

REMOTE REHABILITATION SERVICE FOR ISOLATED AREAS

# **ROSIA DESCRIBED: CURRENT SITUATION & CHALLENGE**





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PROJECT ACRONYM:	ROSIA
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PROJECT DURATION:	54 months



# **ABBREVIATIONS AND ACRONYMS**

IDTs	The interdisciplinary team
MDTs	Multidisciplinary team
NRH	National Rehabilitation Hospital
CARF	Commission for Accreditation of Rehabilitation Facilities
POLAR	Prosthetic, Orthotic & Limb Absence Rehabilitation
PAEDS'	Paediatric Family-Centred Rehabilitation
ABI	Acquired Brain Injury
SCI	Spinal Chordal Injury
VEC	Video-enabled care
IDTs	The interdisciplinary team

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### 1. ROSIA

### 1.1. What is it?

Healthcare systems in Europe are facing a number of combined challenges, among them, and perhaps principally, the significant rise in chronic conditions which inevitably accompanies longevity. These conditions place a growing burden on healthcare systems, on their rehabilitation services and on their community care programmes. The situation is considerably worse in **rural and isolated areas**, where ageing indexes are higher, yet they merely reflect what will be the case in major European population hubs in no more than twenty years. Such circumstances create a pressing need for a fundamental rethink of the way health services and systems are organized.

ROSIA is paving the way towards a **self-care model** to treat chronic conditions and disabilities among the European population. 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 control of their own treatments, building on their own personal capabilities.

Redesigning rehabilitation services to conform to patients' expectations and needs is the most efficient way to warrant their ability to benefit from them - regardless of where they live. All public health and care systems should aim for patient-centred services to effectively support required changes and improve not only health outcomes, but also patients' experiences.

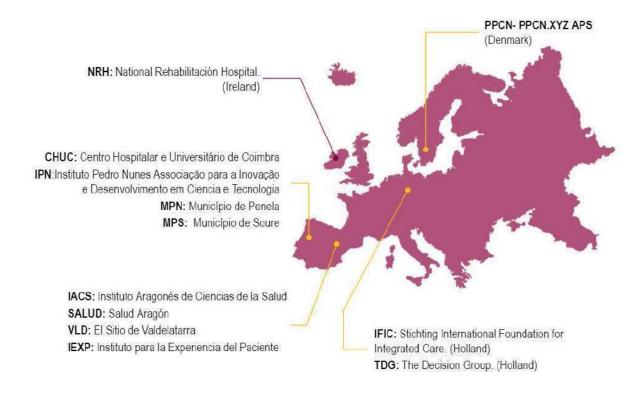
The introduction of self-management programmes requires that patients be provided with appropriate tools and guidance in line with their evolving health and wellbeing, especially following acute health episodes. Such programmes should continue until a full recovery is obtained or rehabilitation programmes are required, thereby increasing overall patient experience and dignity.

### 1.2. Objectives

- 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 which guarantees the long-term sustainability of the ROSIA care model both for the public buyer and for the provider.

### 1.3. Countries involved

The ROSIA's PCP project has partners in Spain, Portugal, North Ireland, The Netherlands and Denmark, that constitute a well-balanced consortium of partner organizations gathering a multidisciplinary team.



### 1.4. Budget

- Total costs of the Project are estimated to be EUR 5 520 871.75 (five million five hundred and twenty thousand eight hundred and seventy-one EURO and seventy-five euro cents).
- The budget assigned to the pre-commercial procurement is EUR 3 900 00.00 (three million nine hundred EURO), distributed equally between the three participant procurers. This budget includes VAT, if appliable.

### 1.5. How will we make it?

The complexity of ROSIA's model goes far beyond the design of the supporting ICT. ROSIA's model merges ICT technologies with research findings related to telerehabilitation and the development of personalized care pathways, to deliver an integrated and flexible telerehabilitation suite of digital health and care services, which as yet is not available for commercial deployment.

Close collaboration between public health and care systems, experts, and industry is essential to tackle this challenge and in order to create commercial solutions sustainable in the long-term.

The methodological approach to create ROSIA's model includes three phases of co-creation:

-24	PHASE 1	PHASE 2	PHASE 3
ROSIA PCP	Solution Design	Prototype Development	Field test
Objective	Develop the <b>feasibility</b> <b>study</b> of selected solutions from awarded bidders	<b>Prototype development</b> of most promising solutions from Phase 1	Validation of best prototyped solutions in real life scenario at each procurer site
Duration	3 months	8 months	18 months
R&D subcontract budget (€)	€ 100.000	€ 900.000	€ 2.900.000
% subcontracting budget	2,56%	23,08%	74,36%
Number suppliers	5	3	2
Budget per supplier	€ 20.000	€ 300.000	€ 1.450.000
	Feasibility study of solution.  Description of co-creation  needs for next stages	Prototype specification and lab demonstration including one or two pathologies, implemented using proposed basic SDK for developers	Field testing integrating third parties solutions
Expected output from each supplier:	Detailed development Plan	Plan for original development of a limited volume of first solutions and field- testing. Detailed description of the ambition of the Developers support development. Change management plan	Field test specification
	Preliminary Business plan	Updated cost/benefits evaluation including a refined business plan	Solution final specification and related technical documents. Change management requirement for commercial deployment
			Updated cost/benefit evaluation Business model for commercial deployment
Evaluation approach	Consistency and feasibility of solution, development plan and envisioned business model. Degree of innovation. Credibility of the Innovation Ecosystem plan for development.	Robustness, flexibility, scalability and consistency of prototyped solution. Change management for field-testing. Sustainability of business plan (value-based business model). Degree of innovation. Ambition and usability of the Innovation ecosystem.	Performance of tested solution. Outcomes of different stakeholders. Sustainability of business plan (value-based business model). Plans for further development of the innovation ecosystem.

Note: VAT included, if applicable

This is only a distribution proposal. It could be changed in the preparation stage of the PCP. It will be finally defined in the tender documents.

### 2. PCP

### 2.1. Why a PCP?

Pre-commercial procurement consists in procuring research and development services at advantageous conditions from several economic operators. Pre-Commercial Procurement (PCP) can be used when there are no near-to-the-market solutions yet and new R&D is needed.<sup>1</sup>

The objective is to conduct a competitive multiple-sourcing procedure for procuring research and development services to face a technologically demanding mid to long-term challenge, the tackling of which is in the public interest. PCP enables the public demand side to challenge the market to develop and validate innovative solutions addressing the common unmet needs of the buyers. 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.

Pre-commercial procurement puts in practice the exemption from the public procurement directive for research and development services in one specific case: where the public buyer does not reserve all the benefits from the research and development service contract exclusively to itself, but shares them with the economic operators under market conditions.

With pre-commercial procurement, it is also possible to shorten time-to-market. In the specific circumstances of the procurement procedure, economic operators have the possibility to develop and test innovative solutions over a certain period. This experience has a twofold benefit, for buyers and for suppliers: buyers have a closer contact with the market players and suppliers get earlier customer feedback on their innovative potential in real circumstances.

This is of particular interest for innovative start-ups, scale-ups or SMEs willing to receive first potential customer references. Access to this procedure is also simplified. As it does not cover the procurement of commercial volumes of innovative solutions, tenderers only need to fulfil professional qualification and financial capacity requirements for the research and development, not for deployment of commercial volumes of solutions.

# Phase 0 Phase 1 Phase 2 Phase 3 Phase 4 Curlosity Driven Research Solution design Prototype development Supplier B Supplier C Supplier D Public Procurement of Innovative Solutions (PPI) Phase 3 Phase 4 Phase 4 Deployment and testing of limited volume of 1st leat products/sonvices Supplier C Supplier C Supplier D Supplier D Supplier D Supplier D Supplier D

### 2.2. <u>How? Rosia PCP Process</u>

Pre-commercial procurement is a narrow down process divided into three competitive phases (solution design, prototyping, initial development and validation/testing of a limited number of initial services), with the number of competing R&D providers reduced after each R&D phase.



On behalf of ROSIA's Consortium, IACS will conduct ROSIA's PCP procurement process and publish the 'contract notice' in the Official Journal of the European Union by the end of March 22. Jointly with the contract notice all relevant information about ROSIA's PCP tender will be made available to potential tenderers, including, among others: time-limit for submission of tenders, the outcome and list of Q&As of the market consultation, the common challenge (using functional or performance based specifications including the outcome of the open market consultation); the evaluation and awarding process of the R&D providers to enter the PCP narrow down competition process; the minimum requirements R&D contractors must comply with during the PCP; arrangements for intellectual property rights, confidentiality, publicity (information about contract award and publication of summaries of R&D results) and rules on applicable law and dispute settlement.

The request for tender will be open for submission for at least two months.

To participate in the tender the majority of the research and development services should be done by the providers, including the work of the main researchers, in the EU Member States or associated countries ('place of performance obligation').

Then, ROSIA's PCP buyers will carry out the evaluation of the submitted tenders. This process will include the individual evaluation of the offers and their classification based on the specifications of the tender documents in accordance with the best value for money criteria and ensuring that the price corresponds to market conditions.

The next step will be awarding a minimum of three contracts to the tenders offering best value for money and a price corresponding to market conditions. The framework agreements (one agreement per selected tenderer) will be signed by IACS, as lead procurer, and set out the terms and conditions to govern the specific contracts.

After that, the specific contracts (one agreement per selected tenderer and PCP phase) will be signed by IACS, as lead procurer, and set out the details of the PCP R&D services purchased (in particular, their quantity per buyer and price).

During the 'contract implementation' of each Phase of the PCP, the buyer's group will monitor R&D services to ensure they are implemented in compliance with the objectives, the planning of resources and the budget of the awarded contract.

### 2.3. Evaluation framework: ROSIA's Value-Based Model

The evaluation framework, the set of indicators to be used to evaluate the project performance and to award the bidders in each Phase of the PCP, will be based on ROSIA's Value-Based model (RVB Model).

In the RVB Model, the value depends on results, not inputs, and it is measured by the outcomes achieved, not the volume of services delivered. Nor is the value measured by the process of care used; process measurement and improvement are tactics but not substitutes for measuring outcomes and costs.

The solutions formulated according to the RVB Telerehabilitation Model will result in a sustainable model thanks to three components: their capacity to generate and create value according to the above definition, their organizational strengths and capabilities, their financial plan and their potential to scale up.

That's why the RVB Model is built on four main pillars:

- a) Patient Value Creation
- b) Organizational sustainability
- c) Financial sustainability
- d) Scalability



The current implementation of the PCP will allow the assessment of the RVB model for scaleup, which is expected to be based on a value-based procurement. The evaluation criteria for the PCP tender will be defined after the OMC ends.

The four RVB Model pillars that enable assessment and scoring of tendered solutions by evaluating their:

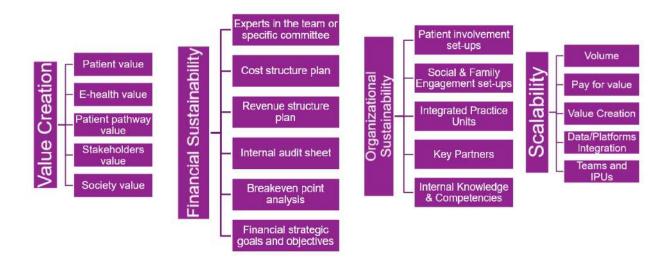
- Core value proposition.
- The relevant medical outcomes the solution influences.
- The relevant process KPIs the solution is impacting on.
- The way the tele-rehab and e-health solution creates value across the care pathway process.
- The way the solution is changing and addressing the specific care delivery pathway.
- The way the solution contains or lowers the costs per patient, payers and providers.
- The impact the solution has on other relevant stakeholders and the society.
- The way the solution is organizational and financially sustainable.
- The way the solution has the potential to scale up.

The Four RVB Model Pillars and requirements list (score card):

1. Value Creation	2. Organizational Capabilities	3. Financial Sustainability	4. Scalability
1.1 Value Proposition*	2.1 Patients Involvement	3.1 Checklist of financial sustainability plan.	4.1 Volume
1.2 Medical Condition Match*	2.2. Social & Family Engagement		4.2 Pay for Value
1.3 Patient Relevant Outcomes*	2.3 IPU		4.3 Value Creation
1.4 Delivery process KPIs*	2.4 Key Partners		4.4 Data/Platform Integration
1.5 E-health Value Creation	2.5 Internal Knowledge & Competencies		4.5 Teams & IPUs
1.6 Care Delivery Pathway			
1.7 Healthcare Costs*			
1.8 Impact on Stakeholders			
1.9 Broader Impact on Society			

<sup>\*</sup> requirements under "patient value". See following table





The model is customized to the seven ROSIA medical conditions and it is applied to e-health/tele-rehabilitation solutions.

### 2.4. Exit plan

ROSIA is purchasing the design of an "all in one" service which will be validated in real life with actual patients in several sites in the participant regions. Services will stop completely when the project ends. However, some patients will be still under tele-rehabilitation treatment at this time.

Those patients using ROSIA's services by the end of the project shouldn't suffer an interruption of the telerehabilitation process, especially if they are in a recovery phase.

An exit plan including a minimum service for those patients previously mentioned will be requested for participant bidders.

