EJP RD Joint Transnational Call 2021

Social sciences and Humanities Research to improve health care implementation and everyday life of people living with a rare disease

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EUROPEAN JOINT PROGRAMME RARE DISEASES

Aims of the call

- To enable scientists in different countries to build an effective collaboration on a common interdisciplinary research project based on complementarities and sharing of expertise, with a clear future benefit for patients.

- To support transnational, innovative, and interdisciplinary humanities and social sciences research projects to improve healthcare implementation and everyday life of people living with a rare disease.

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Definition

The following list of health-related Social sciences and Humanities (SSH) disciplines is used for definition*:

Social sciences, business and law

- Social and behavioural sciences

  Economics, management, sociology, anthropology, demography, geography, psychology, neuropsychology, cognitive science, human rights, law, political sciences, communication, and social studies of science and technology.
- Education science
- Governance

  Public and institutional administration, social and health economic and systems, policy, and social policy

Humanities and the arts

- Humanities

  Cultural studies, linguistics, philosophy, ethics, and history

**Taken from the European Commission (EC), that was adapted from the UNESCO International Standard Classification of Education (ISCED 2011)*

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Definition

Projects shall involve **a group of rare diseases or a single rare disease following the European definition** i.e. a disease affecting not more than **five in 10.000 persons** in the European Community, EC associated states and Canada.

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List of topics

- **Health & social care services** research to improve patient and familial/household health outcomes
- **Economic Impact of Rare diseases**
- **Psychological and Social Impact of Rare diseases**
- Studies addressing the **impact/burden of the delay in diagnosis and of the lack of therapeutic intervention.**
- **e-Health in rare diseases**: Use of innovative technology systems for care practices in health and social services
- Development and enhancement of **health outcomes research methods** in rare diseases
- Effects of **pandemic crisis** and the **global outbreak alert** and response on the rare disease field, and the emergence of innovative care pathways in this regard.

Other research topics are possible as long as they focus on SSH research and are not in the excluded topics list.

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Excluded topics

The following approaches and topics are <u>excluded</u> from the scope of the call:

- Interventional clinical trials to prove efficacy of drugs, treatments, surgical procedures, medical technology procedures. This also includes studies comparing efficacy, e.g. B. two surgical techniques or therapies. Clinical phase IV pharmacovigilance studies cannot be funded either.
- Studies on the exclusive testing of the safety of medical devices.
- Health technology assessment reports (HTA) for a specific product
- Projects focussing on meta-analyses and systematic reviews
- Creation of new registers or establishment of new long-term cohorts and / or promotion of existing registers or long-term cohorts beyond the specific research question of the submitted project.
- Development of new digital or technological tools.
- Projects to accelerate diagnosis and/or explore disease progression and mechanisms of rare diseases as covered in EJP RD JTC 2019.
- Development of new therapies as covered in EJP RD JTC 2020.
- Projects focussing only on rare neurodegenerative diseases which are within the main focus of the Joint Programming Initiative on Neurodegenerative Disease Research (JPND). **Childhood dementias/neurodegenerative diseases are not excluded.**
- Rare infectious diseases, rare cancers, and rare adverse drug events in treatments of common diseases.

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List of participating countries

- Austrian Science Fund (FWF), **Austria**
- Research Foundation Flanders (FWO), **Belgium, Flanders**
- Fund for Scientific Research – FNRS (F.R.S.-FNRS), **Belgium, French-speaking community**
- Canadian Institutes of Health Research – Institute of Genetics (CIHR-IG), **Canada**
- Ministry of Social Affairs (MOSAE), **Estonia**
- French National Research Agency (ANR), **France**
- Federal Ministry of Education and Research (BMBF), **Germany**
- National Research, Development and Innovation Office (NKFIH), **Hungary**
- Chief Scientist Office of the Ministry of Health (CSO-MOH), **Israel**
- Italian Ministry of Health (MoH-IT), **Italy**
- MTuscany Region (RT/TuscReg), **Tuscany (Italy)**
- Research Council of Lithuania (LMT), **Lithuania**
- National Research Fund (FNR), **Luxembourg**
- National Centre for Research and Development (NCBR), **Poland**
- Slovak Academy of Sciences (SAS), **Slovakia**
- National Institute of Health Carlos III (ISCIII), **Spain**
- Swiss National Science Foundation (SNSF), **Switzerland**
- The Scientific and Technological Research Council of Turkey (TUBITAK), **Turkey**
- The French National Institute of Health and Medical Research (INSERM), **France** (will provide dedicated funding only to **Patient Advocacy Organisations**).

