



R O S I A

REMOTE REHABILITATION SERVICE FOR ISOLATED AREAS

## PCP End of Phase

### Results & conclusions

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## Buyers group

Complete this box only one time with the joint conclusions from all procurers in the buyers group

### 1. Procurement need

Describe briefly (in a way that is suitable for publication purposes):

#### The problem / challenge you were trying to address with the procurement

##### The problem

Health and care systems in Europe are facing the rising burden of chronic conditions, while resources remain limited. This situation creates a continuously increasing demand for services, such as rehabilitation, which challenges Health and care systems in Europe. Rehabilitation is a key component of care, treatment and support for many patients living with particular pathologies such as neurological, cardiac, respiratory and orthopaedic conditions. Reorganising rehabilitation services has been identified as an urgent need, due to the significant implications it has on patients' lives, the long and costly processes it incurs for the health care system, the long and difficult journeys for the patient, which also implies shifting costs for the public health and care systems towards transportation rather than towards improved care. Even worse, these difficulties could act as a barrier against those patients receiving adequate and timely rehabilitation treatment, negatively affecting outcomes as a consequence of patients' location. This situation is intensified in depopulated/isolated areas where there is often a higher proportion of elderly people, and long distances to access some health and care services.

This situation creates a pressing need for a fundamental rethinking of how health services and systems are organised.

##### Challenges

Broad deployment of telerehabilitation services can address this situation successfully. This is because the tools are already available: devices and Apps based on state-of-the-art technologies such as virtual reality, augmented reality, gamification, depth cameras, sensors, AI, which have been clinically proven effective in supporting telerehabilitation. However, despite the evidence of the added value from its adoption, there is a gap between research and the integration of digital solutions into the care pathway. In summary, there is an agreement between the demand and supply stakeholders on the most important barriers to be considered:

- Integration of health & social care and patient engagement: The low health and social care integration levels are still a big challenge from a societal perspective. The participation and empowerment of citizens need to be improved to foster system transformation.
- Technical considerations: Procurers stated that the lack of technical expertise and understanding about the tools, standards, and regulations required to facilitate interoperability; inequalities in health and digital literacy; and low digital access are barriers to a more extensive implementation of digital solutions. Transparency regarding the utilisation of data collected by ICT is also a barrier.
- Regulatory framework: While several countries (such as Ireland, Portugal, and Spain) have made progress with the digital transformation of health systems, most regional, national, and European funding schemes do not yet support prescriptions of digital solutions; and IPR, ethics, and regulatory procedures are often burdening, confusing, long, and bureaucratic, impeding agile processes.
- Cost and access: According to a Digital Health Europe report, electronic health records, health facility improvements, and hospital-community integration procedures are the most critical expenditures in many EU countries. However, investments that target prevention, diagnosis, and treatment using digital health



solutions remain limited. In addition, there are obstacles to integrating new ICT solutions into clinical practice, such as a lack of infrastructure, challenges with intellectual property rights (IPR), regulatory harmonisation, and low levels of private sector investment (also in consideration of an unpredictable and slow return on the investments). This situation is further worsened by inadequate or fragmented legal frameworks, including the lack of reimbursement schemes for digital health services and the budgetary silos which made hard the mandatory coordination between all healthcare levels and also with social services.

Consequently, **tele rehabilitation is complex to implement:**

- For the **healthcare system:**
  - o It implies an **internal transformation process** towards specifically tailored integrated-care models with new roles, tools and responsibilities, and increased health and digital literacy for patients.
  - o In addition, it implies handling the transference of sensitive data and **integrating a large and diverse set of digital services** into their ICT systems.
- For the **developer**, fragmented care models, lack of prescription procedures, lack of reimbursement models, and the diversity of ICT health systems to integrate, mean the **costs of development are prohibitive**.

**The tele rehabilitation market is currently locked**, as there is no comprehensive solution for the easy integration of the diverse tools available. **What is required is a solution that opens a path towards the speedy development of new answers and solutions**, while facilitating the integration of these tools in the daily clinical practice of healthcare providers, simultaneously supporting the implementation of tailored clinical pathways.