### 3. OMC: Basic info

In preparation of the PCP call for tenders, an Open Market Consultation (OMC) with potential tenderers will be held to attract and inform about ROSIA's PCP and to gather the views of the market about ROSIA's PCP Challenge. All the information related to the OMC will be published on <a href="tender-right">the website</a>.

### **3.1.** What is it?

The Open Market Consultation 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 body, as well as the requirements to attend the procedure.

In summary, the goals of the Open Market Consultation 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.

The most visible communication activities during this phase are ROSIA's pre- Open Market Consultation informative events. One event per procurers' country and one international workshop webinar has been organized before the OMC. All presentations and videos are available in our website.

During the pre- Open Market Consultation informative events, ROSIA's challenge has been presented, as well as the pre-commercial procurement process. There has also been an opportunity for discussions between the procurers and potential suppliers as well as dedicated time slots for different stakeholders to present their solutions.

### 3.2. Why are we here?

The purpose of the OMC is to canvas wide stakeholder opinion on the suitability of ROSIA's PCP. With the market consultation, the consortium will inform the market about the opportunities ROSIA presents, explain in detail the PCP process and open a dialogue with potential suppliers about the scope of ROSIA's aims. The objective is to prepare an accurate procurement with a feasible scope by finding out whether technologies are commercially available, learn more about the advantages and disadvantages of coverage of the desired functionalities, and assess whether we should include other aspects not initially considered.

- To encourage potential suppliers to participate in ROSIA's OMC and future PCP!
- To inform them about ROSIA's PCP, its opportunities and processes.



- To open a dialogue about scope, budget, functionalities, requirements, business model, IPR ...of the future PCP.
- To facilitate matchmaking among suppliers: WE NEED CONSORTIA THAT ARE ABLE TO FULLY ADDRESS ROSIA'S CHALLENGES!

### 3.3. Integral solutions

In the OMC we seek maximum participation and interaction with all types of organisations to understand the potential market for ROSIA, its conditions and its opportunities.

Therefore, any organisation can complete the OMC questionnaire, present us with any type of solution and help us build the future tender.

However, because we seek comprehensive solutions, we expect to see partnerships between interested organisations.

That is why we have the utmost interest in that the participating entities get to know each other and that synergies arise between them. For this purpose, we have created a platform for matchmaking on ROSIA's website and also in the pre-OMC informative events, where there will always be a place for organisations interested in presenting their projects and potential solutions.

### 3.4. <u>Pre-OMC informative events</u>

Each of ROSIA's procurers has organized a pre-OMC informative event held in the local language. Due to the coronavirus pandemic, all OMC events were held online. The dates of the events were:

- June 16th Spain
  - o 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)
- June 25th International
  - o 10.00 12.30 (10.00 12.30 CEST)
  - Mrs. Sandra García Armesto (Executive Director Institute of Health Sciences in Aragón)
- June 28th Ireland
  - o 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)
- June 30th Portugal
  - o 14.30 17.00 (15.30 18.00 CEST)
  - Alexandre Lourenco (Hospital Administrator Centro Hospitalar e Universitário de Coimbra)

All the information related to these events is published on the website.

### 4. Current situation in tele-rehabilitation in ROSIA's context

### 4.1. Description of the regions' healthcare systems

### **4.1.1.** Situation in Ireland

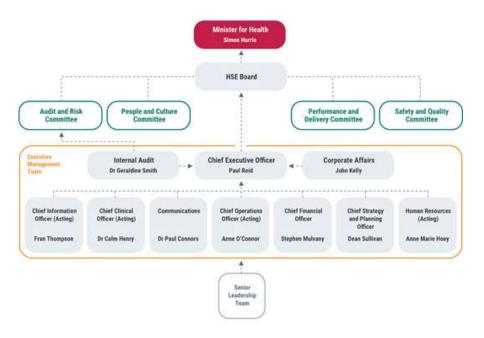
1. How health and social services are provided - including community health services & health care provision model and relationships between levels of care.

Overall responsibility for the health and social care system in Ireland lies with the Government and exercised through the Department of Health and under the direction of the Minister of Health. The original design for the modern Irish healthcare system was set out in the Health Act 1970, which established eight regional Health Boards (RHBs). In 2005 the Health Services Executive (HSE) was established and allocated funding and a service plan to set out the quantum and nature of services to be provided nationally.

In 2017, the Sláintecare Report (All-Party Oireachtas/Political Party - Committee) set out a new vision for the future of healthcare in Ireland over a ten-year period. Its objectives were to deliver a whole-system reform designed to deliver a universal single-tier health and social care system. This new strategy reviewed the funding for health and social care in Ireland, health promotion and disease prevention, eligibility and the expansion of primary and community services. The Sláintecare Action Plan (2019) named key areas of focus under four workstreams:

- 1. Service Redesign and Supporting Infrastructure
- 2. Safe Care, Co-ordinated Governance and Value for Money
- 3. Teams of the Future
- 4. Sharing Progress

Each workstream consists of five main programmes made up of 137 projects in total.



Health Service Ireland - Current Organizational Structure

### *Integrated Care Programmes:*

With the commitment from the Government to create a new integrated model of care which is safe, timely and efficient – as close to home as possible; an integrated care programme outlined the management and delivery of health services. Ensuring patients receive a continuum for preventative, diagnostic, care and support services according to their needs and across the health system services. This model incorporated multi-disciplinary care and support and delivery of appropriate high quality, evidence-based care and in a coordinated manner - which feels seamless to the user.

### 2 Resources and capabilities for rehabilitation services - nationally.

The National Clinical Programme for Rehabilitation Medicine (NCPRM) describes a framework whereby the ability and societal participation of those affected by complex, life-altering conditions can be maximized by early, timely and life-long intermittent access to specialist rehabilitation. The desired outcomes are improved quality of life, sustainable community independence and improved employability for those treated; and, in the early post-injury stage, reduced length of hospital stay and prevention of unnecessary readmissions to acute care.

The NCPRM model of care promotes a seamless transition between different care settings and effective identification and management of the patient / service user's rehabilitative needs. It is in this context that case management is a key strategy in managing lifelong complex effects of severe neurological injuries and illnesses and where the development of more structured community based rehabilitation teams is required and in order to support patients during gradual step-down from tertiary centres and regional units - and so can be supported in reintegrating within their local communities.

### Interdisciplinary teams (IDTs)

The interdisciplinary team (IDT) model of care is widely recognised as the gold standard for rehabilitation provision using a holistic, collaborative and patient focused approach. The key factors distinguishing MDTs (multidisciplinary team) is that team members work together closely in goal setting, treatment, decision making and ongoing problem solving to ensure continuity of care and a more holistic approach. From the time of admission, and in some cases from the time of referral, to the point of discharge the patient, family and the team are working on mutually agreed goals to achieve the optimum outcome. The IDT should have more impact than the sum of its members working individually, requires commitment, collaborative teamwork, communication, negotiation skills, demonstration of respect for all team members and a readiness to blur professional specialisation boundaries.

### Out-patient specialist / Community based rehabilitation

Out-patient services allow continuation of structured rehabilitation programmes following inpatient treatment in acute or subacute health facilities. Out-patient specialist rehabilitation programmes result in earlier transfer of care or discharge from in-patient settings. A number of community-based rehabilitation teams are in operation around the country, however the current geographic spread means that access to these services is patchy and in a number of cases non-statutory organisations offer many innovative services that ensure effective and durable rehabilitation outcomes including work retention and retraining, social inclusion, carer support and long-term management care pathways.



### 3. Current rehabilitation and telerehabilitation processes - NRH

In partnership with patients and families NRH provides an equitable and transparent service responsive to those availing of its services while supporting staff entrusted with programme delivery. A 'person-centred coordinated care' model drives innovation and best practice standards where the NRH's programmes have been accredited by CARF (the Commission for Accreditation of Rehabilitation Facilities). These programmes provide both inpatient & outpatient pathways, MDT consultations, home and community-based services and vocational and learning opportunities. In specific terms, the Acquired Brain and Spinal Injury programmes are specialised programmes with 'goal and outcome' focused agendas with patient care and treatments delivered through Interdisciplinary Teams (IDTs).

- <u>Spinal Cord System of Care Programme</u> provides a continuum of care through both an *inpatient* rehabilitation phase and an *outpatient* programme of care and support. The engagement of interdisciplinary teams and therapy treatments promote greater levels of functional independence, social participation and community reintegration.
- <u>Brain Injury Programme</u> provides a full integrated and comprehensive *inpatient* rehabilitation programme with an *outpatient* rehabilitation service, *community based* and *vocational* programme pathways.
- <u>Prosthetic, Orthotic & Limb Absence Rehabilitation (POLAR) Programme</u> provides prosthetic rehabilitation for people with both amputation and congenital limb absence. The POLAR team engages with community colleagues and delivers education and information related to the POLAR Programme, and collaborates in a more effective way to improve patient rehabilitation outcomes.
- <u>Paediatric Family-Centred Rehabilitation Programme</u> is for children and young people requiring complex specialist interdisciplinary rehabilitation. The PAEDS' vision of a "rehabilitation without walls" is a child and family-centred approach and provides for more fluid movement between the services based on assessment of individual clinical need and social circumstances. The programme accepts referrals following ABI /SCI diagnoses and across Ireland.

### Telerehabilitation Services

NRH's <u>Video Enabled Care-Telehealth</u> allows for a variety of activities to be pursued and across patient care management pathways including:

- 1.Consultants for primarily Telehealth consultations
- 2. Therapists treating programmes to a video-enabled format including:
  - Meet and Teach Group for people with Aphasia
  - The Graded Repetitive Arm Supplementary Programme (GRASP)
  - Pilates Groups
  - Patient Wellness Programme
  - Individual assessment and treatment
- 3.An 'Open Mic', Speech & Language and Occupational Therapy group.
- 4. Development of an Outpatient only Cauda Equina Service.



- 5. The Outpatient Department implemented a video-enabled care (VEC) strategy across its Outpatient programmes (Microsoft Teams initially); now through the national rollout of the 'Attend Anywhere' platform<sup>1</sup>.
- 4. Specific requirements and needs i.e. ERH / health care information / software interoperability, social services; related to ROSIA / community care.

An eHealth Strategy for Ireland demonstrates how the individual citizen, the Irish healthcare delivery systems - both public and private - and the economy as a whole will benefit from eHealth. It shows how the proper introduction and utilisation of eHealth will ensure:

- The patient is placed at the centre of the healthcare delivery system and becomes an empowered participant in the provision and pursuit of their health and wellbeing.
- The successful delivery of health systems reform and the associated structural, financial and service changes planned.
- The realisation of health service efficiencies including optimum resource utilisation<sup>2</sup>.

### Telehealth:

Innovation and initiatives have been developed both from within the public health system at national level and also at local and regional level. To ensure an even and consistent approach to introducing Telehealth into business as usual, Telehealth Leads have been nominated within CHO's and Acute Hospitals.

The role of these Leads is:

- To support the roll out of Telehealth in the local CHO/Service Hospital/Speciality
- Liaise with ACMT, OoCIO and local supports
- Be a super user coordinate and provide top-up training
- Support local policy and protocol development
- Identify and address hardware and environmental factors
- Disseminate information to staff on Telehealth
- Supporting services to apply for Telehealth licences

<sup>&</sup>lt;sup>1</sup> National Rehabilitation University Hospital - 40th Annual Report 2020 (2021) NRH

<sup>&</sup>lt;sup>2</sup> eHealth Strategy for Ireland (2013) Department of Health; Irish Government

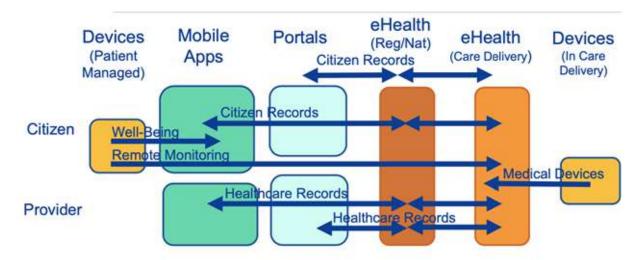


eHealth (Electronic Health) involves the integration of all information and knowledge sources involved in the delivery of healthcare via information technology-based systems. This includes patients and their records, caregivers and their systems, monitoring devices and sensors, management and administrative functions. It is a fully integrated digital 'supply chain' and involves high levels of automation and information sharing.

For each healthcare area/specialty the following elements will need to be considered as part of implementation:

- Approval for Telehealth has been agreed with the clinical service
- You have a process in place to identify suitable patients
- You have considered how to record patient consent where required
- You have considered how to communicate the process to your patient in a way that they will understand
- You have identified staff to schedule the patients for Telehealth appointments
- You can ensure that all patient activity is captured and appropriately recorded
- The process is aligned to local clinical governance policies
- Data governance elements associated with Telehealth have been agreed
- Provision has been made for staff to be appropriately trained in the use of Telehealth<sup>5</sup>
- You have considered the location(s) where virtual clinics will take place, taking into consideration:
  - O A private, well-lit area / and not be disturbed during the consultation
  - Ensure background of the video call is appropriate

New pathways and innovation<sup>6</sup>



### **4.1.2.** Situation in Aragón (Spain)

Aragón is a region located in the north-east of Spain with 1.3M inhabitants. The population density is low, especially in the provinces of Huesca and Teruel. Around 50% of the population live in the capital city, Zaragoza and 71.55% of municipalities have a population density below 10 inh/km². Aragón's population is on average older than the Spanish one and this difference becomes more pronounced in Huesca and Teruel³.

