

PRELIMINARY MARKET CONSULTATION. CALL DOCUMENT

REF: CPM01/2021

Call regulation of project “Minimally Invasive Robotic Surgery Systems (TREMIRS)”, of the Jesús Usón Minimally Invasive Surgery Center Foundation.

According to article 115 of Spanish Law 9/2011, November 8th, transposing into Spanish law the European Parliament and of the Council Directives 2014/23/EU and 2014/24/EU of 26th February 2014 (LCSP), the Spanish contracting authorities may carry out market studies and make enquiries to economic operators in order to properly prepare public procurement tenders, informing to the aforementioned economic operators about their plans and the requirements they will require to attend the procedure. Consequently, the Managing Director of Jesús Usón Minimally Invasive Surgery Center Foundation (CCMIJU), as contracting authority of said Foundation in accordance with article 31.7.b) of its current Statutes, convenes the following:

PRELIMINARY MARKET CONSULTATION

1. INFORMATION OF THE CONTRACTING AUTHORITY AND THE PRELIMINARY MARKET CONSULTATION

<p>CONTRACTING AUTHORITY</p>	<p>Managing Director of Jesús Usón Minimally Invasive Surgery Center Foundation (CCMIJU)</p>
<p>PRELIMINARY MARKET CONSULTATION PURPOSE</p>	<p>The purpose of this preliminary market consultation is to identify and gather innovative solutions in surgical robotics, through the Innovative Public Procurement procedure for the "Robotic platform for laparoscopic surgery" and the "Robotic platform for microsurgery".</p> <p>All this within the framework of the project “Minimally Invasive Robotic Surgery Systems (TREMIRS)”, co-financed with European Regional Development Fund (ERDF), through the Spanish ERDF Pluri-Regional Operative Program (POPE) 2014-2020, and the formalization of the Agreement between the Ministry of Science and Innovation (MCIN) and the CCMIJU, published on December 28, 2020, and co-financed by the Ministry of Economy, Science and Digital Agenda of the Regional Government of Extremadura.</p>

2. BACKGROUND (PROJECT SUMMARY)

The main objective of the TREMIRS project “Minimally Invasive Robotic Surgery Systems” is to solve the needs of the Extremadura region and Spanish Health System in the field of minimally invasive surgery through the development of innovative solutions in surgical robotics that improve existing systems in the areas of laparoscopic surgery and microsurgery. This project seeks to improve the service provided to the patient, improve the surgeon’s ergonomics and offer greater benefits to the surgical team, with the consequent increase in the quality of patient care.

During the three-year duration of the project, a robotic platform is expected to develop for laparoscopic surgery that will enable new surgical approaches, improvements in surgeon’s ergonomics, advances in vision systems for the entire surgical team and the availability of new portable training tools.



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In the field of microsurgery, TREMIRS will provide a teleoperated robotic platform for reconstructive microsurgery, consisting of robotic micro instruments with high maneuverability and precision. It will be used for soft tissue manipulation to perform microsurgical techniques such as anastomosis, suturing and ligation of small anatomical structures including blood vessels, nerves and lymphatic ducts.

This TREMIRS project is framed within the Line of Promotion of Innovation from Demand for Public Procurement of Innovation (FID-CPI Line) of the Spanish Ministry of Science and Innovation with reference CPI-2019-33-1-TRE-14, according to the final resolution proposal of April 8, 2020 signed by the Deputy Assistant Director General for Promotion of Innovation, being co-financed with European funds, through the Spanish ERDF Pluri-Regional Operative Program (POPE) 2014-2020, “A way of making Europe”, and by the Ministry of Economy, Science and Digital Agenda of the Regional Government of Extremadura.

Taking the above into account, the Jesús Usón Minimally Invasive Surgery Center Foundation (CCMIJU) is publishing this call for Preliminary Market Consultation (hereinafter PMC), thus informing the technological operators about the challenges and needs to be solved.

3. PURPOSE OF PMC

The purpose of this PMC is to gather the necessary information for the innovative public procurement with regard to the “Robotic Platform for Laparoscopic Surgery” (Challenge 1) and the “Robotic Platform for Microsurgery” (Challenge 2), and to inform technology operators about the procurement plans and requirements.

This consultation, in which both individual and legal bodies are allowed to participate, enables the presentation of innovative solutions aimed at responding to the challenges posed. To this end, technologies that exceed the capabilities of those currently available in the market will be used, defining their innovative technical and functional specifications, and this can be achieved through public procurement.

The CCMIJU is expected to gather information from the market on the following Challenges for its correct execution:

CHALLENGE 1. ROBOTIC PLATFORM FOR LAPAROSCOPIC SURGERY.

General objectives:

The main objective of this challenge is to provide a robotic platform for laparoscopic surgery that improves existing systems in the market and optimizes conditions during surgery for the patient, the surgeon, the surgical team and medical professionals in training in robotic surgery. To this effect, and as aspects of improvement and innovation, the main limitations of current robotic systems for laparoscopic surgery are expected to be addressed, such as their application in new surgical approaches, limited ergonomic conditions for the surgeon, limited access to 3D vision for the entire surgical team and recording of the 3D image of the surgical procedure for later reproduction, and availability of training tools compatible with 3D vision technologies, portable devices and online services.

