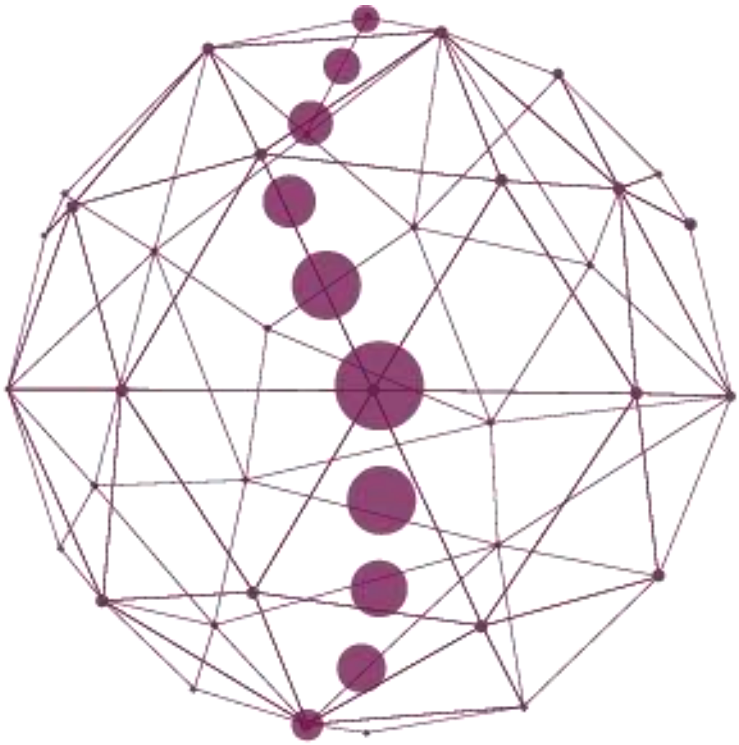

# ROSIA

REMOTE REHABILITATION SERVICE FOR ISOLATED AREAS

# OMC REPORT

This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No 101017606

| | |
|---|---|
| **GRANT AGREEMENT Nº:** | 101017606 |
| **PROJECT ACRONYM:** | ROSIA |
| **FUNDING SCHEME:** | PCP |
| **PROJECT START:** | January 1st |
| **PROJECT DURATION:** | 54 months |

# ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| API | Application Programming Interface |
| COPD | Chronic Obstructive Pulmonary Disease |
| COVID-19 | Coronavirus Disease 2019 |
| DB | Database |
| DICOM | Digital Imaging and Communication On Medicine |
| EAFIP | European Assistance for Innovation Procurement |
| EU | European Union |
| HL7 | Health Level Seven |
| IEEE | Institute of Electrical and Electronics Engineers |
| IPR | Intellectual Property Right |
| IT | Information Technologies |
| NGO | Non-Governmental Organization |
| NRH | National Rehabilitation Hospital |
| OJEU | Official Journal of the European Union |
| OMC | Open Market Consultation |
| PCP | Pre-Commercial Procurement |
| PIN | Prior Inform Notice |
| PPI | Public Procurement of Innovation |
| Q&A | Questions and Answers |
| R&I | Research and Innovation |
| REST | Representational State Transfer |
| ROSIA | Remote Rehabilitation Service for Isolated Areas |
| SOA | Service Oriented Architecture |
| R&D | Research and Development |
| TRL | Technology Readiness Level |
| WP | Work Package |

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# EXECUTIVE SUMMARY

ROSIA is paving the way towards a self-care model for telerehabilitation among the European population, specially those in remote areas. The project is committed to the self-care and self-management of patients and their caregivers, making sure they are as independent as possible and are able to take more control of their rehabilitation process, building on their own personal capabilities. The goal is to create a comprehensive rehabilitation service for patients with 3 key elements: a tailored integrated care model, a certified catalogue of technologies to be prescribed, supported by an open platform, and an ecosystem of developers, and all these under a value based schema .

To inform the market about procurement plans and needs of public authorities, the ROSIA project was launched January 2021 and involves 12 partners across 5 countries. The project received €5.5 million in funding from the EU. Three public entities, Health Department of Aragon Government in Spain, Centro Hospitalar e Universitário de Coimbra, EPE (CHUC) in Portugal, and the National Rehabilitation University Hospital (NRH) in Ireland, are jointly procuring a self-care solution from the market using a Pre-Commercial Procurement (PCP) instrument.

In preparation of the PCP call for tender, an Open Market Consultation (OMC) with potential tenderers was launched to obtain the views of the market about ROSIA scope, and to facilitate consortia development. This report summarizes the result of the ROSIA Pre-Commercial Procurement project (ROSIA-PCP) Open Market Consultation (OMC) process.

The main objectives for the OMC process were:

- To encourage possible suppliers to participate in ROSIA OMC and future PCP
- To inform them about ROSIA PCP opportunities and processes.
- To open a dialogue between the ROSIA consortium and the market about scope, budget, functionalities, requirements, business model, IPR and additional requirements of the future PCP.
- To gather information from market suppliers.
- To facilitate matchmaking among suppliers.

The OMC was preceded by the publication of the Prior Information Notice in the OJEU, with relevant information about ROSIA OMC and future tender, on May 10th, 2021. A modification of this PIN was published on May 28th, 2021.

After that, four Pre-OMC informative events, one per each country involved in the procurement process plus an international event, were held online due to COVID-19 pandemic restrictions. Events took place during June 2021 and brought together 114 companies previously registered for one or more events on the ROSIA webpage. In total, 42 presentations were done and 170 people attended the events.

Rosia OMC was launched on July 12th, 2021 and remained open until September 3rd, 2021. For this phase, different actions were designed to maximise options for companies to send valuable information prior to the tendering phase. All identified suppliers for ROSIA-PCP were encouraged to fill in an online questionnaire; ROSIA webpage included an specific Question & Answers section for OMC participants; a matchmaking tool was created on the ROSIA webpage to encourage collaboration between potential joint bidders and several bilateral meetings were held with

selected companies to deepen the information provided. In parallel, a powerful dissemination strategy was designed and launched through multiple channels and social networks, promoting participation in the consultation and the dissemination impact of the ROSIA-PCP project.

As a result of the OMC process, 40 entities answered the questionnaire. Companies represent 11 different countries and vary in type of organisations and company size. The description of the participating companies as well as the most relevant information provided in the consultation are described in a specific section of this report and several annexes.

As the main conclusion and according to the information received, it was confirmed that none of the participating entities have all-in-one solutions ready that can be adapted and customised to our context. In this sense, preliminary conclusions drawn in the last section of this report should contribute to better define ROSIA future PCP tender.

The questionnaire answers, the proposals received, and the interviews held with the participating companies in the framework of the ROSIA-PCP project are valuable to better understand the scope of the proposed solutions and their level of implementation or TRL (Technology Readiness Level) as well as difficulties encountered by the participants in facing the ROSIA challenges. Thanks to all the conclusions obtained, the Rosia Consortium has been able to complete and design a more robust, feasible and innovative Rosia ecosystem that will be translated, first, into the Rosia 2.0 model and finally into the tender.

# 1. OPEN MARKET CONSULTATION

In preparation for the PCP call for tender, an Open Market Consultation (OMC) with potential tenderers was launched, to gather information from market suppliers and to inform the market about the needs to be covered and procurement plans.

As part of the preparation for an innovative drives procurement action, the OMC involves the proactive analysis of technology offer and provides a pre-information to the market in order to give a congruous time for the preparation of fit-for-purpose proposals.

The purpose of this process is to encourage possible suppliers to participate in ROSIA OMC and especially the upcoming tender; to inform companies about the expected timetable, opportunities and phases during the PCP; to open dialogue about scope, procurers' expectations, allocated budgets, needed technical requirements, business model and other several aspects of the PCP.

The goals of the Open Market Consultation, according to EAFIP toolkit, are:

- To map all companies capable of submitting responses to the tender.
- To get insight into the market: state of the art and future developments in order to develop a call for proposals with the optimal scope.
- To consult with potential suppliers on the validity of the challenge, its specifications and to gather feedback on the feasibility of response.
- To identify the most critical success factors, barriers and enablers.
- To identify remaining gaps and challenges and where R&D is still required.
- To inform the market and attract suitable stakeholders, particularly suppliers but also (future) procurers.
- To facilitate matchmaking so that interested organizations can build consortia to better be able to address the requirements of the project.

## 2.1 Methodology

Articles 40 and 41 of the Public Procurement Directive 24/2014 provide guidelines for an OMC to follow:

- The public procurer needs to proactively communicate its needs, requirements and its planned procurement set-up to all participants in the open market consultation;
- the participation of a potential bidders in the open market consultation must not affect competition in any future tender procedure;
- any information which potential bidders receive during the open market consultation must be shared also with other potentially interested bidders via publication of questions and answers ('Q&A') docs after the open market consultation that are to be referred to within the tender documentation;

- legal assurances must be put in place that all participants' intellectual property rights (IPRs) and trade secrets will be protected, or that they will be entitled to due compensation in case of breach of confidentiality obligations by the public procurer;
- It is mandatory that potential bidders understand that the competitive phase of the public procurement procedure is conducted separately after the open market consultation and all potential bidders are treated equally; this statement should be included in any invitations to open discussions.

### 2.1.1. Pre-OMC Activities

#### 2.1.1.1 PIN publication

Publication of the ROSIA PCP Prior Information Notice (PIN) on the Official European Tenders' database and Journal and into the Procurement Platforms in the buyers' group countries, is the starting point of ROSIA Open Market Consultation process. The PIN contains relevant information on the OMC process and the forthcoming tender. The purpose of this publication is to notify the market of the imminence of the proceedings described therein in advance.

Rosia PIN was published in OJEU on May 10th. A modification of this PIN was published on May 28th. See Annex 1.

#### 2.1.1.2 Pre-OMC Events

Prior to the OMC launching, four Pre-OMC informative events, one per each country involved in the procurement process plus an international event, were held online due to COVID-19 pandemic restrictions. The events were open to companies, associations, NGOs, community service providers, social companies and any other key players of the future ROSIA solution.

Objectives of these activities were to interact with 3 ROSIA procurers to know their specific needs and priorities; get better and detailed information about the upcoming tender; meet possible partners and competitors for the PCP process and let procurers know companies' solutions as possible players in the ROSIA ecosystem.

Events took place during June 2021 and brought together 114 companies previously registered for one or more events on the ROSIA webpage. In total, 42 presentations were done and 170 people attended the events. All sessions were recorded and published for further use on the dedicated ROSIA webpage section. Full access to recorded event and presentations is available at https://rosia-pcp.eu/open-market-consultation/omc-events/and in ROSIA-PCP Youtube channel (https://www.youtube.com/channel/UCuW-pfUAejPObVzVFpzSeBA).

Each session consisted of a presentation of the project and the challenge to be addressed followed by pitch sessions by the attending companies interested in presenting currently available particular solutions with potential to meet the needs described. After that, a round table followed to answer questions regarding the requirements of the procurers or the potential solutions presented.

Dissemination of all events was actively done addressing different target audiences through social media (LinkedIn, Twitter, ROSIA Facebook page, Youtube), ROSIA webpage and individual email contacts.

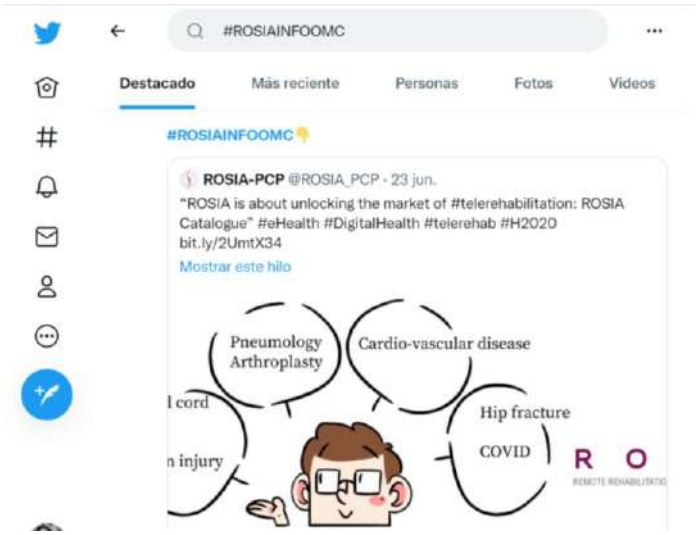



*Figure 1. Tweet message published in the Social Network*

A summary of the companies that presented and their solutions is included in Annex 2.

#### 2.1.1.2.1 Pre-OMC Event 1-Spain June 16th 2021

The Spanish Pre-OMC event was held online, through the Zoom platform in the local language (Spanish) and was chaired by the project coordinator (IACS). The ROSIA project was presented by Juan Coll, General Director of Digital Transformation, Innovation and User Rights at the regional Health Department on behalf of the Spanish procurer (SALUD). The event brought together 49 companies (from 3 different countries) and 80 people attended. 10 companies pitched to show possible solutions to address ROSIA project needs. These companies were: DyCare, Trilema Salud, Evolv, BitBrain, Smart Health TV Solution, Wellola, Universidad de Valladolid, Kineactiv, Kinetikos, GMV.

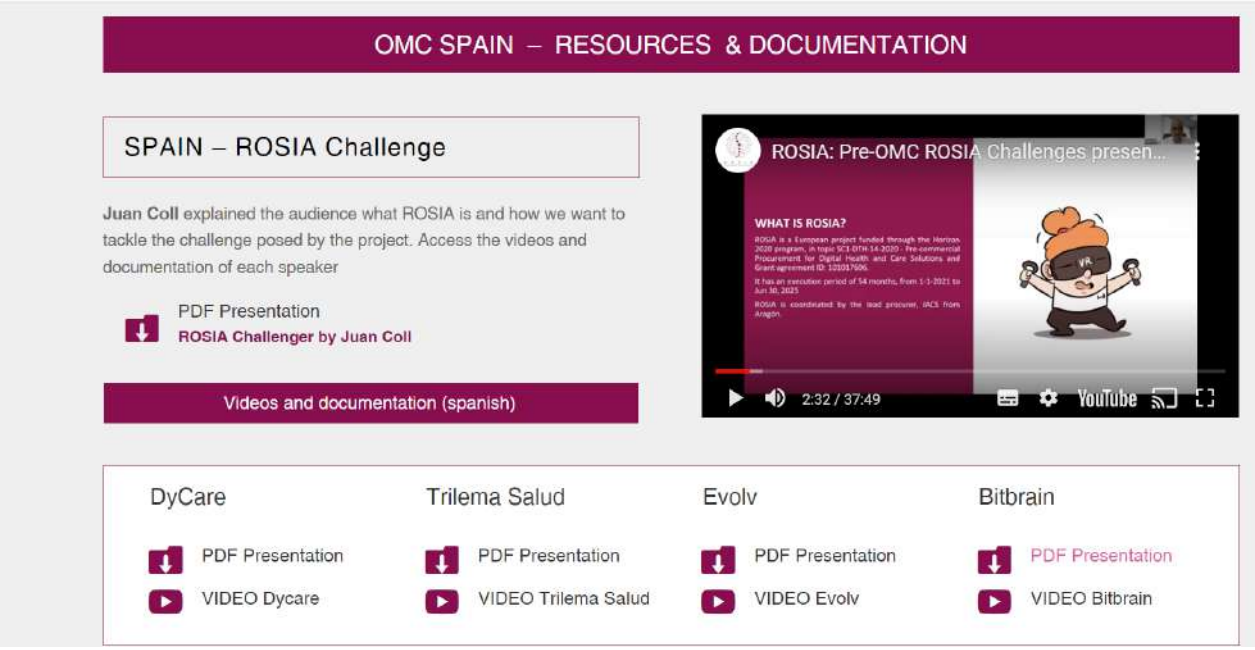



*Figure 2. Pre OMC web page (Spanish event)*

#### 2.1.1.2.2 Pre-OMC Event 2-International June 25th 2021

The International Pre-OMC event was held online, through the Zoom platform. The event was chaired and the ROSIA project presentation was done by Sandra García Armesto, Executive Director at IACS, the project coordinator. The event brought together 44 companies (from 8 different countries) and 66 people attended. 10 companies pitched to show possible solutions to address ROSIA project needs. These companies were: Starlab SL, Smart Health TV Solution, Fisio Consultores SL, Medtronic Ibérica SA, Maximiliana, DyCare, BitBrain, Evolv, Biomax Informatics AG, CT Consulting SRL.


*Figure 3. Pre OMC web page (International event)*

#### 2.1.1.2.3 Pre-OMC Event 3 - Ireland June 28th 2021

The Irish Pre-OMC event was held online, through the Zoom platform in the local language (English) and was chaired by the project coordinator (IACS). The ROSIA project was presented by Áinee Carroll (Rehabilitation Medical Consultant at NRH (the Irish procurer) and John Swords (Head of Procurement, Health Service Executive). The event brought together 30 companies (from 6 different countries) and 52 people attended. 13 companies pitched to show possible solutions to address ROSIA project needs. These companies were: Physio R&D ApS, NearForm, Think Biosolution, Wellola, Kinesis Health Technologies, Prime for life, Kinetikos, CliffrunMedia Ltd., PacSana, Teladoc Health, Zendra Health, Isaac Care, InterSystems Corp.

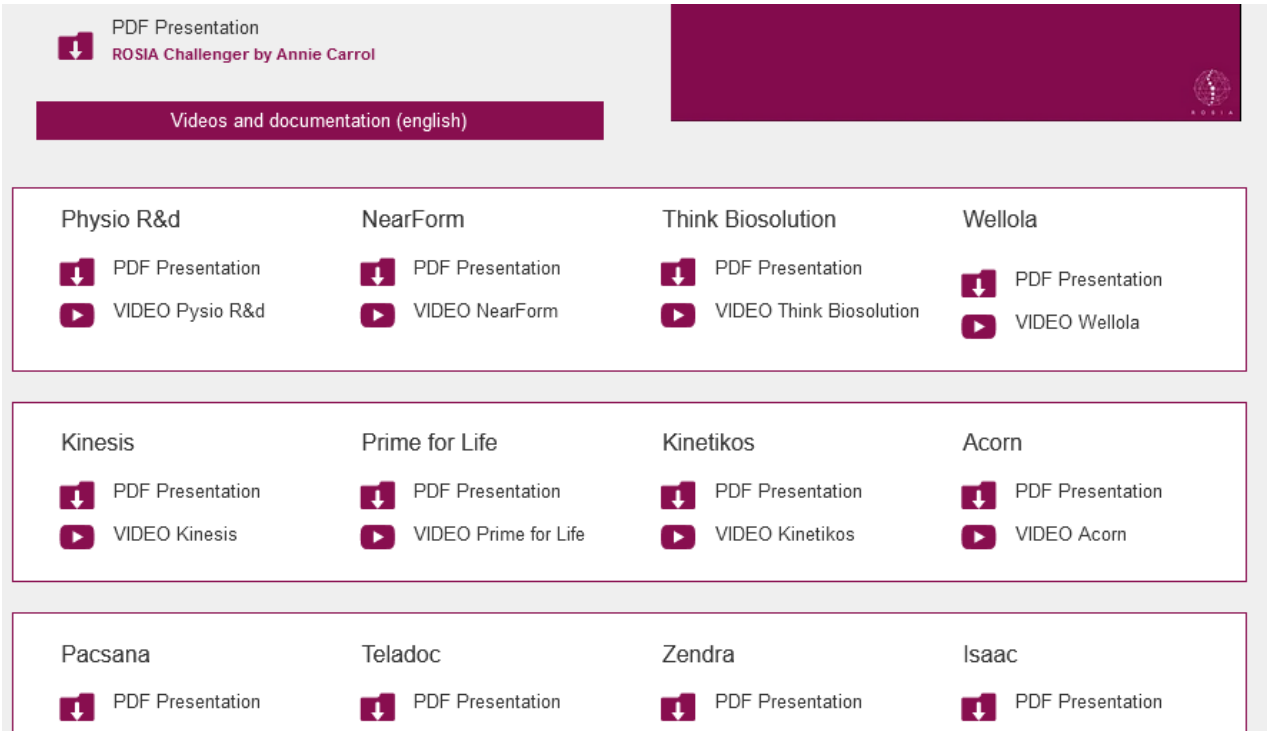



*Figure 4. Pre OMC web page (Irish event)*

#### 2.1.1.2.4 Pre-OMC Event 4 (Portugal) June 30th 2021

The Portuguese Pre-OMC event was held online, through the Zoom platform in the local language (Portuguese) and was chaired by the project coordinator (IACS). The ROSIA project was presented by Alexandre Lourenco (Hospital Administrator - Centro Hospitalar e Universitário de Coimbra) on behalf of the Portuguese procurer (CHUC). The event brought together 37 companies (from 5 different countries) and 54 people attended. 11 companies pitched to show possible solutions to address ROSIA project needs. These companies were: Plux Wireless, SWORD Health, Biodevices, Clynx, Altice Labs, Hope-Care, Kinetikos, Wellola, Anne4Care.

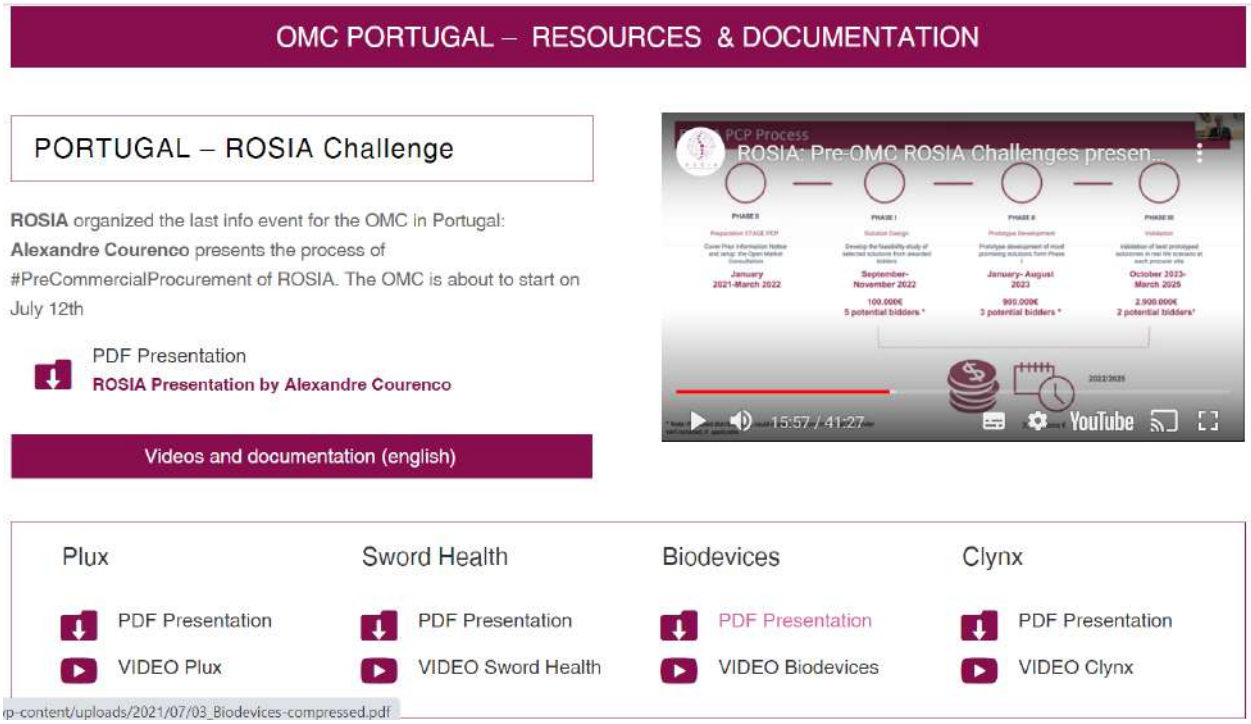



*Figure 5. Pre OMC web page (Portuguese event)*

### 2.1.2 OMC Process

The OMC was launched on July 12th, 2021 and remained open until September 3rd, 2021. For this phase, several different actions were designed to maximise options for companies to send valuable information prior to the tendering phase.

All relevant information about the consultation process such as components of the multidisciplinary technical team, how principles such as transparency or confidentiality would be applied, the steps of the consultation and additional relevant information was collected in a single document and made available to potential participants on the ROSIA website. See Annex 3.

#### 2.1.2.1 OMC Questionnaire

All possible suppliers for ROSIA-PCP were encouraged to fill in an online questionnaire, thoroughly designed to gather as much relevant and detailed information as possible regarding experience and knowledge, existing solutions likely matching procurers' unmet needs and feedback on the PCP scope, budgetary constraints and phases. 40 answers were received from 11 different countries, 6 different types of organizations and 4 different company sizes.
See Annex 4, 5 and 6 for detailed questions designed to gather relevant information within the OMC questionnaire, answers received and solutions presented by entities.


*Figure 6. OMC Questionnaire web page*

### 2.1.2.2 Website Question & Answers Section

During the consultation, a specific Q&A section was set up on the ROSIA website so that potential participants could submit their questions, and these would be answered by the consortium with transparency. https://rosia-pcp.eu/omc-qa/

This section will remain open until the tender is published, so that if the project continues to raise interest and questions beyond the consultation, the answers will also be made public.

### 2.1.2.3 Matchmaking tool

As set for the ROSIA challenge, the goal is to acquire a comprehensive rehabilitation service for patients, supported in 3 key elements: an open platform, an ecosystem of developers and a certified catalogue of technologies to be prescribed. Many PCP bidders may not have technological developments or solutions to cover completely the needs and may need to apply together with different national or international companies in a joint tender (consortium) to be able to fulfil all these requirements. For that purpose, a matchmaking tool was created on the ROSIA webpage to ease these contacts and cooperation (see Annex 7). By October 20th 2021, 44 entities registered their information within the matchmaking tool. 33 are private companies, 6 start-ups, and 1 technological center.
This tool will remain open until ROSIA tender to facilitate the formation of potential partnerships prior to the publication of the call for tender.

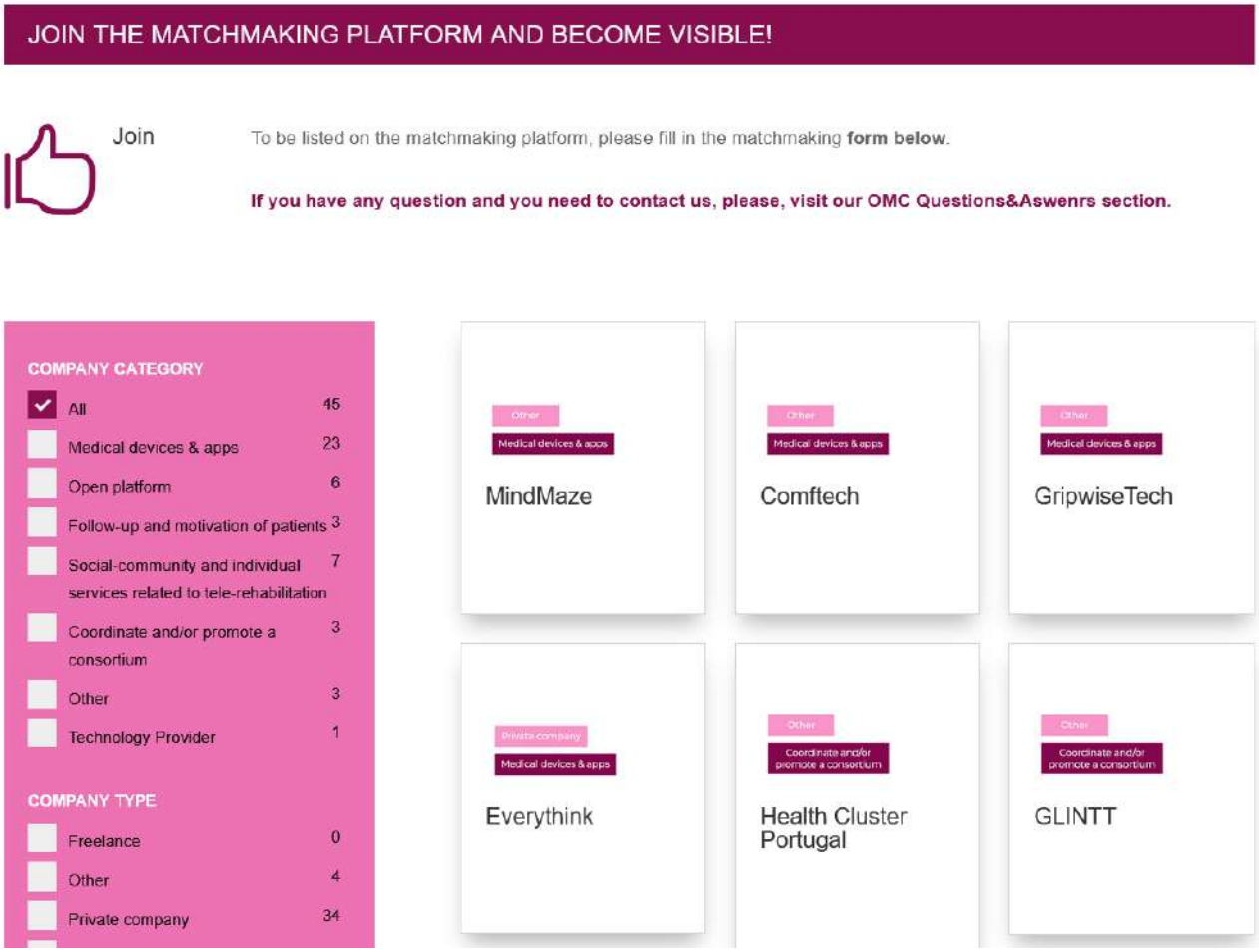



*Figure 7. Matchmaking web page*

| MATCHMAKING PARTNERS (October 20th 2021) | |
|---|---|
| **All** | 44 |
| Open Platform | 6 |
| Apps & Devices | 22 |
| Telerehabilitation | 7 |
| Motivations | 3 |
| Coordinator | 3 |
| Technology provider | 1 |
| Other | 3 |

*Table 1. Matchmaking Partner statistics*

### 2.1.2.4 Bilateral Meetings

After reviewing and classifying all information received via OMC questionnaires, the OMC Technical Committee decided to hold several bilateral meetings as they saw the need of collecting more information from certain companies and sectors of activity.

The OMC Technical Committee was created with members from the ROSIA consortium to lead the OMC. The group was formed by María Bezunartea (IACS), Alba De Martino (IACS), Sofía Moreno (VALDE), Rosana Anglés (SALUD), John Maher (NRH), Alexandre Lourenço (CHUC), Alberto Valejo (IPN) and Claus Nielsen (PPCN).

In selecting the entities to meet with, the Committee took into account different criteria:

- The meetings had to cover the most relevant roles required for a project like ROSIA (open platform providers, application and service providers, and project coordinators).
- In relation to the open platform providers, they should be of sufficient flexibility and future ready for a project as ambitious as ROSIA (three countries, multiple solutions for seven pathologies and more expected in the future, one ecosystem of developers...).
- In terms of device and application providers, those that had participated in integration processes with others and/or with open platforms were of interest.
- Among those that met these criteria, we selected those that in the questionnaire had introduced more innovative or disruptive issues or diverged from some of the key approaches of the project (e.g. technological architecture, IPR...).

The meeting agenda included a first part of presentations and introductions. Then, a brief ROSIA challenge and project summary, a companies' brief introduction and questions from OMC Technical Committee members and companies. Summary of information regarding each bilateral meeting is available in Annex 8.

### 2.1.2.5 Dissemination Actions

The consultation must reach all entities potentially interested in the project and this is achieved through a powerful communication strategy. Some of its key elements are described below:

#### 2.1.2.5.1 Emailing

A total of 1.818 emails have been sent to different target DB informing about the Open Market Consultation activities. The average open rate has been 43%. The mail platform used is Acumbamail.

| Date | Subject | Target/Audience | #emails | Open Rate | Clicks | Language |
|---|---|---|---|---|---|---|
| June 1 | ROSIA - Invitación a participar en proyecto europeo | **Spain BBDD** Companies/innovators identified as being active in the sector and possibly | 34 | 22 | 74 | Spanish |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | interesting bidders (SPAIN) + Web Subscribers | | | | |
| June 2 | ROSIA - Invitation to participate in EU Project | **International BBDD** Companies/innovators identified as being active in the sector and possibly interesting bidders (European + International) + WEB Subscribers | 98 | 51 | 157 | English |
| June 2 | ROSIA: Healthcare Innovation EU Project | **International Influencer**s National and European healthcare Industry associations, hubs, forums, … | 10 | 5 | 53 | English |
| June 2 | ROSIA - Un proyecto europeo de innovación en salud | **Spanish Influencers** Healthcare Industry associations, hubs, forums, (Spain) | 105 | 46 | 133 | Spanish |
| June 8 | ROSIA - Invitation to participate in EU Project - Ready-to-send Invitation | **English influencers** Healthcare Industry associations, hubs, forums, (Ireland) | 8 | 4 | 37 | English |
| June 11 | ROSIA - Invitation to participate in EU Project | **Irish Contacts** Companies/innovators identified as being active in the sector and possibly interesting bidders (Ireland) | 18 | 15 | 56 | English |
| June 14 | Convite para participar no projeto europeu ROSIA | **Portuguese Contacts** Companies/innovators identified as being active in the sector and possibly interesting bidders (Portugal) | 26 | 12 | 11 | Portuguese |
| June 21 | ROSIA PCP project launches its informative events for the Open Market Consultation | **ALL** | 328 | 130 | 95 | English |
| June 23 | ROSIA - Vídeos y presentaciones del evento informativo 16 de junio | **Attendees - Spain** Contacts from Spain Pre-OMC event | 78 | 47 | 47 | Spanish |
| June 24 | ROSIA PCP Reminder- June, 25 - International Information Event - | **International Registered** Contract from ALL Pre-OMC events | 57 | 34 | 5 | English |
| July 12 | ROSIA Open Market Consultation - Come on board! | **ALL** | 422 | 176 | 125 | English |
| July 16 | ROSIA-PCP Open Market Consultation - Come on board! | **National Contact Points** E-health National Contact Points (NCPs) in all H2020 countries | 60 | 10 | 7 | English |
| July 16 | ROSIA-PCP Open Market Consultation - Come on board! | **EU Projects Participant**s Relevant industry initiatives at EU level | 74 | 24 | 0 | English |
| August 5 | ROSIA-PCP Open Market Consultation - Updated info | **ALL** | 486 | 202 | 100 | English |

*Table 2. List of massive mails sent (dissemination)*

Apart from massive mails activities to attract interest in ROSIA, we also use the project's social networks to publicise the different phases of the OMC. In order to reach as many bidders as possible, we mentioned and share our publications with the accounts described in the official PCP promotion guide, namely in the following areas:

- For health/ageing: @EU_Health,@ EU_eHealth, @EIP_AHA

- For H2020/research/innovation: @Horizon2020EU and @EU_H2020 and @H2020SME @ICTinnovEU and @DigitalAgendaEU with #innovation, #research, #startup, #SMEinstrument
- For projects with regional/local impact: @EU_Regional

In addition to using our social media posts, we also contacted (lieve.bos@ec.europa.eu) to provide a short text explaining the scope of the PCP and an invitation to participate in the OMC to be published in DG CNECT's innovation procurement newsletter.
Following the official guidance to promote PCP, we registered ROSIA in the European innovation procurement forum (https://procurement-forum.eu/). On this platform we have been informing about the different activities of the project and explaining the different developments that took place during the OMC.
We did the same exercise on the Catalonia Open Challenges platforms https://openchallenges.accio.gencat.cat/ that is an official platform from the region of Catalonia to publish opportunities for catalan and international companies.

| List name | Description |
|---|---|
| Spain BBDD | Companies/innovators identified as being active in the sector and possibly interesting bidders (SPAIN) + Web Subscribers |
| ernational BBDD | Companies/innovators identified as being active in the sector and possibly interesting bidders (European + International) + WEB Subscribers |
| Irish contacts | Companies/innovators identified as being active in the sector and possibly interesting bidders (Ireland) |
| tuguese contacts | Companies/innovators identified as being active in the sector and possibly interesting bidders (Portugal) |
| nal Contact Points | ehealth National Contact Points (NCPs) in all H2020 countries |
| anish Influencers | Healthcare Industry associations, hubs, forums, (Spain) |
| glish Influencers | Healthcare Industry associations, hubs, forums, (Ireland) |
| national registered | All attendees to PreOMC Events |
| ttendees Spain | Attendees to PreOMC event Spain |
| rsonal contacts | ROSIA's partners sent personal short invitation messages |
| EB Subscribers | Emails collected directly from the website contact form |

*Table 3. List of DB used during email dissemination*

#### 2.1.2.5.2 YouTube

ROSIA Channel on Youtube was created for the Open Market Consultation. The channel is organized in 5 lists. A total of 49 videos have been uploaded, the channel has 15 followers and 189 views.

