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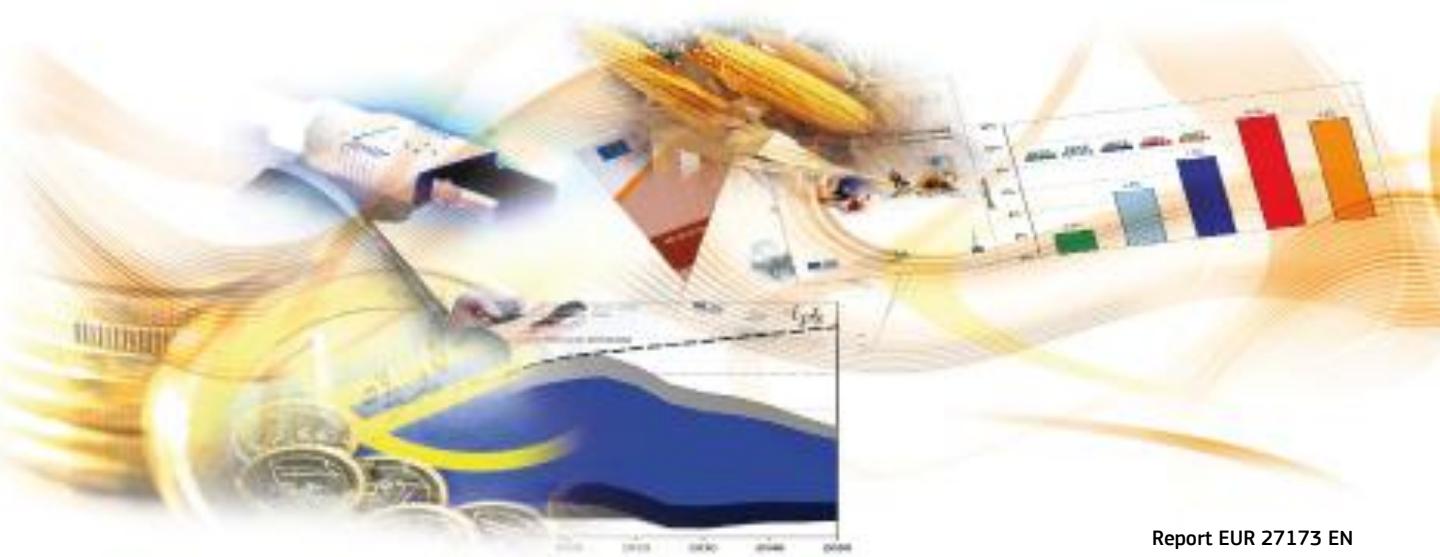
Strategic Intelligence Monitor on Personal Health Systems Phase 3 (SIMPHS3)

*Healthcare PPI, Galicia (Spain)
Case Study Report*

Author:
Ramon Sabes-Figuera

Editor:
Fabienne Abadie

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Contact information

Address: Edificio Expo. c/ Inca Garcilaso, 3. E-41092 Seville (Spain)
E-mail: jrc-ipts-secretariat@ec.europa.eu
Tel.: +34 954488318
Fax: +34 954488300

<https://ec.europa.eu/jrc>
<https://ec.europa.eu/jrc/en/institutes/ipts>

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Abstract

The Public Procurement of Innovation projects and experiences developed in the healthcare system of Galicia, an autonomous community in northwest Spain, are part of its innovation model and related initiatives in this field. The objectives of this model are to transform both the care model and the relationship model between providers, professionals and patients.

As part of this innovation strategy, two plans have been put in place: InnovaSaúde (IS) and Hospital 2050 (H2050). These plans have been established through an agreement with the Spanish Ministry of Economy and Competitiveness which allocated the Galician Public Healthcare provider (Servicio Galego de Saúde, SERGAS) a public grant of €90 million from the European Regional Development Funds (ERDF). These plans are part of the R&D Operational Plans which target private companies.

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Case Outlook

Public Procurement of Innovation projects and experiences in the healthcare system of Galicia, an autonomous community in northwest Spain, are part of Galicia's innovation model and related initiatives in this field. The objectives of this model are to transform both the care model and the relationship model between providers, professionals and patients.

As part of this innovation strategy, two plans have been put in place: InnovaSaúde (IS) and Hospital 2050 (H2050). These plans were established through an agreement with the Spanish Ministry of Economy and Competitiveness which allocated the Galician public healthcare provider (Servicio Galego de Saúde, SERGAS) a public grant of €90 million from the European Regional Development Funds (ERDF). These plans are part of the R&D Operational Plans which target private companies.

InnovaSaúde aims to foster a safe, fast and intelligent patient-centred healthcare system while the objective of H2050 is to develop infrastructures and scenarios to evaluate and validate new health products and services resulting from health innovation projects. Public Procurement of Innovation initiatives developed under the above innovation plans and their sub-projects are of two types: Public (commercial) Procurement of (Innovative) Technology and Pre-commercial Public Procurement of Technology.

The Public Procurement of Innovative Technology process is divided in two consecutive steps, a technical dialogue with the market which informs the next step, the process of procuring the innovative technology. This procurement is characterised by some specific elements which reflect the innovative aspect of the tender's purpose. In relation to the technical dialogue, from the launch of the open call for proposals in April 2012 until September 2014, a total of 296 proposals were received, 228 from private companies and 68 from research entities. The average number of proposals per project was 23 and for some of them, more than 40 proposals were received. A total of 107 entities (96 private companies and 11 research institutions) participated. At the time of writing, 31 tenders were launched for the public commercial procurement of innovative technology for a total of €28.7 million euros and 17 contracts had already been awarded.

As to Pre-commercial Public Procurement of Technology, the InnovaSuMMa project was launched as a pilot project under the Galician Innovation plans, more specifically in the subproject "Knowledge Transfer" of InnovaSaúde. The final aim of the project is to incorporate elements of personalised medicine, i.e. diagnostic and prognostic biomarkers for colon, lung and prostate cancers into the hospital protocols in the oncological field. The aforementioned cancers are among the top concerns of the Galician health system and they have been included in the *Galician Health Priorities Plan 2011-2014*, which was recently extended to 2016. This initiative is aligned with the current policy strategies of SERGAS which focus on personalised medicine. The total budget for this project is €628,000 and the maximum amount of each individual contract with a company is €110,000. The project and the related contract have been divided into three competitive phases: the demonstration of the viability of the proposal, the development of a prototype of the solution proposed and the development of a full demonstrator.