Specific objectives:

The above general objectives of the challenge entail the development of a series of specific objectives:

- To offer greater precision, maneuverability and quality in minimally invasive surgical procedures.
- To apply robotic surgery to new procedures and surgical approaches.
- To improve and personalise the ergonomic conditions of surgeons during the performance of robotic procedures in minimally invasive surgery, with the consequent reduction in the onset of possible musculoskeletal disorders and their effects on the quality of the surgeon's surgical performance and the possible sick leave that may result.
- To provide new surgical assistance tools to the entire surgical team, such as the use of 3D imaging, and virtual, augmented and mixed reality techniques.
- To offer new portable tools for distance training in robotic laparoscopic surgery, as well as improved training material, such as the reproduction of 3D videos of actual robotic laparoscopic procedures.

CHALLENGE 2. ROBOTIC PLATFORM FOR MICROSURGERY

General objectives:

The main objective of this challenge is the development of a teleoperated robotic platform to perform open microsurgery procedures with articulated and interchangeable microinstruments. The platform will consist of a set of robotic microinstruments with high maneuverability and precision, operated in an intuitive way similar to that of conventional microsurgery. These microinstruments will allow the manipulation of small soft tissues to perform microsurgical procedures such as anastomosis, suturing and ligation on small anatomical structures including blood vessels, nerves and lymphatic ducts. The system will be compatible with most optical microsurgical microscopes.

Specific objectives:

The above general objectives of the challenge entail the development of a series of specific objectives:

- Development of initial studies for the definition of clinical and technical specifications of robotic microsurgical instruments.
- Design and implementation of a set of multi-articulated robotic microinstruments with the necessary features to perform basic microsurgical procedures, mainly for vascular and lymphatic surgery.
- Design and implementation of an intuitive control system for the robotic microinstruments. These controls will allow microsurgeons to work in an ergonomically appropriate position similar to that during conventional microsurgery.
- Ability to reduce surgeon's physiological tremors during the handling of the surgical instruments and the scaling of the surgical movements.
- Enable to perform vascular and lymphatic microsurgical procedures with precision and safety. During the development of the project the safety and feasibility of other microsurgical procedures such as epineural and perineural neuroanastomosis, nerve grafts, vascularized lymph node transfer and vascular and lymphatic anastomosis, among other procedures of interest, will also be evaluated.

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- Validation of the teleoperated platform for microsurgery in the performance of basic microsurgical procedures.

4. REGULATIONS

All the European Regulation regarding the application of ERDF Funds, especially HFP/1979/2016 Order, of 29th December, enacting the rules regarding the eligible costs of the operational programmes of the European Regional Development for the 2014-2020 period, or the regulation that replaces it, the Spanish current national regulations in relation to grants, administrative procedure and Legal Regime of the Public Sector, as well as the other regulations included in the Agreement published 28th December, 2020 between the Ministry of Science and Innovation (MCIN) and the CCMIJU.

5. PARTICIPANTS

Consultation is open and is aimed at individuals or legal bodies, public or private, who may provide market information to contracting authority, such as experts or independent authorities, professional associations or, due to their knowledge, manufacturers, marketing companies or partners.

If each individual or legal body, either individually or jointly, presents different proposals, all of them will be admitted, but every proposal shall completely replace the previous one. Therefore, the new proposal must include everything that is considered to be still valid from the previous ones.

Due the informative nature of the proposals presented in this preliminary market consultation, its presentation will not prevent the participation in the subsequent public procurement process.

6. PROCEDURE

6.1.- DEADLINE AND UPDATES

Period for submitting proposals will be from the day following the publication of this call on the Public Procurement Platform until Wednesday, May 12th, 2021 at 2:00 p.m. (CET).

This period may be extended if it is necessary, which will be informed through the Public Sector Procurement Platform.

The Challenges or issues raised in this call may be update by CCMIJU. Therefore, new issues may be added or those already published may be reformulated, as a consequence of the evolution of the CPM itself.

Likewise, information sessions, meetings and any other communication and dissemination actions may be held.



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6.2.- PRESENTATION OF PROPOSALS

Participants must formulate their proposals using Annex 1 (corresponding to Challenge 1) and/or Annex 2 (corresponding to Challenge 2) of this call, which may be completed in part or in full to the best of the participant's knowledge. Proposals must be submitted in an electronically signed pdf format and may be accompanied by any additional documentation deemed appropriate.

Proposals shall be sent to the e-mail address concursos@ccmijesususon.com, indicating in the subject "PMC - TREMIRS + the title of the proposal (which may be an acronym or the name of the participating natural or legal person)". In this e-mail they shall expressly state their decision to participate in this preliminary consultation.

The title of the proposal indicated in the subject of the email will be used in all communications with the CCMIJU during the processing of the PMC.

The costs derived from the participation in the call will be borne by the participants.

Participation in the PMC does not grant any right or preference with respect to the awarding of any contracts that may subsequently take place within the scope of the object of this call and, as a consequence, the CCMIJU is not obliged to finance or accept the proposals submitted in this call.

The CCMIJU, on the basis of the responses received, may request a clarification from the participants.

6.3.- PRINCIPLES OF TRANSPARENCY, EQUAL AND NON-DISCRIMINATION TREATMENT AND DISTORTION OF COMPETITION

The development of this consultation will be carried out with full respect for the principles of transparency, equal treatment and non-discrimination and non-distortion of competition, so that no restriction or limitation of competition may occur, nor may any advantage or preference be granted to its participants with respect to the award of contracts that may subsequently be concluded within the scope of the object of this consultation. In this way, the submission of the questionnaire shall not prevent the submission of bids at the time of the tender subsequently drawn up.

At all times, the CCMIJU will guarantee the confidentiality of the innovative proposals and will take the appropriate measures to guarantee the maintenance of the aforementioned principles, both in the development of this consultation and in the subsequent contracting procedure.