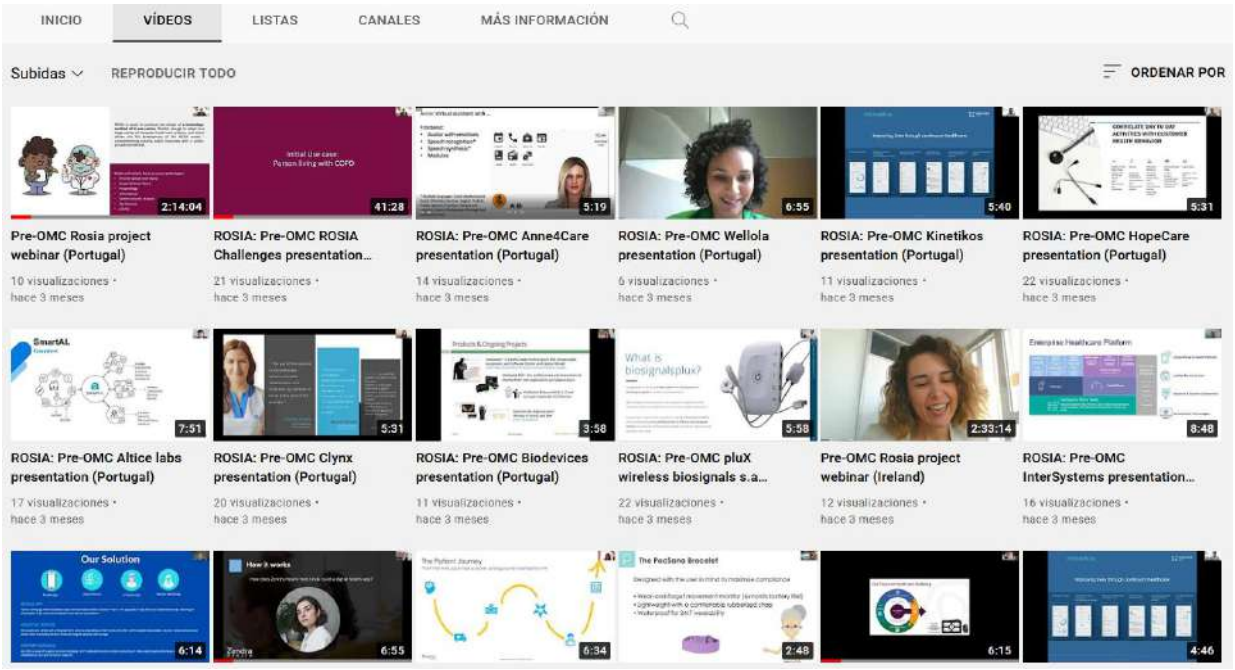



*Figure 8. ROSIA PCP Youtube Channel*

### 2.1.2.5.3 Twitter

ROSIA Twitter account has got 111 followers (75 from June 2021 to September 2021). During the month of June, ROSIA celebrated the Pre-OMC Informative Events, July & August were used to promote the OMC Questionnaire and spread key messages about ROSIA. The ROSIA project Twitter account gained impact in followers, impressions (116.800) and profile visits (11.602).

| | TOTAL | June | July | August |
|---|---|---|---|---|
| **Tweets** | 212 | 137 | 47 | 28 |
| **Impressions (K)** | 117 | 63 | 26 | 27 |
| **Profile visits** | 11602 | 6402 | 2448 | 2752 |
| **Mentions** | 150 | 122 | 13 | 15 |
| **New Followers** | 75 | 41 | 13 | 21 |

*Table 4. Twitter statistics*


*Figure 9. Twitter statistics I (analytics)*


| | |
|---|---|
| Impressions | 4,460 |
| Total engagements | 50 |
| Media engagements | 15 |
| Detail expands | 15 |
| Likes | 8 |
| Retweets | 7 |
| Profile clicks | 3 |
| Replies | 1 |
| Link clicks | 1 |

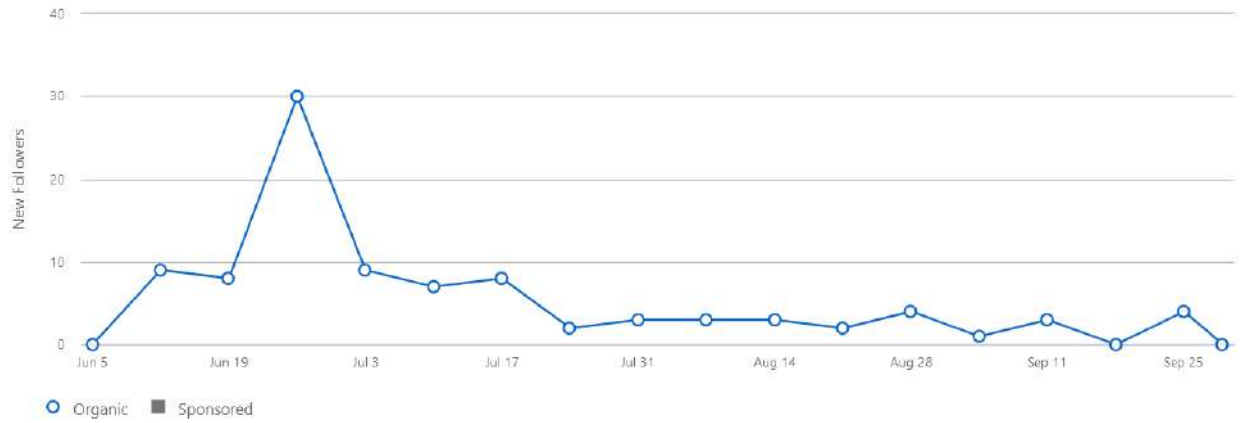

| | |
|---|---|
| Impressions | 2,819 |
| Total engagements | 33 |
| Detail expands | 11 |
| Retweets | 10 |
| Media engagements | 5 |
| Likes | 4 |
| Profile clicks | 2 |
| Link clicks | 1 |

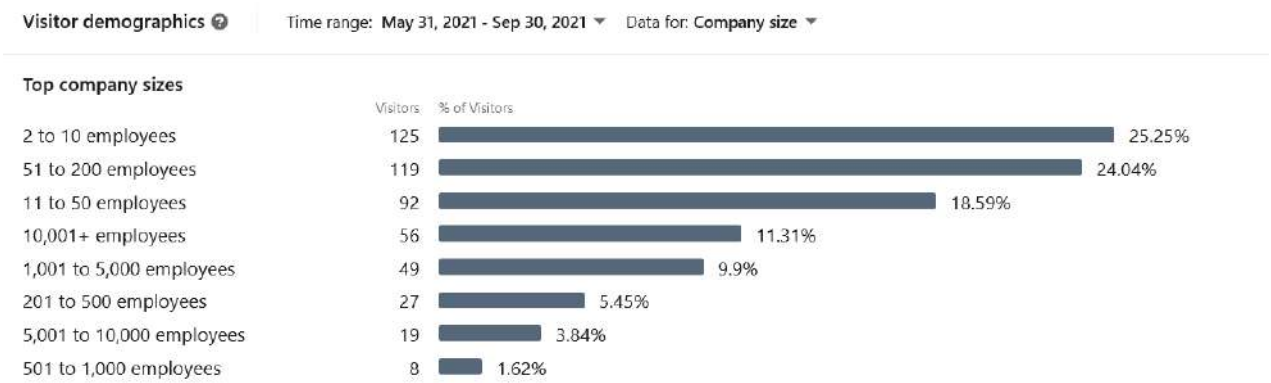

| | |
|---|---|
| Impressions | 1,598 |
| Total engagements | 42 |
| Detail expands | 13 |
| Retweets | 9 |
| Media engagements | 8 |
| Likes | 6 |
| Profile clicks | 3 |
| Replies | 2 |
| Link clicks | 1 |


*Figure 10. Twitter statistics II (analytics)*

### 2.1.2.5.4 LinkedIn

At least 3 posts per week to support the OMC activities from June to September reaching 6.000+ impressions and 135 followers with 67 posts and 7 articles.



**Visitor demographics** Time range: **May 31, 2021 - Sep 30, 2021** Data for: **Location**

**Top locations**

| | Visitors | % of Visitors |
|---|---|---|
| Madrid Area, Spain | 108 | 21.26% |
| Zaragoza Area, Spain | 106 | 20.87% |
| Lisbon Area, Portugal | 38 | 7.48% |
| Coimbra Area, Portugal | 35 | 6.89% |
| Barcelona Area, Spain | 18 | 3.54% |
| Bilbao Area, Spain | 16 | 3.15% |
| Huesca, Spain | 15 | 2.95% |
| Valencia Area, Spain | 14 | 2.76% |
| Amsterdam Area, Netherlands | 14 | 2.76% |
| Porto Area, Portugal | 13 | 2.56% |

**Visitor demographics** Time range: **May 31, 2021 - Sep 30, 2021** Data for: **Industry**

**Top industries**

| | Visitors | % of Visitors |
|---|---|---|
| Government Administration | 92 | 15.49% |
| Information Technology and Services | 84 | 14.14% |
| Hospital & Health Care | 73 | 12.29% |
| Higher Education | 41 | 6.9% |
| Research | 40 | 6.73% |
| Health, Wellness and Fitness | 35 | 5.89% |
| Medical Devices | 30 | 5.05% |
| Management Consulting | 27 | 4.55% |
| Biotechnology | 21 | 3.54% |
| Telecommunications | 18 | 3.03% |

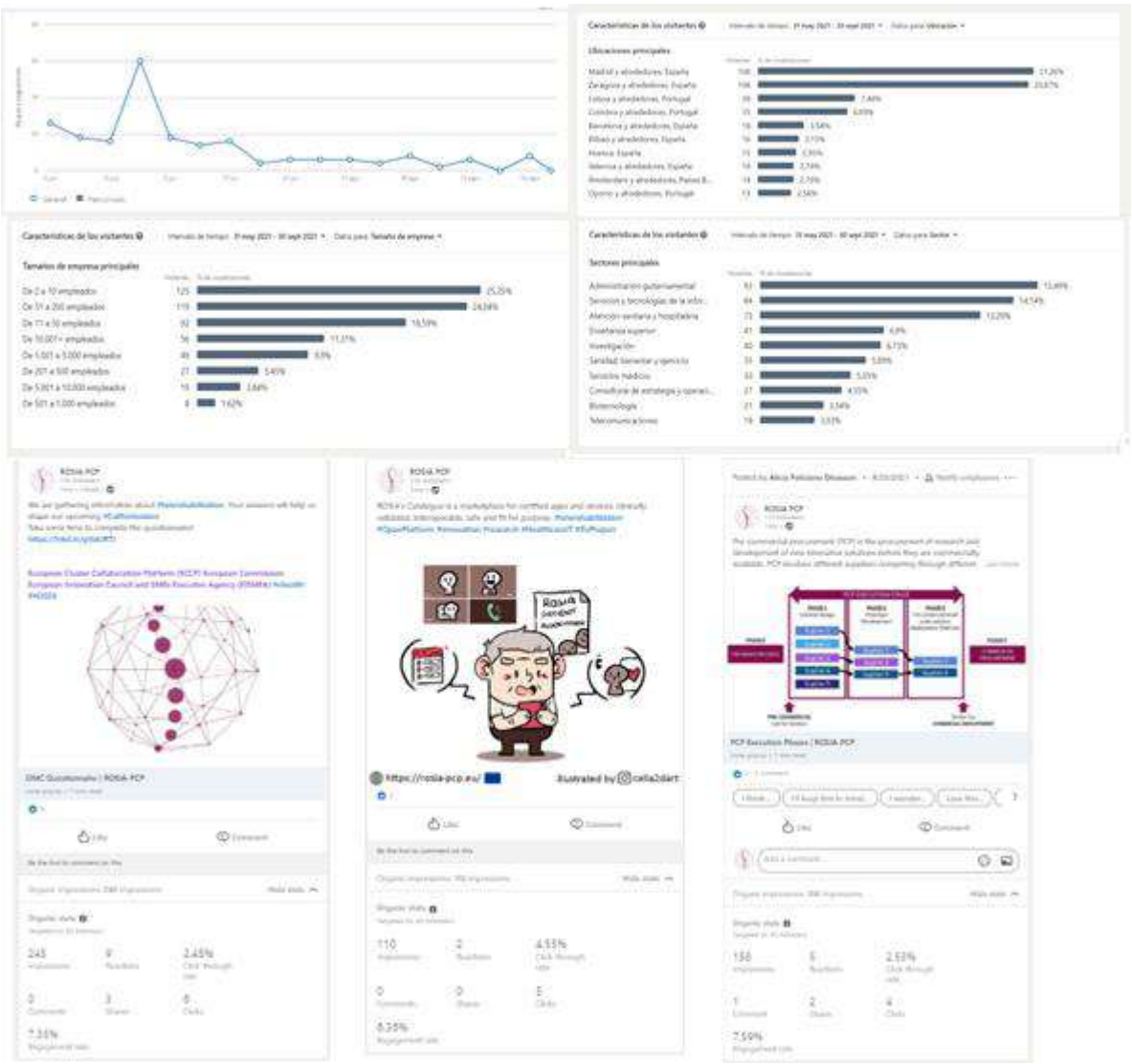


*Figure 11. LinkedIn activity (statistics)*

2.1.2.5.5 Facebook

During Open Market Consultation 30 posts were published. ROSIA project Facebook page has a low number of followers and limited activity. The post with the higher number of impressions reached 189 views.

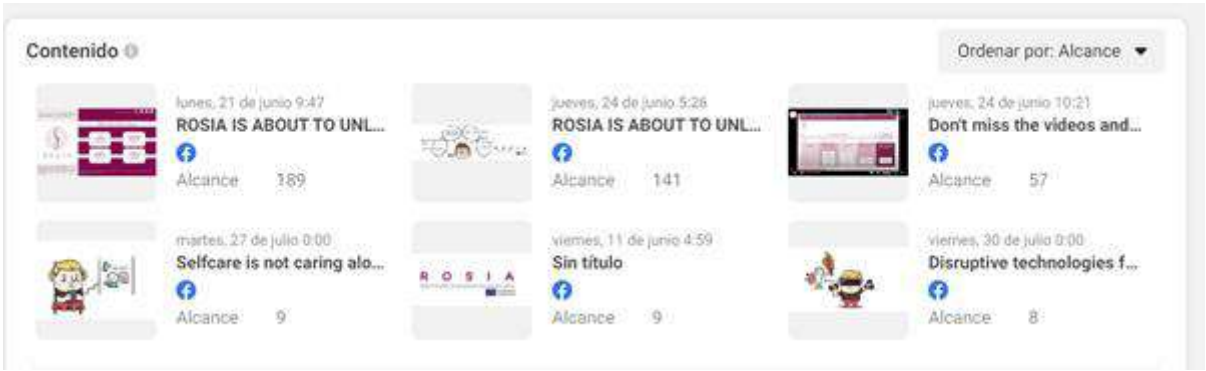



*Figure 12. Facebook activity (statistics)*

2.1.2.5.6 Website

All social media activities focus on bringing visitors to the website. 891 new users and the Average Time on Page is 3.37 minutes. Visitors are mainly from Spain, Portugal, United States and Ireland.

| | June | July | August |
|---|---|---|---|
| **Visits** | 7.418 | 4.106 | 4.523 |
| **Users** | 770 | 432 | 468 |
| **Average Time on Page** | 2min 43 sec | 4 in 44 sec | 3 min 25 sec |

*Table 5. Web page usage statistics*


*Figure 13. Visits per country (website)*

## 2.2 Results

40 entities answered the questionnaire. They come from 11 different countries, 6 different types of organisations and 4 different company sizes.

| | |
|---|---|
| Portugal | 13 |
| Spain | 11 |
| Ireland | 4 |
| Italy | 3 |
| USA | 2 |
| Germany | 2 |
| Amsterdan | 1 |
| Denmark | 1 |
| Sverige | 1 |
| Switzerland | 1 |
| UK | 1 |

| | |
|---|---|
| Private Companies | 27 |
| Startup | 8 |
| Technological Center | 2 |
| Research Center | 1 |
| Consortium | 1 |
| Non-profit | 1 |

| | |
|---|---|
| Large | 8 |
| Medium | 5 |
| Small | 10 |
| Micro | 17 |

*Figure 14. Companies that answered the OMC Questionnaire (sorted by country)*

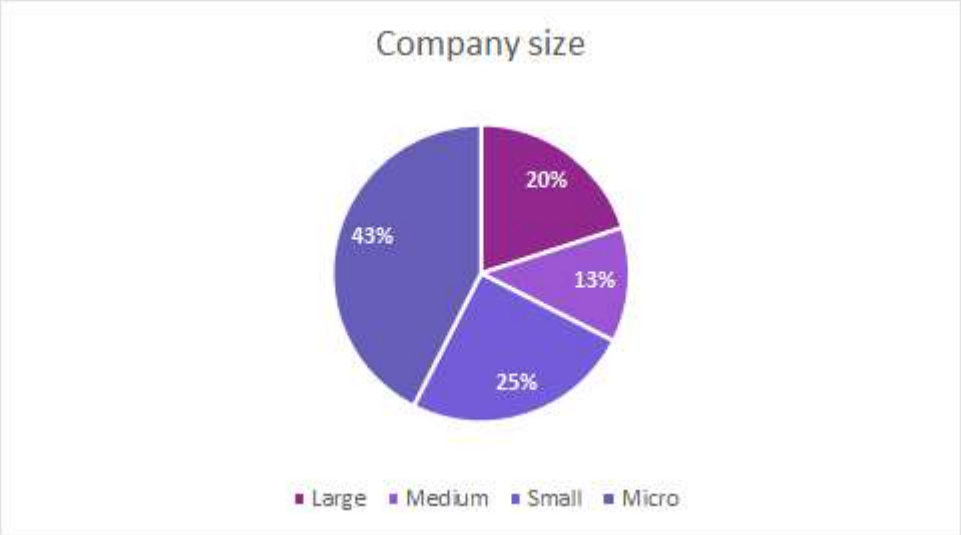



*Figure 15. Pie chart showing the company size of the OMC Questionnaire answers received*

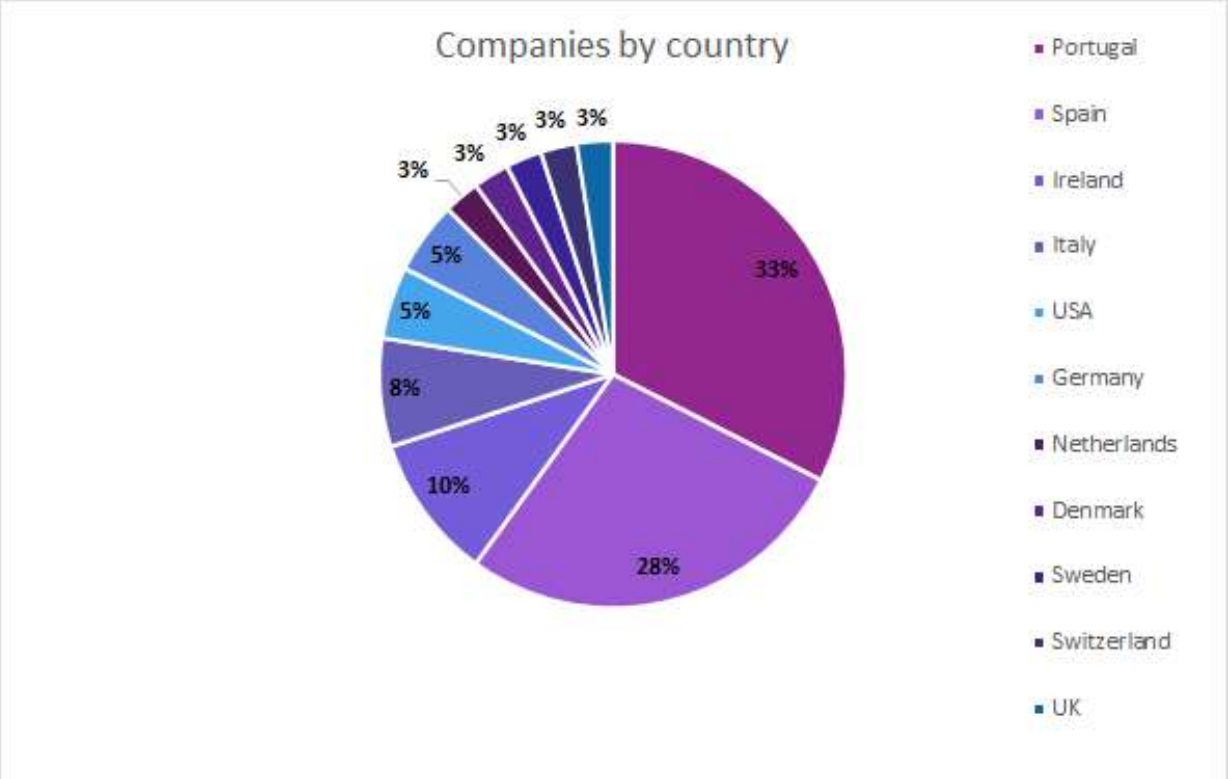



*Figure 16. Pie chart showing the companies organized by country (OMC Questionnaire answers)*

Although most of the responses to the questionnaire are included in Annex 5 (anonymised), descriptive information on some of the questions relating to the ROSIA project is given below.

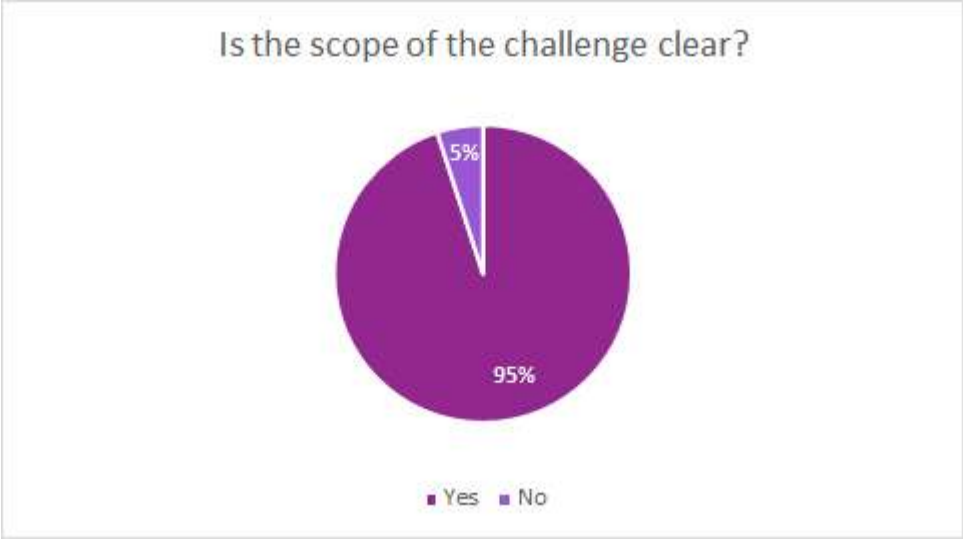



*Figure 17. Pie chart showing clarity of the scope (OMC Questionnaire answers)*

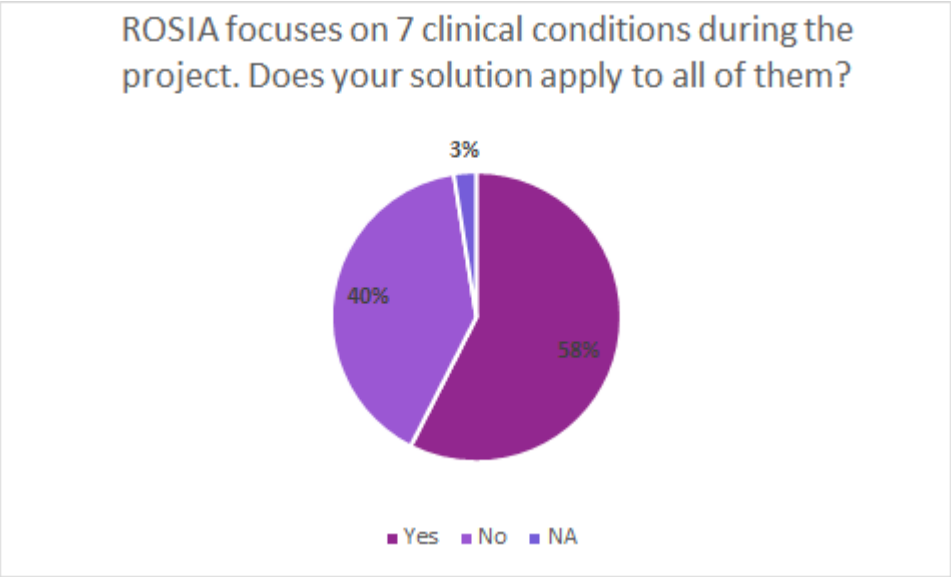



*Figure 18. Pie chart showing the clinical conditions that each solution presented can solve (OMC Questionnaire answers)*

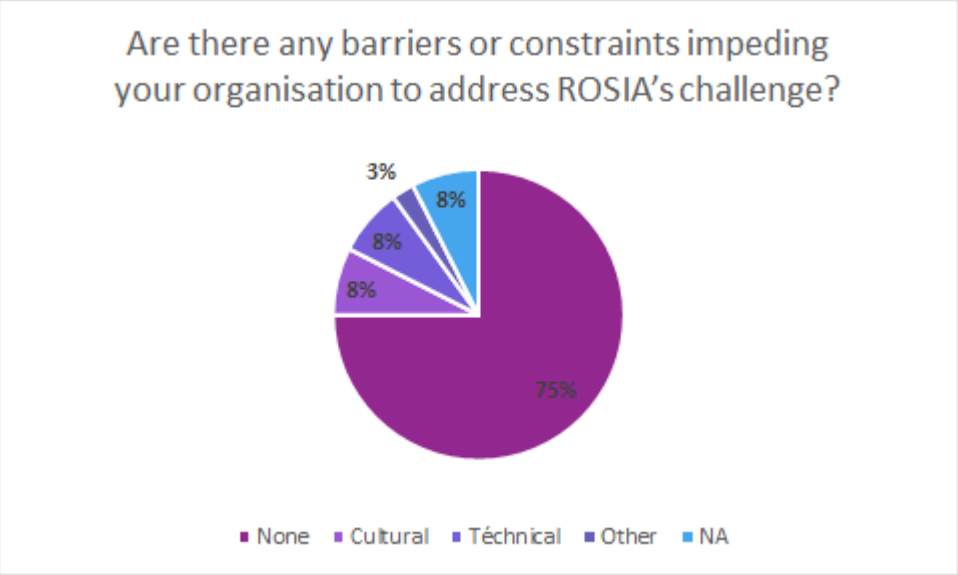



*Figure 19. Pie chart showing the barriers found (OMC Questionnaire answers)*


*Figure 20. Pie chart showing the possibility of granting a license for use the solution (OMC Questionnaire answers)*

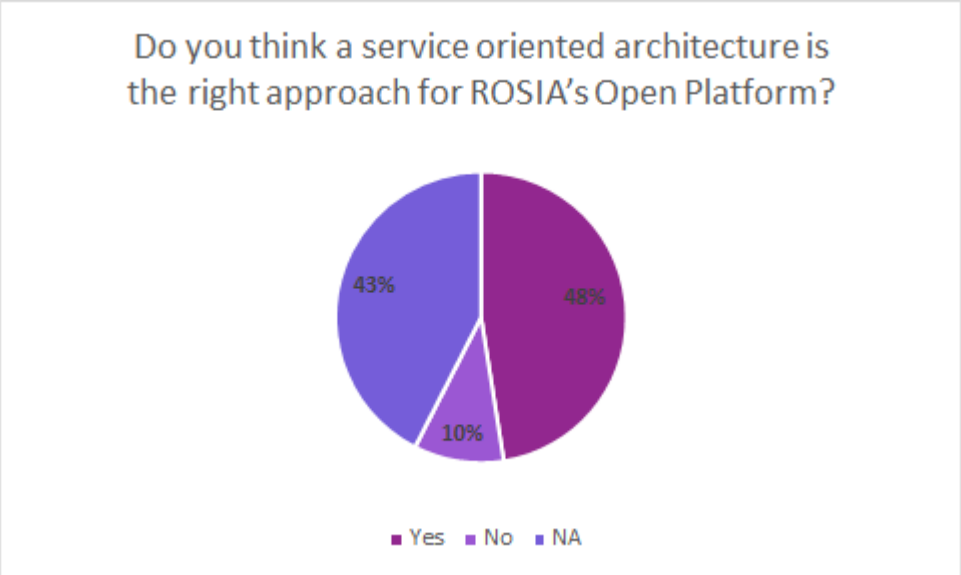



*Figure 21. Pie chart showing the opinion of the companies about SOA approach (OMC Questionnaire answers)*

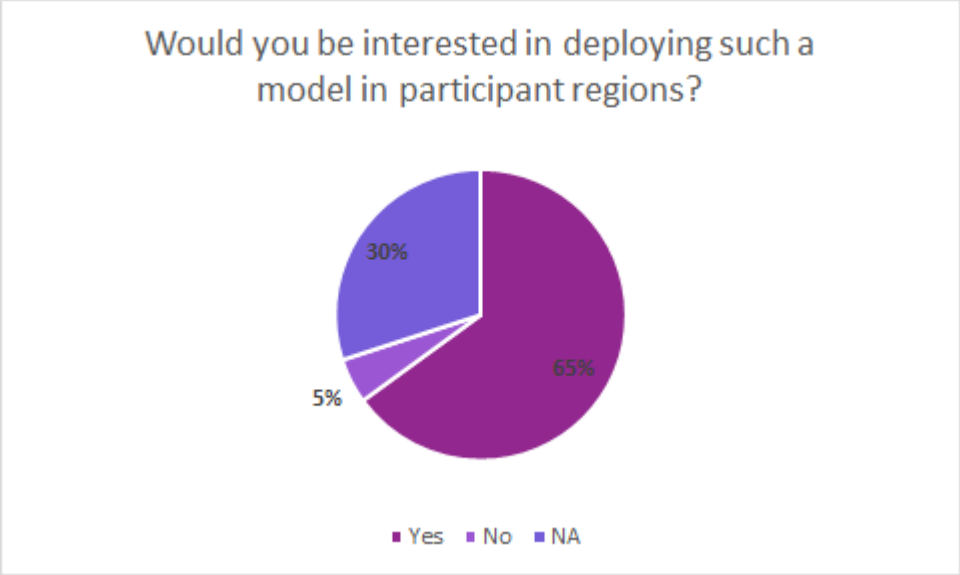



*Figure 22. Pie chart showing the model deployment in all the regions (OMC Questionnaire answers)*

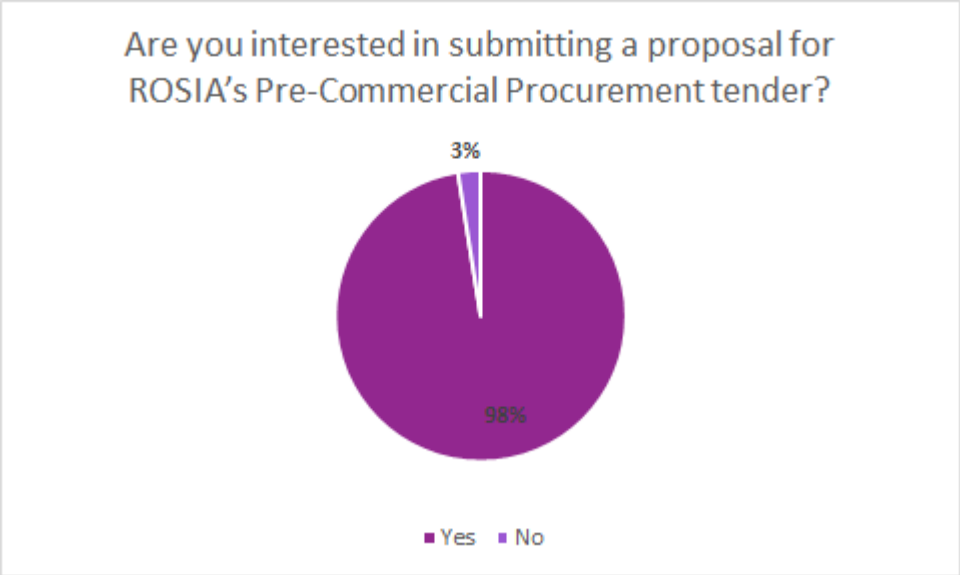



*Figure 23. Pie chart showing the intention of submitting a PCP proposal (OMC Questionnaire answers)*

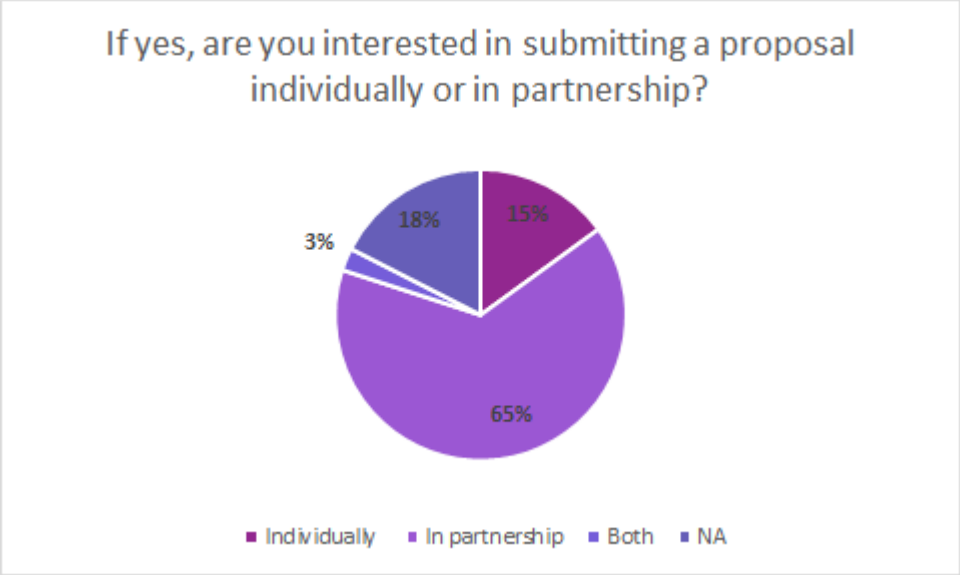



*Figure 24. Pie chart showing the interest of participating individually or in partnership (OMC Questionnaire answers)*

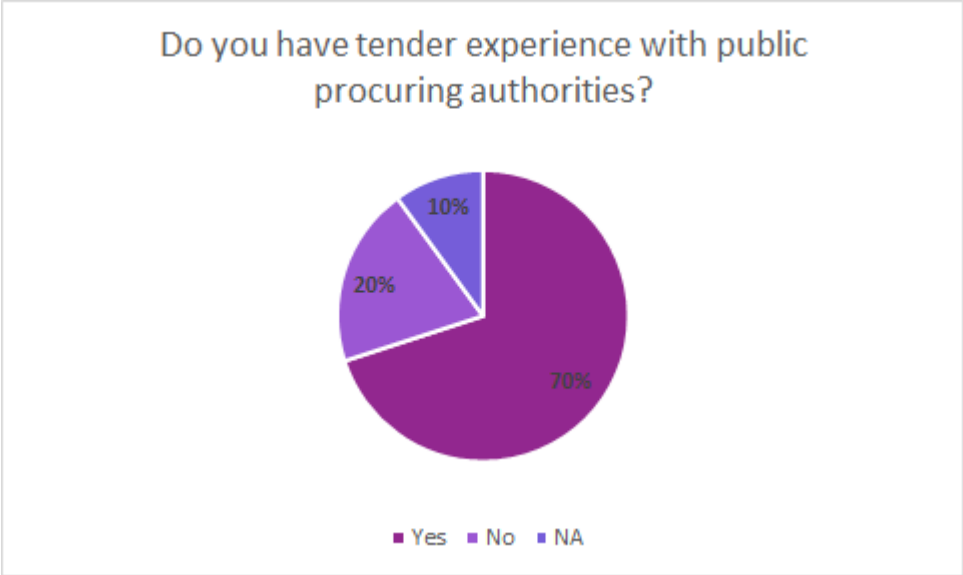



*Figure 25. Pie chart showing the experience working with Public Procuring Authorities (OMC Questionnaire answers)*

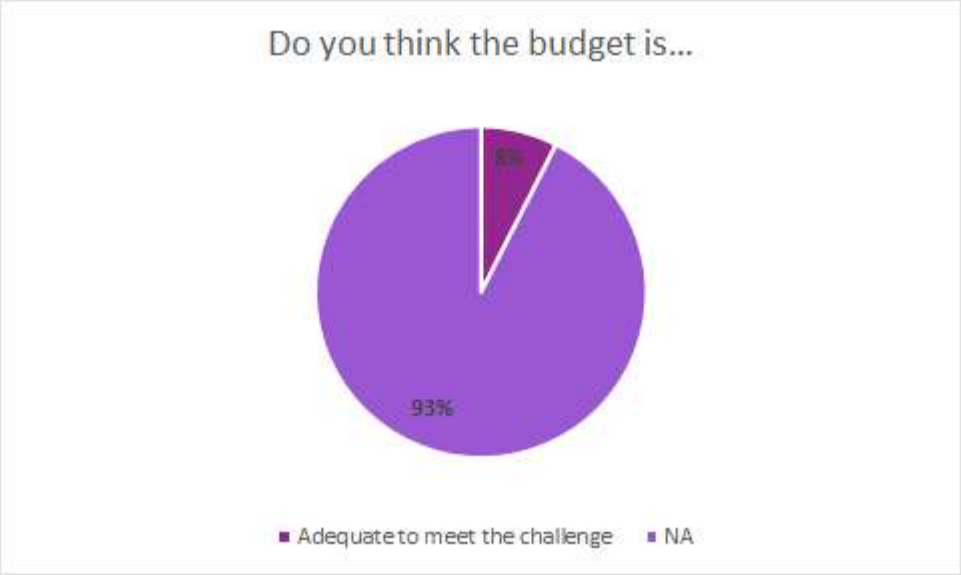



*Figure 26. Pie chart showing the adequation of the budget (OMC Questionnaire answers)*

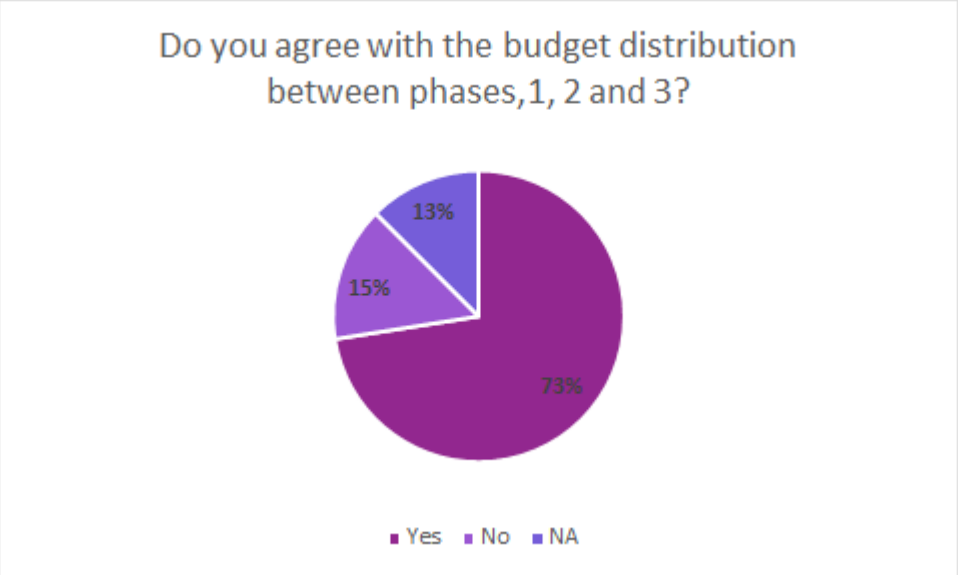



*Figure 27. Pie chart showing the budget distribution opinion (OMC Questionnaire answers)*

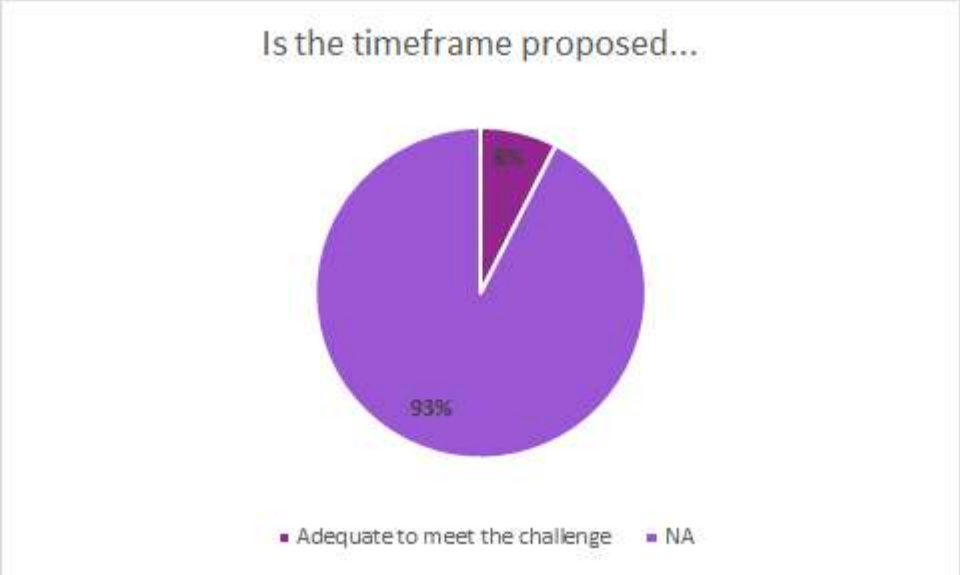



*Figure 28. Pie chart showing the adequation of the timeframe proposed (OMC Questionnaire answers)*

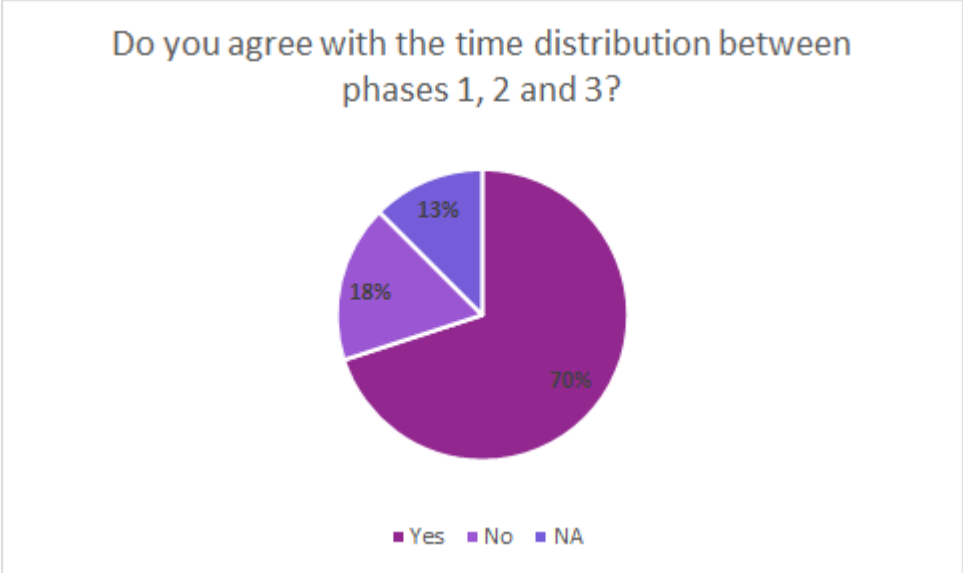



*Figure 29. Pie chart showing the time distribution between phases (OMC Questionnaire answers)*


*Figure 30. Pie chart showing the business model of the companies (OMC Questionnaire answers)*


*Figure 31. Pie chart showing the percentage of companies interested in joint proposals (OMC Questionnaire answers)*

In addition to responding to the questionnaire, participating entities provided information on solutions that could fully or partially address ROSIA challenges. Some of this information was categorised by the company as confidential and is not shown in this report. A list of provided solutions has been included in Annex 6.