The ongoing implementation of the Galician experiences at the time of writing this report does not allow us to draw definitive conclusions on the impact of the initiatives. Nevertheless some lessons can be learned about the initiative's benefits for the Galician healthcare system and for the participating companies.

1. Background

1.1 Spanish social and health care services

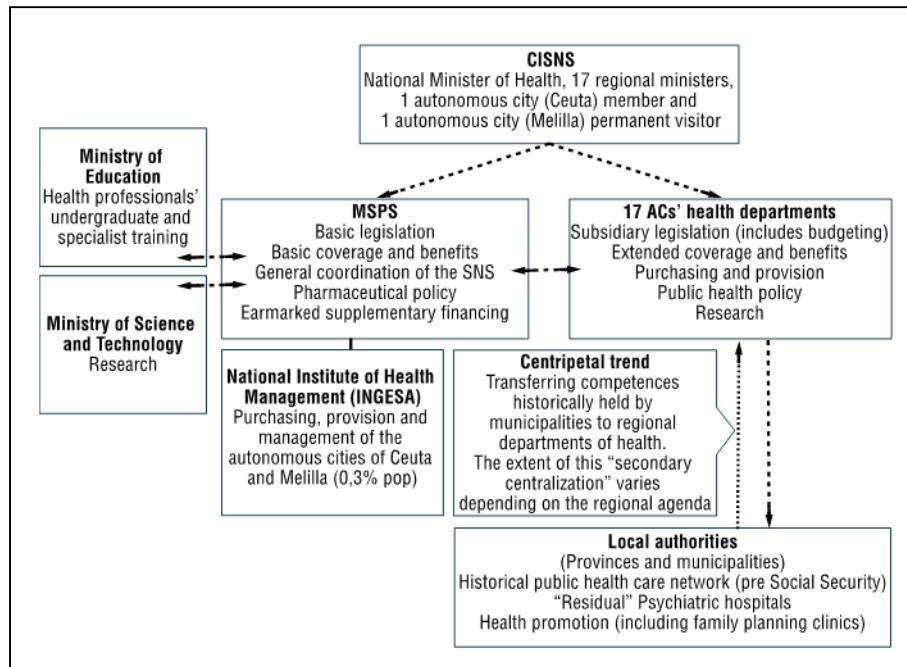
The Spanish Constitution of 1978 established the right to health protection and healthcare for all citizens. As described by the Ministry of Health, Social Services and Equality (2012), the substantive principles and criteria enabling the exercise of this right are as follows:

- Public funding, universal coverage and free healthcare services at the time of use.
- Defined rights and duties for citizens and public authorities.
- Political decentralisation of healthcare devolved to the autonomous regions.
- Provision of comprehensive healthcare, striving to attain high levels of quality duly evaluated and controlled.
- Integration of different public structures and health services under the National Health System.

Spain has a statutory national health system (SNS), which is characterised by universal coverage and is funded by taxes. Services are largely provided free of charge at delivery, whereas most pharmaceuticals prescribed to people aged under 65 require a co-payment of about 40% of the price. Private voluntary insurance plays only a minor role in the Spanish health system. The services provided are mainly complementary to the services provided under the statutory health system, and usually imply reduced waiting times for specialised care or access to services that are limited within the benefits package of the SNS. The political control of the Spanish health system rests with the regional governments (Comunidades Autónomas). There are 17 regional health ministries across Spain, each being in charge of primary jurisdiction over the organisation and delivery of health services within the respective region. In its most typical form, a regional health system of an autonomous community is composed of a regional ministry (Consejería de Salud) which is responsible for the general definition of health policies and the regulation of health care and its planning, and a regional health service in charge of the provision of services. The regional ministry organises and structures the health services in the region and typically two executive organisations provide primary care and specialist care respectively.

However, it has become very frequent for regional health systems to integrate primary and specialist care under a single management structure. A single primary care team (PCT) that is allocated to a patient and not freely chosen, takes the role of gatekeeper to services, as access to specialist care largely depends on prior referral from the GP. As a means of improving waiting list management, some specialised care delivery is contracted out to private hospitals, but around 40% of all hospitals in Spain belong to the SNS. Most of the public health expenditure in Spain is financed through general taxation (>94%), supplemented by contributions from payroll tax and employers contribution, and from the civil servants' health insurance fund.

Figure 1: Spanish National Health System characterization

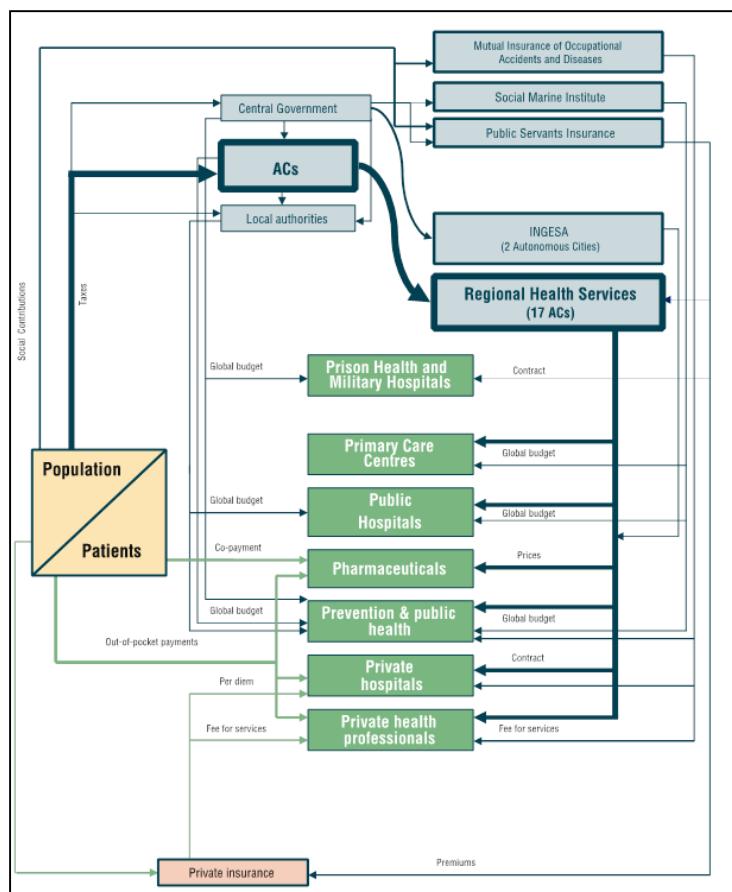


Source: García-Armesto et al (2010)

