



CALL FOR RESEARCH PROJECTS

Rules for submission of projects

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1. Executive Summary

This document describes the Call for Research Projects in the Share4Rare (S4R) platform. S4R uses collective intelligence for the generation of awareness and advanced knowledge to perform research in the field of rare diseases.

The Call will be open from **October 5th CEST** to **November 30th at 17:00h CEST**.

2. The Share4Rare Project

The mission of Share4Rare is to boost research in rare diseases through new knowledge generated from connecting patients, carers and researchers.

Share4Rare is a collaborative digital research platform for people living with a rare disease and their caregivers and families. It incorporates Artificial Intelligence to display a friendly network of peers sharing the same diagnosis, symptoms, or location.

The platform is a secure and private environment where patients and caregivers from all over the world can drive their own research initiatives in rare diseases. Share4Rare enables researchers to gather patient and carers reported outcomes on disease related questions and other areas of scientific interest: burden and impact of the disease, its natural history, side effects of treatment, prognosis, etc.

Share4Rare research tool benefits

Use a global, secure and private platform to collect clinical data and patient reported outcomes from patients and caregivers.

Promote a patient-centred approach to perform research projects based on the clinical data donation of the patients/caregivers.

Access to a data science services to study and analyse the data collected in the platform.

Dedicated team with expertise in the collaborative research initiatives using digital platforms in the field of rare diseases.

Access to patient reported outcomes library. Available:

- PROMIS Paediatric Item Bank v2.0 – Pain Interference;
- Neuro-QOL Item Bank v1.0 –Paediatric Social Relations- Interaction with Peers;
- Neuro-QOL scale on paediatric mobility;
- Neuro-QOL Scale v1.1 –Paediatric Upper Extremity Function- Fine Motor, ADL;
- Neuro-QOL Scale v1.1 –Paediatric Lower Extremity Function- Mobility;
- Neuro-QOL Item Bank v1.0 –Paediatric Social Relations- Interaction with Peers;
- PROMIS® Paediatric Item Bank v2.0 – Depressive Symptoms – Short Form 8a;
- PROMIS® Paediatric Item Bank v2.0 – Anxiety – Short Form 8a;
- OVAMA questionnaires on symptoms/appearance and satisfaction with treatment and outcomes;
- MiniMac Mini Mental Adjustment to Cancer;

- SF-36 Health Survey.

Participants obtain immediate feedback. After finalizing the survey, it is displayed an anonymised graph of all the answers.

Basic 'tool kit' for future Citizen Research projects with forms, templates, support material, customisable home page, etc.

Standard Operating Procedure linking project submission, ethics board approval and general access to the services of the platform

3. Objective

The objective of this Call is to select 2 research projects to be co-implemented and developed on the Share4Rare platform during the period January 2022-December 2022.

4. Calendar

This Call will be open from **October 5th CEST** to **November 30th at 17:00h CEST**.

The evaluation process will consist of 2 stages: Admission and Evaluation.

Fundació San Joan de Déu (FSJD) holds the right to modify the scheduling of the Call due to internal requirements.

5. Application Process

To initiate the submission process, project applicants must complete the **contact form** and the **application form** and provide all the required information.

5.1 Documents to be submitted

Contact form and **application form** have to be completed and sent to the attention of the Share4Rare coordinator together with a signed version of the **financial commitment**.

Contact form and **application form** contain a list of questions that can be found in Appendixes 1 and 2, respectively.

Applications must be completed in English. The coordinator of Share4Rare (FSJD) reserves the right to request for translation of official documents into English, when reasonably justified.

The organization will have access to the information of the applications.

5.2 Who can apply?

Patients' organisations or academic institutions, and other related stakeholders interested to promote patient-centred research in rare diseases.

6. Evaluation Process

The evaluation process is composed of two stages: admission and evaluation. In the first stage, eligibility checks will be conducted by the coordinator of Share4Rare (FSJD). All pre-selected applications will be reviewed to ensure the fulfilment of the criteria published in this rules for Participation. Any application which does not fulfil the criteria published in this Rules for Participation or that do not have the mandatory documents will be rejected and a notification will be sent to the applicant.

6.1 Stage one: Admission

Admissibility check of the proposal

Each application will be first assessed against the admissibility criteria described below.

Admissibility criteria of the proposal

- Submitted through info@share4rare.org before **November 30th at 17:00 CEST**.
- Proposal in English with all the sections completed.
- Only one proposal per investigator/responsible/research group.

6.2 Stage two: Evaluation

Once the admissibility criteria have been checked, the evaluation process will be conducted.

The coordinator of Share4Rare (FSJD) will ask for assessment to an *ad hoc* Data Access Committee (S4RDAC). S4RDAC, consisting of experts belonging to the Share4Rare Consortium and external institutions, is composed by a representative of the coordinator of S4R project, one patient representatives, one data scientist, 2 clinical experts to be confirmed ad hoc. S4RDAC will evaluate each application based on the information available in the application form.

