

	MEDICAL UNIVERSITY OF LODZ		
Type of entity	Public healthcare service provider		
Procurement models	Open Tender (114/year) Direct purchase (5513/year)	Negotiated purchase (19/year)	
Prescriber of solutions	Other: Dzial Zamówien Publicznych		
Stakeholders in development of investment plan	Regional authorities Hospital manager CMO/CNO Economy director	CIO Innovation Units Head of department	
Stakeholders approve investment plan	Hospital manager		
Stakeholders execute investment plan	Hospital manager		
Technology assessment group	No		
Stakeholders in PPI			Medical University of Lodz is not involved in Innovative Public Procurements
Legal services: advice on PPI	Yes		
Points of success in PPI/PCP			
Pain points in PPI/PCP			
Other observations			

6 Conclusions and Future Work

D2.5 Innovative Procurement delivery is a document created in the framework of Task 2.5 Innovative Procurement Phases Delivery, and aims to design the overall procedure for public procurement of innovative AI-based solutions that transform care delivery in hospitals. To succeed in this, it is important to make profit of the perspective of the different stakeholders involved in public procurement processes, supporting the success points they identify and proposing solutions for the identified unmet needs or gaps.

To achieve this goal, this deliverable represents the first step. It provides an analysis to understand the legal framework applied by the European Union and described in the Directives on public procurement of goods, services and works promoted by the European Commission. In this way, each country transposes the Directive into its national decrees and laws, and even into regional and local laws.

Having understood the current legislation in this area, it is important to analyse the types of procurement that exist in public hospitals in Europe and how they are carried out. As an approximation, the hospitals in the ODIN consortium have shared the concrete and detailed innovation procurement procedures that are carried out in their organisations and/or regions. It is important to highlight that the European Commission promotes the adoption of this type of procedures, supporting the inclusion of different stakeholders as SMEs, and encouraging the application of criteria beyond price, such as Best Price-Quality ratio.

For this reason, it is crucial to understand the basis of the value-based healthcare paradigm, which is based on obtaining the best benefits (or best value) at minimum cost. Strategies are based on preventing the development of disease and improving patient health outcomes. This is leading to a perspective shift from the provision of traditional healthcare to the deployment of innovative solutions and services that position the patient at the centre of the system.

For all these reasons, the ODIN project serves as an excellent forum to encourage the participation of all stakeholders in public procurement processes for innovation. D2.5 has also benefited from inputs from the consortium hospitals, which have shared the profiles and professional groups involved in their procurement processes, as well as the success points and pain points currently identified. This valuable information will be further used and developed in T10.2 DEMAND Open Innovation. On the other hand, the perspective of suppliers (medical technology providers) will be further investigated on in T10.3 SUPPLY Open Innovation.

This Deliverable is framed based on the activities established at the end of T2.5:

- Requiring and analysing Supply Side inputs regarding their participation and opinion in public procurement processes for innovation (T10.3).
- Carrying out two focus groups for the Demand Side (T10.2) and the Supply Side (10.3), with the aim of finding out needs, best practices, success and pain points.
- Undertaking a co-creation workshop to foster discussion between both stakeholders, to describe the final implementation plan of the procedure for the procurement of AI-based solutions for care delivery in hospitals in Europe.

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