During the period of presentation of the preliminary consultations, a document of frequently asked questions (FAQs) will be drawn up and published, where the questions and answers considered to be frequent and recurrent within the field will be collected in an orderly manner, with the aim of resolving certain basic questions in the most operative way possible and guaranteeing the information of all participants, respecting the principle of equal treatment and non-discrimination.

This form shall be published on CCMIJU's web: <https://www.ccmijesususon.com/en/preliminary-market-consultation-for-the-tremirs-project-consulta/> and on the Spanish Public Procurement Platform.

6.4.- CONFIDENTIALITY AND PERSONAL DATA PROTECTION

During preliminary consultation process, participants' answers shall not be disclosed to others. The final result of consultation shall be published at the time of its completion.

To ensure the transparency of the process and the effective exchange of information, participants shall expressly state their agreement in order to CCMIJU keep the necessary information, in whole or in part, accessible and updated on their proposals, without prejudice to that which has been identified as confidential.

In this sense, information include in the forms of Annexes 1 and 2 may in no case be classified as confidential and only the documents attached to this form may be designated as such, clearly specifying parts of the documents that are affected by confidentiality.

Personal data that may be included in the proposals, shall be processed in a file for which the CCMIJU is responsible, in order to facilitate communication with the participants during the PMC process, as well as publishing the necessary information in accordance with article 115 of the LCSP. In this sense, the appropriate conclusions may be published. The legitimizing basis for data processing and / or publication is the application of pre-contractual measures and compliance according to the article 6.1.b) and c) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

Participants shall be able to exercise their rights of access, rectification, opposition and deletion, as well as the other rights recognized in the RGPD, sending a mail to concursos@ccmijesususon.com.

6.5.- RESULTS OF PRELIMINARY MARKET CONSULTATION

At the end of the consultation period, actions carried out, the proposals presented by each operator, clarifications requested and those received, if applicable, will be included in a Conclusion Report.

From the Conclusion Report, and focusing on the solutions included in the proposals, CCMIJU will be able to define the characteristics and technical and functional requirements that will be used for subsequent Innovative Public Procurement procedure.

7.- LANGUAGE

Documents of PMC procedure shall be able in Spanish or English. If there is any conflict between Spanish version and English version, Spanish version will prevail.

Participants shall submit their solutions in Spanish or English. Communication with the participants to answer the questions posed may be done in Spanish or English by CCMIJU.

8.- INTELLECTUAL PROPERTY

The data included in the proposals may only be used to carry out the technical and functional specifications that shall be included in the subsequent Innovative Public Procurement.



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9.- TECHNICAL SUPPORT

CCMIJU may take into account the advice provided by other entities or experts when it is needed to the correct execution and conclusion of the CPM. Such entities or experts shall sign a confidentiality agreement about proposals submitted data before they may access to them.

In Cáceres, 26th March 2020,

D. Luis Casas Luengo
Managing Director
Jesús Usón Minimally Invasive Surgery Centre



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ANNEX 1.- CHALLENGE 1 FORM. (ROBOTIC PLATFORM FOR LAPAROSCOPIC SURGERY)

1.- PARTICIPANT AND PROPOSAL INFORMATION

Entity or business name*:			
Legal person*:	<input type="checkbox"/>		
Entity*:	<input type="checkbox"/>		
Joint proposal*:	<input type="checkbox"/> Yes		<input type="checkbox"/> No
Economic field or sector (CNAE) *:			
Entity's main activities:			
Number of employees:			
Entity total turnover in recent years	2020	2019	2018
Name and surname of interlocutor (or representative in case of joint proposal)*:			
Post:			
Phone number*:			
E-mail*:			
PROPOSAL INFORMATION			
Proposal name*:			
Do you intend to apply for future tenders related to the challenge(s) to which you are applying?*	<input type="checkbox"/> Yes <input type="checkbox"/> No		

* required fields

SECTION 1: ROBOTIC PLATFORM FOR LAPAROSCOPIC SURGERY.

This section aims to identify the general aspects that should define the robotic platform for laparoscopic surgery to be developed in the TREMIRS project.

For each item, **please, complete or rate (from 1 -not important- to 5 -essential-)** the degree of necessity for each of the criteria indicated.

1.1. General aspects of the Platform

	Evaluation
The platform should be teleoperated (<i>Please, rate from 1 to 5</i>)	
The platform should be portable (allowing it to be easily moved within the operating room and between operating rooms) (<i>Please, rate from 1 to 5</i>)	
The way in which the platform should be transported (<i>Please, complete</i>)	
Compatibility with the surgical environment (<i>Please, rate from 1 to 5</i>)	
The platform must be modular (with independent arms) (<i>Please, rate from 1 to 5</i>)	
Minimum number of arms for the platform (<i>Please, complete</i>)	
Maximum number of arms allowed by the platform (<i>Please, complete</i>)	
Maximum platform size (mm) (Height x Width x Depth) (<i>Please, complete</i>)	
Maximum radius of action to be achieved by each arm (<i>Please, complete</i>)	
Maximum size of each arm (mm), including its base, if available (Height x Width x Depth) (<i>Please, complete</i>)	
The laparoscopic robotic platform (base platform) should have the CE marking as a medical device for surgical use (<i>Please, rate from 1 to 5</i>)	
The laparoscopic robotic platform (base platform) should have the FDA approval as a medical device for surgical use (<i>Please, rate from 1 to 5</i>)	
TLR ¹ level from which the base platform should start (<i>Please, complete</i>)	
TLR level that would be desirable to achieve in the project (<i>Please, complete</i>)	
The robotic platform should allow certain tasks or procedures to be carried out autonomously (<i>Please, rate from 1 to 5</i>) If so, please detail these tasks/procedures under "Other needs/issues to note" textbox.	

