



# CALL FOR RESEARCH PROJECTS

## Rules for Submission

Updated on June 21, 2024

## **Table of contents**

Executive Summary .....	3
Share4Rare. The platform .....	3
Benefits that Share4Rare brings to the research team in the implementation of the project ....	3
Aim of the call .....	3
Financial aid.....	3
Research topics .....	3
Calendar .....	4
Application process and documentation .....	4
Documentation: .....	4
Application process: .....	4
Language of the application .....	5
Who can apply? .....	5
Evaluation process .....	6
Stage one: Admission .....	6
Stage two: Assessment .....	6
Feedback on the evaluation process.....	7
Appeal Procedure.....	7
Financial contribution .....	7
Financial aid.....	8
General obligations .....	8
Confidentiality .....	8
Data Protection .....	9
Other obligations.....	9
Appendix 1 - Contact Form and pre-proposal.....	10
Appendix 2 – Application Form .....	13
Appendix 3 – Letter of Financial Commitment .....	18

## **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.

## **Share4Rare. The platform**

The mission of Share4Rare (S4R) is to enhance research in rare diseases by generating knowledge collaboratively. Conceived as a platform for interaction between patients and caregivers, S4R promotes communication between users who share needs, doubts and daily challenges.

On the other hand, S4R offers researchers a secure infrastructure to carry out their research, with the accompaniment of a team of professionals trained to provide personalized support and facilitate the research process.

## **Benefits that Share4Rare brings to the research team in the implementation of the project**

- Advice from a team specialized in data-driven research initiatives in the field of rare diseases.
- Tools to facilitate research projects, including forms, scales, support material, guides and recommendations.
- Support from Share4Rare team for registration, validation and enrollment of study participants (in case the applicant is responsible for the participants' recruitment).
- Collection of data and clinical information provided by patients and caregivers in a secure and confidential environment.
- Access to data analysis services.
- Advice and support in the dissemination of the research results among participants.

## **Aim of the call**

The objective of this Call is to select research projects to be implemented and developed on the Share4Rare platform.

## **Financial aid**

Share4Rare will be able to provide €6,000 to the project that obtains the highest score based on the criteria of impact on the patient community and patient involvement in the research (see Evaluation Process section). **(Please note that this point was not included in the original Rules of Submission).**

## **Research topics**

Whether qualitative or quantitative research, the projects that Share4Rare encourages are those that facilitate the understanding of aspects of the rare disease such as its impact on the quality of life of people who suffer from it or who live with it, the description of the natural history of the disease, the prognosis of the disease, etc.

## Calendar

This Call will be open from **March 15<sup>th</sup> 2024** to **August 31<sup>st</sup> 2024 at 17:00 CEST** (Please note the application schedule has been extended).

Evaluation process consists of two phases, (1) Admission, which starts with the reception of the contact form, and (2) Assessment, which takes place after the reception of all documentation.

## Application process and documentation

### **Documentation:**

**Contact and pre-proposal form (Appendix 1):** Contains the basic information on the project and the data from the organization and the person responsible of the project. Applicants must send it to [info@share4rare.org](mailto:info@share4rare.org) before **July 15, 2024**.

**Application form (Appendix 2):** This document contains more detailed information on the Project design and needs, as well as some aspects related to the evaluation and selection criteria. The deadline for sending this document is **August 31, 2024**.

**Letter of financial commitment (Appendix 3):** This document states that applicant has the necessary financial resources to carry out the project, whether the financial aid is rewarded or not. This letter must be sent before **August 31, 2024**.

These three documents must be completed and emailed to the attention of the Share4Rare Coordinator: [info@share4rare.org](mailto:info@share4rare.org) within the specified period. The forms and the letter of financial commitment can be found in **Appendices 1, 2 and 3**.