**What type of innovative solutions and which functionality / performance / price requirements you requested in the tender specifications (specify the minimum and target quality / efficiency improvements that you wanted the innovative solutions to achieve).**

A remote rehabilitation ecosystem consisting of an open platform, an open service catalogue of services and apps, and a developer layer for paradigm shift from hospital-based to home-based rehabilitation. ROSIA Remote rehabilitation ecosystem is enabled by disruptive technologies and a new organisation of rehabilitation care pathways. It consists of 3 elements:

- The ROSIA Open Platform, an open cloud-native, state-of-the-art platform for managing data and communications, and running shared services & solutions (e.g., Integrated Clinical Care Pathway builders, ePROM/ePROM protocol editor, data sharing, consent, login, business logic and other core shared services) and helping to breach the interoperability gap.
- The ROSIA Developer Layer, to facilitate the collaboration between service providers to either develop test and/or deploy services for remote telerehabilitation and continuously improve and multiply the number of services in the catalogue. This layer for developers with open and interoperable APIs & governance tools would facilitate apps and services that uniformly can plug into the diverse backends of the buyer's regional infrastructures. We expect this to be defined as interoperable APIs, which will allow building up solutions based on existing modules and will aid existing research projects in becoming market solutions
- The ROSIA Catalogue of evidence-based safe solutions, which comprises a compliant certified menu of safe telerehabilitation digital therapeutics apps and smart devices to be prescribed for the patient for self-care and self-monitoring, seamlessly integrating into health care and formal and informal care. Additionally, ROSIA Catalogue would work in two ways: make available high-tech innovations with positive clinical evidence and impact for both clinicians and patients; and open opportunities for the European industry to better scale their products into the primary public sector buyer group using ROSIA ecosystem as sandbox and future deployment of developed solutions (always compliant with ethics and data safety).



For Phase 3, the main expected output has been the successful completion of the field-testing of the prototypes developed in Phase 2 by the selected contractors in the environment of the three final users (SALUD, ULS, NRH). For that purpose, the contractors were expected to conduct the following actions:

Preparation:

- Deploy the cloud infrastructure for the ROSIA open platform, the SDK for ROSIA developers, and the ROSIA Catalogue.
- Deploy the sandbox testing tools matching procurers ICT systems setting.
- Integrate the services in the Catalogue that will cover the needs of the patients according to the selected pathologies and modalities of care (validation with the developers users).
- Support procurers in the design of the integrated care models, defined by each procurer, by making use of the tools for the share care plan design for each of the involved pathologies (validation with the healthcare system users).
- Support and train procurers' health care team in the use of the individualised care plan per patient and the services from the ROSIA Catalogue (validation with the healthcare professional users).
- Refine some functionalities to adapt them into the clinical practice of the professionals
- Run intensive testing of the whole system including the services proposed in the ROSIA Catalogue.

Roll-on (validation with the healthcare professional users and patient users):

- Support clinicians and patients in the set-up and use of the selected services according to the description of the "Validation requirements" set for each site.
- Provide support and maintenance to clinicians, patients and their care network during working hours in the operation of the services.
- Keep an updated scoreboard with the proposed KPIs for follow-up.

The final report from contractors at the end of the Phase includes the evaluation of the solution performance, including field testing outcomes and impact report. It also includes:

- A complete description of validations performed: Pilot preparation and Third Party Solutions (TPS) integration, Deployment, installation and support, Solution performance and Technical results
- A section that explains the IPR measures taken by the contractor to protect the results.
- Updated business model and commercialisation plan
- Overall lessons learnt and results achieved from the PCP

During this phase, the maximum budget per contractor was 1,450,000.00€ (Spanish VAT, 21%, included).

(PCP procures R&D services at market price, thus providing contractors with a transparent, competitive, and reliable source of financing for the early stages of their research and development. Giving each contractor the ownership of the IPRs attached to the results it generates during the PCP means that they can widely exploit the newly developed solutions commercially. In return, the tendered price must contain a financial compensation for keeping the IPR ownership compared to the case where the IPRs would be transferred to the procurers (the tendered price must be the 'non-exclusive development price').



## 2. Impact on public sector modernization

*Describe briefly (in a way that is suitable for publication purposes):*

**To what extent the innovative solutions managed to meet the procurement need so far** (which tender requirements were the innovative solutions not able / able / more than able to meet)? For PCPs, specify whether all participating contractors managed to complete the previous phase successfully Did their solutions all meet the procurement need / the tender requirements? What is the current impact of the innovative solution on end-users?

The three contractors participating in Phase 2 completed it successfully, managing to propose promising and valid solutions to satisfy the buyers' unmet needs during Phase 2.

In Phase 3, the two contractors awarded (consortia led by Ethniko Kentro and Fundació Eurecat) have focused on testing their solutions in real environments with developers, patients and clinicians. Efforts have focused on adapting the platforms, their interfaces and functionalities (both for patients and clinicians), in order to meet the requirements of the buyers at each site, taking into consideration the particularities of their healthcare systems and current care delivery processes.