Public health expenditure relates mainly to both in and outpatient specialist care (54%), primary health care (16%), pharmaceuticals (19.8%), and prevention measures and general public health (1.4%). The regional governments administer the largest share of public health resources, whereas the central government and the municipalities account for only about 3% and 1.25%, respectively. The primary care network is completely public, with care professionals working in multidisciplinary teams that can comprise GPs, nurses, social workers, or paediatricians who are linked to laboratories or diagnostic centres.

Figure 2 shows the financial flows across the Spanish NHS. The allocation formula is based on a per capita criterion, weighted by population structure, dispersion, extension and insularity of the territory.

Figure 2: Financial flows across the Spanish NHS



Source: García-Armesto et al (2010)

1.2 Galician healthcare system

Galicia is an autonomous community in northwest Spain with a population of 2,765,940 in 2013 and which has a total area of 29,574 km². The percentage of population older than 65 is higher than in the rest of Spain: 23% vs 17%. Responsibility for public healthcare lies with the Galician Government (Xunta de Galicia) through its Regional Ministry of Health (ConSELLERÍA DE SANIDADE).

The organization responsible for delivering healthcare services is the Servizo Galego de Saúde (SERGAS). The public healthcare system covers 95% of the Galician population, and has an annual budget of €3,400 million, representing more than 40% of the total budget of the Galician Regional Government. SERGAS' resources comprise 14 secondary care trusts and hospitals, 493 primary care centres, 90 emergency centres and 165 homes for the elderly. It employs more than 36,000 people, including 2,200 primary care physicians and 4,741 secondary care physicians. From an administrative perspective, Galicia is divided into 7 integrated healthcare areas.

1.3 Why public procurement of innovation?

The ultimate objective of the SIMPHS research is to provide an understanding of the role of ICT in facilitating integrated health and social care. Therefore, a key consideration is how these technological elements (e.g. devices, platforms, medical records systems) are procured within European health and social care systems and to explore the benefits of innovative approaches to this process. Indeed, the fact that the public sector is by far the largest buyer and consumer of health care products and services in Europe creates an opportunity for using the ICT procurement process strategically. The European Commission is behind several ongoing initiatives and is planning more, with a view to encouraging the use of innovative public procurement tools in the healthcare field and specifically in relation to innovative technologies.¹

It was therefore deemed relevant for the SIMPHS3 research to explore public procurement experiences and try to draw lessons from innovative public procurement initiatives in the healthcare field. We identified the current initiatives by the regional government of Galicia (Spain) as particularly relevant not only because of their comprehensive and ambitious scope, but also because of the highly innovative approach developed and implemented in this region. In addition, as the Galician project makes use of different procurement tools, it allows us to present findings that may be relevant for a wider spectrum of stakeholders and experiences.

2. Public Procurement of Innovation in Galicia

2.1 Public Procurement of Innovation

Innovation procurement is defined as a process where goods and services are bought in a way that stimulates the supply chain to invest in developing better and more efficient innovative solutions to the unmet needs of an organisation. In this context, the power of public authorities is considerable given that for instance in the EU, public procurement accounts for some 19% of GDP. Thus it offers an enormous potential market for innovative products and services (European Commission, 2014). Therefore Public Procurement of Innovation (PPI)² can be used as an innovation policy tool, which can stimulate market uptake of innovative products and services. Public authorities act as launch customers for these goods and services, which typically are not yet available on a large-scale commercial basis or have not even been developed.

Overall, the main objectives of PPI can be defined as:

- **Improving public services** by incorporating innovative goods and services.
- The promotion of **business innovation**.
- Fostering the **internationalisation of innovation** using the local public sector market as a launch client or a reference client.

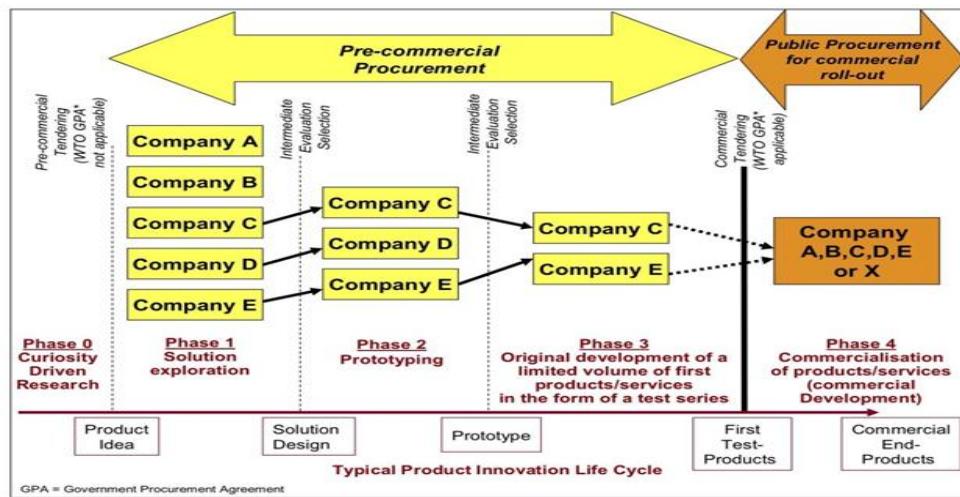
PPI initiatives can be classified in two types: commercial and pre-commercial procurement. The former consists of public procurement of a good or service that does not exist at the

¹ Personalising health and care H2020 call for projects (<http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/2272-phc-29-2015.html>) and ongoing projects (<http://www.innovation-procurement.org/projects/health/>)

² Also referred to as innovative public procurement.

time of purchase but can be developed in a reasonable timeframe with new or improved technology that meets the needs of the purchaser. The latter deals with procurement of Research and Development (R&D) services, rather than actual goods or services. Its objective is to develop innovative solutions that outperform those available on the market. In this particular case of R&D procurement, the buyer (i.e. the public sector) does not reserve the rights over the results of the R&D for their exclusive use, but shares the risk and benefits with the company awarded the contract. However, if the goods or services developed during the R&D phase are to be procured in a later phase, a separate procurement process is required. Figure 3 illustrates these two types of PPI and the complementarity between them.

