GOBIERNO DE ESPAÑA
MINISTERIO DE CIENCIA E INNOVACIÓN

Centro de Cirugía de Mínima Invasión
Minimally Invasive Surgery Centre
Jesús Usón

Fondo Europeo
de Desarrollo Regional
"Una manera de hacer Europa"

Unión Europea

# Preliminary Market Consultation to prepare functional specifications to be included in the procurement file Nº CPM01/2021

Final Report
July 2021

JUNTA DE EXTREMADURA
Consejería de Economía, Ciencia y Agenda Digital

TREMIRS

IDOM

# Contents

# 1. INTRODUCTION

# 1. Introduction

The Jesús Usón Minimally Invasive Surgery Centre Foundation (hereinafter referred to as the Centre or JUMISC) is a multidisciplinary institution dedicated to research, training and innovation in the healthcare field. It has extensive experience in translational research in various fields of specialisation: Laparoscopy, Endoscopy, Microsurgery, Endoluminal Diagnostics and Therapeutics, Anaesthesiology, Pharmacology, Bioengineering and Health Technologies, Cell Therapy and Assisted Reproduction.

The Centre has two main pillars, innovation and medical training. In this sense, since its foundation, the JUMISC has been working with hospitals, clinical professionals and companies in Surgery and Medicine, enabling advances the application of surgical techniques and improvements in the quality of procedures, both in terms of advances in devices and in the application of techniques.

The Centre has therefore decided to take up the challenge of promoting innovation through public procurement in two of its fields of specialisation: Laparoscopy and Microsurgery.

In this context, the JUMISC is promoting the "Minimally Invasive Robotic Surgery Systems (TREMIRS)" innovation programme (www.tremirs.com), which aims to meet the needs of the Extremadura and Spanish Health Systems in minimally invasive surgery by developing innovative solutions in surgical robotics that improve the systems already on the market for their application in laparoscopic surgery and microsurgery.

TREMIRS is financed by European Funds; specifically, the Line for the Promotion of Innovation based on Demand for the Public Procurement of Innovation (FID-CPI Line - *Línea de Fomento de Innovación desde la Demanda para la Compra Pública de Innovación*) of the Ministry of Science and Innovation (Dossier CPI-2019-33-1-TRE-14) and is 80% co-financed by the European Regional Development Fund 2014-2020 (ERDF) and by the Regional Ministry of Economy, Industry and Tourism and Digital Agenda of the Regional Government of Extremadura.

The Promotion of Innovation based on Demand (PID) programme is an instrument of the Ministry of Science and Innovation for the promotion of Public Procurement of Innovation (PPI), financed by multi-regional ERDF funds for the period 2014-2020 and aimed at fostering innovation through the demand for innovative solutions by public administrations.

According to the proposal for the final decision, issued by the Subdirectorate General for the Promotion of Innovation, the Project has a financial budget of 7,345,300.00 euros.

The aid conditions were set on 3 December 2020 in an agreement (DECA) signed with the Ministry of Science and Innovation, which includes, among other aspects, the terms for the proper implementation and execution of the Project.

On 28 December 2020, the agreement between the Ministry of Science and Innovation and the Jesús Usón Minimally Invasive Surgery Centre Foundation was published in the Spanish Official State Gazette, corresponding to the TREMIRS Project "Minimally Invasive Robotic Surgery Systems".

This operation by the Ministry is part of **Priority Axis 01, within Investment Priority 1b:** "The promotion of business investment in R&I, the development of links and synergies between business, research centres and the higher education sector, in particular through the promotion of investment in the development and the higher education sector, and in the **Specific Objective**: **OE.1.2.1 "Boost and promotion of business-led R&I activities, support for the creation and consolidation of innovative companies and support for Public Procurement of Innovation"**, which corresponds to the following dimensions of the POPE as stated in Section 2:

- In Dimension 1, Scope of intervention: Code 096, Institutional capacity of public administrations and services related to ERDF implementation or measures supporting ESF institutional capacity building initiatives.

- In Dimension 2, Form of finance: Code 01: Non-repayable grant. In Dimension 3, Type of territory: Code 07: Does not apply.
- In Dimension 4, Mechanisms for territorial application: Code 07: Does not apply. 12. The selection procedures and criteria applied have been transparent and have respected the general principles set out in Articles 7 and 8 of Regulation (EU) No 1303/2013 (non-discrimination, gender equality and sustainable development).

Part of the submitted Project consisted of a Preliminary Market Consultation (PMC). On 8 March 2021, the Preliminary Market Consultation was published on the Public Procurement Platform to prepare functional specifications to be included in the procurement file.

This Preliminary Market Consultation is governed by Article 115 of Law 9/2017, of 8 November, on Public Sector Contracts, transposing into Spanish Law the Directives of the European Parliament and of the Council 2014/23/EU and 2014/24/EU, of 26 February 2014. Paragraph 1 of this Article states that: *"The contracting authorities may carry out market studies and make inquiries of the economic operators active in the market to prepare the tendering procedure properly and inform the said economic operators of their plans and of the requirements they will have to meet in order to participate in the procedure. Contracting authorities may seek the advice of third parties, which may be independent experts or authorities, professional bodies or, exceptionally, economic operators active in the market."*

# 2. DESCRIPTION OF THE PROPOSAL

# 2. Description of the proposal

## 2.1 Project background and description

**A robotic platform for laparoscopic surgery**

In general, all systems on the market have several features in common such as 3D vision for the surgeon performing the procedure and the use of articulated instruments with a flexible tip.

The Da Vinci™ system (Intuitive Surgical) is currently the most widely used robotic surgery system in the world. This platform is CE-marked, and FDA approved. It is an intuitive device with 8 mm diameter instruments, featuring a flexible tip with 7 degrees of freedom manoeuvrability. The platform also features a tremor control system for instrument operation. The arms of the system are attached to a fixed platform. The Senhance™ (TransEnterix) surgical platform is also CE-marked and FDA approved for major laparoscopic surgery. In this case, the instrument arms are independent and portable. Unlike the Da Vinci™, this system features force feedback. Similarly, it features a system for monitoring (tracking) the surgeon's vision in the control booth to automate the movement of the laparoscopic camera. Other similar platforms are the Versius™ Surgical Robotic System (CMR Surgical Ltd) and the MiroSurge™ System (German Aeroespace Center - DLR).

However, there are many areas for improvement in these platforms, such as their application in recent laparoscopic approaches, progress in surgeon ergonomics, use of new vision technologies (3D, AR and MRI) for the entire surgical team and availability of portable training platforms.

**A robotic platform for microsurgery**

The Da Vinci™ platform is currently the most widely available robotic system on the market for the development of microsurgical procedures, although its application is still very limited. It has very basic instruments for microsurgery (microsurgical forceps and scissors) and tremor control in handling the instruments. However, the main focus of this platform remains laparoscopic surgery. Several limitations need to be improved to ensure an adequate application of robotic technology in microsurgery.

## 2.2 General objectives of the Project

With this Project, the JUMISC aims to cover some general objectives that will improve the field of minimally invasive surgery in the Extremadura and Spanish Health System.

TREMIRS aims to reduce the limitations of current surgical robotic systems on the market for both laparoscopic and microsurgery, to offer a better service to the patient, better ergonomics for the surgeon and greater performance for the surgical team with the consequent improvement in the quality of the care provided. Two lines of action are proposed to develop this Project:

(1) Develop a robotic platform for laparoscopic surgery that addresses the limitations of current commercially available systems for laparoscopic robotic surgery.

(2) Develop a teleoperated robotic platform for reconstructive microsurgery, consisting of robotic micro-instruments with high manoeuvrability and precision.

### 2.2.1 General and specific objectives of Challenge 1 A robotic platform for laparoscopic surgery

General objective

The main objective of this challenge is to have a robotic platform for laparoscopic surgery that improves the current systems iin the market and optimises the conditions for the patient, the surgeon, the surgical team

and the medical professionals trained in surgical robotics during surgery. The main limitations of current robotic systems for laparoscopic surgery, such as their application in new surgical approaches, limited ergonomic conditions for the surgeon, limited access to 3D vision for the rest of the surgical team and recording the 3D image of the surgical procedure carried out for later reproduction, and the availability of training tools compatible with 3D vision technologies, mobile devices and online services, will be addressed as innovative aspects for improvement.

Specific objectives

- Offer greater precision, manoeuvrability and quality in minimally invasive surgical procedures.
- Apply robotic surgery to new surgical procedures and approaches.
- Improve and personalise the ergonomic conditions of surgeons during the performance of robotic procedures in minimally invasive surgery, with the consequent reduction in the appearance of possible musculoskeletal disorders and their effects on the quality of the surgeon's surgical performance and the possible sick leave this may cause.
- Provide new surgical assistance tools to the entire surgical team, such as 3D, virtual, augmented and mixed imaging techniques.
- Offer new portable tools for distance learning in robotic laparoscopic surgery and improved training material, such as the reproduction of three-dimensional videos of real robotic laparoscopic procedures.

### 2.2.2 General and specific objectives of Challenge 2 A robotic platform for microsurgery

General objective

The main objective of this challenge is to develop a teleoperated robotic platform to perform open microsurgical procedures with articulated and interchangeable micro-instruments. The platform will consist of a set of robotic micro-instruments with high manoeuvrability and precision, operated in an intuitive manner similar to that presented during conventional microsurgery. These micro-instruments will allow soft tissue manipulation to perform microsurgical procedures such as anastomosis, suturing and ligation on small anatomical structures such as blood vessels, nerves and lymphatic ducts. The system will be compatible with most microsurgical optical microscopes.

Specific objectives

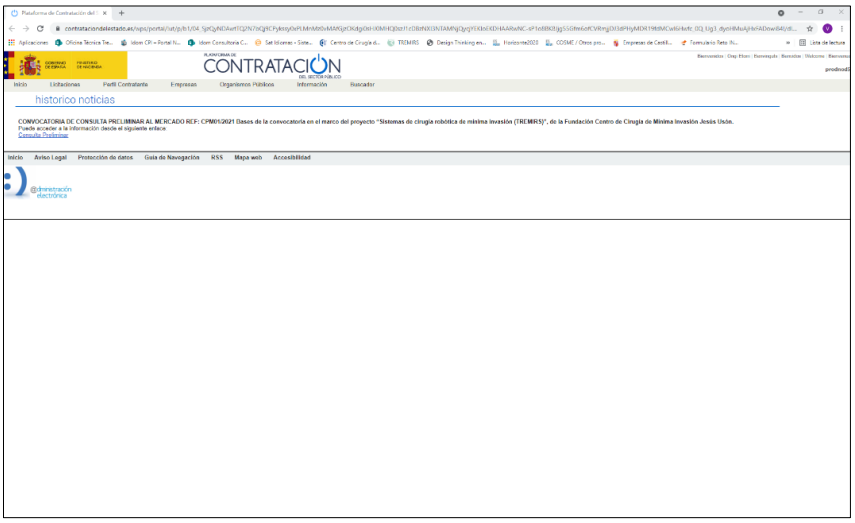
- Provide a set of multi-articulated robotic micro-instruments with the necessary features to perform basic microsurgical procedures, mainly for vascular and lymphatic surgery.
- Provide an intuitive control system for robotic micro-instruments. These controls will allow the microsurgeon to work in an ergonomically appropriate position similar to that presented during conventional microsurgery.
- Eliminate the surgeon's physiological tremors while handling surgical instruments and the scaling of surgical movements.
- Enable vascular and lymphatic microsurgical procedures to be performed with precision and safety.
- Validate the teleoperated platform to perform basic microsurgical procedures.

## 2.3 About the Preliminary Market Consultation (PMC)

This Preliminary Market Consultation (PMC) has been carried out to gather the necessary information for the innovative procurement of the "Robotic Platform for Laparoscopic Surgery" (Challenge 1) and the "Robotic Platform for Microsurgery" (Challenge 2) and inform technology operators about the procurement plans and requirements.

This Consultation was published on 8 March on the Public Procurement Platform, and its deadline was extended, through a second publication, until 27 May 2021. The initial call for proposals was made through the Project's website (www.tremirs.com) and those of the JUMISC and the State Procurement Platform (PLACE - *Plataforma de Contratación del Estado*). These publications can be viewed via the following links:

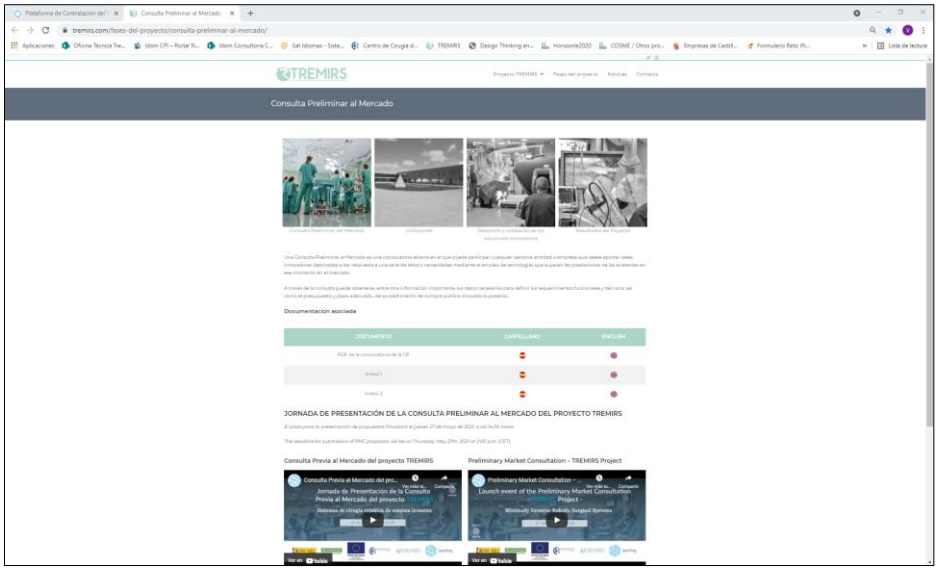
A. Publication of the initial call for PMC on the PLACE (First publication: 8 March 2021 Publication of the amended document:




30 March 2021

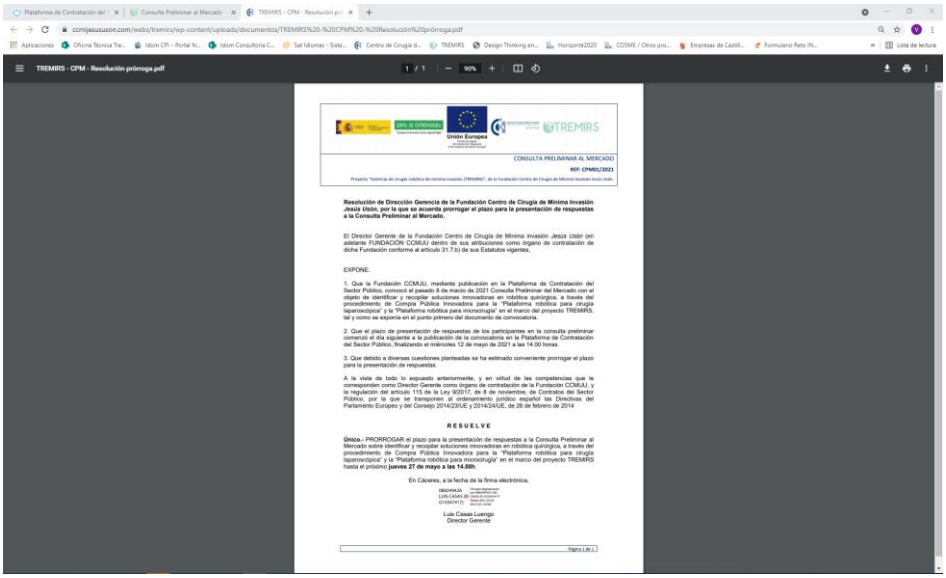
https://contratacionde lestado.es/wps/portal/!ut/p/b1/04_SjzQyNDAwtTQ2N7bQj9CPykssy0xPLMnMz0vMAfGjzOKdgi0sHJ0MHQ0szJ1cDBzNXI3NTAMNjQycjYEKIoEKDHAARwNC-sP1o8BK8Jjg55Gfm6ofCVRmjjDJ3dPHyMDR19fdMCwI6Hwfc_0Q_Ug3_dyoHMuAjHxFADowi84!/dl4/d5/L2dBISEvZ0FBIS9nQSEh/pw/Z7_BS88AB1A0GIL20AMMG1VR100L7/ren/p=WCM_PI=1/p=ns_Z7_BS88AB1A0GIL20AMMG1VR100L7_WCM_PreviousPageSize.4b6d85ef-5694-43da-960d-d1935c35d38c=8/p=ns_Z7_BS88AB1A0GIL20AMMG1VR100L7_WCM_Page.4b6d85ef-5694-43da-960d-d1935c35d38c=10/p=CTX=QCPPLACE_esQCPNoticiasQCASiteQCPNoticiasQCPCPMQCAQCADireccionQCAdeQCAlaQCAFundacionQCACentroQCAdeQCACirugiaQCAdeQCAMinimaQCAInvasionQCAJesusQCAUson/-/?param1=MenuHistorico