If deemed necessary for adequate evaluation, the applicant can be invited to an online/phone interview to present the research project in more detail.

The S4RDAC will decide if the project proposed is approved to be developed within the Share4Rare framework.

During evaluation, experts are asked to score each application that is assigned to them according to three criteria:

Research impact (Score 1-10): score in terms of expected impact of the research project:

- a. Commitment from the applicant to recruit patients to be involved in the research project.
- b. Quality and innovation of the proposal/Research question.
- c. Uniqueness of the study.

Alignment with the interests of the community of patients, proposals covering unmet medical needs will be prioritized.

Network impact (Score 1-10): score in terms of expected impact of the investigator and the research project in the Share4Rare community:

- a. Willingness to participate in the dissemination and communication activities of the research project.
- b. Availability to produce reliable information on the disease.
- c. Willingness to share the Share4Rare platform within their Social Media and institution communication tools.

The evaluation will include comments to clarify and/or justify each of the scores. These comments must be consistent with any scores awarded and serve as input to any consensus discussion and related consensus report. The minimum threshold to retain an application for each individual criterion is 7. The overall threshold, applying to the sum of the two individual scores, is 15. Applications not reaching these minimum thresholds will not be considered for use of S4R platform.

7. Selection process

7.1 Consensus Meeting

Once all the S4RDAC members have completed their individual evaluations, a consensus panel meeting is held. In this meeting, all applications are discussed, and a consensus view is reached on scores, comments and recommendations.

The consensus discussion is moderated by a chairperson ("the moderator"). The role of the moderator is to seek a consensus between the individual views of independent members without any prejudice for or against a particular application or applicant data source, and to ensure a fair and equitable evaluation of each application according to the defined evaluation criteria. If needed, the S4RDAC can request an interview with the applicant during the consensus meeting.

As a result of this joint revision of applications by the S4RDAC, all will get a final score and received it via an Evaluation report. Such report will include the consensus scores and comments for each eligible application, and the overall ranking. Comments to each application should be suitable for feedback to the respective applicants.

If during the consensus discussion it is found that, despite all reasonable efforts to reach consensus, it is impossible to bring all the experts to a common point of view, the moderator may propose actions to reach resolution, which may include a phone/online interview with one or several of the applicants.

7.2 Feedback on the evaluation process

The Share4Rare Coordinator will send an information letter, together with the Evaluation Report relative to the specific application, to all eligible applicants. The applications found to be ineligible or failing to reach any of the threshold scores for evaluation criteria will be formally rejected by the S4RDAC. Rejection does not prevent an applicant to apply again to subsequent calls.

7.3 Appeal Procedure

Applicants have 20 calendar days from the date of sending of the formal decision letter to appeal on the outcome of the evaluation process. This can be done by submitting a reasoned complaint in writing to Share4Rare coordinator at the email address: info@share4rare.org. Share4Rare coordinator will confirm receipt and check if all review procedures have been fully respected and no content has been inadvertently omitted or overlooked during evaluation (e.g. due to technical problems with the portal), and will answer to the applicant within 20 calendar days from the date of reception of the letter of complaint. The Share4Rare coordinator will not re-evaluate the proposal and consequently will not call into question the judgement of the appropriately qualified group of experts that form the S4RDAC.

8. Financial contribution

The total cost of a research project will be 30.000 EUR. This amount will be dedicated to cover:

- **Dedicated staff to guide patients** through the research project and to monitor patient enrolment.
- **Ethics committee** application.
- **IT support** to develop the research project on the S4R platform.
- **Engagement and communication activities** and other services to promote the research project.
- **Monthly (or weekly) feedback reports on the project status.**
- **Data analysis** services including data curation.
- **Report of the results.**
- **Scientific publication advisory support.**
- **Crowdfunding tool.**

FSJD will **CO-FINANCE 50 % of the expenses related to the management** of the research project. All application must agree on a **financial commitment to contribute with 15.000 EUR funding to Share4Rare platform** to cover the expenses incurred from their research project

When necessary, **Share4Rare will facilitate access to a crowdfunding tool** embedded in the platform to help collect the funding necessary to cover the expenses of the research project.

The research project will begin with the approval of the S4RDAC and 30 natural days upon the payment of the 15.000 EUR contribution.

9. General obligations

The use of Share4Rare should be cited on the same basis all software that was used to generate and analyse data in scientific publications. Share4Rare team members won't appear as author in the publications (unless this is requested).

9.1 Confidentiality

The confidentiality of the applications presented is guaranteed throughout the entire process. In any case the general characteristics of the applications may be disseminated and, in course, the name of accepted projects (included logo) a brief description, the name of the project and his/her photo may be published through, without limitation, press releases, e-mails, and website to communicate information about the Call.

The information content and the results of the projects, as well as any other information and documentation exchanged within the framework (including information regarding other project participants) of the Call shall be considered confidential information (hereinafter the “**Confidential Information**”).