	Europe <sup>4</sup>	Spain <sup>5</sup>	Aragón			
	Average	Average	Average		Provinces	
				Huesca	Zaragoza	Teruel
Density (inh/km²)	109 inh/km²	93,8 inh/km²	27,9 inh/km²	14,2 inh/km²	56,3 inh/km²	9,1 inh/km²
Average Age (y.o)	44,7	43,5	44,9	45,5	44,6	46,5
% +65	20,6%	19,4%	21,7%	22,4%	21,2%	24%

Servicio Aragonés de la Salud (SALUD) is the public entity providing health care to the Aragón region in Spain. SALUD's mission is to provide integral healthcare attention, to ensure service accessibility, to promote healthy lifestyles, prevention and protection and to maintain patients' autonomy and their social inclusion.

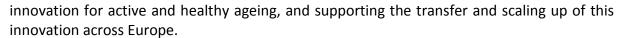
SALUD has been awarded four stars as a reference site from the EIP on AHA (European Innovation Partnership on Active and Health Ageing), recognising its commitment to invest in

<sup>&</sup>lt;sup>3</sup> https://www.aragon.es/-/indicadores-demograficos

<sup>&</sup>lt;sup>4</sup> https://ec.europa.eu/eurostat/databrowser

<sup>&</sup>lt;sup>5</sup> www.ine.es





ROSIA pilots will be held in the Barbastro (Huesca province) and Teruel healthcare areas, where it is expected to have a higher impact due to their extension, dispersed population, weak terrestrial and digital communications and higher average age.

How health and social services are provided (including community health services if available) in each country. Health care provision model and relationships between levels of care.

SALUD is the public organisation in charge of healthcare provision at all care levels including primary care, specialised/hospital care, social services and mental care in the region of Aragón.

Social Care provision is performed by a wide variety of public and private providers working at different levels (regional, local, district). The basket of available services and the assortment of suppliers depends very much on the specific location of a citizen. Integrated care initiatives such as the SMARTCARE programme (which tries to eliminate the silos of social and healthcare provision) are deployed in some areas of the region.

Health department published in 2018 a strategy for Community Care from Primary Care<sup>6</sup> which includes actions regarding the problems and needs related to health of the population of each area and how to address the inequity in their access to the services. The final goal is to promote participation and the capability of people and groups to deal with their health problems and health lifestyles. It includes three lines of action for primary care teams: development of community projects, creation of the community agenda and the community approach based on recommendation and dynamization of health-related assets.

### Description of procurer's resources and capabilities

SALUD has a network composed of 17 hospitals, 118 Primary Health Centres and 873 healthcare cabinets. Almost 30,000 people are currently working at the Health department of Aragón, around 29,000 of them in SALUD.

Rehabilitation services are provided at three main levels:

### Specialized care.

- General hospitals have specific rehabilitation units driven by rehabilitation doctors and physiotherapists. They provide rehabilitation services to both inpatients during their admission (e.g., after surgery) and also to outpatients during their recovery period. Physical Medicine and Rehabilitation departments at each centre offer a specific basket of services depending on their human and material resources. Besides general rehabilitation, there are some centres that cover specific rehabilitation areas (e.g., cardiovascular disease) and some also that count with monographic areas built upon the coordination of different services (e.g., hip fracture).
- Medium and long term centres. Those patients in the need of longer recovery periods are referred to this type of centres, which are also focused on geriatric care.

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<sup>&</sup>lt;sup>6</sup> https://atencioncomunitaria.aragon.es/

<u>Primary care.</u> Basic rehabilitation is one of the services included in the primary care basket of services. The kind of activities that belong to this group are prevention of development of musculoskeletal disease and functional improvement in chronic musculoskeletal problems.

### Description of the current rehabilitation and telerehabilitation process in procurer's context

The rehabilitation process depends very much on the type of pathology and also on the patient's profile. Each patient is evaluated under their specific circumstances in order to design an adequate rehabilitation plan adapted to their needs. Even though all the services are available for all the patients in the region, not all the services are offered in all the centres. As a consequence, some patients must be referred to facilities located in premises far from their homes.

Some of the processes related to the diseases that have been selected for ROSIA are summarized below:

- <u>Cardiovascular disease.</u> Rehabilitation is conceived as an internal process including physical but also psychological and life-style related factors. Specific cardiovascular disease units are located in the capital city of Zaragoza. They perform the rehabilitation and the follow up of patients belonging to the three provinces (Huesca, Zaragoza and Teruel). Rehabilitation for cardiovascular disease is normally divided into four phases:
  - Phase 0 / Preliminary Phase where the patient is prepared for surgery (specially oriented for patients whose intervention is scheduled, e.g. heart transplant)
  - Phase I / Acute phase. Patient who is admitted at the hospital after intervention.
  - Phase II / Recovery. Patient in an 8/16-week programme tailored to the patient's risk level, including supervised physical activity and monitoring at a specific rehabilitation unit.
  - O Phase III / Maintenance. Patient is discharged and they are expected to adapt their lifestyle to their new condition. During this phase, patients should introduce changes in their lifestyle related to, among others, diet and physical activity. Associations such as Re-late<sup>7</sup> (Aragón Cardiac Rehabilitation Patients Association) play an important role in giving assistance to patients in this phase, where self-motivation and family support are essential.

Acute post COVID-19 syndrome<sup>8</sup>. A considerable amount of people who have suffered from COVID-19 still have symptoms weeks and even months after the first COVID 19 episode, regardless of its severity. Even though the definition of "persistent COVID" or "long COVID" has not yet been precisely agreed on, it seems clear that a large number of people are affected by it and this is causing a great health, social and personal impact. Some of these people are suffering from functional inabilities that are affecting their daily routines. The UK National Institute of Statistics has estimated that 1 in 5 people with COVID have symptoms 5 weeks and 1 in 10, 12 weeks after the episode. These problems include, but are not restricted to dyspnoea, fatigue or musculoskeletal pain. The high number and variety of symptoms referred by these citizens adds complexity to the diagnosis and to the requirement of multidisciplinary care needed to deal with each specific case. Some of these patients are referred to the medical

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<sup>&</sup>lt;sup>7</sup> www.re-late.org

 $<sup>^{8}\</sup> https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/Documento\_CLINICA.pdf$ 



rehabilitation services so as to be evaluated and participate in activities such as physiotherapy at the rehabilitation unit, self - outpatient treatment following some instructions, physical conditioning at home. Some of these patients are also referred to respiratory physiotherapy. On-line resources have also been put at disposal of patients for their recovery period<sup>9</sup>.

**Arthroplasty.** The generic procedure for rehabilitation after an arthroplasty intervention is divided into three phases (admission, post-discharge/recovery and maintenance). The recovery plan depends very much on the patient's profile (e.g., if it is the first replacement, age, weight, preliminary physical condition...)

**Hip-Fracture** comprises a wide assortment of patient profiles, which include quite often social needs, cognitive impairment and comorbidities. Some hospitals have "fast track" and multidisciplinary procedures oriented to improve as much as possible the degree of autonomy of the patient before discharge<sup>10</sup>. The rehabilitation phases (admission, post-discharge/recovery and maintenance) are tailored to the specific patient needs. Some patients are referred first to a long/medium stay center where they continue recovery before they can come back to their residence.

Specific requirements and needs (i.e. ERH, health care information / software interoperability, social services...) related to the project.

SALUD infrastructure allows all healthcare professionals in the region sharing patient health-related info at all assistance levels (primary and hospital care). The regional EHR is following a process of deep transformation to achieve a full patient –centred approach. This new EHR is called GUHARA (Global and Unique Electronic Health Record in Aragón) and it has a modular architecture.

GUHARA is composed by some primary components (as forms manager, e-prescription) that interact with both external components (as BDU for user information or CoreSALUD for offer of services) and with departmental applications (as PACS).

Besides GUHARA, the set of technological components that are compatible with it include, among others one telemonitoring platform, one Integrated Care platform, the e-prescription application and communication tools.

## 4.2. <u>Shortcomings for ROSIA's 7 subject conditions</u>

The review on rehabilitation shortcomings for the 7 conditions subject to ROSIA's research listed the main limitations on current rehabilitation processes as described in literature. During the workshops with rehabilitation experts for 5 of the 7 ROSIA conditions, additional shortcomings emerged; mainly attached to local conditions and in no way contradictory with literature findings. The following tables list the main findings of literature and of the local workshops.

<sup>&</sup>lt;sup>9</sup> http://sectorbarbastro.salud.aragon.es/es/servicios/cys/rehabilitacion

<sup>10</sup> https://sectorzaragozados.salud.aragon.es/uploads/documentos/documentos proceso fractura cadera osteoporotica ef6b1494.pdf



### 1. CARDIOVASCULAR DISEASE

Research	Expert and patient Workshops Aragón
Inadequate systems and connections may lead to underutilization.	Patient associations play a key role in lifestyle changes, follow up and motivation, but they are not included or engaged in the rehabilitation process.
Many changes must be made in patients' lifestyle, which means follow up and motivation of the patient are crucial and not always carried out.	Monitoring and education are essential; but currently they almost do not take place. Presurgery training as well as rehab could be done remotely.
Technological barriers for some age groups.	Great geographical dispersion, healthcare pressure and short rehab time at hospital are key limitations.
In telerehabilitation communication is crucial.	Improvements needed in EMR, case management and indicator management.
Mental health needs more attention. Patients feel scared, may have depression and anxiety.	Municipal resources (machines facilities, staff) are critical success factors and value drivers, but not used currently.

### 2. ARTHROPLASTY:

Research	Expert and patient Workshops Aragón
Going to rehabilitation can be an inconvenience for some patients, so telerehabilitation is a great solution.	Acute patients; the chronicity lies in rehabilitation and follow up. Follow up is poor and progress cannot be properly monitored.  Shortage of professionals to travel to regional hospitals; geographical dispersion.
Lack of consensus over proper rehabilitation pathways.	Not enough resources to invest in the full recovery time needed.
Pain management during the first months may lead to difficulties in following the telerehabilitation.	Home rehabilitation and follow up would mean freeing up resources and pressure on hospitals.
User friendliness and adaption to age and social profiles.	Regular online contact with HCP is important.
Without follow-ups and motivation, the rehabilitation program might be abandoned.	Municipal and community resources for instrumental activities.
Technology must be adapted to every group age.	Value drivers: Adherence, follow up and long-term physical activity. Currently not widely used.
Mental health must be taken into consideration: patients might deal with depression and anxiety.	



# 3. HIP FRACTURE

Research	Patient Workshop Aragón
As we are talking about an elderly group age, some patients might also deal with dementia, which can make the whole process difficult.	Many patients show dementia, comorbidities or cognitive problems.
Traveling for rehabilitation can be unpleasant for some patients.	Distance of many patients to the healthcare centre: sometimes conflict occurs due to the cost of transport.
Mental health is important: lack of motivation, feeling dependent.	Reduced social services support leads to institutionalization in elderly homes.
There is a high risk of getting the hip injured again if they do not follow rehabilitation.	No occupational therapy in hospitals due to lack of resources.  Involvement of municipalities, social services
	and primary care allows remote rehab and reduces institutionalization
Recovery is limited; it is often difficult.	Home rehabilitation and follow up fast track as well as occupational rehab when no comorbidities or dementia.
Technology must be accessible for every group age.	Value drivers: less institutionalization and patient transfers, rehab out of hospitals, hospital release. Currently not used.



### 4. COVID

Research	Expert and patient Workshops Aragón
Lack of evidence about rehabilitation programs in patients with COVID-19.	Younger patients with sequelae and need for musculoskeletal rehab.
Most published articles are based on past literature and have mostly considered general symptoms related to COVID-19, such as neuromuscular, psychological, and respiratory symptoms owing to post-acute syndrome and anxiety related to the idea of being infected with the novel coronavirus.	Long recoveries that cannot be done at hospitals; no materials and facilities available; lack of coordination; geographical dispersion and transportation costs.
Early respiratory rehabilitation is not recommended for severely and critically ill patients during periods of possible and progressive deterioration.	Accessibility and transportation.
Patient profiles and ages have to be considered.	Control at home and time for listening reduces resource consumption, but it does not take place.
Normal rehabilitation protocols simply do not apply because patients must be discharged earlier than usual to make hospital beds available	High demand is expected and resources are scarce.
Costs need to be considered.	Community facilities are essential but not used.
There should be no major rehabilitation interventions for critically ill patients until they become medically stable or unless there are signs of progressive deterioration.	Many value drivers that are currently not used: release pressure on hospitals, reduce transportation cost, more attention to non-Covid patients and reduction of sick leaves.



### 5. COPD

Research	Expert Workshop and Patient Questionnaire Portugal
Mental health issues affect the participation in rehabilitation programs.	High prevalence and mortality; yet lack of social awareness of the problem. No cure; rehab and medication avoid worsening and maintain QoL.
For some people, going to rehabilitation or their medical centres can be a much bigger problem than may seem at first sight.	Hospital saturation and distance to hospital are main limitations.
Barriers: referral practices, travel, transport, disability and lack of program staffing.	Patients have to pay for travel; rehab programs do not reach working patients.
Lack of organizational support and resources, telecare experienced as threatening due to changes in work routines, workload and skills set, as well as equipment reliability.	Need for rehabilitation. Not considered a priority by patients.
No access to exercising equipment.	For professionally active workers, schedules do not fit often and cannot go twice a week to rehabilitation.
Only a very small percentage of eligible people ever attend a program.	Primary care is too busy with other pathologies.
Prevention is key to disease management.	Patients prefer to rely on medication.
Need for more IT staff in order to install the technology at the patients' houses.	Main value drivers that could be activated: prevention, cost reduction, reach a wider population.