Figure 3: Pre-commercial and commercial procurement of innovation.



Source http://cordis.europa.eu/fp7/ict/pcp/links_en.html

The European Commission has produced or supported the production of several guides (Procurement of Innovation Platform, 2014 and European Commission, 2007 and 2014) on this topic and in one of them 10 elements of good practice have been identified which deal with innovative solutions in public procurement (see Table 1).

Table 1: Elements of goods practices in PPI

1. Act as an 'intelligent' customer.
2. Consult the market before tendering.
3. Involve key stakeholders throughout the process.
4. Let the market propose creative solutions.
5. Seek value for money, not just the lowest price.
6. Take advantage of electronic means.
7. Decide how to manage risks.
8. Use contractual arrangements to encourage innovation.
9. Develop an implementation plan.
10. Learn for the future.

Source: European Commission (2007).

The relevance of Public Procurement of Innovation has also been highlighted in the European Commission's Europe 2020 flagship initiative, the "Innovation Union":³

³ http://ec.europa.eu/research/innovation-union/index_en.cfm

"From 2011, Member States and regions should set aside dedicated budgets for pre-commercial procurements and public procurements of innovative products and services. This should create procurement markets across the EU starting from at least €10 billion a year for innovations that improve the efficiency and quality of public services, while addressing the major societal challenges. The aim should be to achieve innovative procurement markets equivalent to those in the US. The Commission will provide guidance and set up a (financial) support mechanism to help contracting authorities to implement these procurements in a non-discriminatory and open manner, to pool demand, to draw up common specifications, and to promote SME access."

2.2 Galicia's innovation plans: InnovaSaude and Hospital 2050

Galicia's PPI projects and experiences in its healthcare system are part of its innovation model and related initiatives in this field. The objectives of this model are to transform both the care model and the relationship model between providers, professionals and patients. It aims to achieve these general objectives through:

- A change from a reactive care model to a proactive one.
- Measures that ensure the continuum of care.
- The evaluation of the health and cost impact of technologies and treatments.
- Bringing care closer to citizens through technology, and making the home a place of care.

As part of this innovation strategy, two plans have been put in place: InnovaSaúde and Hospital 2050 (H2050). These plans have been established through an agreement with the Spanish Ministry of Economy and Competitiveness which allocated the Galician Public Healthcare provider (Servizio Galego de Saúde, SERGAS) a public grant of €90 million from the European Regional Development Funds (ERDF). These plans are part of the R&D Operational Plans which target private companies. This means that private companies are involved through the use of innovative public procurement as a policy tool, the overall objective being to foster innovation and the internationalisation of companies. By coordinating and strengthening technology demand, these plans therefore promote health innovation and the generation of new goods and services with which the entrepreneurial sector should be able to compete at international level. The main characteristics of these two complementary innovation plans are described below.

InnovaSaude is composed of 14 different subprojects (see Table 2). It aims to foster a safe, fast and intelligent patient-centred healthcare system. More specifically its objectives are to:

- Develop an open innovation model in which the different healthcare stakeholders of Galicia participate, thus enhancing the knowledge, capacities and potential of the Galician Healthcare system.
- Respond to challenges and current and future requirements of the healthcare system through systematically and carefully planned innovative solutions.
- Develop adequate business models for the products and services implemented in the framework of the collaborative projects carried out.
- Foster new business opportunities and markets for Galician and Spanish companies.

- Encourage the creation of positive and lasting synergies between the main healthcare stakeholders, i.e. SERGAS, various public bodies including the Spanish Ministry of Science and Innovation, companies and knowledge centres.

H2050: the objective of H2050 is to develop infrastructures and scenarios to evaluate and validate new health products and services resulting from health innovation projects and improve intra-hospital processes and services. These products and services will be tested in a large hospital environment (Hospital complex of Ourense, part of the Galician health Service) through living lab methodologies. The design of the services to be tested will be based on an open and participative approach with the patient at the centre. H2050 is composed of 9 different subprojects (see Table 2) and its final objective is to enable the development of a "hospital of the future" which has to be:

- A safe hospital: patient safety has become very important over the last few years for both the patients and their families, and also for hospital managers and healthcare professionals.
- A green hospital, improving environmental performance of healthcare services, leading to immediate economic and environmental benefits.
- A sustainable and efficient hospital.
- A hospital which is open to the rational use of new technologies and to their evaluation.

Table 2: InnovaSaude and H2050 subprojects

InnovaSaude Subprojects	H2050 Subprojects
<ul style="list-style-type: none"> • Mobile diagnostic-therapeutic healthcare point • Medical imaging centre • Hospital at home • Multi-speciality teleconsultation products • Digital (care) home assistance • Patient expert 2.0. • Smart multilevel alert system • Advanced medical simulation centre • Computer-aided diagnosis systems • Professional 3.0 • Innovation space for healthcare services • Integrated information and management system for clinical and epidemiological data for research • Transfer of the results of research and innovative healthcare projects • Integrated system for digitalisation, indexation, storage and management of clinical information 	<ul style="list-style-type: none"> • Smart management system for emergency services • Integrated traceability system for patients and resources • Hospital robotics • Self-sustainable hospital • New HIS 2050. Integrated patient management system • Smart ward • Experimental Hospitalisation H2050 • Secure digital hospital • Preservation of clinical information

Source: <http://www.sergas.es/>h2050-innovasaude

2.3 PPI initiatives in Galicia

The PPI initiatives developed under the above innovation plans and their subprojects are of the two types previously described: Public (commercial) Procurement of (Innovative) Technology and Pre-commercial Public Procurement of technology. We will start by presenting the distinctive features of the PPIT process as implemented in Galicia before illustrating how it has been implemented in a particular case of integrated care.

