

TERMS AND CONDITIONS OF THE CALL FOR PRELIMINARY MARKET CONSULTATION OF THE PRECISAÚDE HEALTH INNOVATION PLAN IN THE FIELD OF 5P MEDICINE IN THE CONTEXT OF THE GALICIAN HEALTH SERVICE

1. Project background

The Galician Health Service is responsible for the public management of health care in the Autonomous Community of Galicia. As a public body, the Galician Health Service is responsible for coordinating, managing, and supervising health services; always guaranteeing the quality, equity, and accessibility of medical care for all Galician citizens. Since it has been created, it has carried out several initiatives and innovative projects to improve the quality and efficiency of health services highlighting, among other, the following:

- Hospital 2050 and *InnovaSaúde*, with a budget of 90 million euros, funded by the *Innocompra* Line using ERDF 07-13 funds.
- *Código 100*, with a budget of over 13 million euros, funded by the FID Lines using ERDF 14-20 funds.
- *Innova MicroLab*, with a budget of over 5 million euros, funded by the FID Line using ERDF 14-20 funds (currently in progress).
- INNOVATRIAL, with a budget of over 10 million euros, tendered by CDTI (Galician Industrial Technology Development Centre) and funded by the PRTR (currently in progress).

In this context of continuous improvement and innovation, the concept of 5P medicine is gaining particular importance as a comprehensive, multidisciplinary approach to healthcare that combines five key elements: prevention, prediction, participation, personalisation, and population-based approach. This paradigm seeks to transform current healthcare by focusing on disease prevention, risk prediction, active participation of patients, personalisation of treatments, and the implementation of health policies based on the needs of the population.

Following the legal framework established by Law 9/2017, of 8th November, on Public Sector Contracts (LCSP, by its Spanish acronym), public procurement of innovation is conceptualised as the main tool for a public entity (such as the Galician Health Service) to demand solutions to challenges not currently addressed by the market, promoting innovation in the business sector from the demand side. In any case, due to the lack of such market solutions, the task of designing the corresponding conditions of bidding is particularly complex due to the asymmetry of the existing information among the entities that are working on innovations that could be of interest and the Public Administration's vision of the market.

Therefore, in accordance with article 115 of the LCSP, the Galician Health Service has the power to carry out preliminary market consultations with the aim of raising

a series of challenges with regards to 5P medicine for which no suitable market solutions have been identified, in order to, through a contrast with the agents of the healthcare innovation ecosystem, gather information on available solutions and trends in innovation to boost subsequent tenders for public procurement of innovation. These consultations allow the Galician Health Service to identify possible solutions and suppliers, as well as promote the exchange of knowledge and experiences between different agents in the health sector. By carrying out this preliminary market consultation, the Galician Health Service seeks to promote new initiatives and projects to improve the quality and efficiency of health services in Galicia, maintaining its commitment to innovation and excellence in health care.

This is the Preliminary Market Consultation. Its procedure is set out in this document, which is supplemented by the description of unmet needs (**ANNEX I**) and the forms for participation in this Preliminary Market Consultation (**ANNEXS II, III and IV**).

2. Call

A Preliminary Market Consultation is utilised within the PRECISAÚDE project for innovation in the field of 5p medicine in the context of the Galician Health Service.

3. Purpose

The purpose of this Preliminary Market Consultation is to obtain the necessary information to prepare a possible contracting process in accordance with the provisions of article 115 of the LCSP, within the framework of the PRECISAÚDE project for innovation in the field of 5p medicine.

This Consultation seeks to promote the participation of economic operators active in the market that can respond to the challenges described in **ANNEX I** of this call (available in the contracting party's profile of the Galician Health Service).

Specifically, it is intended that, based on the results of this Consultation, the Galician Health Service will have knowledge about innovative solutions and capacities existing in the market; as well as sufficient information to enable it to better define the technical and functional specifications of the possible projects/scope to be tendered.

4. Participants

This call is open to natural or legal persons, public or private, with demonstrable experience in the field of 5P medicine and, in particular, those in the field of activities linked to the challenges set out in Annex I of this Consultation.

These entities should seek to bring forward a comprehensive proposal for one or more of the challenges posed by 5P medicine in the framework of this consultation, mobilising either their own or third-party capabilities in the necessary fields such as, but not limited to, genomics, the development biomarker-based diagnostic kits, the manufacture of medical simulation systems, or the development of solutions for automated genomic processing. In this sense, each agent applying to this consultation should, beforehand, try to bring together the capabilities of different knowledge-creating and business entities to submit a proposal that details said capabilities in a coherent proposal that addresses the challenges posed.

Several answers may be submitted by the same natural or legal person, either individually or jointly with others.

5. Submission of responses

For the submission of answers, participants shall adhere to the following rules:

1. Participants should submit their answers by filling in the online form accessible at the following URL <https://enquisas.stg.xunta.local/index.php/644967> or the following URL <https://precisaude.sergas.gal/formularioCPM> which follows the model in **ANNEX II** of this call. Please, respect the character limits indicated in **ANNEX II** by focusing your answers on key aspects for the analysis of the approach. In addition, the declaration set out in the model in **ANNEX III**, duly signed by a representative of the entity, must be provided as an attached document.