Other needs/issues to note:

¹ TLR (Technological Readiness Level)

https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl_en.pdf

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1.2. General aspects of robotic surgical instruments

	Evaluation
The tip of the surgical instruments should be flexible (<i>Please, rate from 1 to 5</i>)	
Minimum number of degrees of freedom that the surgical instruments should have (<i>Please, complete</i>)	
The surgical instruments should be compatible with conventional laparoscopic trocars (<i>Please, rate from 1 to 5</i>)	
The surgical instruments should be reusable -sterilizable- (<i>Please, rate from 1 to 5</i>)	
Minimum number of uses that surgical instruments should have (<i>Please, complete</i>)	
Maximum diameter (mm) that the surgical instrument shaft should have (<i>Please, complete</i>)	
Maximum diameter (mm) that the tip of the surgical instrument should have (<i>Please, complete</i>)	
The surgical instruments should offer, as a minimum, the following types of actuators (e.g., grasping forceps, scissors, needle holder, etc.) (<i>Please, complete</i>)	
The surgical instruments should offer a minimum movement accuracy of (mm, degrees) (<i>Please, complete</i>)	

Other needs/issues to note:

1.3. Platform Functionalities

	Evaluation
The platform should enable 5G connectivity (<i>Please, rate from 1 to 5</i>)	
The platform should allow surgical procedures of the digestive tract to be performed (<i>Please, rate from 1 to 5</i>)	
The platform should allow urological surgical procedures to be performed (<i>Please, rate from 1 to 5</i>)	
The platform should allow gynecological surgical procedures to be performed (<i>Please, rate from 1 to 5</i>)	
The platform should allow thoracic surgical procedures to be performed (<i>Please, rate from 1 to 5</i>)	
The platform should allow a single-port surgical approach to be performed (<i>Please, rate from 1 to 5</i>)	
The platform should allow a surgical approach through natural orifices (<i>Please, rate from 1 to 5</i>)	



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Maximum time required for complete assembly and set-up of the platform (<i>Please, complete</i>)	
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Other needs/issues to note:

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1.4. Functionalities of robotic surgical instruments

	Evaluation
Surgical instruments should allow monopolar coagulation (<i>Please, rate from 1 to 5</i>)	
Surgical instruments should allow bipolar coagulation (<i>Please, rate from 1 to 5</i>)	
Surgical instruments should be compatible with Ligasure™ technology for sealing and hemostasis (<i>Please, rate from 1 to 5</i>)	
Surgical instruments should be compatible with harmonic cutting technology (ultrasonic) (<i>Please, rate from 1 to 5</i>)	
Surgical instruments should provide a clip applicator (<i>Please, rate from 1 to 5</i>)	
The clip applicator should allow the use of clips of different sizes (<i>Please, rate from 1 to 5</i>)	
Surgical instruments should provide a mechanical suture applicator (<i>Please, rate from 1 to 5</i>)	
Surgical instruments should provide a stapler (<i>Please, rate from 1 to 5</i>)	
Surgical instruments should provide an ultrasound imaging system (<i>Please, rate from 1 to 5</i>)	
Instruments should be compatible with technology that provides force feedback to the surgeon (<i>Please, rate from 1 to 5</i>)	
Instruments should be compatible with technology that provides haptic/sensory feedback to the surgeon (<i>Please, rate from 1 to 5</i>)	
Surgical instruments should be interchangeable (<i>Please, rate from 1 to 5</i>)	
The system should be compatible with conventional laparoscopic instruments (<i>Please, rate from 1 to 5</i>)	
The system should be compatible with instrumentation from other robotic platforms for laparoscopy (<i>Please, rate from 1 to 5</i>)	
The system should allow changing only the actuator of the surgical instruments (<i>Please, rate from 1 to 5</i>)	
Maximum time required to change surgical instruments (<i>Please, complete</i>)	
Surgical instruments should be antiferromagnetic or allow to be demagnetized (<i>Please, rate from 1 to 5</i>)	



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Other needs/issues to note:

SECTION 2: SURGICAL VISUALIZATION AND ASSISTANCE SYSTEM.

This section aims to identify the general aspects that should define the visualization and surgical assistance system of the robotic platform for laparoscopic surgery to be developed in the TREMIRS project.

For each item, **please, complete or rate (from 1 -not important- to 5 -essential-)** the degree of necessity for each of the criteria indicated.

2.1. General aspects

	Evaluation
The visualization system should be adjustable in height to suit the surgeon's posture (<i>Please, rate from 1 to 5</i>)	
The system should allow the visualization of the procedure by means of a stereoscopic system (one visor for each eye) (<i>Please, rate from 1 to 5</i>)	
The system should allow the visualization of the procedure by means of a 3D vision screen (<i>Please, rate from 1 to 5</i>)	
The system should allow connection to external displays for viewing of the procedure by the rest of the surgical team (<i>Please, rate from 1 to 5</i>)	
The system should allow the rest of the surgical team to visualize the procedure through 3D HD vision screens (<i>Please, rate from 1 to 5</i>)	
The system should allow the rest of the surgical team to visualize the procedure through Full HD vision screens (<i>Please, rate from 1 to 5</i>)	
The system should allow the rest of the surgical team to visualize the procedure through 4K vision screens (<i>Please, rate from 1 to 5</i>)	
The system should allow the rest of the surgical team to visualize the procedure through 8K vision screens (<i>Please, rate from 1 to 5</i>)	