## 2.3 OMC Conclusions and recommendations for the future tender

The information management process for OMC procedures has worked well, allowing questionnaires, documents and submissions to be available on the ROSIA website during the whole process.

According to the information received, it was confirmed that participating entities do not have all-in-one solutions ready in the market that can currently meet the needs identified within the ROSIA project or can be adapted and customized to our context. In this sense, preliminary conclusions have been drawn that will serve to better define the needs of the specifications for future tender.

The following conclusions are the result of the analysis of the content of the proposals and bilateral meetings and grouped according to similar themes:

## Group 1: Understanding/Awareness of ROSIA Project and Scope

The conclusions described below emphasise the lack of clarity that OMC respondents have regarding the ROSIA project, its scale, and its scope.

### Conclusion One:

Although 95% of the companies that answered the questionnaire stated that the challenges of ROSIA were clear, it became evident, in the bilateral meetings, that the complexity of the project was unclear. Especially in relation to the ROSIA ecosystem involved. Therefore, it is relevant for the project correct execution that the challenge brief provides an understanding of all project components and their interrelationships.

### Conclusion Two:

ROSIA Consortium is looking for all-in-one solutions that require the involvement of different roles:

a. Service providers: Beyond the health services integrated in the portfolio of the 3 purchasers and which will be part of ROSIA, it is planned to provide other services such as IT assistance at home to install the necessary IT resources at patients' homes and their maintenance, or motivational support for monitoring of the various prescribed activities...
b. Open platform providers
c. Innovative application and devices developers to make up ROSIA's catalogue of applications.
d. Systems integrators, who can facilitate integrations between roles b and c
e. Project coordinators

There are few companies that have all of these roles. So the joint participation of different companies is essential. It would be advisable for the possible partnerships to be set up before the tender is published, as the deadline for submitting proposals is expected to be around two months and is very tight.

This can be a major barrier to participation in ROSIA that needs to be addressed. The ROSIA matchmaking tool was designed for that purpose and during this period, 43 companies have registered in it.

### Conclusion Three:

According to the economic operators involved in the consultation, the services to be provided by ROSIA are not entirely clear.

The information generated in ROSIA, through supervised self-care, should be integrated into their care plan enabling better care. Besides that, the provision of other services related to the use of technology in remote settings (home or community) and the motivation required for self-care activities is being considered. These services may be provided by the providers or by the community itself, but at the expense of the project.

### Conclusion Four:

ROSIA Telerehabilitation Care Model aims at describing practices and services within health and care systems for individuals in need of rehabilitation care in remote areas, to ensure that they get the right care, at the right time, by the right team, and in the right place, as they progress through the stages of a condition, injury or event for 7 health conditions (cardiovascular condition, acquired brain injury, spinal cord injury, COPD, COVID-19, knee arthroplasty, and hip fracture).

Taking into account that the tele-rehabilitation market is not mature and regarding the timeframe and budget set for the project, it could seem too ambitious to form 5 consortia of bidders with enough capacity to provide tele-rehabilitation services to the 7 given medical conditions.

### Recommendations for future tender:

The delineation of all these issues (challenge dimensions; medical conditions, different bidder roles and services provided) should be clearly reflected in the Challenge Brief.

An intensification in dissemination strategy should be considered, integrating the OMC findings to keep attracting new companies. This includes but is not limited to increased social media engagement, dissemination of materials (i.e. brochures), expansion of the Q&A section of the ROSIA website and dissemination of this via social media channels/mailing lists, and interviews with consortium members sharing information on the issues listed previously.

The ROSIA buyer group could offer a higher score in tender evaluation to bidders including a coordinator or systems integrator profiles.

The buyer group could agree to limit the number of medical conditions to which the solutions presented should, at least, respond to. However, it is required for the solution provided to be opened to any clinical condition/pathology.

## Group 2: Technology Readiness Levels (TRL)

The conclusions described below relate to the TRLs of the ROSIA solution.

### Conclusion Five:

Considering the solution to ROSIA's challenges as a comprehensive one, it is foreseen that the project will start with a TRL level of 5-6 and end at TRL 8-9.

However, some applications/devices, integrated in the solution, could have a higher initial TRL. In these cases, the innovation would be generated:

a. By removing barriers in the market development: existing innovative-disruptive high tech solutions for telerehabilitation at home can't be integrated in the common general practice of public health care providers since they are not connected, rather standalone, isolated, disease specific and usually not integrated into the care workflow or health system infrastructure
b. From the ability of the ROSIA ecosystem to allow flexible and easy data exchanges from any certified health device/application that may exist in 5 years, improving remote rehabilitation services provided.
c. From the utilization of certain applications and devices for different uses than their initial purposes by integration of SDKs suppliers into a dynamic integrated telerehabilitation care model for supported self-management
d. By a value based model for business and long term sustainability.

On the other hand, given that interoperability with devices is evolving so much and so fast, it would be possible to introduce the possibility in the tender to include some elements of the proposals to be submitted with a lower TRL, in such a way that would allow some very novel developments in ROSIA that would generate relevant competitive advantages even if they are more risky (e.g. testing federating learning to share device information...).

### Recommendations:

The solution to ROSIA's challenges will be composed by different elements at a various TRLs. With independence of TRL, the integrated solutions must demonstrate reliability for field testing with final end users.

## Group 3: Technical Elements

The conclusions described below relate to the technical components of the ROSIA solution, although have specific recommendations for each.

### Conclusion Six:

Open platform is a trusted layer where services can share data, analytics and targeted interventions can be developed. During the OMC process the multidisciplinary technical team has confirmed that ROSIA's open platform concept is in line with the generally accepted concept for such a platform by the market.

Its most relevant aspects are:

a. ease of use
b. flexibility
c. interoperability with applications and devices is achieved through non-proprietary APIs that enable as many integrations as possible
d. adoption of most known interoperability standards like HL7, DICOM and IEEE 11073, among others, for achieving data, sharing, data curation and data alignment
e. Governance

### Conclusion Seven:

Most of the companies providing open platforms seemed to agree, when answering the questionnaire, that service oriented architecture (SOA) is the right approach for ROSIA's platform because SOA, including microservices and RESTful architectures, fits well with the current state of interoperability in the healthcare industry. And that was consistent with the conclusions of the state of the art analysis.

However, the multidisciplinary technical team considers this is not the only possible approach. Moreover, combining these other approaches with agile development methodologies can lead to more innovative and dynamic solutions for ROSIA.

### Conclusion Eight:

Integration with public health care IT systems is often complex. In the case of ROSIA, three health systems from three different countries are involved, which increases the complexity enormously.

For this reason, the Consortium has planned to include in the tender the development of a sandbox that will allow, during the project execution, to make available a minimum set of data to be provided by the health care systems of the three procurers and some solution for the needs of information flow to implement integrated care models. Of course, this sandbox must be complemented by the essential requirement in the tender documents that the solutions presented will comply with certain integration standards, in order to ensure real integration with health care IT systems in the future. This readiness for integration will be tested during the execution.

Those companies offering open platforms participating in the bilateral meetings identified integration with the health/social IT systems as a high barrier to enter the competition, and were very supportive of implementing a sandbox solution instead.

Company developers of agile cloud native open platforms made clear that workshops with the IT departments of all procurers will be needed for the full development and integration of solutions.

### Conclusion Nine:

Some, but not all, of the applications and devices presented in the OMC comply with all European legal requirements for medical devices.

The ROSIA project should contribute to their achievement through the definition and implementation of ROSIA Certification Process, aligned with the Medical Devices directive. This process could include technical aspects (such as security or usability), legal aspects (compliance with data protection) and others such as scientific evidence supporting the real impact of those devices. It would be interesting to consider the use of technologies that ensure transparency and traceability of the process, in order to build trust among potential participants in the ROSIA ecosystem.

### Recommendations for the future tender:

ROSIA will seek to include the elements of the open platform listed in Conclusion Six in the tender documentation.

ROSIA will consider not restrict the type of architecture proposed in the tender to allow for alternative approaches to be suggested for the open platform architecture.

ROSIA will include in the tender the possibility of developing a sandbox during the execution of the project and the integration standards required.

ROSIA should ask for the implementation of a ROSIA Certification Process, aligned with the Medical Devices directive, for applications and devices included in the ROSIA catalogue

## Group 4: Business Models & PCP Budgeting and time phase distribution

The conclusions described below relate to different issues in relation to the business model and PCP budgeting and time phase distribution of the ROSIA solution, although have specific recommendations for each.

### Conclusion Ten:

Although 70% of the entities answering the questionnaire considered that the budget is sufficient to address ROSIA's challenges, it is not clear to the multidisciplinary technical team that they fully understood the dimension of the challenge to be addressed.

15% of the participants feel that the ROSIA Consortium should increase phase one (estimated duration is three months) somewhat. This could be worth considering because there are many different roles in the consortium within the joint providers to align and three countries and 7 medical conditions to respond to.

### Conclusion Eleven:

One of the items in the questionnaire referred to the keys to the business model of the different entities. Around half of respondents base their business model on activity, while the other half link it to results.

It is interesting to note, however, that several entities considered it very feasible that the companies themselves, that were part of the ROSIA ecosystem, would be willing to pay to enter the ecosystem and be supported in the validation/certification process promoted by ROSIA for tele-rehabilitation in remote areas.

This has important implications for the sustainability of the solution itself and its deployment via a future PPI in many European regions.

### Conclusion Twelve:

One third of the participants in the consultation would not be willing to grant a free user licence to buyers when the project is completed and would therefore find it difficult to participate in the future tender. However, 58% would be willing to do so.

Perhaps more relevant to the bidding process is that the companies that are more reluctant seem to have a greater understanding of the clinical reality behind the ROSIA challenge. On the other hand, those promoting more open approaches seem to require more clinical knowledge, which

they will have to seek from potential consortium partners. It would be very interesting to have representatives of both approaches competing in ROSIA PCP to compare results, timing and budgets.

Recommendations for future tender:

ROSIA will consider reviewing the distribution of budget and time for the phases and consider extending the allocated time for Phase one, in particular if there are lower TRLs in the bidder's application.

The questionnaire answers, the proposals received and the interviews held with the participating companies in the framework of the ROSIA-PCP project are valuable to better understand the scope of the proposed solutions and their level of implementation or TRL (Technology Readiness Level) as well as difficulties encountered by the participants in facing ROSIA challenges. Thanks to them, the ROSIA Consortium has been able to complete and design a more robust, feasible and innovative ROSIA solution that will be translated into the ROSIA model and to the tender.

# ANNEXES

R O S I A

REMOTE REHABILITATION SERVICE FOR ISOLATED AREAS

**Spain-Saragossa: Research and experimental development services**
**2021/S 090-233129**

**Prior information notice**

**This notice is for prior information only**

**Services**

**Legal Basis:**
Directive 2014/24/EU

**Section I: Contracting authority**

I.1) **Name and addresses**

Official name: Instituto Aragonés de Ciencias de la Salud
Postal address: C/S. Juan Bosco, 13
Town: Zaragoza
NUTS code: ES243 Zaragoza
Postal code: 50009
Country: Spain
Contact person: José Antonio Navarro
E-mail: contratacion.iacs@aragon.es
**Internet address(es):**
Main address: https://www.iacs.es/
Address of the buyer profile: http://www.rosia-pcp.eu

I.1) **Name and addresses**

Official name: Servicio Aragonés de Salud
Postal address: Plaza de la Convivencia, 2 50071 Zaragoza
Town: Zaragoza
NUTS code: ES243 Zaragoza
Postal code: 50071
Country: Spain
Contact person: Modesto Sierra
E-mail: innovation.hbrb@salud.aragon.es
**Internet address(es):**
Main address: https://www.aragon.es/-/servicio-aragones-de-salud-14
Address of the buyer profile: http://www.rosia-pcp.eu

I.1) **Name and addresses**

Official name: National Rehabilitation Hospital
Postal address: Rochestown Avenue
Town: Dún Laoghaire
NUTS code: IE06 Eastern and Midland
Postal code: A96 E2H2
Country: Ireland
Contact person: Sarah Kearney
E-mail: sarah.kearney@nrh.ie
**Internet address(es):**
Main address: https://www.nrh.ie/
Address of the buyer profile: http://www.rosia-pcp.eu

I.1) **Name and addresses**

Official name: Centro Hospitalar e Universitário de Coimbra EPE
Postal address: Praceta Prof. Mota Pinto
Town: Coimbra
NUTS code: PT16E Região de Coimbra
Postal code: 3004-561
Country: Portugal
Contact person: Sandra de Sousa
E-mail: sandramsousa@chuc.min-saude.pt
**Internet address(es):**
Main address: https://www.chuc.min-saude.pt/
Address of the buyer profile: http://www.rosia-pcp.eu

I.2) **Information about joint procurement**

The contract involves joint procurement
In the case of joint procurement involving different countries, state applicable national procurement law:
This PCP is carried out by Instituto Aragonés de Ciencias de la Salud, lead procurer acting in the name and on behalf of the buyers group in I.1). The applicable national procurement law is Spanish.

I.3) **Communication**

Additional information can be obtained from the abovementioned address

I.4) **Type of the contracting authority**

Regional or local agency/office

I.5) **Main activity**

Other activity: Health R&D

## Section II: Object

II.1) **Scope of the procurement**

II.1.1) **Title:**

Pre-commercial Public Procurement of Comprehensive Services to Patients in Need of Tele-rehabilitation in Isolated Areas, enhanced by Edge Technology, New Care Pathways and Community Support (ROSIA)

II.1.2) **Main CPV code**

73100000 Research and experimental development services

II.1.3) **Type of contract**

Services

II.1.4) **Short description:**

This PIN announces an open market consultation and provides information about a planned pre-commercial procurement (PCP) carried out by the ROSIA PCP project, addressing the rising need of comprehensive services, enhanced by edge technology, to patients in need of tele-rehabilitation in depopulated and distant areas. ROSIA PCP is looking to procure the development of an all in one service supported in an open platform which will integrate ICT enabled services including telerehabilitation and monitoring devices for self-care, implementation of new care pathways fostering community support, and resources for enabling patient activation.
More information about the upcoming open market consultation is provided in section II.2.14).

II.1.5) **Estimated total value**

Value excluding VAT: 3 081 000.00 EUR

II.1.6) **Information about lots**

This contract is divided into lots: no

II.2) **Description**

II.2.2) **Additional CPV code(s)**

32441100 Telemetry surveillance system
32441300 Telematics system
33000000 Medical equipments, pharmaceuticals and personal care products
33100000 Medical equipments
33190000 Miscellaneous medical devices and products
33195000 Patient-monitoring system
33196000 Medical aids
33197000 Medical computer equipment
33692000 Medical solutions
48000000 Software package and information systems
48180000 Medical software package
48814000 Medical information systems
48814200 Patient-administration system
48814400 Clinical information system
72000000 IT services: consulting, software development, Internet and support
72212180 Medical software development services
72212190 Educational software development services
72212211 Platform interconnectivity software development services
72212930 Training and entertainment software development services
72212931 Training software development services
75122000 Administrative healthcare services
80320000 Medical education services
80420000 E-learning services
80561000 Health training services
85140000 Miscellaneous health services
85141210 Home medical treatment services
85323000 Community health services
48211000 Platform interconnectivity software package

II.2.3) **Place of performance**

NUTS code: ES24 Aragón
NUTS code: IE06 Eastern and Midland

NUTS code: PT16E Região de Coimbra
Main site or place of performance:
The contract will be executed at the institution of each member.

II.2.4) **Description of the procurement:**

The procurement will take the form of a joint pre-commercial procurement (PCP). The objective is to conduct a competitive multiple-sourcing procedure for procuring research and development services to face a joint technologically demanding mid to long-term challenge. The competitive process will be executed in three phases where different suppliers will compete to develop their solution in a narrowed down R&D framework of service contracts. The 3 phases are: solution design, prototype development, original development and validation and testing of a limited volume of first products or services. All the solutions in Phase 3 will be tested in the three buyers' countries (Ireland, Portugal and Spain) to ensure that a comparison can be made of performance, both across sites and across solutions. Each procurer will identify a sample population to implement the proof of concept of the final awarded solutions.
Each selected operator will be awarded a framework agreement that covers three R&D phases. After each phase, intermediate evaluations will be carried out to select the best of the competing solutions. The contractors with the best value- for-money solutions will be offered a specific contract for the next phase. Contracts will include provisions on risk benefit sharing under market conditions, and a clear separation with the subsequent (possible) Public Procurements of Innovative solutions (PPI) focusing on deployment of commercial volumes of end-products.
The selected operators will retain ownership of the intellectual property rights (IPRs) that they generate during the PCP and will be able to use them to exploit the full market potential of the developed solutions.
This PIN invites all interested operators (regardless of their geographic location, the size or governance structure) to take part in an open market consultation (OMC).
The OMC will consist of:
— online events: one per procurers' country (Ireland, Portugal and Spain) and another international one will be organized during the OMC. All meetings will be announced on the website (https://ROSIA-pcp.eu/),
— a questionnaire made available at Rosia´s web (https://ROSIA-pcp.eu/). The confidentiality terms applied to the information provided by the respondents during the OMC will be detailed at the questionnaire,
— individual meetings with respondents to the questionnaire. The meetings and phone calls schedule will be set up by the procurers according to interest and availability.
Interested operators can participate in the PCP call for tender even if they did not participate in the OMC. Participation in the OMC will not be a requirement to submit a proposal to the tender, does not lead to any rights or privileges for the participants, and is not part of any pre-qualification or selection process.
This procurement receives funding from the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No 101017606 — ROSIA PCP (https://ROSIA-pcp.eu/). The EU has given a grant for this procurement, but is not participating as a contracting authority in the procurement.

II.2.14) **Additional information**

Estimated total value: EUR 3 900 000 incl. VAT, if applicable.
The procurement is expected to be published in March 2022, to start in September 2022 and to end in May 2025.
OMC will be held from June to August 2021.
All information provided during the OMC will be published, at least, in English.

II.3) **Estimated date of publication of contract notice:**

31/03/2022

## Section IV: Procedure

IV.1) **Description**

IV.1.8) **Information about the Government Procurement Agreement (GPA)**

The procurement is covered by the Government Procurement Agreement: no

**Section VI: Complementary information**

VI.3) **Additional information:**

The PCP procurement is exempted from the WTO Government Procurement Agreement (GPA), the EU public procurement directives and the national laws that implement them (because it concerns the procurement of R&D services where the benefits do not accrue exclusively to the contracting authority for its use in the conduct of its own affairs). This PIN is published to announce an open market consultation on a future procurement procedure. The PIN is not a commitment to procure.

VI.5) **Date of dispatch of this notice:**

05/05/2021

**Spain-Saragossa: Research and experimental development services**
**2021/S 102-269087**

**Corrigendum**

**Notice for changes or additional information**

**Services**

**(Supplement to the Official Journal of the European Union, 2021/S 090-233129)**

**Legal Basis:**
Directive 2014/24/EU

**Section I: Contracting authority/entity**

I.1) **Name and addresses**

Official name: Instituto Aragonés de Ciencias de la Salud
Postal address: C/S. Juan Bosco, 13
Town: Zaragoza
NUTS code: ES243 Zaragoza
Postal code: 50009
Country: Spain
Contact person: José Antonio Navarro
E-mail: contratacion.iacs@aragon.es
**Internet address(es):**
Main address: https://www.iacs.es/
Address of the buyer profile: http://www.rosia-pcp.eu

I.1) **Name and addresses**

Official name: Servicio Aragonés de Salud
Postal address: Plaza de la Convivencia, 2 50071 Zaragoza
Town: Zaragoza
NUTS code: ES243 Zaragoza
Postal code: 50071
Country: Spain
Contact person: Modesto Sierra
E-mail: innovation.hbrb@salud.aragon.es
**Internet address(es):**
Main address: https://www.aragon.es/-/servicio-aragones-de-salud-14
Address of the buyer profile: http://www.rosia-pcp.eu

I.1) **Name and addresses**

Official name: National Rehabilitation Hospital
Postal address: Rochestown Avenue
Town: Dún Laoghaire
NUTS code: IE06 Eastern and Midland
Postal code: A96 E2H2
Country: Ireland
Contact person: Sarah Kearney
E-mail: sarah.kearney@nrh.ie
**Internet address(es):**
Main address: https://www.nrh.ie/
Address of the buyer profile: http://www.rosia-pcp.eu

I.1) **Name and addresses**

Official name: Centro Hospitalar e Universitário de Coimbra EPE
Postal address: Praceta Prof. Mota Pinto
Town: Coimbra
NUTS code: PT16E Região de Coimbra
Postal code: 3004-561
Country: Portugal
Contact person: Sandra de Sousa
E-mail: sandramsousa@chuc.min-saude.pt
**Internet address(es):**
Main address: https://www.chuc.min-saude.pt/
Address of the buyer profile: http://www.rosia-pcp.eu

## Section II: Object

II.1) **Scope of the procurement**

II.1.1) **Title:**

Pre-commercial Public Procurement of Comprehensive Services to Patients in Need of Tele-rehabilitation in Isolated Areas, enhanced by edge Technology, New Care Pathways and Community Support (ROSIA)

II.1.2) **Main CPV code**

73100000 Research and experimental development services

II.1.3) **Type of contract**

Services

II.1.4) **Short description:**

This PIN announces an open market consultation and provides information about a planned pre-commercial procurement (PCP) carried out by the ROSIA PCP project, addressing the rising need of comprehensive services, enhanced by edge technology, to patients in need of tele-rehabilitation in depopulated and distant areas. ROSIA PCP is looking to procure the development of an all in one service supported in an open platform which will integrate ICT enabled services including telerehabilitation and monitoring devices for self-care, implementation of new care pathways fostering community support, and resources for enabling patient activation.
More information about the upcoming open market consultation is provided in section II.2.14).

## Section VI: Complementary information

VI.5) **Date of dispatch of this notice:**

24/05/2021

VI.6) **Original notice reference**

Notice number in the OJ S: 2021/S 090-233129

**Section VII: Changes**

VII.1) **Information to be changed or added**

VII.1.2) **Text to be corrected in the original notice**

Section number: II.2.4)

Place of text to be modified: Description of the procurement:

Instead of:

The OMC will consist of:

— online events: one per procurers' country (Ireland, Portugal and Spain) and another international one will be organized during the OMC. All meetings will be announced on the website (https://ROSIA-pcp.eu/),

— a questionnaire made available at Rosia's web (https://ROSIA-pcp.eu/). The confidentiality terms applied to the information provided by the respondents during the OMC will be detailed at the questionnaire,

— individual meetings with respondents to the questionnaire. The meetings and phone calls schedule will be set up by the procurers according to interest and availability.

Interested operators can participate in the PCP call for tender even if they did not participate in the OMC. Participation in the OMC will not be a requirement to submit a proposal to the tender, does not lead to any rights or privileges for the participants, and is not part of any pre-qualification or selection process.

This procurement receives funding from the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No 101017606 — ROSIA PCP (https://ROSIA-pcp.eu/). The EU has given a grant for this procurement, but is not participating as a contracting authority in the procurement.

Read:

The OMC will consist of:

— a questionnaire made available at Rosia's web (https://ROSIA-pcp.eu/). The confidentiality terms applied to the information provided by the respondents during the OMC will be detailed at the questionnaire,

— individual meetings with respondents to the questionnaire. Procurers, according to interest and availability, will set up the meetings and phone calls schedule.

Previously to the OMC launching, the buyers group will promote 4 online events: one per procurers' country (Ireland, Portugal and Spain) and another international one. All events will be announced on the website (https://ROSIA-pcp.eu/),

Interested operators can participate in the PCP call for tender even if they did not participate in the OMC. Participation in the OMC will not be a requirement to submit a proposal to the tender, does not lead to any rights or privileges for the participants, and is not part of any pre-qualification or selection process.

This procurement receives funding from the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No 101017606 — ROSIA PCP (https://ROSIA-pcp.eu/). The EU has given a grant for this procurement, but is not participating as a contracting authority in the procurement.

Section number: II.2.14)

Place of text to be modified: Additional information

Instead of:

OMC will be held from June to August 2021.

Read:

OMC will be launched on 12 July.

VII.2) **Other additional information:**

# Annex 2: Pre-OMC Events. Additional information

## Pre-OMC Event 1: Spain

- June 16th 10.00 - 12.30 (10.00 - 12.30 CEST)
- Juan Coll (General Director of Digital Transformation, Innovation and User Rights - Health Department - Government of Aragón)
- People registered: 80
- Number of different companies: 49
- Registered for pitch: 12 (2 companies repeated 2 times)
- Country of origin: 3 (Spain, Portugal, Ireland/UK)
- Number of pitches: 10. Companies: DyCare, Trilema Salud, Evolv, BitBrain, Smart Health TV Solution, Wellola, Universidad de Valladolid, Kineactiv, Kinetikos, GMV
- Companies and organisations attended:
    - AMGEN
    - ASERHCO
    - Bahía Software
    - Bitbrain
    - Centro Hospitalar e Universitário de Coimbra (CHUC)
    - Cluster de la Salud de Aragón (Arahealth)
    - CSC
    - DARWIN Biomedical
    - Dataebro S.L.
    - Departamento de Sanidad Gobierno de Aragón
    - Doole Health
    - EDUCATE SERVICIOS
    - Eodyne Systems
    - EURECAT
    - Everis
    - Evolv
    - Fisio Consultores SL
    - Fundación INTRAS
    - GMV
    - Grupo Trilema
    - Healthinn
    - Hospital Royo Villanova
    - IDES S.L.
    - Indra
    - INEAVA
    - Inetum
    - Instituto Aragonés de Ciencias de la Salud (IACS)
    - International Foundation for Integrated Care (IFIC)
    - ITAINNOVA
    - Izertis
    - Karis Digital
    - Kineactiv
    - Medtronic Iberia
    - MicroHealth
    - PPCN.xyz ApS
    - Roche diagnostics
    - STARLAB SL
    - Tecnalia Research & Innovation
    - Teladoc Health
    - Trilema Salud
    - Tunstall Healthcare
    - Ubikare
    - Unidad Neurorhb S.L.
    - Universidad de Zaragoza
    - VALDE Innova S.L.
    - Vicomtech

Elevator pitch / presentations:

| | Date | 16/06/2021 | Time | 10:00 CEST |
|---|---|---|---|---|
| Company | DyCare | | | |
| Company description | DyCare's core activity is to design solutions that revolutionize the tele-rehabilitation process. We offer two solutions to provide much higher throughput of patient diagnosis and treatment: Lynx and ReHub. | | | |
| Description of the proposal presented during the Pre-OMC event | REMOTE-REHABILITATION SOLUTION. ReHub is an evidence-based digital platform that offers effective remote rehabilitation and personalization. Personalized treatment / Real-time monitoring / Progress evaluation. | | | |
| Video | https://youtu.be/7TF80dh-qE4 | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/1.-DyCare_ReHub-updated-compressed.pdf | | | |

| | Date | 16/06/2021 | Time | 10:00 CEST |
|---|---|---|---|---|
| Company | Trilema Salud | | | |
| Company description | Trilema Salud proposes a healthcare model with greater weight in the patient's capacities to manage their disease. We strengthen your skills and provide you with technology that facilitates your self-care.<br>We develop platforms for remote monitoring of patients and adapt them to the needs of care plans and care routes. | | | |

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| Description of the proposal presented during the Pre-OMC event | Trilema Solutions:<br>1. Healthcare Platform: Chronic Patient Management. Home patient control platform. Remote patient control portal for health workers.<br>2. Virtual Consultation: Virtual waiting room. Appointment management. Teleconsultation<br>3. Socio-sanitary monitoring solutions: Remote medical management in residences. Control of the old man at her home.<br>4. Digital Production: Audiovisual production in health programs. Training portals. |
| Video | https://youtu.be/pkdSaOPxG4U |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/2.-Trilema-Salud-Rosia-compressed.pdf |

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|---|---|---|---|---|
| | Date | 16/06/2021 | Time | 10:00 CEST |
| Company | Evolv | | | |
| Company description | Evolv is a CE certified medical device manufacturer specializing in software and hardware development in the Digital Health field, specifically for rehabilitation. We are a spin-off of the company<br>Our product development is driven by our direct interaction with all the main stakeholders in the rehabilitation pathway: patients, their caregivers, therapists and the institutions that provide therapy services. | | | |
| Description of the proposal presented during the Pre-OMC event | EvolvRehab®: is a clinically validated CE marked virtual therapy platform that extends the services of traditional therapy. Uses motion capture technologies + VR + Gamification to make the rehabilitation more pleasant and increase adherence. | | | |

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| Video | https://youtu.be/85O74UTvYH0 |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/3.-Evolv_TeleRehab_ROSIA_es_no-vid-compressed.pdf |

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| | Date | 16/06/2021 | Time | 10:00 CEST |
| Company | BitBrain | | | |
| Company description | Remote brain monitoring and stimulation for telerehabilitation. We provide self-management devices for EEG and other physiological variables monitoring and follow up, and several interventions for cognitive and sleep rehabilitation. Cloud based system for data management and analysis, and on-the-edge and cloud-IA systems for personalization interventions and follow-up. All Bitbrain monitoring and rehabilitation neurotechnologies are end-to-end solutions that follow the medical regulatory paths. Open platform for telerehabilitation. We provide a platform that provides several telerehabilitation programs based on our devices and interventions. | | | |
| Description of the proposal presented during the Pre-OMC event | Digital neurohealth platform:<br>Acquisition system. Use Case 1-Demo: easy to use EEG by non-specialist. Very clean technology, quick collocation and removal.<br>Use Case 2-Demo: Self-management EEG.<br>Digital neurohealth platform. Use Case 2 - Diagnostic/Monitoring/Intervention (Neurorehab).<br>Cognitive rehabilitation (monitoring + neurostimulation): self-management at home. IA driven personalized setup and progress. | | | |
| Video | https://youtu.be/W27XqhLrnpU | | | |

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| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/4.-Rosia-Project-Bitbrain-compressed.pdf |

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| | Date | 16/06/2021 | Time | 10:00 CEST |
| Company | Smart Health TV Solution | | | |
| Company description | SmartHealth TV has developed a health/Socialcare Smart TV platform based on Android/Linux to eliminate the Seniors barriers accessing advanced health/social care technologies/apps at home, including all the tele-rehabilitation services. | | | |
| Description of the proposal presented during the Pre-OMC event | Support Smart TV platform to Telecare and telemedicine at home for the elderly and dependents. Basic functionalities: Videoconference, Reminders, Multimedia content, Medical device monitoring, Personal multimedia content, and Cognitive games and other third-party apps. | | | |
| Video | https://youtu.be/K1nh8cLNHp8 | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/5.-SHTVS-ROSIA-Publica-2021-ES-v1-compressed.pdf | | | |

| | Date | 16/06/2021 | Time | 10:00 CEST |
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| Company | Wellola | | | |
| Company description | Our platform has been in development for the past few years and our experienced leadership team believes that only the sickest of the sick should be hospitalized. Wellola offers a highly interoperable, adaptable patient-facing communications platform.<br>It connects to hospital and GP systems alike, giving patients access to their healthcare information – both clinical and administrative. It has the potential to offer huge cost savings on paper, post and no shows whilst, more importantly, supporting preventive and community based care delivery. | | | |
| Description of the proposal presented during the Pre-OMC event | Patient portal platform. All-in-one communication portal: Share educational material remotely. Monitoring your own symptoms. Completion of forms and remote evaluations. Secure messaging. Appointment management. Remote payments (private centers) | | | |
| Video | https://youtu.be/qhPs-4ISeMI | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/6.-Wellola-Rosia-Project-2021-Espanol-compressed-SPANISH-compressed.pdf | | | |

| | Date | 16/06/2021 | Time | 10:00 CEST |
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| Company | Universidad de Valladolid | | | |
| Company description | Universidad de Valladolid (Grupo de Telemática e imagen). Our main objective is to help people, updating society in general and the service sectors of the most disadvantaged population in particular, the most modern technologies to create applications and products with application in the fields of health, work and education. | | | |

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| | Development of serious tools and games for the rehabilitation of physical / cognitive disabilities and promoting active aging |
| Description of the proposal presented during the Pre-OMC event | Research Group “Telemática e Imagen”: Tele-rehabilitation systems with RGB-D cameras. Self-developed technology with wearable sensors. Low cost system for therapies in the patient's natural environment. Artificial intelligence for analysis of movements |
| Video | https://youtu.be/BEUv8auqMrA |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/7.-UniversidadValladolid_GrupoTelematicaImagen_small-updated-compressed.pdf |

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| | Date | 16/06/2021 | Time | 10:00 CEST |
| Company | Kineactiv | | | |
| Company description | Kineactiv is a digital health solution that, through personalized games, allows senior patients to improve their overall health status. Expertise: Aging, Rehab, Software development.<br>Our product development is driven by our expertise in the rehabilitation and aging field and seeks to reduce the technological barrier through a simple and intuitive interface that allows the patient to use the platform from the first moment. | | | |
| Description of the proposal presented during the Pre-OMC event | A remote rehabilitation tool. Kineactiv in 3 steps:<br>The patient attends consultation with his doctor and he performs a face-to-face consultation. A general assessment of the patient's health status is made based on: State of muscular strength. Joint mobility range. Risk of falls. Independence in activities of daily life. | | | |

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| | Kineactiv is installed on the patient's address.<br>Medical check-up and patient follow-up: The doctor reviews the compliance, adherence and evolution of the patient through a management software called Kineactiv Manager. The doctor contacts the patient through a call or video call to see the evolution of the same and propose changes in the routine by the patient. |
| Video | https://youtu.be/DTKfuq_Zi5c |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/8.-Dossier-Kineactiv-18M_compressed-2-compressed.pdf |

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| | Date | 16/06/2021 | Time | 10:00 CEST |
| Company | Kinetikos | | | |
| Company description | Digital health company revolutionising the standard of care for people with Movement Disorders. We instantly translate a patient's movement into clinical insight. | | | |
| Description of the proposal presented during the Pre-OMC event | mKinetikos is a Mobile app for treatment monitoring. Used by patients and caregivers. Track your activity. Reminders for your medication and prescription update. Keep track of symptoms and daily events. Chat with your healthcare team. Customized exercises from a healthcare provider. Get a full healthcare report. | | | |
| Video | https://youtu.be/DsaSbKUKpsI | | | |
| DF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/9.-21W24D12-Kinetikos-Health-Intro.pdf | | | |

| | Date | 16/06/2021 | Time | 10:00 CEST |
|---|---|---|---|---|
| Company | GMV | | | |
| Company description | Established in 1984, GMV is a private capital technology business group with an international presence. With excellence as our perpetual objective, we have reached a position of leadership in many areas. Our areas of activity include: Aeronautics, Automotive, Cybersecurity, Defense and Security, Space, Finance, Industry, Healthcare, Digital Public Services, and Intelligent Transportation Systems (ITS). | | | |
| Description of the proposal presented during the Pre-OMC event | Antari Home Care, Antari Professional, and Antari Evidence Telemedicine platform adaptable to different scenarios: patient-physician/physician-physician deployed in the home or at healthcare centers and hospitals. Platform for follow-up on telerehabilitation programs and Platform for epidemiological and clinical data.<br><br>Antari® features: solutions in the area of chronic patient care, primary/specialized care telemedicine systems, epidemiological control systems, telerehabilitation and digital radiology systems | | | |
| Video | https://youtu.be/eg5QLpcsfaE | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/10.-GMV-Antari-Professional-Care-2021-ROSIA-PCP-compressed.pdf | | | |