Regardless of whether or not proposals are submitted using the aforementioned form (model in **ANNEX II**), those entities interested in establishing partnerships to apply to this consultation, and the tenders that may result from it, may fill in and send the form corresponding to model in **ANNEX IV** through the following URL <http://enquisas.stg.xunta.local/index.php/371869> or this URL <https://precisaude.sergas.gal/colaboracionCPM>.

2. Responses will **ONLY** be received through the online form available at the following URL: <https://enquisas.stg.xunta.local/index.php/644967> or this URL <https://precisaude.sergas.gal/formularioCPM>. The Galician Health Service shall not be obliged to consider responses submitted using any other channel.

3. Each entity may submit different proposals responding to different challenges or groupings of challenges using different project acronyms. Likewise, successive versions of the same proposal may be submitted using the same acronym, in which case, each response submitted will replace the previous one. Therefore, the new response must include everything that is still valid from the previous ones.

4. In the event that a response is submitted jointly by a group of people or entities, a single email address must be used for the purposes of identifying the response and communicating with the participants.

5. The Galician Health Service is not obliged to fund or accept the responses submitted in this call.
6. The costs of participating in the consultation shall be borne by the participants.

6. Application of the principles of transparency, equal treatment, and non-discrimination and non-distortion of competition

Participation in the Preliminary Market Consultation, contacts with participants, or exchanges of information shall be governed by the community principles of transparency, equal treatment, and non-discrimination, and shall not have the effect of restricting or limiting competition, nor of conferring advantages or exclusive rights in a subsequent tendering.

Participation in the Preliminary Market Consultation shall not confer any right or preference with regards to the contract award that may subsequently take place within the scope of this call and, as a consequence, does not entail any obligation to fund or accept the responses submitted.

If deemed necessary, the Galician Health Service may contact a specific participant to obtain further information about their response to the consultation, to clarify doubts or to request demonstrations.

Likewise, information days, meetings with participants, and any other communication and dissemination actions deemed appropriate may be held.

Without prejudice to the use of other channels, all updated information on the consultation shall be available on the contracting party's profile of the Galician Health Service.

During the development of the consultation, any information exchanged with participants which guarantees the fulfilment of the principles of transparency, equal treatment, and non-discrimination shall be published. This information may be made public through the profile of the contracting party of the Galician Health Service, as well as through public workshops, information documents, early demand maps, or other means intended for this purpose. In any event, the confidential nature of the information that has been identified as such shall be respected, and this confidential nature may not be extended to all the documentation provided, except in a reasoned manner with regards to some specific aspects.

Once the consultation is over, in addition to the report on the actions carried out, the "Early Demand Map" of the future contract or contracts that are to be called for as a result of the consultation may be published sufficiently in advance in the contracting party's profile of the Galician Health Service for the purpose of informing the market so that it can prepare appropriate offers in advance; therefore, facilitating planning and risk reduction.

The lack of publication of the "Early Demand Map" shall not prevent the Galician Health Service from promoting tenders in the future that totally or partially satisfy the needs that have been the object of prior consultation.

7. Intellectual and Industrial Property Rights Exploitation (IPR)

As this is a public project based on public procurement of innovation, where the aim is to promote R&D activities, the risks and benefits will be shared by the public and private sector, which implies establishing an appropriate regime for the exploitation of the results obtained, which will be defined after the analysis of the results of the Preliminary Market Consultation in a possible subsequent procurement procedure.

Before holding the Preliminary Market Consultation, the Galician Health Service will obtain an unlimited licence to use the developments achieved, including the right to modify them by its own means or by third parties, but not to market or distribute them to third parties. It is also anticipated to include the use of all its own or third parties' licences and industrial and intellectual property rights which are necessary to keep the pilots developed operational if they remain in the possession of the Galician Health Department.

Intellectual and Industrial Property Rights Exploitation (hereinafter IPR) derived from the developments carried out are anticipated to belong to the grantee companies as well as the entities that collaborate with them and, based on their role, may claim a share in them. The bidding conditions may also stipulate that the grantee companies should pay a certain percentage of the turnover or the profits obtained from the commercial exploitation of the results of the tender as royalties to the Galician Health Service.

Based on the applicable state legislation on assistance, it is expected to require that IPRs from the developments should be made accessible to third parties (other companies or agents interested in their use) under market conditions. For the purposes of determining such conditions in future public procurement innovation (PPI) tenders, this consultation includes in **ANNEX II** aspects aimed at seeking the views of market players on how such conditions should be determined at a methodological and numerical level. This is intended to provide legal certainty and certitude to the parties, using criteria that are the result of a comparison of the proposals received in the framework of an open consultation with market agents.

It is also expected to include a call-back provision to ensure that IPRs that cannot be exploited by the grantee company itself or the grantee companies are used on the public interest. This clause will only be invoked if the grantee companies do not exploit the IPRs within a certain period of time (e.g., 5 years).