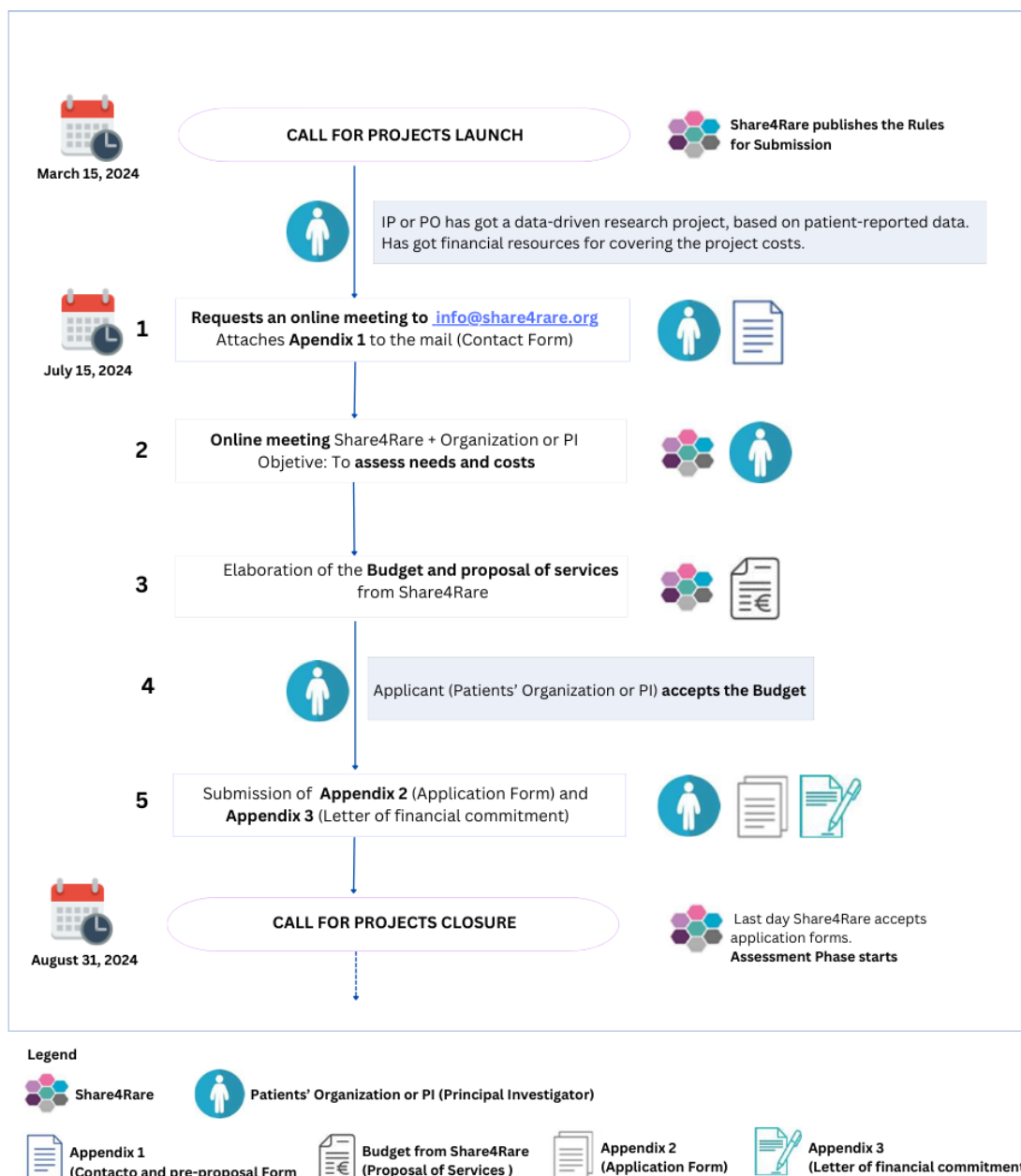
### **Application process:**

While sending the documents, applicants shall ask the Share4Rare Coordinator for an advisory meeting with a double objective: assessing the needs of the proposal and making a first assessment of the services needed from Share4Rare. Appendix 1 will be the base document for the meeting discussion.

Based on the information and agreements from this meeting, the S4R Coordinator will prepare a **Budget and proposal of services**.

Once this Budget is approved, the applicant will send the **Letter of financial commitment (Appendix 3)** and the **Application form (Appendix 2)**, which will contain more information and details.

The following figure displays the submission process:



### Language of the application

Proposals must be written fully in one of the following languages: Spanish, Catalan or English.

### Who can apply?

Patients' organisations or academic institutions and other related stakeholders interested in promoting research in which patients are key for the gathering of relevant information about the rare disease.

### **Evaluation process**

The evaluation process is composed of two stages: (1) Admission and (2) Assessment.

#### **Stage one: Admission**

During this stage, the Share4Rare (FSJD) Coordinator will verify the eligibility of the applications, assuring the compliance of all criteria published in these Rules for Submission.

Also in this stage the advisory meeting between the applicant and the Share4Rare Coordinator will be held. Definition of some of the Project details –type of study, scope, simple details, methodological aspects, etc.– and discussion on the project needs will lead to a definition of the proposal of Services from Share4Rare.

Applications submitted until August 31, 2024 (included) and written entirely in Spanish, Catalan or English will be accepted. Applications must be accompanied by the contact form and the letter of financial commitment. Applications that do not comply with these Rules for Submission will be refused and applicants will be notified.