2.3.1 Public Commercial Procurement of Innovative Technology (PPIT) in Galicia

The process carried out in Galicia is divided into two consecutive steps. The first one is a technical dialogue with the market and the second is the procurement process of the innovative technology, which is informed by the results of the previous phase.

a) Technical dialogue

A technical dialogue is a procedure that aims to enable the contracting authority to become familiar with the best, most beneficial and most up-to-date technical, technological and organisational solutions on the relevant market for the contract it plans to award. It also allows the contracting authority to compare its needs against the capacity of a constantly changing market to meet those needs. It has to be differentiated from the competitive dialogue procedure that is defined as a procedure “*in which any economic operator may request to participate and whereby the Contracting Authority conducts a dialogue with the candidates admitted to that procedure, with the aim of developing one or more suitable alternatives capable of meeting its requirements, and on the basis of which the candidates chosen are invited to tender*”.⁴

The objectives of the technical dialogue in the SERGAS case were to identify relevant solutions and technologies for the technological challenges of the InnovaSaúde and H2050 innovation plans. As a first step, an open call for proposals for innovative solutions for the subprojects defined under these plans was launched. The information available to companies for each subproject was a brief “fact sheet” (3 pages) containing a generic project description, focussing on the objectives to be met by the technology to be developed, together with the possible main uses and target users (e.g. departments and professionals). Based on this information, companies submitted proposals that had to contain at least the following information:

- Proposer data,
- Sub-projects addressed by the proposal,
- Brief summary of the solution (i.e. main features),
- Duration of the proposal,
- Benefits of the proposal for the Public Health System, Users of the Public Health System and other stakeholders,
- Innovation aspects and expected R&D results,
- Associated standards and regulations,
- Authorisation for use of data submitted,
- Compulsory declaration (rights of exploitation and use of the proposal).

⁴ Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts

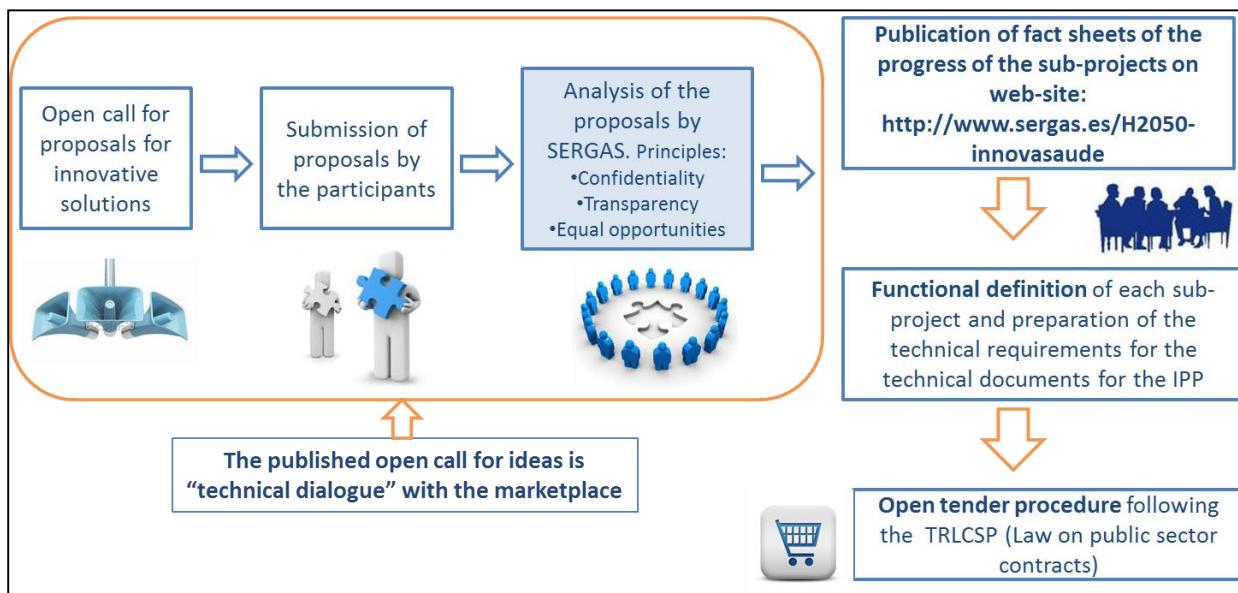
Once the proposals were received, they were validated and sent to the coordinators of each subproject working group. These groups then evaluated the proposals and decided whether they were of interest or not to the subproject. In the case that they were not of interest and outside of the scope of the subprojects, they checked whether the proposals were of more general interest to SERGAS. As part of this evaluation process, companies could be contacted for clarification by the subprojects working groups. Nevertheless, as a general rule, proponents were not informed of the outcome of their proposal evaluation. Companies were only informed in the cases where their proposal was of interest to SERGAS.

The next step was to define an “advanced fact sheet” for each subproject, based on the information gathered through the open call. These fact sheets contained a detailed description of the subprojects and of the technological solutions required. Furthermore, information on the companies and entities that submitted a proposal was provided. The objectives of these fact sheets were to:

- Define the functional scope of the subprojects,
- Anticipate future procurement needs,
- Establish collaboration with providers,
- Disseminate information on the entities that participated,
- Foster the creation of consortia between participating entities.

Based on these more refined definitions of the subprojects, an early tender map was generated linking each tender to one or more subprojects and specifying an estimated value for each tender. This demand-driven tender map is a useful innovative procedure to signal anticipated needs to the market and allow companies to align their R&D efforts towards future tenders. Figure 4 summarises the technical dialogue process.

Figure 4: Technical dialogue process.



Source: <http://www.sergas.es/h2050-innovasaude>

Results and impact of the technical dialogue

From the launch of the open call for proposals in April 2012 until September 2014, a total of 296 proposals were received, 228 from private companies and 68 from research entities. The average number of proposals per project was 23 and for some of them, more than 40 proposals were received. A total of 107 entities (96 private companies and 11 research institutions) participated. In 73% of the cases, the proposals were submitted by individual companies while in 7% of the cases, a consortium of entities was created. In relation to the evaluation of the proposals, 52% were deemed relevant for the H2050 and InnovaSaude projects, 35% were deemed relevant for SERGAS but not for the innovation plans, while the remaining 13% were not relevant.