B. Publication of the initial call for PMC on the Project website (08 April 2021)




https://www.tremirs.com/fases-del-proyecto/consulta-preliminar-al-mercado/

C. Publication of the extension on the Centre's website (20 April 2021)




https://www.ccmijesususon.com/webs/tremirs/wp-content/uploads/documentos/TREMIRS%20-%20CPM%20-%20Resoluci%C3%B3n%20pr%C3%B3rroga.pdf

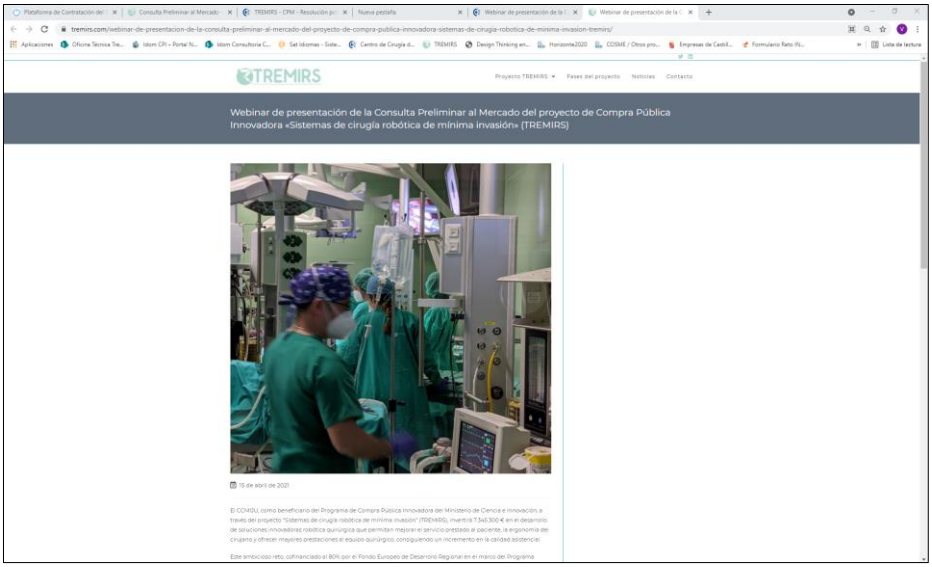
Besides the publication of the call for the Consultation, the JUMISC held a webinar on 21 April 2021 to present the details of the challenges, the objective of the Project and the preliminary consultation process to the innovation ecosystem.

The webinar was convened by the JUMISC and the Project's websites. You can view the calls and recordings by clicking on the following links:

D. Publication of webinar details on the Centre's website (15 April 2021)


https://www.ccmijesususon.com/webinar-de-presentacion-de-la-consulta-preliminar-al-mercado-del-proyecto-de-compra-publica-innovadora-sistemas-de-cirugia-robotica-de-minima-invasion-tremirs/

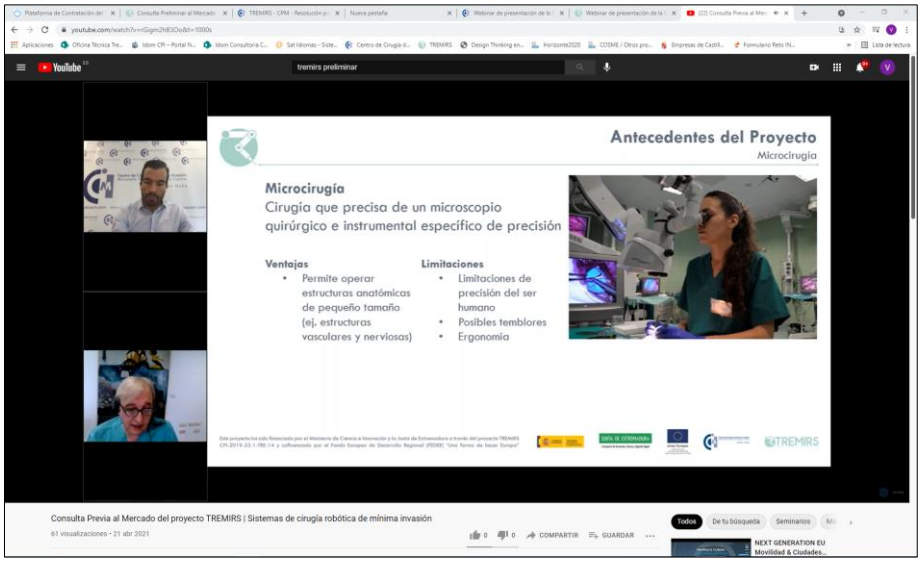
E. Publication of the details of the webinar on the Project's website on 21 April 2021.




https://www.tremirs.com/webinar-de-presentacion-de-la-consulta-preliminar-al-mercado-del-proyecto-de-compra-publica-innovadora-sistemas-de-cirugia-robotica-de-minima-invasion-tremirs/

This webinar can be viewed in both English and Spanish on these links.

F. Recording of the webinar on YouTube.




Spanish https://www.youtube.com/watch?v=rGigm2hB3Oo&feature=emb_logo

English https://www.youtube.com/watch?v=F-bcrWPu-mE&t=1154s

Both the calls and the recordings of the videos were disseminated on the social media profiles (Twitter and LinkedIn) of the JUMISC and the Project.

## 2.4 The objective of the Preliminary Market Consultation (PMC)

The objective of the PMC was **to gather the necessary information for the innovative procurement** of the "Robotic Platform for Laparoscopic Surgery" (Challenge 1) and the "Robotic Platform for Microsurgery" (Challenge 2) and inform technology operators about the procurement plans and requirements.

This Consultation, in which both natural and legal persons participated, allowed the presentation of innovative solutions aimed at responding to the challenges posed by technologies that exceed the performance of those currently available on the market, defining functional specifications that involve innovation and that are easy to achieve with a subsequent public procurement.

## 2.5 Envisaged results

Considering the objectives set out in the PMC and the results of the process, these improvements that would benefit the Project and the public services are highlighted:

### A. New technologies or modifications developed

#### *"Robotic platform for laparoscopic surgery" Line*

- Robotic instruments for laparoscopic surgery adapted and validated for new minimally invasive approaches.
- Control console with optimal and customisable ergonomic conditions for the surgeon. This console will prevent and reduce possible musculoskeletal disorders during surgery intelligently.
- A vision system that provides a three-dimensional vision of the work area and using new technologies for surgical assistance, such as augmented reality, mixed reality and fluorescence, to the entire surgical team.
- Portable training platform for laparoscopic surgical robotics.

#### *"Robotic platform for microsurgery" Line*

- Articulated robotic micro-instruments enable micro-manipulation of small soft tissues. The micro-instruments would be adapted and validated to perform vascular and lymphatic microsurgical procedures with precision.
- A set of articulated robotic micro-instruments such as dilator, needle holder and scissors is suitable for handling microsurgical sutures.
- A portable robotic platform for microsurgery that can be used with any standard visual magnification system for microsurgery. The platform will feature intuitive controls of the articulated robotic micro-instruments and could eliminate the surgeon's physiological tremors during use, scaling natural surgical movements and enabling high precision positioning of surgical instruments.
- A platform designed to allow the microsurgeon to work in an ergonomically appropriate position similar to that presented during conventional microsurgery.

### B. New innovative goods or services on the market

With the development of the two lines of action proposed in this Project, a set of innovative robotic solutions will be obtained to address the current limitations in minimally invasive surgery, specifically in laparoscopic surgery and robotic microsurgery. These solutions will have a direct benefit on the quality of the surgical service provided to the patient.

First, a robotic platform for laparoscopic surgery will be developed, which would allow a greater number of laparoscopic surgical procedures to be performed, taking advantage of the benefits of robotic technology, such as improved precision and manoeuvrability of movements. It would also improve the surgeon's ergonomic conditions during the procedure, reducing possible musculoskeletal disorders. Similarly, this platform would offer new tools for surgical assistance and training, improving the quality of surgical procedures and the training of healthcare professionals in minimally invasive surgical robotics.

Moreover, it would provide a platform for robotic microsurgery. This innovative solution would address surgeons' main physical limitations when performing microsurgery by improving the precision in handling microsurgical instruments in complex microsurgical procedures, increasing the number of possible procedures, reducing tremors during use and improving the surgeon's ergonomic conditions during surgery.

### C. Public service improvements

The improvements expected from the two workstreams of "Minimally Invasive Robotic Surgical Minimally Invasive Surgical Systems (TREMIS)" are as follows:

In the "Robotic platform for laparoscopic surgery" Line, we expect to:

- Benefit from the advances offered by robotic technology in the performance of laparoscopic surgery, such as greater precision and manoeuvrability of movements and a three-dimensional image of the surgical field.
- Test the safety and feasibility to perform new robotic-assisted laparoscopic procedures.
- Improve and personalise the ergonomic conditions of surgeons during the performance of laparoscopic robotic procedures, with the consequent reduction in the appearance of possible musculoskeletal disorders and their effects on the quality of the surgeon's surgical performance and the possible sick leave this may cause.
- Provide new surgical assistance tools to the entire surgical team, such as 3D, virtual, augmented and mixed imaging techniques.
- Offer new portable tools for distance learning in robotic laparoscopic surgery and improved training material.

In the "Robotic platform for microsurgery" line of work, we expect to:

- Benefit from advances in robotic technology to perform microsurgical procedures, offering a robotic platform for microsurgery compatible with leading visual magnification systems.
- Improve the precision in performing microsurgical procedures by using a set of robotic micro-instruments, which will improve the quality of the intervention and facilitate the performance of more complex microsurgical procedures.

## 2.6 Indicators

After defining the results expected from implementing the innovative solutions derived from the identified objectives, these impacts must be related to several indicators that allow them to be measured and monitored.

Relevant indicators to measure the effectiveness of the proposed solutions are estimated below:

**Health impact, including clinical safety**

- Indicator 1: Reduction of at least 15% of hospital stay for minimally invasive robotic surgery (MIS) procedures.
- Indicator 2: Improvement of at least 5% of functional outcomes in CRMI procedures.
- Indicator 3: Improvement of at least 5% in the learning curve for CRMI procedures over conventional laparoscopic surgery.

**Organisational and quality of care impact**

- Indicator 4: Reduction of at least 5% of musculoskeletal disorders resulting from CRMI procedures.
- Indicator 5: 10% annual increase in training activities in minimally invasive robotic surgery.
- Indicator 6: Reduction of at least 0.15% of the costs of surgeries for cancer treatment.

To define the technical and functional characteristics of the innovative solutions proposed by the market for Challenge 1 and Challenge 2, the JUMISC attached to the PMC call for proposals a form for each challenge, divided into blocks for their different parts. These blocks are mentioned in Section 3.3. Review of the ideas received.

# 3. DEVELOPMENT OF THE PMC

# 3. Development of the Preliminary Market Consultation (PMC)

## 3.1 Summary of the publication of the call for proposals

The announcement of the call for Preliminary Market Consultation was published and disseminated on the Public Procurement Platform, so it did not distort competition. Details can be found in Section 2.3. About the Preliminary Market Consultation (PMC)

This announcement included, among other things, these aspects:

- Details of the requesting contracting authority and the Preliminary Market Consultation
- Background (summary of the TREMIRS Project)
- Subject of the Preliminary Market Consultation
- Applicable regulations
- Participants
- Procedure
- Language
- Industrial and intellectual property
- Technical support

The above provides access and the possibility of contributing to all possible interested parties, in compliance with Article 115.1 of Law 9/2017, of 8 November, on Public Sector Contracts.

> *"Before starting the consultation, the contracting authority must publish the purpose of the consultation, when it will start and the names of the third parties that will participate in the consultation, on the contracting profile on the Public Sector Procurement Platform or equivalent information service at regional level so that all potentially interested parties may have access and the possibility of making contributions. The reasons for the choice of the external advisors selected shall also be published in the contractor's profile. "*

In this sense, the Project team provided the form through the Project's website so any interested, natural or legal persons, could apply to participate in the Consultation and present their innovative solutions to one of the two challenges identified.

This form should include the necessary identification data and any information relevant for analysis and consideration.

Finally, Article 115.3 establishes the need to draw up this report of findings and its contents:

> "*Where the contracting authority has carried out the consultations referred to in this article, it shall record the actions taken in a report. The report will list the studies carried out and their authors, the organisations consulted, the questions posed to them and the responses to these questions. This report shall be reasoned, form part of the procurement dossier and be subject to the same obligations of publicity as the specifications, i.e. on the contracting body's contracting profile.*

The use of the content of the information provided is not binding and is limited exclusively to its possible inclusion in the Project definition process to be implemented in the specifications of a possible subsequent procurement procedure by the Centre.

## 3.2 Organisation

In compliance with the stipulations of the Project, and in view of the expected high participation in the Consultation and its technological diversity, the Centre's Project team resorted to expert advice, according to Law 9/2017 on Public Sector Contracts and the signed Agreement. A minor contract was published to provide Technical Assistance Services for the presentation, via webinar, of the Preliminary Market

Consultation. Then the analysis of the bids received and the organisation of the two rounds of interviews with the participating organisations, including the closure procedure and presentation of the Report, was managed by the company awarded the contract for the management of the PPI Technical Office of the Project.

IDOM CONSULTING, ENGINEERING, ARCHITECTURE was the company selected for its knowledge and experience, both in the field of Public Procurement of Innovation and in the application of new technologies to solve the challenges.