In addition, constraints imposed by regulatory requirements and Ethical Committees for the testing were communicated by the Buyers Group to both contractors, who had to adapt the solutions to be piloted while maintaining the main objectives, technical requirements and challenges defined in the original tender specifications.

Regarding the impact of the innovative solutions on end-users, the solutions has successfully reached TRL7, as planned.

Reaching **TRL 7** in the PCP means that the rehabilitation platform has evolved from a research prototype into a **fully functional and integrated system demonstrated in a real clinical environment**. The solution has been **tested with healthcare professionals and patients**, showing that it operates reliably under real-world conditions and meets the technical, usability, and safety requirements of the healthcare setting. This achievement confirms the platform's **technical maturity and readiness for large-scale validation or early deployment**, marking a critical step toward future certification, commercialization, and adoption in routine rehabilitation practice.

For contractors this is a remarkable milestone.

To progress from **TRL 7 to TRL 8**, which is out of scope of this PCP, contractors will need to focus on **finalizing development, validation, and regulatory readiness**. This stage involves refining the platform based on feedback from real-world testing, ensuring **full compliance with medical, ethical, and data protection standards** (such as MDR and GDPR), and conducting **extended clinical validation studies** that confirm its performance, safety, and effectiveness at scale. Contractors should also prepare the **technical documentation and quality management systems** required for certification, while advancing **industrialization, interoperability, and maintenance plans**. Achieving TRL 8 will demonstrate that the platform is not only technically robust but also **ready for deployment in operational healthcare settings and market introduction**.

For the **buyers**, the PCP experience has been a **crucial step in analyzing their real needs and supporting future adoption decisions**. Through direct experimentation with innovative solutions, clinical and technical teams have gained a **clearer understanding of the functional, technical, and organizational requirements truly needed** for a rehabilitation platform to be effective and sustainable in their context. This shared learning process has strengthened their ability to **formulate evidence-based procurement demands** and to **align technological innovation with actual healthcare priorities and operational workflows**. As a result, the buyers are now **well positioned to define a clear adoption strategy**, building on the knowledge and evidence gathered throughout the PCP process to identify the **most suitable technological options**, the **organizational changes required for integration**, and the **procurement pathways** that will enable the solution's sustainable implementation.

**What level of quality / efficiency improvements do the innovative solutions enable to achieve** (use measurable indicators to quantify the impact achieved on the operation of your public service, e.g. *25% reduction in maintenance costs, 30% reduction in mortality rate of patients in your hospital*)



ROSIA model aims to enable the deployment at scale of the paradigm shift from hospital-based to home-based rehabilitation, including patient self-management, enabled by disruptive technologies and new ways of working, starting with designing and testing its application in the rehabilitation processes of people living in remote areas. The approach is to be first validated in the field of rehabilitation but is expected to become a game changer for any long-term condition, initially addressing the needs of people in remote areas, but paving the way for full coverage of all the population in need of rehabilitation.

Regarding the expected key performance indicators (KPIs), while some limitations were encountered during impact measurement—such as modest and heterogeneous patient sample sizes across sites and pathologies, and a relatively short pilot timeframe—the project was still able to demonstrate meaningful results.

To obtain Ethics Committee approvals, the pilots primarily focused on usability and user adherence. In response to these constraints, the KPI calculation methodology was adapted accordingly. This adaptation was complemented by qualitative assessments and literature reviews for selected indicators, allowing for a more comprehensive evaluation of the project's outcomes and impact.

In this regard, both solutions (Rehabify and RAISE) were able to increase the overall number of contacts with care team as a result of telerehabilitation. This increase was of a 128.3% in the case of RAISE, and a 365.7% in the case of Rehabify. In terms of user adherence, behavioral changes were observed throughout the testing of the pilots in the sites, in terms of adherence to rehabilitation routines (EARS), perceived autonomy and self-management (IEXPAC), and ease of integrating telerehabilitation into daily life (SUS usability perception). These parameters increased in comparison to traditional rehabilitation and reflect the impact of ROSIA on patient engagement and self-care. Similarly, both solutions achieved an increase in user capability to use the ROSIA remote rehabilitation platform, with more than the 50% of involved patients reporting familiarity and comfort with the platform in both cases. Regarding interoperability, between the two solutions, a total of 15 third-party solutions (TPS) were successfully incorporated, and a TPS integration and support process was developed.

### 3. Other benefits obtained

*Describe briefly any other benefits obtained from the procurement, not only for the public procurers involved but also wider benefits for society (in a way that is suitable for publication purposes), e.g.:*

**-Reducing market fragmentation:** ROSIA project is willing to unlock the tele rehabilitation market by purchasing the development of a technological innovation ecosystem, enabling service providers to provide tele rehabilitation, and self-management & self-care of rehabilitation at home, at scale.