Other needs/issues to note:

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2.2. Imaging technology

	Evaluation
The system should allow the capture of the intracorporeal image in 3D HD quality (<i>Please, rate from 1 to 5</i>)	
The system should allow the capture of the intracorporeal image in Full HD quality (1920x1080 pixels) (<i>Please, rate from 1 to 5</i>)	
The system should allow the capture of the intracorporeal image in 4K quality (<i>Please, rate from 1 to 5</i>)	
The system should allow the capture of the intracorporeal image in 8K quality (<i>Please, rate from 1 to 5</i>)	
The system should allow the use of LIDAR (light detection and ranging) or depth detection technology (<i>Please, rate from 1 to 5</i>)	
Minimum and maximum number of frames per second at which the system should be able to capture the surgical scene (<i>Please, complete</i>)	
Minimum and maximum Hertz (Hz) at which the surgical image should be displayed (<i>Please, complete</i>)	
The system should allow a field of view of up to 180° (<i>Please, rate from 1 to 5</i>)	
The system should allow a field of view of up to 360° (<i>Please, rate from 1 to 5</i>)	
Optics should have a temperature control system (<i>Please, rate from 1 to 5</i>)	
Optics should have a lens self-cleaning system (<i>Please, rate from 1 to 5</i>)	

Other needs/issues to note:

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2.3. Recording system

	Evaluation
The system should allow recording and subsequent playback of the surgical video in 3D HD quality (<i>Please, rate from 1 to 5</i>)	
The system should allow recording and subsequent playback of the surgical video in Full HD quality (<i>Please, rate from 1 to 5</i>)	
The system should allow recording and subsequent playback of the surgical video in 4K quality (<i>Please, rate from 1 to 5</i>)	
The system should allow recording and subsequent playback of the surgical video in 8K quality (<i>Please, rate from 1 to 5</i>)	
The system should be able to record the movements of surgical instruments during surgery (<i>Please, rate from 1 to 5</i>)	
The system should be able to record voice annotations during surgery (<i>Please, rate from 1 to 5</i>)	



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The system should be able to store haptic information from instruments during surgery (<i>Please, rate from 1 to 5</i>)	
The system should allow recording and subsequent playback of virtual surgical assistance content (e.g., Augmented Reality) (see section 2.4) during surgery (<i>Please, rate from 1 to 5</i>)	
The system should be able to record and playback image depth information (e.g., LIDAR -Light Detection and Ranging-) (<i>Please, rate from 1 to 5</i>)	
Video and data storage capabilities that the system should provide (<i>Please, complete</i>)	
Video and data file management features that the system should provide (<i>Please, complete</i>)	
The system should allow live broadcasting of the surgery (<i>Please, rate from 1 to 5</i>)	
Minimum resolution (pixels) at which the system should broadcast the live surgery (<i>Please, complete</i>)	

Other needs/issues to note:

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2.4. Surgical assistance system

	Evaluation
The system should provide near infrared imaging (Fluorescence) (<i>Please, rate from 1 to 5</i>)	
The system should allow simultaneous viewing of the actual image of the surgery and the near infrared image (Fluorescence) (<i>Please, rate from 1 to 5</i>)	
The platform should provide a planning system for optimal positioning of the trocars according to the surgical procedure to be performed and the patient (<i>Please, rate from 1 to 5</i>)	
The platform should provide a planning system for optimal positioning of the arms in the trocars according to the surgical procedure to be performed and the patient (<i>Please, rate from 1 to 5</i>)	
The system should provide a surgical planning tool based on preoperative studies (<i>Please, rate from 1 to 5</i>)	
The system should provide a surgical assistance tool using Augmented Reality technology (<i>Please, rate from 1 to 5</i>)	
The surgical assistance system should be compatible with Mixed Reality technology (<i>Please, rate from 1 to 5</i>)	
The system should provide a surgical assistance tool based on Artificial Intelligence (<i>Please, rate from 1 to 5</i>)	
Please indicate what type of assistance it would be helpful to provide to the surgeon during surgery (<i>Please, complete</i>)	
Other surgical assistance tools that should be included in the system (<i>Please, complete</i>)	



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The system should provide a collision alert tool between the platform arms and the surgical instruments (<i>Please, rate from 1 to 5</i>)	
The system should provide a method for moving the laparoscopic camera by the surgeon's head and eyes motion (<i>Please, rate from 1 to 5</i>)	

Other needs/issues to note:

SECTION 3: CONTROL CONSOLE.

The objective of this section is to identify the general aspects that should define the control console of the robotic platform for laparoscopic surgery to be developed in the TREMIRS project.

For each item, **please, complete or rate (from 1 -not important- to 5 -essential-)** the degree of necessity for each of the criteria indicated.

3.1. General aspects

	Evaluation
The console should be portable (allowing it to be easily moved within and between operating rooms) (<i>Please, rate from 1 to 5</i>)	
The console should be compatible with the robotic platform for laparoscopic surgery defined in SECTION 1 (<i>Please, rate from 1 to 5</i>)	
The console should be compatible with the laparoscopic instruments defined in SECTION 1 (<i>Please, rate from 1 to 5</i>)	
The console should be compatible with display systems based on the use of screens defined in SECTION 2 (<i>Please, rate from 1 to 5</i>)	
The console should be compatible with stereoscopic display systems (one visor for each eye) defined in SECTION 2 (<i>Please, rate from 1 to 5</i>)	
The control console should be open (<i>Please, rate from 1 to 5</i>)	
Maximum console size (Height x Width x Depth) (<i>Please, complete</i>)	
Type of surgical instrument control manipulator (e.g., joystick, forceps handle, laparoscopic instrument handle, etc.) (<i>Please, complete</i>)	

Other needs/issues to note:

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3.2. Functionalities.