Several experts and professionals from the JUMISC and the Technical Office participated in the process, which are mentioned below:

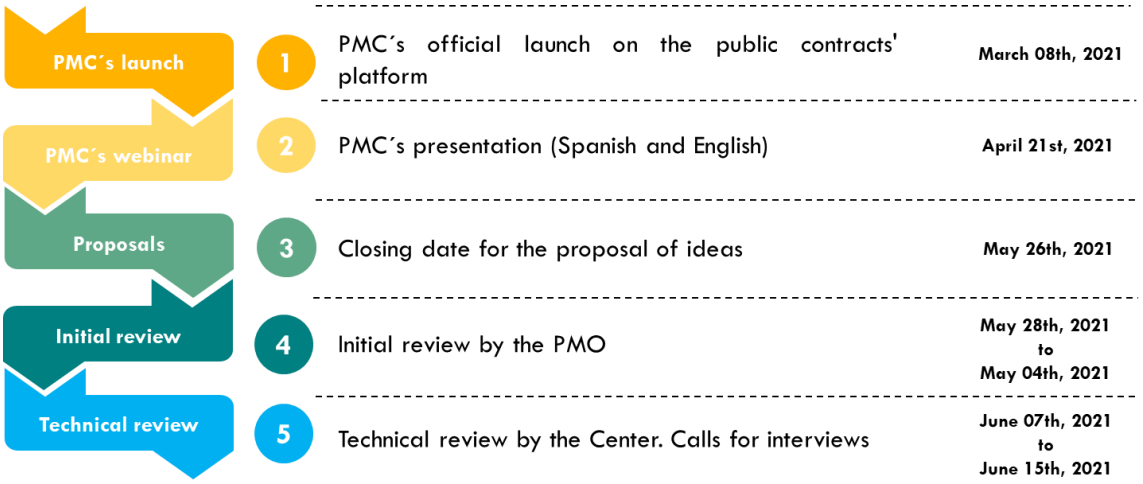
**Jesús Usón Minimally Invasive Surgery Centre Foundation work group:**

- Francisco Miguel Sánchez Margallo. Project Director and Lead Researcher
- Luis Casas Luengo. Contract Manager and Project Finance Manager
- Juan Alberto Sánchez Margallo. Project Manager
- José Luis Añover Ortiz. Legal Advice Manager
- Virginia Vidarte Bermejo. Administrative Purchasing Technician
- Elisabet Tamargo Bravo. Administrative Project Technician

**IDOM's team of expert advisors:**

- Sandra Sinde Cantorna - Head of PPI Technical Office
- Marta Albertí Ibarz - PPI Senior Project Consultant
- Carmen de Guerrero - Legal consultant - PPI expert
- Victor Lovera Viloria - PPI Project Consultant

The work carried out by the Project team was structured in several stages:




| | | |
|---|---|---|
| 6 | Meeting between the Technical Team and the selected entities. | June 16th, 2021 to June 25th, 2021 |
| 7 | Workshop with external experts | July 12th, 2021 to July 16th, 2021 |
| 8 | Final preliminary market consultation report. Selecting Public Procurement for Innovation procurements. | July 18th, 2021 to July 23rd, 2021 |
| 9 | Publication of the Final Preliminary Market Consultation Report | July 28th, 2021 |
| 10 | Publication the Final PMS report on the public contracts' platform | Today July 28th, 2021 |

Essential aspects of these stages are described in the following sections:

### 3.3 Review of the ideas received

Twelve organisations submitted their proposals by sending in the form. These organisations are listed below in alphabetical order:

1. Abex Exelencia Robótica, S.L
2. Asseco Spain, S.A
3. BBZ, S.R.L
4. CMR Surgical Ltd.
5. Cyber Surgery
6. Fernando Mateo Arias
7. Medical Micro Instrument SpA
8. Medtronic Ibérica, S.A.
9. Servocad Microtronics, S.L.
10. Surgitrainer, S.L
11. Tecnalia Research & Innovation
12. Vicomtech (Fundación Centro de Tecnologías de Interacción Visual y Comunicaciones – Vicomtech)

Graph 1. Organisations participating in the PMC


Initially, after receiving the proposals sent by the participating organisations, the PPI Technical Office team reviewed the proposals to determine the general features of the proposals, among which the following stand out:

- Origin of the organisations
- Type of entity
- Size of the entity
- Proposals to challenges
- TRL level
- Budget of the challenges

This first review aimed to determine whether the forms were filled in correctly and then get an overall picture of the participating organisations and the general data on the challenges, i.e. discover which challenge and their components interested the participating organisations most. This information was provided to the Technical Management of the Project and the team of experts so that from the onset of their analysis, they were aware of the general data and trends of the proposals, thus facilitating their subsequent evaluation. These data are presented below:

Origin of the organisations

European organisations had the highest participation in the Consultation. Of the total of participating organisations, 50% are Spanish. It is worth mentioning that most of the foreign organisations have a head office in Spain, as seen in the following table.

Table 1. Origin of the organisations participating in the PMC

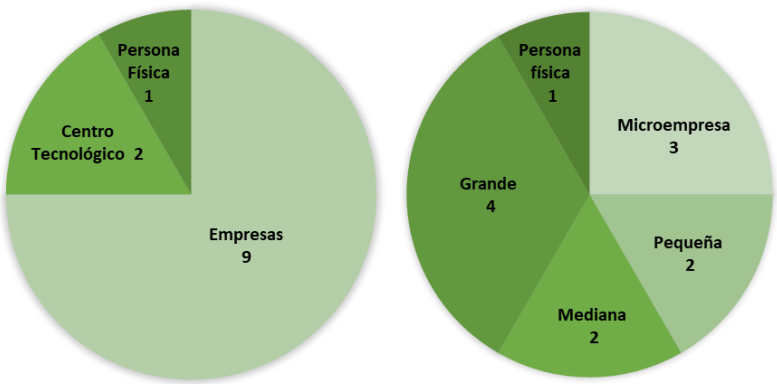
| Country | Head Office |
|---|---|
| Spain | 6 |
| United States | 1 |
| Italy | 3 |
| Poland | 1 |
| United Kingdom | 1 |
| **Total** | **12** |

Source: The author

Type of organisation

Of the twelve proposals received, nine were made by companies, two by technology centres and one was submitted by an individual. In terms of size, it can be concluded there is a great variety, which allows us to point out that all types of organisations have participated in this Consultation, from individuals to international companies.

Graph 2 Type and size of the organisations

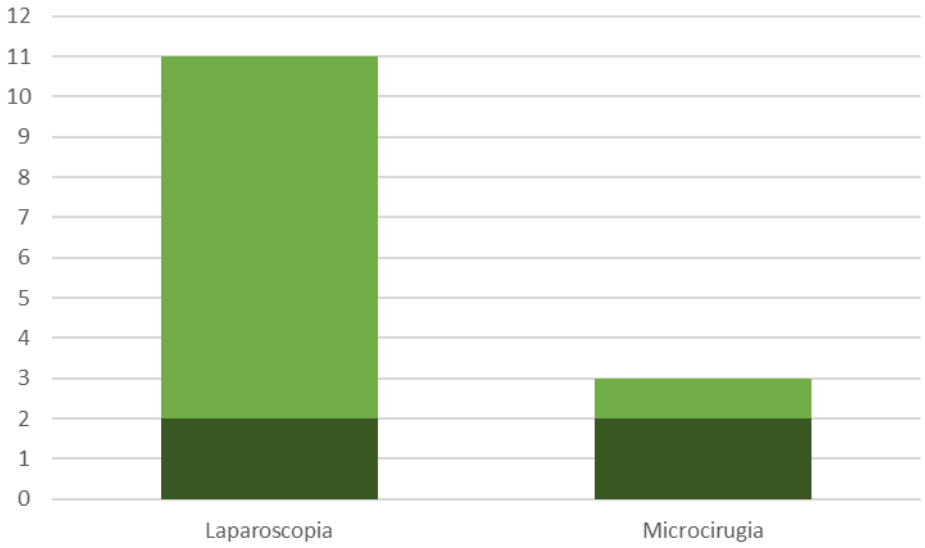



Source: The author

Proposals to challenges

There was a majority participation for the Laparoscopy Challenge 1, with nine of the twelve organisations making proposals for this challenge. One company made a proposal exclusively for Microsurgery Challenge 2, and two organisations made proposals for both challenges. Although most proposals were in Spanish, the participation of European entities with proposals in English is also worthy of note (25% of the proposals).

Graph 3 Proposals submitted for Challenge 1 (Laparoscopy) and Challenge 2 (Microsurgery).




Source: The author

The forms were aimed at discovering, in most questions, how important several functionalities and/or characteristics of the challenge components were for organisations.

These components of the challenges mentioned at various points in the document above sought to bring together aspects that must be contained in the proposed solutions. This grouping does not mean that future tenders will be divided into lots; the groupings were intended to facilitate the analysis of the forms and, at the same time to understand the organisations' interest in such blocks/components. The blocks for each challenge are listed below:

For Laparoscopy Challenge 1, the form was divided into four blocks:

1. A robotic platform for laparoscopic surgery
2. Surgical viewing and assistance system
3. Control console
4. Online training tools

For Microsurgery Challenge 2, the form was divided into three blocks:

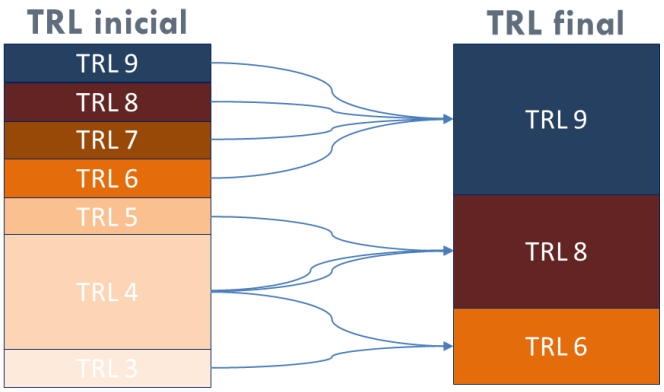
1. A robotic platform for microsurgery
2. Robotic micro-instruments
3. Control console

Participation or interest per block was very varied in both challenges. Most proposals focused on blocks 1 and 4 for the Laparoscopy Challenge. The interest for each block in both challenges is detailed below according to the proposals received.

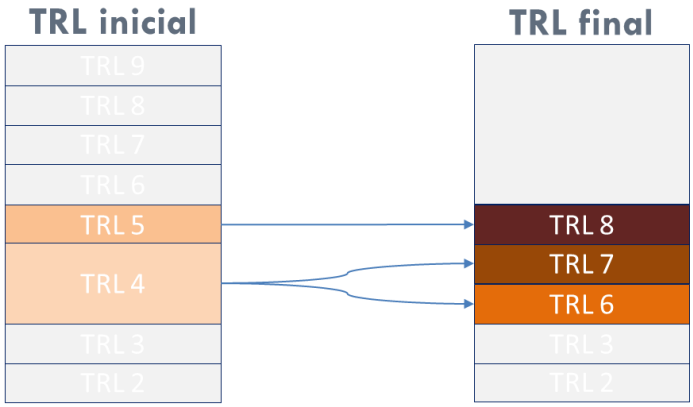
| Sections | Laparoscopic | Microsurgery |
|---|---|---|
| **Section 1. Robotic platform** | 81,81 % | 100 % |
| **Section 2. Surgical visualization and assistance system (Laparoscopic) / Robotic microinstruments (Microsurgery)** | 63,63 % | 100 % |
| **Section 3. Control console** | 63,63 % | 100 % |
| **Section 4. Portable training tools.** | 81,81 % | - |

TRL level

According to the level of participation per challenge and the answers, the laparoscopy market appears to be more developed than the microsurgery market, a reality that can be verified by the answers initially mentioned in the forms on the initial and final TRL levels. For Laparoscopy Challenge 1, most organisations stated that they could achieve high levels of platform development (Block 1), with final TRLs of 8 and 9.




In contrast, the proposals for Microsurgery Challenge 2 showed lower levels of development for the platforms (Block 1) at both the start and end.




It is essential to mention that these TRLs presented in the graphs above are only on the platform component. The level of development of other components, such as control consoles or micro-instruments, is not considered. For all these reasons, one of the initial objectives of the interviews was to explore in-depth the TRLs of each proposal interviewed. These results are presented in bullet point 4, "Results of the PMC".

Budget of the challenges

The last part of the form was intended to elicit organisations' considerations on the costs of each block of the two challenges. Considering that each proposal differs from the other and it is impossible to compare the proposed solutions exhaustively, the Project team drew up an average of the amounts proposed for each block to make a first approximation of the budget for future tenders. These amounts shall not condition or limit the final budget of the tenders.

Presupuestos promedio de los cuatro bloques para el reto de la cirugía laparoscópica

| Bloque Nº 1. Plataforma robótica para cirugía laparoscópica. | Bloque Nº 2. sistema de visualización y asistencia quirúrgica. | Bloque Nº 3. Consola de control. | Bloque Nº 4. Herramientas de formación online. |
|---|---|---|---|
| 1.180.000,00 € | 318.000,00 € | 996.250,00 € | 467.142,86 € |

Presupuestos promedio de los tres bloques para el reto de la microcirugía

| Bloque Nº 1. Plataforma robótica para microcirugía | Bloque Nº 2. Microinstrumentos robotizados | Bloque Nº 3. Consola de control. |
|---|---|---|
| 650.000,00 € | 45.000,00 € | 500.000,00 € |

After this first review, the team started the first technical analysis of the proposals. Each of the ideas received was analysed based on two aspects:

- Does the proposal fit the resolution of the need?
- How innovative is the proposal?

After this first analysis, the Project Manager and the Technical Office selected the proposals that required clarification on some of the points raised in their responses. These clarifications were resolved through individual interviews with the institutions.

All the proposals received were studied and used to draw up this report on the closing of the Preliminary Market Consultation.

### 3.4 Interviews with companies

To gain greater insight and detail on each solution selected in the above analysis, the Project team, made up of members of the JUMISC and the Project's Technical Office, interviewed each of them individually.

Twelve interviews, organised in two rounds, were conducted between 16 and 25 June 2021. The interviews were convened by mail, offering two alternative dates and times. After confirmation by the organisation, the Technical Office sent the link to the meeting by videoconference. Eight interviews were conducted in the first round and four in the second, which are shown below:

| Organisation | First round | Second round |
|---|---|---|
| BBZ, S.R.L | Wednesday, 16th June | - |
| CMR Surgical Ltd. | Monday, 21st June | Thursday, 24th June |
| Medtronic Ibérica, S.A. | Wednesday, 16th June | Friday, 25th June |
| Medical Micro Instrument SpA | Wednesday, 16th June | - |
| Servocad Microtronics, S.L. | Thursday, 17th June | Friday, 25th June |
| Surgitrainer, S.L | Thursday, 17th June | - |
| Tecnalia Research & Innovation | Friday, 18th June | Friday, 25th June |
| Vicomtech. (Fundación Centro de Tecnologías de Interacción Visual y Comunicaciones – Vicomtech) | Thursday, 17th June | - |

Arranged in alphabetical order.

The second round of interviews was conducted to answer questions that arose during the first round. Given the technical complexity of the different solutions proposed, in some cases, additional information was requested to obtain a greater level of detail and to homogenise the information received. Besides the information provided through the form and in the presentations made during the first round of interviews, detailed information on the TRLs for each block completed by the organisation was also requested.