The Share4Rare Coordinator, the Committee and all the applicants, as well as any other person attending the activities, shall undertake, unless prior authorization in writing is received from the other parties, to:

- Keep the Confidential Information strictly confidential and not to disclose it to any Third Parties.
- Not use the Confidential Information for any purpose other than the development of the project.
- Restrict access to the Confidential Information exclusively to those employees, collaborators, and/or professional advisers that, under the obligation of confidentiality, need to access the Confidential Information strictly for the devilmnt of the Project; and
- Return the Confidential Information without keeping any copies or summaries when the Call is terminated.

Confidential Information does not include information that: (a) is or becomes publicly known or available before or at the moment at which it is received or obtained; (b) the information is obtained without being subject to any confidentiality obligation; or (c) the disclosure of the information is required by law or judicial order in which case said disclosure request must be previously notified, in advance, to the other party, so that the latter can implement the actions it considers necessary to prevent or limit the disclosure.

9.2 IP Rights

Under no circumstances will the Call be construed as an assignment or transfer of any industrial and/or intellectual property right held or owned by the applicant prior to the research project or of any other industrial and/or intellectual property right obtained as a result of the development of the research project. At the time of application to this Call and at least until the moment of research project is implemented and developed on the Share4Rare platform, all intellectual and/or industrial property rights over the assets shall be owned by the applicant.

In the event that the applicant is selected, a co-ownership agreement will be signed between the parties.

9.3 Data Protection

The applicants authorize Share4Rare Coordinator to access, use, and share information from the projects submitted to the Call, including all documents referred to therein, whether submitted at the time of the application or at a later stage, for the purposes of this Call and to the extent necessary, including but not limited to, the evaluation, selection and following up the projects.

Data subjects can ask for more information and/or exercise their rights of access, rectification, erasure, restriction, portability, and objection before the Data Protection Officer of FSJD at Carrer de Santa Rosa, 39-57, 08950 Esplugues de Llobregat, Barcelona or at the e-mail address are dpd@sjdhospitalbarcelona.org.

9.4 Other obligations:

1. Applicants shall collaborate with Share4Rare representatives on the implementation of the activities indicated in the proposal in line with the highest quality standards and state-of-the-art scientific development, and in compliance with the provisions of all legal obligations under applicable EU, international and national law.
2. Applicants are sole responsible for the recruitment of users for their research study, which will be supported by Share4Rare dedicated staff on the registration, validation and enrolment to the study.
3. Applicants must provide any information requested by Share4Rare in writing at any time to verify the proper implementation of the activities in compliance with the general obligations.
4. Applicants must immediately inform Share4Rare of any situation affecting the implementation of the activities foreseen in the proposal. In particular the applicant must promptly provide any relevant information on:
 - a. any obstacles and/or limitations that may prevent or are likely to affect or delay implementation of the activities foreseen in the proposal;
 - b. any relevant changes in the applicant legal, financial, technical, organisational or ownership status that may affect implementation of such activities;
 - c. any circumstances that may affect the applicant's due diligence in the management of the Financial Contribution or the compliance with the obligations of this Call for Research Projects.

Appendix 1 - Contact Form

Contact details of the person in charge of the proposal
Name and Surname
Email
Legal name of the organisation
Address of the organisation
Disease of interest
Title of the project
Objective/s of the project (max. 1000 characters)
Summary of what you intend to do / study (max. 1 page)

Please return the completed contact form to info@share4rare.org.



Appendix 2 – Application form

Research opportunity details
Title of project
Name and affiliation of the person in charge of the proposal
Is a patient organisation involved in the research study? (If yes)
Does this patient organisation have a scientific advisory board?
Research experience of the person in charge of the proposal (or the group) during the past 5 months, if any
Stage of the project
Funded/Pre-funding
If pre-funding, please give details of the planned source of funding and the key dates for submission, resolution and the beginning of the funding
Do you plan to use the Share4Rare Crowdfunding tool to fund your research project?
Yes/No
Has the project been approved by an ethics committee? If yes, please attach the correspondent approval
Yes/No
Please give a summary of the proposed activity in the format provided below
Study title: Justification of the need: Hypothesis: Objectives: What next/who to contact:
Target population - Disease: - Who can participate? - How many patients are you planning to enrol?
Methodology - Stage of the project where are you planning to incorporate the Share4Rare research tool - How many questionnaires will be used? - Are them validated scales? - How many questions per questionnaire?



- Which information do you plan to collect?
- Which statistics will you use?

How will the study benefit people affected by the disease?

Is there any patient organization that will support recruitment?

How do you expect to recruit the users for your research project?

Please notice Share4Rare will not be responsible of the users' recruitment.

Has the project sponsorship of a pharma company? Which is the purpose of this support?

Yes/No

How will you feedback to Share4Rare and the people who get involved regarding how their involvement has made a difference and of the outcome of the research?