The analyses of the proposals and the corresponding development of the “advanced fact sheets” led to the drafting of a demand-driven tender map, divided in two steps and containing a description of the tenders to be launched by SERGAS through Public Procurement of Innovative Technology. The first step (March 2013) included 18 tenders with a total budget of €18.4 million while the second step (April 2014) provided information on 12 tenders with a total budget of €13.9 million.

b) Procurement of the innovative technology

The procurement process of the tenders identified through the technical dialogue is characterised by some specific elements which reflect the innovative aspect of the tenders' purpose:

- **Intellectual and industrial property rights** related to the goods and services developed under the tender will belong to the companies. Therefore, the exercise of the rights of use, reproduction, distribution, and transformation will belong exclusively to the company which wins the tender.
- **Royalties offer.** The contracts include a clause which stipulates that companies have to offer SERGAS a percentage of participation in the future commercialisation benefits for the technology developed under the contract.
- **Phases of execution.** 5 phases have been identified, including demonstration scenarios to allow for the evaluation of the project during its development.
- **Evaluation criteria of the proposals.** The offers are evaluated mainly taking into consideration the following criteria:
 - The level of innovation
 - Compliance with the healthcare objectives of SERGAS
 - Compliance with objectives of scalability to the general system
 - Percentage of royalties offered.
 - Effort and investment on the part of the bidder
 - Price

Results and impact of the tender process

At the time of writing, 31 tenders had been launched for the public commercial procurement of innovative technology for a total of €28.7 million euros and 17 contracts had already been awarded. The following can be noted:

- SMEs participate in 80% of the awarded contracts.
- Galician companies participate in 73 % of the awarded contracts.

- There is an average of 4 offers per tender.
- 58% of the selected companies had participated in the technical dialogue.
- 25% of the awarded contracts are led by a consortium of companies.
- The average level of royalties offered to the Galician Healthcare system on the newly developed products is 53%.

The whole process of Public Procurement of Innovative Technology (PPIT) carried out in Galicia was evaluated by the companies that participated through an online survey. Table 3 shows some of the findings.

Table 3: Results of the survey of participating companies

83%	Considered the technical dialogue process interesting or very interesting
72%	Considered the call had fulfilled their expectations.
89%	Participated in the Technical Sessions organised to present the subprojects
83%	Considered the publication of the tender maps interesting or very interesting
31%	Kept or increased their staff after having knowledge of the publication of the tender maps
50%	Created consortia and presented collaborative proposals based on the information published on the web

c) An integrated care related example

Several of the tenders launched under the InnovaSaúde and H2050 plans had some integrated care components. Given the scope of the SIMPHS3 research, for the sake of this report, it was decided to focus on the tender most closely related to the field of integrated care, namely the "Development of electronic medical records oriented towards comprehensive patient follow-up across the healthcare continuum to facilitate chronic patient care" (reference number AB-SER113-069).

This tender received the highest budget with almost €4 million. This contract, as shown in the early tender map, was linked to three InnovaSaúde subprojects: Hospital at home, Digital Home and Patient expert 2.0.

The objective of the contract was to develop the necessary functionalities within the existing electronic medical records system to allow innovative and integrated care of patients with chronic diseases. The model of care to be facilitated by the tools that would be developed foresaw the involvement of healthcare organisations, patients and their families. The technical specifications included the following components and functionalities:

- A process-oriented electronic medical record
- Prescriptions and medical orders manager
- Care protocols manager
- Clinical variables repository
- Scales
- Clinical Nursing tool, including care plans and special register system
- Mobile Electronic Medical records (i.e. the possibility of accessing EMR through mobile devices).

Besides these specific functionalities, the technical specification also specified that the developed systems should ensure interoperability with other current and future ICT systems (to be developed as part of other InnovaSaúde and H2050 subprojects). Therefore, and according to these specifications, the main objective was to update and complement the existing electronic medical records system to foster the integrated care of patients.

The information on the subprojects linked to this tender and on the related technical dialogue, the “fact sheets” and the “advanced fact sheets”, shows that:

- In relation to the Home digital subproject:
 - 47 entities submitted proposals for this subproject.
 - In the “fact sheet”, this subproject was described in generic terms as a telemedicine system which would connect healthcare organisations and patients in a bidirectional way. This system would have to include reminders and the monitoring of vital signs to allow patients follow-up.
 - The “advanced fact sheet” described in much more details the main objective of the subproject which is to offer patients all possible services/care which can be provided via new technologies in their home with the aim of increasing quality of care as well as reducing bureaucracy and administrative hurdles.
 - It also provided a thorough description of the characteristics of the telemonitoring solution, including technical specifications, together with details of how it should be integrated into the electronic clinical records.
- In relation to the Hospital at Home subproject:
 - 41 entities submitted proposals for this subproject.
 - The “fact sheet” for this subproject contained a broad description of the technical requirements for a (temporary) home hospitalisation system, focussing more on the general objectives of such a solution and on how to evaluate it.
 - The “advanced fact sheet” provided detailed information on the process of home hospitalisation, the required information, and the health professionals and care levels involved. It also described how this care process should be integrated with the rest of SERGAS’ activities.

2.3.2 Pre-commercial Public Procurement (PCPP) in Galicia

There is currently one PCPP initiative in Galicia, which is being developed under the project InnovaSuMMA. This pilot project is part of the Galician Innovation plans, more specifically of the subproject "Knowledge Transfer" of InnovaSaúde. The final aim of the project is to incorporate elements of personalised medicine, i.e. diagnostic and prognostic biomarkers for colon, lung and prostate cancers, into the hospital protocols in the oncological field. This initiative is aligned with the current policy strategies of SERGAS which focus on personalised medicine. The total budget for this project is €628,000 and the maximum amount for each individual contract with a company is €110,000.

The InnovaSuMMA project is partly based on the findings of a previous project developed by the Spanish Association of Biocompanies (ASEBIO), where the early demand for technologies in personalised medicine in the areas of oncology and haematology was analysed at Spanish level. The collaboration with the heads of oncology units at the

Galician public hospitals and with the Galician Oncology Society allowed the adaption of these results to the Galician context.