8. Deadline and updates on the Preliminary Market Consultation

The deadline for the submission of responses will begin the day after the publication of this call in the profile of the contracting party of the Galician Health Service and will end on Monday 31th July at 23:59.

The Galician Health Service may publish updates according to the needs of this call by publishing an amendment to the annexes. Therefore, it may add new requirements or reformulate the published requirements as a result of the evolution of the market consultation process.

All those who have thus far participated in the consultation will be notified of these updates via email, using the address from which the response was sent. They should also be published, at least, in the profile of the contracting party of the Galician Health Service.

The closure of the consultation shall be determined for each published need when the Galician Health Service:

- Has sufficient information on the responses to that need to initiate a possible public procurement process, or
- Considers that the need has not generated sufficient interest in the market to maintain the consultation, or
- Considers that the opportunity to raise the need has passed.

The notice of closure of a requirement may be revoked at any time by informing about it using the same means by which said closure was communicated.

9. Language

Participants shall present their solutions in Spanish or Galician. Communication with participants to answer the questions posed will be in Spanish or Galician.

10. Technical support

The Galician Health Service may take advantage of the advice from other entities that it considers appropriate for the correct execution and resolution of doubts and questions that may arise during the Preliminary Market Consultation.

For the analysis of the different proposals submitted, a Technical Committee may be appointed. It will be made up of personnel from the Galician Health Service and/or other public bodies considered to be of interest. This Committee may seek the opinion of external experts with voice, but without vote in the deliberations.

The name of the advisors/experts or advisory bodies involved in the Preliminary Market Consultation shall be published in the profile of the contracting party of the Galician Health Service prior to their intervention in the process.

11. Results from the Preliminary Market Consultation

The Galician Health Service will study the responses submitted and may use them to define the detailed administrative, functional or technical specifications that may be used in the contracting procedures that may subsequently be called. In any case, neither the proposals received nor this consultation process will be binding for the Galician Health Service or the agents that may participate in future tenders.

12. Protection of personal data and confidentiality

The Galician Health Service shall store the contact details of the participants in the procedure for the sole purpose of establishing a communication channel with the participants during the Preliminary Market Consultation process.

In order to ensure the transparency of the process, the availability of as much information as possible, and the effective exchange of experiences and opinions, participants shall expressly state their agreement regarding the fact that the Galician Health Service shall keep accessible and updated the necessary information, in whole or in part, about the responses, without prejudice to the ones which have been marked as confidential.

In order to do so, participants shall indicate which documentation or technical or commercial information in their response is confidential, and shall not make a generic statement or declare that all information is confidential. This confidentiality protects, in particular, technical or commercial secrets and confidential aspects of the solutions.

The content of the information contained in the form set out in **ANNEX II** may in no case be classified as wholly confidential. In the case of the information linked to the proposed conditions for third party access to the IPRs generated (section 10 of **ANNEX II**), it will be considered confidential by default because of its particular sensitivity. Apart from this exception regarding section 10, **ANNEX II** may not, in general, contain confidential information. Any additional confidential information must be provided as additional documents annexed and indicated as such.

13. Scope of use of collected information

The use of the content of the responses is limited exclusively to their possible inclusion in the administrative, functional or technical specifications of a possible subsequent procurement procedure. In any case, as indicated in the second point of article 115 of the Public Sector Contracts Law:

"The consultations carried out may not result in a subject of the agreement that is so specific and delimited that it only conforms to the technical characteristics of one of those consulted. The result of the

studies and consultations must, where appropriate, be specified in the introduction of generic characteristics, general requirements or abstract formulas that ensure a better satisfaction of public interests. The consultations carried out cannot, in any case, entail advantages with regards to the award of the contract for the companies participating in them”.

14. Capacities and areas of collaboration

ANNEX IV is specifically designed to collect information on the capacities and areas of collaboration of the entities participating in this consultation. Its content may be published at any time during the period of validity of the consultation and after its closure to facilitate the participation in subsequent tenders. The submission of the information in **ANNEX IV** will be carried out independently from the submission of proposals (**ANNEXES II and III**), so each entity may decide whether to submit both annexes (project proposal and willingness to collaborate) or only one of them.

15. Public procurement

Based on the ideas for solutions collected because of this call, the Galician Health Service may define the technical and/or functional specifications, which will serve as a basis for the definition, with the necessary degree of specificity, of the object of procurement of the corresponding subsequent public procurement procedure.

This possible subsequent procedure will be open to all tenders that meet, where appropriate, the conditions of such a procedure, whether or not they have participated in this preliminary market consultation.

16. Queries

From the publication of the resolution approving this call and until the Galician Health Service considers it as closed, those interested in this process may submit their queries by sending an email to the following address Precisaude@sergas.es. Additionally, a frequently asked questions section (FAQs) shall be published on the project website (<https://precisaude.sergas.gal>). Please, check this section before asking any question by email.