

## RDR Challenges call FAQ

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## Preparation and submission of the proposal

- ↓ Can I participate in only one proposal, even if I am not coordinating?

  One applicant can participate in project(s) submitted to one challenge only.

  Within this challenge, he/she can participate to several proposals.
- Why is it mandatory to nominate a project lead applicant within the consortium of applicants? What will be his/her role?

  Each proposal must nominate a project lead applicant among the project partner principal investigators, excluding the industry sponsor. The lead applicant will represent the consortium externally and will be responsible for its internal scientific management (such as controlling, reporting, and intellectual property rights issues). The lead applicant will also be the contact person for FFRD.
- Is it mandatory to include a patient advocacy organization (PAO) as partner applicant?
  Involving PAO is mandatory for Challenge 3 'Characterize Rare Bone Disorders (RBD) Mobility Challenges in Real World Setting'.
  For all challenges, consortia of applicants are strongly advised to include patient representatives and patient advocacy organizations (PAOs), which are eligible to receive funding for their activities.
  If patient involvement is not deemed appropriate within a research project, this should be explained and justified.
- How should the consortia be composed? Is it mandatory to include in each consortium SME, health service organization and patient advocacy organization?

The Rare Diseases Research Challenges (RDR Challenges) scheme objective is to promote and facilitate active collaboration between academia, Small and Medium-sized Enterprises (SMEs), Patients Advocacy Organizations (PAOs) and Industry.

The consortium submitting an application for a RDR Challenge must involve a minimum of two eligible applicants (researchers <u>and/or</u> health care professionals <u>and/or</u> SME(s) <u>and/or</u> patient advocacy organization(s)) from at least two different countries participating in the EJP RD.

♣ What is the maximum number of partners participating in a consortium? The maximum number of eligible applicants in an applying consortium is six applicants.



Do the industry sponsors count in the total number of applicants of a consortium?

The industry sponsors do not count in the total number of applicants.

- ♣ What is the role of industry sponsors within the consortium of applicants?
  - 1) Before the submission

It is mandatory for every applicant or consortium of applicants to contact industry sponsors before submitting a proposal.

II) Once the consortium of applicants is formed and the proposal is funded

Industry sponsors join the consortium of applicants once the consortium has been selected.

The consortium of applicants has to establish and sign a consortium agreement for cooperation with industry sponsor.

↓ Can other collaborators be participants in the consortium?

There can be other collaborators that do not request funding if it is well justified within the proposal. These collaborators should state in the proposal that they have secured funds to participate in the project. They do not count in the

♣ What is the maximum budget that can be requested per project?

The maximum budget that can be requested is:

maximum number of partners within the consortium.

- 575.000€ for Challenge 1: Development of a non-invasive tool for measuring rare disease patient mobility in daily living
- 487.500€ for Challenge 2: Delivery system for intranasal administration of biological drugs to neonates
- 487.500€ for Challenge 3: Characterize Rare Bone Disorders (RBD)
  Mobility Challenges in Real World Setting
- 487.500€ for Challenge 4: Pre-clinical assay to detect instability of microsatellite repeat expansions
- Are indirect costs (overheads) associated with these awards? Indirect costs and administrative costs are not eligible.
- How to respond to the RDR Challenges call
  You will have to submit a full online application at the outset of the process.



## Results and management of the grants

- How many projects will be funded?
  Only one project per challenge will be awarded.
- When will I get the results of the call? If granted, what will I have to do before receiving the grant?
  List of granted projects will be published in December 2020 on the EJP RD website.

A grant agreement (GA) will be established between FFRD and all participants of the consortium and the industrial sponsor(s) for projects to start by March 2021. The project consortium will have to establish and sign a consortium agreement (CA) for cooperation with industry sponsor.

- ➡ Will each project start in 2021? If so, when will money be available? All funded projects shall start in March 2021 the latest. The first round of funding will be transferred to the lead applicant of the consortium at that time. It corresponds to 25% of the total amount of the first installment proposed by the consortium of applicants and validated by the Scientific Evaluation Committee. The remaining 75% of the first installment will be transferred when the CA is signed.
- → How will funding be managed?

  FFRD is responsible for managing the EC financial contribution.

  Industry sponsor contribution management (financial and in-kind) shall be indicated in the GA: amount/ beneficiaries/ payments etc.
- ♣ Who will receive the budget? The lead applicant will receive the budget from the Call secretariat FFRD in two main installments: for the first phase of 18 months and for the second phase of 12 months only if the project enters the second phase. The in-cash industry sponsor contribution will be sent directly to the lead applicant. The lead beneficiary institution of the lead applicant will receive the funds from FFRD and will distribute it within partners as defined by their activities and as defined in the Grant and Consortium Agreements.
- When financial contribution from industry sponsors has to be provided? And how? And to whom?
  Budget from Industry sponsor will be transferred according to the provisional budget to the lead applicant and associated calendar of the research.
  First instalment which is associated to the 18-month phase shall be granted after GA signature by March 2021.



- ♣ Who are the members involved in the consortium agreement?
  - Industry sponsors
  - Partners belonging to one of the following categories may be involved:
  - •academia (research teams working in universities, other higher education institutions or research institutes)
  - •clinical/public health sector (research teams working in hospitals/public health and/or other health care settings and health organizations)
    - •small and medium-sized enterprises (SMEs)
    - patient advocacy organizations (PAOs)

The FFRD is not involved in the consortium agreement.

What is the role of the consortium agreement?

It sets up rights and obligations of each party during the lifetime of the project. It will address all issues related to ethical considerations, communication, background and foreground IP and confidentiality, exploitation of results, contribution expected from all beneficiaries.

When has the consortium agreement to be signed?

It is mandatory that the consortium signs the consortium agreement early during the lifetime of the project.