**- Wider benefits to society:** Increasing **equity, quality of care, and efficiency** and so contributing to the **long-term sustainability of the health care system:** capability of treating patients directly at home and at a lower cost than it would be possible without using ROSIA solution; increasing treatment intensity and duration and thus, improving the rehabilitation outcomes and the quality of life of patients; capability of delivering these rehabilitation services to more patients using the same available resources.

**-Contribution to growth and jobs:** For the two contractors implementing Phase 3, all staff involved (100%) was either from EU or H2020 associated countries.

**-Triggering other innovation procurements:** the partners are discussing and gathering information on the way forward to a post-PCP purchase. In particular, funding programmes, like Public Procurement of Innovation (PPI) schemes, are being considered and evaluated for suitability.

**Other benefits / lessons learnt:** *complete if applicable*

**-Budget Constraints and Procurement Expectations**



Aligning procurement expectations with available budgets presents a significant challenge. During the preparation of tender documents, it is necessary to calibrate the ambitions of procurers to the financial resources at hand. In some cases, concerns about feasibility have led to certain requirements being framed as “desirable” rather than essential. Although initial contractor proposals may reflect a strong commitment to addressing all specified challenges, subsequent project phases often reveal limitations. Contractors may revise their deliverables to meet only the minimum contractual obligations, which, while legally compliant, may fall short of initial expectations.

### **-Evaluation and Assessment Capacity**

Professional evaluation of contractor proposals and deliverables requires the ability to distinguish between aspirational language and concrete commitments. This skill is critical to ensure that project outcomes align with procurement objectives. Training in this area is recommended to strengthen assessment capabilities across PCP initiatives.

### **-The Time Paradox in PCPs**

Multidisciplinary collaboration and co-creation are key drivers of innovation within PCPs. However, they also introduce a paradox: while PCPs are designed to foster innovation, their extended timelines can hinder the rapid development and deployment of new solutions. At the same time, project milestones impose pressure to accelerate progress, often at the expense of thorough iteration and refinement. This tension between the need for speed and the value of collaboration underscores the importance of balancing efficiency with quality. Not all objectives require rapid execution; some merit the time necessary to ensure robust and sustainable outcomes.

### **-The Rigidity Paradox in PCPs**

Innovation inherently requires flexibility—to adapt, iterate, and respond to emerging insights. However, PCPs are structured around predefined phases and rigid timelines, which can constrain the innovation process. The strict scheduling of tasks and deliverables may limit opportunities for further demonstrations, refinements, or unexpected breakthroughs. To fully support innovation, PCP frameworks should consider incorporating mechanisms that allow for adaptive planning and responsive adjustments.

**Lessons learned and recommendations for the European Commission** (from White Paper on Challenges, lessons learned and recommendations for PCPs implementation elaborated by group 2Care4EU):

#### **- Policy and process improvements:**

- Establish a dedicated regulatory helpdesk to support PCP implementation. A centralised helpdesk could guide procurers and suppliers on legal, compliance, and procurement-related challenges, ensuring smoother PCP execution and reducing administrative burden.
- Encourage more flexible procurement models that allow for iterative development, phased funding mechanisms, and adaptability to emerging technologies while maintaining compliance with EU procurement rules.
- Simplify ethical and regulatory approvals: Streamlining ethical clearance and MDR compliance processes would prevent lengthy delays that currently hinder PCP implementation. Coordinating with national regulatory bodies to align approval processes would enhance efficiency.

#### **- Strategic vision for the future of PCPs:**

- Enhance monitoring and impact assessment of PCP-funded solutions. Implement systematic tracking of PCP-funded innovations to assess their long-term adoption, scalability, and economic impact. This would provide valuable data, such as adoption rates and/or cost savings to improve future PCP funding and policy decisions.
- Align PCPs with broader EU Health and Data Strategies. Ensuring PCPs align with initiatives like the European Health Data Space (EHDS), AI Act, and Digital Health Strategy will improve integration and adoption.