Each meeting was called to take 45 minutes. A common standard script was followed in all meetings, and these aspects were discussed:

*BLOCK I - Information on how the interview works and Presentation of the JUMISC*

- **Information on the functioning and timing of the meeting**
    - Comment on the blocks and times of the meeting
- **Project presentation**
    - Comment on the Consultation procedure
        - Inform about the next steps and estimated deadlines by the JUMISC
        - Comment on general observations on the proposal by the JUMISC

*BLOCK II - Presentation and clarification of the proposal*

- **Presentation of the proposing organisation**
    - Brief presentation of the organisation
    - Presentation of the proposal by the organisation
- **Questions on the proposal**

*BLOCK III - Q&A and closing the interview*

- **Q&A from the organisation**
- **End of the interview**

Most interviews were conducted in English since there were foreign organisations and/or some of the organisations' staff did not speak Spanish. The meeting minutes are listed below in alphabetical order according to the name of the organisation:

| | **BBZ, S.R.L** |
|---|---|
| Date of the interview on the first round | Wednesday, 16th June 2021 |
| Attendees | |
| JUMISC | Juan Alberto Sánchez Margallo - Project Leader<br>José Luis Añover Ortiz. - Legal Advisor |
| Technical Office | Víctor Alfonzo Lovera Viloria - PPI Consultant |
| BBZ | Davide Zerbato (CEO and co-founder) |
| Topics covered | |
| General presentation of the proposing organisation<br>Technical and functional presentation of the proposal (Laparoscopy Challenge 1).<br>Resolution of technical questions.<br>Request for additional information. | |

| | |
|---|---|
| CMR SURGICAL | **CMR Surgical Ltd.** |
| Date of the interview on the first round | Monday, 21st June 2021 |
| Date of the interview on the second round | Thursday, 24th June 2021 |
| Attendees | |
| JUMISC | Juan Alberto Sánchez Margallo - Project Leader<br>José Luis Añover Ortiz. - Legal Advisor |
| Technical Office | Víctor Alfonzo Lovera Viloria - PPI Consultant |
| CMR Surgical | Franz Mazzone - Commercial Lead Southern Europe<br>Filippo Gabbia - Commercial Lead Italy CMR Surgical<br>Steven Bishop - Head of Research and Strategy |
| Topics covered | |
| General presentation of the proposing organisation<br>Technical and functional presentation of the proposal (Laparoscopy Challenge 1).<br>Resolution of technical questions.<br>Request for additional information. | |

| | |
|---|---|
| Medtronic | **Medtronic Ibérica, S.A.** |
| Date of the interview on the first round | Wednesday, 16th June 2021 |
| Date of the interview on the second round | Friday, 25th June 2021 |
| Attendees | |
| JUMISC | Juan Alberto Sánchez Margallo - Project Leader<br>José Luis Añover Ortiz. - Legal Advisor |
| Technical Office | Víctor Alfonzo Lovera Viloria - PPI Consultant |
| Medtronic | Santiago Herrera - Business Developer Surgical Robotics Iberia<br>Kristian Guldahl - Senior Marketing Manager Surgical Robotics - EMEA |
| Topics covered | |
| General presentation of the proposing organisation<br>Technical and functional presentation of the proposal (Laparoscopy Challenge 1).<br>Resolution of technical questions.<br>Request for additional information. | |

| | |
|---|---|
| MMI Microinstruments | **Medical Micro Instrument SpA** |
| Date of the interview on the first round | Wednesday, 16th June |
| Attendees | |
| JUMISC | Juan Alberto Sánchez Margallo - Project Leader<br>José Luis Añover Ortiz. - Legal Advisor |
| Technical Office | Víctor Alfonzo Lovera Viloria - PPI Consultant |

| | |
|---|---|
| MMI | Hannah Teichmann - Co-Founder, Board member and VP Clinical Development<br>Iris De Falco - Clinical Engineer |
| Topics covered | |
| General presentation of the proposing organisation<br>Technical and functional presentation of the proposal (Microsurgery Challenge 2).<br>Resolution of technical questions.<br>Request for additional information. | |

| | |
|---|---|
| SERVOCAD | **Servocad Microtronics, S.L.** |
| Date of the interview on the first round | Thursday, 17th June |
| Date of the interview on the second round | Friday, 25th June |
| Attendees | |
| JUMISC | Juan Alberto Sánchez Margallo - Project Leader<br>José Luis Añover Ortiz. - Legal Advisor |
| Technical Office | Víctor Alfonzo Lovera Viloria - PPI Consultant |
| SERVOCAD | Jesús Hernández - Administrator<br>Carlos Pérez |
| Topics covered | |
| General presentation of the proposing organisation<br>Technical and functional presentation of the proposal (Laparoscopy Challenge 1 and Microsurgery Challenge 2).<br>Resolution of technical questions.<br>Request for additional information. | |

| | |
|---|---|
| surgitrainer | **Surgitrainer, S.L** |
| Date of the interview on the first round | Thursday, 17th June |
| Attendees | |
| JUMISC | Juan Alberto Sánchez Margallo - Project Leader<br>José Luis Añover Ortiz. - Legal Advisor |
| Technical Office | Víctor Alfonzo Lovera Viloria - PPI Consultant |
| Surgitrainer | Alicia Casals - Scientific Director<br>José Luis Pérez - CEO |
| Topics covered | |
| General presentation of the proposing organisation<br>Technical and functional presentation of the proposal (Laparoscopy Challenge 1).<br>Resolution of technical questions.<br>Request for additional information. | |

| | |
|---|---|
| tecnalia MEMBER OF BASQUE RESEARCH & TECHNOLOGY ALLIANCE | **Tecnalia Research & Innovation** |

| | |
|---|---|
| Date of the interview on the first round | Friday, 18th June |
| Date of the interview on the second round | Friday, 25th June |
| Attendees | |
| JUMISC | Juan Alberto Sánchez Margallo - Project Leader<br>José Luis Añover Ortiz. - Legal Advisor |
| Technical Office | Víctor Alfonzo Lovera Viloria - PPI Consultant |
| Tecnalia | Leire Martínez Beitia - Project Manager in Medical Robotics<br>Arantxa Renteria - Project Director<br>Joseph McIntyre - Ikerbasque Research Professor |
| Topics covered | |
| General presentation of the proposing organisation<br>Technical and functional presentation of the proposal (Laparoscopy Challenge 1).<br>Resolution of technical questions.<br>Request for additional information. | |

| vicomtech MEMBER OF BASQUE RESEARCH & TECHNOLOGY ALLIANCE | **Vicomtech (Fundación Centro de Tecnologías de Interacción Visual y Comunicaciones – Vicomtech)** |
|---|---|
| Date of the interview on the first round | Thursday, 17th June |
| Attendees | |
| JUMISC | Juan Alberto Sánchez Margallo - Project Leader<br>José Luis Añover Ortiz. - Legal Advisor |
| Technical Office | Víctor Alfonzo Lovera Viloria - PPI Consultant |
| Vicomtech | María Moral Molina - Technology Transfer Manager<br>Iván Macia -<br>Gorka Marcos -<br>Álvaro Bertelsen Simonetti |
| Topics covered | |
| General presentation of the proposing organisation<br>Technical and functional presentation of the proposal (Laparoscopy Challenge 1 and Microsurgery Challenge 2).<br>Resolution of technical questions.<br>Request for additional information. | |

### 3.5 Validation and Workshop with technical experts on key issues

To clarify some technical and functional aspects of the proposed solutions, six experts were invited to advise the technical team on each point concerning Laparoscopy Challenge 1. Similarly, three external experts were invited to advise on Microsurgery Challenge 2.

This expert group analysed all technical and functional aspects of the PMC, especially those where the technical team needed a third opinion. They were provided with a form prepared by the Project's technical team so that the experts could quickly and efficiently answer the questions raised and present their vision of the Project's challenges. The last analysis enabled concluding the results of the PMC.

These analyses are not binding and may be used by the JUMISC when defining the specifications of a possible subsequent procurement procedure.

# 4. RESULTS OF THE PMC

# 4. Result of the PMC

## 4.1 Participation data

For the presentation of the Preliminary Market Consultation (PMC), several announcements were made inviting organisations to participate in the webinar where all the Consultation details were presented. These announcements were made through the State Procurement Platform, the Centre's website and the Project's website, supported by different social media pages.

The webinar, held on 21 April 2021, in both Spanish and English (recording available on the Project's website), was attended live by 42 people (the recording in Spanish by 12 July 2021 had 60 views), in which the most important details of the Project and the PMC were mentioned, including the deadline for the submission of proposals.

The deadline for receipt of applications closed on 27 May 2021, and applications were analysed. The results were as follows:

- Fourteen (14) proposals were received in the Consultation.
- Eleven (11) proposals were submitted for Laparoscopy Challenge 1 and three (3) for Microsurgery Challenge 2
- Twelve (12) participating organisations.
- Two (2) Companies submitted proposals for both challenges.
- 60% of the companies are SMEs and micro-SMEs. One natural person applied.
- Two (2) technology centres were presented
- One (1) proposal from a multinational company with a significant presence in several business areas.
- Four (4) large companies.
- One (1) *spin-off*.

Highlights:

- There was high interest in conducting the interviews. These were confirmed within a short period by the institutions.
- The organisations mentioned the interest, should the opportunity arise, to present themselves as a consortium or jointly in future procedures.
- They repeatedly requested that the tender documents allow for the feasibility of the whole process, especially if it is to be divided into lots.
- Participation included private market players of all ranks, both large multinationals and small and medium-sized enterprises, as well as niche companies, two research centres and one *spin-off*.
- One company mentioned that it had submitted the proposal as a single organisation but that it has the support of others, with which it has alliances.
- There was significant participation of foreign companies, in particular Italian.
- Most proposers have experience in the development or projects of technologies and/or methodologies similar to those needed to solve the challenges posed.

## 4.2 Conclusions

In procedural terms, the information management and coordination process for the Preliminary Market Consultation procedures has worked correctly. There have been no incidents, and the forms and other documents provided to the organisations for this PMC have been available at all times. The proposals were analysed in compliance with the principles of transparency, equal treatment and confidentiality in the required cases, for which purpose confidentiality agreements were signed, and all the necessary security controls were taken to process the data.

The interviews held with the organisations participating in the TREMIRS Project have served to better understand the scope of the proposed solutions, their maturity and technological development. This, in turn, has made it possible to confirm the opportunity for innovation that the Project offers for the JUMISC, the National Health System and the economic operators.

The results obtained from the PMC process with the participating organisations and the consultations with the experts in both Project challenges are presented below.

### TRL levels

The following are the levels of TRL as described by the PMC participants after the interviews.

*Challenge 1 Laparoscopy*

| TRLs | Mean | SD |
|---|---|---|
| **Block 1. A robotic platform for surgery** | Initial: 3.75<br>End: 7.25 | Initial: 1.26<br>End: 0.96 |
| **Block 2. Surgical viewing and assistance system** | Initial: 3.33<br>End: 6.00 | Initial: 1.53<br>End: 1.00 |
| **Building Nº3. Control console** | Initial: 5.00<br>End: 7.00 | Initial: 0.82<br>End: 0.82 |
| **Building Nº4. Online training tools** | Initial: 3.33<br>End: 7.00 | Initial: 1.37<br>End: 1.10 |

*Challenge 2 Microsurgery*

| TRLs | Mean | SD |
|---|---|---|
| **Block 1. A robotic platform for Microsurgery** | Initial: 4.50<br>End: 7.50 | Initial: 0.71<br>End: 0.71 |
| **Block 2. Robotic micro-instruments** | Initial: 4.50<br>End: 7.50 | Initial: 0.71<br>End: 0.71 |
| **Building Nº3. Control console** | Initial: 3.67<br>End: 7.00 | Initial: 1.53<br>End: 1.00 |

### CHALLENGE 1: Conclusions of the organisations participating in the PMC

Below are the colour codes to identify at a glance the average rating of the responses of the participating organisations to the PMC. A rating of 1 to 2 will be considered as "not at all/not very important" and 4 to 5 as "important or very important".

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|

| | Mean | SD |
|---|---|---|
| **BLOCK 1. ROBOTIC PLATFORM FOR LAPAROSCOPIC SURGERY** | | |
| **1.1. General aspects of the platform** | | |
| The platform should be teleoperated (Rate from 1 to 5) | 5.00 | 0.00 |
| The platform should be portable (allowing it to be easily moved within and between operating theatres) (Rate from 1 to 5) | 5.00 | 0.00 |
| Form of transporting the platform (Please complete) | Wheels | |
| Compatibility with the surgical environment (Rating from 1 to 5) | 4.71 | 0.76 |
| The platform should be modular (Rate from 1 to 5) | 4.43 | 1.51 |
| Minimum number of arms on the platform (Please complete) | 2.29 ±1.11 | |
| Maximum number of arms allowed on the platform (Please complete) | 4.71 ±0.76 | |
| Maximum platform size (H x W x D) (Please complete) | Height: 1551.00±734,86 mm<br>Width: 840.00±228,14 mm<br>Depth: 1096.00±661,08 mm | |
| Maximum radius of action to be achieved by each arm (Please complete) | 1125.00±298,61 mm | |
| Maximum size of each arm, including its base, if available (H x W x D) (Please complete) | Height: 1743.25±897,26 mm<br>Wide: 805.00±293,20 mm<br>Depth: 800.00±502,26 mm | |
| The laparoscopic robotic platform (base platform) must be CE-marked as a medical device for surgical use (Rate from 1 to 5) | 3.86 | 1.95 |
| The base platform must be approved by the FDA as a medical device for surgical use (Rating from 1 to 5) | 2.43 | 1.90 |
| TLR level from which the base platform starts (Please complete) | 5.71 ±2.29 | |
| Desirable TLR level in the Project (Please complete) | 8.14 ±1.07 | |
| The robotic platform should be able to carry out specific tasks or procedures autonomously (Please rate from 1 to 5) | 1.71 | 1.50 |
| Other needs/issues to be highlighted: | | |
| | | |
| **1.2. General aspects of robotic surgical instruments** | | |
| The tip of the surgical instruments should be articulated (Rate from 1 to 5) | 5.00 | 0.00 |
| Minimum number of degrees of freedom of surgical instruments (Please complete) | 7 DoF | |
| Surgical instruments should be compatible with conventional laparoscopic trocars (Rate from 1 to 5) | 3.86 | 1.57 |
| Surgical instruments should be reusable - sterilisable - (Rate from 1 to 5) | 4.86 | 0.38 |
| Minimum number of uses of the surgical instruments (Please complete) | 23.43 ±34.52 | |
| Maximum diameter of surgical instrument shank (Please complete) | 6.30±1,49 mm | |
| Maximum diameter of surgical instrument actuator tip (Please complete) | 4.85±2,69 mm | |
| Surgical instruments shall offer, as a minimum, the following types of actuators (e.g. Gripping forceps, scissors, needle holders, etc.) (Please complete) | Gripping pliers: 100%<br>Scissors: 100%<br>Needle holder: 100%<br>Hook: 20%<br>Clipper: 20%<br>Stapler: 20% | |
| Surgical instruments shall have a minimum accuracy of movement of (mm, degrees): (Please complete) | 2.18±3.07 mm | |
| Other needs/issues to be highlighted: | | |
| | | |
| **1.3. Platform functionalities** | | |

| | | |
|---|---|---|
| The platform should allow 5G connectivity (Rate from 1 to 5) | 3.00 | 2.00 |
| The platform should allow for digestive system surgeries to be performed (Rate from 1 to 5) | 4.71 | 0.76 |
| The platform should allow for urological surgeries to be performed (Rate from 1 to 5) | 5.00 | 0.00 |
| The platform should allow for gynaecological surgeries to be performed (Rate from 1 to 5) | 5.00 | 0.00 |
| The platform should allow for chest surgeries to be performed (Rate from 1 to 5) | 4.86 | 0.38 |
| The platform should allow a single-port surgical approach to be carried out (Please rate from 1 to 5) | 2.71 | 2.14 |
| The platform should allow a surgical approach through natural orifices (Please rate from 1 to 5) | 3.29 | 2.14 |
| Maximum time required for complete assembly and set-up of the platform (Please complete) | 21.67±9.83 min | |
| Other needs/issues to be highlighted: | | |
| | | |
| **1.4. Functionalities of robotic surgical instruments** | | |
| Surgical instruments should allow for monopolar coagulation (Rate from 1 to 5) | 5.00 | 0.00 |
| Surgical instruments should allow for bipolar coagulation (Rate from 1 to 5) | 5.00 | 0.00 |
| Surgical instruments should be compatible with active instrument technology (Ligasure™ type) for sealing and haemostasis (Rate from 1 to 5) | 3.71 | 1.70 |
| Surgical instruments should be compatible with ultrasonic scalpel technology (harmonic) (Rate from 1 to 5) | 3.14 | 1.86 |
| Surgical instruments must provide a clip applicator. (Rate from 1 to 5) | 3.86 | 1.21 |
| The clip applicator should allow the use of different sized clips (Rate from 1 to 5) | 3.43 | 1.62 |
| Surgical instruments should provide a mechanical suture applicator (Rate from 1 to 5) | 2.57 | 1.81 |
| Surgical instruments must provide a stapler. (Rate from 1 to 5) | 3.57 | 1.90 |
| Surgical instruments must provide an ultrasound imaging system (Rate from 1 to 5) | 3.00 | 2.00 |
| Instruments should be compatible with the technology that provides force feedback to the surgeon (Rate from 1 to 5) | 3.29 | 2.14 |
| Instruments should be compatible with the technology that provides haptic/sensory feedback to the surgeon (Rate from 1 to 5) | 3.29 | 2.14 |
| Surgical instruments should be interchangeable. (Rate from 1 to 5) | 5.00 | 0.00 |
| Surgical instruments should be compatible with conventional laparoscopic instruments (Rate from 1 to 5) | 4.00 | 1.73 |
| The system should be compatible with the instruments of other robotic platforms for laparoscopy (Rate from 1 to 5) | 1.86 | 1.46 |
| The system should allow only the actuator of the surgical instruments to be changed (Rate from 1 to 5) | 2.86 | 2.04 |
| Maximum time required for the change of surgical instruments (Please complete) | 60.00±55.23 s | |
| Surgical instruments should be anti-ferromagnetic or allow for demagnetisation (Rate from 1 to 5) | 3.57 | 1.90 |
| Other needs/issues to be highlighted: | | |
| | | |
| **BLOCK 2. SURGICAL VISUALISATION AND ASSISTANCE SYSTEM** | | |
| **2.1. General aspects** | | |