## Pre-OMC Event 2: International

- June 25th 10.00 - 12.30 (10.00 - 12.30 CEST)
- Sandra García Armesto (Executive Director - Institute of Health Sciences in Aragón)
- People registered: 66
- Number of different companies: 44
- Registered for pitch: 10
- Country of origin: 8 (Spain, Greece, Germany, Portugal, UK, Italy, Ireland, Australia)
- Number of pitches: 10. Companies: Starlab SL, Smart Health TV Solution, Fisio Consultores SL, Medtronic Ibérica SA, Maximiliana, DyCare, BitBrain, Evolv, Biomax Informatics AG, CT Consulting SRL
- Companies and organisations attended:
    - Ab.Acus srl
    - Alchemit
    - Anne4Care
    - Aragón Health Cluster (Arahealth)
    - Biomax Informatics AG
    - Check Point R&D Ltd
    - Centro Hospitalar e Universitário de Coimbra (CHUC)
    - Cluster Saúde de Galicia, CSG (Galician Health Cluster)
    - Community Options Australia
    - Coquus
    - E process Med S.L
    - Eodyne
    - eResult SRL
    - Evolv Rehabilitation Technologies
    - Foundation for Research and Technology Hellas (FORTH)/ Institute of Computer Science
    - GeneticAI
    - GMV
    - Health Insight Solutions GmbH
    - Hospital de Sant Pau
    - IDES S.L.
    - Imaginary srl
    - Instituto Aragonés de Ciencias de la Salud (IACS) / Institute for Health Sciences in Aragon
    - Instituto Pedro Nunes
    - Integrated Systems Design and Development S.L.
    - International Foundation for Integrated Care (IFIC)
    - Kinestica
    - Kinetikos
    - Knowhedge S.r.l.
    - Medtronic
    - Neutroplast
    - NRH Hospital
    - Physio R&D ApS
    - PPCN.xyz ApS
    - Servicio Aragonés de SALUD
    - Sensing Future
    - Tech4Care srl
    - Ticbiomed
    - Trilema Salud
    - Tunstall Healthcare
    - University of Zaragoza
    - VALDE Innova S.L.
    - Vicomtech
    - Vola
    - Wellola
    - Winchannel

Elevator pitch / presentations:

| | Date | 25/06/2021 | Time | 10:00 CEST |
|---|---|---|---|---|
| Company | Starlab SL | | | |
| Company description | Remote Brain Stimulation Telerehabilitation: Real-time remote monitoring, Real remote access control and Cloud based data management.<br>Algorithm and Model development: EEG signal processing, Computational Intelligence, Machine learning, Data-mining, Big-Data, Biomarker evaluation, Multi-modal and Multi-sensory data fusion.<br>Electroencephalography (EEG) and neuroimaging: Protocol design, experimental and clinical trials, biomarker discovery, real-time and off-line data analysis, visualization and reporting.<br>End-to-end systems, application layer, and cloud-based data management and analysis. | | | |
| Description of the proposal presented during the Pre-OMC event | Starstim -Home Technology: Multi-channel and simultaneous tES-EEG with real-time remote supervision. Optimized usability for home use. Real remote access control. Real-time remote monitoring. Simultaneous EEG recordings. Bipolar, HD, or multi-channel tES and Video and task integrations.<br><br>Bird´s-Eye View on the solution: Plattform, Starstim tCS Home Kit, Notifications and Portal. | | | |
| Video | https://youtu.be/gDycK0T9i24 | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/2.-STARLAB-compressed.pdf | | | |

| | Date | 25/06/2021 | Time | 10:00 CEST |
|---|---|---|---|---|
| Company | Smart Health TV Solution | | | |
| Company description | SmartHealth TV has developed a health/Socialcare Smart TV platform based on Android/Linux to eliminate the Seniors barriers accessing advanced health/social care technologies/apps at home, including all the tele-rehabilitation services. | | | |
| Description of the proposal presented during the Pre-OMC event | Support Smart TV platform to Telecare and telemedicine at home for the elderly and dependents. Basic functionalities: Videoconference, Reminders, Multimedia content, Medical device monitoring, Personal multimedia content, and Cognitive games and other third-party apps. | | | |
| Video | https://youtu.be/SGgZzr7fmbA | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/3.-Smart-Health-TV-Solution-compressed.pdf | | | |

| | Date | 25/06/2021 | Time | 10:00 CEST |
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| Company | Fisio Consultores SL | | | |
| Company description | Fisio Consultores has quickly become a leading company in delivering impactful products and services to the health care/physiotherapist sector.<br><br>We have contributed in the design and transfer of new products and services to the Physiotherapy market, such as the , a medical device to self-manage muscle pain, or Hefora, a platform for personalized exercise prescription. Our expertise is in the area of Physiotherapy, | | | |

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| | helping companies to design, validate and transfer new products, services and technology to the Physiotherapy sector. |
| Description of the proposal presented during the Pre-OMC event | Background: Patented 3 Tool -www.3-tool.com-: facilitate prevention and self-management. Software for personalized prescription of exercise. Sensor for remote diagnosis and Technology for gait rehabilitation. |
| Video | https://youtu.be/ErkE66RlT_E |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/4.-iHealty-compressed.pdf |

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| | Date | 25/06/2021 | Time | 10:00 CEST |
| Company | Medtronic Ibérica SA | | | |
| Company description | We fuse technology, a deep understanding of the body, and leading medical science to create never-before-seen solutions. Whether it's less invasive surgical approaches to minimise a patient's downtime or creating the smallest pacemaker, our potential to transform lives knows no limits.<br><br>We take insights gleaned from data to make substantial improvements in care, tailoring therapies in real time. And our work on the forefront of technology pushes care forward, such as reimagining robotic-assisted surgery to bring advanced precision and predictability to more people. | | | |

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| Description of the proposal presented during the Pre-OMC event | The future of rehabilitation & Patient monitoring and empowerment.<br><br>Portable rehabilitation tool that will speed up the patient's recovery.<br><br>1. Smart Solutions for personalized tele-rehabilitation therapy at home for patients with motor, cognitive and language deficits that accelerate the recovery of their normal life in a secure way.<br>2. Tool for patient monitoring and empowerment: educate and monitor the evolution of the patient while promoting an active engagement and empowerment of the patient.<br>3. Tool for multidisciplinary and inter-level management of medical cases: facilitate communication, coordination and decision-making between healthcare professionals at a distance. |
| Video | https://youtu.be/ljnET2zS1nc |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/5.-Medtronic-compressed.pdf |

| | Date | 25/06/2021 | Time | 10:00 CEST |
|---|---|---|---|---|
| Company | Maximiliana | | | |
| Company description | The Maximiliana smartphone is adapted to the elderly and only answers calls and video calls. Location, loudspeaker, remote assistance and blocked to avoid errors. | | | |
| Description of the proposal presented during the Pre-OMC event | Maximiliana is a self-sufficient phone aimed at old people or people with technology difficulties that works totally independently. The objective is to break the digital gap, to give the opportunity to everybody to have easy access to visual communication and take advantage of it, and to assure they feel comfortable and integrated in the modern society. | | | |
| Video | https://youtu.be/n7mRqEmbASg | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/6.-Maximiliana-corporate-compressed.pdf | | | |

| | Date | 25/06/2021 | Time | 10:00 CEST |
|---|---|---|---|---|
| Company | DyCare | | | |
| Company description | DyCare's core activity is to design solutions that revolutionize the tele-rehabilitation process. We offer two solutions to provide much higher throughput of patient diagnosis and treatment: Lynx and ReHub. | | | |

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| Description of the proposal presented during the Pre-OMC event | They design portable solutions that revolutionize the rehabilitation process of patients with musculoskeletal, respiratory, neuronal and chronic disease. They have three important items in mind: Personalised treatments, more precise and contrasted clinical results and reduction of health costs.<br><br>Rehub is a digital rehabilitation platform based on medical evidence that delivers effective, personalized home rehabilitation for people who suffer from muscle-skeletal problems. Personalized treatment, Real time follow up and progress evaluation. |
| Video | https://youtu.be/qdloctXP5_4 |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/10/1.-DyCare_ReHub-updated-2-compressed.pdf |

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|---|---|---|---|---|
| | Date | 25/06/2021 | Time | 10:00 CEST |
| Company | BitBrain | | | |
| Company description | Remote brain monitoring and stimulation for telerehabilitation. We provide self-management devices for EEG and other physiological variables monitoring and follow up, and several interventions for cognitive and sleep rehabilitation. Cloud based system for data management and analysis, and on-the-edge and cloud-IA systems for personalization interventions and follow-up. All Bitbrain monitoring and rehabilitation neurotechnologies are end-to-end solutions that follow the medical regulatory paths. Open platform for telerehabilitation. We provide a platform that provides several telerehabilitation programs based on our devices and interventions. | | | |

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| Description of the proposal presented during the Pre-OMC event | Digital neurohealth platform:<br>Acquisition system. Use Case 1-Demo: easy to use EEG by non-specialist. Very clean technology, quick collocation and removal.<br>Use Case 2-Demo: Self-management EEG.<br>Digital neurohealth platform. Use Case 2 - Diagnostic/Monitoring/Intervention (Neurorehab).<br>Cognitive rehabilitation (monitoring + neurostimulation): self-management at home. IA driven personalized setup and progress. |
| Video | https://youtu.be/Qv96rU1cG50 |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/10/4.-Rosia-Project-Bitbrain-2-compressed.pdf |

| | Date | 25/06/2021 | Time | 10:00 CEST |
|---|---|---|---|---|
| Company | Evolv | | | |
| Company description | Evolv is a CE certified medical device manufacturer specializing in software and hardware development in the Digital Health field, specifically for rehabilitation. We are a spin-off of the company<br><br>Our product development is driven by our direct interaction with all the main stakeholders in the rehabilitation pathway: patients, their caregivers, therapists and the institutions that provide therapy services. | | | |
| Description of the proposal presented during the Pre-OMC event | EvoleRhab is being employed to treat persons of all ages and levels of disability and for a wide variety of pathologies. The simple one-button star system means that no technology means that no technology experience is required and allows patients of all ages and levels of disability to have greater autonomy when choosing when to do their rehabilitation. | | | |

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| Video | https://youtu.be/RUiJwR3CHlQ |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/8.-Evolv-compressed.pdf |

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| | Date | 25/06/2021 | Time | 10:00 CEST |
| Company | Biomax Informatics AG | | | |
| Company description | Biomax Informatics provides services and software solutions for efficient decision making and knowledge management at the intersection of life sciences, healthcare and information technologies. Biomax facilitates digital transformation within biotech, pharma, agriculture, food and chemical industries as well as research institutes. | | | |
| Description of the proposal presented during the Pre-OMC event | BioXM is perfectly suited to support home-telerehabilitation: intelligent digital linking and integration, Interoperability, KI-based patient stratification, Individualized treatment, Holistic patient-oriented approach, Reduce redundancy and improve therapeutic success. | | | |
| Video | https://youtu.be/dpmQG33-4Bw | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/9.-Biomax-compressed.pdf | | | |

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| | Date | 25/06/2021 | Time | 10:00 CEST |

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| Company | CT Consulting SRL |
| Company description | In support of vulnerable / elderly people, we provide them with a communication tool that connects them directly to the family and support facilities to ensure their safety and immediate help when needed. |
| Description of the proposal presented during the Pre-OMC event | TV-Phone: technology for assistance and security of fragile people at home: the family providing the Hotellerie business. The care manager provides assistance, with monitoring of therapeutic adherence, extending its effectiveness, promoting a prolonged family life condition and delaying institutionalized hospitalization of the Patient, and the technological platform carrying out all communication and administrative activities. Through a simple, - the integration between television and telephone- it was possible to transform a technology already used and known to all into a powerful and easy-to-use interactive communication platform. |
| Video | https://youtu.be/kA4bMqhj5mw |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/10.-CT-Consulting-compressed.pdf |

## Pre-OMC Event 3: Ireland

- June 28th 10.00 - 12.30 (11.00 - 13.30 CEST)
- John Swords (Head of Procurement Health Service Executive)
- Ainee Carroll (Rehabilitation Medical Consultant - National Rehabilitation Hospital)
- People registered: 52
- Number of different companies: 30
- Registered for pitch: 14 (1 company repeated 2 times)
- Country of origin: 6 (Spain, Ireland, UK, Portugal, France, Holland)
- Number of pitches: 13. Companies: Physio R&D ApS, NearForm, Think Biosolution, Wellola, Kinesis Health Technologies, Prime for life, Kinetikos, CliffrunMedia Ltd., PacSana, Teladoc Health, Zendra Health, Isaac Care, InterSystems Corp
- Companies and organisations attended:
    - Anne4Care
    - Bitbrain
    - Centro Hospitalar e Universitário de Coimbra (CHUC)
    - Cliffurn Media Ltd
    - Conseil Régional PACA
    - DyCare
    - Fisio Consultores SL
    - Fundació Eurecat
    - Global Peace Community Interest Company
    - GMV
    - Health Innovation Hub Ireland (HIHI)
    - Instituto Aragonés de Ciencias de la Salud (IACS)/ Institute for Health Sciences in Aragon
    - Instituto Pedro Nunes (IPN)
    - International Foundation for Integrated Care (IFIC)
    - InterSystems Corporation
    - MS Ireland
    - myPatientSpace Limited
    - National Rehabilitation Hospital (NRH)
    - NeuroCONCISE Ltd
    - Nextage Srl
    - PacSana
    - PPCN, xyz ApS
    - Servisource Workforce Solutions
    - Teladoc Health
    - UCD
    - University of Zaragoza
    - VALDE Innova S.L.

Elevator pitch / presentations:

| | Date | 28/06/2021 | Time | 11:00 CEST |
|---|---|---|---|---|
| Company | Physio R&D Aps (José Cerdán - CEO) | | | |
| Company description | Optimov is dedicated to optimizing holistic health and healthcare through an innovative approach to health. It includes online treatments for general physical health and well-being, as well as specialized telerehab programs for chronic diseases, such as COPD and CVD.<br><br>The Optimov platform is part of the VAPA Project (Virtual Autonomous Physiotherapy Agent). A team of professionals have joined forces to bring VAPA to market. The idea of VAPA was to bring to market an innovative remote physiotherapy product designed for patients with chronic diseases. By combining a biometric sensor, augmented reality (AR) glasses and software, a 3D animated agent would guide and support patients in real time, keeping their interest in doing exercises. Thus, VAPA would be an effective and certified way to keep patients active at home. Clinical certification is about to be obtained from clinical trials executed at hospitals in Scandinavia.<br><br>VAPA project redefines what people thought was possible, changing their lives beyond anything else that is available by delivering effective telerehabilitation and preventive exercise sets based on flexibility, use independence and time balance. | | | |
| Description of the proposal presented during the Pre-OMC event | Web APP for rehabilitation programs, Biometrics, VR/AR Glasses, Vata Mobile APP<br><br>Multiple exercises based on a gamification solution that gives you points depending on your intensity. Adaptable solution. Adaptable to proactive patients, self-help patient, fragile patients | | | |
| Video | https://youtu.be/-MsqRwoTSII | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/07/1.-Physio-Rd-compressed.pdf | | | |

| | Date | 28/06/2021 | Time | 11:00 CEST |
|---|---|---|---|---|
| Company | NearForm (Connor O'Neil) | | | |
| Company description | We are technologists and pioneers. By putting the 'human' at the heart of everything we do, NearForm creates software solutions that accelerate enterprise success, enrich customer experience and contribute to the development of our community. Life's complicated enough, so we prefer to keep things simple. | | | |
| Description of the proposal presented during the Pre-OMC event | Cloud-based clinical trials, state covid apps, vaccination platform, digital partner<br><br>Design, frontend, data/analytics, cloud and other services<br><br>Several Open Source tools used for different projects<br><br>IoT, Machine Learning and wearables | | | |
| Video | https://youtu.be/T_Q48ko3vSg | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/07/2.-NearForm-compressed.pdf | | | |

| | Date | 28/06/2021 | Time | 11:00 CEST |
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| Company | Think Biosolution | | | |

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| Company description | The founders have developed the present technology for the past 7 years. The team is currently developing predictors for fitness and health, powered by deep learning, for our present and future products. Located in the technological hub of Dublin, Ireland and Rochester, NY, USA our full stack team works in conjunction with experts from the health and fitness world to develop innovative IoT products. |
| Description of the proposal presented during the Pre-OMC event | Risk indicators and digital therapeutics for at-home telerehabilitation of Spinal Injury<br><br>StrokeDetect, CardiacDetect, and HypertensionDetect modules AI-powered (risk indicators)<br><br>StrokePrevent, CardiacPrevent, and HypertensionPrevent for telerehabilitation<br><br>Wants to work with NRH for remote monitoring and telerehabilitation programme for post discharged at-home spinal cord injury patients (currently is only deployed in long term care facilities).<br><br>License out and develop features such as exercise tracking in the spinal cord injury telerehabilitation programme |
| Video | https://youtu.be/nauYRFbs5eI |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/10/3.ThinkBiosolution-compressed.pdf |

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| | Date | 28/06/2021 | Time | 11:00 CEST |
| Company | Wellola | | | |

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| Company description | Our platform has been in development for the past few years and our experienced leadership team believes that only the sickest of the sick should be hospitalized. Wellola offers a highly interoperable, adaptable patient-facing communications platform.<br>It connects to hospital and GP systems alike, giving patients access to their healthcare information – both clinical and administrative. It has the potential to offer huge cost savings on paper, post and no shows whilst, more importantly, supporting preventive and community based care delivery. |
| Description of the proposal presented during the Pre-OMC event | Adaptable Patient-Facing Communication Platform: integrated care pathway, support & empower patients to self-care, facilitate remote communication & care delivery<br><br>Key tool in providing remote care to patients in Ireland & a critical tool in helping avoid further contagion of Covid-19<br><br>More integrated model of care delivery; Move to preventative, personalised care models; Remote, community-based care delivery via digital tools.<br><br>Product: fully interoperable-FHIR APIs, all core communication tools, includes video, option to white-label, ISO27001, DCB0129 certified, hosted AWS EU/UK & managed by Deloitte |
| Video | https://youtu.be/bbnsEI2ZPio |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/6.-Wellola-Rosia-Project-2021-Espanol-compressed-SPANISH-compressed.pdf |

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| | Date | 28/06/2021 | Time | 11:00 CEST |
| Company | Kinesis Health Technologies (Barry Greene - CTO) | | | |

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| Company description | Kinesis Health Technologies is a leading provider of scientifically validated, machine learning technologies for evaluation of falls risk and rehabilitation as well as for monitoring response to subsequent preventive interventions.<br><br>From specialized laboratories to ambulatory and residential care, Kinesis technologies provide reliable measures, are easy to use and set up, and provide immediate, exportable results. Designed to cover many test conditions, from long walking trials on a treadmill to protocols restricted by space or time, our range of products enable assessment of participants of all ages and physical conditions, accounting for mobility aids, prosthesis, orthotics, and rehabilitation. |
| Description of the proposal presented during the Pre-OMC event | Kinesis solution: screen, assess, intervene, monitor (clinical and personal use)<br><br>Kinesis balance: remote assessment of physical function. Accurate assessment of falls risk, personalised intervention to prevent falls, customisable content, precise measurement of physical function, validated machine learning algorithms, cloud storage & data integration<br><br>Benefits: engage and empower older adults on falls, facilitates self-assessment, tracks function and falls risk overtime, scale up services, drives primary prevention |
| Video | https://youtu.be/VPZm3n7rOeQ |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/07/5.-Kinesis-compressed.pdf |

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| Date | 28/06/2021 | Time | 11:00 CEST |

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| Company | Prime for life (Niall Ó Tuathail - CEO) |
| Company description | Prevention Research Institute, Inc. (PRI) is a private nonprofit organization dedicated to helping people reduce the incidence of alcohol and drug-related problems. We build partnerships for change, working with dedicated professionals to reduce high-risk alcohol and drug use throughout the world.<br><br>PRI is committed to being research-based and providing effective programs, quality training, and superior service. |
| Description of the proposal presented during the Pre-OMC event | Fighting frailty with fitness<br><br>Digital coach interactions with suggested programmes (tracking progress).<br><br>Solution: supervised self and community care of rehabilitation at the patient environment; flexible and scalable value-based model of care; tailored integrated care model; motivation by strong implication of the community and virtual coaching tools.<br><br>Open platform to fit within the ROSIA pathway: video and educational content provided by specialist unit/centre; programme selected by specialist team leading care; patient and family have access to patient app to access programme, interact with coach and other patients; community caregivers (GP, dedicated coaches, volunteers) can onboard as digital coaches for motivation of receive data and reports on progress; potential for risk stratification and alarm systems/nudges for engagement |
| Video | https://youtu.be/Jx92pXeyCvw |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/07/6.-Prime-for-Life-compressed.pdf |

| | Date | 28/06/2021 | Time | 11:00 CEST |
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| Company | Kinetikos | | | |
| Company description | Digital Health company specialised in human movement analysis.<br><br>"*Digital health company revolutionising the standard of care in movement disorders*"<br><br>Founded in 2015, won MIT Portugal/BGI acceleration program in 2017. | | | |
| Description of the proposal presented during the Pre-OMC event | Two solutions to measure the movement:<br><br>● Kinetikos Pro: SaaS Platform with detailed kinematic movement analysis. Used by research and clinical trials.<br>● mKinetikos: Mobile app for treatment monitoring. Used by patients. (http//bit.ly/mKinetikos)<br><br>Monitoring functional activity in 3 aspects. Only solution is: medical device, commercially available, not wereable dependent, validated ecological measure, not limited to a short period assessment. | | | |
| Video | https://youtu.be/k1NGmN4VYgA | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/07/7.-Kinetikos-compressed.pdf | | | |


| | Date | 28/06/2021 | Time | 11:00 CEST |
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| Company | CliffrunMedia Ltd. (Phillip Hogan - CEO) |
| Company description | Age-Tech solutions, bridging the digital divide<br><br>Building digital solutions for our older population. |
| Description of the proposal presented during the Pre-OMC event | Acorn Modular platform solution<br><br>● Dedicated tablet solutions<br>● Connected devices<br>● Administrative portals<br>● Companion applications<br><br>ACORN Age Friendly Smart tablet: informed, interactive, involved. ACORN CARE (Clinical Care Team; Virtual Ward Management); ACORN PATIENT (Self Management); ACORN SOCIAL (Digital Inclusiveness). Carer/Clinician Portal Management<br><br>82 organisations using the solution; 1825 ACORN Users. |
| Video | https://youtu.be/jlUGbpsJ_Lw |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/8.-Dossier-Kineactiv-18M_compressed-2-compressed.pdf |

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| Date | 28/06/2021 | Time | 11:00 CEST |

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| Company | PacSana (Mark Nolan) |
| Company description | PacSana incorporates a team with extensive industry knowledge in providing technical, design and marketing solutions.<br><br>Early in 2018, we decided to look at the area of Technology Enabled Care. We looked at how to deliver solutions that put the end user at the centre of the solution.)<br><br>Our aim is to enable end users with technology to live longer, happier lives in their own homes. Our vision of technology enabled care is one that puts the user at the heart of the solution.<br><br>The solution engages the user as little or as much as they need but it delivers on the users' requirements.<br>● Provide an insight that reassures while respecting users' dignity and privacy<br>● Earn enthusiastic user support by focussing on ease of use and comfort – Wear and Forget<br>● Simplify installation and support to enable family and agencies to focus on caring |
| Description of the proposal presented during the Pre-OMC event | PacSana bracelet: designed with the user in mind to maximise compliance.<br><br>● Wear-and-forget movement monitor (6-month battery life)<br>● Lightweight with a comfortable rubberized strap<br>● Waterproof for 24/7 wearability<br>● No smartphone required<br><br>PacSana Gateway<br><br>● Two or more sensors are positioned around the users home<br>● Simplicity: Easy to set up either by a user, family member or carer<br><br>The PacSana Solution<br><br>Bracelet (location & data); PacSana Home Gateway; Pules engine and machine learning; Rich visualisations and smart alerts. |

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| Video | https://youtu.be/lSQCHrQUdRM |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/07/9.-Pacsana-compressed.pdf |

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| | Date | 28/06/2021 | Time | 11:00 CEST |
| Company | Teladoc Health (Lucía Osoro - EMEA Sales Operations Manager) | | | |
| Company description | Enabling Remote Rehabilitation Services for Isolated Areas<br><br>Teladoc Health is the global leader in whole-person virtual care—offering the technology to connect, expertise you can trust and the power to improve health for all | | | |
| Description of the proposal presented during the Pre-OMC event | Teladoc Health is the world's only integrated virtual care system for delivering, enabling and empowering whole-person health—from wellness and prevention to acute care to complex healthcare needs.<br><br>SOLO Virtual Care Platform is not only a software but an ecosystem to enable the communication and interoperability for Jack and his caregivers. | | | |
| Video | https://youtu.be/lDLOP5Iu2o4 | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/07/10.-Teladoc-compressed.pdf | | | |

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| | Date | 28/06/2021 | Time | 11:00 CEST |

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| Company | Zendra Health |
| Company description | Digitalised personalised care.<br><br>Zendra Health is an ISO 13485 certified company that democratises digital health. Their team has worked with world-renowned healthcare organisations such as Stanford University, Apple, and Mount Sinai, and the technology is already proven in rehabilitative care.<br><br>They are not just a solution, they are a partner. They have worked with the best in the world and there to deliver personalised rehabilitation to acquired brain injury patients at the comfort of their own home whilst giving care teams visibility of patient progress outside the four walls of a clinic. |
| Description of the proposal presented during the Pre-OMC event | Companion Platform<br><br>"*Using Zendra's proven technology, in just a few clicks, the Companion Platform will deliver personalised rehabilitation to acquired brain injury patients at the comfort of their own home whilst giving care teams visibility of patient progress outside the four walls of a clinic*".<br><br>● No-code platform (patient-centric health apps can be created in minutes).<br>● Insights (the platform provides insights to track performance and outcomes measures).<br>● Content Management System (the platform's intuitive Content Management System allows to create new care plans, educational materials, engage with service users and customise health app content instantly).<br><br>Medical devices: ISO 13485:2016 NSAI Certified. Care teams can check remotely in on service users from the clinician dashboard and swiftly determine if any further intervention is required. |
| Video | https://youtu.be/QCCPhmspXp0 |

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| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/10/11.-Zendra-compressed.pdf |

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| | Date | 28/06/2021 | Time | 11:00 CEST |

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| Company | Isaac Care |
| Company description | **Complete Independent Living Solution**<br><br>Enabling our clients to live independently at home for longer with a combination of technology and in person care support.<br><br>**10 Years Experience in Homecare**<br><br>We have been providing high quality homecare across Ireland for 10+ years.<br><br>**Innovative and Future Focused**<br><br>We believe that a blend of technology and care is needed to future proof our health system. |
| Description of the proposal presented during the Pre-OMC event | **MOBILE APP**<br><br>Family caring app which facilitates easy communication within "Circles of Care". The app pulls in data from the peripheral devices allowing all information to be viewed and shared in one easy to use platform.<br><br>**ASSISTIVE DEVICES**<br><br>We provide our clients with a bespoke kit of devices depending on their needs.We offer a GPS enabled fall pendant, discreet motion |

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| | sensors and smart vitals monitoring devices which all integrate directly with the app.<br><br>**SUPPORT SERVICES**<br><br>We offer a range of support services including a 24/7 telehealth service, remote monitoring of vitals, early hospital discharge support, rehabilitation care and homecare supports. |
| Video | https://youtu.be/scGdoX-RLn0 |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/07/12.-Isaac-compressed.pdf |

| | Date | 28/06/2021 | Time | 11:00 CEST |
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| Company | InterSystems Corp | | | |
| Company description | • Global leader in healthcare data management and integration; founded in 1978.<br>• Privately held and stable business built on partnerships.<br>• Highly rated by KLAS, Forrester, Gartner Peer Insights, Gartner Magic Quadrant and IDC www.intersystems.com/analyst<br>• Proud to be a partner of National Rehabilitation Hospital, Ireland. | | | |
| Description of the proposal presented during the Pre-OMC event | **Enterprise Healthcare Platform**<br><br>• Comprehensive Health Platform<br>• Unified Record of Care<br>• Analytics & Solution Components<br>• Development Technologies | | | |

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| | **InterSystems and ROSIA**<br><br>● Self-care of rehabilitation at home<br>○ Patient entered multimedia data<br>○ Data captured from a device<br>○ Information sharing (bi-directional)<br>● Data driven intervention<br>○ Real-time analytics<br>○ AI & ML capabilities<br>○ Population Health Management<br>○ Clinical Decision Support<br>● Multidisciplinary Care Coordination<br>○ On-demand access to patient records<br>○ Cross agency care planning |
| Video | https://youtu.be/xV6tpS-s3Xs |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/07/13.-InterSystems-compressed.pdf |

## Pre-OMC Event 4: Portugal

- June 30th 14.30 - 17.00 (15.30 - 18.00 CEST)
- Alexandre Lourenco (Hospital Administrator - Centro Hospitalar e Universitário de Coimbra)
- People registered: 54
- Number of different companies: 37
- Registered for pitch: 11
- Country of origin: 5 (Spain, Ireland, Netherlands, Portugal, UK)
- Number of pitches: 9. Companies: Plux Wireless, SWORD HEalth, Biodevices, Clynx, Altice Labs, Hope-Care, Kinetikos, Wellola, Anne4Care
- Companies and organisations attended:
    - a*a*i*t
    - ANI - Agência Nacional de Inovação
    - BRIGHT
    - Capgemini Engineering
    - Centro Hospitalar e Universitário de Coimbra (CHUC)
    - Coimbra Hospital and University Centre
    - CRO
    - GlamHealth Medical Services, Lda
    - Glintt
    - GMV
    - Grape Ways
    - Instituto Aragonés de Ciencias de la Salud (IACS)/ Institute for Health Sciences in Aragon
    - International Foundation for Integrated Care (IFIC)
    - INESC TEC
    - Instituto Pedro Nunes (IPN)
    - Municipio de Penela
    - Municipio de Soure
    - Neuroinova, Lda
    - Neutroplast
    - NS IT
    - Politécnico de Viseu, Escola de Saúde
    - PPCN.xyz ApS
    - PROMPTLY
    - Sensing Future Technologies
    - Servicio Aragonés de SALUD
    - Teladoc Health
    - TICE.PT
    - University of Zaragoza
    - VALDE Innova S.L.
    - Wisify Tech Solutions, Lda

Elevator pitch / presentations:

| | Date | 30/06/2021 | Time | 15:30 CEST |
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| Company | Plux Wireless | | | |
| Company description | They develop biosignals acquisition toolkits for medical R&D and product development.<br>● Located in Lisbon (Portugal), started in 2007.<br>● Team over 34 dedicated members, half of them in R&D<br>● Wireless biosignal acquisition platforms<br>● Biosignal engineering services | | | |
| Description of the proposal presented during the Pre-OMC event | Solutions that cover the entire lifecycle of the biosignals experience: from the first contact up to the fully-featured medical device.<br>● Bitalino: Wireless toolkit for rapid prototyping, entry-level research and education.<br>● Biosignalsplux: Wireless toolkit for biosignals research and product development. The most versatile platform for the acquisition of physiological signals for research and development. Supports data acquisitions using up to 8 sensors per device and continuously growing portfolio of over 20 different interchangeable sensors.<br>● Physioplux: biofeedback guided physiotherapy | | | |
| Video | https://youtu.be/SccmoQC8CCI | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/10/21_Plux-Wireless-Biosignals-compressed.pdf | | | |

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| | Date | 30/06/2021 | Time | 15:30 CEST |
| Company | SWORD Health | | | |
| Company description | Founded in 2014, 190 employees. Present in Europe, North America and Australia. CE mark, GDPR compliant, FDA and HIPAA certified | | | |
| Description of the proposal presented during the Pre-OMC event | **Telerehabilitation for physiotherapists**<br><br>Motion sensors, digital therapist, SWORD Portal. Simple and supported onboarding: after filling out the survey, they have a 30 min video call with the physiotherapist. Then, the physio creates a tailored program, and mail a SWORD kit to the doorstep to start the telerehabilitation process. Data analysation to adjust the program, and motivational, educational and CBT content curated with the participant. The solution allows the physio to adjust all the rehabilitation processes to motivate and improve results. 3x more engaging than traditional PT.<br>Easy and effective solution integration in the ROSIA ecosystem. | | | |
| Video | Confidential / not authorised | | | |
| PDF File | Confidential / not authorised | | | |


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| | Date | 30/06/2021 | Time | 15:30 CEST |

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| Company | Biodevices |
| Company description | Biodevices is a Biomedical Engineering Systems company established in 2007 that as the mission to develop, market and export Biomedical Engineering solutions to support medical diagnosis<br><br>In 2017 Biodevices and dynasis (the major shareholder now) joined forces and crossed paths. Since then, Dynasys, as developer and manufacturer of electronic based equipment, and system integrator, under Biodevices guidance, in what aims are concerned, is performing a process of updating and enlarging the VitalJacket ECG range, and developing from scratch other solutions, for diagnosis and measurement of the evolution in patients subject to therapies on hands and feet pathologies. |
| Description of the proposal presented during the Pre-OMC event | • VitalJacket –1 s medical grade ECG ultraportable equipment, and Software (Holter and Cardiac Rehab)<br>• VitalJacket SDK –for professionals and researchers to develop their own applications and data analysis<br>• VitalJacket Baby and Kids 1, 5 leads VitalJacket ECG Monitor<br>• Solutions for diagnosis and therapy of hands and feet |
| Video | https://youtu.be/JviTUCGHTP8 |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/07/03_Biodevices-compressed.pdf |

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| Date | 30/06/2021 | Time | 15:30 CEST |

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| Company | Clynx |
| Company description | Digital Health Solutions to track progress and increase motivation. Founded in 2018 and based in Lisbon (Portugal) |
| Description of the proposal presented during the Pre-OMC event | Motiphy+: An engaging and gamified physiotherapy (available at the Clinic and at Home)<br>● Motion sensor cameras to detect patient's joints to create a virtual body model<br>● Gamified exercises: the treatment plan is selected by the physiotherapist and each specific exercise is customized according to the patient clinical profile<br>● Progress portal: easily design customized treatment plans on our platform for both the physician and patient to consult.<br>B2B approach: the kit includes software, body tracking 3D camera and technical support |
| Video | https://youtu.be/MjcnPikDG4k |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/10/24_Clynx-compressed.pdf |

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| Date | 30/06/2021 | Hour | 15:30 CEST |

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| Company | Altice Labs |
| Company description | Altice Labs plays an active role in the Innovation Ecosystem, working in collaboration with Universities, R&D Institutions, suppliers and customers in various projects benefiting from national and international funding in research and innovation programs.<br><br>Programs: European H2020, Portuguese P2020, Universities, startups, SMEs and Enterprises. |
| Description of the proposal presented during the Pre-OMC event | Smart AL Telemonitoring System<br><br>SmartAL offers a set of technologies, devices and support devices, which allows the monitoring, in real time, of the chronically ill, the elderly and people in convalescence, home hospitalization, confinement, post-hospitalization, etc., as it allows the telemonitoring of vital signs, teleconsultations and support for activities related to health, well-being and safety.<br><br>Apps and interfaces, bluetooth devices.<br><br>Functionalities: remote monitoring of vital signs, videocall, reports, informed consent, questionnaires, plan and daily task management, alerts, notifications, reminders, content tutorials, security and privacy |
| Video | Confidential / not authorised |
| PDF File | Confidential / not authorised |

| | | | | |
|---|---|---|---|---|
| | Date | 30/06/2021 | Hour | 15:30 CEST |
| Company | Hope-Care | | | |

| | |
|---|---|
| Company description | Hope Care is one of the first national companies in the area of Digital Health to combine services, technology platforms, and products, allowing the delivery of a totally innovative social and health service.<br><br>Build a disruptive health care proposal that leads to better results with a social impact for citizens.<br><br>Ensure the delivery of an excellent Digital Health service, exceeding customer expectations. |
| Description of the proposal presented during the Pre-OMC event | • Health/vital signs data: objective data from HC App: glucose, SpO2, blood pressure, body temperature.<br>• Activity: activity from fitness and wellbeing apps, sports preference, sleep, physical activity, nutrition<br>• Personal behavior: medication compliance, mood, stress, pain, holidays, tailored surveys, nutrition, virtual visits (booking)<br>• Enviromental data: location, weather, local NHS alerts, flu, covid-19,...<br>• Social data: caregivers, care plan, family and friends portal, social media activity<br><br>**Proximity app concept:**<br><br>• Telehealth and telemonitoring in one place<br>• My health - BYOD<br>• Family, friends, and caregivers contacts<br>• Virtual visits appointments<br>• Dynamic Media Contents. |
| Video | https://youtu.be/Y9NHAcGlM4U |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/07/06_HopeCare-compressed.pdf |

| | Date | 30/06/2021 | Hour | 15:30 CEST |
|---|---|---|---|---|
| Company | Kinetikos | | | |
| Company description | Digital Health company specialised in human movement analysis<br><br>"*Digital health company revolutionising the standard of care in movement disorders*"<br><br>Founded in 2015, won MIT Portugal/BGI acceleration program in 2017. | | | |
| Description of the proposal presented during the Pre-OMC event | Two solutions to measure the movement:<br><br>● Kinetikos Pro: SaaS Platform with detailed kinematic movement analysis. Used by research and clinical trials.<br>● mKinetikos: Mobile app for treatment monitoring. Used by patients. (http//bit.ly/mKinetikos)<br><br>Monitoring functional activity in 3 aspects. Only solution is: medical device, commercially available, not wereable dependent, validated ecological measure, not limited to a short period assessment. | | | |
| Video | https://youtu.be/-Oci28qc3AU | | | |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/07/7.-Kinetikos-compressed.pdf | | | |

| | Date | 30/06/2021 | Hour | 15:30 CEST |
|---|---|---|---|---|
| Company | Wellola | | | |

| | |
|---|---|
| Company description | Our platform has been in development for the past few years and our experienced leadership team believes that only the sickest of the sick should be hospitalized. Wellola offers a highly interoperable, adaptable patient-facing communications platform.<br><br>It connects to hospital and GP systems alike, giving patients access to their healthcare information – both clinical and administrative. It has the potential to offer huge cost savings on paper, post and no shows whilst, more importantly, supporting preventive and community based care delivery. |
| Description of the proposal presented during the Pre-OMC event | Adaptable Patient-Facing Communication Platform: integrated care pathway, support & empower patients to self-care, facilitate remote communication & care delivery<br><br>Key tool in providing remote care to patients in Ireland & a critical tool in helping avoid further contagion of Covid-19<br><br>More integrated model of care delivery; Move to preventative, personalised care models; Remote, community-based care delivery via digital tools.<br><br>Product: fully interoperable-FHIR APIs, all core communication tools, includes video, option to white-label, ISO27001, DCB0129 certified, hosted AWS EU/UK & managed by Deloitte |
| Video | https://youtu.be/wDfSreUMxL8 |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/06/6.-Wellola-Rosia-Project-2021-Espanol-compressed-SPANISH-compressed.pdf |

| | | | | |
|---|---|---|---|---|
| | Date | 30/06/2021 | Hour | 15:30 CEST |
| Company | Anne4Care | | | |

| | |
|---|---|
| Company description | Part of Virtask B.V, existed for 10 years, custom technology, 16 employees, international projects and international partners |
| Description of the proposal presented during the Pre-OMC event | Anne: virtual assistant with avatar emotions, speech recognition, speech synthesis, modules (multiple languages).<br><br>Anne (technology): offline basic functionality, flexible and modular, GDPR compliant, backend: dashboard, telemetry, deep learning.<br><br>Anne (telerehabilitation)<br><br>● Measuring = knowing: build user profile; use telemetry; measure feedback, deep learning<br>● Purpose: individual attention, automated customization, motivation matching |
| Video | https://youtu.be/C7PmUBmQtmE |
| PDF File | https://rosia-pcp.eu/wp-content/uploads/2021/10/09_Anne4Care-2-compressed.pdf |

# Annex 3:

# OMC Legal Document/framework. Basic conditions

# OPEN MARKET CONSULTATION (OMC). BASIC CONDITIONS.

## 1.- ANNOUNCEMENT

The Open Market Consultation (OMC) is launched to attract and inform about the ROSIA PCP and to gather the views of the market about the ROSIA PCP Challenge.