#### **- Enhancing PCP impact:**



- Ensure timely allocation of funding for sustainability actions beyond project timelines. Many PCP innovations fail to transition to full-scale adoption due to a lack of financial support after project completion. Dedicated funding mechanisms should be available at the right time to bridge this gap, ensuring that promising solutions receive the necessary resources for commercialisation, deployment, and long-term impact.
  - Expand support for clinical trials, MDR certification, and early-stage pilot design. Many PCP solutions face barriers in obtaining market approval, particularly in regulated sectors like healthcare. Additional funding and advisory support for clinical trials, CE/MDR certification, and regulatory navigation would improve the market readiness of innovative solutions.
  - Encourage public-private partnerships (PPPs) for co-financing PCP innovations. Establish incentives and funding schemes to attract private-sector investment in PCP-developed solutions.
  - Reduce the administrative burden on PCP participants. PCPs' administrative complexity can deter participation from small companies and startups. Streamlining application processes and compliance requirements would improve inclusivity and participation rates. Besides, more agile and flexible mechanisms may be better adapted to healthcare organizations' innovation needs and challenges.
  
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#### 4. Scalability — Wider deployment<sup>1</sup>

Describe briefly (in a way that is suitable for publication purposes):

**How easy it would be for other procurers to deploy the solutions resulting from the procurement** (which parts of the solution are generic /can be replicated by other procurers across Europe versus which parts would still need adaptation / modification to other markets etc.)

ROSIA is by design ready to be easily adapted to any EU Healthcare system. The joint procurement facilitates the achievement of this goal by defining a unique set of requirements for the current three participant regions. Interoperability with existing IT systems at each Health Care region is an unavoidable task for integration, which complexity will depend on the level of standardization of such systems, but ROSIA is expected to be flexible enough to integrate with any organisational model in place and will facilitate that this integration is made only once, not for every app/service.

**What actions did you already take to help diffuse the innovative solutions to wider markets e.g.**

- did you / the suppliers in your procurement contribute to standardisation
- did you / the suppliers publish results / lessons learnt of the procurement
- did you require the solutions for your procurement to be based on open interfaces / open source?
- did your dissemination activities promote results / impacts achieved to other procurers?
- did you help the suppliers to go for wider commercialisation of the innovative solutions (e.g. via joint supplier-procurer presentations of the solutions/impacts at trade fairs, actively acting as first customer reference to other customers, introducing the suppliers to investors, etc.)
- at the end of the project: did you update the initial tender specifications with the lessons learnt during the procurement and did you publish these updated tender specifications so that other procurers can use them in future procurements?

Because ROSIA is designed to be adopted by as many health systems as possible, it is built on an open platform and includes a software development kit. Everyone, both demand and supply, benefits from creating critical mass. The decision-making process within public health systems requires the availability of clinical and cost-effectiveness evidence. For this reason, we have postponed dissemination to procurers until we have been able to, or are in the process of, generating this evidence, which will be during Phase 3.

According to this initial approach, during Phase 3, several initiatives were carried out to, on one side, disseminate the project in general, and, on the other side and more specifically, to promote its results among end-users (clinicians and patients) and potential buyers. Thus, suppliers showcased their prototypes in several fairs and conferences and, through their business plan, have been working on identifying potential market opportunities.

On the consortium side, various actions were performed to diffuse the innovative solutions. On one hand, a series of co-creation sessions were carried out with stakeholders related to the project, namely patients, clinicians and application developers. The last-mentioned session was especially fruitful since it helped suppliers (who were present in all the sessions) to identify and get in contact with companies and research centres that have telerehabilitation tools that can potentially be integrated into the Rosia platform.

Additionally, throughout this Phase, the coordinator shared with partners and suppliers potential congresses and events where the results could be presented and disseminated, along with graphical material (two pager, roll-up...) that could be used to showcase the project.

Regarding the dissemination to other procurers outside the consortium, several actions have been planned for the last months of the project, once the exploitation plan strategy is defined:

- Exploitation webinar: prior to this webinar, a list of 2nd tier procurers with potential interest in the innovative solutions has been prepared. They will be invited to join the webinar in which the final results will be presented and the possibilities for adoption will be discussed
- Policy workshop: in this session, the lessons learnt of the project, along with the challenges encountered will be shared and discuss with the mentioned 2nd tier procurers as well as representatives of the European Commission
- Publications: a positioning paper will be elaborated and distributed among the potential buyers, together with the lessons learnt that are currently under development

**Which aspects of the initial tender specifications (*in particular functionality / performance / price requirements*) you would change / update after this procurement based on the lessons learnt, to make sure that later procurements that go for wider deployment would run as smoothly as possible**

When preparing the tender documents, it is necessary to adapt our expectations to the available budget. The fear of asking for more than is feasible has led in some cases to the requirement being presented as a proposal, and although the initial bids from contractors appear to be enthusiastic about meeting all the challenges, as the project develops and complications arise, some contractors make an adjustment to the minimum commitments, which may not meet the initial expectations, even if they are in line with the legality of the contract.