| | | |
|---|---|---|
| The viewing system should be height adjustable to suit the surgeon's posture (Rate from 1 to 5) | 5.00 | 0.00 |
| The system should allow viewing the procedure through a stereoscopic system (one viewer for each eye) (Rate from 1 to 5) | 3.67 | 2.07 |
| The system should allow viewing the procedure with a 3D vision screen (Rate from 1 to 5) | 3.83 | 1.83 |
| The system should be connectible to external screens for the rest of the surgical team to visualise (Rate from 1 to 5) | 5.00 | 0.00 |
| The system should allow the rest of the surgical team to view the procedure through 3D HD vision screens (Rate from 1 to 5) | 4.00 | 1.55 |
| The system should allow the rest of the surgical team to view the procedure using Full HD screens. (Rate from 1 to 5) | 4.00 | 1.26 |
| The system should allow the rest of the surgical team to view the procedure via 4K screens. (Rate from 1 to 5) | 3.40 | 1.14 |
| The system must allow the rest of the surgical team to view the procedure via 8K screens. (Rate from 1 to 5) | 2.00 | 1.73 |
| Other needs/issues to be highlighted: | | |
| | | |
| **2.2. Imaging technology** | | |
| The system should allow the capture of the intracorporeal 3D HD image (Rate from 1 to 5) | 4.80 | 0.45 |
| The system should allow the capture of the intracorporeal image in Full HD (1920×1080 pixels) (Rate from 1 to 5) | 4.80 | 0.45 |
| The system should allow intracorporeal image capture in 4K. (Rate from 1 to 5) | 2.60 | 1.67 |
| The system must allow intracorporeal image capture in 8K. (Rate from 1 to 5) | 1.20 | 0.45 |
| The system should allow the use of LIDAR (light detection and ranging) or depth-sensing technology. (Rate from 1 to 5) | 2.67 | 1.53 |
| Minimum and maximum number of frames per second at which the system should allow the surgical scene to be captured (Please complete) | 60 FPS | |
| Minimum and maximum Hertz (Hz) at which the surgical image is to be displayed (Please complete) | >50Hz | |
| The viewing system should allow a field of view of up to 180°. (Rate from 1 to 5) | 2.40 | 1.95 |
| The viewing system should allow a field of view of up to 360°. (Rate from 1 to 5) | 1.20 | 0.45 |
| Optical devices must have a temperature control system (Rate from 1 to 5) | 2.67 | 1.51 |
| Optical devices must have a self-cleaning lens cleaning system (Rate from 1 to 5) | 3.00 | 1.90 |
| Other needs/issues to be highlighted: | | |
| | | |
| **2.3. Recording system** | | |
| The system should allow recording and playing the surgical video in 3D HD (Rate from 1 to 5) | 4.50 | 0.84 |
| The system should allow recording and playing the surgical video in Full HD (Rate from 1 to 5) | 4.83 | 0.41 |
| The system should allow recording and playing the surgical video in 4K. (Rate from 1 to 5) | 2.50 | 1.38 |
| The system must allow recording and subsequent playback of surgical video in 8K. (Rate from 1 to 5) | 1.17 | 0.41 |
| The system should be able to store the movements of the surgical instruments during the surgery (Rate from 1 to 5) | 4.50 | 0.84 |

| | | |
|---|---|---|
| The system should be able to store voice annotations during the surgery (Rate from 1 to 5) | 2.83 | 1.72 |
| The system should be able to store haptic information from instruments during surgery (Rate from 1 to 5) | 3.00 | 1.67 |
| The system should allow recording and playing the virtual (e.g. Augmented Reality) surgical assistance content (Section 2.4) during surgery (Rate from 1 to 5) | 2.67 | 1.63 |
| The system should be able to record and playback image depth information (e.g. LIDAR -Light Detection and Ranging-) (Rate from 1 to 5) | 2.60 | 1.82 |
| Video and data storage facilities to be provided by the system (Please complete) | Unlimited | |
| Video file and data management system to be provided by the system (Please complete) | - | |
| The system should allow live streaming of the surgery (Rate from 1 to 5) | 3.67 | 1.75 |
| Minimum resolution (pixels) at which the system must stream live surgery (Please complete) | FullHD | |
| Other needs/issues to be highlighted: | | |
| | | |
| **2.4. Surgical assistance system** | | |
| The system must provide near-infrared (Fluorescence) imaging (Rate from 1 to 5) | 4.33 | 0.82 |
| The system should allow simultaneous viewing of the actual surgery image and the near-infrared (Fluorescence) image (Rate from 1 to 5) | 3.83 | 1.60 |
| The platform should provide a planning system for the optimal positioning of the trocars according to the surgical procedure to be carried out and the patient (Rate from 1 to 5) | 3.17 | 1.47 |
| The platform should provide a planning system for the optimal positioning of the arms on the trocars according to the surgical procedure to be performed and the patient (Rate from 1 to 5) | 3.33 | 1.63 |
| The system should provide a surgical planning tool based on preoperative studies (Rate from 1 to 5) | 1.83 | 1.17 |
| The system should provide a tool for surgical assistance using Augmented Reality technology (Rate from 1 to 5) | 2.67 | 1.63 |
| The surgical assisting system should be compatible with Mixed Reality technology (Rate from 1 to 5) | 2.50 | 1.52 |
| The system should provide an Artificial Intelligence-based surgical assistance tool. (Rate from 1 to 5) | 2.67 | 1.63 |
| State what kind of assistance would be useful to the surgeon during the surgery (Please complete) | Fluorescence.<br>Surgical table integrated with the system. | |
| Other surgical support systems to be included in the system (Please complete) | Clutch system | |
| The system should provide a collision warning tool between platform arms and between surgical instruments (Rate from 1 to 5) | 3.83 | 1.60 |
| The system should provide a method to move the laparoscopic camera with the movement of the surgeon's head and eyes (Rate from 1 to 5) | 2.00 | 1.67 |
| Other needs/issues to be highlighted: | Collect data for training.<br>Tools for assistance during surgery. | |
| | | |
| **BLOCK 3. CONTROL CONSOLE** | | |
| **3.1. General aspects** | | |

| | | |
|---|---|---|
| The console should be portable (allowing it to be easily moved within and between operating theatres) (Rate from 1 to 5) | 4.75 | 0.46 |
| The console should be compatible with the robotic platform for laparoscopic surgery described in Block 1 (Rate from 1 to 5) | 5.00 | 0.00 |
| The console should be compatible with the laparoscopic instruments described in Block 1 (Rate from 1 to 5) | 4.50 | 1.41 |
| The console should be compatible with display systems based on the screens described in Block 2 (Rate from 1 to 5) | 4.88 | 0.35 |
| The console should be compatible with stereoscopic display systems (one viewer for each eye) described in Block 2. (Rate from 1 to 5) | 3.50 | 2.07 |
| The control console should be open (Rate from 1 to 5) | 3.88 | 1.64 |
| Maximum console size (H x W x D) (Please complete) | Height: 1766.25±281,11 mm<br>Wide: 935.00±69,52 mm<br>Depth: 1145.00±430,31 mm | |
| Type of surgical instrument control manipulator (e.g. Joystick, clamp, laparoscopic instrument handle, etc.) (Please complete) | Thimbles: 42.88%<br>Pistol grip: 14.28%<br>Joystick: 14.28%<br>Thimbles + Pistol grip: 28.57% | |
| Other needs/issues to be highlighted: | | |
| | | |
| **3.2. Functionalities** | | |
| Surgical instrument control manipulators should provide force feedback to the surgeon regarding the interaction of the surgical instruments with the tissues (Rate from 1 to 5) | 2.88 | 1.89 |
| Surgical instrument control manipulators should provide haptic/sensory feedback to the surgeon regarding the interaction of the surgical instruments with the tissues (Rate from 1 to 5) | 2.88 | 1.89 |
| Surgical instrument controls should provide control of the surgeon's tremor when using them (Rate from 1 to 5) | 4.88 | 0.35 |
| Surgical instrument controls should provide for the possibility of scaling movements during the control of the surgical instruments (Rate from 1 to 5) | 5.00 | 0.00 |
| The console should provide the surgeon with a communication system with the rest of the surgical team (Rate from 1 to 5) | 3.63 | 1.77 |
| Types of communication systems with the rest of the surgical team (Please complete) | Audio | |
| The control platform should provide a system for automatic triangulation of surgical instruments (Rate from 1 to 5) | 2.86 | 1.57 |
| Other needs/issues to be highlighted: | | |
| | | |
| **3.3. Economic aspects** | | |
| The control console should be height adjustable (Rate from 1 to 5) | 5.00 | 0.00 |
| The control console should be adapted to below average height surgeons, both male and female (Rate from 1 to 5) | 4.75 | 0.46 |
| The control console should allow for tilt adjustment (Rate from 1 to 5) | 3.13 | 1.89 |
| The control console should allow the proximity of the display system to be regulated (Rate from 1 to 5) | 4.75 | 0.46 |
| The pedals of the control console must be adjustable in position and height according to the surgeon's posture (Rate from 1 to 5) | 3.86 | 1.57 |
| The pedals of the control console should be configurable according to the surgeon's needs (Rate from 1 to 5) | 2.86 | 2.04 |
| The control console should allow being used with conventional surgeon chairs (Rate from 1 to 5) | 4.13 | 1.46 |

| | | |
|---|---|---|
| The control console should be equipped with an ergonomic chair for the surgeon (Rate from 1 to 5) | 3.50 | 1.41 |
| The control console chair should have lockable wheels to facilitate mobility near the console workstation (Rate from 1 to 5) | 3.00 | 1.41 |
| The control console chair should have lumbar support for the surgeon (Rate from 1 to 5) | 4.13 | 0.99 |
| The control console chair must have cervical support for the surgeon (Rate from 1 to 5) | 3.38 | 1.51 |
| The control console should have armrests for the surgeon (Rate from 1 to 5) | 4.13 | 1.25 |
| Surgical instrument controls should allow for adjustment to the surgeon's posture (Rate from 1 to 5) | 4.00 | 1.41 |
| Controls on surgical instruments should be such that they can be adapted to different sizes of hand (Rate from 1 to 5) | 2.88 | 1.64 |
| The surgeon should be able to use the controls of the surgical instruments in both sitting and standing positions (Rate from 1 to 5) | 2.88 | 1.64 |
| The system should allow changing the position of the control manipulators while keeping the position of the surgical instruments fixed with a clutch system (Rate from 1 to 5) | 4.75 | 0.71 |
| The console should provide criteria of adaptability for people with functional diversity (Rate from 1 to 5) | 3.43 | 1.62 |
| Other ergonomic aspects to be highlighted (Please complete) | | |
| Other needs/issues to be highlighted: | | |
| | | |
| **Block 4 Online training tools** | | |
| **4.1. General aspects** | | |
| The platform should be portable (Rate from 1 to 5) | 4.71 | 0.49 |
| Maximum platform size (H x W x D) (Please complete) | Height: 640.14±451.27 mm<br>Wide: 526.00±287.67 mm<br>Depth: 379.00±207.45 mm | |
| The platform should enable training activities to be carried out via cloud computing (Rate from 1 to 5) | 3.63 | 1.06 |
| The platform should have downloadable training software (Rate from 1 to 5) | 3.75 | 0.89 |
| The platform should allow the use of 3D training environments (Rate from 1 to 5) | 4.63 | 0.74 |
| The platform should allow combining virtual content with images/videos of real surgical procedures (Rate from 1 to 5) | 3.75 | 0.71 |
| The platform should have controls that mimic the surgical instrument control manipulators of a real robotic platform for laparoscopic surgery (Rate from 1 to 5) | 4.50 | 1.41 |
| Type of controls allowed (e.g. Mouse, Keyboard, Joystick, haptic interface, commercial control platforms, etc.) (Please complete) | Thimbles: 33.33%<br>Haptic joystick: 33.33% | |
| The training platform should simulate the use of articulated robotic instruments (Rate from 1 to 5) | 4.43 | 1.51 |
| Type of simulated robotic instruments (Please complete) | Same as the robotic platform: 71.42%<br>Tweezers: 28.57%<br>Scissors: 28.57%<br>Needle holder: 14.28%<br>Dissector: 14.28%<br>Hook: 28.57% | |
| The platform must be compatible with mobile devices (Smartphone, Tablet) (Rate from 1 to 5) | 2.75 | 1.91 |

| | | |
|---|---|---|
| The platform should be compatible with desktop or laptop computers (Rate from 1 to 5) | 3.25 | 1.49 |
| The platform should be compatible with Virtual Reality devices (e.g. Oculus, HTC, etc.) (Rate from 1 to 5) | 2.25 | 1.49 |
| Type of viewing technology allowed (e.g. 3D display, Virtual Reality or Mixed Reality Glasses, etc.) (Please complete) | 3D screen: 42.85%<br>Stereoscopic viewfinder: 28.57%<br>RV System: 14.28%<br>The same as the robotic platform: 28.57% | |
| The platform controls should simulate force feedback during the training activities (Rate from 1 to 5) | 2.88 | 1.73 |
| The platform controls should simulate haptic/sensory feedback during the training activities (Rate from 1 to 5) | 3.00 | 1.77 |
| Other needs/issues to be highlighted: | Objective assessment of surgical skills: 33.33% | |
| | | |
| **4.2. Functionalities** | | |
| The platform should simulate basic training tasks in laparoscopic robotic surgery (Rate from 1 to 5) | 5.00 | 0.00 |
| The platform should allow training tasks and procedures in laparoscopic robotic surgery adapted to the user's level of experience (Rate from 1 to 5) | 4.25 | 0.89 |
| The platform should allow training tasks and procedures in laparoscopic robotic surgery adapted to the surgical speciality to be carried out (Rate from 1 to 5) | 3.88 | 0.99 |
| The platform should allow for training in technical skills in laparoscopic robotic surgery (Rate from 1 to 5) | 5.00 | 0.00 |
| The platform should enable training in cognitive skills in laparoscopic robotic surgery (Rate from 1 to 5) | 3.38 | 1.69 |
| The platform should have a scoring/evaluation system (Rate from 1 to 5) | 4.50 | 0.93 |
| The platform should provide mentoring and guided learning (Rate from 1 to 5) | 4.50 | 0.76 |
| The platform should allow for the collection of data on progress (Rate from 1 to 5) | 4.63 | 0.74 |
| The platform should allow the user to update the training activities he/she can carry out (Rate from 1 to 5) | 4.13 | 0.83 |
| Learners can have their own user profile (Rate from 1 to 5) | 4.38 | 0.92 |
| The platform should have a web portal with updated information on the system, demonstrations, new training activities, data on the user's training activity, etc. (Rate from 1 to 5) | 3.75 | 1.58 |
| Other functions that the platform should simulate in terms of robotic platforms for laparoscopic surgery (Please complete) | 5.00 | 0.00 |
| Other needs/issues to be highlighted: | Assessment of cognitive skills. | |