# 6. Spinal Chordal Injury (SCI)

Research	Expert Interviews and  Patient Questionnaires Eire
The literature is limited in exploring outcomes associated to potential role models or inspiring others specifically in the SCI community.	Getting good information when consultants come from other hospitals.
There is an issue of control in physical rehabilitation for people with spinal cord injuries, which can result in a fight with oneself or with healthcare professionals to regain the control that has been lost.	Community team members could assess the patient and avoid trips.
Patients in home-based rehabilitation improved the mental component; however, in the physical aspect no improvement was noted.	Training is difficult for personal caregivers, especially in distance.
Regarding the use of virtual reality, commercial models must be differentiated from those that do not use it. More studies should be carried out to find out the capabilities of each.	The quality of an IT system may be questionable and are there are risks of cyberattacks.
There is resistance to new technologies in certain areas. Providers should accept this preference and wait for new-technology acceptance through the aging population.	Discharge planning: it is difficult to get community services to take the care of the patients.
Technical errors of varying kinds can occur (e.g., the system does not always recognize the user's responses or accept responses that it is not prepared to hear).	Not connected to other hospitals: if acute issues occur, transport by ambulance.
The system includes statements to explain these limitations, but users may still ultimately be frustrated at times.	

# 7. Acquired Brain Injury (ABI)

Research	Expert Interviews and Patient Questionnaires Eire
Higher cost in relation to access to the health service, hospitalization and the economic losses derived from them.	Need to discharge people who still need rehabilitation, especially older people.
Have found no significant differences in motor function and capacity to carry out daily routine activities between conventional rehabilitation and telerehabilitation.	Institutionalization to care homes.
Measuring activity levels of patients with minimal invasiveness in their natural environment has potential advantages over traditional self-reported and clinic-based measures.	Younger people have to be treated in older people's care homes too. Social viewpoint based on age.
There are no randomized trials that include cost-disease ratio. Approaches are needed to facilitate this issue.	It seems easier to find funding for attending people in care homes than to fund home care and attend people in their home. Especially if many care hours are needed or if you need 24/7 attention.
Use of rehabilitation in neurological populations is still primarily in an observational or validation phase.	Follow up is very difficult.
It is difficult to implement telerehabilitation in isolated areas and with very specific cultural contexts.	Distance and access to transport
Many commercially available monitors (accelerometer) have not yet been evaluated in neurological populations.	Comorbidities
The cost of the software that analyses the monitor data is too expensive.	No capacity for follow up
Poor reporting of clinical implementation parameters related to frequency, intensity, duration and number of sessions of remotely supervised interventions. Without this specific information, clinical replication of the intervention can be difficult.	
Poor exploration of the efficacy of other types of technology found in the current scoping review such as virtual reality or smartphone application.	



### 4.3. Relevant results of State of Art Analysis (SotA)

This is a summary of SotA conclusions about technological issues. They are obtained from Desktop exercises based on PRISMA - Preferred Reporting Items for Systematic review and meta-Analysis. We are considering five stages in this systematic review:

- 1. Literature search
- 2. Article selection
- 3. Data extraction
- 4. Data analysis
- 5. Data synthesis

### 4.3.1. Systematic Review of open platforms for Telerehabilitation

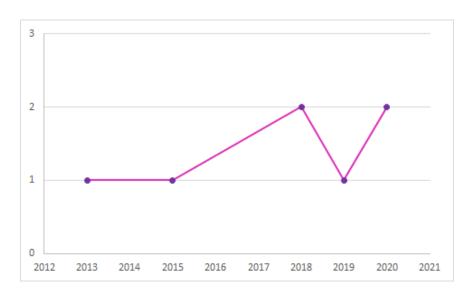


Figure 2 - Number of articles published per year for Digital Open Platforms.

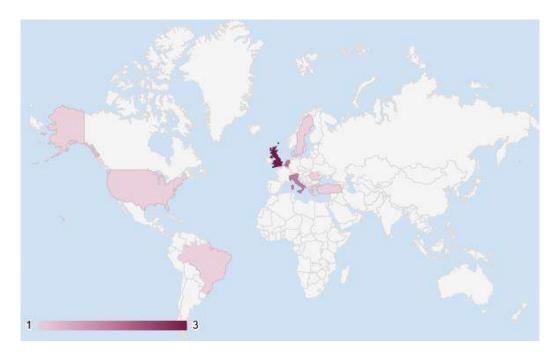


Figure 3 - Geographical distribution of the included articles around the world for Digital Open Platforms.

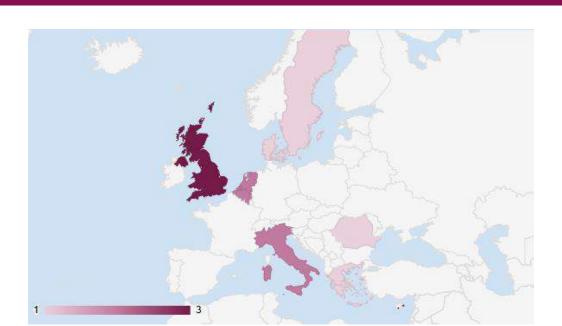


Figure 4 - Geographic distribution of included articles in Europe for Digital Open Platforms.

### 4.3.1.1. Conclusions:

This systematic review had the objective of creating an overview on the topic of the implementation of digital open platforms, which are considered enablers for building digital ecosystems. The focus of this review was identifying the types of frameworks currently being used and deployed from the technological, integration and interoperability perspectives. This review also identified which were the most common types and methods used for the validation of digital open platforms. Finally, through external resources this review also identified some noteworthy instances of digital open platforms currently being developed and deployed in the context of European Innovation and Research Programs, applied to the areas of Ambient Assisted Living and to the Healthcare Sector.

This review has followed the specifications of the PRISMA protocol to produce a review based on 7 articles which were selected according to the predefined eligibility criteria and workflow proposed in Table 2 and Figure 1. From the data extracted from these articles, and following the extraction strategy included in Table 4, a statistical analysis of the data was produced.

The main results of our systematic analysis suggest digital open platforms tend to follow the architecture model proposed for Service Oriented Architecture (SOA), which takes advantage of its loosely coupled model and availability of a variety of technology frameworks supporting the implementation of this model. Some key aspects for implementing an open platform following such an approach consequently will be dictated by the integration workflow and interoperability mechanisms.

Looking into the technologies involved in the implementation of digital open platforms, we found Python, Java, PHP, Javascript and HTML appear as the most popular programming languages. We assume this is the case because of the proliferation of open source tools and repositories associated with several frameworks implemented using these programming languages. For example, consider the cases of full stack frameworks like Django (Python), Play Framework (Java), Spring (Java), Node.js (Javascript). In terms of backend components, implementation appears to use mainly the tools for web servers like Apache Tomcat, Apache HTTP and for database servers like MySQL, Apache Hadoop, MongoDB. Communication between components is mainly formatted either in XML or JSON files. Another aspect of digital open platforms is the support to the connection to physical components, such as sensors or medical devices, the communication with such components is usually achieved through wireless connections like Bluetooth, Zigbee, GPRS and wired connections using USB.

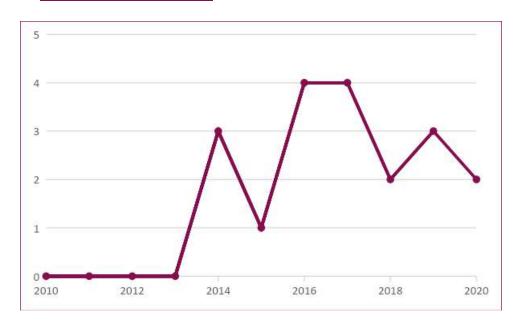
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The complexity associated with implementing SOA architectures, due to the number of components and heterogeneity of such components, require resorting to integration frameworks and tools. Most commonly, as appearing in literature, Docker, WSO2 ESB, Confluence/Kafka, among other similar tools.

Associated with integration aspects, interoperability concerns are also mentioned, yet not in such a prominent way. Overall, this is not a topic that is changing so rapidly in terms of new proposed standards or practices, as these often require relatively long lifecycles to be adopted and deployed in real world applications. Nevertheless, it seems that interoperability between different systems is achieved through APIs, with most common use of RESTful approaches (more prevalent now than SOAP, which were quite adopted in the past). Achieving data sharing, data curation and data alignment is also another challenge when guaranteeing interoperable ecosystems. Hence, representing knowledge while maintaining syntax and semantic coherence is of main importance. Currently, the adoption of ontologies as knowledge representation mechanisms is gaining some traction, and can potentiate the wide adoption of most known standards like HL7, DICOM and IEEE 11073, among others.

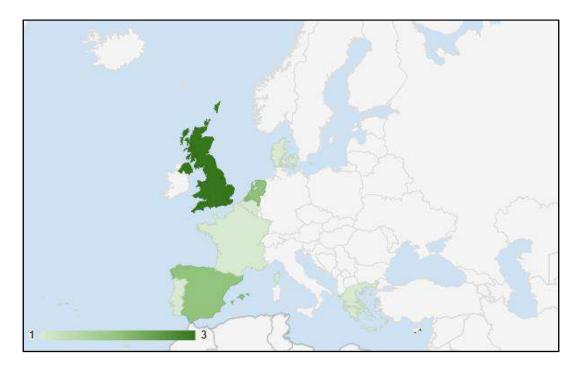
On the other hand, despite the variety and maturity of technological tools, the evidence of how such technologies are being adopted, used and validated in real-world applications is much more unclear. First, there is not an apparent common approach that is followed similarly for the validation of all considered platforms. For example, we found different studies that were conducted either focusing on feasibility or usability or comparing distinct datasets and cohorts, but because of the disparity in the approaches it is not possible to benchmark the different proposed platforms. Moreover, the validation methods used also do not follow a common set of measurement instruments. Although there are some indications of commonly used measurement instruments, associated with the corresponding study typology (e.g., PSSUQ for usability). Therefore, validation aspects can be considered as a factor of concern when developing a digital open platform, but the lack of clear guidelines or benchmark tools may impose barriers for deployment and adoption by end-users.

# 4.3.2. <u>Systematic Review of Technological solutions for tele-rehabilitation and home-based rehabilitation</u>

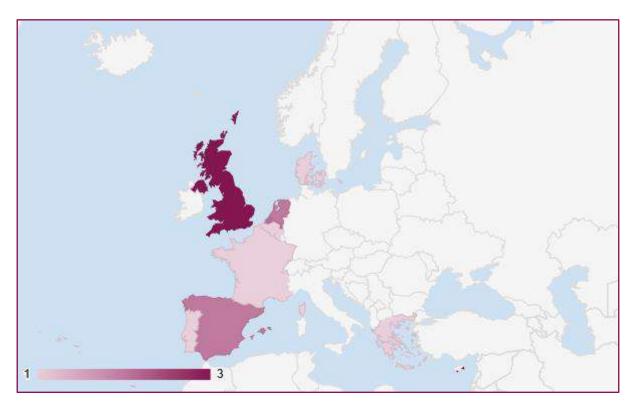


Number of articles published per year.



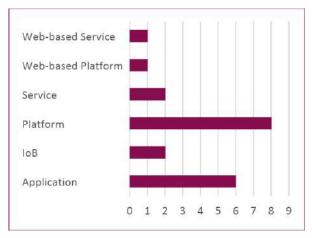


 $Geographical\ distribution\ of\ the\ included\ articles\ around\ the\ world$ 



Geographic distribution of included articles in Europe

### Distribution of topics regarding the aspect of: Technology being deployed.



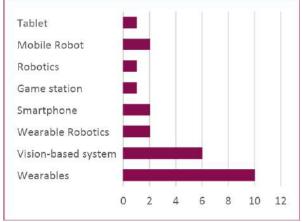
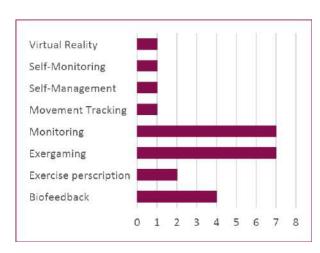


Figure 14 - Graphics showing the topic distributions for the aspect of technology being deployed: Left – Distribution on the topics of integration framework; Right – Distribution on the topics of devices being used.