	Evaluation
Surgical instrument control manipulators should provide force feedback to the surgeon regarding the interaction of the surgical instruments with the tissues (<i>Please, rate from 1 to 5</i>)	
Surgical instrument control manipulators should provide haptic/sensory feedback to the surgeon regarding the interaction of the surgical instruments with the tissues (<i>Please, rate from 1 to 5</i>)	
Surgical instrument control manipulators should provide a method of tremor reduction during the use of surgical instruments (<i>Please, rate from 1 to 5</i>)	
Surgical instrument control manipulators should provide the ability to scale movements during surgical instrument control (<i>Please, rate from 1 to 5</i>)	
The console should provide the surgeon with a communication system with the rest of the surgical team (<i>Please, rate from 1 to 5</i>)	
Types of communication systems with the rest of the surgical team (e.g., audio communication) (<i>Please, complete</i>)	
The control console should provide a system for automatic triangulation of surgical instruments (<i>Please, rate from 1 to 5</i>)	

Other needs/issues to note:

3.3. Ergonomic aspects

	Evaluation
The control console should be adjustable in height (<i>Please, rate from 1 to 5</i>)	
The control console should be adapted to below average heights for both male and female surgeons (<i>Please, rate from 1 to 5</i>)	
The control console should be adjustable in inclination (<i>Please, rate from 1 to 5</i>)	
The control console should allow to adjust the proximity of the display system to be adjusted (<i>Please, rate from 1 to 5</i>)	
The pedals of the control console should be adjustable in position and height with respect to the surgeon's posture (<i>Please, rate from 1 to 5</i>)	
The pedals of the control console should allow to be configured according to the surgeon's needs (<i>Please, rate from 1 to 5</i>)	
The control console should be suitable for use with conventional chairs (<i>Please, rate from 1 to 5</i>)	
The control console should have a chair with ergonomic criteria for the surgeon (<i>Please, rate from 1 to 5</i>)	

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The control console chair should have lockable wheels for easy mobility (<i>Please, rate from 1 to 5</i>)	
The control console chair should have lumbar support for the surgeon (<i>Please, rate from 1 to 5</i>)	
The control console chair should have cervical support for the surgeon (<i>Please, rate from 1 to 5</i>)	
The control console should have armrests for the surgeon (<i>Please, rate from 1 to 5</i>)	
Surgical instrument controls should allow for adjustment to the surgeon's posture (<i>Please, rate from 1 to 5</i>)	
Surgical instrument controls should allow for adaptation to different hand sizes (<i>Please, rate from 1 to 5</i>)	
The surgeon should be able to use the control console in both sitting and standing positions (<i>Please, rate from 1 to 5</i>)	
The system should have a clutch system that allows changing the position of the control manipulators while keeping the position of the surgical instruments fixed (<i>Please, rate from 1 to 5</i>)	
The console should provide adaptability criteria for people with functional diversity (<i>Please, rate from 1 to 5</i>)	
Other ergonomic aspects to be taken into account (<i>Please, complete</i>)	

Other needs/issues to note:

SECTION 4: PORTABLE TRAINING TOOLS.

This section aims to identify the general aspects that should define the portable training tools of the robotic platform for laparoscopic surgery to be developed in the TREMIRS project.

For each item, **please, complete or rate (from 1 -not important- to 5 -essential-)** the degree of necessity for each of the criteria indicated.

4.1. General aspects

	Evaluation
The training platform should be portable (<i>Please, rate from 1 to 5</i>)	
Maximum training platform size (Height x Width x Depth) (<i>Please, complete</i>)	
The training platform should enable training activities to be carried out via cloud computing (<i>Please, rate from 1 to 5</i>)	
The training platform should have downloadable training software (<i>Please, rate from 1 to 5</i>)	



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The training platform should allow the use of 3D training environments (<i>Please, rate from 1 to 5</i>)	
The training platform should allow combining virtual content with images/videos of actual surgical procedures (<i>Please, rate from 1 to 5</i>)	
The training platform should have controls that mimic the surgical instrument control manipulators of a real laparoscopic surgery robotic platform (<i>Please, rate from 1 to 5</i>)	
Type of controls the training platform would allow (e.g., Mouse, Keyboard, Joystick, haptic interface, commercial control devices, etc.) (<i>Please, complete</i>)	
The training platform should simulate the use of flexible robotic instruments (<i>Please, rate from 1 to 5</i>)	
Type of simulated robotic instruments (<i>Please, complete</i>)	
The platform should be compatible with mobile devices (Smartphone, Tablet) (<i>Please, rate from 1 to 5</i>)	
The platform should be compatible with desktop or laptop computers (<i>Please, rate from 1 to 5</i>)	
The platform should be compatible with Virtual Reality devices (e.g., Oculus, HTC, etc.) (<i>Please, rate from 1 to 5</i>)	
Type of vision technology that should be allowed (e.g., 3D display, Virtual Reality or Mixed Reality Glasses, etc.) (<i>Please, complete</i>)	
The training platform controls should provide force feedback during training activities (<i>Please, rate from 1 to 5</i>)	
The training platform controls should provide haptic/sensory feedback during training activities (<i>Please, rate from 1 to 5</i>)	

Other needs/issues to note:

