



FAQ DOCUMENT PRELIMINARY MARKET CONSULTATION

REF. CPM01/2021

Project "Minimally Invasive Robotic Surgery Systems (TREMIRS)", of the Jesús Usón Minimally Invasive Surgery Centre Foundation.

FREQUENTLY ASKED QUESTIONS

- What does the Consultation seek to achieve?

This Preliminary Market Consultation (PMC) seeks to attract innovative proposals aimed at responding to the challenges posed by the use of technologies that exceed the performance of those currently available on the market.

These proposals will assess market capacities and define functional and technical specifications involving readily achievable innovation feasible through a possible Public Procurement of Innovation (PPI) or other public procurement instruments.

The purpose of this type of procedure is not to receive bids per se but to receive the assessment of critical aspects of the future contract for developing solutions to help solve the unmet needs of the Extremadura and Spanish Health System in minimally invasive surgery.

- How do participants who do not have a registered office in Spain participate? Would they have problems in bidding for future PPI tenders?

The call for consultation is open to any natural or legal person who may submit their response in English or Spanish.

For future tenders, the capacity of non-Spanish entrepreneurs who are nationals of the Member States of the European Union nor signatory States of the Agreement on the European Economic Area to contract will be accredited by their registration in the appropriate Registers in accordance with the legislation of the State where they are established, or by the presentation of a sworn statement or a certificate, under the terms established by regulation, in accordance with the applicable Community provisions and with the list of Registers included in Annex I of the General Regulations of the Public Administration Contracts Law.

Natural or legal persons from States not belonging to the European Union or from non-signatory States of the Agreement on the European Economic Area shall accredit their capacity to contract with a report issued by the Permanent Diplomatic Mission or Consular Office of Spain of the place where the company is registered, stating, after accreditation by the company, that they are registered in the local professional, commercial or similar register or, failing this, that they habitually operate in local traffic in the activities covered by the contract.

It must also include a reciprocity report (drawn up by the corresponding Spanish Economic and Commercial Office abroad), except for contracts subject to harmonised regulations, in which case it will be replaced by a report from the Permanent Diplomatic Mission or the General Secretariat for Foreign Trade of the Ministry of Economy on the



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status of signatory State of the World Trade Organisation's Agreement on Government Procurement.

They must accredit their economic, financial and technical or professional solvency that may be required in the same way as required of Spanish entrepreneurs, notwithstanding the provisions on registration in the corresponding Registers.

- What are the deadlines for implementing the PMC?

The deadline for implementation is 27 May 2021 at 2 PM (Spanish time).

- Can additional documentation be included in the response to the PMC?

Proposals may come with any additional documentation deemed appropriate. This supporting documentation may be designated as confidential, clearly specifying in such documents the aspects affected by such a declaration of confidentiality. However, the contents of Annexes 1 and 2 shall never be classified as confidential.

- Is it possible to submit a proposal in partnership with another entity?

Proposals in response to the consultation can be submitted both individually and jointly with other entities.

- Is it necessary to participate in both challenges?

No. Participants may respond to the challenges they deem appropriate or both.

- Can foundations or public institutions (hospitals and universities) participate either individually or in joint ventures?

Yes, but taking into account the following considerations:

Natural or legal persons, Spanish or foreign, individually or in a Joint Venture or Temporary Business Association (UTE) with full capacity to act and are not subject to the prohibitions for contracting provided in Article 71 of the LCSP (Public Procurement Law) may apply for this tender.

Legal persons may be awarded contracts only for services that fall within the aims, purpose, or field of activity specific to them according to their articles of association or founding rules.



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- Is a specific TRL established for the solutions to be developed through the PPI project?

No specific TRL is established. This will be an aspect to be examined in this PMC. However, solutions with a maturity level of at least TRL 6-7 (Technology validated/demonstrated in a relevant environment) are expected due to the project.

- Would the budget be for the complete solution or just as needed to develop the innovation?

The budget should include the complete solution.

- Could you elaborate on your expectations for the public-private partnership during the project's implementation phase from a legal viewpoint?

As a public-private partnership, the intention is to establish a legal link between a private entity and a public sector entity, through a long-term contract specifying the risks to be assumed by each party for the provision of a service of public interest, including the conditions and principles that will govern this link.

In this case, the public interest is given by a research service for developing an innovative technology related to robotics applied to surgery, a robotic platform for laparoscopic surgery that will facilitate new surgical approaches, improvements in surgeon ergonomics, advances in vision systems for the entire surgical team and the availability of new portable training tools. It also aims to develop a teleoperated robotic platform for reconstructive microsurgery, consisting of robotic micro-instruments with high manoeuvrability and precision. It is intended for soft tissue manipulation to perform microsurgical techniques such as anastomosis, suturing and ligation on small anatomical structures such as blood vessels, nerves and lymphatic ducts.