### Distribution of topics regarding the aspect of: Approaches to rehabilitation.



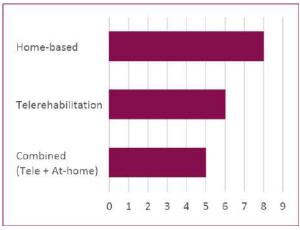
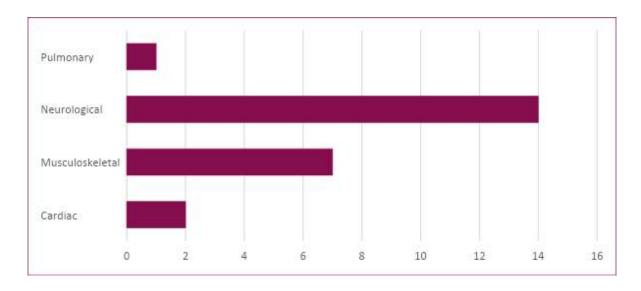


Figure 15 - Graphics showing the topic distributions for the aspect of the approach to rehabilitation: Left – Distribution of the topics on the rehabilitation delivery approach; Right – Distribution of the topics on the type of rehabilitation being delivered.

### Distribution of topics regarding the aspect of: Medical conditions being addressed.



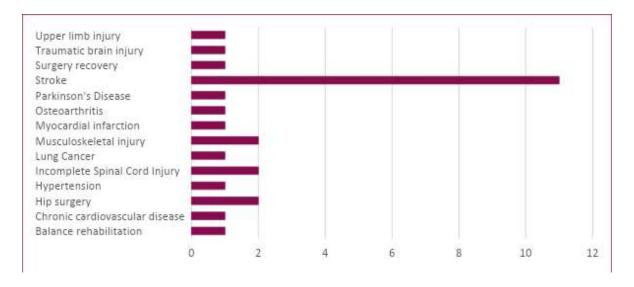


Figure 16 - Graphics showing the topic distributions for the aspect of the medical conditions being addressed: Up — Distribution of the topics on the medical area of focus; Down — Distribution of the topics on the medical condition being addressed.

### 4.3.2.1. Conclusions:

This systematic review had the objective of creating a high-level overview on the topic of telerehabilitation and home-based rehabilitation focusing on the technical and medical area of application aspects. From the technical perspective the focus was defining the types of devices and technologies being employed for remote rehabilitation, the types of integration frameworks that coordinate the rehabilitation-enabling devices and the type of approach that each solution enables. From the medical perspective the focus was defining which was the most common area of application of these kinds of solutions and to define the most common medical conditions targeted by solutions for remote rehabilitation at-home or with synchronous remote components.

This review has followed the specifications of the PRISMA protocol to produce a review based on 19 articles which were selected according to the predefined eligibility criteria and workflow proposed in Table 10 and Figure 10. From the data extracted from these articles, following the extraction strategy included in Table 12, a statistical analysis of the data was produced.

From a technical perspective the most common devices are identified to be wearables devices and vision-based systems, more often coupled with integration strategies that encompass the creation of dedicated applications and physical platforms. It is worthy of note however the appearance of web-rooted integration frameworks like web-based platforms, services and IoB which have a better scale-up capacity. In terms of delivery, it can be noted that most solutions are built for the delivery of asynchronous or autonomous rehabilitation at-home, however it is of importance to point out the appearance of combined approaches of asynchronous procedures from the patient side with synchronous and asynchronous monitoring from the health professional side. As shown in the topic analysis, the most common approach to rehabilitation is the usage of exergames and remote patient monitoring as tools for delivering and guiding the remote rehabilitation process.

From a medical perspective the most commonly addressed area of focus is on the rehabilitation of medical conditions with neurologic manifestations, however medical conditions with musculoskeletal implications are also frequently addressed. From the previous analysis it can be observed that strokes are the most common medical condition targeted for remote rehabilitation, followed by incomplete spinal cord injury, both having neurological implications, and then hip surgery recovery and musculoskeletal injuries, both having musculoskeletal implications.



As a final remark, it is to be noted that although the eligibility of the solutions was bound to the TRL range of 4 to 6, which entails validation and demonstration, most validation studies were implemented either as proof-of-concept and proof of usability tests and most times leaving out the evaluation of the impact of the rehabilitation solution in terms of the outcomes of the targeted medical condition. This is however not unexpected since most articles are ranked as TRL 4 and 5 and none detail a TRL 6 solution.

### 5. ROSIA's Challenge

This section provides the use cases and the table with the functional and non-functional requirements based on the activities undertaken within WP2 Remote Rehabilitation Model Design.

The main objective of WP2 is to develop a unified vision of the ROSIA telerehabilitation model and the unmet needs. This vision has been devised by combining the expertise of the knowledge partners (top-down) and the needs and wills of the local ecosystems in each procurer location (bottom-up) in a co-creation process with continuous dialog with all involved stakeholders. ROSIA's model is built on top of the updated state-of-the-art in technology, integrated care and value-based healthcare models. Furthermore, it has aligned the perspective of the involved stakeholders with the long-term view of the policy makers.

Based on this, this section reports on the extracted horizontal and vertical unmet needs and care delivery shortcomings to support telerehabilitation ecosystem components, user perspective, updated state-of-the-art technology, integrated care and value-based healthcare models.

### 5.1. Use case

Generic descriptive structure of how a person in need of rehabilitation living in remote areas will have access to telerehabilitation care.

ID	Generic use case
Title	Person living in remote area in the need of rehabilitation
Summary	ROSIA will support a digital rehabilitation pathway in remote areas. Once the rehabilitation needs of a person living in a remote area are identified and a comprehensive assessment is in place, the care team will assess the feasibility of using ROSIA for that case.
	ROSIA will build an open platform of services and solutions to help service providers deliver and possibly scale up their telerehabilitation services. The digital rehabilitation pathway for people living in remote areas will have the flexibility to adapt to personalised functional needs and goals of the patient, including a whole range of guided exercises and lifestyle changes, as well as community services, peer support, and motivational and coaching features.
	ROSIA will ensure a seamless transition between different care settings, facilitate multidisciplinary care team (MDT) communication and coordination during the course of the digital rehabilitation pathway in all the stages of the rehabilitation and self-management process.
	All the members of the care team and support services will have access to the necessary information that includes the Shared Care Plan and individual goals in the data dashboard that allows information-based decision-making.
	Long-term management and monitoring should be enabled by leveraging electronic health records (EHR) data and linking assessment results with an interface to the care team.
	The Shared Care Plan should be updated and reassessed regularly and adapted to the changing needs and goals of the person in rehabilitation to support personalised care strategies



Actors	<ul> <li>Person in need of rehabilitation</li> <li>Carers and family members</li> <li>Primary health care</li> <li>Care coordinator</li> <li>Social care</li> <li>Community link worker</li> <li>Specialist's care (cardiologist, surgeon, rehabilitation, etc)</li> <li>Other community care settings: care homes, rehabilitation centres, hospitals at home, etc.</li> <li>Counselling, psychological support, mental health</li> <li>Other support services: technical aid support, local government services, transport, etc.</li> <li>Nutritionist</li> <li>Physiotherapist</li> <li>Cognitive and dependency assessment and support services</li> <li>Administration</li> <li>Municipalities</li> <li>Peer support groups and patient associations</li> </ul>
Preconditions	<ul> <li>Person in need of rehabilitation living in a remote area</li> <li>A comprehensive need assessment and goal settings are in place</li> <li>A shared care plan has been set up</li> <li>Multidisciplinary care team is involved</li> <li>Social and health services are involved</li> <li>EHR are reliable and safe</li> <li>A digital care pathway is feasible</li> <li>ROSIA open platform of services and solutions is available and accessible</li> </ul>
Entry point	<ul> <li>Several care settings that can prescribe a rehabilitation plan:</li> <li>Specialist inpatient or outpatient care: specialist care, rehabilitation care team, primary health care, etc.</li> </ul>

Stone involved	
Steps involved	<ul> <li>Person with rehabilitation needs and living in remote areas is identified.</li> </ul>
	<ul> <li>Comprehensive assessment including functional and rehabilitation needs.</li> </ul>
	<ul> <li>Shared care plan and personalised goals are set up.</li> </ul>
	<ul> <li>Accessibility assessment: technical, and health and digital literacy.</li> </ul>
	<ul> <li>Identify training and support needs. Ensure the needed training and support is offered before transition to the digital rehabilitation pathway.</li> </ul>
	<ul> <li>Personalised digital rehabilitation pathway using one or more of the services or solutions in the ROSIA catalogue tailored to the functional and individual needs of the person.</li> </ul>
	<ul> <li>ROSIA's services in the catalogue should adapt the interface and the communications channel to the accessibility needs of the person.</li> </ul>
	<ul> <li>Discharge plan and digital rehabilitation pathway are set up before transitions between care settings.</li> </ul>
	<ul> <li>The care team can access, modify and adapt the Shared Care Plan including patient goal setting based on their role in the care team.</li> </ul>
	<ul> <li>Regular follow-up and monitoring. Long-term management and monitoring will be enabled by leveraging EHR data and linking assessment results with an interface to the care team.</li> </ul>
	<ul> <li>Self-management training and patient activation are available in the chosen services from ROSIA's catalogue.</li> </ul>
	<ul> <li>Alerts and alarms can be set up to inform the person in rehabilitation and the care team of any problem or warning.</li> </ul>
	<ul> <li>ePROMs and ePREMs are collected regularly and available for data sharing for individual experience analysis as well as the intervention analysis by the care providers.</li> </ul>
Frequency	Adaptable and personalised for each person
	Through all the stages of the rehabilitation
	Whole life-course
	Continuously real-time
User perspective	<ul> <li>ROSIA provides a high quality and reliable rehabilitation service to people living in remote areas.</li> </ul>
	<ul> <li>ROSIA will improve the functional improvement and physical experience</li> </ul>
	<ul> <li>ROSIA provides a better psychological experience with improved communication and support.</li> </ul>
	<ul> <li>ROSIA improves the care experience enabling the shared care plan and personalised goal setting with a seamless care experience.</li> </ul>
	<ul> <li>ROSIA improves the emotional experience with increased motivation and engagement in the rehabilitation programme as well as in the adoption of healthy lifestyle habits.</li> </ul>
	<ul> <li>ROSIA provides a better social experience with virtual peer support groups to decrease the feeling of isolation and provides a social identity.</li> </ul>



	<ul> <li>ROSIA improves the work and rehabilitation balance as well as being more inclusive with underserved people, improving the gender balance and getting better results.</li> </ul>
Integrated care perspective	<ul> <li>Enhanced patient experience</li> <li>Personalised and individualised care</li> <li>Patient activation and empowerment</li> <li>Health and digital literacy</li> <li>Patient access to health and care information</li> <li>Improve provider satisfaction and care team well-being</li> <li>Improve patient safety</li> <li>Reduce cost and/or increase value of the intervention</li> <li>Better outcomes</li> <li>Digital solutions and electronic health records</li> <li>Improved workforce capacity and capability</li> </ul>
Technological and innovation ecosystem perspective	In relation to ROSIA's Open Platform, the following principles should be observed:  • ROSIA's Open Platform should be available to its users anytime, and
	<ul> <li>in any channel of their choosing (desktop, mobile, etc).</li> <li>ROSIA's Open Platform should be designed with a high degree of flexibility.</li> </ul>
	<ul> <li>ROSIA's Open Platform should be able to respond to the workload at any given time, automatically.</li> </ul>
	<ul> <li>ROSIA's Open Platform should exhibit a high tolerance to service failure events.</li> </ul>
	<ul> <li>ROSIA's Open Platform should follow a methodology that enables fast deployment of services and fast bug fixing and patching.</li> </ul>
	<ul> <li>ROSIA's Open Platform should enable fast integration within multiple systems from its different architectural layers.</li> </ul>
	<ul> <li>ROSIA's Open Platform should implement a data interoperability strategy to ensure data handling and transparency between the devices and services associated with its architectural layers.</li> </ul>
	<ul> <li>ROSIA's Open Platform should implement data protection and privacy protocols in minimum compliance with the GDPR.</li> </ul>
	<ul> <li>ROSIA's Open platform should implement a governance model that facilitates cooperation with all stakeholders and that describes procedures for education, maintenance and handover to buyers.</li> </ul>
	<ul> <li>ROSIA's Open platform should facilitate light user interfaces relying on a "heavy" infrastructure.</li> </ul>
	<ul> <li>ROSIA's Open Platform should not accept proprietary solutions.</li> </ul>
	<ul> <li>ROSIA's Open Platform should support BYOD (Bring Your Own (medical) Device) wherever feasible.</li> </ul>
	In relation to ROSIA's Developer's Layer, between Services and the Open Platform, the following principles should be observed:
	ROSIA's Developer's Layer should provide solution developers with the SDK's and ADI's processory to greate integrate and deploy now.

services to the catalogue.

the SDK's and API's necessary to create, integrate and deploy new



- ROSIA's Developer's Layer should provide solution developers with the documentation for the SDK's and API's necessary for development,
- ROSIA's Developer's Layer should provide solution developers with the necessary integration, development and quality assessment workflows.
- ROSIA's Developer's Layer should implement the development processes in light of the current standards and regulations for the deployment of medical devices, for instance, and other relevant requirements such as the GDPR.

# In relation to ROSIA's Catalogue, the following principles should be observed:

- ROSIA's Catalogue should support only services and devices built with open access software and hardware.
- ROSIA's Catalogue should ensure the accessibility of the services and devices provided.
- ROSIA's Catalogue should integrate the relevant solutions available for a given condition into each given step of the care pathway.

#### Value-based perspective

ROSIA improves patient value (quality of life, quality of care) and lowers total healthcare costs by the optimization of healthcare delivery, making use of ehealth solutions. It engages patients in their health management by providing them with insights in the relation between their complaints, lifestyle, health status and therapy. By making use of smart algorithms, ROSIA's Open platform becomes a scalable and affordable concept aiming to increase patient empowerment and quality of life at lower costs.