CHALLENGE 1: Expert responses

| | Mean | SD |
|---|---|---|
| **BLOCK 1. ROBOTIC PLATFORM FOR LAPAROSCOPIC SURGERY** | | |
| **1.2. General aspects of robotic surgical instruments** | | |
| Surgical instruments should be compatible with conventional laparoscopic trocars (Rate from 1 to 5) | 2.83 | 1.47 |

| | | |
|---|---|---|
| Surgical instruments shall offer, as a minimum, the following types of actuators (e.g. Gripping forceps, scissors, needle holders, etc.) (Please complete) | Gripping pliers: 100%<br>Scissors: 100%<br>Needle holder: 100%<br>Hook: 40%<br>Clipper: 60%<br>Stapler: 60%<br>Separator: 40% | |
| **1.3. Platform functionalities** | | |
| The platform should allow a single-port surgical approach to be carried out (Please rate from 1 to 5) | 3.17 | 0.75 |
| The platform must allow a surgical approach through natural orifices (Please rate from 1 to 5) | 3.67 | 1.03 |
| **1.4. Functionalities of robotic surgical instruments** | | |
| Surgical instruments should be compatible with active instrument technology (Ligasure™ type) for sealing and haemostasis (Rate from 1 to 5) | 4.80 | 0.45 |
| Surgical instruments should be compatible with ultrasonic scalpel technology (harmonic) (Rate from 1 to 5) | 4.33 | 0.82 |
| Surgical instruments must provide a clip applicator. (Rate from 1 to 5) | 4.33 | 0.82 |
| The clip applicator should allow the use of different sized clips (Rate from 1 to 5) | 4.17 | 0.98 |
| Surgical instruments should provide a mechanical suture applicator (Rate from 1 to 5) | 4.33 | 0.82 |
| Surgical instruments must provide a stapler. (Rate from 1 to 5) | 4.50 | 0.55 |
| Surgical instruments must provide an ultrasound imaging system (Rate from 1 to 5) | 3.83 | 1.17 |
| **BLOCK 2. SURGICAL VISUALISATION AND ASSISTANCE SYSTEM** | | |
| **2.1. General aspects** | | |
| Which 3D viewing system do you prefer: stereoscopic (one viewer for each eye) or 3D viewing screen? (Please complete) | Stereo system: 80%<br>3D screen: 20% | |
| **2.3. Recording system** | | |
| The system should be able to store voice annotations during the surgery (Rate from 1 to 5) | 2.83 | 1.17 |
| The system should allow live streaming of the surgery (Rate from 1 to 5) | 4.33 | 4.33 |
| **2.4. Surgical assistance system** | | |
| The platform should provide a planning system for the optimal positioning of the trocars according to the surgical procedure to be carried out and the patient (Rate from 1 to 5) | 4.00 | 0.63 |
| The platform should provide a planning system for the optimal positioning of the arms on the trocars according to the surgical procedure to be performed and the patient (Rate from 1 to 5) | 4.00 | 0.63 |
| The system should provide a tool for surgical assistance using Augmented Reality technology (Rate from 1 to 5) | 4.33 | 0.52 |
| The system should provide an Artificial Intelligence-based surgical assistance tool. (Rate from 1 to 5) | 3.67 | 1.03 |
| The system should provide a collision warning tool between platform arms and between surgical instruments (Rate from 1 to 5) | 4.00 | 1.26 |
| **BLOCK 3. CONTROL CONSOLE** | | |
| **3.1. General aspects** | | |
| Control console must be opened or closed (Please complete) | Open: 60%<br>Closed: 40% | |
| Type of surgical instrument control manipulator (e.g. Joystick, clamp, laparoscopic instrument handle, etc.) (Please complete) | Thimbles: 100% | |
| **3.2. Functionalities** | | |

| | | |
|---|---|---|
| Surgical instrument control manipulators should provide force feedback to the surgeon regarding the interaction of the surgical instruments with the tissues (Rate from 1 to 5) | 4.20 | 1.30 |
| Surgical instrument control manipulators should provide haptic/sensory feedback to the surgeon regarding the interaction of the surgical instruments with the tissues (Rate from 1 to 5) | 4.20 | 1.30 |
| **3.3. Economic aspects** | | |
| The pedals of the control console must be adjustable in position and height according to the surgeon's posture (Rate from 1 to 5) | 4.67 | 0.52 |
| The pedals of the control console should be configurable according to the surgeon's needs (Rate from 1 to 5) | 4.67 | 0.52 |
| The control console should be equipped with an ergonomic chair for the surgeon (Rate from 1 to 5) | 4.33 | 0.82 |
| The control console chair should have lockable wheels to facilitate mobility near the console workstation (Rate from 1 to 5) | 4.17 | 0.75 |
| The control console chair must have cervical support for the surgeon (Rate from 1 to 5) | 3.00 | 1.22 |
| Controls on surgical instruments should be such that they can be adapted to different sizes of hand (Rate from 1 to 5) | 3.67 | 1.37 |
| The surgeon should be able to use the controls of the surgical instruments in both sitting and standing positions (Rate from 1 to 5) | 1.50 | 0.55 |

CHALLENGE 2: Conclusions of the organisations participating in the PMC

| | **Mean** | **SD** |
|---|---|---|
| **BLOCK 1. ROBOTIC PLATFORM FOR MICROSURGERY** | | |
| **1.1. General aspects** | | |
| The platform should be teleoperated (Rate from 1 to 5) | 5.00 | 0.00 |
| The platform should be portable (Rate from 1 to 5) | 5.00 | 0.00 |
| Form of transporting the platform (Please complete) | Wheels: 100% | |
| Compatibility with the surgical environment (Rating from 1 to 5) | 5.00 | 0.00 |
| Maximum platform size (H x W x D) (Please complete) | Height: 1670.00±240.42 mm<br>635.50±191.63 mm<br>Depth: 862.00±511.95 mm | |
| Maximum radius of action to be achieved by each arm (Please complete) | 285.00±304.06 mm | |
| The platform should be suitable for use with optical surgical microscopes (Rate from 1 to 5) | 5.00 | 0.00 |
| The platform must offer its own viewing system (Rank from 1 to 5) | 3.00 | 0.00 |
| The microsurgery robotic platform (base platform) must be CE-marked as a medical device for surgical use (Rate from 1 to 5) | 5.00 | 0.00 |
| The base platform must be approved by the FDA as a medical device for surgical use (Rating from 1 to 5) | 2.00 | 1.41 |
| TLR level from which the base platform starts (Please complete) | 4.50 ±0.71 | |
| Desirable TLR level in the Project (Please complete) | 7.50 ±0.71 | |
| The robotic platform should be able to carry out specific tasks or procedures autonomously (Rate from 1 to 5) | 1.00 | 0.00 |
| If yes, please detail these tasks/procedures under "Other needs/issues to be highlighted." | | |
| Other needs/issues to be highlighted: | | |
| | | |
| **1.2. Functionalities** | | |
| The platform should be able to switch between robot-assisted microsurgery and conventional microsurgery (Rate from 1 to 5) | 5.00 | 0.00 |

| | | |
|---|---|---|
| The platform should be able to perform microsurgical anastomoses (Rate from 1 to 5) | 5.00 | 0.00 |
| The platform should allow for the manipulation of blood vessels (Rate from 1 to 5) | 5.00 | 0.00 |
| The platform should allow for the manipulation of nerves (Rate from 1 to 5) | 5.00 | 0.00 |
| The platform must allow for the manipulation of lymphatic ducts (Rate from 1 to 5) | 5.00 | 0.00 |
| Other microsurgical procedures to be allowed by the platform (e.g. pedicled free flap reconstruction, lymphatic-venous anastomosis, etc.) (Please complete) | Eye surgery (Vitrectomy);<br>Lymphatic-venous anastomoses;<br>Perforator flaps (Supermicrosurgery) | |
| The platform should allow microsurgical anastomosis to be performed (Rate from 1 to 5) | 5.00 | 0.00 |
| Other needs/issues to be highlighted: | | |
| | | |
| **BLOCK 2. ROBOTIC MICRO-INSTRUMENTS** | | |
| **2.1. General aspects** | | |
| The tip of the surgical micro-instruments should be articulated (Rate from 1 to 5) | 5.00 | 0.00 |
| Minimum number of degrees of freedom of surgical micro-instruments (Please complete) | 7 DoF | |
| Surgical micro-instruments should be reusable - sterilisable - (Rate from 1 to 5) | 3.50 | 2.12 |
| Minimum uses of surgical micro-instruments (Please complete) | 5.50±6.36 mm | |
| Maximum diameter of surgical micro-instrument shank (Please complete) | 4 mm | |
| Maximum diameter of surgical micro-instrument actuator tip (Please complete) | 0.7 mm | |
| Surgical micro-instruments should offer the following types of actuators at least (e.g. tweezers, scissors, needle holders, etc.) (Please complete) | Needle holder;<br>Dilating forceps;<br>Scissors; | |
| Surgical micro-instruments should have a minimum accuracy of movement of (mm, degrees): (Please complete) | Translation: <0.1mm<br>Rotation: <3 degrees | |
| Other needs/issues to be highlighted: | | |
| | | |
| **2.2. Functionalities** | | |
| Surgical micro-instruments should allow for bipolar coagulation (Rate from 1 to 5) | 4.50 | 0.71 |
| Micro-instruments should be compatible with the technology that provides force feedback to the surgeon (Rate from 1 to 5) | 3.00 | 2.83 |
| Micro-instruments should be compatible with the technology that provides haptic/sensory feedback to the surgeon (Rate from 1 to 5) | 3.00 | 2.83 |
| Surgical micro-instruments should be interchangeable. (Rate from 1 to 5) | 5.00 | 0.00 |
| Surgical micro-instruments should be compatible with conventional laparoscopic instruments (Rate from 1 to 5) | 3.00 | 2.83 |
| The system should allow only the actuator of the microsurgical instruments to be changed (Rate from 1 to 5) | 3.00 | 0.00 |
| Microsurgical instruments must be suitable for handling 8-0 (0.040-0.049 mm) to 12-0 (0.001-0.009 mm) sutures (Rate from 1 to 5) | 5.00 | 0.00 |
| Microsurgical instruments should be anti-ferromagnetic or allow for demagnetisation (Rate from 1 to 5) | 5.00 | 0.00 |
| Other needs/issues to be highlighted: | | |

| | | |
|---|---|---|
| **BLOCK 3. CONTROL CONSOLE** | | |
| **3.1. General aspects** | | |
| The console should be compatible with the microsurgical instruments described in Block 1 (Rate from 1 to 5) | 5.00 | 0.00 |
| The control console should be open (Rate from 1 to 5) | 3.67 | 1.15 |
| Type of microsurgical instrument control manipulator (e.g. Joystick, clamp, microsurgical instrument handle, etc.) (Please complete) | Imitating microsurgical instruments: 100% | |
| Other needs/issues to be highlighted: | | |
| | | |
| **3.2. Functionalities** | | |
| The console should have an intuitive control system for robotic micro-instruments (Rate from 1 to 5) | 5.00 | 0.00 |
| Microsurgical instrument control manipulators should provide force feedback to the surgeon regarding their interaction with the tissues (Rate from 1 to 5) | 3.00 | 2.00 |
| Microsurgical instrument control manipulators should provide haptic/sensory feedback to the surgeon regarding their interaction with the tissues (Rate from 1 to 5) | 3.00 | 2.00 |
| Microsurgical instrument controls should provide control of the tremor during the use (Rate from 1 to 5) | 5.00 | 0.00 |
| Microsurgical instrument controls should provide for the possibility of scaling movements during their control (Rate from 1 to 5) | 5.00 | 0.00 |
| Minimum allowable movement scaling factor (Please complete) | 5x | |
| Other needs/issues to be highlighted: | | |
| | | |
| **3.3. Economic aspects** | | |
| The control console should be height adjustable (Rate from 1 to 5) | 4.67 | 0.58 |
| The control console should allow for tilt adjustment (Rate from 1 to 5) | 4.33 | 1.15 |
| The control console should allow being used with conventional (microsurgery) surgeon chairs (Rate from 1 to 5) | 3.67 | 1.53 |
| The control console should be equipped with an ergonomic chair for the surgeon (Rate from 1 to 5) | 4.67 | 0.58 |
| The control console should have armrests for the surgeon (Rate from 1 to 5) | 4.67 | 0.58 |
| Microsurgical instrument controls should allow for adjustment to the surgeon's posture (Rate from 1 to 5) | 4.67 | 0.58 |
| Controls on microsurgical instruments should be such that they can be adapted to different hand sizes (Rating 1-5) | 4.33 | 1.15 |
| The pedals of the control console must be adjustable in position and height according to the surgeon's posture (Rate from 1 to 5) | 4.33 | 1.15 |
| The pedals of the control console should be configurable according to the surgeon's needs (Rate from 1 to 5) | 3.67 | 2.31 |
| Other needs/issues to be highlighted: | | |

CHALLENGE 2: Expert responses

| | Mean | SD |
|---|---|---|
| **BLOCK 1. ROBOTIC PLATFORM FOR MICROSURGERY** | | |
| **1.2. Functionalities** | | |
| Other microsurgical procedures to be allowed by the platform (e.g. pedicled free flap reconstruction, lymphatic-venous anastomosis, etc.) (Please complete) | Lymphatic-venous anastomoses: 66.67%<br>Vascular anastomoses: 66.67% | |
| **BLOCK 2. ROBOTIC MICRO-INSTRUMENTS** | | |
| **2.1. General aspects** | | |
| Surgical micro-instruments should offer the following types of actuators at least (e.g. tweezers, scissors, needle holders, etc.) (Please complete) | Needle holder: 100%<br>Dilating forceps: 100%<br>Tweezers: 100%<br>Scissors: 50% | |
| **2.2. Functionalities** | | |
| Surgical micro-instruments should be compatible with conventional laparoscopic instruments (Rate from 1 to 5) | 4.33 | 1.15 |
| **BLOCK 3. CONTROL CONSOLE** | | |
| **3.2. Functionalities** | | |
| Microsurgical instrument control manipulators should provide force feedback to the surgeon regarding their interaction with the tissues (Rate from 1 to 5) | 5.00 | 0.00 |
| Microsurgical instrument control manipulators should provide haptic/sensory feedback to the surgeon regarding their interaction with the tissues (Rate from 1 to 5) | 3.33 | 1.53 |
| **3.3. Economic aspects** | | |
| The control console should allow being used with conventional microsurgery surgeon chairs (Rate from 1 to 5) | 3.67 | 1.15 |
| The pedals of the control console should be configurable according to the surgeon's needs (Rate from 1 to 5) | 4.00 | 1.00 |

Updated budget of the challenges

The last part of the interviews aimed to discover the organisations' considerations on the costs related to each block of the two challenges, especially after the TRL data mentioned in the interviews. This allowed the Project team to update the average amounts proposed for each block. These amounts do not condition or limit the final budget of the tenders.

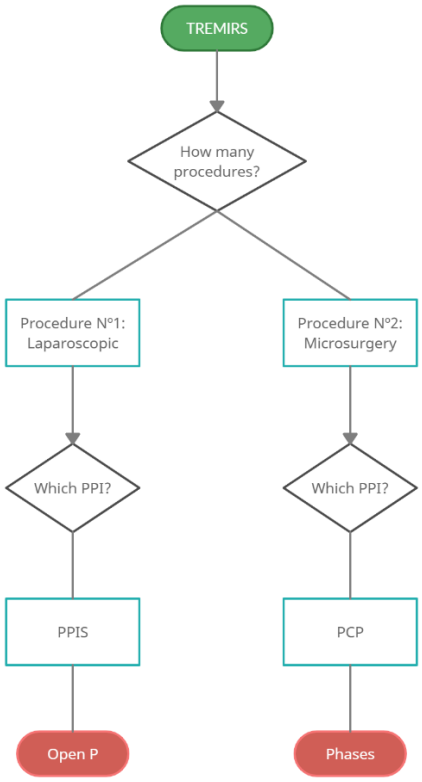
*Challenge 1. A robotic platform for laparoscopic surgery and Challenge 2. A robotic platform for microsurgery.*

| Section Nº 1. Robotic platform for laparoscopic surgery. | Section Nº 2. Surgical visualization and assistance system. | Section Nº 3. Control console | Section Nº 4. Portable training tools. |
|---|---|---|---|
| 1.276.000,00 € | 385.000,00 € | 953.000,00 € | 522.857,14 € |

Average budgets of the three blocks for the challenge of microsurgery

| Section Nº 1. Robotic platform for microsurgery | Section Nº 2. Robotic microinstruments. | Section Nº 3. Control console |
|---|---|---|
| 852.500,00 € | 425.000,00 € | 685.000,00 € |

## 4.3 Early demand map and characteristics of future tenders




Considering the results and conclusions of the Consultation, along with the recruitment planning carried out by the Project team, **a first draft of the early demand map is developed below, which will allow the market to anticipate the recruitment plans designed by the Jesús Usón Minimally Invasive Surgery Centre (JUMISC)** for the different challenges.

