

From challenge to adoption: Acceleration of paediatric orphan medical devices

Tender for Contracting

WP2: Implementation of the "Acceleration 4RARE" programme







1. Content

| 1. | . 11 | NTRODUCTION: | 2 |
|----|------|---|---|
| 2. | . C | CONTRACTING SERVICE: | 3 |
| 3. | R | REQUIREMENTS FOR THE SUPPLIER: | 3 |
| 4. | R | REQUERIMENTS FOR THE PROPOSAL OF SERVICE: | 3 |
| 5. | . V | VORKING METHODOLOGY: | 3 |
| 6. | В | BUDGET: | 3 |
| 7. | S | SUBMISSION OF PROPOSALS AND EVALUATION: | 3 |
| | 7.1. | . Deadline for the submission of the proposals: | 3 |
| | 7.2. | Documentation to be submitted: | 3 |
| | 7.3. | Criteria of evaluation: | 3 |
| 8. | . C | CONTRACT DURATION: | 4 |
| 9 | А | ADDITIONAL INFORMATION: | 4 |

INTRODUCTION:

The requested services are part of the i4KIDS 4RARE project, cofounded by the European Health and Digital Executive Agency of the European Union – No 101161079.

Spinal muscular atrophy (SMA) is a group of inherited neuromuscular disorders caused by deletion and/or homozygous mutation of the 5q SMN1 gene, which predominantly affects the motor neurons of the medullary anterior horn, causing progressive muscle weakness and atrophy. The loss of lower motor neurons leads to progressive muscle weakness, muscle wasting (atrophy) and low muscle tone (hypotonia) that is typically more pronounced in muscles closest to the trunk of the body (proximal muscles) such as the shoulders, hips and back. However, neurons controlling most voluntary muscles can be affected, including those that control muscles involved in feeding, swallowing and breathing. The incidence of SMA is approximately 1 in 10,000 live births, and it affects females and males equally.

The rehabilitation exercises performed in non-ambulatory patients can be repetitive and uninspiring for the patient, thus reducing their motivation and adherence to treatment. In addition to this, for patients using wheelchairs it can be more difficult travelling to reference centres that are far away from their homes, to perform rehabilitation sessions. Being able to perform at-home exercises with the supervision of the therapist is an ideal situation.

For these types of patients, who need to perform almost daily rehabilitation routines, maintaining the motivation becomes a challenge. Additionally, for the portion of therapy that patients complete at home, the inability to monitor their compliance with the prescribed exercise regimen makes traditional rehabilitation outcomes difficult to predict, and potentially less likely to succeed.

Thus, there is a need to provide a new way to promote home rehabilitation for those patients, while monitoring their exercises and increasing their adherence.

To address this unmet need, the HSJD's rehabilitation and innovation teams have been working together to design a Virtual reality (VR) video game for home rehabilitation of SMA-II-III patients to improve adherence to home rehabilitation treatment and monitor their exercises to follow their progress (Fantastic Quest).

i4KIDS 4RARE is an accelerator initiative specific for rare diseases and orphan medical devices. This program showcases its power by **accelerating a device in Pediatric Motor Rehabilitation**.

The scope of the i4KIDS 4RARE project is divided into the following Specific Objectives:

- Demonstrate validation and valorisation capability of the identified medical device solving an unmet medical need in the area of spinal muscle atrophy in young children and adolescents.
- Demonstrate the potential of a challenge-based programme (industry and clinical) in paediatric rare diseases.
- Communicate and disseminate the activities and results of i4KIDS 4RARE to raise awareness and actively involve and engage stakeholders.

2. CONTRACTING SERVICE:

i4KIDS 4RARE is looking for an external organization for the development of a proof of concept (PoC) to validate the feasibility of implementing a virtual reality video game (Fantastic Quest) to monitor and increase adherence to home rehabilitation of young children and adolescents with spinal muscle atrophy (SMA). Once the PoC has been developed, a small pilot study will be carried out to validate safety and some efficacy data before further valorisation activities are undertaken.

The **prototype video game** will allow testing the monitoring and viability of home rehabilitation through virtual reality.

3. REQUIREMENTS FOR THE SUPPLIER:

- Proven expertise in the narrative and creative aspects of VR video game development.
- Ability to adapt to the schedules and availability of clinicians.
- Demonstrated experience in the healthcare industry.

4. REQUERIMENTS FOR THE PROPOSAL OF SERVICE:

Design the framework to create every deliverable detailed in this tender, including:

- Detailed planning of creation and validation process.
- Calendar
- Team
- Budget

5. WORKING METHODOLOGY:

The selected contractor will work under the coordination of FSJD and collaborate with other consortium partners. To ensure alignment with the proposal, bi-weekly or monthly online meetings will be organized.

6. BUDGET:

The quality of the service descriptions and the proposed budget will be key factors in the contractor selection process. Please note that the primary objective is the development of a prototype, not a final solution.

7. SUBMISSION OF PROPOSALS AND EVALUATION:

7.1. <u>Deadline for the submission of the proposals:</u>

The deadline to submit proposals is 15 days after the publication of this tender at 12pm CET.

7.2. Documentation to be submitted:

- Documentation about the supplier: Credentials with case studies of related content or actions
- Composition of the team: Resume of the staff involved in the activities.

7.3. Criteria of evaluation:

An interdisciplinary team from FSJD and HSJD will assess the submitted proposals. This team will include:



- Innovation Project Manager of Fantastic Quest
- Project Coordinator of Fantastic Quest
- Principal Investigator of Fantastic Quest

The proposals will be evaluated based on both expertise and proposed activities. The evaluation criteria and maximum scores are as follows:

- Expertise of the institution in video game development: 5 points
- Relevant case studies with similar content: 5 points
- Creation and validation process: 10 points
- Budget: 5 points

Proposals must achieve a minimum of 20 points to be considered for the contract. The contractor with the highest overall score and the most reasonable budget will be selected.

8. CONTRACT DURATION:

The contract will start as soon as the organization has been selected and the provision of services contract has been signed by both parties and will last until the end of May 2026.

9. ADDITIONAL INFORMATION:

For any additional information related to this tender, the contact person and email will be: sofia.ferreira@sid.es