ROSIA will consist of home measurement devices connected with applications for smartphone or tablet, integration of home measurements with electronic patient file, a dedicated team that interprets home measurements supported by smart algorithms and a nationwide network of outpatient clinics that can be visited by the patient if needed.

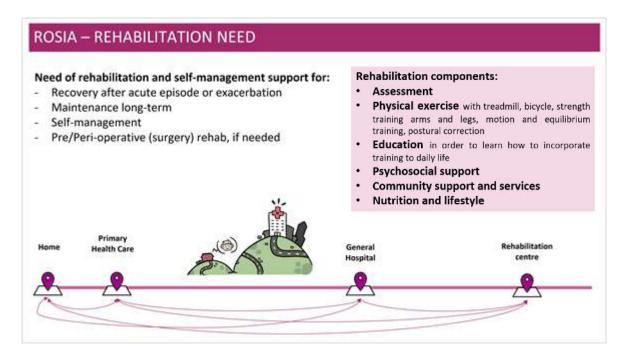
An interdisciplinary team continuously monitors patients' data and adapts therapy based on home measurements and contact with the patients. Interventions include lifestyle advice if appropriate, changes in medication, education about the condition and/or additional diagnostics, thereby forming an integrated practice unit (IPU).

ROSIA's Open platform is financed through bundled premium-based and shared-risk payment schemes and hence it is sustainable and scalable.

ROSIA's Open platform will improve relevant outcomes for the condition and goals of the patient. Measures of relevant outcomes may include: degree of health or wellbeing, sustainability over time, long-term impact or consequences of the therapy, or others.

#### A use case of a person in need of rehabilitation living in a remote area

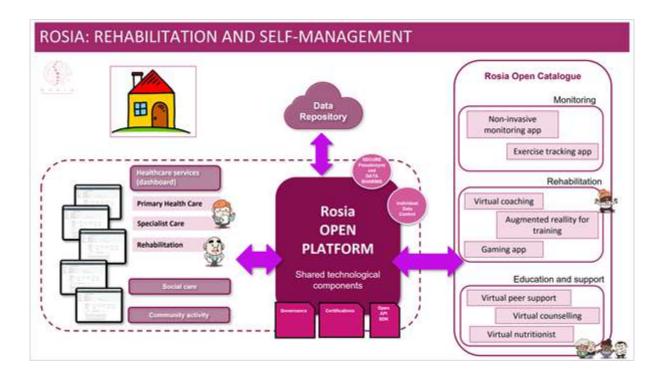
Let's think of a person living in a rural area, with the nearest primary health care service 5 km away, the general hospital 60 km away and the nearest central rehabilitation service 150 km away. This person develops a chronic condition that after an acute episode will need intensive rehabilitation for a few weeks, followed by long-term maintenance, rehabilitation and self-management support.



If we consider the traditional care pathway for chronic care and rehabilitation, this person would have their care team distributed in several locations such as a primary health care centre, the specialist in the nearest general hospital and the rehabilitation team in the reference rehabilitation centre. This person would need to contact different care team members, repeat the information to each member of the care team and travel from one location to another, including a long distance to the rehabilitation centre. What is the reality for this person? Poor experience and quality of care, with difficulties to access rehabilitation services, delay in the treatment, with the consequent risk of poor recovery, poor functional independence and work reintegration, as well as increased risks and complications. That is, a poor quality of life.

What would the ROSIA's Care Model and ROSIA's Open platform offer this person?

Imagine we can develop an integrated digital care pathway with the availability of ROSIA's Open Platform of services and solutions. The service provider would be able to access a catalogue of services and solutions through the platform that could be tailored and adapted to the needs of the person in rehabilitation and those of the care team.



After an initial assessment of needs, including socioeconomic and cultural context, health and digital literacy and access to technology at home, the user would be trained to use the platform. The care team would be able to, for example:

- Prescribe safe and regulated apps and devices for training (e.g., augmented reality device with built in walking game, other gaming apps, intelligent training shirt or shoes, or virtual coaching).
- Prescribe medical quality monitoring apps for physical activity pattern or biometric parameters as well as wearable devices connected via Bluetooth (e.g., a smartwatch with BP/HR/HRV/Spo2/Glucose measurement and a connected medical weight scale).
- All apps and devices send data through ROSIA's Open Platform and are shared in an easy-to-understand dashboard adapted to the needs of different care teams and the user.
- Offer a tailored virtual coaching programme with formative and adaptable physical therapy and rehabilitation approach.
- ROSIA's Open Platform communicates via video or messages of the person in rehabilitation with the care team.
- ROSIA's Open Platform facilitates virtual peer support and links with community services.
- Information of PROMs and PREMs is collected in ROSIA's Open Platform to facilitate the assessment of the service by the care providers.

Because of the use of ROSIA's platform, this person feels more control of their care plan and it is easier for them to make decisions. The whole care process is better coordinated because everybody involved is updated with all the right information. Most evitable emergency and primary care visits have been avoided because the existing channel of communication through the platform allows easier communication between users.

JSER	PROVIDER
Better experience Better quality of life Better and relevant outcomes	Better service     Lower cost     Workforce satisfaction
Empowerment Self-management Person-centred care Personalised goal setting Shared care plan Family involvement	<ul> <li>Scalable, affordable</li> <li>Medical quality of data</li> <li>Data integration</li> <li>Interoperable</li> <li>Risk shared</li> <li>Paid for value</li> </ul>

ROSIA improves value for the person in rehabilitation (quality of life, quality of care) and lowers total healthcare costs by optimizing healthcare delivery and making use of e-health solutions. ROSIA's Open Platform is a scalable and affordable concept aiming to increase users' empowerment and quality of life at lower costs.

The care team feels the quality of the care offered to the patient in rehabilitation is better using ROSIA's Open Platform. An interdisciplinary team continuously monitors the data and adapts therapy based on home measurements and contact with the user. Interventions include lifestyle advice if appropriate, changes in medication, education about the condition and/or additional diagnostics, thereby forming an integrated practice unit. Because all members of the care team are in contact, members with more expertise are always available to answer questions, making the rest of the team feel safer.



### **5.2.** Functional and non-functional requirement table

The table of functional and non-functional requirements presents the requirements to provide telerehabilitation care in remote areas for each one of the four components of ROSIA's Model: user perspective, updated state-of-the-art in technology, integrated care and value-based healthcare models.

### R1 Integrated Care

R1 Integrat	R1 Integrated Care				
ID_R1	Category	Short description of the category	Sub requirement	Short description of the requirement	
R1.1	Person-centred	Person-Centred Integrated Care can improve outcomes and experience for persons in need of complex interventions or multidisciplinary approach, or with multiple long-term and complex conditions.	R1.1.1 Person-centred care	ROSIA should enable a person-centred care, putting the needs and the experience of persons living in remote areas in the centre of how the rehabilitation services are organised and delivered. ROSIA should facilitate a coordinated and integrated care, tailored to the needs and preferences of patients in rehabilitation with a comprehensive approach to wellbeing and supporting decision-making processes and self-management.	
R1.2	Community	Rehabilitation care depends on organisational cooperation between different stakeholders in the local community. Digital solutions enhance integrated care by supporting multisectoral coordination and cooperation.	R1.2.1 Support coordination of the care team.	ROSIA should be able to bring together the care team.	



R1.3	Delivery System Design	"Meaningful Use" requires the redesign of health care delivery systems to meet the emerging eHealth technologies to be implemented nationwide.	R1.3.1 Facilitate interoperability for the exchange of data and information electronically.	ROSIA should facilitate the exchange of data and information electronically as needed to provide the individuals more autonomy over their health data and information.
			R1.3.2 Facilitate access to and control over personal health data.	ROSIA should facilitate an individual's access to their personal data and ensure their records and care plan are correct and updated.
			R1.3.3 Create care team/individual's communication portal.	ROSIA should provide a safe space to promote care team/individuals' interactions, engagement, and mutual trust.
R1.4	Self- Management Support	The use of a Patient Health Records can support an informed and activated patient, as well as increase the rehabilitation care in the areas of self- management support and productive interactions	R1.4.1 Encourage patient engagement.	ROSIA should encourage patient engagement by facilitating preparation for appointments, tracking test results and diagnostic studies, involving them in health promotion, preventive care, and screening, and supporting individuals to decide the course of treatment with their care teams.
			R1.4.2 Measure patient activation	ROSIA should be able to measure Patient Activation by using standard and validated measures such as Patient Activation Measure (PAM).

R1.5	Decision Support	Shared decision making is a joint process in	R.5.1 Shared care plan	ROSIA should enable the update and exchange of
		which health and care practitioners work together with a person to reach a decision about their care, based		a shared care plan and personalised goals in real time.
		on existing evidence but also on the person's individual preferences, beliefs, and values. The decision-support implies that the care team and the person on treatment have access to the resources and information needed for	R1.5.2 Care teams' access to resources to support clinical shared decision process	ROSIA should enable the clinical decision support (CDS) as a method to ensure care teams have access to the most current evidence-based clinical guidelines, protocols, and standards of care.
		a shared decision-making process. This process ensures that the person understands the risks, benefits and possible consequences of different options through discussion and information sharing.	R1.5.3 Patient needs to support clinical decision process	ROSIA should respond to a patient's specific needs, such as: (1) visual access to data, (2) access to protocols, (3) care standards and evidence for self-management, (4) info buttons to access clinical guidelines, (5) reminders for both the patients and providers.
R1.6	Clinical Information Systems	The clinical information systems (CIS) automate the process of electronic data collection from different devices and provide a real-time spreadsheet with arithmetic accuracy.	R1.6.1 Inclusion of telehealth and mobile devices	ROSIA should count with the inclusion of telehealth and mobile devices in the rehabilitation care.
R1.7	eHealth Education	Health literacy is essential for eHealth. Low health literacy is a long-standing problem in the current health	R1.7.1 Being adaptable for different health literacy levels	ROSIA should address different levels of patients' of health literacy.
		care system. Training for both individuals and care team members	R1.7.2 Developing training for individuals	ROSIA's solution should have an introductory training for individuals.
		may improve the efficacy of the use of eHealth tools.	R1.7.3 Developing training for care teams	ROSIA's solution should have an introductory training for care team members.





R1.8	Complete Feedback Loop	Interventions that include the complete feedback loop are required for technology to promote improved	R1.8.1 Patient empowerment	ROSIA's solution has to give control to individuals to work in a cooperative partnership with the care team.
		health status.	R1.8.2 Care team response	ROSIA's solution has to provide timely responses to patients.
R1.9	Health System	Health systems that consciously implement and encourage the use of eHealth technologies can achieve a higher level of patient engagement, satisfaction, and selfmanagement support.	R1.9.1 Support and measure patient engagement, patient satisfaction and self-management  R1.9.2 Collection of ePROMS and ePREMS	ROSIA should be able to support and measure patient engagement, patient satisfaction and self-management.  ROSIA should be able to enable the collection of ePROMs and ePREMs to provide procurers with the evidence of user experience on the effectiveness and quality of the remote rehabilitation service provision.



### R2 User requirements

R2 User req	R2 User requirements		
ID_R2	Category	Sub-requirement	
R2.1	Service decentralisation and reduction of	R2.1.1 Early assessment (at least partially)	
	saturation	R2.1.2 Full range rehabilitation at home or in community services	
		R2.1.3 Remote intervention of specialists from central services	
		R2.1.4 Empowerment of primary care and social services or local hospitals for community rehabilitation	
		R2.1.5 Link to Electronic medical/health records (EMR/EHR)	
R2.2	Follow up and monitoring	R2.2.1 Create a follow-up and monitoring strategy involving key actors.	
		R2.2.2 Design a follow-up and monitoring functionality.	
		R2.2.3 Share results between central rehabilitation services and local primary care and community services.	
		R2.2.4 Self-monitoring for patients and carers	
R2.3	Rehabilitation training of the care team	R2.3.1 Design training packages and repositories.	
		R2.3.2 Include virtual real-time and interactive training to offer dynamic learning opportunities (not only videos or reading material).	
		R2.3.3 Specific training for community care team, including primary health care and community services	
		R2.3.4 Training material and opportunities for local workforce,	

		including primary health care and
		community rehabilitation or services
R2.4	Digital literacy	R2.4.1 Design a digital empowerment strategy considering the individual's cultural environment, the condition and their rehabilitation needs.
		R2.4.2 Include digital literacy package for all users including patients, caregivers and workforce.
		R2.4.3 Emergency training, information, resources and information: ideally hotline with emergency
R2.5	Community engagement	R2.5.1 Use community infrastructures in isolated areas
		R2.5.2 Local assistance for remote rehabilitation
		R2.5.3 Use of local resources: gym, pool, facilities, personnel
R2.6	Support services	R2.6.1 Support at individual and family level, psychological support
		R2.6.2 Specific support for people living in remote areas, isolation or loneliness
		R2.6.3 Include peer support and/or from patient associations
R2.7	Risks and complications	R2.7.1 Risk, comorbity and complication identification and monitoring
		R2.7.2 Include support for co-morbidity management.
		R2.7.4 Pre-surgery rehabilitation (CVD)
R2.8	Health promotion and prevention	R2.8.1 Nutrition, non-smoking and healthy lifestyle promotion and support



### R3 to R5 ROSIA Innovation Ecosystem

ID_R3	Name	Short Description	Sub-requirements
R3.1	Availability	ROSIA's Open Platform should be available to its users at any time, and in any channel of their choosing (desktop, mobile, etc).	
R3.2	Flexibility	ROSIA's Open Platform should be designed with a high degree of flexibility.	R3.2.1 ROSIA's Open Platform should be able to accommodate the integration of a heterogenous variety of technological frameworks.
R3.3	Scalability	ROSIA's Open Platform should be able to respond to the workload at any given time, automatically.	R3.3.1 ROSIA's Open Platform should be able to spin-up additional service instances during periods of high usage using e.g., load balancers.
			R3.3.2 ROSIA's Open Platform should be able to terminate excess service instances during periods of low usage.
			R3.3.3 ROSIA's Open Platform should be able to measure the usage of each service and its associated instances at any given time.
R3.4	Resilience	ROSIA's Open Platform should exhibit high tolerance to service failure events.	R3.4.1 ROSIA's Open Platform should be able to detect failure events on any given service instance.
			R3.4.2 ROSIA's Open Platform should be able dispose of failing service instances automatically.
			R3.4.3 ROSIA's Open Platform should be able to automatically build and spin-up replacement service instances.
R3.5	Faster development and automatic deployment	ROSIA's Open Platform should follow a methodology that enables fast deployment of services and fast bug fixing and patching.	