The following data result from theoretical and practical workshops held between the Technical Office and the JUMISC team, in which different group exercises were developed, supported by digital tools, to define the contracting plans considering the vision of all those involved, especially the technical vision of the Project and the administrative-legal vision.

The image on the left results from an internal team discussion that started with the following question: How many procedures are necessary to efficiently achieve the Project's objectives?

Based on this initial question, the Technical Office's own methodology allowed the JUMISC team to define the types of PPI and procedures according to the objectives and reality of each challenge. The results obtained from these exercises are presented in the table below

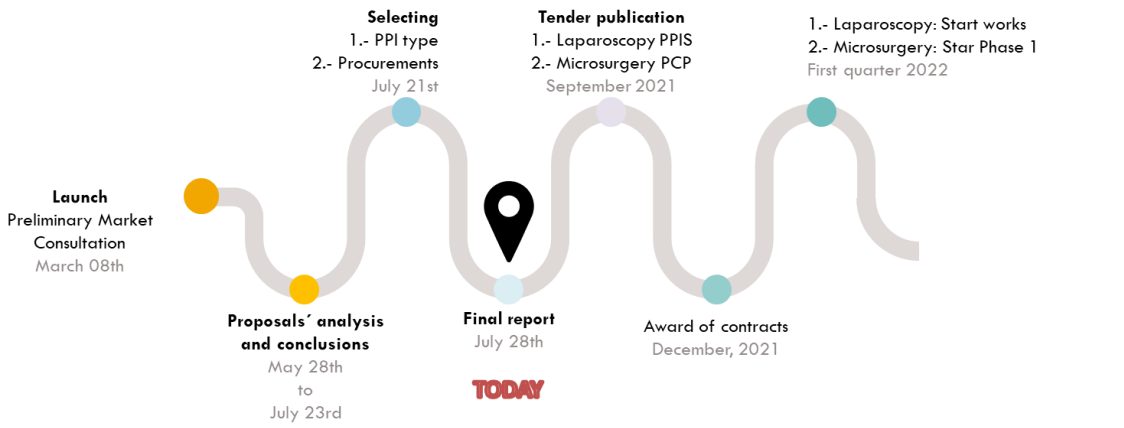
| Challenge | Type of PPI | Procedure | Batch |
|---|---|---|---|
| **Challenge 1. A robotic platform for laparoscopic surgery** | Public Procurement of Innovative Technology (PPI) | Open | Batch 1: Solution<br>Batch 2: Online training tool |
| **Challenge 2. A robotic platform for microsurgery** | Pre-commercial Public Procurement | Outside the LCSP/2017 | No batch |

### Estimated timetable for the publication of tender documents

Sufficient information appears to have been gathered to close the Consultation on each challenge that makes up this Project and move on to the possible drafting of specifications.

Furthermore, in view of the results of the Preliminary Market Consultation, the information obtained from it, the implementation deadlines and considering the deadlines imposed by the schedule of the IDF and ERDF calls for proposals, the corresponding calls for tenders should be performed soon.

Below is the preliminary schedule detailing the possible tendering process.




**NOTE: the dates given here are indicative and may be subject to change*

## Project funding

This contract is co-financed by the European Regional Development Fund (ERDF) included in the ERDF Operational Programme 2014-2020 of the Ministry of Science and Innovation. Up to 7,345,300.00 euros, of which 80% will be provided by the Spanish Pluriregional Operational Programme (POPE) 2014-2020 through the Agreement signed) and by the Regional Ministry of Economy, Science and Digital Agenda of the Regional Government of Extremadura.

Where appropriate, it shall be included in the public list provided for in Article 115(2) of Regulation (EU) No.1303/201 and the successful tenderer of the contract shall be subject to the information and publicity obligations contained in that Regulation in the Communication Plan of the ERDF Operational Programmes.

# 5. ANNEXES

# 5. Annexes

## 5.1 Annex 1: Preliminary Market Consultation Form for Challenge 1 A robotic platform for laparoscopic surgery

### 1. APPLICANT INFORMATION

| | | | |
|---|---|---|---|
| Company/Organisation*: | | | |
| Individual*: | ☐ | | |
| Legal person*: | ☐ | | |
| A joint proposal from several natural or legal persons*: | ☐ Yes | ☐ No | |
| Sector or field of activity (CNAE) *: | | | |
| Organisations' main activities: | | | |
| Size of your organisation at present (No. of staff): | | | |
| Total turnover of your organisation in the last years | 2020 | 2019 | 2018 |
| | | | |
| Name and Surname of the interlocutor (or representative in case of joint solution)*: | | | |
| Position of the interlocutor: | | | |
| Telephone number*: | | | |
| Email*: | | | |
| **BASIC DETAILS OF THE PROPOSAL** | | | |
| Proposal title: | | | |
| Do you intend to apply for future tenders related to the challenge(s) you are applying for? | ☐ Yes<br>☐ No | | |

*** Mandatory field**

### BLOCK 1. ROBOTIC PLATFORM FOR LAPAROSCOPIC SURGERY

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

For each section, please **complete or rate (from 1 -not at all important- to 5 -essential-)** the degree of need for each of the criteria stated.

### 1.1. General aspects of the platform

| | Assessment |
|---|---|
| The platform should be teleoperated *(Rate from 1 to 5)* | |
| The platform should be portable (allowing it to be easily moved within and between operating theatres) *(Rate from 1 to 5)* | |
| Form of transporting the platform *(Please complete)* | |
| Compatibility with the surgical environment *(Rate from 1 to 5)* | |
| The platform should be modular (with independent arms) *(Rate from 1 to 5)* | |
| Minimum number of arms on the platform *(Please complete)* | |
| Maximum number of arms allowed on the platform *(Please complete)* | |
| Maximum platform size (Height x Width x Depth) (Please complete) | |
| Maximum radius of action to be achieved by each arm (Please complete) | |
| Maximum size of each arm, including its base, if available (Height x Width x Depth) *(Please complete)* | |
| The laparoscopic robotic platform (base platform) must be CE-marked as a medical device for surgical use *(Rate from 1 to 5)* | |
| The base platform must be approved by the FDA as a medical device for surgical use *(Rate from 1 to 5)* | |
| TLR [1]level from which the base platform starts *(Please complete)* | |
| Desirable TLR level in the Project *(Please complete)* | |
| The robotic platform should be able to carry out certain tasks or procedures autonomously *(Rate from 1 to 5)*<br>If yes, please detail these tasks/procedures under "Other needs/issues to be highlighted." | |

Other needs/issues to be highlighted:

| |
|---|
| |

### 1.2. General aspects of robotic surgical instruments

| | Assessment |
|---|---|
| The tip of the surgical instruments should be articulated *(Rate from 1 to 5)* | |
| Minimum number of degrees of freedom of surgical instruments *(Please complete)* | |
| Surgical instruments should be compatible with conventional laparoscopic trocars *(Rate from 1 to 5)* | |
| Surgical instruments should be reusable - sterilisable - *(Rate from 1 to 5)* | |
| Minimum number of uses of the surgical instruments *(Please complete)* | |

[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

| | |
|---|---|
| Maximum diameter of surgical instrument shank *(Please complete)* | |
| Maximum diameter of surgical instrument actuator tip *(Please complete)* | |
| Surgical instruments shall offer, as a minimum, the following types of actuators (e.g. Gripping forceps, scissors, needle holders, etc.) *(Please complete)* | |
| Surgical instruments shall have a minimum accuracy of movement of (mm, degrees): *(Please complete)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

### 1.3. Platform functionalities

| | **Assessment** |
|---|---|
| The platform should be allow for 5G connectivity *(Rate from 1 to 5)* | |
| The platform should allow for digestive system surgeries to be performed *(Rate from 1 to 5)* | |
| The platform should allow for urological surgeries to be performed *(Rate from 1 to 5)* | |
| The platform should allow for gynaecological surgeries to be performed (Rate from 1 to 5) | |
| The platform should allow for chest surgeries to be performed *(Rate from 1 to 5)* | |
| The platform should allow a single-port surgical approach to be carried out (Rate from 1 to 5) | |
| The platform should allow a surgical approach through natural orifices (Rate from 1 to 5) | |
| Maximum time required for complete assembly and set-up of the platform (Please complete) | |

Other needs/issues to be highlighted:

| |
|---|
| |

### 1.4. Functionalities of robotic surgical instruments

| | **Assessment** |
|---|---|
| Surgical instruments should allow for monopolar coagulation *(Rate from 1 to 5)* | |
| Surgical instruments should allow for bipolar coagulation *(Rate from 1 to 5)* | |
| Surgical instruments should be compatible with Ligasure™ for sealing and haemostasis *(Rate from 1 to 5)* | |
| Surgical instruments should be compatible with harmonic cutting technology (ultrasound) *(Rate from 1 to 5)* | |
| Surgical instruments should provide a clip applicator *(Rate from 1 to 5)* | |
| The clip applicator should allow the use of different sized clips *(Rate from 1 to 5)* | |
| Surgical instruments should provide a mechanical suture applicator *(Rate from 1 to 5)* | |

| | |
|---|---|
| Surgical instruments should provide a stapler *(Rate from 1 to 5)* | |
| Surgical instruments must provide ultrasound imaging system *(Rate from 1 to 5)* | |
| Instruments should be compatible with technology that provides force feedback to the surgeon *(Rate from 1 to 5)* | |
| Instruments should be compatible with technology that provides haptic/sensory feedback to the surgeon *(Rate from 1 to 5)* | |
| Surgical instruments should be interchangeable *(Rate from 1 to 5)* | |
| Surgical instruments should be compatible with conventional laparoscopic instruments *(Rate from 1 to 5)* | |
| The system should be compatible with the instruments of other robotic platforms for laparoscopy *(Rate from 1 to 5)* | |
| The system should allow only the actuator of the surgical instruments to be changed *(Rate from 1 to 5)* | |
| Maximum time required for the change of surgical instruments *(Please complete)* | |
| Surgical instruments should be anti-ferromagnetic or allow for demagnetisation *(Rate from 1 to 5)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

## BLOCK 2. SURGICAL VIEWING AND ASSISTANCE SYSTEM

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

For each section, please **complete or rate (from 1 -not at all important- to 5 -essential-)** the degree of need for each of the criteria stated.

### 2.1. General aspects

| | **Assessment** |
|---|---|
| The viewing system should be height adjustable to suit the surgeon's posture (*Rate from 1 to 5)* | |
| The system should allow viewing the procedure through a stereoscopic system (one viewer for each eye) *(Rate from 1 to 5)* | |
| The system should allow viewing the procedure with a 3D vision screen *(Rate from 1 to 5)* | |
| The system should be connectible to external screens for the rest of the surgical team to visualise *(Rate from 1 to 5)* | |
| The system should allow the rest of the surgical team to visualise the procedure through 3D HD vision screens *(Rate from 1 to 5)* | |
| The system should allow the rest of the surgical team to view the procedure using Full HD screens *(Rate from 1 to 5)* | |
| The system should allow the rest of the surgical team to view the procedure via 4K screens *(Rate from 1 to 5)* | |
| The system should allow the rest of the surgical team to view the procedure via 8K screens *(Rate from 1 to 5)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

### 2.2. Imaging technology

| | Assessment |
|---|---|
| The system should allow the capture of the intracorporeal 3D HD image *(Rate from 1 to 5)* | |
| The system should allow the capture of the intracorporeal image in Full HD (1920×1080 pixels) *(Rate from 1 to 5)* | |
| The system should allow intracorporeal image capture in 4K *(Rate from 1 to 5)* | |
| The system should allow intracorporeal image capture in 8K *(Rate from 1 to 5)* | |
| The system should allow the use of LIDAR (light detection and ranging) or depth-sensing technology *(Rate from 1 to 5)* | |
| Minimum and maximum number of frames per second at which the system should allow the surgical scene to be captured *(Please complete)* | |
| Minimum and maximum Hertz (Hz) at which the surgical image is to be displayed *(Please complete)* | |
| The viewing system should allow a field of view of up to 180° *(Rate from 1 to 5)* | |
| The viewing system should allow a field of view of up to 360° *(Rate from 1 to 5)* | |
| Optical devices must have a temperature control system *(Rate from 1 to 5)* | |
| Optical devices must have a self-cleaning lens cleaning system *(Rate from 1 to 5)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

### 2.3. Recording system

| | Assessment |
|---|---|
| The system should allow for recording and subsequent playback of surgical video in 3D HD *(Rate from 1 to 5)* | |
| The system should allow recording and subsequent playback of surgical video in Full HD *(Rate from 1 to 5)* | |
| The system should allow recording and subsequent playback of surgical video in 4K. *(Rate from 1 to 5)* | |
| The system should allow recording and subsequent playback of surgical video in 8K. *(Rate from 1 to 5)* | |
| The system should be able to store the movements of the surgical instruments during the surgery *(Rate from 1 to 5)* | |
| The system should be able to store voice annotations during the surgery *(Rate from 1 to 5)* | |
| The system should be able to store haptic information from instruments during surgery *(Rate from 1 to 5)* | |

| | |
|---|---|
| The system should allow the recording and subsequent playback of virtual (e.g. Augmented Reality) surgical assistance content (Section 2.4) during surgery *(Rate from 1 to 5)* | |
| The system should be able to record and playback image depth information (e.g. LIDAR -Light Detection and Ranging-) *(Rate from 1 to 5)* | |
| Video and data storage facilities to be provided by the system *(Please complete)* | |
| Video file and data management system to be provided by the system *(Please complete)* | |
| The system should allow live streaming of the surgery *(Rate from 1 to 5)* | |
| Minimum resolution (pixels) at which the system must stream live surgery *(Please complete)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

### 2.4. Surgical assistance system

| | **Assessment** |
|---|---|
| The system must provide near-infrared (Fluorescence) imaging *(Rate from 1 to 5)* | |
| The system should allow simultaneous viewing of the actual surgery image and the near-infrared (Fluorescence) image *(Rate from 1 to 5)* | |
| The platform should provide a planning system for the optimal positioning of the trocars according to the surgical procedure to be carried out and the patient *(Rate from 1 to 5)* | |
| The platform should provide a planning system for the optimal positioning of the arms on the trocars according to the surgical procedure to be performed and the patient *(Rate from 1 to 5)* | |
| The system should provide a surgical planning tool based on preoperative studies *(Rate from 1 to 5)* | |
| The system should provide a tool for surgical assistance using Augmented Reality technology (Rate from 1 to 5) | |
| The surgical assisting system should be compatible with Mixed Reality technology *(Rate from 1 to 5)* | |
| The system should provide an Artificial Intelligence-based surgical assistance tool *(Rate from 1 to 5)* | |
| State what kind of assistance would be useful to the surgeon during the surgery (*Please complete)* | |
| Other surgical support systems to be included in the system *(Please complete)* | |
| The system should provide a collision warning tool between platform arms and between surgical instruments *(Rate from 1 to 5)* | |
| The system should provide a method to move the laparoscopic camera by movement of the surgeon's head and eyes *(Rate from 1 to 5)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

## BLOCK 3. CONTROL CONSOLE

This block aims 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 section, please **complete or rate (from 1 -not at all important- to 5 -essential-)** the degree of need for each of the criteria stated.