#### **Stage two: Assessment**

Once the admission criteria have been checked, the assessment process will be carried out.

The Share4Rare (FSJD) Coordinator will evaluate each application based on the information shown on the **application form**.

If needed, the Share4Rare (FSJD) Coordinator may request an online interview to the applicant in order to obtain more information or details on the proposal.

The assessment will take into account the following criteria (Scoring 1 to 10):

- a. *Impact on the patient community: The study or project responds to relevant needs of the patient group.*
- b. *Patients are involved in the design and development of the project or study, as well as in the return of the results.*
- c. Quality and innovation of the proposal/research question.
- d. Sample size is adequate to answer the research hypothesis.
- e. Uniqueness of the study (scope of research, participation of researchers/patients at an international level, etc.).
- f. The proposal considers the creation of informative and educational content related to the study to nourish the Share4Rare platform.
- g. The proposal considers participation in dissemination and communication actions of the project among and outside the Share4Rare community.
- h. The Patient Organization applying to the Call is a registered member of Share4Rare or plans to be, to strengthen the community and serve as a reference for patients.

The minimum threshold to retain an application for each individual criterion is 7. Proposals that do not meet these minimum criterion will not pass the evaluation process.

*The scores on (a) Impact and (b) Patient Involvement criteria will count in the selection of the project susceptible to financial aid (€6,000 bonus)*

#### **Feedback on the evaluation process**

The Share4Rare Coordinator will send a decision letter and an evaluation report to all eligible applicants.

The Share4Rare Coordinator will formally reject all applications not eligible or failing to reach any of the threshold scores for evaluation criteria. Rejection does not prevent an applicant to apply again to subsequent calls.

#### **Appeal Procedure**

Applicants have 20 calendar days from the date of sending of the formal decision letter to request clarification of the evaluation process. This can be done by submitting a request to Share4Rare coordinator at the email address: [info@share4rare.org](mailto:info@share4rare.org). Share4Rare coordinator will confirm receipt and respond to the request within a maximum period of 15 calendar days.

#### **Financial contribution**

After the initial meeting among the applicant and the Share4Rare Coordinator, and based on the information from Appendix 1, the Share4Rare Coordinator will elaborate an estimate budget.

Once budget is accepted, the applicant agrees to assume the cost of the project and will send the Share4Rare Coordinator the financial commitment letter along with the application form.

The amount of financial contribution will be dedicated to cover:

- Ethics committee application.
- Guidance of patients for their enrolment and during the research project.
- Creation of the landing page for the participants' enrollment to the study.
- Design and implementation of questionnaires for patients' data collection.
- Translation of the questionnaires, scales and landing pages to other languages, if needed.
- Design of engagement and communication activities to promote the research project.
- IT support to develop the research project on the S4R platform
- Project management (includes regular meetings with the applicant/research team).
- Data analysis services.
- Report of the results
- Scientific publication advisory support.

The research project will begin with the approval of the proposal and 30 natural days upon payment of 50 % of the budget. The remaining 50% will be due in two terms: 25% in the mid-term of the project, and 25% at the end of it.

### **Financial aid**

If the project is selected for financial aid, the total cost of the project will be reduced by 6,000 Euros. Share4Rare will issue the new updated invoice with the €6,000 discount.

### **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).

### **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, applicants and any other person attending the activities, shall undertake, unless prior written authorization 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 development of the Project.
- 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.

### **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, removal, restriction, portability, and objection before the Data Protection Officer of FSJD at C/Santa Rosa, 39-57, 08950 Esplugues de Llobregat, Barcelona, or at the e-mail address [hospitalbarcelona.dpd@sjd.es](mailto:hospitalbarcelona.dpd@sjd.es).

### **Other obligations**

- 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.
- 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.
- 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.
- 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:
  - any obstacles and/or limitations that may prevent or are likely to affect or delay implementation of the activities foreseen in the proposal;
  - any relevant changes in the applicant legal, financial, technical, organisational or ownership status that may affect implementation of such activities;
  - 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 and pre-proposal**

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, focus of research
Title of the project
Objective/s of the project (max. 1000 characters)

**Summary of what you intend to do / study (max. 1 page)**

**Regarding the population of study:**

**What is the expected sample size?**

**In what countries is the study going to be held?**

**In what languages is the study going to be held?**

**Regarding the timing of study:**

**How long is the Project going to last?** (Please, take into account that the Budget will be annual, but it is convenient to have an estimation of the total duration of the Project, as well as if there will be any iterations on the questionnaires)

