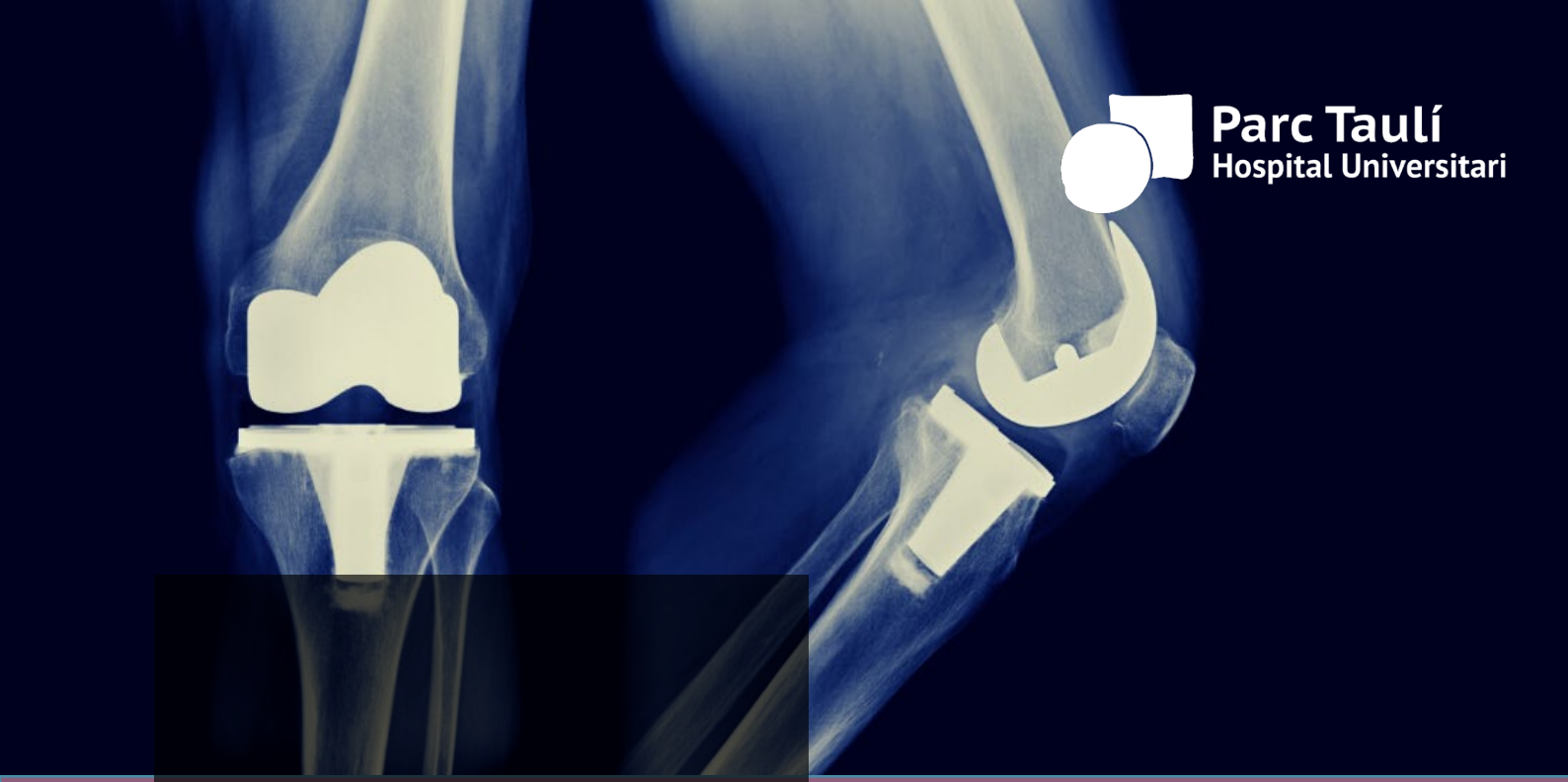

Parc Taulí
Hospital Universitari

Market Readiness Report

Innovation in the joint replacement care pathway to improve patient outcomes

May 2022

Corporació Sanitaria Parc Tauli

Market Readiness Report

Table of contents

Introduction

The current report aims to describe the actions performed by Corporació Sanitaria Parc Tauli (CSPT) during the market consultation stage. CSPT identified, engaged and consulted potential suppliers as well as conducted a market readiness assessment to understand the capacity, capability and appetite of the supply-chain to deliver demanded solutions.