The announce of this OMC was included in a Prior Information Notice with the following publishing references:

Original notice sent via eNotices:

TED eSender login: ENOTICES

TED eSender customer login: ECAS_n002jpk5

Notice reference: 2021-060431

Notice number in the OJ S: 2021/S 090-233129

Publication date: 10/05/2021

Corrigendum reference: 2021- 069228

Corrigendum notice number in the OJ S: 2021/S 102-269087

All the information related to the Rosia OMC will be published on the website

## 2.- DESCRIPTIVE REPORT OF ROSIA CHALLENGE AND SCOPE OF THE CONSULTATION

The present OMC, based on the provision of Article 40 of the Public Procurement Directive 2014/24/EU, is the pre-phase of the pre-commercial procurement aiming to get insight into the market to correctly prepare the tender and inform about the contracting plans of the corresponding buyer's group for ROSIA PCP project, as well as the requirements to attend the procedure.

In summary, the goals of the Open Market Consultation are:

- To conduct a detailed need analysis of the buyers group (the three partner procurers).
- To map all companies capable of submitting responses to the tender.
- To get insight in the market: state of the art and future developments in order to develop a call for proposals with the optimal scope.
- To consult with the potential suppliers on the validity of the challenge, its specifications and to gather feedback on the feasibility of response.
- To identify the most critical success factors, barriers and enablers to be considered.
- To identify remaining gaps and challenges and where R&D is still required.
- To inform the market and attract suitable stakeholders, particularly suppliers but also (future) procurers. to solicit market information on possible solutions to the need for improving the processes and procedures in a renewed GuíaSalud website, using new technologies.

The overall objective is the development of an intelligent platform for telerehabilitation services for patients in remote areas. Applications and devices from the ROSIA Catalog will be connected to the aforementioned platform, allowing community services and supervised self-care to be integrated into the care plan of each patient.

The ROSIA PCP challenge is explained in the descriptive documentation published on the website.

**3.- MULTIDISCIPLINARY TECHNICAL TEAM**

They are part of the multidisciplinary technical team:

- Director of Financial Operations, Instituto Aragonés de Ciencias de la Salud (IACS)
- Rosia Innovation Manager, Instituto Aragonés de Ciencias de la Salud (IACS)
- Rosia Procurement Coordinator, Valde
- Innovation Unit Project Coordinator , Servicio Aragonés de Salud (Salud)
- National Rehabilitation Hospital (NRH) representant
- Hospital Administrator, Centro Hospitalar Universitário de Coimbra (CHUC)
- Rosia Task 2.1. leader, Instituto Pedro Nunes (IPN)
- Technology expert (PPCN)

Its function in this procedure, prior to the contract, is to advise ROSIA PCP buyer's group to prepare the questionnaires and information that will be used to support the OMC, and to resolve the doubts and questions that arise during the same.

In addition, the technical team will participate in the preparation of the report containing the results of the consultation.

**4.- APPLICATION OF THE PRINCIPLES OF TRANSPARENCY, EQUALITY OF TREATMENT AND NON-DISCRIMINATION**

Participation in the consultation, contacts with participants or exchanges of information shall in no case lead to infringements of the Community principles of transparency, equal treatment and non-discrimination in public procurement, and shall not have the effect of restricting or limiting competition, or grant advantages or exclusive rights.

**5.- PROCEDURE OF CONSULTATION.**

1. The call is open and is addressed to individuals or legal entities who intend to collaborate with ROSIA PCP buyers' group by providing information on the state of science or the market as to whether there are certain developed or developing solutions related to the subject of this consultation and, where appropriate, submitting proposals specifying both the definition and scope of tasks, such as its implementation and degree of technological innovation.

The submission of several proposals by the same individual or legal entity will be allowed.

2. All those interested in participating in the consultation will complete the OMC questionnaire, available on the website:

http://www.rosia-pcp.eu/open-market-consultation/OMC-Questionnaire

For the any doubts and questions, interested parties may complete the corresponding form:

http://www.rosia-pcp.eu/open-market-consultation/OMC-Q&A

The doubts and questions asked will be answered and published by ROSIA PCP buyers' group on the website:

http://www.rosia-pcp.eu/open-market-consultation/OMC-Q&A

All forms must include the necessary identification data as well as any information deemed

appropriate.

3. This OMC lasts till the 3rd of September.

4. Once the deadline for submitting proposals has been reached (3rd of September), the contracting authority will compile the proposals submitted, as well as the other information gathered during the consultation or the pre-OMC informative events. If it is deemed necessary, it may request those who have participated to clarify some points of their proposals in bilateral meetings. In addition, it reserves the right to convene participants individually to make a more detailed presentation or to expand information on their proposal.

5. The contracting body, with the assistance and participation of the multidisciplinary technical team, will prepare a final report that will be part of the future tender, which will include all the information collected with the consultation. In particular, the report shall include all actions taken; the contributions received from the participants in the consultation; where appropriate, the studies carried out and their authors; the entities consulted, the questions that have been asked and the responses they have given. The Final Report with the results of the Consultation will be published on the website, respecting the principle of confidentiality.

6. The use of the content of the proposals will be limited exclusively to their use in the definition of the specifications of any contracting procedure that follows the OMC.

**6.- LANGUAGE OF THE CONSULTATION**

The official language of this open market consultation is English.

**7.- CONTENT OF THE SOLUTIONS FACILITATED BY PARTICIPANTS**

If the participants proposed a solution for the ROSIA PCP project in the consultation, they should facilitate the level of development in which the proposed solution is, the estimated execution time and the economic impact assessment.

**8.- CONFIDENTIALITY**

Participants will include in the information to facilitate their express consent so that the contracting authority can disseminate their participation and the issues and/or solutions raised in the consultation process.

However, the contracting authority may not disclose any technical or commercial information that may have been provided by the participants, which they have designated and reasoned as confidential.

It is the participants who must identify the documentation or the technical or commercial information that they consider to be confidential, and it is not permissible for them to make a generic declaration or declare that all documents or all information is confidential. Participants may designate some of the documents submitted as confidential.

This circumstance should be clearly reflected (in any form or in the margin) in the document itself designated as such.

**9.- PROTECTION OF COMMERCIAL SECRETS**

The protection of all information considered a commercial secret is guaranteed.

It is considered a trade secret in accordance with Clause 2 of Directive 2016/943 of the European

Parliament and of the Council of 8 June 2016 on the protection of undisclosed information and business information (trade secrets ) against its unlawful acquisition, use and disclosure of information unknown to the general, relevant, public; which has commercial value; and that it has been the subject of measures to keep it secret, that although it does not refer to industrial secrets, there is nothing to prevent them from understanding that they are excluded, so that it may be understood that business secrets include commercial and industrial secrets.

**10.- CONSENT FOR DISSEMINATION OF INFORMATION**

In order to ensure the transparency of the process, the availability of the best possible information and the effective exchange of experiences and opinions, the participants give their consent for the contracting authority to include in an accessible and up-to-date form the information communicated in the framework of the consultation.

Specifically, the participants in the consultation give their consent to use the information provided throughout the procedure and in the OMC final report.

**11.- PROTECTION OF PERSONAL DATA**

In accordance with the rules of Data Protection, participant personal data will be processed and incorporated into the processing activity "Gestión Económica y Jurídico-Administrativa (Economic and Legal-Administrative Management)", for which the Instituto Aragonés de Ciencias de la Salud (IACS) is responsible, in order to manage your participation in the open market consultation procedure. The lawfulness of the processing is based on the consent to participate in this consultation. Personal data may only be communicated to the partners of the ROSIA PCP Project (Remote Rehabilitation Service for Isolated Areas) in the framework of your participation in the open market consultation carried out by IACS as Coordinator of the same for the management of internal communications and compliance with the requirements of the aforementioned Project. You may revoke your consent as well as exercise your rights of access, rectification, deletion, portability of your data, limitation and opposition to its processing before IACS, at Avda. San Juan Bosco, 13. 50009, Zaragoza, or at the address protecciondatos.iacs@aragon.es. You may consult additional and detailed information on this processing activity by accessing the following link: https://aplicaciones.aragon.es/notif_lopd_pub/details.action?fileId=758

**12.- INFORMATION OF PATENTS AND OTHER INDUSTRIAL OR INTELLECTUAL PROPERTY RIGHTS**

Solutions and technical specifications communicated in the context of the open market investigation may refer to a particular make, type, manufacture or provenance or specific procedure, or refer to a patent or other intellectual or industrial property rights.

**13.- ROSIA FUTURE TENDER**

The provisional forecast for the future tender is March of 2022 and it is considered to have an estimated value of 3.900.000 € (VAT included, if applicable).

In that tender the contracting authority will define the functional specifications of the systems, services, products or works to be developed based on the solution ideas collected as a result of the consultation. In any case, these procedures will be open to all possible proposals that meet the established conditions, whether or not they were linked to the preliminary market consultation. Preliminary consultations may not entail the generation of incentives or advantages for the companies participating in it when awarding contracts, nor can it be

recognized as an award criterion or as a favourable value to the same prior participation in the process of the award.

"This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017606"

## Annex 4: OMC Questionnaire Model and Results

### 1. OMC Questionnaire Model

If you have any question and you need to contact us, please, write an e-mail to: omc@rosia-pcp.eu Fields marked with * are mandatory.

**A) COMPANY INFORMATION**

- Contact person (Full name)*
- Job Title
- Email address*
- Organisation name*
- Headquarters Country
- Type of organisation: Freelance, private company; public company, research center; university; technological center, start-up, others*
- Sector or scope of activity (NACE code or describe it):
- Year of establishment
- Company size
    - Micro (<10 employees and ≤ € 2 m turnover)
    - Small (< 50 employees and ≤ € 10 m turnover)
    - Medium (< 250 employees and ≤ € 50 m turnover)
    - Large
    -
- Market Presence
    - National
    - European
    - International
- Turnover in the last three years (2020, 2019, 2018)

| 2018 | 2019 | 2020 |
|---|---|---|
| | | |

- Website:

**B) ROSIA CHALLENGE AND POTENTIAL SOLUTIONS**

The procurement will address the specific objectives below:

**1.** Make available to the telerehabilitation market disruptive technological solutions for

self-management and patient-centred rehabilitation services for isolated – rural areas.

**2.** Enable data driven insight interventions and tailored to patient's needs and context. **3.** Implement a flexible model to build personalized integrated care pathways and procedures to support patient self-management and redesign the rehabilitation services and shifting away from the 'all in-person' models of care.

**4.** Strengthen 'community support' for the multidimensional needs of individuals and advantages of social networking channels, motivation and peer support groups, complementary rehabilitation treatments and healthy lifestyle programmes.

**5.** Empower patients and/or families to become self-reliant as possible while supported through all necessary educational, motivational, and technological resources. **6.** Validate and generate evidence of value for each of the components of the telerehabilitation model from clinical outcomes, economical options, patient experiences and workforce satisfaction perspectives.

**7.** Create an open platform - including a governance model; designed and configured to deliver the features and functionality described in the above objectives.

**8.** Generate a business model that guarantees the long-term sustainability of the ROSIA care model both for the public buyer and for the provider.

**Download the Additional information document if you want to know more about ROSIA challenge:**

The ROSIA project focuses on the development of an open platform for telerehabilitation services for patients in these areas. Applications and devices from the ROSIA Catalog will be connected to the aforementioned platform, allowing community services and supervised self-care to be integrated into the care plan of each patient.

ROSIA will initially focus on seven clinical conditions: Chronic spinal cord injury, acquired brain injury, pneumology, arthroplasty, cardio-vascular disease, hip fracture and COVID.

The objective is to get the participation of companies that:

- Are developing applications and devices that can make up ROSIA's catalogue of telerehabilitation services
- Provide open platforms that allow the connection of said applications
- Manage social-community and individual services related to tele-rehabilitation ● Manage the follow-up and motivation of patients for whom tele-rehabilitation services are prescribed in remote areas.
- Coordinate and/or promote a consortium including all of the above
- Is the scope of the challenge clear?
    - Yes/No

**If you wish to explain your answer:**

| |
|---|
| |

- Do you have any solution or experience to address the challenge proposed (fully or partially)?
  - Yes/No
  - Fully/Partially
  - If you respond partially, what % of the challenge do you think that your solution covers the whole ROSIA challenge.

- Where would be your added value? (open question)

| |
|---|
| |

- What patient safety or standards, certifications or regulatory requirements do your solution need to observe? (open question)

| |
|---|
| |

- ROSIA focusses on 7 clinical conditions during the project. Does your solution apply to all of them?
  Yes/No

  If you answered no, do you think it could expand its use to cover the 7?
  Yes/No

  **If you wish to explain your answer:**

| |
|---|
| |

- ROSIA is planning the design of all in one service including supply chain management and any other extra resource that could be identified to make the model works. After the project ends, value based payment is foreseen for the scale-up. Some payments will be linked to results.
  The catalogue is to be populated with services which are expected to include advanced technologies, although it is not mandatory, as there could be services involving only personal interventions. From your perspective (main contractor, integrator, service provider, device provider).

- What would be the most convenient supply chain model? (open question)

- Should the device suppliers also develop the services or just the technology for the main contractor to elaborate on them? (open question)

- When should all service providers be included in the development of the PCP competition?
  - Phase 1
  - Phase 2
  - Phase 3
  - Other: specify

  **If you wish to explain your answer:**

- Local implementation of ROSIA services. ROSIA should be designed to have potential for large scale-up within participant regions. Some of the services will need to be supported by local service providers.
  - What are the profile of local entities that you foresee to integrate in your solutions? (open question)

- How will you manage with local languages (Spanish, Portuguese, English)? (open question)

- How could we help you to find local partners? (open question)

- ROSIA solution should be designed in line with the current Data Protection Regulation. Which privacy-by-design strategies would you implement?

- What do you think about the idea of giving the users full control over their data? How to build trustworthiness? Would it be convenient to include a trusted third party? Is there any other approach that you would suggest to create this trusted enviroment?(open question)

- And how do you think this can be applied ? (open question)

- How can we enable that data in the platform is also available for research and other purposes, without revealing the identity of the use? (open question)

- Are there any barriers or constraints to address the challenge proposed by ROSIA by your organisation?
    - Legal: ex. GDPR, health product regulation, contracting regulation
    - Technical: ex. interoperability, standards
    - Policy
    - Cultural
    - Other: Specify
    - None

**If you wish to explain your answer:**

- Would you be open to grant a free license to use the solution for the procurers' organisations once the project is over?

Yes/no

**If you wish to explain your answer:**

| |
|---|
| |

● Please, share with us your relevant comments about Intellectual Property Rights relevant for the tender (open question)

| |
|---|
| |

● What ROSIA dimension addresses your solution/experience?

- ■ Applications and devices that can makeup ROSIA's catalogue of telerehabilitation services
- ■ Open platforms that allow the connection of said applications
- ■ Social-community services related to tele-rehabilitation
- ■ Follow up and motivation of patients with tele-rehabilitation services
- ■ Coordinate and/or promote a consortium including all of the above
- ■ Others: specify

**B.1 IF YOUR SOLUTION INCLUDES AN OPEN PLATFORM:**

● What relevant standards do you think ROSIA should require for data interoperability ? ○ HL7/FHIR
○ ITU H.813
○ IHE
○ Other: specify

● Is he "Service oriented architecture" the right approach for the ROSIA Open Platform? Yes/no

**If you wish to explain your answer:**

| |
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| |

● What shared services do you think would be needed to have in the ROSIA Open platform? (open question)

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|---|
| |

● How do you see the governance of such an Open platform?

(open question)

- Are there already developers using your API and your open platform?
  (open question)

**B.2 QUESTIONS RELATED WITH ROSIAS' TELE-REHABILITATION CATALOGUE:**

ROSIA plans to open the door of the public healthcare services by building a catalogue of solutions by a qualification procedure which allows prescription of solutions (as the NHS Apps Library). Elaboration of SDK and requirements for the Catalogue will be part of the tender.

- Would you be interested in such a model to be deployed in the participant regions?
  Yes/no
  **If you want to explain your answer:**

- Do you suggest any alternative procedure?
  Yes/no
  **If you have answered yes, please explain this procedure:**

ROSIA will design a solution ready to be mainstreamed after the project ends. It means at least five years. To guarantee that the solution will be still trending edge technologies should be used. It is to be expected that some of the services will complete their validation process participating in ROSIA.
What TRL should be requested for those services to be integrated in the catalogue to be used in the pilots by year 2024? (open question)

- How fit for purpose could be assessed for those solutions? (open question)

**B.3 QUESTIONS RELATED WITH SELF-MANAGEMENT FOR REHABILITATION:**

Self-management for telerehabilitation includes a loop of: evaluation, defining exercises, assessing performance during rehabilitation, providing feedback. It also demands motivation and assessment of emotional status.

- How do you think it could be developed for diverse clinical conditions in an effective way? (open question)

- Could some modules of hardware or software could be used for more than one? (open question)

- How? (open question)

C) ROSIA PRE-COMMERCIAL PROCUREMENT

The process starts with the launch of an open European-wide call for tenders which is expected to happen in March 2022. Suppliers are then invited to submit proposals. Proposals are then reviewed and ranked. Up to 5 teams/consortia/individual companies will be invited to enter a competitive itinerary divided in 3 phases. The three phases are: solution design, prototyping, validation and testing of a limited set of first products or services. After each phase, intermediate evaluations will be carried out to select the best of the competing solutions. The contractors with the best-value-for-money solutions will be offered a specific contract for the next phase.

- Are you interested in submitting a proposal in the ROSIA Pre-Commercial Procurement tender?
    - Yes/No
- Individually or with other partners?
    - Individually
    - With other partner(s)

If you answer with other partners, could you clarify if you already know these partners or not?

- Do you have tender experience with public procuring authorities?
  - Yes/No

- If a supplier/consortia passes through the 3 phases, the minimum budget available for the contract will be, at least, €1,770,000 (VAT included, if applicable). Select from the below options if the budget is…

  a) insufficient to meet the challenge

  b) adequate to meet the challenge

  c) more than sufficient, it is generous

  * **Please, estimate roughly the budget necessary to meet the challenge**

- Do you agree with the budget distribution between phases,1, 2 and 3 (see ROSIA Additional information)?

  Yes/no

  If no, please indicate reasons and alternatives

- Is the timeframe proposed...?

  a) insufficient to meet the challenge

  b) adequate to meet the challenge

  c) more than sufficient, it is it is too long

  Please, estimate roughly the timeframe necessary to meet the challenge

- Do you agree with the time distribution between phases 1, 2 and 3?

  Yes/No

  If no, please indicate reasons and alternatives

- We will use the ROSIA Value Based model (see additional document) to award passing through PCP phases.
  What set of criteria do you consider more important in the evaluation during the PCP? (1= not important, 5 =very important)
  - ★ Value creation
  - ★ Organizational capabilities
  - ★ Financial sustainability
  - ★ Scalability

- Your business model is focussed in:
  - ○ Volume of activity
  - ○ Pay for value
  - ○ Others: specify

  If you answered others, please indicate which one:

PARTNER SEARCH

- Are you interested in seeking partners for a joint proposal?
  - ○ Yes/No
- What expertise/products/services are you expecting from the new partners?

Please, let us know if you have any other comment

## Appendix 5: OMC Questionnaire Results

For confidentiality issues, sensitive data may be omitted. Content displayed has not been edited. 40 answers were received from 11 different countries, 6 different types of organizations and 4 different company sizes.

| | | | |
|---|---|---|---|
| Portugal | 13 | Private Companies | 27 |
| Spain | 11 | Start-up | 8 |
| Ireland | 4 | Technological Centre | 2 |
| Italy | 3 | Research Centre | 1 |
| USA | 2 | Consortium | 1 |
| Germany | 2 | Non-profit | 27 |
| Netherlands | 1 | | |
| Denmark | 1 | Large | 8 |
| Sweden | 1 | Medium | 5 |
| Switzerland | 1 | Small | 10 |
| UK | 1 | Micro | 17 |

| **Is the scope of the challenge clear?** | **Yes (38/40)** | **No (2/40)** |
|---|---|---|
| If you wish to, please elaborate on your answer | I do not know if at this stage we need to receive more information about the patients capabilities. Regarding the question below, I can develop total solutions for Patients to operate. What about the Language? These can be overcome but nice to know. Exclusions if they are in a comma. | |
| | 24-hour access to specialists: doctors and nurses integrated internet platform connecting patients with, first contact doctors, nurses, pharmacy network, medical equipment | |
| | We are a little uncertain as to how we might secure a place in phase one of the process? Can you advise if we will complete a conventional tender process and demonstrate/ pitch our proposed solution as part of this? | |
| | It is not clear for us what ROSIA's open platform contains/will contain, who will develop it and who will exploit it. In addition, something is mentioned about shared SDK and developers, without specifying who they are/will be, if the provider is bringing the complete solution/service already. | |
| | There are many open points, but the main one is whether to determine the services to be provided. | |
| | The company has wide experience in providing telemedicine services with different use cases. An example would be a network that we have built for dialysis alongside a medical device company, where patients in France, Germany or the UK attend their follow up appointments remotely with the | |

| | |
|---|---|
| | medical and nursing staff guiding them while they remain at home. The main beneficiary of the solution is the patient who can easily dial in into his/her session or organize an appointment for solving technical or clinical issues, as well as clarify any concern related to the use of the medical device in his own setup (at home). |
| | Our understanding of the challenge is that the main objective is to reach patients in isolated areas where access to necessary, professional, quality and timely healthcare is very limited or non-existent, mainly due to the fact that the healthcare system has resources very limited, which makes it necessary to have the help, not only of the health system and its professionals, but also of the patients themselves, their families and other institutions (eg. patient associations, social workers, etc.) to create a sustainable model of self-care that treats patients with chronic diseases and disabilities to: 1) improve the health or reduce health ailments of patients living with chronic diseases or disabilities, 2) improve the quality of life in areas of lower population density, areas remote areas with few healthcare services and 3) achieve equity in the provision of social services and medical care. A self-care model that allows increasing the capacity of the health system with the same resources, while facilitating the work of health professionals. |
| | |
| **Do you have a solution or relevant experience to address the challenge proposed (totally or partially)?** | |
| **Totally/Partially** | Partially |
| | Partially 5% |
| | Partially |
| | Partially 35% |
| | Partially 50% |
| | Partially 50% |
| | Partially 20% |
| | Fully |
| | Yes (Fully) |
| | Yes (Fully) |
| | Yes (Fully) |
| | Yes (Partially) 50% |
| | Yes |
| | Yes (Partially) 80-90% |
| | Yes (Partially) 70% |
| | Yes (fully) |
| | Yes(Partially) 15% |
| | Yes (Partially) 20% |
| | Yes (Fully) |
| | Yes (Partially) 60% |
| | |
| | Yes (Partially) 80% |
| | Yes (Fully) |

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|---|---|
| | Yes (Fully) |
| | Yes (Partially) 40% |
| | Yes (Partially) 40-60% |
| | Yes |
| | Yes (Fully) |
| | Yes |
| | Yes (Partially) 50% |
| | Yes (Partially) |
| | Yes (Fully) |
| | Yes (Fully) |
| | Yes (Partially) |
| | Yes (Partially 50%) |
| | Yes (Partially) |
| | Yes (Partially) 50% |
| | Yes (Partially) |
| | (Partially) 60% |
| | Yes |
| | |
| **Where would your added value lie?** | |
| **Open Question** | The company offers a complete scalable open platform, adherent to main healthcare interoperability standards. It can be offered as cloud or on premise. |
| | The company has expertise in biosignals acquisition. We've developed a platform for wireless (Bluetooth) data acquisition from a wide range of sensors, like ECG, EMG, Movement, Respiratory, SpO2 (Oxygen Saturation), Heart Rate, Heart Rate Variability, scales, force platform, and others. Our sensors stream continuous raw data or post-processed data. |
| | We have 8 years international proven experience with tele-rehabilitation (research and applied) we develop our solution starting from participatory design both with specialists and patients we have |
| | User Centred Design, Human Factor expertice, Comprehensive knowledge of the value chain associated with the development of medical devices, Artificial Intelligent applied to health status assessment and patient's follow-up |
| | The company added value lies in our execution ability. We have an extensive record of delivering complex Enterprise and Public Sector Apps using the best of Agile Methodologies, Open Source, DevOps and Cloud. Our global success with Covid-19 Apps and various Health and Life Sciences Platforms proves that our approach is ideal for a project like ROSIA. |
| | Algorithms to support remote assessment and monitoring of physical function, prediction of falls and frailty. |
| | |
| | My added value will be that Solutions will cover from basic to advanced so that they can live independently. There are several Solutions customised for the Patient so that as they advance, their improvement will be obvious. |
| | For the patient: medical consultation, diagnosis and recommendations, implementation of receipt; for clinics: geolocalization, customer scoring and specialists, administrator panel; interfaces for paying systems, doctors and nurses; knowledge about customers, marketing communication; application server in the calculating cloud or on the central server |

Platform to analyze and treat medical information of patients, reviews and outcomes of consultations

The solution is a modularised end-to-end patient communication platform designed to plug-in to multiple electronic patient record (EPR) systems. We offer primary and secondary care providers a means to offer community based care through tools such as video, symptom tracking, remote device connectivity, educational resource sharing etc. and give patients greater access to their medical records (both clinical and administrative) supporting self-management of care and a collaborative care model.

In how to motivate and assure the chronic patients exercise as expected by the therapist.

We offer personalized health advisors for territories, which gives to each citzen a tailored diet recommendation, exercise plan, health habit advices, and we are working to offer new features related with pain management, stress/depression/emotion management, and more. We offer in addition a personalized health risk map, where the person can see the main risk factor they have based in their health data (is a questionnarie, and you neeed a blood analysis data).

A first-of-its-kind, the solution -neurorehabilitation system- is designed to keep patients training for longer across the continuum-of-care. FDA cleared and CE marked, the solution´s game-based digital therapies have benefited more than 3,300 patients in 90 leading centres around the world. Created to promote the kind of movements a patient would typically practice with a physiotherapist, the system is completely customisable to each individual's needs and progress. So it can be used in acute inpatient settings, outpatient clinics and even at home. Not to mention, a comprehensive telemedicine service, through a HIPAA-compliant web service. The solution home therapy programme is the next step in telerehabilitation. The system can be set up and calibrated in in less than 5 minutes. Then, remotely monitored and tailored by each patient's therapist. We've found patients are training with the same intensity they would in a clinic, while enjoying a new level of ownership over their treatment. The programme is currently being offered by therapists in key centres of excellence across the US and Europe – including Mount Sinai Abilities Research Center, Johns Hopkins, the Royal Buckinghamshire Hospital, NTRehab, Birkdale Neuro Physio, Swiss Rehabilitation or PhysioFunction. Additionnal added values include: • Fully customisable programme of therapies • Patient ownership of therapy programme • Unlimited daily usage • Live video sessions with healthcare professionals

We have experience in deploying digital platforms that can: * Produce a data-driven recommendation for the intervention of the patient abiding by the clinical guides for each health condition. * Coach the patient to perform the prescribed rehabilitation exercises and maintain a healthy lifestyle by analyzing several sources of data (e.g. monitorization devices, rehabilitation assessment metrics) to guarantee the achievement of medical goals and detect undesired events. * Contribute to the self-management of the clinical condition by providing informatic tools that can guide the patient through programs to treat the clinical conditions and maintain healthy habits. * Interact with and support monitoring and intervention devices or systems by implementing standard interoperability protocols.

We have 14 years of experience in developing, implementing and supporting telemonitoring solutions. Our solutions have been installed in 14 European countries with different health and social care systems in place. We have an extensive network of competent partners covering already most of the requirements of ROSIA and we intend to co-opt into the consortium that are

building additional partners providing vertical telerehabilitation solutions that we will integrate with our existing solutions

The solution, which is CE certified for stroke rehabilitation among others, provides transcranial direct current stimulation (tDCS) for the motor rehabilitation of stroke patients. To our knowledge it is the only technology of this type that can be applied for telerehabilitation, i.e. home rehabilitation.

Wearable technology + platform

Our technological brand we have a solid, robust and mature platform that allows us to adapt the access environment and personalize the care plan to the needs of each project, each pathological profile, each specialty or disease. In short, it is a horizontal mobile personal health record. (PHR), integrated with a remote control and monitoring web manager for surveillance and monitoring of professionals. The same platform provides services to patients with heart disease, oncological, paediatric or chronic multi-pathological complexes, but each group has a specific environment adapted and personalized to their needs set by the researchers.

Telerehabilitation solution to exercise at home (focus on the elderly population) and Solution for monitoring the risk of pressure ulcers in bedridden users

The company has a large experience providing development services for several Spanish Health Services (Galicia, Aragon, Cantabria, Andalucía, …). We would like to highlight our experience with Tele health and App´s development for patients information management. Related to the pathologies on which ROSIA is focused our company has experience with Cardiovascular diseases, mental diseases and COVID. We have several solutions: Solution 1: is an Intelligent virtual adviser for cardiovascular prevention and well-being. The aim of this solution that includes Gamification is to make it easier for citizens, health professionals and health services to promote activities for primary prevention of cardiovascular diseases at the population level, seeking a change in social habits. Thus, a challenge in modern society is addressed by promoting cardiovascular healthy habits through a change in people’s roles. It can also be used after a heart attack in the rehabilitation part. Solution 2: Predictive and intelligent platform that supports the management of cardiac rehabilitation. Solution 3: The objective of this project was to design neurological therapies based on daily activities for people suffering from mild cognitive impairment (MCI). It intends to make people who begin to have memory problems more self-sufficient while reassuring their families and informing the health service through noninvasive monitoring, which will substantially improve health care. Solution 4: a platform that helps informal caregivers to understand and aid their demented relatives. AAL Programme. The company has collaborated with many Regional Public Health Services developing solutions related with COVID. Additionally the company, apart from have worked for Aragon Public Health Service, is located in Galicia so Portuguese market is a Natural Market and Portuguese is also a close language to Galician.

In the scope of the ROSIA's challenge, we certainly would add value in a twofold way. Firstly, from the platform's integration perspective, our added value would lie in providing a Centralization of integrations for Rosia Innovation Ecosystem, assuring integrations between third-party solutions, eHealth Services Platforms, and multi-device applications. We can ensure high availability of the data integration platform; The use of international standards; Real-time monitoring; Launch actionable alerts about business data quality and accuracy. Secondly, from the data privacy perspective, our added value would lie in our solid experience on data privacy and data de-identification (anonymization, pseudonymization and synthetic data)

solutions to enabling innovative, GDPR-compliant, and value-driving sharing of data through the ROSIA open platform.

Integrated open tele rehabilitation software platform already in the market. It has been integrated with several medical devices for different rehabilitation purposes (stroke, gait, neurological diseases, cardio-rehabilitation, general monitoring and monitoring of acute diseases). Each integration has followed an evaluation and validation process involving clinical pilots with Hospitals and Rehabilitation Centres in Spain and other countries in Europe (Portugal, Ireland, Netherlands)

We developed a RPM system to monitor Chronic conditions such Heart Failure, COPD, Diabetes and others. For 6 year we telemonitor at home COPD pateints and for 4 years CHF patients. Recently we are involved on tracking COVID-19 oateints and Diabetic patients.

Connection to hospital systems in Portugal, where we hold 80% of the Portuguese market share. Our solution is used in 75% of hospital beds and over 50% of private healthcare facilities. Connection to community pharmacy software, where we hold a 90% market share.

There are many open points, but the main one is whether to determine the services to be provided.

see attached document

The proposed project is based in a solution that can be fitted to different types of bottles and caps (as an over cap). The use of the solution allows the remote monitoring of medication intake and improvement of medication adherence, by generating alerts to the patient in the solution and mobile app, when it is time to take the medication. The data related to the adherence can be accessed remotely and can be used as a tool to facilitate rehabilitation process, by sharing the patient's medication intake data with care givers and/or responsible doctors. The product was designed to be easy-to-use and ergonomic for empowering elderly patients and other chronic patients that suffer from motor issues such as rheumatoid arthritis.

Our cloud-based telehealth platform is highly configurable and flexible and can support a wide variety of virtual clinical use cases across the care continuum within a single licensable SaaS platform and experience. The platform offers an intuitive user interface for seamless virtual visits for healthcare providers and patients with IT integration capabilities to enable end-to-end care coordination. Configurable software modules and purpose-built devices can be layered on to enable solutions in a wide variety of care settings across the patient care journey including chronic care self-management in the home. Our solution creates a scalable virtual care experience for any use case, care setting and budget. In addition to he solution, we offer a new kind of experience for people living with chronic conditions. We are successfully bringing the consumer-first mindset to the market and making it easier for people to stay healthy. Our chronic condition management platform, which leverages human coaching, data science and technology, creates personalized experiences to help people (our members) manage their chronic conditions. Our integrated suite of programs promotes sustainable health behavior change based on easy, real-time data capture supported by devices, insights driven by data science, proactive outreach to engage members, closing gaps in care and expert coaches. Moreover, our investment in data science and being proactive with our members creates a sustainable competitive advantage.

The company provides tools for the automatic planning and scheduling of highly personalized rehabilitation pathways, and can adapt the planning to measured outcomes. We work in partnership with ICS Maugeri SpA, the largest Italian research hospital recognized by the Health Ministry for

rehabilitation on neuro-motor, pulmonary, cardiology domains. Maugeri has about 30 research laboratories dedicated to different topics and will provide research results and prototypes in the field of remote rehabilitation.

The company is a digital health company revolutionising the standard of care for movement disorders. Our integrated solution, which combines a secure cloud-based platform and a smartphone App, enables patients and providers for accurate assessment of functional mobility and remote treatment monitoring in movement disorders care. Our proprietary machine learning algorithms are used to fully characterise patients' movement and postural signatures, filling the gap between infrequent clinical examinations that do not capture fluctuating and rare events. Our mobile app allows the monitoring of individuals' mobility from ecologically valid and person-relevant settings. A mobile app for long-term unsupervised walking mobility quantification, remote assessment of motor signs, longitudinal (one-time or regular) assessments of self-reported global health outcomes and medication management.

Three mayor pillars in which the company will add value: - Solution. A solution that covers the principal needs: o Access to rehabilitation through a portable rehabilitation tool, that will speed up the patient recovery. A neurorehabilitation tool based on brain theory, gaming theory and virtual reality with artificial intelligence highly tested in real environment with real patients with positive results. The tool adapts the games to the conditions of each patient to get a higher engagement. o Reduce the levels of treatment abandonment through a tool that guides them in their treatment and empowers them, thus improving their experience as a patient and their engagement to their own health. The tool accompanies the patient in their illness by providing information about the disease in question, educating and guiding them in their treatment, allowing, at the same time, allowing the professional to monitor the patient's condition and try to prevent any medical complications before they arise. o Coordinate and improve communication between different health professionals and interlocutors who participate in the patient's health through a tool for multidisciplinary and inter-level management of medical cases. The tool gives a workspace where all the professionals involved in the patient care can share the patient's medical records, actions, insights and clinical decisions. - Experience. The company, have experience in the implementation of good solutions that improve the patients' conditions and empower people (professionals, patients, and caretakers) when and where it is needed. Each partner has experience in specific fields that will allow to create a solution that will cover the patient journey taking into account the different actors and health levels (professionals in hospitals and primary care, patients and their relatives and caretakers, social workers, etc.). - Knowledge. We have knowledge in patient remote monitoring for different pathologies (both solutions and process improvement), project management and product market launch, and extensive knowledge in different dimensions of the rehabilitation and innovative technologies like virtual reality for different devices and artificial intelligence.

Provision of a data platform, spanning data management, interoperability, transaction processing, data normalization, and analytics. The company solution´s supports every major global healthcare messaging standard, applications built on it can rapidly ingest, normalize, and share information. It also includes deep support for FHIR. All data can be stored as FHIR resources, and the solution comprehensive REST APIs make granular data available for development of SMART on FHIR and other FHIR applications.

We “bridging” the digital divide and remove the accesibility barriers that older adults and other type of patients have using digital technology at Home and leaves them out of the benefits of using technology in tele-rehabilitation and tele-medicine.

The solution is used in remote treatment, training, consulting and collaboration in 63 organizations around the globe

With a team of over 80 hired researchers and a client portfolio from a broad range of areas, such as health, agriculture, retail or energy. The organization has consolidated competences in Human-Centred Design, Artificial Intelligence and Cyber-physical systems. User analysis in different environments, computer vision, cognitive and decision support systems, and the internet of things are some of the fields of study which steers its activities towards applied research and its clients’ success, with whom it establishes close cooperation for the development of innovative, intuitive, accessible and ubiquitous technological solutions. Currently, the innovation themes of interest to the organization are the following: - Cognitive connected solutions - Digital farming - Accountable artificial intelligence - Decentralised health technology - Living and ageing with data

Since the end of 2019, a group of members the organization has been working on the development of an integrated solution to remotely monitor patients for continuous disease management in order to promote improved quality of care to patients and alerts to health professionals and caretakers with little effort and lower cost than currently available solutions. The features of this modular and flexible solution include sensors and wearables to remotely monitor patients, data integration and interoperability processes, as well as the development of tools and interfaces for data-driven support of clinical decision. The value of the organization lies in the complementary and collaborative nature, as each of them brings specific know-how, technological inputs and network of partnerships. Moreover, the trust and collaborative environment built prompts them to rapidly respond to new challenges and advance novel, modular and adaptable solutions, namely in the tele-rehabilitation segment.