--

4.2. Functionalities

	Evaluation
The training platform should simulate basic training tasks in laparoscopic robotic surgery (<i>Please, rate from 1 to 5</i>)	
The training platform should enable training tasks and procedures in laparoscopic robotic surgery tailored to the user's experience level (<i>Please, rate from 1 to 5</i>)	
The training platform should allow for training tasks and procedures in laparoscopic robotic surgery tailored to the surgical specialty (<i>Please, rate from 1 to 5</i>)	
The platform should enable training of technical skills in laparoscopic robotic surgery (<i>Please, rate from 1 to 5</i>)	
The platform should enable training of cognitive skills in laparoscopic robotic surgery (<i>Please, rate from 1 to 5</i>)	
The platform should have a scoring/evaluation system (<i>Please, rate from 1 to 5</i>)	
The platform should provide mentoring and guided learning (<i>Please, rate from 1 to 5</i>)	



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The platform should allow the collection of progress data (<i>Please, rate from 1 to 5</i>)	
The platform should allow the update of the training activities that the user can perform (<i>Please, rate from 1 to 5</i>)	
Students could have their own user profile (<i>Please, rate from 1 to 5</i>)	
The platform should have a web portal with updated information about the system, demonstrations, new training activities, data of the user's training activity, etc. (<i>Please, rate from 1 to 5</i>)	
Other functions that the platform should simulate with respect to robotic platforms for laparoscopic surgery (<i>Please, complete</i>)	

Other needs/issues to note:

ADDITIONAL INFORMATION SECTION. EVALUATION OF THE WORK

ESTIMATED BUDGET FOR COSTS ASSOCIATED WITH THE DEVELOPMENT OF EACH SECTION	
SECTION 1: ROBOTIC PLATFORM FOR LAPAROSCOPIC SURGERY.	
SECTION 2: SURGICAL VISUALIZATION AND ASSISTANCE SYSTEM.	
SECTION 3: CONTROL CONSOLE.	
SECTION 4: PORTABLE TRAINING TOOLS.	
We would be interested in participating in:	<input type="checkbox"/> SECTION 1: ROBOTIC PLATFORM FOR LAPAROSCOPIC SURGERY.
	<input type="checkbox"/> SECTION 2: SURGICAL VISUALIZATION AND ASSISTANCE SYSTEM.
	<input type="checkbox"/> SECTION 3: CONTROL CONSOLE.
	<input type="checkbox"/> SECTION 4: PORTABLE TRAINING TOOLS.
Please, justify the previous answer	



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ANNEX 2.- CHALLENGE 2 FORM (ROBOTIC PLATFORM FOR MICROSURGERY)

1.- PARTICIPANT AND PROPOSAL INFORMATION

Entity or business name*:			
Legal person*:	<input type="checkbox"/>		
Entity*:	<input type="checkbox"/>		
Joint proposal*:	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Economic field or sector (CNAE) *:			
Entity's main activities:			
Number of employees:			
Entity total turnover in recent years	2020	2019	2018
Name and surname of interlocutor (or representative in case of joint proposal)*:			
Post:			
Phone number*:			
E-mail*:			
PROPOSAL INFORMATION			
Proposal name*:			
Do you intend to apply for future tenders related to the challenge(s) to which you are applying?*	<input type="checkbox"/> Yes <input type="checkbox"/> No		

* Required fields

SECTION 1: ROBOTIC PLATFORM FOR MICROSURGERY

This section aims to identify the general aspects that should define the teleoperated robotic platform for microsurgery to be developed in the TREMIRS project.

For each item, **please, complete or rate (from 1 -not important- to 5 -essential-)** the degree of necessity for each of the criteria indicated.

1.1. General aspects

	Evaluation
The platform should be teleoperated (<i>Please, rate from 1 to 5</i>)	
The platform should be portable (<i>Please, rate from 1 to 5</i>)	
Way of transporting the platform (<i>Please, complete</i>)	
The platform should be compatible with the surgical environment (<i>Please, rate from 1 to 5</i>)	
Maximum platform size (Height x Width x Depth) (<i>Please, complete</i>)	
Maximum radius of action that should be reached by each arm (<i>Please, complete</i>)	
The platform should allow its use with surgical optical microscopes (<i>Please, rate from 1 to 5</i>)	
The platform should offer its own vision system (<i>Please, rate from 1 to 5</i>)	
The robotic platform for microsurgery (base platform) should be CE marked as a medical device for surgical use (<i>Please, rate from 1 to 5</i>)	
The base platform should have the FDA approval as a medical device for surgical use (<i>Please, rate from 1 to 5</i>)	
TLR ² level from which the base platform should start (<i>Please, complete</i>)	
TLR level that would be desirable to achieve in the project (<i>Please, complete</i>)	
The robotic platform should allow certain tasks or procedures to be carried out autonomously (<i>Please, rate from 1 to 5</i>) If so, please detail these tasks/procedures under "Other needs/issues to note" textbox.	

Other needs/issues to note:

² TLR (Technological Readiness Level)

https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl_en.pdf



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1.2. Functionalities

	Evaluation
The platform should allow switching between robotic-assisted microsurgery and conventional microsurgery (<i>Please, rate from 1 to 5</i>)	
The platform should allow microsurgical anastomosis to be performed (<i>Please, rate from 1 to 5</i>)	
The platform should allow manipulation of blood vessels (<i>Please, rate from 1 to 5</i>)	
The platform should allow manipulation of nerves (<i>Please, rate from 1 to 5</i>)	
The platform should allow manipulation of lymphatic ducts (<i>Please, rate from 1 to 5</i>)	
Other microsurgical procedures that the platform should allow (e.g., pedicled free flap reconstruction, lymphatic-venous anastomosis, etc.) (<i>Please, complete</i>)	
The platform should enable supermicrosurgery to be carried out (<i>Please, rate from 1 to 5</i>)	

Other needs/issues to note:

SECTION 2: ROBOTIC MICROINSTRUMENTS.