### 3.1. General aspects

| | Assessment |
|---|---|
| The console should be portable (allowing it to be easily moved within and between operating theatres) *(Rate from 1 to 5)* | |
| The console should be compatible with the robotic platform for laparoscopic surgery described in Block 1 *(Rate from 1 to 5)* | |
| The console should be compatible with the laparoscopic instruments described in Block 1 *(Rate from 1 to 5)* | |
| The console should be compatible with display systems based on the use of screens described in Block 2 *(Rate from 1 to 5)* | |
| The console should be compatible with stereoscopic display systems (one viewer for each eye) described in Block 2 *(Rate from 1 to 5)* | |
| The control console should be open *(Rate from 1 to 5)* | |
| Maximum console size (H x W x D) *(Please complete)* | |
| Type of manipulator controlling the surgical instruments (e.g. Joystick, forceps, laparoscopic instrument handle, etc.) (*Please complete*) | |

Other needs/issues to be highlighted:

| |
|---|
| |

### 3.2. Functionalities

| | Assessment |
|---|---|
| Surgical instrument control manipulators should provide force feedback to the surgeon regarding the interaction of the surgical instruments with the tissues *(Rate from 1 to 5)* | |
| Surgical instrument control manipulators should provide haptic/sensory feedback to the surgeon regarding the interaction of the surgical instruments with the tissues *(Rate from 1 to 5)* | |
| Surgical instrument controls should provide control of the surgeon's tremor during the use of surgical instruments *(Rate from 1 to 5)* | |
| Surgical instrument controls should provide for the possibility of scaling movements during the control of the surgical instruments *(Rate from 1 to 5)* | |
| The console should provide the surgeon with a communication system with the rest of the surgical team *(Rate from 1 to 5)* | |
| Types of communication systems with the rest of the surgical team *(Please complete)* | |
| The control platform should provide a system for automatic triangulation of surgical instruments *(Rate from 1 to 5)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

| |
|---|
| |

### 3.3. Economic aspects

| | Assessment |
|---|---|
| The control console should be height adjustable *(Rate from 1 to 5)* | |
| The control console should be adapted to below average height surgeons, both male and female *(Rate from 1 to 5)* | |
| The control console should allow for tilt adjustment *(Rate from 1 to 5)* | |
| The control console should allow the proximity of the display system to be regulated *(Rate from 1 to 5)* | |
| The pedals of the control console must be adjustable in position and height according to the surgeon's posture *(Rate from 1 to 5)* | |
| The pedals of the control console should be configurable according to the surgeon's needs *(Rate from 1 to 5)* | |
| The control console should allow being used with conventional surgeon chairs *(Rate from 1 to 5)* | |
| The control console should be equipped with an ergonomic chair for the surgeon *(Rate from 1 to 5)* | |
| The control console chair should have lockable wheels to facilitate mobility near the console workstation *(Rate from 1 to 5)* | |
| The control console chair should have lumbar support for the surgeon *(Rate from 1 to 5)* | |
| The control console chair must have cervical support for the surgeon *(Rate from 1 to 5)* | |
| The control console should have armrests for the surgeon *(Rate from 1 to 5)* | |
| Surgical instrument controls should allow for adjustment to the surgeon's posture *(Rate from 1 to 5)* | |
| Controls on surgical instruments should be such that they can be adapted to different sizes of hand *(Rate from 1 to 5)* | |
| The surgeon should be able to use the controls of the surgical instruments in both sitting and standing positions *(Rate from 1 to 5)* | |
| The system should allow changing the position of the control manipulators while keeping the position of the surgical instruments fixed with a clutch system *(Rate from 1 to 5)* | |
| The console should provide criteria of adaptability for people with functional diversity *(Rate from 1 to 5)* | |
| Other ergonomic aspects to be highlighted *(Please complete)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

## BLOCK 4. ONLINE TRAINING TOOL

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

For each section, please **complete or rate (from 1 -not at all important- to 5 -essential-)** the degree of need for each of the criteria stated.

### 4.1. General aspects

| | **Assessment** |
|---|---|
| The platform should be portable *(Rate from 1 to 5)* | |
| Maximum platform size (Height x Width x Depth) *(Please complete)* | |
| The platform should enable training activities to be carried out via cloud computing *(Rate from 1 to 5)* | |
| The platform should have downloadable training software *(Rate from 1 to 5)* | |
| The platform should allow the use of 3D training environments *(Rate from 1 to 5)* | |
| The platform should allow combining virtual content with images/videos of real surgical procedures *(Rate from 1 to 5)* | |
| The platform should have controls that mimic the surgical instrument control manipulators of a real robotic platform for laparoscopic surgery *(Rate from 1 to 5)* | |
| Type of controls allowed (e.g. Mouse, Keyboard, Joystick, haptic interface, commercial control platforms, etc.) *(Please complete)* | |
| The training platform should simulate the use of flexible robotic instruments *(Rate from 1 to 5)* | |
| Type of simulated robotic instruments *(Please complete)* | |
| The platform must be compatible with mobile devices (Smartphone, Tablet) *(Rate from 1 to 5)* | |
| The platform should be compatible with desktop or laptop computers *(Rate from 1 to 5)* | |
| The platform should be compatible with Virtual Reality devices (e.g. Oculus, HTC, etc.) *(Rate from 1 to 5)* | |
| Type of viewing technology allowed (e.g. 3D display, Virtual Reality or Mixed Reality Glasses, etc.) *(Please complete)* | |
| The platform controls should simulate force feedback during the training activities *(Rate from 1 to 5)* | |
| The platform controls should simulate haptic/sensory feedback during the training activities *(Rate from 1 to 5)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

### 4.2. Functionalities

| | Assessment |
|---|---|
| The platform should simulate basic training tasks in laparoscopic robotic surgery *(Rate from 1 to 5)* | |
| The platform should allow training tasks and procedures in laparoscopic robotic surgery adapted to the user's level of experience *(Rate from 1 to 5)* | |
| The platform should allow training tasks and procedures in laparoscopic robotic surgery adapted to the surgical speciality to be carried out *(Rate from 1 to 5)* | |
| The platform should allow for training in technical skills in laparoscopic robotic surgery *(Rate from 1 to 5)* | |
| The platform should enable training in cognitive skills in laparoscopic robotic surgery *(Rate from 1 to 5)* | |
| The platform should have a scoring/evaluation system *(Rate from 1 to 5)* | |
| The platform should provide mentoring and guided learning *(Rate from 1 to 5)* | |
| The platform should allow for the collection of data on progress *(Rate from 1 to 5)* | |
| The platform should allow the user to update the training activities that he/she can carry out *(Rate from 1 to 5)* | |
| Learners can have their own user profile *(Rate from 1 to 5)* | |
| The platform should have a web portal with updated information on the system, demonstrations, new training activities, data on the user's training activity, etc. *(Rate from 1 to 5)* | |
| Other functions that the platform should simulate with respect to robotic platforms for laparoscopic surgery *(Please complete)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

## ADDITIONAL INFORMATION BLOCK ASSESSMENT OF THE WORKS

| ESTIMATED BUDGET FOR COSTS ASSOCIATED WITH THE DEVELOPMENT OF EACH BLOCK | |
|---|---|
| BLOCK 1. ROBOTIC PLATFORM FOR LAPAROSCOPIC SURGERY | |
| BLOCK 2. SURGICAL VIEWING AND ASSISTANCE SYSTEM | |
| BLOCK 3. CONTROL CONSOLE | |
| BLOCK 4. ONLINE TRAINING TOOL | |

| | |
|---|---|
| Please indicate in which blocks you would be willing to participate: | ☐ BLOCK 1. ROBOTIC PLATFORM FOR LAPAROSCOPIC SURGERY |
| | ☐ BLOCK 2. SURGICAL VIEWING AND ASSISTANCE SYSTEM |
| | ☐ BLOCK 3. CONTROL CONSOLE |
| | ☐ BLOCK 4. ONLINE TRAINING TOOL |
| Justify the above answer | |

## 5.2 Annex 2: Preliminary Market Consultation Form for Challenge 1 A robotic platform for microsurgery

### 1. APPLICANT INFORMATION

| | | | |
|---|---|---|---|
| Company/Organisation*: | | | |
| Individual*: | ☐ | | |
| Legal person*: | ☐ | | |
| A joint proposal from several natural or legal persons*: | ☐ Yes | ☐ No | |
| Sector or field of activity (CNAE) *: | | | |
| Organisations' main activities: | | | |
| Size of your organisation at present (No. of staff): | | | |
| Total turnover of your organisation in the last years | 2020 | 2019 | 2018 |
| | | | |
| Name and Surname of the interlocutor (or representative in case of joint solution)*: | | | |
| Position of the interlocutor: | | | |
| Telephone number*: | | | |
| Email*: | | | |
| **BASIC DETAILS OF THE PROPOSAL** | | | |
| Proposal title: | | | |
| Do you intend to apply for future tenders related to the challenge(s) you are applying for? | ☐ Yes<br>☐ No | | |

*** Mandatory field**

## BLOCK 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 section, please **complete or rate (from 1 -not at all important- to 5 -essential-)** the degree of need for each of the criteria stated.

### 1.1. General aspects

| | **Assessment** |
|---|---|
| The platform should be teleoperated *(Rate from 1 to 5)* | |
| The platform should be portable *(Rate from 1 to 5)* | |
| Form of transporting the platform *(Please complete)* | |
| Compatibility with the surgical environment *(Rate from 1 to 5)* | |
| Maximum platform size (Height x Width x Depth) *(Please complete)* | |
| Maximum radius of action to be achieved by each arm *(Please complete)* | |
| The platform should be suitable for use with optical surgical microscopes *(Rate from 1 to 5)* | |
| The platform must offer its own viewing system *(Rank from 1 to 5)* | |
| The microsurgery robotic platform (base platform) must be CE-marked as a medical device for surgical use *(Rate from 1 to 5)* | |
| The base platform must be approved by the FDA as a medical device for surgical use *(Rating from 1 to 5)* | |
| TLR [2]level from which the base platform starts *(Please complete)* | |
| Desirable TLR level in the Project *(Please complete)* | |
| The robotic platform should be able to carry out specific tasks or procedures autonomously *(Rate from 1 to 5)*<br>If yes, please detail these tasks/procedures under "Other needs/issues to be highlighted." | |

Other needs/issues to be highlighted:

| |
|---|
| |

[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

### 1.2. Functionalities

| | Assessment |
|---|---|
| The platform should be able to switch between robot-assisted microsurgery and conventional microsurgery *(Rate from 1 to 5)* | |
| The platform must be able to perform microsurgical anastomosis *(Rate from 1 to 5)* | |
| The platform must allow for the manipulation of blood vessels *(Rate from 1 to 5)* | |
| The platform must allow for the manipulation of lymphatic ducts *(Rate from 1 to 5)* | |
| The platform must allow for the manipulation of lymphatic ducts *(Rate from 1 to 5)* | |
| Other microsurgical procedures to be allowed by the platform (e.g. pedicled free flap reconstruction, lymphatic-venous anastomosis, etc.) *(Please complete)* | |
| The platform should allow microsurgical anastomosis to be performed *(Rate from 1 to 5)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

## BLOCK 2. ROBOTIC MICRO-INSTRUMENTS

This block aims to identify the general aspects that should define the surgical micro-instruments of the robotic platform for microsurgery to be developed in the TREMIRS project.

For each section, please **complete or rate (from 1 -not at all important- to 5 -essential-)** the degree of need for each of the criteria stated.

### 2.1. General aspects

| | Assessment |
|---|---|
| The tip of the surgical micro-instruments should be articulated *(Rate from 1 to 5)* | |
| Minimum number of degrees of freedom of surgical micro-instruments *(Please complete)* | |
| Surgical micro-instruments should be reusable - sterilisable - *(Rate from 1 to 5)* | |
| Minimum uses of surgical micro-instruments *(Please complete)* | |
| Maximum diameter of surgical micro-instrument shank *(Please complete)* | |
| Maximum diameter of surgical micro-instrument actuator tip *(Please complete)* | |
| Surgical micro-instruments should offer the following types of actuators at least (e.g. tweezers, scissors, needle holders, etc.) *(Please complete)* | |
| Surgical micro-instruments should have a minimum accuracy of movement of (mm, degrees): *(Please complete)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

### 2.2. Functionalities

| | Assessment |
|---|---|
| Surgical micro-instruments should allow for bipolar coagulation *(Rate from 1 to 5)* | |
| Micro-instruments should be compatible with technology that provides force feedback to the surgeon *(Rate from 1 to 5)* | |
| Micro-instruments should be compatible with technology that provides haptic/sensory feedback to the surgeon *(Rate from 1 to 5)* | |
| Surgical micro-instruments should be interchangeable *(Rate from 1 to 5)* | |
| Surgical micro-instruments should be compatible with conventional laparoscopic instruments *(Rate from 1 to 5)* | |
| The system should allow only the actuator of the microsurgical instruments to be changed *(Rate from 1 to 5)* | |
| Microsurgical instruments must be suitable for handling 8-0 (0.040-0.049 mm) to 12-0 (0.001-0.009 mm) sutures *(Rate from 1 to 5)* | |
| Microsurgical instruments should be anti-ferromagnetic or allow for demagnetisation *(Rate from 1 to 5)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

## BLOCK 3. CONTROL CONSOLE

This block 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 section, please **complete or rate (from 1 -not at all important- to 5 -essential-)** the degree of need for each of the criteria stated.

### 3.1. General aspects

| | Assessment |
|---|---|
| The console should be compatible with the microsurgical instruments described in Block 1 *(Rate from 1 to 5)* | |
| The control console should be open *(Rate from 1 to 5)* | |
| Type of microsurgical instrument control manipulator (e.g. Joystick, clamp, microsurgical instrument handle, etc.) *(Please complete)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

### 3.2. Functionalities

| | Assessment |
|---|---|
| The console should have an intuitive control system for robotic micro-instruments *(Rate from 1 to 5)* | |
| Microsurgical instrument control manipulators should provide force feedback to the surgeon regarding their interaction with the tissues *(Rate from 1 to 5)* | |
| Microsurgical instrument control manipulators should provide haptic/sensory feedback to the surgeon regarding their interaction with the tissues *(Rate from 1 to 5)* | |
| Microsurgical instrument controls should provide control of the tremor during the use *(Rate from 1 to 5)* | |
| Microsurgical instrument controls should provide for the possibility of scaling movements during their control *(Rate from 1 to 5)* | |
| Minimum allowable movement scaling factor *(Please complete)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

### 3.3. Economic aspects

| | Assessment |
|---|---|
| The control console should be height adjustable *(Rate from 1 to 5)* | |
| The control console should allow for tilt adjustment *(Rate from 1 to 5)* | |
| The control console should allow being used with conventional surgeon chairs *(Rate from 1 to 5)* | |
| The control console should be equipped with an ergonomic chair for the surgeon *(Rate from 1 to 5)* | |
| The control console should have armrests for the surgeon *(Rate from 1 to 5)* | |
| Microsurgical instrument controls should allow for adjustment to the surgeon's posture *(Rate from 1 to 5)* | |
| Controls on microsurgical instruments should be such that they can be adapted to different hand sizes *(Rate from 1 to 5)* | |
| The pedals of the control console must be adjustable in position and height according to the surgeon's posture *(Rate from 1 to 5)* | |
| The pedals of the control console should be configurable according to the surgeon's needs *(Rate from 1 to 5)* | |

Other needs/issues to be highlighted:

| |
|---|
| |

## ADDITIONAL INFORMATION BLOCK ASSESSMENT OF THE WORKS

| ESTIMATED BUDGET FOR COSTS ASSOCIATED WITH THE DEVELOPMENT OF EACH BLOCK | |
|---|---|
| BLOCK 1 ROBOTIC PLATFORM FOR MICROSURGERY | |
| BLOCK 2 ROBOTIC MICRO-INSTRUMENTS | |
| BLOCK 3 CONTROL CONSOLE | |