R3.6	Integration capability	ROSIA's Open Platform should enable fast integration of multiple systems from its different architectural layers.	
R3.7	Data Interoperability	ROSIA's Open Platform should implement a data interoperability strategy to ensure data handling and transparency between the devices and services associated with its architectural layers.	3.7.1 ROSIA's Open Platform should be able to accommodate relevant standards like e.g., HL7/FHIR, IHE, ITU H.813 for data interoperability and communication.
R3.8	Data Protection, sharing Privacy and ethics	ROSIA's Open Platform should implement data protection and privacy protocols in minimum compliance with the GDPR.	3.8.1 ROSIA's Open Platform should be designed with privacy and data ethics in mind, so that the patient can exercise individual data control, and decide with whom they share their data and be able to see who has access to it. The platform should use technologies and services that create and communicate trust to users.  3.8.2 ROSIA's Open Platform should be designed to share data directly with all stakeholders involved in the integrated care pathway across sectors, and to facilitate involvement of patients.  3.8.3 ROSIA's Open Platform should facilitate methods to allow anonymous data donation for secondary uses, using best of breed 0-proof of knowledge technologies.
R3.9	Governance & handover	ROSIA's Open Platform should implement a governance model that facilitates cooperation with all stakeholders and that describes procedures for education, maintenance and handover to buyers.	
R3.10	Interfaces	ROSIA's Open Platform should facilitate light user interfaces relying on a "heavy" infrastructure.	
R3.11	Openness	ROSIA's Open Platform should not accept proprietary solutions.	3.11.1 ROSIA's Open Platform should have proven existing EU, national and/or regional infrastructure components as first choice.



R3.12	Devices	ROSIA's Open Platform shoul support BYOD (Bring Your Ow (medical) Device) whereve feasible.	rn
R4 ROSIA	's Catalogue		
ID_R4	Name	Short Description	
R4.1	Openness	ROSIA's Catalogue should support access software and hardware.	only services and devices built with open
R4.2	Accessibility	ROSIA's Catalogue should ensure devices provided.	e the accessibility of the services and
R4.3	Integrated Care Pathway	ROSIA's Catalogue should integra given condition into each given ste	te the relevant solutions available for a ep of the care pathway.
R5 ROSI	A's Developers		
ID_R5	Name	Short Description	Sub-requirements
R5.1	Developer Tools	ROSIA's Developer's Layer should provide solution developers with the SDK's and API's necessary to create, integrate and deploy new services to the catalogue.	
R5.2	Developer Support	ROSIA's Developer's Layer should provide solution developers with the documentation for the SDK's and API's necessary for development.	
R5.3	Development Process	ROSIA's Developer's Layer should provide solution developers with the necessary integration, development and quality assessment workflows.	R5.3.1 - ROSIA's Developer's Layer should implement an automated Continuous Integration / Continuous Deployment (CI/CD) pipeline for the inclusion of new services and solutions into the platform.
			R5.3.2 - ROSIA's Developer's Layer should provide solution developers with a best practices document for integration and deployment.
			R5.3.3 - ROSIA's Developer's Layer should implement a Quality Assessment pipeline.



R5.4	Regulatory Compliance	ROSIA's Developer's Layer should implement the development processes in light of the current standards and regulations for the deployment of e.g., medical devices and other relevant requirements such as the GDPR.	R4.4.1 ROSIA's Developer's Layer should provide solution developers with the SDK's and API's necessary to create, integrate and deploy a new service to the catalogue.
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## R6 to R9 Value-based care

ID_R6	Category	Short Description	Sub requirement	Specifics of sub requirements
R6.1	Value Proposition	The requirement aims to assess the core value and aim of the tender solution. The tender will explain how the patient value is defined, if the patient-relevant outcomes for the medical condition(s) are specified and the medical problem(s) the initiative tackles.		
R6.2	Medical Condition Match	The requirement aims to assess the tender's solution match with ROSIA's medical conditions. The requirement enters into the specifics of the initiative. The tender will be asked to indicate:	R6.2.1 The Medical Speciality(ies)  R6.2.2 The Medical Condition(s) among them COPD, acquired brain injury, CV disease, COVID-19 infection, hip fracture, arthroplasty, and chronic spinal injury.  R6.2.3 Prevalence (country(ies) of initiative)	



R6.3	Patient Palevant	The requirement aims to	R6.3.1	Survival
	Relevant Outcomes	assess which type of patient-relevant outcome measures are used in the tender. The tenderer is asked to indicate the three major outcomes using the sub-requirements list. If the outcomes do not fit in the provided list, others can be indicated. The tenderer is also asked to incorporate patient relevant medical outcome sets if used.	Health/well-being status achieved or maintained - Outcomes in this tier measure the direct and short-term effects of care delivery on the health status (physical, mental functioning) of the patient with survival being the	
		Examples are ICHOM, NHS, local registries, lead hospitals, international associations and/or international	most distinct and clear level at the top of the hierarchy.	Degree of health/well-being
		benchmarking, DSM-5, ICD- 11, ROMS, and 'Positive Health' by Machteld Huber.	R6.3.2 Health/well-being sustainability - Outcomes in this tier measure if health gains and recovered functions are sustainable in the long-term. Long-term successes of care delivery as well as long-term undesired consequences like care-induced illnesses are placed in this tier.	Sustainability of health/well-being over time  Long term consequences of therapy
R6.4	Delivery Process KPIs	The requirement aims to assess which type of process delivery KPIs are used in the tender. The KPIs measure both times to recovery or normal functioning and undesired effects of care	R6.4.1 Patient Reported Outcome Measures (PROMs) maintenance or improvement	

			1
	delivered to the patient that hinder expected recovery/rehabilitation. It also includes reporting and measurements. The tenderer is asked to indicate at least five of the delivery process KPIs from the suggested list. If the KPIs do not fit the list, they can indicate others.	R6.4.2 Patient Reported Experience Measures (PREMs) maintenance or improvement  R6.4.3 Existence of high quality data	
		R6.4.4 Support in measuring, reporting and analysing outcomes/data	
		R6.4.5 Improved process of rehabilitation	Time to recovery  Communication process  Interdisciplinary treatment
			Emotional/psychological support  Remote supervision
			Self-management
		R6.4.6 Reduce exacerbations and/or acute episodes	
		R6.4.7 Reduce complications	
		R6.4.8 Personalized treatment with more responsive support	
		R6.4.9 Patient health literacy and information provision	



			R6.4.10 Patient and/or relative's comfort and convenience	
R6.5	E-health Value Creation	This requirement aims to assess the way the tendered solution impacts the ehealth care delivery process and medical condition. The tenderer will indicate their ehealth contribution using the list.	R6.5.1 Remote Supervision - e.g., is the solution keeping an eye on the patient and taking action if something	Health living Prevention Diagnosis Treatment
		the list.	unusual happens?	Homecare
			R6.5.2 Care Coordination -	Health living
			e.g., is the solution	Prevention
			informing caregivers about	Diagnosis
			daily activities and sharing messages?	Treatment  Homecare
			R6.5.3 Care	Health living
			Assessment - e.g., is the solution	Prevention
			detecting early signs of well-being and	Diagnosis
			proactively adapting the care	Treatment
			to changing needs?	Homecare
R6.6	Care Delivery Pathway	This requirement aims to assess the way the tendered e-health solution contributes to the patient care delivery pathway for the selected medical condition. The tenderer is asked to show the patient pathway, and how the e-health solution changes the pathway and how the change results in better outcomes. The tenderer can use the Care Delivery Value Chain to describe activities.		



R6.7	Healthcare Costs  This requirement aims to assess the ability of the tendered solution to contain or lower costs per patient or patient episodes per year, to have an effect on the patient population level and generate savings effects on providers and payers.	R6.7.1 Contain or lower costs per patient  R6.7.2 Estimation of the cost effect on the population level.  R6.7.3 Savings/costs	Operational Budge Provider	
			effects on	Operational Budget Payer
			providers and payers (give	Realized Savings Provider
			estimations)	Realized Savings Payer
				Best Scenario Savings Provider
				Best Scenario Savings Payer
R6.8	Impact on Stakeholders		R6.8.1 Health and social care professional	Secure usage for clinical and social providers (no bigger risk for adverse events)
			benefits	Ease of use/handling & functionality of telerehabilitation application tool
				Training and access to education
				Improved workforce satisfaction
				Improved digital literacy
			R6.8.2 Provider benefits	Maintainability & technical service support
				Support on administration
				Alignment and support with reimbursement structure (no lost income)
				Strategic fit for provider and support of strategy
				Reduced long term costs of treatment and social care



			R6.8.3 Health and social care system benefits	Reduction of rehospitalization/number of treatments and care visits  Care optimization across integrated clinical and social care pathway
R6.9	Broader Impact on Society	This requirement aims to assess how and if the tender solution has a broader impact on the community and society. The tenderer must indicate the three major areas where their solution will impact the most.	R6.9.1 Innovation  R6.9.2 Environmental sustainability	Availability of new solutions for providing self-managed telerehabilitation  Contribution to development of health and social care solutions  Environmental impact by reduced travelling and/or less resource utilization
				Socially responsible product value chain
			R6.9.3 Socioeconomic impact	Patients' access to information and new communications channels
				Burden carried by nonprofessional care providers
				Patients' personal freedom and choice
				Patients' social inequalities
				Patient's inclusiveness

### **R7 Organisational Capabilities**

ID_R7	Category	Short Description	Sub requirement	Specifics of sub requirement
R7.1	Patient's Involvement	The requirement aims to assess how and if the tender solution has a patient involvement setup in place.		
R7.2	Social & Family Engagement	The requirement aims to assess how and if the tendered		



		solution has social methods in place to engage social workers and the patient's family.		
R7.3	Integrated Practice Unit (IPU)	The requirement aims to assess how and if the tendered solution involves interdisciplinary teams in the form of integrated practice units (IPU). To integrate all current medical, paramedical and other specialities around the patient, an IPU needs to be built. Leadership and coordination need to be arranged to make the IPU work. If IPUs are not applicable, the tenderer can specify any potential plan to use them so it can be assessed to what extent the tendered solution is able to work with or be part of an IPU. Key elements of an IPU are (explain how/if applicable):	R7.3.1 An IPU is organized around the patient's medical condition  R7.3.2 Involves a dedicated, multidisciplinary team that devotes a significant portion of time to the condition  R7.3.3 Providers are part of a common organizational unit  R7.3.4 Team takes responsibility for the full cycle of care  R7.3.5 Patient education, engagement and follow-up are integrated into care  R7.3.6 A single administrative and scheduling structure is issued  R7.3.7 Care is co-located in dedicated facilities  R7.3.8 A physician team captain or clinical care manager oversees each patient's care process  R7.3.9 Team measures outcomes, costs, and processes for each patient using common measurement platform  R7.3.10 Team meets formally and informally on a regular basis	
			accountability for outcomes and costs	





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R7.5	Internal Knowledge & Competencies	The requirement aims to assess if the tendered solution/tenderer team includes specific knowledge in the creation of value for patients' methods and tools, or if people with a technical background are present in the team.	R7.5.1 Value for patients' core concepts	Improve interaction within the team (patient & family - doctor & team)  Create joint decision-making processes  Measure medical outcomes for patient  Patient recorded outcome  Patient experience
				Measure of costs of individual activities  Delivery care
				solutions, treatment plans, and diagnosis in teams.  Include individual patient need vs
			R7.5.2 People with a medical background/VBHC knowledge/consultants/external advisors in the team/network.	protocols



R8 Financial Sustainability				
ID_R8	Category	Short Description	Sub requirement	Specifics of sub requirement
R8.1	Checklist of Financial Sustainability Plan	The requirement aims to prove the strengths and sustainability of the tendered solution's financial plan. A	R8.1.1 List of experts in your management team OR creation of a specific committee	
		checklist is provided, and tenderers are asked to prove the elements of the checklist.	R8.1.2 Cost Structure Plan	The tenderer should indicate:  Fixed costs  Variable costs  Indirect costs  The most important costs inherent to the business model.  The key resources and key activities that are most
				expensive.  An analysis of the breakeven point (quantity, price, costs and revenues) to show what the investment payback horizon is.