The objective of this section is to identify the general aspects that should define the surgical microinstruments of the robotic platform for microsurgery to be developed in the TREMIRS project.

For each item, **please, complete or rate (from 1 -not important- to 5 -essential-)** the degree of necessity for each of the criteria indicated.

2.1. General aspects

	Evaluation
The tip of the surgical microinstruments should be flexible (<i>Please, rate from 1 to 5</i>)	
Minimum number of degrees of freedom that surgical microinstruments should have (<i>Please, complete</i>)	
The surgical microinstruments should be reusable -sterilizable- (<i>Please, rate from 1 to 5</i>)	
Minimum number of uses of the surgical microinstruments (<i>Please, complete</i>)	
Maximum shaft diameter of the surgical microinstruments (<i>Please, complete</i>)	
Maximum diameter of the actuator tip of the surgical microinstruments (<i>Please, complete</i>)	



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The surgical microinstruments should offer, as a minimum, the following types of actuators (e.g., forceps, scissors, needle holders, etc.) (<i>Please, complete</i>)	
The surgical microinstruments should offer a minimum movement accuracy of (mm, degrees): (<i>Please, complete</i>)	

Other needs/issues to note:

2.2. Functionalities

	Evaluation
The microsurgical instruments should allow bipolar coagulation (<i>Please, rate from 1 to 5</i>)	
The microinstruments should be compatible with technology that provides force feedback to the surgeon (<i>Please, rate from 1 to 5</i>)	
The microinstruments should be compatible with technology that provides haptic/sensory feedback to the surgeon (<i>Please, rate from 1 to 5</i>)	
The surgical microinstruments should be exchangeable (<i>Please, rate from 1 to 5</i>)	
The system should be compatible with conventional microsurgical instruments (<i>Please, rate from 1 to 5</i>)	
The system should allow changing only the actuator of the microsurgical instruments (<i>Please, rate from 1 to 5</i>)	
The microsurgical instruments should be suitable for handling sutures from 8-0 (0.040-0.049 mm) to 12-0 (0.001-0.009 mm) (<i>Please, rate from 1 to 5</i>)	
Microsurgical instruments should be antiferromagnetic or allow to be demagnetized (<i>Please, rate from 1 to 5</i>)	

Other needs/issues to note:

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SECTION 3. CONTROL CONSOLE.

This section aims to identify the general aspects that should define the control console of the robotic platform for microsurgery to be developed in the TREMIRS project.

For each item, **please, complete or rate (from 1 -not important- to 5 -essential-)** the degree of necessity for each of the criteria indicated.

3.1. General aspects

	Evaluation
The control console should be compatible with the microsurgical instruments defined in SECTION 2 (<i>Please, rate from 1 to 5</i>)	
The control console should be open (<i>Please, rate from 1 to 5</i>)	
Type of manipulator to control the microsurgical instruments (e.g., Joystick, forceps handle, microsurgical instrument handle, etc.) (<i>Please, complete</i>)	

Other needs/issues to note:

3.2. Functionalities

	Evaluation
The control console should provide an intuitive control system for the robotic microinstruments (<i>Please, rate from 1 to 5</i>)	
The microsurgical instrument control manipulators should provide force feedback to the surgeon regarding the interaction of the instruments with the tissues (<i>Please, rate from 1 to 5</i>)	
The microsurgical instrument control manipulators should provide haptic/sensory feedback to the surgeon regarding the interaction of the instruments with the tissues (<i>Please, rate from 1 to 5</i>)	
The microsurgical instrument controls should provide a method of tremor reduction during instrument use (<i>Please, rate from 1 to 5</i>)	
The microsurgical instrument control manipulators should provide the ability to scale movements during the control of the instruments (<i>Please, rate from 1 to 5</i>)	
Minimum movement scaling factor that should be allowed by the control console (<i>Please, complete</i>)	

Other needs/issues to note:

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3.3. Ergonomic aspects

	Evaluation
The control console should be adjustable in height (<i>Please, rate from 1 to 5</i>)	
The control console should be adjustable in inclination (<i>Please, rate from 1 to 5</i>)	
The control console should be suitable for use with conventional chairs (<i>Please, rate from 1 to 5</i>)	
The control console should have a chair with ergonomic criteria for the surgeon (<i>Please, rate from 1 to 5</i>)	
The control console should have armrests for the surgeon (<i>Please, rate from 1 to 5</i>)	
Microsurgical instrument controls should allow for adjustment to the surgeon's posture (<i>Please, rate from 1 to 5</i>)	
Microsurgical instrument controls should allow adaptation to different hand sizes (<i>Please, rate from 1 to 5</i>)	
The pedals of the control console should be adjustable in position and height with respect to the surgeon's posture (<i>Please, rate from 1 to 5</i>)	
The pedals of the control console should allow to be configured according to the surgeon's needs (<i>Please, rate from 1 to 5</i>)	

Other needs/issues to note:

ADDITIONAL INFORMATION SECTION. EVALUATION OF THE WORK

ESTIMATED BUDGET FOR COSTS ASSOCIATED WITH THE DEVELOPMENT OF EACH SECTION	
SECTION 1: ROBOTIC PLATFORM FOR MICROSURGERY	
SECTION 2: ROBOTIC MICROINSTRUMENTS	
SECTION 3: CONTROL CONSOLE	