The next step was to launch a pre-commercial procurement process to develop a tender for R+D services in the oncological areas identified. It was considered that this approach adequately focused market development efforts on the needs of SERGAS. Both the risks and the benefits are shared between companies and SERGAS so there are incentives for future commercialisation of developed products. In order to reduce the risks, the contract is divided into three competitive phases:

- **Phase 1 - Demonstration of the viability of the proposal.** The objective is to guarantee the adaptation of the initial proposal to the clinical and organisational contexts of SERGAS and especially to the services where the technology has to be developed and/or tested. During this phase, approvals from Regional Ethics Committees and other organizations with regulatory responsibilities in this kind of investigation will be obtained. This phase lasts one month and a maximum of 4 companies can participate.
- **Phase 2 - Development of a prototype of the solution proposed.** The objective is to improve prototypes of the technology proposed considering the actual context of the oncological services of SERGAS and to obtain preliminary results with real patients, validating technologies and associated diagnostic services. This phase lasts 6 months and a maximum of 3 companies can participate.
- **Phase 3 - Development of a full demonstrator.** The aim of this phase is to evaluate the proposal's viability with regard to incorporating the tests developed into the current hospital protocols, considering any adjustments and complementary tests needed. A maximum of 2 companies can participate in this phase that lasts 6 months.

A key aspect of the pre-commercial procurement contracts by SERGAS is the way intellectual property rights of the research developed have been defined. These rights are given or transferred to the companies. As compensation for this transfer of rights, SERGAS receives a percentage of the net profits of the commercial exploitation of the products developed during the contract, which cannot exceed 20%. This facilitates company sales and development in the healthcare and biotech sectors, an industry particularly concerned with IP rights. Nevertheless, SERGAS keeps the option to retrieve these rights in the case that the company does not exploit them commercially within 5 years, thus ensuring public availability of the technology. The possibility has also been considered of licensing out the developed solutions to third party suppliers under fair and reasonable market conditions.

Expected benefits and impact

The project is expected to have positive impacts on participating companies and on the Galician healthcare system:

- **Companies:**
 - It allows the participating companies to test their products in the actual healthcare context, enabling them to adapt the products to the actual needs of clinicians and of the system.
 - Through the collaboration with clinicians, future research projects may be unveiled.

- Companies will be able to demonstrate relevant expertise for their possible participation in other Spanish and international pre-commercial procurement initiatives.
- Their participation in the project implies that their product has been implemented, a criteria usually considered by other possible buyers.
- **Galician healthcare system**
 - It provides better clinical tools for the treatment of patients, that otherwise would not have been developed or, at least, would have had a longer time-to-market.
 - It provides new protocols with a possible impact on the sustainability of the system (i.e. cost reduction).
 - If the products developed under contract are commercialised, SERGAS receives a percentage of the profits which is invested in the public health system.
 - The experience acquired may have a positive impact on the qualifications and skills of SERGAS professionals, both those in charge of procurement services and the clinicians.
 - It offers opportunities for further collaboration in R+D projects between SERGAS and the participating companies.

2.4 Evaluation of impact

At the time of writing this report, the impact and results of the innovation plans and related subprojects were going to be evaluated by a specific evaluation study. A call for tenders for this study was launched and the resulting contract will be funded by the same grant provided by the European Regional Development Funds which funded the innovation plans. The study was planned in 3 phases over a period of 10 months:

- 1) First phase: the company which wins the tender will meet the coordinators of the subprojects working groups in order to adapt and update the evaluation proposal according to data availability and gain inside knowledge of the subprojects.
- 2) Second phase: based on the updated proposal, the company will start the gathering of evidence and data.
- 3) Third phase: Presentation of the evaluation results.

The information on this tender allows us to highlight some interesting features of the evaluation study and the approach that will be adopted:

- It will have a flexible methodological approach, justified by the innovative aspects of the object(s) of the evaluation and their heterogeneity. The Galician Health Technology Assessment Agency (Avalia-T) was involved in the development of the tender to ensure that the HTA standard approach was taken into consideration.
- It will produce two different types of evaluation reports: an impact and results study for each of the InnovaSaúde and H2050 subprojects⁵ and two reports, which will adopt a comprehensive and transversal approach, exploring separately the impact of InnovaSaúde and H2050.
- In relation to the evaluation indicators to be selected:

⁵ Given its characteristics it was decided not to evaluate the subproject “Sustainable Hospital”.

- The tender suggests that some dimensions in the proposals should be specified and it provides a minimum set of features that needs to be considered in the evaluation for each of the subprojects.
- The inclusion of health, clinical, and integrated care outcomes in the evaluation of subprojects is suggested (if relevant), together with cost analyses.
- Bidders are encouraged to include in their proposals some indicators that will allow the evaluation (by SERGAS) of the long-term impact of the projects. For subprojects which will be in the early stages of implementation when the evaluation project is carried out, these long-term indicators (or evaluation guide) will be the only measurable outcomes of the project.
- Based on the results of the evaluation, the evaluation study should also make suggestions to improve the projects and their modus operandi.

3. Lessons

The PPI initiatives and implementation of the tools developed under the health innovation plans InnovaSaúde and H2050 were still ongoing at the time of writing this report which is why no results or impact evaluation are available. Nevertheless, based on the analysis of the available documentation and the insights from the experts in charge of the initiatives, some key points and lessons can be highlighted:

- The **involvement of healthcare professionals** in both PPI initiatives seems to have played an important role and is likely to have a positive impact on the expected outcomes. In the PPIT initiatives, specifically in the technical dialogue, professionals from different levels of healthcare (primary and secondary) and from a variety of fields (doctors, nursing staff, managers, administration staff, clinical coders) were actively involved in the process through their participation in the subproject working groups. In the PCPP project, clinicians (oncologists) helped to define the aims and objectives of the initiative from the beginning, and they are collaborating with the participating companies.
- The **impact and added-value of the technical dialogue** varied among the different innovation subprojects. In some, it helped to define more accurately the technical characteristics of the suggested solution. In others, it changed substantially the approach and the scope of the solution initially suggested. This variation may be related to the **maturity level of the technology** or solution involved in each subproject. For more mature technologies, the technical dialogue process helped refine their definition in the SERGAS context, while for less mature ones, it served to define their main features.
- The general objectives of the innovation plans and its subprojects needed to be adapted when the related PPI tools were developed given the (unavoidable) **lack of flexibility of public contracts laws**. For instance, the general evaluation criteria of the tenders were shaped in compliance with the law, which implied more rigid criteria. As a consequence, some characteristics of the offers such as the companies' investment plans could not be evaluated through a specific tender criterion. Instead they were evaluated indirectly through other characteristics of the offer such as technical maintenance and business plan.