In May 2021, Corporació Sanitaria Parc Tauli (CSPT), in collaboration with the Agency for Health Quality and Assessment of Catalunya (AQuAS), launched a market sounding exercise to seek feedback from all parts of the supply chain on the different options that are, or could be, available given the right market conditions, that will enable CSPT and its partners to enhance patient outcomes through innovative solutions in to improve the joint replacement care pathway.

On November 30th 2021, CSPT and AQuAS remotely delivered the Market Consultation and Procurement Strategy workshop. The aim of this workshop was to further explore needs and options, discuss further barriers and how these might be addressed and, ultimately, to inform the development of a procurement specification and strategy that is capable of delivering innovation in the joint replacement care pathway to improve patient outcomes.

Following the Market Consultation and Procurement Strategy workshop, both CSPT and AQuAS contacted all participants to ask for comments and publicly opened the possibility for any company that was interested to participate in 1-1 interviews (40') to follow up on the additional questions that were raised during the event. As a result, 40' structured interviews were performed with four companies between December 2021 and January 2022.

The pre-defined requirement

The requirements for a new approach to the personalised surgical process for joint replacements were considered and developed by a cross-disciplinary team drawn from across the Catalan Health System.

The unmet need

The unmet need that we have identified can be summarised as a personalised surgical process for joint replacements, incorporating:

- The design and on-demand manufacture of tailor-made joint replacements and patient specific instrumentation

- Pre-operative precision measurement incorporating whole body assessment to optimise the personalised biomechanical performance
- The monitoring and full traceability of both the manufacturing and surgical process

The solution should:

- Deliver demonstrable clinical, cost and resource benefits
- Have the potential to be applied to other areas of elective surgery
- Meet all necessary standards in relation to quality, approvals, ethics and data protection, inter-operability, etc.

Prior Information Notice (PIN) and Market Sounding

In May 2021 CSPT published a Prior Information Notice (PIN) in the Official Journal of the European Union to provide advance notice of this tender and launch a period of market sounding and consultation in advance of the formal tender process.

The aim was to call on all parts of the supply chain together with innovation networks to respond to this call for innovation. In moving this procurement forward, we needed to understand the current state of the art, product and service developments coming on stream, ideas emerging from R&D projects, and opportunities for co-creation with suppliers to help us to deliver a progressive and forward shifting from a 'best fit' scenario to tailor-made joints for each patient.

We were interested in hearing from all parts of the supply-chain on the appetite, capability and capacity of the market to offer solutions that meets our requirements. We were interested in information and innovation from all parts of the supply chain that could:

- Contribute to achieving improvements in one or more aspects of the requirement
- Contribute and provide a new total solution
- Provide information on potential barriers that would need to be overcome to deliver the solution
- Scope for co-creation with suppliers
- Involve incremental improvements or a step change in the short, medium and long term

Interested parties from all parts of the supply chain were invited to express their interest and register for market consultation events by completing a response form, for which the deadline was originally defined for September 3rd but extended to November 30th 2021, when the Market Consultation Workshop took place.

Market Sounding Response

Overall, the market sounding process has:

- made our requirement visible to the market and stimulated a response from the supply chain
- provided information on a number of services, products and technologies, and the contribution that they could make to achieving the required outcomes, some of which were previously unknown or unfamiliar to us
- given us a sense of the barriers to delivery of our requirement that would need to be addressed to deliver a solution

We have been encouraged by the level of interest, the quality of the responses and the range of solutions and ideas that have been suggested and believe that our requirement, although demanding, is achievable.

- 12 considered responses, many of which offer detailed descriptions as to how they would address the requirement.
  - 7 respondents confirmed to be ready to proceed with the designing and on-demand manufacturing of tailor-made join replacement and patient specific instrumentation
  - 10 respondents are specialised in pre-operative measurement through AI and algorithm modelling
  - 6 respondents have experience in the monitoring and full traceability of both the manufacturing and surgical process
- Overall, the supply chain responded positively to the challenge of providing innovative solutions, goods or services that would contribute to delivering the required transformation outcomes during this pilot project.

Among the potential barriers or problems to be overcome, the supply chain defined:

- Compliance with existing medical device regulations
- Medical records from patients are usually sensitive information protected by law. Often the available information in public databases is not complete

enough to develop artificial intelligence-based software tools, and may find difficulties to get access to complete sets of patient information.