Our company has focused its activity on developing new technologies with the aim of facilitating people’s lives. Our solution comprises a system that integrates a digital dynamometer with a smart connected load cell that evaluates handgrip strength. The device communicates via Bluetooth with a mobile app (iOS or Android), including gyroscope and accelerometer used for gamified purposes. The app has the needed data and workflows for the assessment of the patients, and this assessment can be done periodically to track progress. This hardware combination is portable, simple to use, and does not require any special technical skills to operate, being easily used by a caregiver.
Our portable dynamometer has numerous advantages over other nutritional, functional and health indicators, as it is a cheap and easy-to-use method. It provides a complete evaluation for rehabilitation and physiotherapy.

We offer a complete ecosystem where communication flows from the user and the healthcare professional responsible for monitoring the patient. All data collected is pseudo-anonymized as the solution system will store the information gathered in a GDPR compliant Cloud Platform. Thus, we can provide access to rural areas and easier monitoring remotely patients from this setting. Our solution provides a useful and complete intervention to fully support the healthcare professional, and the patients, reinforcing the Health Care System connection. The health professional can assess and prescribe different physiotherapies, nutrition, and physical activity to the patients with the solution, in a fast and integrated way, using the associated app. The

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| | solution system has different accessories and games associated, so the patient can practice physical activity, which aims to strengthen different muscle groups and maintain functionality. This is a way for the patients to remain active, rehabilitated and engaged with their health professionals. This project is structured to develop a set of free and hybrid applications for Android and iOS, as follows:<br>- A gamified process in the apps, which keeps users engaged and motivated to play (which translates into frequent completion of the exercises);<br>- Set of 3 existing accessories, with the possibility of creation of new ones for specific muscular groups. This allows to assess the tensile or compressive forces, to assess the normal/orthogonal forces, application of an accessory on the knees to assess the strength of the adductors and abductors. This also allows functional capacities to be strengthened. The developed games will then be integrated with the solution and its accessories in order to offer a complete solution. |
| | We impact the Digital Health field and our mission is to make Physiotherapy an enjoyable and motivating experience for patients. We develop technological solutions that are lined up with the strongest trends in Health: digitalization; home-based treatments; value-based and patient-centered care; whose importance has been reinforced worldwide during the COVID-19 Pandemics. With our solution, the physiotherapy session takes place in an engaging game-like scenario. The patient exercises while interacting with a gamified environment, using a single off-the-body sensor for body tracking (a user-friendly 3D camera), that is key to determine relevant clinical and motion information that can be remotely consulted. The solution is easy to use and portable, thus suitable to be used both in-clinic and at home-based treatments.<br>We have experience in operating at in-clinic pysiotherapy sessions and, most importantly, in telerehabilitation settings. This experience comes from the collaboration with both private and public healthcare entities (e.g. CHOeste - Unidade de Caldas da Rainha, from the NHS). |
| | |
| **What patient safety standards, certifications or regulatory requirements does your solution need to observe?** | |
| **Open question** | Our Cloud Infrastructure adheres to GDPR, HIPAA, different ISOs and various country specific data protection legislation.<br>We have CE marking for the company devices plus a medical device certification Class I for our physiotherapy solution. We are an ISO13485 certified company.<br>Crypted data transmission GDPR compliant CE medical device class I<br>Medical Device Certification Support (ISO 13485)<br>We are ISO 9001 and 27001 certified and have worked on projects for customers that involve ISO13485, SOC 2, FedRAMP and NIST800-171.<br>Class I medical devie under the MDR 2017/745 GDPR compliant<br><br>MDR: Within class II or IIa. |

We follow all of the GDPR from Portugal and the European Union. All data is anonymized and all consumers rights regarding privacy rights and data protection are met.

We are ISO27001:13 certified (information security management) and DCB0129 (patient authentication standard) compliant. We are working toward certification ISO27701 (data privacy). Our solution is hosted in AWS and security and back-ups are managed by Deloitte; both of these partners also meet ISO27001:13 among other ISO standards.

CE Medical Device Class 2A

It doesn't need, as is a tool for health improvement, not for disease management. Our focus is the prevention: health promotion.

The medical devices and software are designed, developed, manufactured, distributed and followed-up according to applicable European regulations and relevant best practices. This includes but is not limited to international organizational standards and technical requirement standards. Moreover, the solution has setup its internal processes to meet the annex II “Full quality assurance system” of the EU Medical Device Directive 93/42/EEC and, from 2020, the Medical Device Regulation 2017/745/EEC as well. More specifically, every single product development is based on a dedicated regulatory plan. This deliverable is used as a design input in order to develop device for being CE marked as medical device. The solution has received an ISO 13485 certification recognising its quality management system.

We need to assess if some of the modules can be classified as medical devices, their classification and if the required certification can be obtained in the scope of the project. * We need to implement the required mechanisms to protect the patients’ personal data following GDPR.

We expect the solution that we will develop in the context of ROSIA to require certification as Class IIa Medical Device for its commercialisation after the end of the PCP project

Our solution has CE certification for the rehabilitation of stroke in combination with traditional rehabilitation interventions.

ISO 13485 (SFT is a certified company)

We consider that the solution provider should meet the following management standards: R&D and Innovation System Management - UNE 166002:2006 Quality and Ongoing Improvement: - CMMi Level 2-3 Quality Management System: - ISO 9001 Environmental management system: - ISO 14001 - Verified Environmental Management-EMAS Information Technology Service Management System: - ISO-IEC 20000-1 or UNE-ISO-IEC20000-1 Information Security Management System: - ISO-IEC 270001 or UNE-ISO-IEC-27001 Occupational Health and Safety Management System: - OHSAS 18001 Communication stardards like HL7 (or similar) should be met too. Regarding regulatory requirements complying with GDPR requirements will be essential About patient standards we consider that contractors should specify preferences.

ISO27001; GDPR; European Union Agency for Cybersecurity (ENISA); European Regulation on Interoperability; Health Level Seven International (HL7 standard); Fast Healthcare Interoperability Resources (FHIR standard); Integrating the Healthcare Enterprise (IHE standard);

ISO/IEC 27701 Gestión de Información de Privacidad. ISO 22301:2012 Sistemas de Gestión de Continuidad de Negocio. UNE 166002:2014 Gestión de la I+D+i. CMMI level 3 (Capability Maturity Model Integrated). Certificación OMOP CDM para el mapeo de bases de datos clínicas. UNE-ISO/IEC

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| | 27001:2014 Gestión de Seguridad de Sistemas de Información. ISO 13485:2003 Sistemas de Gestión de Calidad de Dispositivos Médicos. UNE-EN ISO 9001:2015 Gestión de la Calidad. UNE-ISO/IEC 20000-1:2011 Gestión de Servicios TIC. |
| | The solution is under ISO 13 485 certification process as Class IIb Medical Device classification and Medical Device Regulation (MDR) 2017/745. |
| | |
| | In all our projects we apply RGDP, ISO 27000, TLS protocol (Transport Layer Security), and HTTPS (HyperText Transfer Protocol Secure). All personal data is anonymised and encrypted. |
| | |
| | The solution needs to be fully compliant with the RGPD to ensure security of patient's personal data. The device will have to be certified as low-power electronics device to allow commercialization in the EU economic space, together with CE marking. |
| | The solution and other information to the highest standard and regards data security as a top priority. We are HITRUST CSF 9.2 certified, which aligns with NIST. We also have certifications with ISO including, ISO 27001, ISO9001 and ISO13485 and other frameworks. The solution maintains a formal security program, inclusive of a Security Council, Security Officer and security engineering resources. The formal security plan is audited annually through the HITRUST v9.2 CSF Certification program. Data standards are managed and audited in compliance with industry-defined requirements for protecting and securing sensitive patient and healthcare information. In addition, we offer in-country or in-region data residency with our cloud-based hosting of our Solo platform in multiple locations throughout the world. We are currently compliant with GDPR and many other regionally based regulations within the countries where our solutions are currently deployed. Please note that the solutions herein proposed are not medical devices, are high quality ICT solutions that support the healthcare acts and services provided by solution's customers. |
| | The process management platform does not require specific regulations. Devices to be included in the solution will be CE marked. A data protection impact assessment will be done and a data management plan prepared according to GDPR and relevant regulations. |
| | Our solution is already CE marked medical device class I and we hope to soon have the CE mark for class IIa. |
| | CE Medical Certification |
| | All proposed tools comply with all GDPR requirements. Additionally, the portable telerehabilitation tool has the CE markup, class I, and it is expected that its artificial intelligence module will obtain the CE class IIA during the year 2022. In addition to complying with data protection law, end-to-end encryption, strict access controls, etc., ethical approval actions will be required during third phase of the ROSIA PCP, the field test. |
| | The solution supports every major healthcare interoperability standard. Standards and certifications. |
| | Our Solution is based on consumer electronic and digital tv standards, it is not a medical device. We intégrate and connect Third Party medical devices currentlly availble on the european market |
| | GDPR, HIPPA, HL7, SMART FAST, NHS Security Passport |
| | The solutionis undertakes the best development practices, however, the safety standards, certifications and regulatory requirements should be considered by the technology taker, that will commercialize the solution. |
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| | -RGPD compliance -Medical device certification: some of the devices included in this solution are already certified, others are in process. -HL7/FHIR protocol compliance: The different electronic devices in our portfolio already communicate through an HL7/FHIR protocol, and this standard should be kept in the solutions that will integrate our future developments.<br>Our company is implementing ISO 13485 certification requirements to produce medical devices, and we are also on the path to obtain CE certification as a class 1 medical device for the solution. We have already a certification as medical devices producers from the Portuguese regulatory entity (Infarmed). To guarantee information security, all data collected is pseudo-anonymized, since the solution system will store the information gathered in a GDPR compliant Cloud Platform. Only authorized healthcare professionals can access data information from the webapp or mobile apps. It will also be able to export/exchange data using the HL7/FHIR protocol, directly "out of the box", offering the possibility to integrate the gathered data into different health care ICT systems.<br>Compliance with data protection regulations. |
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| **ROSIA focuses on 7 clinical conditions during the project. Does your solution apply to all of them?** | **Yes (23/49)** | **No (16/40)** | **NA (1/40)** |
| **If you answered no, do you think it could expand its use to cover the 7?** | No answers were received | | |
| **If you wish to, please elaborate on your answer** | I do not know if at this stage we need to receive more information about the patients capabilities. Regarding the question below, I can develop total solutions for Patients to operate. What about the Language? These can be overcome but nice to know. Exclusions if they are in a comma.<br>24-hour access to specialists: doctors and nurses, integrated internet platform connecting patients with, first contact doctors, nurses, pharmacy network, medical equipment<br>We are a little uncertain as to how we might secure a place in phase one of the process? Can you advise if we will complete a conventional tender process and demonstrate/ pitch our proposed solution as part of this?<br>It is not clear for us what ROSIA's open platform contains/will contain, who will develop it and who will exploit it. In addition, something is mentioned about shared SDK and developers, without specifying who they are/will be, if the provider is bringing the complete solution/service already.<br>There are many open points, but the main one is whether to determine the services to be provided.<br>The company has wide experience in providing telemedicine services with different use cases. An example would be a network that we have built for dialysis alongside a medical device company, where patients in France, Germany or the UK attend their follow up appointments remotely with the medical and nursing staff guiding them while they remain at home. The main beneficiary of the solution is the patient who can easily dial in into his/her session or organize an appointment for solving technical or clinical issues, as | | |

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| | well as clarify any concern related to the use of the medical device in his own setup (at home). |
| | Our understanding of the challenge is that the main objective is to reach patients in isolated areas where access to necessary, professional, quality and timely healthcare is very limited or non-existent, mainly due to the fact that the healthcare system has resources very limited, which makes it necessary to have the help, not only of the health system and its professionals, but also of the patients themselves, their families and other institutions (eg. patient associations, social workers, etc.) to create a sustainable model of self-care that treats patients with chronic diseases and disabilities to: 1) improve the health or reduce health ailments of patients living with chronic diseases or disabilities, 2) improve the quality of life in areas of lower population density, areas remote areas with few healthcare services and 3) achieve equity in the provision of social services and medical care. A self-care model that allows increasing the capacity of the health system with the same resources, while facilitating the work of health professionals. |
| | The solution can be applied in all types of rehabilitation and physiotherapy since the assessment of handgrip strength is a widely used biomarker for different conditions. Furthermore, our solution integrates a set of accessories that can be used to access different muscle groups, thus broadening the application of solution. The core structure of solution allows for different shaped attachments and enables the development of multiple kinds of accessories. Those can be created for different assessments according to the healthcare professionals and patients need.<br>On the other hand, it's also possible to add new connected devices and software developments that can be used in cognitive assessments in a gamified way. |
| | Our solution is currently designed to address 5 of the 7 conditions on focus (Chronic spinal cord injury, acquired brain injury, arthroplasty, hip fracture and COVID). Regarding the pneumology and cardio-vascular disease conditions, these are clinical applications to which we still have not prepared an approach, but we are confident that our solution could easily be extended to these new technologies by using the same technologies and patient-centered strategies. |
| **ROSIA's catalogue is expected to include mostly services involving advanced technologies, although it may also offer services involving only personal interventions. From your perspective (whether main contractor, integrator, service provider or device provider):** | |
| **What would be the most convenient supply chain model?** | |
| **Open question** | The company is agnostic to supply chain models. |
| | We need to partner with other companies. But the solution can position itself as a hardware provider and service provider, for the software APIs, companion apps, etc. |
| | |
| | We have no position on this question. |
| | |

Service provider or device provider

To provide an accurate response kindly provide examples of patients capabilities. I intend to initially provide audio, At this stage I do not know if it should be interactive since this is crucial and if they provide wrong information there will be no benefits. Just thinking aloud.

Subscription

the platform can be downloaded as an app or log-in through any browser

We are open to a collaborative or consortium approach and are willing to work with the procurers to meet their supply chain requirements. We typically would work as a main contractor or subcontractor to an EPR provider.

Service provider and device provider

In order to have a real impact in the health of citizens, you need to work directly with them throug app for smartphones and other devices, and offer the possibilitiy that the patient can export the data to family doctors, to improve the early detection and prevention of this conditions.

For patients in remote areas, we rely on a mixed B2B2P model, with field specialists (physiotherapists, neuropsychologists, etc.) being the backbone of the chain. They can adhere to the device provider services, and canalize the access to the technology to the patients.

In our opinion, the health system should design a model of payments per use to the providers according to the type of service that each of them offers and the expected savings that such services produce considering the volume of patients that will use them.

An agile supply chain model.

This question can't be answer (yet) without understanding the business model in detail. Supply chains in hardware/manufacturing dramatically differ from software/services.

Direct sales, or by distributors

The custom configured model seems the most suitable. We recommend the use of Agile methodologies.

Service provider

The service should be provided and operated by an organisation in direct contact with both patients and doctors carrying out the rehabilitation process. Initially the system should be operated by personnel of each hospital because they have all data, receive the patient, can handle informed consent and because in many cases the first phase of the rehabilitation takes place in the hospital. The role of the physicians of the hospital will be mainly to monitor of abnormal activity and respond if that happens, either calling directly the patient, reformulating the therapy plan, etc. However, we understand that a third-party could provide the normal (day-to-day) services, like answering patient's common doubts, technical problems, involving and engaging with family members, etc. This provider, not directly the Hospital, could offer services at a lower cost to an increasing number of people.

Our distribution model for Patient software is bases in android and iOS stores. This allow a fast distribution. Because our solution is cloud-based, the clinical access is fast using only browser access. In our view, distribution and access is online. The challenge is about hardware, such medical devices: we use local pharma distributor in order to store and shipment process

It will depend on the services that will ultimately be provided. It is important to be efficient in the supply chain, so if services are not face-to-face, non-local suppliers can be used and vice versa.

see attached document

With the use of our solutions will be a device provider. The company can be developed as a device directly to the consumer or as a service that can include data analyzes and integration, beside the use of the device. In the latter case the supply chain should include a company focused on the data analyzes and processing and also could include health care providers that would then analyze the data and follow the patient according to the medication adherence or other monitored health parameters.

The bulk of our offerings are software and cloud-based IT licenses, and do not require physical distribution. For our purpose-built telehealth hardware devices, we offer full support services and can ship to a distributor or directly to an end customer based on their needs. The platform can enable virtual care on any device, including Bring Your Own Device (BYOD) and is supported through our cloud and communications network and WebRTC functionality.

The ideal model should be an open platform for the management of patients and treatment plans which can be operated and customized by national partners who will deliver the service to patients. The platform can receive data from a number of approved rehabilitation devices as device availability may change from country to country.

Flexible

The model as-a-service provides with enough flexibility, lower cost and freedom for healthcare institutions, while it is flexible enough to be adapted to a value-based healthcare model where the outcomes are taken into account to establish the pricing. This requires embracing a supply chain model that combines one time device fulfilment (for the portable tele-rehabilitation device only) with device services (customization and maintenance) into a continuous flow that provides a seamless end-to-end customer experience. During the project, it is necessary to analyze in greater detail which is the most appropriate model depending on the devices that are needed and the suppliers, since if there is close collaboration with suppliers and joint management of the DaaS model (device-as -a-service) can also be very interesting.

Through a network of partners, healthcare services for more than two-thirds of the U.S. population and hundreds of millions of people worldwide are delivered on the solution software. This provides the solution with significant experience of dealing with varying consistency of demand, customisation and configuration requirements as well as fluctuating patterns of demand peaks and throughs. Consequently, we have flexible internal process that can support supply chain models which focus on efficiency and responsiveness.

We are considering several supply chain options (like BYOD model) that will be defined later dependiente on the final solution requirements and deployment conditions at patients homes.

eCommerce with “Buy online and Pick-up (BOPU)” capability in local Pharmacy or home delivery

We will provide the solution according to technology taker specifications. Technology taker will commercialize the solution and assure its implementation and maintenance. Subcontracting third parties for implementation and maintenance activities could be considered as well.

A flexible supply chain model is most adequate for this proposal, since the suggested medical devices are built on demand and the main resources are

| | |
|---|---|
| | electronics components which can be found from different suppliers at low cost variations. Also, there might be a team responsible for managing several component suppliers which would deliver all the components to one or a few assemblers to produce the final solutions(). This assembly line could include customized and standard components, tools, manuals and packaging solutions. |
| | At an early stage, we have sufficient resources to do the production of our equipment internally. Regarding primary activities, we intend to follow the subsequent strategy:<br>- Inbound logistics: Our suppliers provide the injection of the polymers and related accessories, as well as the electronic components.<br>- Operations: Our own team at our facilities, already certified by Infarmed, assembles, registers, and calibrates the equipment according to ISO 13485 and distributes to the external logistics warehouse. We are already working on a remote quality control process in assembly outsourcing.<br>- Outbound logistics: External logistics warehouses will send the hardware to the different customers.<br>- Marketing e sales: we have our own team that will monitor and manage the whole process. However, our goal is to have local teams of distributors/representatives that will have the function of giving support to the sales component.<br>- Service: Technical team for training, system configuration and support to final customers in health and physiotherapy.<br>Regarding support activities, these are based on the following:<br>- Support structure: It is essentially based on the cloud platform connecting mobile devices, software/ hybrid applications (iOS/android) and equipment manufacturing facilities.<br>- Human resources: We essentially have three teams: a technical support team to do the system configuration; a team of healthcare professionals to support the technical component and the implementation of the system in the field (use of the device, application, and accessories), as well as the development of new functionalities (R&D); a marketing and sales team that will work on content and after-sales support.<br>- Technology development: We rely on the clinical team to gather customer feedback and to explore new market opportunities. Together with the CTO and the technical team, they will seek to implement new functionalities in the final solution, in addition to those already planned in the roadmap of future developments.<br>- Procurement: Is established according to the rules defined by ISO 13485 and in close connection with the other activities and technical needs of the company. |
| | The agile model |
| | |
| **Do you think device suppliers should also develop services, or should they just offer the technology for the main contractor to elaborate on it?** | |
| **Open question** | As the IoT Services Cloud provider we would advice to on board devices which support industry standards |
| | We believe that suppliers should also provide services. |
| | |

we should provide services so that our technology can be seamlessly integrated into a wholistic connected digital solution

In general terms, it is worth noting that medical device companies are increasingly moving towards a more holistic view of service, offering tools that take medical devices beyond the point of care. Pay-per-subscription models for turnkey services are a way for medical technology companies to expand their service offerings, while helping healthcare organisations meet their financial goals and constraints.

We believe device suppliers should provide APIs, SDK, reference apps and reference architectures that enable others in the ecosystem to build upon. All of the above would ideally be Open Source.

Device providers may need to provide support with integration and care pathways to deploy their devices onto the platform

Device suppliers should be able to provide the service. Why? What if there are questions about the device? What if the Patient requests information. Remote services are vital for all information. How does the Supplier know the true capability of the equipment?

They should just offer the technology

Services should, in our view, be delivered by a device supplier alongside the hardware/ software. The rationale includes: (1) Support & Maintenance: Whilst we would be open to offering a managed service and first line of support, device suppliers would need to take responsibility for second line support, particularly around maintenance of devices and their associated software. (2) Information Governance: They would also need to clarify roles and responsibilities in terms of data sharing, security, privacy (e.g. who is processor/ controller of the data, how is it secured, encrypted, anonymised etc,). (3) Regulatory Compliance: the solution is not a medical device; where devices connect to our solution, the user would need to be informed of this context to ensure we are delineating between our solution and a regulated medical device.

Just offer the technology to the main contractor or parther with supplier of services.

In my experience, they don't have the experience neither the desire to develop services over their devices, with very few exceptions. The problem is not develop the services, it is to assure and evolve the services. Suppliers thinks only in their new launch/model. It is much better every partner focus in which their are excellent.

Yes, definitely. For instance, in our specific case, and in order to incentivize therapists to join company network of therapists, the solution deploys a certification for VR use in therapy. This certification will become an asset for the therapist's professional carrier.

They could provide both, but they should comply with the interoperability interface provided by the ROSIA framework to guarantee a correct integration. If possible, device suppliers should participate in the discussion about interoperability interfaces provided by ROSIA.

In our opinion device suppliers should focus on getting their devices better and better and leave to others, more competent in this field, the task of developing the services. This is particularly true in the case of ROSIA where the platform needs to address several different clinical conditions each of which is likely to require a specific type of devices

Device suppliers should also develop services. It would be counterproductive for the main contractor to elaborate on complex technologies such as ours

(electrical stimulation of the brain), as very few companies have the expertise to develop this kind of technology.

We're a device developer/manufacturer with an IoT platform and services. Especially in rural areas there's a need to consider EDGE computing which then brings about the relevance of central / distrubuted computing including services

Yes, services should be considered, because in some situations can compensate financially.

We think that the device suppliers have to meet international communication standards and has to closely collaborate with the platform provider in order to guarantee a perfect understanding of what kind of information is going to provide. Device suppliers should meet main contractor’s requirements

They should focus on developing devices and the technology for the main contractors to integrate and elaborate on it, meaning to develop services logic and applications involving several devices and other data sources.

It depends on the technology. For simple monitoring devices (heart rate, blood pressure, breath volume) manufacturers only provide the device. In this case it's not necessary that the manufacturers provide the SW, usually because to be reliable the devices need to come from big companies. However, these big companies are usually reluctant to open their SW or integrate it with open solutions. They base their profits on volume-based sales and these kind of integrations is not financially good for them. For specialised equipment, like those used in the rehabilitation of stroke or other neurological pathologies manufacturers usually have their own SW to control the devices and are usually open to integrate them in existing platforms. Their software is usually complex and involve much more than extracting physiological variables. In many cases the SW contains games, set-up procedures that cannot be replicated by the underlying open platform. In these cases the best approach is an integration with the SW provided by the manufacturer.

Depends if we are talking about hardware or software. The trend is to include services, starting for support, installation, training, etc. But it is not similar for hardware or software.

It depends on the requirements of the contractors, for standard devices, these suppliers could offer the technology to the main contractor.

Device suppliers must provide the technology for the main contractor to integrate them into the system. In addition, they must take care of the distribution and maintenance of the devices.

see attached document

Depending on the technology that is offered and its complexity, device suppliers can also develop services. This would require a more robust structure in the companies that compass all of the required know how and skills. In the case of the development of devices that require the know-how in design, hardware, software, health care, focus on each of the specific should be given with focus in only part of the development.

The company employs a highly experienced team of virtual care experts who assist clients with developing, launching, growing, and scaling their virtual care software solutions and programs. Our solution design and implementation teams are heavily involved in developing a solution that best fits the goals and objectives of a client’s telehealth program. With over 18 years of experience in technical project management for implementing complex virtual care programs, we work to ensure that our product and solution recommendations are customized based on our client’s unique

needs and goals Once we define the requirements of the telehealth program, we will determine the number of resources to allocate to the client team. Included in our implementation team resources offerings are hardware product specialists who are locally or regionally based to react to client or call center-initiated trouble tickets, proactively monitor all devices in their territory, and take effective action to avoid potential issues before they arise. Product specialists have experience with wireless networks, set up, configuration and troubleshooting as well as technical support. They are required to meet standard requirements by various vendor clearance agencies used by clients (including but not limited to background investigations, drug screenings and vaccinations). Additional responsibilities include: Troubleshooting and resolving technical issues with the solution, managing ongoing product and technical support at client sites, Promoting adoption, utilization and expansion of products at client sites, Partnering with corporate and field staff to develop training materials and Conducting preventative product maintenance and client validation of products. We can integrate with clinical and other healthcare information systems through HL7 or API integrations. We offer an open, standards-based solution which increases our integration capabilities across a wide breadth of third-party healthcare applications. We can support HL7, FHIR, CCDA, CCD, JSON, XML and other formats. For outbound/inbound interface, we can support CCD, HL7, ANSI X12 transactions (837) and RESTful APIs. We modify features to match the overarching goals of the customer.

The entire service should be operated by organizations of professional clinicians/therapists and existing organizations that already deliver community care services. The devices should be independent and interchangeable for maximum coverage of different regions/areas.

they can offer a all in one product/service

We think that best solutions are those where all the views or perspective of all principal partners involved are taken into account working together in order to find a solution with no gaps. This requires some kind of services and involvement. This also provide the possibility to generate more collaboration to create a better and more innovative business model

This would depend on the complexity of the device and the technology used to develop it.

We are a device supplier who also develop some core services running in the device (for instance the videoconference service). But our solution must to include an open and clear interface to integrate third-party applications, services and devices (medical, sensors and also patients smartphones if available).

Yes, most use cases require workflow and content delivery to assist in clinician care delivery and decision making. These require additional services than simply the technology.

Fully depends on the business model defined and the specific functionalities made available.

Both, as in some cases, device suppliers may be best suited to provide specific services related to their technology. The basic requirements for the solution could be defined by the main contractor. Suppliers could provide a hybrid solution product/service.

Our company will provide both: the product and the service that will be configured and customised together with the main contractor.

We believe that the suppliers should develop the devices and technological solutions to the main contractors (healthcare providers), and that the latter

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| | should keep the control about the services provided to the end users (patients). |

| When should service providers be included in the development of the PCP competition? | |
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| Open Question | Phase 1, Phase 2, Phase 3 |
| | Phase 1, Phase 2, Phase 3 |
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| | Phase 1 |
| | |
| If you wish to, please elaborate on your answer | We are offering a foundational healthcare enablement platform not specific to individual use case or conditions. |
| | Our sensors can adapt to most health conditions. |
| | our solution is certified for neurology patients (post stroke, MS, Parkinson's and spinal cord injury) we are working on cardiac patients at present and on rare diseases |
| | |
| | The solution builds custom solutions and can deliver on all 7 clinical conditions if required. |
| | Solution applies to hip fracture and to a general case where remote assessmen and monitoring of falls, frailty and physical function is required. |
| | |
| | My response is based on the understanding that Patients understand English (not a problem if they do not but need to know); they are conscious for example. |
| | |
| | The platform is easy to use and it allows the patient to fully monitor its vital signs, have real-time consultations with specialized doctors, review consultations information and medication which will improve medication adherence |
| | Our solution can be applied in any clinical setting and configured for any clinical cohort. At present users of our system include medics, nurses, nutritionists, counsellors, psychotherapists, psychologists caring for patients with various physical and mental healthcare concerns. |
| | We can scientifically prove our efficacy with: CARDIOVASCULAR DISEASE and COPD. The other ones we need to adapt our sstem and use other kind of sensors. |
| | The overweight is a risk factor for all the diseases related in ROSIA, and a factor of worst evolution. We have specific exercises tables for the prevention of certains diseases as cardio-vascular d., and we can offer tailored prevention programs of nutrition and exercise for all this diseases, in addition to offer a questionnarie to evaluate the personalized risk to develop each disease. |
| | Currently, our portfolio of digital therapeutics provides evidence-based therapies for the major neurological diseases, including stroke, traumatic brain injury, spinal cord injury, Alzheimer’s, Disease, Multiple Sclerosis, and Parkinson’s Disease. Ongoing clinical studies include further conditions including COVID-19 and ageing. |
| | The platform can be formulated to consider the interventions and parameters that are necessary to treat each condition, such that the various core modules (coaching, data-driven recommendation, etc.) can interact with the specialized solutions (e.g. monitoring devices, rehabilitation applications or systems) provided for each of them. |
| | We intend to cover all the 7 clinical conditions through proper alliances with organisations which have already developed vertical telerehabilitation solutions |
| | No, our solution just applies to stroke rehabilitation. However, it is scalable and we are in R&D stage for the development of protocols to tackle a variety of neurological disorders, such as Epilepsy, Brain Cancer, Alzeihmer's and Parkinson's. |

We're a developer and manufacturer of assisted living solutions.

The company has defined more than forty protocols for the management of pathologies. Of those that are required in the project, we do not have experience in Chronic Spinal Cord Injury but we do in the rest.

We have experience with Cardio-vascular diseases rehabilitation, dementia or mild cognitive impairment and COVID but we could adapt our solution easily to other clinical conditions with clinical experts collaboration.

We recognize the ROSIA project as an integrated care rehab model focused on the seven pathologies, and therefore we envision a toolset that acts as a centralized system of clinical and demographic processed data transmission for such a scenario. It will enable us to collect, interpret, route, and audit standard messages/protocols such as HL7, DICOM, or other more generic XML messages. As a result, it will provide mechanisms to obtain business operational data and define institutional overall system integration rules using applicable IHE international standards. The same agnostic approach applies to the data privacy solutions, as it applies to all the data exchange and processed by the ROSIA project and therefore is transversal to all the seven clinical conditions targeted by the project.

The parameters that we can track at patients home, such SpO2, BP, Heart Rate, ECG, physical activity, body temperature and weight, allow us to create the algorithms in order to design the care pathway for Pneumology (COPD), Cardio-vascular diseases (CHF) and COVID. These areas are mature in our system.

We would need further development to respond to all requirements.

Our architecture is modular and allows for easy customisation of health plans associated with each clinical condition. This capability allows us to assign the most appropriate plan to each patient.

but yes, our model is applicable to other chronic diseases

Since the proposed solution is focused on the patient's adherence to medication data, any health condition that can be treated with medication would benefit from the data acquired from the device. The data can be further used as parameters for improving the medical treatments of the patients via the integrated and remote data platform, through the remote supervision of the patient’s medication intake.

The solution platform is highly configurable, and customers can develop workflows per their unique requirements at their own pace by setting up and configuring virtual “waiting rooms” or services based on the needs of each clinical use case. This also allows clients to customize the patient experience based on requirements for each use case. Our configurable software modules enable clinicians to view the patient’s continuous care journey for any applicable use case, rather than by each episode of care—all on a single interface. The Solo platform can enable virtual care on any device and is supported through our cloud and communications network and WebRTC functionality. We partner with clients to provide whole solutions for over 60 clinical use cases. We have developed a host of purpose-built telehealth devices for use across non-acute and acute use cases. Our trusted and highly reliable devices create an easy experience for both patients and providers.

The company provides comprehensive know-how on all the identified conditions and is designed to be not pathology-specific, highly flexible, and customizable.

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| | Our solution applies to clinical conditions where objective and reliable movement monitoring can support clinical decision making. |
| | See attach |
| | |
| | As an open standards data platform with a high performance database at its core, the solution could be used as a 'data lake' for all 7 clinical conditions. It could support real time analysis of data (e.g. to support clinical decision support) or AI and ML algorithms. The solution could also be used by third parties to build high-performance, machine learning-enabled applications that connect data and application silos. |
| | Our solution apply to all conditions in general and can be adapted specifically for every conditions independetly. The only limitación is that our solution is Home based, not for use out of home. For instante, videoconference is a general tool/funcional for all the conditions, but vídeo análisis could be only requiered at HIP Fracture and oximetrer integration is ley at COVID |
| | |
| | Our solution applies to: - Cardiovascular Disease - Arthroplasty - Hip Fracture |
| | The first use case being addressed is Chronic Pulmonary Obstructive Disorder (COPD), but we aim to extend this to other previously identified chronic disorders (including diabetes, cardiac insufficiency/heart failure, and Alzheimer's disease). Moreover, the modular design and nature of this solution enables a flexible response to novel challenges such as the case of rehabilitation. E.g. One of the proposed solutions of the Chronic Diseases Management Platform, DOSEA, is tailored to improve medication adherence by patients in regular intervals of medication intake. The system was designed to be mainly adopted by chronic diseases treatments', but can also be used to improve the patient's recovery in the clinical conditions focused by ROSIA. |
| | |
| | |

**Local implementation of ROSIA's services: ROSIA should be designed to be scaled-up within participant regions, and some of its services will need to be supported by local service providers.**

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| **What profile would you look for in local providers when deploying your solution?** | |
| **Open question** | Be adherent to international standards common in the healthcare domain, such as HL7, FHIR, ICD10, SNOMED etc. |
| | SW development companies with skills in data integration, cloud, HL7, FHIR, others. |
| | openness to experiment tele-rehab |
| | Mainly professional carers, training staff, technical support and maintenance providers |
| | As we would propose a custom open platform with clear APIs and integration points, we would not pre-judge any particular profile for local providers. This |

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| | flexibility should ensure that novel and interesting new solutions and providers can appear. |
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| | |
| | Doctors, nurses, pharmacy network, medical equipment |
| | providers with large client's data-bases |
| | This is a challenging question to fully understand. If the ask is local healthcare providers utilsing our system- we work with both sole traders and large enterprises. If the ask is local customer success teams, we would look for suppliers that would align with our in-house practices; we would be comfortable training and supporting local service providers where required. |
| | Hospital and rehabilitation centers, but also providers of telemedicine services as transportation of equipment and installation at home if needed. |
| | It depends the final scope. If it is needed to integrate the solution with local Public Health Agencies, with I strongly not recommend as requisite, we will need health software companies whith an extensive knowledge of every Public Health Agencie IT requisites to make the integration. It is much better to make very easy that every person can to share the documentation with the doctor via pdf or authorized access in the ROSIA platform. |
| | Specialization in neurorehabilitation |
| | Companies with products for the intervention or monitoring of the considered conditions that can conform to the interoperability mechanisms provided by the ROSIA platform. |
| | Organisations able to integrate the solution developed by the core partners of the Consortium with the health and social care information systems already in place in the procurers' sites, to install it in the procurers' premises if required by the Tender and support the users during the field testing |
| | An ideal local provider should be have experience carrying out studies with patients with conditions included in the 7 areas of interest of the ROSIA project. Ideally they would have a large patient base in remote areas and have some experience carrying at home studies, and they could provide support during the study. |
| | Care providers ... servicing independ living (community dwelling) patitents |
| | |
| | Ability to integrate the solution. Adaptation of the solution to existing procedures. Experience in other technologies. |
| | The key collaboration is with the Health Services in order to meet all the requirements. We also will need help with the identification of Internet Services Provider, Community Services Providers, Patients Associations, NGOs that operate locally. |
| | Regarding the integration services, we would look for essentially three types of providers: hospitals and e-care institutions; tech companies with integrations experts; universities or tech companies with integrations, security, and data science experts (analytics, AI/ML). Similarly, we would look for tech companies or universities with experience in data privacy projects and innovative anonymization/pseudonymization tools for data privacy services. |
| | Level 1 Technical Support. It's important that the patient or their families can contact somebody who can physically go to their homes in case of problem. Problems like the Bluetooth connection is down, the phone/laptop has no battery, no connectivity to the network should be provided by someone close to the patients |
| | |

We will a provider(s) that cover: 1 - Instalation and training process 2 - First Line technical support

Experience working for this specific sector, references provided, specific knowledge about these type of PCPs.

We will look for availability and readiness of resources for the production and high-quality standards, since the product is a one-time purchase that can be reused many times by the patient. The electronics components should have the needed quality to ensure that the product can endure its lifetime. Local providers should also be capable of troubleshooting any issues related to the device or its use.

Regarding the integration services, we would look for essentially three types of providers: hospitals and e-care institutions; tech companies with integrations experts; universities or tech companies with integrations, security, and data science experts (analytics, AI/ML). Similarly, we would look for tech companies or universities with experience in data privacy projects and innovative anonymization/pseudonymization tools for data privacy services.

Local service providers already engaged in delivering home care treatments and patient monitoring. Thanks to the platform, devices & protocols, it will be not mandatory to have specific clinical rehabilitation know-how.

flexible

We would look to work with local providers who are interested in adopting new models of operation and who have an appetite for leveraging technical innovation to improve the delivery of care. The willingness and ability to commit time and effort to work collaboratively to assist in the definition and piloting of new solutions will be a vital success factor.

The local provider must be able to do at home installation or telephone installation support (if caregiver is available) in the local lenguaje.

Health Systems and Clinicians with local practices/presence and openness to new care delivery models/technology capabilities

Local providers should have the capacity to internalize the solution and mass produce it and to provide support to the final product after deployment.

Mostly healthcare providers that are very experienced with these diseases (public and private hospitals, care centres and homecares, physical rehabilitation clinics and hospitals, etc.

Entities that are already in the market of this type of devices and that are fluent in the local language and in English.

We are looking forward joining forces and build great solutions with: healthcare entities, to learn, validate and customize solutions built upon the health professionals insight; technology companies and startups, to integrate different technologies and approachs towards a complete and optimized product; logistics companies, such as suppliers and distributors.