**Regarding the design of the study:**

**Write down the name and features of each one of the questionnaires that will be used:**

- **Questionnaire 1:** (Name/Title). Validated/Not validated. Number of questions. Is there iteration? Type of information collected

- **Questionnaire 2:** (Name/Title). Validated/Not validated. Number of questions. Is there iteration? Type of information collected

- **Questionnaire 3:** (Name/Title). Validated/Not validated. Number of questions. Is there iteration? Type of information collected

**Stage of the project: Funded/Pre-funding**

(Please, take into account the mandatory financial contribution and the payment terms)

Please, complete this contact form and send it via email to [info@share4rare.org](mailto:info@share4rare.org)

## Appendix 2 – Application Form

[illegible]

**Stage of the project: Funded/Pre-funding**

(Please, take into account the mandatory financial contribution and the payment terms)

**Has the project been approved by an ethics committee? Yes/No**

If yes, please attach the correspondent approval.

**Please give a summary of the proposed activity in the format provided below (3 pages max.):**

**Justification of the need:**

**Hypothesis:**

**Objectives:**

**Regarding the study:**

**Target population:**

- **Who can participate? (patients, caregivers, specific disease, age rank)**
  
  
  
  
  
  
  
  
  
- **In what countries is the study going to be held?**
  
  
  
  
  
  
  
  
  
- **In what languages is the study going to be held?**
  
  
  
  
  
  
  
  
  
- **What is the expected sample size?**

**Methodology:**

**Write down the name and features of each one of the questionnaires that will be used:**

- **Questionnaire 1:** (Name/Title). Validated/Not validated. Number of questions. Type of information collected
  
- **Questionnaire 2:** (Name/Title). Validated/Not validated. Number of questions. Type of information collected
  
- **Questionnaire 3:** (Name/Title). Validated/Not validated. Number of questions. Type of information collected
  
- **Questionnaire 4:** (Name/Title). Validated/Not validated. Number of questions. Type of information collected
  
- **Questionnaire X:** (Name/Title). Validated/Not validated. Number of questions. Type of information collected

**Describe the data analyses needed to be done by Share4Rare: what variables and what statistical tests**



<p>How will this Project benefit to people affected by <u>(name of disease)</u> _____?</p>
<p><b>Patients recruitment:</b> Will you need support in recruiting patients? (Yes/No)</p>
<p><b>In case the applicant will recruit the patients, please describe how it is going to be done.</b> Please, take into account that Share4Rare will give technical support and guidance to patients enrollment through the online registration process.</p>
<p><b>Has the project got a sponsorship from a pharma company? Yes/No</b></p>
<p><b>If yes, which is the purpose of this support?</b></p>
<p><b>How will you give feedback to Share4Rare and the people who get involved regarding how their involvement has made a difference and of the outcome of the research?</b> (Examples: a <i>thank you</i> letter with the final report, a webinar, a video, an infographic document, etc.)</p>
<p><b>Do you have any dissemination actions planned that will bring visibility to the study and help recruit participants?</b> Please describe them briefly.</p>
<p><b>Is the applicant (Patient Organization) a member of the Share4Rare Community or is planning to be?</b></p>

Please, complete this application form and send it to [info@share4rare.org](mailto:info@share4rare.org)

## **Appendix 3 – Letter of Financial Commitment**

From:

(Name and surname of the proposal's responsible)

(Name of the Organization or Institution)

(Mailing Address)

(E-mail)

To:

Begonya Nafria Escalera

Share4Rare Coordinator

Fundació Sant Joan de Déu (FSJD)

C/ Santa Rosa, 39-57, 08950 Esplugues de Llobregat, Barcelona

[info@share4rare.org](mailto:info@share4rare.org)

Dear,

I declare that I am aware of the economic conditions required for the development of the research project on the Share4Rare platform and that I will comply with the following financing agreements:

- The annual cost of the project will be financed by the applicant\*.
- The applicant commits to make a first payment of 50% of the budgeted cost 30 days after the start of the project, 25% of the budget cost in the middle of the project, and the remaining 25% at the end of the project.

Likewise, I undertake to comply with the financial obligations described in the Rules for Submission and to inform of any change or financial situation that may affect the development of the project.

\*Financial aid: In case the project is selected for financial aid, the total cost of the project will be reduced by 6,000 Euros. Share4Rare will issue the new updated invoice with the €6,000 discount.

Sincerely,

(Applicant's signature)

(Applicant's name and surname)

(Place and date of the signature)

Please, fill in this letter of financial commitment and send to [info@share4rare.org](mailto:info@share4rare.org)