- Does this procedure include a briefing meeting with each applicant for technical discussion?

Yes, before the development of the report on the conclusions of the PMC, meetings will be held with the companies to discover more about the proposals put forward in the PMC.

- Is it preferable to respond to the preliminary consultation individually or as a consortium?

Both options are entirely acceptable and not binding on subsequent possible participation in the PPI tendering process.

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- Could you elaborate a little more on the augmented reality needs of the surgical team? Why are current solutions not adequate?

The aim of the consultation on the use of augmented reality technology as a surgical assisting tool is to discover whether the participants in this PMC consider it a necessary assisting tool to be included in the surgical robotics platform in laparoscopic surgery and whether it can be improved.

- No mention has been made of the need to provide robots with greater cognitive and decision-making capabilities (even if limited). Is this considered a major limitation in TREMIRS?

All these improvements in terms of surgical assistance tools can be stated in the section "Other needs/issues to be highlighted".

- Can we count on the active participation of the Jesús Usón Minimally Invasive Surgery Centre (CCMIJU) in implementing the project? Can you describe it? Will this participation be budgeted for as part of the procurement process, or will the CCMIJU have a separate budget for these activities?

The CCMIJU will manage the processing of the PPI procedure to ensure its correct execution, besides monitoring it in all its phases.

If necessary for the participating company, the services of the CCMIJU as CRO could be contracted for developing the project. This participation is not initially included in the PPI budgets, so it will be up to the participating institution to consider its inclusion for developing its innovative solution.

- Who would own the rights to possible new patents?

In principle, unless the conclusions of the PMC indicate otherwise, all exploitation rights will remain with the company or entity awarded the contract. Only the possibility of licences for research use in favour of the CCMIJU Foundation or related public administrations has been considered.

- Would there be a place for artificial intelligence and virtual and augmented reality in this project?

Yes. The institution participating in the PMC can detail these aspects as they see fit in the "Other needs/issues to highlight" section.



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- Can institutions apply for both robotics and microsurgery challenges simultaneously?
Yes. Participants can submit answers to queries for both challenges. Similarly, for the PMC, the institutions can apply for the tender documents they deem appropriate.
- How can we as participants interact to see if the technologies we provide individually can be complementary to act in a consortium?
Contact details have been shared among those attending the PMC presentation days to encourage these collaborations.
- Is tendering expected to be through "Innovation Partnership", or will it be an open tender?
In principle, unless the conclusions of the PMC state otherwise, an open tender will be chosen.
- Would this project be done on a pre-commercial purchase basis or as a purchase of innovative technology?
The project will be developed within the framework of the Public Procurement of Innovative Technology modality.
- What are the industrial property rights implications of this project? What will happen to the prototype generated?
In principle, unless the conclusions of the PMC indicate otherwise, all exploitation rights will remain with the company or entity awarded the contract. Only the possibility of licences for research use in favour of the CCMIJU Foundation or related public administrations have been considered.
- There is talk of laparoscopic robotic surgery for soft tissue applications. Can solutions for minimally invasive operations in traumatology and neurosurgery be envisaged?
The solutions sought in this project focus on the field of laparoscopic surgery and microsurgery. However, their application in traumatology and neurosurgery adds value to the proposed solutions to the corresponding challenges.
- Are you going to take any action to encourage the formation of consortia? For example, Will the list of attendees at this PMC presentation day be made public?
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- Can the cost of the microsurgery project include the cost of a unique machine to produce micrometric heads?

The cost estimate should include everything considered appropriate to achieve the innovative solution to the challenge.

- Could we have the presentation we have seen sent by email?

The presentations, both in English and Spanish, are published on the project website (www.tremirs.com).

- Should a company lead it, or can it be a research centre?

In principle, either a company or a research centre could lead the implementation of the project.

- Will more points be given if the final product is already approved for commercial sale?

The evaluation/scoring criteria will be detailed in the PPI specifications.

- What is the format for submitting applications and supporting documentation?

The format shall be Word or PDF.

- Once the application has been submitted, what are the procedures?

At the end of the consultation period, a conclusions report will be drawn up containing the actions carried out, a summary of the proposals submitted by each operator, the clarifications requested, and those received if any. The principle of confidentiality will be respected throughout the PMC procedure, as indicated in the call document and the participants' proposals.

In addition, if deemed appropriate, the drafting and processing of the tender can begin based on the information gathered as a result of the consultation. These procedures will be open to all possible proposals that meet the conditions laid down, whether they have been linked to the preliminary market consultation.

- How should proposals be submitted?

Proposals should be sent by email to the following address concursos@ccmijesususon.com. The following subject line should be included in the mail: "PMC - TREMIRS + Title of the proposal".