**How will you manage with local languages (Spanish, Portuguese, English)?**

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| **Open question** | Our platform offers native localization mechanisms. |
| | Ok for the 3 languages. |
| | Our system is already in 14 languages in our team we all speak English, so communicating should not be a problem |
| | 100% |
| | We have built many multi-lingual solutions and have staff in 29 countries globally, many of who speak Spanish, Portuguese and English. |
| | We will localise the solution into specified languages and certify translation per MDR 2017/745. |
| | |
| | At this stage only English. Should I know in advance the need for other languages that can be catered for at a later stage. Access to Patients records, details, pictures, mental, physical capability etc. Internet connection with video and audio to the patient who can communicate direct with the supplier. |
| | multilingual |
| | yes. English, Spanish and Portuguese are our native languages |
| | r site is currently available in German, English, Spanish and Portuguese. We are in the process of localising our application for these jurisdictions. Additionally we have team members that speak all of these languages and are actively expanding our business units into these countries over the next 18-24 months in response to market demand. |
| | We have human resources that can handle those languages. |
| | With translators. We speak english and spanish, and we understand portuguesse, but we prefer use translators specialized in health. |
| | Our products (interface, manuals, etc.) are available in different languages including both Spanish and English among many others. Portuguese is in the pipeline. |
| | We have experience including mechanisms (in similar digital platforms) that facilitate the adaptation the user interfaces including those provided by 3rd party apps/services to the user preferences. |
| | All our solutions are multilingual and we have already successfully supported users in 14 countries in their national language either directly or through agreements with local partners |
| | Our company has staff that is fluent in these 3 languages. |
| | We've already an multi-lingual approach (Dutch, English, German). Specific translations/implementations would be through local partners. |
| | Looking for local businesses. |
| | Providing the solution in Portuguese and English. |
| | Our personnel speaks Spanish, English and Galician. Galician is a very similar language to Portuguese and our Company has carried out several project with Portuguese clients without any issue in the communications and a complete understanding between the parts. |
| | Our solutions supports spanish, portuguese and english. |
| | We are bilingual (Spanish and English) and have offices in Portugal and many of our staff come from Portugal, so we'll communicate in the three languages. |
| | English and Portuguese |
| | The company has offices in Portugal and Spain, with multiple clients in both countries. English is a common language for our employees, so no difficulties are expected. |
| | Multilanguage is supported by the platform with a simple interface. The user can choose the way of visualisation both on the web and in the APP. It is |

possible to define local documents (one language only) or global documents that must be available in all languages (Portuguese, English and Spanish).

The platform will have to be translated in different languages, to ensure that patients from all the countries can properly use product. Since the device itself is intuitive and ready to use as is, no language translation is needed except from the mobile app and platform.

We currently has dedicated staff that manages translations with the utilization of a translation and localization management software application to support hundreds of languages including unique regional dialects. Our staff works directly with the customers to support specific translation needs based on their users' locale or region, as well as for customized white-labeling, intake forms and clinical notes that require local language translations. The company has local presence in jurisdictions with Spanish (both Castillan and Lationamerican Spanish), Portuguese (both, for Portugal and Brazilian market) and English (in countries such as US, UK, Canada and Australia & New Zealand)

We will translate and validate our solution with local clinicians and service providers. We will allocate budget to involve service providers since the design process.

The company has always been committed to a strategy of internationalisation. In this sense, English is the main language at the company. Portuguese is the native language of most of the collaborators and, given the geographical proximity, fluency in the Spanish language has made it easier to approach the market. Therefore, managing in local languages will not be difficult for us.

it's not a problem

The company operates a 24/7 multilingual to support customers in Spain, Portugal and Ireland.

Yes.

Our device converts to 17 languages, including English, Spanish, Portuguese, German, etc.

The organization is located in Porto and was born in a partnership between the Fraunhofer Society (Fraunhofer Gesellschaft), the Foundation for Science and Technology and the University of Porto. Hence, Portuguese and English languages are daily used for communications.

The solution being developed - Chronic Disease management Platform - is targeted to the international market; As such, and though it is primarily being developed in Portuguese, it can be easily translated to other languages, including Spanish and English. We have experience managing the adequate translation for these purposes using international standards of medical terminology.

Language is not a problem for us as our team is Portuguese and fluent in English. Furthermore, we plan to hire a local team or at least one local partner to follow all the steps in each country involved.

Our solution is already translated in Portuguese and English, in October we will launch new versions in Spanish and Italian, as we estimate to enter these markets. The technological basis for the translation of our solution is very simple, thus it will not be a barrier in product management.

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| **How can we help you find local partners?** | |
| **Open question** | Matchmaking events.<br>A possibility would be promoting a meeting with all potential local partners. |
| **Any solution to ROSIA's challenge needs to be designed in line with current Data Protection Regulation. Which privacy-by-design strategies would you implement?** | |
| **Open question** | We are already developing the cloud backend using a certified platform (chino.io), that simplifies the integration of the data. This Cloud is completely compliant with the medical-grade requirements of the GDPR. To guarantee privacy, the data gathered is pseudo-anonymized.<br>The strategy we follow is to have two backends: one for record the personal identification in the chino.io, encrypted to the level of each registry on the database (server in Germany); other for record the Clinical data in another platform with encrypted database (server in Portugal). Only through our system, that can join the information from both backends, is possible to identify to whom belongs the medical data.<br>Another possibility is through our mobile apps. They are capable of connecting through VPN to an ICT database, and with a successful login, exchange data through FHIR/HL7 protocol, without storing any information in the local database. In this way, using only a user_ID it's possible to ask the ICT database in the Hospital or Clinic for the specific medical data regarding the specific patient, use it to develop the training protocol, and in the end, after transmitting the data regarding the quantified exercises to the ICT, erase all local data.<br>We have a completely GDPR compliant solution and follow Data Protection good practices, such as reducing to the minimum the quantity of personal data collected, signing NDA's with all collaborators and involved stakeholders. |
| **What is your view on giving users full control over their data? How would you build trustworthiness? Do you think it would be convenient to include a trusted third party? Is there any other approach that you would suggest to create this trusted environment?** | |

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| **Open question** | The company is know for their robust privacy and security practices. Out platforms are highly secure and architected to support various privacy data model globally. |
| | we are entering a partnership with Microsoft - they will take care of data privacy issues |
| | The company is part of the MyData initiative, which is a prestigious international non-profit organisation that aims to empower individuals in relation to the use and exploitation of their personal data. MyData aims to enhance the individuals rights to self-determination with respect to their personal data. MyData Global, with more than 90 corporate members and more than 600 individual members, has a presence in 40 countries and over six continents.<br>In addition, the organization as a representative of MyData, developed the Valencia Data initiative, which pursues the welfare and quality of life of people through a digital transformation, while increasing the competitiveness of products and services offered by the business sector aimed at health and quality of life care. |
| | There are many initiatives in this space and through our membership of the Linux Foundation Public Health project, we could facilitate these discussions. |
| | How would you build trustworthiness? Do you think it would be convenient to include a trusted third party? Is there any other approach that you would suggest to create this trusted environment? |
| | |
| | When they are told they will be cured and they experience gradual improvement trust is automatically built. Trust comes from within. It is an integral part in Human Beings. Sure some deceive. Some lie. None can stop this only they themselves from within. |
| | Yes |
| | we build trust by letting people know we are protecting and actively watching that their privacy rights are being protected all along the supply chain and requirements met by all the parties involved |
| | Our experience has been that the healthcare providers we work with use discretion on what data is pushed our from an electronic record system (e.g. sending frightening lab results without a manual release of same alongside an appointment might be preferable to automatically pushing data into a communications portal). Our solution is modularised, so some providers only use appointment management and video, others share the medical record, the symptom tracker and educational resources etc. This allows for flexibility in terms of what is shared between a patient and their care provider. In terms of trust building, tools that can be used are privacy notices that are accessible and user-friendly, certifications and compliance with regulations, registering with the Data Protection Commissioner of Information Commissioner's Office in a given jurisdiction, ensuring data is hosted in the EU for EU patients etc. |
| | Yes patient should own their own data collected in our platform. If a provider can make it easy to collect and create reports for the patient, it will be great for us as well. |
| | By law, common sense and interest, users have to be in charge and full control of their data. By the same reasons, we should to facilitate they can share with security with their health collaborators (inviduals) via pdf, or with trusted third parties (health agencies) via API. |
| | Market as well as regulatory trends are in this direction (patient owning her electronics patient records; EPR). One option, but not the only one, is to rely on neutral, external agents that facilitate data transfer among the different |

healthcare establishments (e.g. in-patient hospital, out-patient clinic). Also the “right to be forgotten” should be taken into consideration.

Our view on this, is in line with the user rights described under the GDPR, which refers as a fundamental right for users to be provided with tools for gaining control of their personal data. Users should be provided with a clear (understandable by non-experts) communication (digital and physical) describing the personal data that is being used, how is processed and the benefits of it, together with the rights the user can apply and how they can realize their rights, regarding their personal data. A rehabilitation service offered by a trusted third party where a public institution is involved (e.g., in the governance board) would facilitate users trust for service usage. Alternatively, having the ROSIA service provider registered as an authorized health provider (and listed) within health departments of countries or regions adopting ROSIA would help creating such a trusted environment.

In the commercialisation of the final solution, we do not see ourselves selling the solution directly to end users but rather to health authorities/health providers. These are organisation usually trusted by end users. We do not see the need to include trusted third-parties

A data rights management platform would be built to give subjects full access of their data. This would give users choice on whether to withdraw right to consent, access the data, rectify the data, erase the data and the right to object to automated processing. Subjects would be notified of all of these aspects before any data recording takes place in order to build trust.

The focus on data is too shortsighted; it's the data + decisions that provide meaningful info to patients. By default this takes place in different domains (user/patient, community nurse, GP, specialist) each with their specific legal /privacy aspects and usuability/shring aspects

The patient registration process on the platform that requires the incorporation of personal data is carried out against the server of the corresponding country. We will therefore have TWO profiles for professional access to the platform, a profile that will be able to view personal data and a profile that will NOT be able to view personal data. - Doctors, nurses and patient support personnel from a country who are authorized to view their patients' data will only be able to view personal data for patients from their own country. - Researchers, data analysts and / or qualified technical teams who access global data on patients from the five countries and who require consolidated information to carry out their studies will always access anonymized data and therefore will not have the possibility to view personal data of the patients.

Right now this is the process used by SFT. All information is on the client's side and we do not have any access to the information. But in telerehabilitation products, this situation will hardly be maintained.

The platform will be transparent in the sense that, from the point of view of the patient and the rest of the users, the relationship will always be with the Healthcare Entity so that a different situation will not be created from that experienced by users when they go to a Hospital or a Rehabilitation Center.

Data controllers are expected to be highly transparent about processing and using personal data from the perspective of most legislation texts. It is also expected that each user has full control over their data, including the right to access, rectify and delete them. Moreover, the user must also control his consent when sharing his data and revoking this permission at any time. When users have control over their data, they tend to trust on the relationship with a controller. For initiatives such as the ROSIA project, demonstrating trust is essential for building respectful relationships with data subjects and regulators. The real challenge is to ensure sustainable and long-

term trusted relationships. But giving users full control over their data is not enough to build trust. Here, trustworthiness strongly relies on transparency and can be achieved by: (1) explaining, in the most transparent and comprehensible way, what data is collected and how it is used for; (2) treating personal data as restricted by only disclosing it in ways that data subjects would expect or generally consider reasonable; (3) keeping data secure from threads and keep data safe for unauthorized access (for example, adopting anonymization or pseudonymization pipelines and restricted access control); and (4) acting in the interests of data subjects, or at least not acting against their interests, especially when reusing the data. The use of a Trusted Third Party (TTP) is convenient to achieve the (3). Both the GDPR and the ISO 25237:2017 standard admit using a Trusted Third Party (TTP) to map the personal data to its pseudonyms. A TTP is typically used to enable these uses for the pseudonymization: (1) when multiple data associated with the same person is pseudonymized at different sources; (2) when multiple pseudonyms are used for the same person, the mapping can be used to bring together all data associated with the same person; and (3) when, in particular cases, the reidentification is need. So, the use of a TTP seems to be reasonable to fulfil the ROSIA's requirements of "to let the citizens be able to share their data for research securely and without being able to be identified" and "to give the citizens full control of their data and with whom they share it with." In this way, the TTP must offer ways to control the users' personal data, connecting with the pseudonymized data on the ROSIA's datasets. Pseudonymization at the source could be used as an alternative to the use of a TTP for the ROSIA scenario. However, this must be carefully studied because while on the one hand, this setup simplifies the data sharing with third parties, on the other hand, it makes pseudonyms management much more complex.

Data belongs to the patients. They need to have the ability to get and use it. It's not an easy question because having data controlled by an entity eases the process of storing, managing, govern and provide that data for research without having to contact directly the patient (that in either case cannot be done by privacy laws).

Our view is that patient is owner of his personal and health data. They have acces to personal vital signs data and clinical protocol. They can ask for them all time. Regarding clinical decisions, these must be defined by the health provider and the patient. It is not a company decision, but a provider/patient relationship and their particular decision. Yes, a Trusted third party is always a must have in order to assure compliance in all process.

Giving users full control over their data is the main way to create a trusted environment. Many efforts have been done, however, different national regulations are still an issue. Patients must have easier access to their test results, medication lists, procedures, and care plans from across all parts of the health system through patient apps, for example. Records must also be shared between systems to allow faster and more specialised treatment.

no problem with third parties. we do not want to own the data

Our view is that personal data should be fully controlled by the user, in a secure environment that is privacy-by-design built and in line with the GDPR guidelines. The project will build trustworthiness with the users by demonstrating the strategies implemented to keep the data safe, i.e. separating the user’s personal data from the treatments data. The inclusion of third parties is not considered in the scope of this project since the data environment will be built having in mind the data security strategies and GDPR guidelines to ensure trustworthiness. The clear demonstration of the data’s security is the best way to develop trust between user and system.

When rendering healthcare services, the healthcare center has the duty to have a robust and adequate medical record data base where all relevant information about the patient is contained. Medical records are highly regulated in the relevant laws and regulations concerning content, access, retention, and the purpose of the same; likewise, medical records are a key element to support medical decisions. Thus, patients (data owners) should have full access and knowledge about healthcare data but should not be able to delete or change it (otherwise, the healthcare services and obligations might not be met). Additionally, depending on the information we might be considering, the healthcare professional would like to provide it to the patient jointly with an explanation in lay language so for the patient to better understand. Thus, we do not recommend grating user full control over their data (implying, for instance, full erase right of his/her data), but this is for the healthcare center to consider and might depend on a case by case basis and the information we are talking about.

We will implement right to delete and right to forgot, to allow patients delete data at any time they would intend to withdraw from the service.

we can include a trusted third party

The company provides customers with a platform that addresses each customers' specific needs and requirements, including how the customer would design and deploy an application on IRIS for Health to address privacy protections, security safeguards, and individual access.

All the data generated or stored in our solution can be managed by the patient, their caregiver or the healthcare provider. In our opinion the solution must be able to define per application or service, what data are available, Who will recibe this data and for what this data are collected. We can help patients and caregivers, using the system user interface in an easy way, to control and understand data and privacy management.

Individual data privacy and data ethics will be considered to allow patients to exercise individual data control, and decide with whom they share their data. Trustworthiness will be built through based on co-design and validation by end-users and service providers. A trusted third party should be considered as partner to assure the compliance with GDPR and data integration with service providers.

The ownership of the data is always of the patient themselves. This is a key point of our platform and fully compliant with the GDPR. The data always belongs to the end consumer and therefore only they can identify who can access the data and for what purposes. Our cloud platform system is based on two backends, one in Germany (Chino.io), that stores the identification data information, and the other in Portugal that stores the medical data information. Without the connection between both it’s impossible to understand whose medica data belongs to. Our Chino.io backend is protected with:

- Data encryption to ensure compliance with EU and US regulations and medical standards (e.g. GDPR, HIPAA, DVG, NHS Security Toolkit, HDS, etc). It takes one API call to store your data with secure record level encryption.
- Pseudonymisation and de-identification: encrypt parts of your health records or personal identifiers. De-identification relieves you from privacy implications. Our data architect can give you an assessment and help design your setup.

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| | - Secure user management and data sharing: Plug and play sign-up, authentication and session management with our OAuth2.0 as a Service. The service also implements flexible record-level access control for compliant data sharing among users and applications. This gives you all the granularity you need to implement compliant data storage.<br>- Verifiable Audit Logs and monitoring: Implement immutable, verifiable and legally-valid logging for your project. The Chino.io audit log service is designed to meet all compliance and medical standards. You can create custom events, in addition to the Platform modules which automatically create compliant logs. Logs can be queried via API to define alerts.<br>- User Consent management: The Chino.io consent management module allows you to collect, store, query and update consents of your users. Consent is often the legal basis for storing personal data and is a key part of GDPR. Our system makes it easy for your users to view the consents they gave, and modify or withdraw them at any time. For this purpose, we rely on chino.io as a trusted third party. Additionally, our solution can adapt other possibility. Our mobile apps, are also prepared to work according to the FHIR/HL7 protocol, through a login to external ICT systems. In this case, the data would be stored in the Hospital's or Clinics ICT databases, not needing for any local data storage, and in that sense, our system wouldn't present any security threat. |
| | That could be a good approach. |
| | |
| **If so, how would you proceed to apply it?** | |
| **Open question** | We'd be happy to share our privacy and security best practices gained globally during the consultation phase. |
| | We currently apply all of the above in our current system. |
| | Giving access to our database to a provider that can create reports for the patient |
| | The users have to explicity give the third party access via the user app. This access should be clearly limited in the time (1 day, 1 month, 6 months, 1 year). |
| | It depends on each country's healthcare system. For example, in Switzerland there are national initiatives for EPR and private companies offering these services. |
| | First of all, a data protection officer would need to be appointed to oversight data processing activities and evaluate user rights inquiries and requests. For the clear communication with the user, a specific section on ROSIA project service website and similarly on paper documents, reporting on the data used, processing methods, benefit, and ways for users to realize their rights. The adopted relationship with public health department for building a trusted environment around the ROSIA rehabilitation service should also be made clear on the digital and paper-based communication. |
| | Suggest to apply the collection and establishment of data access/privacy requirements and specifications for "federated data" and personal data, using Authorized Public Purpose Access [APPN] guidelines |
| | The education server hosts the Moodle platform and the supporting multimedia content. This server will be fully integrated with the Core platform so that the patient will only access this machine from their App (using the web service that we will build from the CORE server to the education server). The Education server does not host any personal data of the patient The control of the visualization of multimedia content or the |

results of its evaluation are related to the internal alphanumeric code of the platform user and never with the patient's personal data.

With an expert partner

It is worth mentioning that there is no fit-to-all solution when it comes to data privacy. So, we must design technical solutions that take into consideration the whole context of ROSIA's project (e.g., type of data, entities involved, model of sharing, and risk of indirect re-identification) and that incorporate complete control over data access to ensure proper use, pseudonymization (at the source or through a TTP), and encryption in transit and in the field.

An hybrid approach could be analysed giving the patient the data they request but also having a trusted party that can handle all the difficulty (a big one) of managing health data.

First, we are under ISO 13 485 certification process, meaning that we have audits to assure that the system, as medical device, complies with standards. Secondly, we have external audits in order to check if the system complies with industry standards. We are audited by MIcrosoft, for instance, to assure security levels. and some of our customers also audit us in order to check wif we comply with GDPR and security levels they have (like insurance companies)

Based on the direction of the data controller. This is a complex assessment to be made on a case by case basis depending on the characteristics of the project, the purpose of the same and the technology available for the whole project.

We will rely on continuous external data audit and security assessments from independent third parties.

Not Applicable.

Regarding the possibility of assessing and deleting all the information stored about a patient, our platform is prepared to, at any time and at the request of the end user, give information about what data is stored about himself and, if it is his intention, to delete it. The construction of our platform was based on this purpose from scratch. Our mobile applications also incorporate the possibility of accessing external platforms so that each patient's information is not stored on our local platform. This allows, for example, the patient, with a mechanographic number corresponding to his/her own file, to register in the application and perform the prescribed exercises, without, under any circumstances, revealing his/her identity. In this way, the quantified data of the activities carried out will only be recorded in the database of the service provider (i.e hospital, clinic...). According to the needs and clinical option of the service provider, the follow-up and monitoring of the patient's evolution is managed according to the evaluation of the health professionals who will be given access to the collected information. Healthcare professionals will work as a multidisciplinary team, so they will be able to access all the information considered relevant for the treatment of their patients. In addition, since our Cloud Platform is compliant with GDPR, and our mobile apps work with FHIR/HL7protocol, it can be integrated into other systems and centralise all data, reducing possible leaks.

**How can we ensure that data in the platform is also available for research and other purposes, without**

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| **revealing users' identities?** | |
| **Open question** | The company has a lot of experience working with Clinical Research organizations throughout the world. Our platform features strong data privacy capabilities including masking, anonymization or pseudonimization. |
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| | Through homomorphic encryption, datasets can maintain key information while preventing access to personal information. These encrypted datasets will have the relevant information available for use in both research projects and clinical studies. |
| | We have successfully implemented such an approach for the Covid-19 Exposure Notification Apps whereby anonymised aggregated data was sent to the Central Statistics Office to provide the data they required for reporting. Again, there are many initiatives in this space involving members of the Linux Foundation Public Health which should prove useful. |
| | |
| | On understanding individual patients from their records as well as directly through my own method, communication verbally will be exchanged for them to agree or disagree. Only what they agree to, that is what will be my approach. Hence later when they see only what has been agreed is progressing, they will automatically have trust. |
| | |
| | we have implemented this model for more than 4 years. we are a recognized company and all our partners are aware of our policies |
| | With a patient's consent, the healthcare provider or customer could outline in their privacy policy and terms and conditions of use that data for research purposes could be opted into. Data could be anonymised and or aggregated for same. The company offer tools to facilitate data lakes and support data analytics at scale. |
| | We just shade identity and share the rest in a different database. |
| | Easily, via anonomization by design, and with a robust API. |
| | Clinical trials are regulated by local Ethics Committees. Any research study/protocol must be approved by these committees. |
| | Both anonymization and synthetic data generation techniques can be used. Anonymization masks or obfuscate parts of the data containing personally identifiable data, while synthetic data is created by using a model trained or built to replicate a real data set. Generally, synthetic data simulates the real data set based on its distributions and statistical characteristics. Anonymized data has re-identification risk, while synthetic data has the risk of not correctly representing the real data set. Additionally, anonymized dataset creation requires a case-by-case approval leading to expensive project delays. Due to the concerns on anonymized data re-identification, access to these datasets is granted either within controlled environments or shared with researchers under specific usage contracts. Synthetic data is more targeted towards releasing more openly to the public, with the idea to allow scientific community to develop ML/AI models, that if successful, can be re-trained with real data by the data owner within his protected cloud. |
| | We already use anonymisation and pseudonymisation algorithms which have been considered absolutely adequate by our current customers, which have profiles very similar to those of the ROSIA procurers |

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| | The company would transfer all data in a pseudonymized form, and the data receivers would not have access to the codes. |
| | As part of prior GDPR effort all data is anonymously stored; creating references when events are processed. |
| | Finally, the terminology server is just a table converter that will allow us to guarantee the semantic interoperability of the project and the unification of data between the 5 countries. This machine will handle the conversion to ICD-10 standards for diagnoses and symptoms or health problems, LOINC standards for laboratory test results that can be incorporated into the study and SNOMED CT standards for clinical data and biomedical data collected from the Apps and, especially , from medical devices at home. This server has no relationship or influence with personal data of patients. The mirror server will have the same security treatment and data policies as the main CORE server since it acts as a security backup for the entire platform. |
| | With an expert partner |
| | It will require an additional effort. Elaboration and execution of a Data Management Plan to be implemented in the solution for anonymization and subsequent exploitation. All this has to be performed in close collaboration with researchers to know the content and structure of the data that provide value. |
| | It will depend on the research purpose, but it will usually rely on anonymization or pseudonymization pipelines. Each option has its pros and cons. Fully anonymized data has the benefit of being unlinked to the original data (which gives an elevated security level) but usually ensures that by suppressing some data and reducing the utility of the data. Also, fully anonymized data do not allow data aggregation from multiple sources (for example, to construct a patient pathway). Pseudonymization enables data aggregation from multiple sources, but once pseudonyms are linked to the original data, de-identification is still possible. |
| | Data have to be stored anonymised in whatever platform or registry that is used. The information linking the patient identity with the record in the database have to be in separate locations. However, for different reasons that is a complex process given the regulation and privacy laws. We consider the best way to share this information is using Federated Platforms, that can be used to make research on health data without the need of sharing the data. That is, data never leaves the datacenter's of the hospital that owns the data. This way, because the data is not moved, only the computation and the algorithms, patient data is protected. GMV has experience and products in this field, that are also used to train AI models in federated environments. |
| | |
| | As mentioned above, the data are anonymised and encrypted so that it is not possible to identify patients by their data. This system is maintained for all interfaces that are designed and references to patients will always be anonymous. |
| | |
| | The data will be directly linked to deviceID’s, which will have no personal information aggregated to it. The anonymization of the data will allow its use for research and other relevant purposes, without revealing any sensitive personal user data. |
| | The use of personal data for secondary purposes needs to follow local data privacy rules from a transparency perspective but also from a processing perspective. In this regard, if the research can be performed on a fully anonymized basis, the company can help on the full-anonymization process; |
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| | if the research needs to pseudonymize data as full-anonymization is not feasible for technical or regulatory/compliance constraints, then the company can support on the relevant pseudonymization process. Afterwards, the processing can be made securely as our solution is GDPR compliant. As the data processor, the company works with the customer (data controller) to support data disclosure requests and/or comply with customer requirements. For example, some of our customers have chosen to pseudonymize patient names, and our Solo user interface supports the use of a client generated pseudonym where a patient name would normally be stored. |
| | We will provide fully de-identified datasets to researchers built in a way to be compliant with best practices to avoid reversal risk and linkability risk. |
| | The platform architecture shall be designed to ensure maximum protection of uses' data. The use of two, logically separated databases may guarantee the logical separation between the identification of the users' data (metadata) and the collected data. For research purposes, data access could be provided through a web interface, with user authentication, data encryption on transmission and audit logs on system access. |
| | EU regulation |
| | |
| | The platform provides strong mechanisms for de-identifying data to provide datasets for research and analytic purposes. The success of this process is dependent on a flow of clean, well structured data to the data repository. The platform is designed to provide this. |
| | In our solution, all the data generated by our device can be easily anonymized. |
| | |
| | Allowing patients to exercise individual data control, and decide with whom they share their data, even if it is anonymized. |
| | Through data anonymization processes. |
| | We are developing our cloud backend based on the certified platform chino.io. This Cloud backend is completely compliant with the medical-grade requirements of the GDPR including a tool that can be configured for the collection of Informed Consent for research purposes. To guarantee privacy, the data gathered is pseudo-anonymized. |
| | We are completely in favor to the idea of enabling the data for research purposes. To do so, this data needs to exclude all variables that could unmistakably identify the person (i.e. name, citizen or social security number, and e-mail). |

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| **Are there any barriers or constraints impeding your organisation to address ROSIA's challenge? Legal, Technical, Policy, Cultural, other (please specify)** | **None (30/40)** | **Cultural (3/40)** | **Technical: i.e., interoperability, standards (3/40)** | **Other* (1/40)** | **NA (3/40)** |
| | *(no additional answer was provided) | | | | |

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| **If you wish to, please elaborate on your answer** | To cope with cultural and other organizational challenges, the company is bringing multi year experience in delivering Healthcare specific projects across the globe and the vast network of partners. |
| | I will not be able to travel at any stage since I am in the UK and there are restrictions on covid passports etc. All will be undertaken remotely. |
| | we adjust our business model according to every new country we join in order to be more adaptive and less disturbing for the population |
| | We actually provide this servicies for territories. |
| | The main difficulty is to adapt the solution to the requirements of local medical professionals. It is very difficult to find a satisfactory standard for different professionals. The protection of medical data is a challenge due to the different regulations. We would also highlight the need for collaboration with device suppliers who have to ensure interoperability. The company proposes the use of standards recognized at European level. Another important difficulty is the great ambition of the project, which has proposed 7 different rehabilitation challenges. Each one has its specifications and collaboration with specialist professionals is very important. |
| | Not applicable. |
| | Our experience is that we need to adapt always to local the procedures, clinical protocols, user manuals, training... |
| | Our main challenge is the size of the challenge and the need to involve multiple partners from other countries to create a stronger consortium |
| | The company solutions are already widely present in the EU as well as in other geographies across the world such as Australia, United Kingdom, United States, Latin America, China, or Middle East. |
| | The company provides customers with a platform that addresses each customers' specific needs and requirements, including how the customer would design and deploy an application on IRIS for Health to address privacy protections, security safeguards, and individual access. |
| | The only barriers to consider will be the Internet connection availability in rural areas with enough bandwidth and reliability at affordable cost. |
| | The organization cannot commercially exploit the solution. We license our technologies to be exploited by our partners. |
| | We are an engineering Startup. What we have created was the key initial elements for future development of accessories and games to comply with the project needs. To address the needs in the rehabilitation process, we need to have health care providers feedback on the best way to train any specific articulation or muscle group, in order to develop the best fit for the needs in terms of hardware and software. |

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| **Would you be open to granting a free license for the use of your solution to the procurers' organisations once the project is over?** | **Yes (23/40)** | **No (13/40)** | **NA (4/40)** |

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| | The company is proved to be among the most transparent software vendors in the industry with regards to intellectual property. We are strict about our |

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| **If you wish to, please elaborate on your answer** | IP and we don't pretend or bind our customers and partners to share IP rights for new things developed with our tools or on top of our platform. |
| | It will depend on the final solution. |
| | Our developments are our own IPR |
| | As we are a private company we are not in a positon to provide free usage to our solutions. Individual suppliers must be allowed to own their background IP prior to entering the project. IP licensing on foreground IP could be negotiated |
| | My desire is for everyone to have Health. I wish to eventually have my own Clinic to teach my methods to all. I am not interestered in IP rights. All those interested in promoting my approach, let us all obtain mutual benefit to improve lives. |
| | If we are paid we have no problem to grant a free license use for the project, defining clearly the scope (territories, time of the licence, type of licence, etc. ). Of course, ee are not selling our previous IP, but we can collaborate with the success of the project in a reasonable agreement. |
| | Regarding free licenses after project completion, we are open to discuss collaboration modalities to ensure project continuity. Regarding IPR, partners should provide necessary pre-existing know-how in order to contribute to the success of the project. Partners shall respect each other's background IP. IPR should, at a minimum, address the protection and the rights of the parties. A contractual agreement should define the scope and ownership criteria of Foreground Intellectual Property (FIP). FIP can be owned by a single partner or by several partners, depending on the contribution to its creation. Any FIP that is shared by partners will include use rights for all of the partners. |
| | For the development of this proposal, we start from software libraries owned by the company, considered as background and on which it will be necessary to define the optimal transfer mechanism. The company is open to evaluate different options such as generation of royalties for additional sales, or additional services as a preferred customer. It is considered necessary to define the final scope of the solution to establish these conditions in detail. |
| | Will we share the implementation and services but nor disclose our IP unless there's new IP to be establihed (which I don't consider this to be the case - based on the information available) |
| | A free license would be granted to the entity that collaborates in the definition of the solution. We believe that the industrial property should belong to the company that develops the solution, which should grant an unlimited license for use to the Public Health Service who collaborates and is involved in the definition and validation of the solution. |
| | N/A |
| | The technical support would not be included. IPR needs to be owned by the party that creates it. Otherwise, the tender would be limited to creating new developments, something not feasible within the time frame of the project. We, for example, have spent more than 5 years creating our product and validating it in real environments (clinical pilots and trials). We can give a free and perpetual license to the procurers after the project, but not all the IPR. |
| | For a commercial company, this is a sensitive point that would need to be negotiated, the main concern is the maintenance costs of the solutions. |
| | Yes. A free license of the solution for the procurer's organizations will be a great means of dissemination of the project's results, that will be ready to be launched onto the market once the project ends. The rights of the intellectual property will be shared between the partners involved in the development and implementation phases of the product, considering the background knowledge of each of the parts. IP strategy should also be discussed amongst |

| | |
|---|---|
| | the partners upon the contract signing, to assure a proper risk and benefits balance for all the partners. |
| | Yes, although considering the legal framework (interaction with public administration and the applicable antibribery and public procurement laws) and the terms of the same. |
| | We will retain IPRs and we will grant a non-transferable license to the procurers. We are open to discuss an IPR agreement to license the platform to third parties. |
| | The PIN provides that the IPR generated by a selected operator will be retained and without the benefit of further detail and information, it is assumed that a traditional license model would be put in place. For certain deliverables / outputs under the proposal PCP there could be a deviation from this model (but never in respect of the company products and technologies), however, to confirm this possibility, many factors require evaluation by the company including the Contracting Authority's inputs and contributions to each Phase. |
| | We understand and agree with the general rules about intellectual property rights defined at the European Commission guide on PCP. |
| | Retaining Intellectual Property rights is essential to the value of products and services. After investing € Millions in content and solution development, companies need to retain control of the property rights to ensure recovery of that investment through sales of their products and services. |
| | We are open to discuss the best business model that better suits the needs of end users while also granting the due IP rights to the companies and other organizations involved in their development. |
| | |

| **Please, share with us your thoughts on intellectual property rights** | **Yes (25/40)** | **No (4/40)** | **NA (10/40)** |
|---|---|---|---|

| | |
|---|---|
| **Open question** | The device is a result from years of research at the University of Porto, which detains an international patent for the device. The company has exclusive agreement rights to explore it and shall make part of pre-existing rights declaration, according to the #6.2 of the "Rosia-Description-for-OMC-FINAL" document. We are comfortable with the rules adopted by ROSIA, according to the European Commission guide on PCP. |
| | |

| **Where does your solution/experience lie?** | |
|---|---|
| **Open question** | App&Dev, OP, TR, Motivation, Coordinator, Other |
| | Open platforms that allow the connection of said applications. |
| | Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services. |
| | Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services., Follow up and motivation of patients with tele-rehabilitation services . |
| | Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services., Follow up and motivation of patients with tele-rehabilitation services ., Coordinate and/or promote a consortium including all of the above. |

Applications and devices that can become a part of ROSIA’s catalogue of tele-rehabilitation services., Open platforms that allow the connection of said applications.

Applications and devices that can become a part of ROSIA’s catalogue of tele-rehabilitation services.

Open platforms that allow the connection of said applications.

Applications and devices that can become a part of ROSIA’s catalogue of tele-rehabilitation services., Others: specify If you wish to explain your answer: I have several flexible concepts. Only on receipt of patients health & capability I will be able to accurately respond.

Applications and devices that can become a part of ROSIA’s catalogue of tele-rehabilitation services., Open platforms that allow the connection of said applications., Social-community services related to tele-rehabilitation., Follow up and motivation of patients with tele-rehabilitation services ., Coordinate and/or promote a consortium including all of the above.

Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services., Follow up and motivation of patients with tele-rehabilitation services ., Coordinate and/or promote a consortium including all of the above.

lications and devices that can become a part of ROSIA’s catalogue of tele-rehabilitation services

Applications and devices that can become a part of ROSIA’s catalogue of tele-rehabilitation services., Follow up and motivation of patients with tele-rehabilitation services ., Coordinate and/or promote a consortium including all of the above.

Applications and devices that can become a part of ROSIA’s catalogue of tele-rehabilitation services., Open platforms that allow the connection of said applications., Follow up and motivation of patients with tele-rehabilitation services ., Coordinate and/or promote a consortium including all of the above.

Applications and devices that can become a part of ROSIA’s catalogue of tele-rehabilitation services.

Applications and devices that can become a part of ROSIA’s catalogue of tele-rehabilitation services., Open platforms that allow the connection of said applications., Social-community services related to tele-rehabilitation., Others: specify

Applications and devices that can become a part of ROSIA’s catalogue of tele-rehabilitation services., Open platforms that allow the connection of said applications., Follow up and motivation of patients with tele-rehabilitation services .

Applications and devices that can become a part of ROSIA’s catalogue of tele-rehabilitation services.

Open platforms that allow the connection of said applications., Follow up and motivation of patients with tele-rehabilitation services

Open platforms that allow the connection of said applications.