- The **low weight that the offers' price** had in the evaluation, only 5% of the total evaluation scoring, is worth noting. It reflects the fact that PPI tools focussed on the development of innovative technological solutions to respond to the challenges faced by the healthcare system, not on seeking cheaper solutions. Nevertheless, the impact of the solutions on costs for SERGAS was one of the aspects to be detailed by the bidders in their offers.
- From the analysis of the **outcomes of the technical dialogue** in the subprojects related to the **specific tender** “*Development of electronic medical records oriented towards comprehensive patient follow-up across the healthcare continuum to facilitate chronic patient care*” the following lessons can be learnt:
 - The technical dialogue **shaped the solutions initially suggested in the subprojects** from generic descriptions of telemedicine and hospitalisation at home to much more detailed descriptions of functional and technical requirements for a specific solution.
 - It also helped to define the **links between the different (electronic) information systems** more clearly in order to allow the seamless transfer of clinical and organisational data between levels of care and professionals, and between professionals and patients.
 - In the specific tender it was possible **to define accurately** the **services and systems to be contracted** based on the process and outcomes of the technical dialogue of the two related subprojects (Hospital at Home and Digital Home).
 - While the object of the tender was not specifically telemedicine or hospitalisation at home services, it consisted of the adaption and the development of a new model to substitute the current electronic medical records systems so that **the services described** in these related subprojects could be developed.
 - The technological solution to be provided through the contract will enable, in theory, the **provision of healthcare in an integrated way**. This is reinforced by the requirement imposed on the contractor to ensure **interoperability** of the solution with other systems being developed as part of the InnovaSaude and H2050 innovation plans.
- Concerning the pre-commercial public procurement initiative, the InnovaSuMMA project, several aspects can be highlighted:
 - The initiative allows companies to develop a product in direct contact with its main future users, the clinicians. From the first phase of the initiative, this allows **companies to base their work on the actual needs and requirements of the final users**.
 - The possibility of working with **real patient data** increases the chances that any R&D solution developed answers the needs of the healthcare system adequately.
 - As mentioned previously, the benefits for the companies of their involvement in the pre-commercial procurement initiatives are quite significant, not only in relation to this specific initiative. First, they obtain working knowledge on **how the healthcare systems is organised and functions**. Second, they

gain **experience** in this type of **procurement process** which may be useful for their involvement in future projects in other contexts. And finally, and maybe the most relevant benefit for the development of the companies, they **can demonstrate to other possible clients** that their product has already been acquired.

- The **evaluation of the PPIT contracts** includes a phase named “*evaluation and demonstration*” whose results have to be delivered to SERGAS by the companies. The evaluation results will most probably address the **number of users and applications** deployed rather than more comprehensive evaluation outcomes. Nevertheless, as mentioned before, the outline of the project plan that bidders should include in their offers specifies that this plan should contain detailed explanations of how the suggested solution will have a positive impact on healthcare costs.
- Based on the available information on the planned evaluation of the innovation plans, it seems that outcomes such as the impact of the plans on the health of covered population were being considered.
- Last but not least, given the current stage of the PPI initiatives and the related subprojects and innovation plans, there is not enough information to provide lessons on a key aspect of the initiative, namely the **criteria** upon which the **decision on the further implementation of the technological solutions** developed/contracted will be made, and how these criteria may relate to the PPI initiatives. The intention is that only successful experiences will be implemented in the whole Galician healthcare system. However, two difficulties arise: firstly, there does not seem to be any clear definition or framework that defines success in this context. It seems that this will depend on the technology to be implemented and on its maturity level. For instance, projects concerning the further development of or improvements to the electronic medical records seem to be more likely to be adopted than more experimental or less mature technological solutions. Nevertheless, it is acknowledged that SERGAS’ priorities together with the results of ad-hoc evaluation studies will have a significant weight in the deployment decisions to be taken. And secondly, the current legal framework in Spain does not allow the direct extension and full deployment of the initial innovative development process to the whole organisation. A second tender process must be launched, and no advantages can be given to the innovative solution that has been tested. The new European legal framework (DIRECTIVE 2014/24/EU) opens up the possibility of using a new and specific procurement procedure, to establish a long-term innovation partnership that will guarantee that innovative products or services, or innovative processes can ultimately be delivered to agreed performance levels and costs, without the need for a separate procurement procedure for their purchase.

4. Conclusions

ICT technologies play an important role in fostering integrated health and social care. Therefore, a key aspect to be analysed in relation to ICT-supported integrated care is how these technologies are procured within European health and social care systems. The specific characteristics of health technologies require that their procurement processes are designed differently from traditional procurement processes. These technologies are mostly innovative, they continuously evolve not only to answer the very specific needs of healthcare systems but also because they are subject to the fast pace of innovation that characterises ICTs in general. As a consequence, the best possible technological solution may not yet have been developed or be available on the market when a given need is identified. Furthermore, the predominant role of public organisations in the healthcare field makes it possible to pursue a complementary objective when planning the purchase and integration of new technologies – i.e. fostering and incentivising new companies and markets. This contributes to economic growth and it is in this context that the PPI tools can play an instrumental role.

The ongoing implementation of the Galician experiences at the time of writing this report does not allow us to draw definitive conclusions on their impact. Nevertheless some lessons can be learned. The PPI tools have allowed SERGAS' decision makers to define the technological solutions that were required to fulfil, in theory, the organisational and health outcome objectives they had set. This was done in a collaborative process between the professionals who will use and implement these technologies and the companies that will be developing them, putting both sides in a win-win situation. In addition, the PPI initiatives are expected to have a positive impact on the participating companies, way beyond the mere fact of having won a procurement contract.

The planned evaluation of the innovation plans and subprojects will in due course offer more evidence on the final impact of the technologies procured, and in turn provide further elements to evaluate the implementation of the PPI tools.

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