- Aligning the manufacture with surgical scheduling. Given the development and engineering time required for custom-made devices, manufacturing times may vary. It is advisable that a date for surgery is not set until the custom component has been confirmed to be complete and ready for shipment.
- Difficulty to predict the price of custom-made solutions according to the type of device.
- Custom-made solutions can be expected to have a higher price than conventional implants.
- Custom-made implants are designed and manufactured without the benefit of mechanical testing or clinical trials. These are supplied sterile and without special instrumentation, unless otherwise indicated.
- The risk of revision of a custom device is yet unknown and, as regular implants, might depend on patient-specific factors, such as anatomy, medical condition and lifestyle (for example, weight and activity level), device materials, procedure and surgical process.

Lastly, the supply chain stated that CSPT could support to the delivery of the solution by:

- Continuous communication and collaboration through meetings with health care professionals to fulfil the technical side
- Sharing of datasets for complex segmentation, as developing AI-based systems requires large amounts of annotated data
- Having the recognition that the pilot-project can lead companies to scale solution's business, potentially leading to business partnerships.
- Provide an accurate information on patient-specific factors, device materials, procedure and surgical process
- Data management

Market Consultation and Procurement Strategy workshop

On November 30th 2021, the market consultation and procurement strategy workshop took place from 10:00h to 12:30h CET. The agenda of the event was as follows:

Indicative programme - November 30th

10.00	Welcome and opening comments	Anna Ullastres i Coll – Scientific Management Board Advisor, Parc Taulí Research and Innovation Institute
10.10	Background and market response	Ferran Fillat – Surgeon and 3D Lab Director, CSPT
10.30	Questions and discussion	Anna Aguilar – European Project Manager, Parc Taulí Research and Innovation Institute
11.00	Break	
11.15	Co-designing the procurement strategy	Facilitators / Groups
12.00	Conclusion session	Facilitators
12.15	Procurement timeline and next steps	Ion Arrizabalaga – Innovation Project Manager, AQuAS
12.30	Conclusions and closing comments	Ramon Maspons – Chief Innovation Officer at AQuAS

The objectives of the workshop were:

- To inform participants about the development of a procurement specification and strategy

- To explore further needs
- To discuss further barriers and how these barriers might be addressed

A total of 36 people from 23 different companies were registered for the event. These companies were specialised in different areas: 30% of them were focused on designing and on-demand manufacturing of tailor-made joint replacements and patient specific instrumentation, 40% were focused on pre-operative precision measurement, 15% were focused on the monitoring and full traceability of both the manufacturing and surgical processes and 15% are focused on all three areas mentioned above.

In the "Questions and discussion" the attendees were asked different questions, and for example, 93% of the participants answered that it was the first time they had participated in an innovation procurement procedure. 41,67% of the participants have worked in designing and on-demand manufacturing of tailor-made joint replacements and patient specific instrumentation, 33,33% have worked in pre-operative precision measurement, 25% have worked in monitoring and full traceability of both the manufacturing and surgical processes and 16,67% have experience and have worked in all three areas.

We also asked them if they consider it feasible to develop an innovative solution/service that meets CSPT's demands and if the solution/service can be adopted in the next 12 months given the right market conditions. 46,67% of the participants answered "yes, it is feasible as long as the right market conditions are taken into account", 53,33% answered "not sure, too many aspects need to be taken into account" and 0% answered "no, impossible to develop a solution that meets the demands published by CSPT".

In the "Co-designing the procurement strategy" session, people were divided among 4 rooms. 6 open questions were prepared to obtain more information from companies. As a result, here is a summary of the answers:

1. Do you consider that it is a challenge to develop an integrated innovative service that is compliant with existing medical device regulation?

In this question, the 4 rooms concluded that it is a considerable barrier, but can be solved if proper actions are performed by both, supply chain and the hospital. For example, obtaining the CE mark is a problem because it is not an easy task and regulatory aspects were considered long processes. One measure would be to clarify the regulation and make it more accessible and transparent for bidders and to have specialised regulatory teams. The companies considered that the involvement of the hospital is very important. Continuous communication between the hospital team and the company team is crucial to address these issues. They also think that the participation of governments in the improvement or adaptation of legal conditions is important.

One action that was highlighted to overcome this barrier is the definition of the specific uses that the hospital wishes to address.