Open platforms that allow the connection of said applications., Follow up and motivation of patients with tele-rehabilitation services ., Coordinate and/or promote a consortium including all of the above.

| | |
|---|---|
| | Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services., Open platforms that allow the connection of said applications. |
| | Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services., Open platforms that allow the connection of said applications., Social-community services related to tele-rehabilitation. |
| | Open platforms that allow the connection of said applications., Follow up and motivation of patients with tele-rehabilitation services ., Coordinate and/or promote a consortium including all of the above. |
| | Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services., Open platforms that allow the connection of said applications., Social-community services related to tele-rehabilitation., Follow up and motivation of patients with tele-rehabilitation services ., Coordinate and/or promote a consortium including all of the above. |
| | Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services., Open platforms that allow the connection of said applications., Follow up and motivation of patients with tele-rehabilitation services . |
| | Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services., Open platforms that allow the connection of said applications., Social-community services related to tele-rehabilitation., Follow up and motivation of patients with tele-rehabilitation services . |
| | Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services., Open platforms that allow the connection of said applications., Follow up and motivation of patients with tele-rehabilitation services |
| | Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services. |
| | Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services. |
| | |
| | Open platforms that allow development and connection of applications. |
| | |
| | Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services., Open platforms that allow the connection of said applications., Social-community services related to tele-rehabilitation., Follow up and motivation of patients with tele-rehabilitation services ., Coordinate and/or promote a consortium including all of the above. |
| | |
| | Applications and devices that can become a part of ROSIA's catalogue of tele-rehabilitation services., Open platforms that allow the connection of said applications., Coordinate and/or promote a consortium including all of the above. |
| | Applications and devices that can makeup ROSIA's catalogue of telerehabilitation services |
| **Others: specify** | |
| **Open question** | We (I) have participated in several EU R+D projects. Our focus is the development of expert system for health promotion, and health management. |
| | Wearable technology - we're an OEM |
| | Software solution for tele-rehabilitation management, patient empowerment, patient and family support and training |
| | |

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| | We provide specific expertise in the automation, orchestration and optimization of complex rehabilitation workflows including artificial intelligence-based capacity planning tools to size new services and check their scalability potential. |

## B.1 IF YOUR SOLUTION INCLUDES AN OPEN PLATFORM

| What relevant standards do you think ROSIA should require for data interoperability? | |
|---|---|
| Open question | HL7, ITU, IHE, Other |
| | HL7/FHIR, IHE |
| | HL7/FHIR, ITU H.813, IHE |
| | HL7/FHIR |
| | HL7/FHIR, ITU H.813, IHE |
| | HL7/FHIR |
| | HL7/FHIR, IHE |
| | HL7/FHIR |
| | HL7/FHIR, ITU H.813, IHE |
| | HL7/FHIR |
| | HL7/FHIR, IHE |
| | HL7/FHIR |
| | HL7/FHIR |
| | HL7/FHIR, ITU H.813, IHE |
| | HL7/FHIR, IHE |
| | HL7/FHIR |
| | HL7/FHIR |
| | HL7/FHIR |
| | HL7/FHIR, ITU H.813, IHE |
| | HL7/FHIR, ITU H.813 |
| | HL7/FHIR |
| Other: specify | |
| Open question | Please specify HL7/FHIR and OMOP. The latter is becoming the standard de facto in clinical research. |
| | CDA and DICOM |

| Do you think a service oriented architecture is the right approach for ROSIA's Open Platform? | Yes (19/40) | No (4/40) | NA (17/40) |
|---|---|---|---|

| | |
|---|---|
| | |
| **If you wish to, please elaborate on your answer** | SOA incl. microservices and RESTful architectures fit well current state of interoperability in the healthcare industry |
| | SOA is a very old approach to building solutions and platforms. Newer, more lightweight and agile approaches are much more prevalent now and are more much amenable to modern Cloud deployments |
| | Service-oriented architecture, allow for software components to be reusable and interoperable via service interfaces. Services use common interface standards and an architectural patterns that allow to rapidly incorporate them into new applications. The service interfaces provide loose coupling, so they can be called with little or no knowledge of how the service is implemented underneath, reducing the dependencies between applications. |
| | In alternative to Service-Oriented Architecture (SOA), a Microservice Based Architecture (MSA) seems to be also suitable. In fact, it will depend on the complexity and the number of integrated systems/services. In some cases, a MSA is more efficient than a SOA since it enables a framework of multiple services that are flexible, portable and a platform-agnostic, allowing each service to have different operating systems and databases while running in its own process. |
| | SOA's was a big topic years ago, but it remained in not used frameworks because of their difficult implementation and use. They are a topic of research papers but have not matured enough. Even if theoretically interesting, there is not an established standard that is open and mature enough. We consider that the market and current solutions have evolved towards a more direct and flexible approach using open APIS (WS, Restful, etc). This can be considered a form of SOA, but more simple in its approach and something that many device manufacturers have done. |
| | Yes, otherwise is only technology. |
| | Service and Patient oriented would be the vision for an ideal rehabilitation platform. |
| | ROSIA should go for a microservice architecture. |
| | We can answer this question until the final specification and services definition, because micro services could be also a good architecture |

| | |
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| **What shared services do you think would be needed in ROSIA's Open Platform? (open question)** | |
| **Open question** | The company's platform has a set of out of the box healthcare data services, such as patient deduplication or terminology mappings, clinical documents exchanges and so on. The exact set of key services rather be agreed and developed within a bidding consortium. |
| | It is too early in the process for us to have an answer to this question. |
| | Authentication and authorization, Service catalogue, Data access and modification logging |
| | The platform should make pathologies independent. In this way, growing in protocols will be very easy. Our platform already includes it. |
| | Strong access control, security and privacy policies, governance, documented set of APIS to discover and use services, offline communication (messaging, etc), videoconference with very low latency and bandwidth consumption, ability to involve carers and family, ability to create/modify the therapy plan, visualisation to view the progress of the patients, configurable alerts and |

| | |
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| | alarms, appointment capacity, clinical record, interoperable with medical devices. Also, it's quite important that the platform has been already tested and validated in clinical tests involving patients. |
| | HRE, Health plans, Training, Patient assessment, Dashboard, Communication tools |
| | Interoperability services; a catalogue of approved device / applications; shared research data repositories. |
| | |
| **How do you see the governance of ROSIA's Open Platform?** | |
| **Open question** | The company has the enterprise governance approach at its heart. Whereas the exact policies and procedures needs to be established between the company and the application developers under ROSIA specific circumstances, years of offering SaaS services to the global market and the multiyear experience in governing its own Cloud Applications Marketspace gives to the company a headway in sharing best practices around platform governance. |
| | We would recommend a highly transparent approach to governance with stakeholders from ROSIA itself, key vendors and patient representative groups. |
| | Regarding authentication, a federated authentication approach through federated indentity management is suggested. Other governance aspects to consider include GDPR directive logging requirements, such as tracking access to data and tracking data modifications. * Depending on the ROSIA's scope, in addition to security and privacy goals, other data governance framework methods can be applied to monitor the quality of the data used by services, catalogue the existing and newly created data assest, for services monitoring and improvement, and new services development. |
| | We see a cooperative governance model where a governing body representing device and services suppliers is also part of the decision-making for the steering activities. This collective or collaborative governance model must be solutions-oriented, where diverse stakeholders can work in partnership to improve the management of the resources and delivery of services/products. Regarding data management, the ROSIA's governance model must enforce the use of standards (open standards favour interoperability) and policies, enabling a consistent, integrated, and comprehensive approach across the ROSIA's stakeholders to anticipate, mitigate, and address risks specific to each developed solution. Also, it must ensure all design and development decisions are preserved into formal documentation and linked with the functional requisites involved, allowing to understand, at any time, why certain decisions were made the way they were and by whom. Also, considering the development of health data ecosystems in rehabilitation research is one of the utmost ROSIA contributes, the governance model must include clear policies for all stakeholders' access and secondary use of the data. Regarding results management, the ROSIA's governance model must include procedures to promote the active participation of all stakeholders in a targeted communication and education campaign with crucial information and tools that should be produced to explain the functioning and purpose of the infrastructure. |
| | Data governance procedures are important for this tender, to know where the data lies, who has access to it, and also a strong access control. Also, the platform has to be dynamic and highly configurable because we are addressing not a single use case but an entire field (rehabilitation) |

| | |
|---|---|
| | ROSIA's consortium should define standard architecture and guidance and provide test cases and environments (like IHE Connectathon) |

| **Are developers already using your API and your open platform?** | |
|---|---|
| **Open question** | The company's platforms are very well documents, The API documentation is publicly available. There's a broad community of development partners, using the company technology world wide. |
| | We would be building a custom platform based on agreed specifications so this question is not applicable to us. |
| | Yes. Coaching and data-driven recommendation has been developed within the where the interaction of the different modules of the solution with other providers has been realised through open and well-defined APIs. |
| | Some developers have already used our API to integrate our current solutions with their solutions |
| | yes |
| | Our Predictive and intelligent platform that supports the management of cardiac rehabilitation has APIS which allow the integration of a Gamification tool developed by other company. It also has APIS to integrate Intelligent virtual adviser for cardiovascular prevention and well-being developed by the company.. |
| | Yes |
| | Yes, although these developers are from the partners we have contracts with (medical device manufacturers, for example). |
| | Yes, our API is already in use in different projects. |
| | Yes, the company is already being tested in several customers and also in H2020 project for social care. |
| | Only the automatic planning platform is currently used with an API by researchers for test purposes |
| | No |
| | Yes |

**B.2 QUESTIONS RELATED WITH ROSIA´S TELE-REHABILITATION CATALOGUE**

**ROSIA plans to build a catalogue of services curated through a qualification procedure (such as the NHS Apps Library) from which treatments can be prescribed by health professionals. Elaborating SDK and requirements for the catalogue will be a part of the tender's requirements.**

| **Would you be interested in deploying such a model in participant regions?** | **Yes (26/40)** | **No (2/40)** | **NA (12/40)** |
|---|---|---|---|
| | | | |
| | Since ROSIA will have a catalogue then I would certainly be delighted in my Solutions to be deployed. | | |

| | |
|---|---|
| **If you wish to, please elaborate your answer** | To develop independient apps for specific purposes is an excellent idea.<br>1 - We will elaborate the SDK and requirements regarding our system for the catalogue.<br>2 - We expect to have our solution on the TRL 9. However, the new technologies to be integrated, should be at least at TRL 7.<br>3 - They need to cover relevant needs in terms of the actual tender objectives and digital connectivity interface. |

| **Would you like to suggest an alternative procedure?** | **Yes (3/40)** | **No (25/40)** | **NA (12/40)** |
|---|---|---|---|

| | |
|---|---|
| **If you wish to, please elaborate your answer** | There is an opportunity for ROSIA to also expand to the UK. I see Dublin on the list but not UK. I would like to establish a Global Centre in Innovative Holistic Healing, curing, regenerating...etc... using, if your permission true life stories from the patients who have recovered or improving.<br>Yes, we would be interested to collaborate in the creation of this tool.<br>Solutions can be licensed to be exploited by partners the prove to be suitable to deploy them in participant regions. |

**ROSIA is designing a solution that will be ready to be mainstreamed once the project ends; this means in at least five years. In order to guarantee that the solution will still be relevant after that period, edge technologies should be used whenever possible. It is therefore to be expected that some of the services will complete their validation process participating in ROSIA.**

| **What TRL should be requested from those services if they are to be integrated in the catalogue and be used in pilots by 2024? (open question)** | |
|---|---|
| **Open question** | At least 4 or TRL 5.<br>TRL9<br>TRL7<br>TRL Levels 5 and higher seem appropriate where new technologies are being used.<br>TRL 4<br>It is still very early to decide this. Given the current Covid and biological weapons attacking all life, there will be several unknown diseases later this year.<br>TRL 7-8<br>TRL7-9<br>7-8 at least. There is an abyss between the technology and a functional product.<br>At least TRL7<br>At least TRL 6 at the start of the project |

| | |
|---|---|
| | TRL 6 or TRL 7 |
| | TRL-8 |
| | The architecture will be interoperable, multi-language, with connection layers so that new advances in the platform can be implemented. |
| | TRL 5-6 Demonstration Less than that doesn't make sense |
| | TRL8. |
| | TRL7+ |
| | TRL 5, once they have a 3 year period to be fully develope |
| | A minimum TRL of 5 will be required for the services to be offered. |
| | TRL 6-7 |
| | TRL5 - Laboratory testing of integrated system. |
| | TRL6 |
| | it would be apply in all of the life cycle |
| | TRL equal or grater 7 |
| | 8 |
| | At least TRL7. |
| | We believe at leat TRL 6 |
| | |
| **How can we assess whether those services are fit for purpose?** | |
| **Open question** | The solutions need to be assessed singularly and then as a connected care solution in different contexts |
| | Agile methodologies can be used here too where rapid prototypes of those bleeding edge solutions along with early prototypes of the platform can be tested and iterated on together. This means that any issues with the new solutions can be found much earlier in the process. Those technologies can then either be fixed, improved or discarded as appropriate. |
| | Patients to decide |
| | Doctors, nurses, pharmacy network, medical equipment |
| | The more, the better. |
| | We expect their fitness for purpose to be assessed by independent rehabilitation specialists contracted by the service providers themselves |
| | Quantitavely evaluate the effectiveness of the solutions in patients outcomes, Qualitatevely study usability for both patients and clinicians. Evaluate savings in costs with respect to in-clinic approaches. |
| | don't understand this question |
| | Photos or videos (real) of the solution Indication of where it was used/tested |
| | Services must provide a clear operational advantage and high added value to the project. |
| | The data sharing is fulcral for the integration in ROSIA's open platform, so the security and data interoperability and safety standards should be the focus on the assessment. |
| | Proposed technologies should have been already demonstrated in real-world environment in a rehabilitation context, or at least as a technology demonstrator during a completed research project with contribution from rehabilitation hospitals as validation. |
| | Analysis of the commercialization potential. Scalability potential. Continuous market and state-the-art research. |

| | |
|---|---|
| | By testing and validating the solutions in controlled settings, assessing their usability in different complexity scenarios, e.g. in the following simplified order. 1) test in validation scenarios within the clinical and development teams; 2) test in in-clinic scenario by a sample of healthy patients; 3) test on a telerehabilitation scenario with healthy users; 4) test on a telerehabilitation scenario with patients.<br>Each of these steps should follow specific and representative samples, durations and methodologies, and only after having those successfully completed should we do an analysis to the results collected under the 4th step, assessing relevant clinical, satisfaction and usability variables. |

**B.3 QUESTIONS RELATED WITH SELF-MANAGEMENT FOR REHABILITATION:**

**Self-management in telerehabilitation includes four steps: evaluation, defining exercises, assessing performance, and providing feedback. It also demands motivation and taking into account emotional states.**

| **How do you think this process can be developed for use in treating diverse clinical conditions in an effective way?** | |
|---|---|
| **Open question** | This process needs to be developed separately for the diverse clinical conditions an overall "container" system decoupling work of specialists and patients needs to be put in place, which guarantees versatility of clinical pathways The single clinical conditions need to be properly studied both considering present approaches to each of these, but also characterizing patients and their motivation, which changes not only with age but also with the conditions themselves |
| | The strategy should be focused on the improvement of daily life activities in normal contexts (home, work or social interaction among others). The use of non-instructive technologies or wearable can provide valuable information, not available so far, about how patients live and how the impairments affect their normal living. By means this information, can be defined specific and personalized terapies at different levels and at the same time, empower the patient about their real health status. |
| | Yes |
| | Regarding your 7 different disease conditions, I think we would need adaptations for each of them, because we would not always measure same variables for each of them. It can happened we would have some variables that are equal for all of them as time of exercise performed or pause in between, but to evaluate a COPD patient we would need a Pulse oximeter and for a Cardic patient a ECG maybe so, data collected to give feedback will come from different resources or datasets. |
| | our solution provides high-intensity, high-dosage training programs via gamified virtual environments. Evaluation, therapy definition and performance assessment are enabled in easy-to-use interfaces for the healthcare professionals. |

| | |
|---|---|
| | As we explain below the four steps can remain the same irrespective of the clinical conditions but the system can be fed with different knowledge bases to address different clinical conditions |
| | The question is 'vague' ... Are you asking about the development process as a generic business process with spefiic domain specific elements to be included ? That would be an one hour presentation |
| | We will need collaboration from experts in order to identify information that must be gathered for an effective illness management and to adapt work flows to the different pathologies |
| | The platform needs to interact with monitoring devices and doctors. The doctors initially create the therapy plan (frequency, intensity, etc), the difficulty of the games or exercises, etc. The patients carry out the exercises and the doctor will only intervene (weekly usually) to monitor the advance or in case of alarms. Direct contact with people will help motivate patients. |
| | Although the workflow is the same for all conditions, health plans must be personalised. Each plan should be made up of monitoring and evaluation indicators, objectives, communication tools, training and information for each patient. In addition, these plans will include both pharmacological and non-pharmacological treatments (exercise, nutrition, etc.). |
| | By means of a user-friendly interface that allows patients to understand how their actions can impact their recovery/treatment process. |
| | The care protocols delivered by the provided technologies should be unique per single clinical condition. We foresee the possibility of some features (e.g. therapy adherence, clinical data management, workflow orchestration) to be common for all pathologies. |
| | |
| **Could some modules of hardware or software be used for more than one of the above steps?** | |
| **Open question** | Definitely yes |
| | Yes, in our platform we can use videoconsultations, chats, questionnaires, e-learning and digital patient journal for any kind of patients, but for exercise prescription we are best for cardiopulmonar diseases. |
| | Our solution (hardware and software) already addresses all 4 steps: evaluation, defining exercises, assessing performance, and providing feedback. |
| | We doubt that hardware modules could be reused because devices for rehabilitation tend to be clinical conditions specific. On the other hand some software modules could be generic enough to be reusable for more than one clinical conditions. |
| | Yes |
| | Yes |
| | Yes, there are devices that can be used to track variables pertaining to different conditions. |
| | All the elements that make up a plan can be used by several plans and at different stages of the process. |
| | The platform should be able to use general-purpose tools (wearables and other devices) capable to bring different and tailored content to patients so that the key effort will be on developing the content for diseases, and not on creating a number of different apps or devices. |
| | Our solution could be used in all the steps, mainly the hardware modules. For software modules, tools like videoconference can be used in all of steps. |

| | |
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| | Our Hippo Virtual Care platform improves collaboration between caregiver and physicians in all four steps of the rehab process (evaluation, defining exercises, assessing performance and providing feedback). As an open platform and work flow engine it can assist in managing checklists, providing content, collaborating with remote caregivers, recording exercise performance and assisting in immediate feedback from remote clinicians). |

| | |
|---|---|
| **How?** | |
| **Open question** | for example a mobile phone can be used to assess certain biomechanical parametres related to functional status (gait, balance of even strenght at lower limb level). At the same time, this device, with other app, can be used to guide and assess the patient performance through a customized rehabilitation exercice while following the instructions of a virtual assistant on their smart TV |
| | he behaviour of the generic software modules is driven by the knowledge base they are fed with. So, by providing them with a knowledge base for each clinical condition they can cover all of them |
| | The SW should be versatile enough to create plans and exercises for multiple diseases. It needs to allow to create new activities in a quasi-open way, and enter the required variables to be monitored. It has to allow different kind of exercises or activities, from entering raw/numeric/tex data, getting data from medical devices, personalised recommendations or questionnaires (quite important) |
| | A common repository of elements that can be associated with the different plans will be defined. These elements could be data collection forms, devices, training, etc. Each health plan can be customised to be used at different times of treatment. |

### C) ROSIA'S PRE-COMMERCIAL PROCUREMENT (PCP)

**ROSIA's PCP process starts with the launch of an open European-wide call for tenders which is expected to take place March 2022. Suppliers are then invited to submit proposals. Proposals are reviewed and ranked. Up to 5 teams/consortia/individual companies will be invited to enter into a competitive itinerary that is divided into 3 phases. The three phases are: solution design, prototyping, and validation and testing of a limited set of first products or services. After each phase, intermediate evaluations will be carried out to select the best among the competing solutions. Contractors with the best-value-for-money solutions will be offered a specific contract for the next phase.**

| | | |
|---|---|---|
| **Are you interested in submitting a proposal for ROSIA's Pre-Commercial Procurement tender?** | **Yes (39/40)** | **NA (1/40)** |

| | | | | |
|---|---|---|---|---|
| **If yes, are you interested in submitting a proposal individually or in partnership?** | **Individually (6/40)** | **In partnership (26/40)** | **Both (1/40)** | **NA (7/40)** |
| **If you wish to submit a proposal in partnership,** | | | | |

| | |
|---|---|
| **would you clarify if you already know your partners?** | |
| **Open question** | The company has a wide partnership network in many locations. As a platform provider we are open to any added value partnership and looking to establish also some specific relationships for this project. |
| | Health Cluster 1; Company1 |
| | Not yet |
| | We currently do not know our partners. |
| | We wish to find a suitable partner through the matchmaking tool. |
| | Ideal scenario is in partnership. I looked on your site but so far because of language or geographic location have not been able to find a partner. I am also trying to find employees/Partners for Global Peace CIC. Current difficulties I do not have a bank account because Banks in the UK only accept information on line. They all refer to submitting selfies. I do not have a Smart phone...I do not wish to own one either...this is one barrier. The second is I applied for VAT Registration several months ago sent a reminder recently but no reply. These are my weaknesses. My strengths are Innovation, solution provider. |
| | No, we are searching for them |
| | Yes, a company, expert developers of technological platforms. If needed, we have a partner for technological integration with the health systems. |
| | We know already the core partners. The additional partners to complete the consortium will be searched in the next few months |
| | We already know some of our potential partners beforehand. |
| | No |
| | We need local partners, hardware manufacturers for medical devices, logistics partners and clinical partners. |
| | in definition |
| | Although not yet finished, we foresee a joint proposal in partnership with Company 1, company 2 and Health Cluster. |
| | We already know our main partners |
| | We do not currently know the potential partners |
| | we are already a consortium, open to partner with other actors |
| | We would involve in a largest national research hospitals network on rehabilitation, which provides a number of research laboratories and already has existing research results to be further implemented and brought to the market. They provide also clinical expertise on all of the ROSIA's identified diseases, clinical trial and ethical expertise for pre-approval of solutions dedicated to such vulnerable patients. We will also involve companies with specific expertise in wearable devices, secure cloud platforms for data transfer and storage, and AR/VR technologies. |
| | We are interested in joining a consortium, in which our skills can add value. |
| | No not at this time. |
| | Yes |
| | Our partners are: - company 1, company 2, company 3 |
| | As previously mentioned, we are already working as a group of organizations working together to fulfill a goal and our working model is flexible enough to are open to integrate other institutions. |
| | Some of them yes. They are related to the an a Health Cluster |
| | We have had some superficial conversations, but not yet |

| | | | |
|---|---|---|---|
| **Do you have tender experience with public procuring authorities?** | **Yes (28/40)** | **No (8/40)** | **(4/40) NA** |

| | | |
|---|---|---|
| **If a supplier/consortia qualifies through the 3 phases, the minimum budget available for the contract will be €1,770,000 (VAT included, if applicable). Do you think the budget is…** | **b) Adecuate to meet the challenge (3/40)** | **NA (37/40)** |

| | |
|---|---|
| **Please, provide a rough estimate of the budget you consider necessary to meet the challenge** | |
| **Open question** | Phase 3 may require more funds considering it runs for 18 months and there is no clarity about future revenue commitments (e.g. cloud subscriptions, etc.) |
| | Actually it depends on the readiness of the single existing pieces that need to be connected. It is adequate if most of the clinical conditions have already been studied both from the clinical point of view as well as from the patients characterisation and their motivational profiles |
| | challenge I say adequate because I do not know the actual condition of patients. My desire is to address all the challenges My desire is to see a smile on their faces. My desire is for them to say, I now wish to become a teacher. I have been cured. I wish to join you. I do not know what level of funding is required |
| | €2Mio |
| | It is adequate, but the distribution is not quite ok. We find the present total budget fine. |
| | 1.5M - 2M |
| | We consider that at this point we need more detailed information in order to estimate a real budget. |
| | The budget will depend on the number of people/locations in which we have to deploy and test the solution. Effective Medical devices for rehabilitation are expensive. We've said "Adequate" but if the number of locations required to test the solution is big, that budget may be not enough. |
| | For the full development of the solution some optimizations are required for the hardware and software. Also, a large study with multiple patients in different locations will be required which will be time and resource consuming. The solution has already been used in the scope of a European project, Gloria, so prior experience in setting up the study has been acquired. |
| | Based on an initial assessment of 100 clinical users, 100 patients (50 using their own device, and 50 using the solution iOS tablet), with the intention to |

| | |
|---|---|
| | integrate the system with other 2 third party applications, including 5 different sites (hospitals) and the required professional development services, including the multilanguage option, and upon the Solution Design team evaluation once the project requirements go live. The estimated solution price would be: - Setup Fees: 300,000 € (VAT excluded) - Subscription Fees (Annual): 350,000€ (VAT excluded) This would mean an approximate initial investment of 1.35 € million (VAT excluded) based on the assumption of 36 months subscription, without including any expansion. All to be reviewed based on the final requirements established by the procurement and clinical team at ROSIA. |
| | 9500 |
| | 800000 |
| | |

| | | | |
|---|---|---|---|
| **Do you agree with the budget distribution between phases,1, 2 and 3 (see ROSIA document *Additional Information*)?** | **Yes (29/40)** | **No (6/40)** | **NA (5/40)** |
| **If no, please indicate reasons and alternatives** | | | |
| **Open question** | The budget in phase 1 should be somewhat higher. In-depth analysis is essential for a multidisciplinary platform. | | |

| | | |
|---|---|---|
| **Is the timeframe proposed...** | **b) Adecuate to meet the challenge (3/40)** | **NA (37/40)** |
| **Please, provide a rough estimate of the timeframe you consider necessary to meet the challenge** | | |
| **Open question** | We feel that the timelines are very long and a more iterative agile approach that delivers usable pieces of functionality quickly should be taken instead. As new functionality is released, it can be evaluated and validated, creating an efficient feedback loop into the development process. | |
| | Only when I know the actual condition of patients who are my only concern then I can respond as my solutions are tailor made | |
| | 3 years | |
| | 2 to 2.5 years | |
| | The timeframe is ok, but the distribution is not sound. We will need more time for the Fase 2. Otherwise, there will be overlapping with Fase 3 | |
| | 4-5 years | |
| | not possible at this time | |
| | We see Phases 1 and 2 as especially short. There will always be delays that will be detrimental to Phase 3. Design: 6 months (in close collaboration with clinical experts); development: 10 months; validation: 18 months | |

| | |
|---|---|
| | It will be adequate if the solution/Platform has already been developed and evaluated with real patients. If not, or it requires big modifications, the allocated time is not enough. |
| | between 2 and 3.5 years. |
| | 2 years |
| | The platform is already live, the time to meet the challenge requirements is entirely up to the specific customer requirements and the number of integrations required. |
| | Phase 1 should be a little bit longer and with a larger budget as the design effort is at least 8-10 person month. Phase 3 budget is ok considering it will allow accommodating further technical activities to refine, tune the platform and fix errors, all the technologies, and also include all the technology to be provided plus the professionals (tech and clinical) involved. |
| | 18 months |
| | The proposed timeframe seems realistic and achievable (i.e. Solution Design: Sept - Nov 2022 / Prototype Development: Jan - Aug 2023 / Validation: Oct 2023- March 2025. |
| | In our opinion 4 years is too long to complete the project. Other projects or commercial initiatives may launch commercial product to the market with Rosia objectives before the Rosia phase 3 ends. |
| | 2 years |
| | Around 2 years |

| | | | |
|---|---|---|---|
| **Do you agree with the time distribution between phases 1, 2 and 3?** | **Yes (28/40)** | **No (7/40)** | **NA (5/40)** |

| | |
|---|---|
| **If no, please indicate reasons and alternatives** | Phase 2 could perhaps be shortened to 6 months, to keep it agile and more easily fit within the Phase 2 budget. |
| | We would turn Phase II and Phase III into a large number of smaller phases where there is not a single prototype but many prototypes that are validated and then hardened. |
| | Six month for the development is not enough. We are talking of a multicultural solution, in several languages with different legal requirements. It is not only de development, you have to integrate with others partners, you have to translate it, you have to adapt, etc. |
| | We find the proposed timeframe fine, but we believe that the distribution should be modified, as it should be lineal according to the duration of the phases. No, development phase is too short. |
| | We think that the solution should be designed in close collaboration with clinical experts and It would take longer (7 different pathologies are also too many) |
| | The final phase should be longer. |
| | Phase 1 - 5 months Phase 2 - 10 months Phase 3 - 18 months |
| | We believe the 3-month Solution design and 8-month Prototyping development are very adequately estimated. Regarding the last phase, of Validation, we also find the 18 months adequate but potentiatilly these could be split in two or three, to allow for solutions feedback, iteration and refinement (for instance 3 cycles of 5-months test + 1-month analysis and iteration) |

**We will use ROSIA's Value Based model (see Additional Information document) to evaluate who qualifies through the various phases of the PCP.**

| Which set of criteria do you consider more important in this evaluation? (1 = not important, 5 = very important) | Value creation | Organizational capabilities | Financial sustainability | Scalability |
|---|---|---|---|---|
| Open question | 4 | 5 | 4 | 5 |
| | 5 | 4 | 4 | 5 |
| | 5 | 4 | 4 | 5 |
| | 5 | 4 | 4 | 5 |
| | 5 | 4 | 4 | 3 |
| | 4 | 3 | 3 | 5 |
| | 3 | 4 | 3 | 4 |
| | 5 | 5 | 1 | 5 |
| | 5 | 5 | 3 | 5 |
| | 5 | 5 | 5 | 5 |
| | | | | |
| | 4 | 3 | 3 | 4 |
| | 5 | 5 | 3 | 4 |
| | 4 | 4 | 5 | 5 |
| | 4 | 4 | 4 | 5 |
| | 4 | 5 | 5 | 5 |
| | 5 | 3 | 3 | 5 |
| | 4 | 2 | 4 | 4 |
| | 5 | 3 | 4 | 5 |
| | 4 | 4 | 5 | 5 |
| | 3 | 3 | 3 | 3 |
| | 5 | 4 | 3 | 4 |
| | 4 | 3 | 4 | 5 |
| | 5 | 4 | 4 | 4 |
| | 5 | 5 | 5 | 4 |
| | 5 | 4 | 4 | 4 |
| | 5 | 3 | 3 | 5 |
| | 5 | 4 | 5 | 4 |
| | 5 | 4 | 4 | 5 |
| | 5 | 4 | 4 | 3 |
| | 5 | 5 | 4 | 5 |
| | 5 | 4 | 4 | 5 |
| | | | | |
| | 5 | 4 | 5 | 5 |
| | 5 | 4 | 5 | 5 |
| | | | | |
| | 5 | 4 | 4 | 5 |
| | 5 | 4 | 4 | 3 |
| | 5 | 4 | 4 | 5 |
| | 5 | 4 | 4 | 5 |

| Your business model is focused on | Volume of activity (14/40) | Pay for value (15/40) | Others (4/40) | NA (7/40) |
|---|---|---|---|---|
| | The comopany transfers technologies to enable businesses to be more competitive and to have a positive impact on society, in line with our social commitment. | | | |
| | Currently its B2B license based, depending on the number of integrated systems. | | | |
| | A licensing system with volume discounts should be explored. An incentive system for achieving targets could be incorporated. | | | |
| | Subscriptions based on the number of users, Setup costs based on the requirements of the ecosystem, Hardware to be included in the ecosystem | | | |
| | Software licensing based on scope and scale of usage. | | | |

## Partner search

| Are you interested in seeking partners for a joint proposal? | Yes (2/40) | NA (38/40) |
|---|---|---|

| What expertise/products/services are you expecting from your partners? | |
|---|---|
| Open question | A spin-off from the University of Porto, develops innovative solutions that allow citizens to increase their quality of life, making people more autonomous and conscious about their health. Using entertainment tools based on gamification as the main engine of innovation, BRIGHT manages to increase the motivation and training of medical teams and citizens. With a focus closely linked to adherence to therapy and the comfort of its users, new solutions allow to balance the use of medical resources and to improve medication management. The "xx" project received international media attention when it won several awards, such as the Red Emprendia Award, the Social Entrepreneurship Diogo Vasconcelos Award, the Astellas C3 Prize Award and the Active Citizenship Award. In 2020, the company was mentioned in an article in the Financial Times for the success of its interventions in health promotion and health literacy. Company 2: a company which will develop new features for the system application, for iOS and Android. Company 2 is a recognized software company that works with projects such as “Acredita Portugal”, already familiar with the communication model of the Bluetooth module already selected, which will accelerate the development of the App and the Cloud Platform to obtain and analyze information. |

| | |
|---|---|
| | Company 3 with a dedication to the development of the mechanical project including:<br>- the study of existing commercial solutions for the evaluation of the strength of different muscle groups;<br>- the development of the concept of having a central body, comprising a double load cell and the accommodation of electronics, capable of receiving the assembly of different accessories depending on the desired strength assessments;<br>- finite element simulation of the efforts absorbed by the mechanical components developed;<br>- manufacture of prototypes for validation of the different components. |

| | |
|---|---|
| **Please, let us know if you have any other comment** | |
| **Open question** | A small demo video of the technology that is the base of the future proposal: https://1drv.ms/b/s!AhikJNdTw_nCuLwoLmVYtHv4uxiv-w?e=goQVVu<br>We share the following demo video to illustrate the general functionning of our telerehabilitation solutions. https://youtu.be/NYGWXpkor1s |

## Annex 6: Company Solutions OMC Questionnaire

| | Company Name | Solution |
|---|---|---|
| 1 | PLUX Wireless Biosignals S.A. | Biosignalsplux, bitalino, physioplux |
| 2 | Physio R&D ApS | Optimov |
| 3 | MindMaze | MindMotion |
| 4 | Starlab Barcelona SL | Starstim |
| 5 | Trilema Salud | MOVISALUD |
| 6 | GMV | Antari Home Care, Antari Professional, and Antari Evidence Telemedicine Platform |
| 7 | Neutroplast Indústria de Embalagens Plásticas S.A. | Smartcover |
| 8 | Teladoc Health International, S.A.U. | TeledocHealth, SOLO Virtual Care Platform |
| 9 | SurgiQ srl | SurgiQ. |
| 10 | Kinetikos Health | mKinetikos (mobile app), kinetikos Pro (SaaS Platform) |
| 11 | Medtronic Ibérica SA | RGS@home, RGS@wear |
| 12 | InterSystems Corporation | Enterprise Healthcare Platform |
| 13 | VisionID Ltd. | Hippo |
| 14 | Gripwise Tech Lda | Gripwise |
| 15 | Clynx (Clynxio LDA) | Motiphy+ |

## Annex 7: Matchmaking tool

https://rosia-pcp.eu/matchmaking/

### MATCHMAKING FORM

Form

To be listed on the matchmaking platform, please fill in this form.

**If you have any question and you need to contact us, please, visit our OMC Questions&Aswers section!**

### COMPANY INFORMATION

Contact person (Full name)

Job Title

Email address

Company name

Headquarters Country

**Company size**

- Micro (less 10 employees and less equal €2 m turnover)
- Small (less 50 employees and less equal € 10 m turnover)
- Medium (less 250 employees and less equal €50 m turnover)

**Company type**

- Freelance
- Private company
- Public company
- Research center
- University
- Technological center
- Start-up
- Other

**Market Presence**

- National
- European
- International

Expertise, products and services

Expectations partners (areas of cooperation sought)

**Category**

- Social-community and individual services related to tele-rehabilitation
- Medical devices & apps
- Open Platform
- Follow-up and motivation of patients
- Coordinate and/or promote a consortium
- Other

Overall description (250 characters)

Website

**Willing to share further information under a Non-Disclosure Agreement**

- Yes
- No

I accept the privacy policy and legal terms

15 + 2 =

Send

## Annex 8: Bilateral meetings

| | Date | 21/09/2021 | Time | 10:00 CEST |
|---|---|---|---|---|
| OMC Technical Committee | María Bezunartea and Alba De Martino (IACS), Sofía Moreno (Valde Innova), Rosana Anglés (Salud), John Maher (NRH), Alberto Valejo (IPN), Claus Nielsen (PPCN) | | | |
| Advisory Member | Alli McClean (NRH)<br>Patricia Crouceiro (CHUC) | | | |
| Company | **Oracle**<br>Miguel Coelho - Business Development Director (EMEA &LatAm)<br>Dmitry Etin - Solutions Architect | | | |
| Topics covered | Delve into the information submitted in OMC Questionnaire<br>Q&A to solve doubts to the company | | | |

| | Date | 21/09/2021 | Time | 12:00 CEST |
|---|---|---|---|---|
| OMC Technical Committee | María Bezunartea and Alba De Martino (IACS), Sofía Moreno (Valde Innova), Rosana Anglés (Salud), John Maher (NRH), Alberto Valejo (IPN), Claus Nielsen (PPCN) | | | |
| Advisory Member | Allie McClean (NRH)<br>Patricia Crouceiro (CHUC) | | | |

| | |
|---|---|
| Company | **Balidea**<br>Mª del Carmen López Pérez - Business development<br>Alessandro Bigliani - International Procurement Area |
| Topics covered | Delve into the information submitted in OMC Questionnaire<br>Q&A to solve doubts to the company |

| | | | | |
|---|---|---|---|---|
| | Date | 30/09/2021 | Time | 11:00 CEST |
| OMC Technical Committee | María Bezunartea (IACS), Rosana Anglés (Salud), Claus Nielsen (PPCN) | | | |
| Advisory Member | Alli McClean (NRH)<br>Patricia Crouceiro (CHUC) | | | |
| Company | **GMV**<br>Javier Téllez Chacón - Innovation Manager<br>Adrián Rodrigo Salas - Smart Health Solutions and Data Evidence Specialist | | | |
| Topics covered | Delve into the information submitted in OMC Questionnaire<br>Q&A to solve doubts to the company | | | |

| | Date | 01/10/2021 | Time | 13:00 CEST |
|---|---|---|---|---|
| OMC Technical Committee | María Bezunartea and Alba De Martino (IACS), Sofía Moreno (Valde Innova), Claus Nielsen (PPCN) | | | |
| Advisory Member | Alli McClean (NRH)<br>Patricia Crouceiro (CHUC) | | | |
| Company | **NearForm**<br>Larry Breen - Head of Health & Life Sciences<br>Ben Williams - Sales and Marketing Research Associate | | | |
| Topics covered | Delve into the information submitted in OMC Questionnaire<br>Q&A to solve doubts to the company | | | |

| | Date | 04/10/2021 | Time | 13:00 CEST |
|---|---|---|---|---|
| OMC Technical Committee | María Bezunartea and Alba De Martino (IACS), Sofía Moreno (Valde Innova), Claus Nielsen (PPCN) | | | |
| Advisory Member | Alli McClean (NRH)<br>Patricia Crouceiro (CHUC) | | | |
| Company | **NUICROSS Scandinavian Consortium**<br>Petter Hedberg, Project Manager NUITEQ®<br>Manuel Gonzalez Garcia, Chief Commercial Officer, Alnorte VM Konsult AB | | | |

| | |
|---|---|
| | Gert-Olof Bostrom, Owner and CEO. Probits AB<br><br>Camilla Ollin, Key Account Manager. Cross Technology Solutions AB<br><br>Dag Westberg, Director Sales & Strategic Alliances. Cross Technology Solutions AB |
| Topics covered | Delve into the information submitted in OMC Questionnaire<br><br>Q&A to solve doubts to the companies |

| | Date | 08/10/2021 | Time | 09:00 CEST |
|---|---|---|---|---|
| OMC Technical Committee | María Bezunartea and Alba De Martino (IACS), Sofía Moreno (Valde Innova), Claus Nielsen (PPCN) | | | |
| Advisory Member | Alli McClean (NRH)<br><br>Patricia Crouceiro (CHUC) | | | |
| Company | **Grupo CMC**<br><br>José María Botana - Insurance & Health Manager<br><br>Juan Manuel Vidal Zulueta - Insurance & eHealth Director | | | |
| Topics covered | Delve into the information submitted in OMC Questionnaire<br><br>Q&A to solve doubts to the company | | | |

| | Date | 08/10/2021 | Time | 10:00 CEST |
|---|---|---|---|---|
| OMC Technical Committee | María Bezunartea and Alba De Martino (IACS), Sofía Moreno (Valde Innova), Rosana Anglés (Salud), Alberto Valejo (IPN), Claus Nielsen (PPCN) | | | |
| Advisory Member | Alli McClean (NRH)<br><br>Patricia Crouceiro (CHUC) | | | |
| Company | **Health Cluster Portugal**<br>Patrícia Patrício (HCP)<br><br>Ana Luís, Wiselife (Health literacy and contents)<br><br>Ricardo Moura, Wisify (medical sensors)<br><br>Júlio Martins, Everythink (product/service design and development)<br><br>Isabel Araújo, Neuroinova (cognitive health monitoring products)<br><br>João Almeida, Neutroplast (medicines packaging and compliance)<br><br>Nelson Cardoso, Fraunhofer (R&D in communications solutions)<br><br>Sónia Silva, Centi (R&D in med tech)<br><br>Liliana Amorim, P5 (digital healthcare provider) | | | |
| Topics covered | Delve into the information submitted in OMC Questionnaire<br><br>Q&A to solve doubts to the companies | | | |

# R O S I A

REMOTE REHABILITATION SERVICE FOR ISOLATED AREAS