R8.1.3 Revenue Structure Plan	The tenderer should indicate:
	The type of revenue model (e.g. asset sale, usage fee, subscription fees, lending, renting, leasing, licensing, brokerage fees, advertising, dynamic pricing, fixed pricing).
	If Grants & Donors are available
	The partners that are business enablers
	The strategic complements that reinforce the business model and need to be involved in the business plan.
	If they can already show customers/clients that are willing to pay for the product and service (industries target).
R8.1.4 Internal Audit Sheet	
R8.1.5 Breakeven Point Analysis	
R8.1.6 Financial strategic goals and objectives (min 3 years)	



R9 Scala	R9 Scalability			
ID_R9	Category	Short Description	Sub requirement	
R9.1	Volume	The requirement aims to assess if the solution is able to reach new patients, tackle a higher number of medical conditions, provide an increased number of services, have a higher subscription number and expand geographically.	R9.1.1 Greater patient volume per medical condition	
			R9.1.2 Greater services volume per medical condition	
			R9.1.3 Greater volume of medical conditions	
			R9.1.4 Greater subscriptions volume	
			R9.1.5 Geographic expansion	
R9.2	Pay for Value	The requirement aims to assess if the solution is able to evolve its	R9.2.1 Lower fees per patient with higher subscriptions	
		payment structure, have risk- sharing and bonus-based	R9.2.2 Bundled Payments	
		solutions, and get paid for its value.	R9.2.3 Bundled Payments with premium/bonus structure per outcome	
			R9.2.4 Integrated with IPUs risk adjusted bundled payments	
R9.3	Value Creation	The requirement aims to assess if the solution is able to create value for the patient and the other relevant stakeholders.	R9.3.1 Improved patients' relevant outcomes	
			R9.3.2 Improved Delivery Process KPIs	
			R9.3.3 Improved values for other stakeholders	
			R9.3.4 Improved/reduced costs	
			R9.3.5 Increasing process efficiency	
			R9.3.6 Reputation improved	
			R9.3.7 Improved the e-health VBHC matrix (see requirement 12.5) and the patient care pathway	
R9.4	Data/Platform	The requirement aims to assess if	R9.4.1 Better information clinical data	
	Integration	the solution is able to use data and platform to advance outcomes, costs, teams coordination and collaboration.	R9.4.2 Costs of IT, measurement and process improve	
			R9.4.3 Data used for personalized treatment	
			R9.4.4 Data used for real time research	



			R9.4.5 Data are better integrated with existent IT infrastructures
			R9.4.6 Data provide integrated services across the e-health VBHC matrix (see requirement 12.5)
			R9.4.7 Data used to increase collaboration (within teams and across teams) and outside the region/nation.
			R9.4.8 Platforms increased planning and coordination between different locations and facilities
R9.5	Teams & IPUs	The requirement aims to assess if teams and IPUs have advanced to their next level.	R9.5.1 More fully dedicated teams (more different specialties are in the team)
			R9.5.2 More tailored facilities
			R9.5.3 Teams improved services across the e-health VBHC matrix (see requirement 12.5)
			R9.5.4 Teams experience a reduction in workload while increasing outcomes
			R9.5.5 Teams in different locations are better connected

### 5.3. ROSIA CHALLENGE for the technical solution model.

How to create a safe innovative tele-rehabilitation ecosystem & open marketplace that empowers patients and healthcare professionals?

Our analysis behind, that we see a number of amazing innovations both in the applied research field as seen in our State-of-the-art Analysis, SME's with ground-breaking new concepts, new devices, exergaming as we have encountered in our mapping. We have also seen that the many services and devices for telerehabilitation have difficulties to scale.

ROSIA aims to change the playing field for how vendors can engage, deploy and hopefully scale their solution of services and innovative devices in many different regional health and care ecosystems, that today often is having very different local requirements that each vendor meet, but in terms of regulatory compliance and data interoperability or lack thereof.

To be able to get the data from the new innovative devices and surrounding services to the right care and community staff is vital order to achieve the goals of having integrated care pathways and pave the way for new incentive models for value-based healthcare model, ROSIA proposes to enable open transparent data sharing across different service providers/competitors for both formal and informal care staff, patients & secondarily for research and new insights.

The missing piece is to develop the enabling ROSIA Open Platform where innovators can plug in their services, and care staff easily can access and use the services safely same way a doctor can prescribe medicine

In order to solve the ROSIA challenge we have created a wish list for the principles of the ROSIA technical model for the open platform inspired by best practices we have identified.

### **Key principles for Rosia Open Platform**

That the Rosia Open platform is built

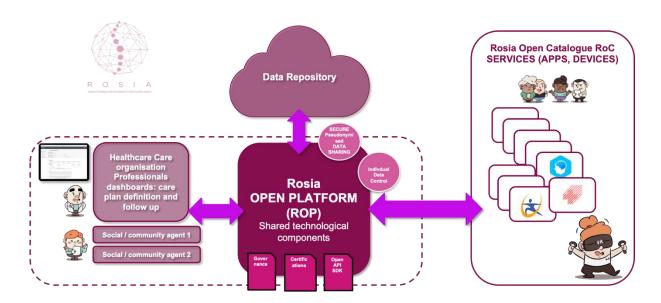
- with a high degree of flexibility.
- To share data across sectors and facilitate involvement of patients
- To ensure a high degree of automation
- To facilitate light user interfaces relying on a "heavy" infrastructure
- To support BYOD (Bring Your Own (medical) Device) where feasible
- To have existing EU, national and/or regional infrastructure components as first choice
- To be based on standards
- Not to accept proprietary solutions
- To be developed using proven cloud native platform tools
- To let the citizens be able to share their data for research securely and without being able to be identified
- To give the citizens full control of their data and with whom they share it with

The ROSIA Innovation Ecosystem is proposed to be composed by three core elements that the 3 buyers can share across regions in 5 years from now.

**ROSIA Open Catalogue**: A menu of evidence based safe certified ICT solutions and services that could be prescribed by the care team.

**ROSIA Developer:** This the development of an architecture and layer for developers with open API's & governance tools to facilitate that apps and services that uniformly can plug-in to the diverse backends of the buyer's regional infrastructures. We expect this to be define interoperable APIs, which will allow building up solutions based on existing modules shared modules, will aid existing research projects in becoming market solutions. Cooperation with any other related initiatives will be prioritized in order to aggregate demand.

**ROSIA Open Platform**: An agile open cloud native platform to host shared services, communication, and manage e.g. data sharing, consent, login, business logic and other core shared services, that can be derived from the shortcomings and use cases as described previously



We see the proposed ROSIA Catalogue for app & devices as only the tip of iceberg and we are happy to see the maturity level and innovation height of many of the services & devices pitched by the vendors in the OMC



Examples: Some examples of catalogues could be found in <u>European mhealth hub | Health apps repositories in Europe</u>



To summarise we see the concept of ROSIA Open Platform will consist of a service oriented architecture, using a modern, micro service based dynamic cloud infrastructure, that is geared towards supporting regional or even a nationwide construction of a highly modern and scalable IT-platform that can encompass all regional or government level services, and provide standardized environment for applications and APPs in the health and care sector. Only an endeavour in that direction can support a continued expanding array of services and solutions - providing all necessary services to allow 3rd party developers to develop innovative APP and services that can be deployed and maintained in concert with the underlying services.

In order to build this Rosia Open Platform infrastructure, we believe the materialisation of the ROSIA Open Platform with its ROSIA Developer layer and ROSIA catalogue all comes down to how the development is handled through these 4 thematic approaches to deliver the ROSIA open platform:

- Best Practices and Standards
- Openness
- Handover & Education for each region
- Governance

### 6. Scale up model and sustainability

### 6.1. Intellectual Property Rights (IPR)

### Ownership of results (foreground)

According to the European Commission guide on PCP, each contractor will keep ownership of the IPRs attached to the results they generate during the PCP implementation. The tendered price is expected to take this into account.

The ownership of the IPRs will be subject to the following:

- the buyers group has the right to:
  - access results, on a royalty-free basis, for their own use
  - grant (or to require the contractors to grant) non-exclusive licences to third parties to exploit the results under fair and reasonable conditions (without the right to sub-license)
- the buyers group has the right to require the contractors to transfer ownership of the IPRs if the contractors fail to comply with their obligation to commercially exploit the results or use the results to the detriment of the public interest (including security interests).

Details will be included in the documentation requested for the tender.

However, according to the EAFIP toolkit, when the parties wish to deviate from this default position and vest the IPR in the public procurer, then the IPR will need to be expressly assigned to the other partner by way of an instrument of assignment for copyright or registering the change of ownership in the patent register of the relevant patent office. A clause reflecting the obligations of the parties with respect to the latter should be included in the contract.

#### **Declaration of pre-existing rights (background)**

The ownership of pre-existing rights will remain unchanged.

In order to be able to distinguish clearly between results and pre-existing rights (and to establish which pre-existing rights are held by whom):

- tenderers are requested to list the pre-existing rights for their proposed solution in their offers
- procurers and contractors will be requested to establish a list of pre-existing rights to be used before the start of the contract

### 6.2. Value based payment

As explained in section 2.2, the evaluation framework, the set of indicators to be used to evaluate the project's performance and to award the bidders in each Phase of the PCP, will be based on ROSIA's Value-Based model (RVB Model).

According to the European Commission guidance on PCP, there are two types of award criteria (on/off criteria and weighted criteria) that tenders must comply with in PCP phases. They could be related to the definition of R&D services, to the performance of the contract, to the compliance with ethics or security requirements, to the reach of certain technical thresholds... But ROSIA's partners will not apply any Value Based Payment model (VBP) during the PCP.

However, the whole logic of defining ROSIA's Value-Based model (RVB Model) and the use of some of its KPIs as awarding criteria on PCP phases is based on the premise that the telerehabilitation service model that ROSIA advocates will be financed by paying for value in the future. The reason is clear: under value-based payment (VBP) models, payments to healthcare providers will be tied to quality, efficiency, and positive patient experience.

The VBP model is an essential element of the "scalability" requirements. Thus, it can only be understood by looking into the specifics of the requirement. Also, the VBP is *not* a stand-alone condition and it can only work if the core elements of the RVB Model are in place.

#### 6.2.1. Scalability

Scalability is intended as the capacity of the solution to increase its volume, payment structure, value, data and platform integration, and the IPUs and team satisfaction.

Since the focus is on the crucial facilitators of growth in a business model applied to VBHC, the environmental sustainability requirements have been suspended and included in the second stage of scalability.

Therefore, the RVB Model selected the five most important scalability requirements that need to be present in tenders' solutions:

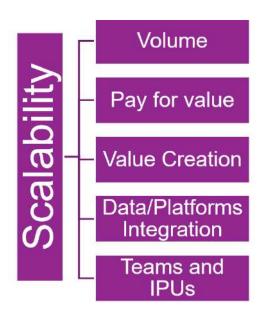


Figure 6 - The Scalability Requirements

#### 1. Volume

The solution has the potential to scale up when it is in a position to reach new patients, tackle a higher number of medical conditions, provide an increased number of services, have a higher subscription number and expand geographically. The tenderer will describe if and how scalability in volume applies to their solution.

#### 2. Pay for Value

To scale up, the solution should evolve its payment structure. The payment structure is considered able to scale up if it lowers the fee per patient through higher subscription rates, if it uses bundled payment schemes and/or if these are complemented by premium and/or risk sharing structures. The link between payment, outcomes and value creation is essential.

With bundle payments, providers are paid for the care of a patient's medical condition across the full cycle of care. It is a contract between providers and payers that contains at least the elements in the figure below (Figure 7). Bundled payments can be complemented by premium based structures. It means that the solution provider's payment is based on performance and outcomes reached.

Also, bundled payments can have risk sharing plans the same way insurance companies work. In the same way, the solution provider participates in the premium paid by the insurer and takes partially the risk of its performance while getting paid in bundled and for outcomes reached.

It is important to notice that the value-based payment structure is *not* a stand-alone condition and it can only work if the core elements of the RVB Model are in place.



Figure 7 - Bundled Payments

#### 3. Value Creation

Scaling up includes the capability of the solution to increase value for patients and all the other relevant stakeholders. Value is a function that depends on outcomes and costs. Hence, if the value is improving it means that costs are decreasing or outcomes are improving.

### 4. Data/Platform Integration

Technology, data and platforms are crucial in the scalability requirement. The solution will use new technologies to collect better information on clinical data and data used for personalized treatments, and real time R&D. Data and platforms will also enable collaboration among teams in and outside the region, and facilities.

#### 5. Teams & IPUs

With the use of technology and platforms, teams and IPUs can also advance to their next level. The teams have different specialties, present more tailored facilities, are able to improve the services across the e-health care delivery pathway (see the requirements table 12.5), they experience a reduction in the workload while increasing outcomes. The solution will gradually include teams in different locations.





REMOTE REHABILITATION SERVICE FOR ISOLATED AREAS

