2. Do you consider getting access to complete sets of patient's information is a challenge? (e.g, patient's magnetic resonance)

In this question, most of the participants concluded that it is a problem that can be solved. There are hospitals that provide companies with anonymized resonance and diagnostic tests that allow companies to proceed with the design and manufacture of prostheses and guides. Therefore, they attach great importance to communication between companies and the hospital. They consider that it is important for clinicians and health providers to see at first hand the benefits of implementing a certain technology or innovation. If they are not convinced, they will not give access to the patient's information. They commented that a protocol could be made to share clinical records with the industry.

3. Do you consider obtaining a lower price for custom-made solutions according to the type of device is a challenge?

In this question, most of the companies consider that the cost of custom prostheses is higher than conventional prostheses, but they consider that the price may be reasonable taking into account the savings that the hospital can obtain by savings related to the sterilisation of prostheses, surgery time, cases of revisions of non-ideal prices implanted in the patient or simply with the benefits for the patient. There should be an economic valuation that supports the savings produced by the innovation, but for this they need data.

They also state that this change of model will mean savings for companies, since today many parts are produced that finally end up not being used, resulting in losses for the company itself.

4. Do you foresee additional barriers that need to be taken into consideration by CSPT for the supply chain to be able to provide an integrated solution?

In their response, companies commented again that they see barriers in legal and regulatory issues, in the price of the solution, in logistics and in data protection. They also commented on the need to generate evidence regarding the PROM's (patient reported outcomes measures) function, etc...in order to reach the market or future adoption of the innovation.

Finally, they commented that integration in the hospitals depends on the involvement of different departments. Sometimes it is difficult to integrate a new technological solution.

5. Would you consider partnering to provide an integrated solution that meets defined requirements in the tender?

50% answered that they would consider partnering to provide an integrated solution because creating a consortium will increase service capacity and quality and the other 50% of participants answered that they have not decided yet.

6. What additional actions can be conducted by CSPT to enable and facilitate the delivery of an innovative solution?

In this final question, participants answered that an additional action to enable and facilitate the delivery of an innovative solution would be establishing win-win relationships with the industry. They consider the innovative solutions to be an advantage in tenders along with creating international partnerships and communication for collaborative education.

After this session, the participants all returned to the main room where the procurement timeline and next steps were explained and finally the event closed with the conclusions and closing comments.

1:1 Bilateral Meetings

After the Market Consultation and Procurement Strategy workshop that took place remotely in November 30th, 2021, both CSPT and AQuAS opened a period of interviews during the months of December 2021 and January 2022. Interested supply chain representatives were invited to participate in 1-1 interviews (40') to follow up on the questions and issues raised in the workshop plus additional questions that could arise out of discussion.

As a result, four remote bilateral interviews were carried out.

- Interviewee 1:
  Date: December 14th 2021 - 9am CET
  Position: Director of Innovation and business development / Research and QA&RA Director)

- Interviewee 2:
  Date: December 15th 2021 - 9am CET
  Position: Manager / Senior Sales Executive

- Interviewee 3:
  Date: December 15th 2021 - 12pm CET
  Position: CEO / Innovation Specialist

❖ Interviewee 4:

Date: December 22nd 2021 10am CET

Position: Professor and Researcher

The interviews were structured in accordance with the points discussed in both Market Sounding Prospectus and the Market Consultation Workshop:

1. Welcome and introduction by CSPT and AQuAS
2. Introduction and description of interviewed company
3. Describe company's expertise (if applicable) in the following areas:
    a. Designing and on-demand manufacturing of tailor-made join replacements and patient specific instrumentation
    b. Pre-operative precision measurement
    c. The monitoring and full traceability of both the manufacturing and surgical process
4. Description of previous experiences working with Healthcare organisations
5. What are the main barriers that need to be taken into consideration by CSPT for the supply chain to be able to provide an integrated solution?
6. What mitigation actions would need to be performed?
7. How could CSPT support delivery of a solution and help to create the right market conditions for innovation in this area?
8. Do you consider any question or information that would be necessary for you to be included in the Market Consultation Report and/or the Call for Tender?
9. Further questions/comments by the Company to be included in the Market Consultation Report.

Once the introductions were performed, the interviewees described the field of expertise where they could provide solutions:

a. Designing and on-demand manufacturing of tailor-made join replacements and patient specific instrumentation

   This could be supplied/performed by: *Interviewee 1, Interviewee 3 and Interviewee 4*

b. Pre-operative precision measurement

   This could be supplied/performed by: *Interviewee 3 and Interviewee 4*

c. The monitoring and full traceability of both the manufacturing and surgical process

This could be supplied/performed by: *Interviewee 1*

Among the considerations discussed, interviewees identified the need for software that integrates/communicates all the areas/processes. This software will work by connecting the different stakeholders along the whole service provision, allowing processes digitalization and the management of activities along the different parts of the service provision.

Among the potential barriers or problems to overcome, interviewees highlighted the following aspects:

- Compliance with existing medical device regulations.
- Medical records from patients are usually sensitive information protected by law. Often the available information in public databases is not complete enough to develop artificial intelligence-based software tools, and companies may find difficulties to get access to complete sets of patient information.
- Given the development and engineering time required for custom-made devices, it would be difficult to align the manufacture with surgical scheduling. Manufacturing time may vary depending on the case.

Among the different actions that CSPT could implement to support the delivery of required innovative solution, the interviewees highlighted that:

- Continuous communications and collaboration with health care professionals will be needed to fulfil the technical side.
- Having the recognition that the pilot-project can lead companies to scale solution's business, potentially leading to business partnerships.
- Provide accurate information on patient-specific factors, device materials, procedure and surgical process.

To conclude, it is important to underline that none of the companies interviewed could cover all the areas defined by CSPT, which might lead to a requirement for the economic operators to temporarily collaborate with each other to offer an integrated solution that can respond to the defined challenge.

Conclusions

CSPT positively engaged with different parts of the supply chain together with innovation networks to respond to CSPT's call for innovation. To that end, the Market Readiness Assessment covers four major activities:

- Prior Information Notice (PIN) launching on May 2021
- Market Sounding from May 2021 until September 2021
- Market Consultation Workshop on November 30th 2021
- Structured bilateral meetings with interested supply chain representatives between December 2021 and January 2022

As a result, CSPT and AQuAS made the requirement visible to the market and better understood the current state of the art, as it provided information on a number of services, products and technologies, and the contribution that they could make to achieving the required outcomes, some of which were previously unknown or unfamiliar to us.

In the same way, specialised parts of the supply-chain confirmed their appetite, capability and capacity to offer solutions that meets our requirements. In the same way, we gathered information of current innovations from related parts of the supply chain that could contribute to achieving improvements in several aspects of the requirement.

Overall, the supply chain offered detailed descriptions as to how they would address the requirement in the following fields:

- pre-operative measurement through AI and algorithm modelling
- designing and on-demand manufacturing of tailor-made join replacement and patient specific instrumentation
- monitoring and full traceability of both the manufacturing and surgical process.

In the same way, the supply chain provided relevant input on potential barriers that would need to be addressed to deliver the solution, such as compliance with medical device regulation and access to medical records from patients. CSPT took a careful note of defined barriers as well as the actions that need to be adopted by different parts for these barriers to be overcome.

All gathered feedback has been vital and will help us to deliver a progressive and forward shifting from a 'best fit' scenario to tailor-made joints for each patient.

Follow up

With the Market feedback, both CSPT and AQuAS are collaboratively working to define the pro-innovation tendering strategy:

- Design of the tendering process in a way that supports and enables innovative solutions to be presented, given due consideration and valued
- Gives innovative solutions and new suppliers a chance to compete on an equal playing field
- Reflect the impact of the tendering process on innovation and innovators
- Adapted to the procurement question and the local framework conditions

Once the pro-innovation tendering strategy is completed, a call for tender will be published in both the Contracting Platform of the Government of Catalunya as well as the Official Journal of European Union (OJEU).

General information:

gaynor.whyles@jeraconsulting.com

www.ecoquip.eu

Specific information on the document:

ion.arrizabalaga@gencat.cat

aaguilara@tauli.cat

www.tauli.cat/en/institut

About EcoQUIP+

EcoQUIP Plus (www.ecoquip.eu) is a collaborative innovation procurement project in the healthcare sector. EcoQUIP Plus aims to demonstrate how pro-innovation procurement methods can improve the efficiency, quality and sustainability of healthcare and to increase the take up of much needed innovative solutions though collaborative actions.

If you would like to find out more about EcoQUIP+, please visit

www.ecoquip.eu @EcoQuipPlus

Co-funded by the COSME programme of the European Union