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Type of studies

- Qualitative analysis
  - Qualitative studies are often the starting point for identifying relevant questions for further quantitative studies. The projects can also include further development of scientific instruments and methods and their validation in practice. The sole translation, evaluation and/or testing of individual questionnaires is not funded.
- Non-interventional quantitative studies
  - This includes observational studies like anthropological studies, case control studies, cross-sectional and longitudinal studies as well as cost-effectiveness studies
- Interventional studies on care implementation
  - These are comparative interventional studies to evaluate the effectiveness of practices under everyday conditions
  - Feasibility must be clearly demonstrated regarding the 3 years duration of the project, including realistic timelines for regulatory aspects like ethical approval etc. in different countries; ECRIN can provide advice for the planning and design of cluster randomized controlled trials or randomized and practice-based studies.

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Project and consortium make-up

- **Consortia have to include clinical expertise and SSH expertise in their proposals.** Interdisciplinary research projects relying on SSH methodologies are expected.
- Partnering different groups from different structures, will allow a **broader understanding of the cost of care, optimal care, and ultimately benefit patients.**
- **Moreover, patient involvement is strongly encouraged for patient-centred successful applications.**

- **The maximum duration of the project is three years**.

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Consortium make-up

Partners belonging to one of the following categories may request funding under a joint research proposal (according to country/regional regulations):

- 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),
- enterprises (all sizes of private companies). Participation of small and medium-sized enterprises (SMEs) is encouraged when allowed by national/regional regulations,
- patient advocacy organizations

➔ All partners shall contact their respective funding organizations and confirm eligibility in advance of submitting an application

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Consortium make-up

Each consortium submitting a proposal must involve:

- **3 to 6 eligible principal investigator partners**
- Partners from **at least 3 different participating countries**
- **No more than 2 eligible partners from the same country**

The number of partners can be increased to 8 in two cases:

- The inclusion of partners from participating countries usually underrepresented in projects (Slovakia, Hungary, Lithuania, Poland, and Turkey).
- The inclusion of Early Career Researchers as full partners

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What is a partner? a collaborator? a sub-contractor?

PARTNER

- eligible for funding
- contribute substantially to at least one of the projects work package

COLLABORATOR

- secure their own funding
- cannot be work package leaders

SUB-CONTRACTOR

- may cover only a limited part of the action
- according to country/regional regulations

- Do not count in the total number of partners in the consortium
- Can come from non participating countries

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PAOs involvement and funding

Consortia are strongly advised to include patient representatives and patient advocacy organizations (PAOs).

- From an early stage in proposal development, applicants should consult relevant disease-specific patient organizations and/or alliances of rare disease patient organizations.

Depending on their activities within the consortium and on the specific guidelines from funding agencies, PAOs from participating countries, can participate:

- as partners
- as collaborators
- as sub-contractors

If PAOs partners cannot be funded by their respective national/regional funding organisations, they can be eligible for direct funding through INSERM (with exception of Estonia, Italy, Spain).

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Looking for collaborations: Matchmacking tool

https://live.eventtia.com/en/jtc2021matchmaking

The matchmaking tool aims to:

- help you find teams with the necessary expertise to build multidisciplinary research projets
- help you find a consortium looking for your team's expertise

Do not hesitate to register!

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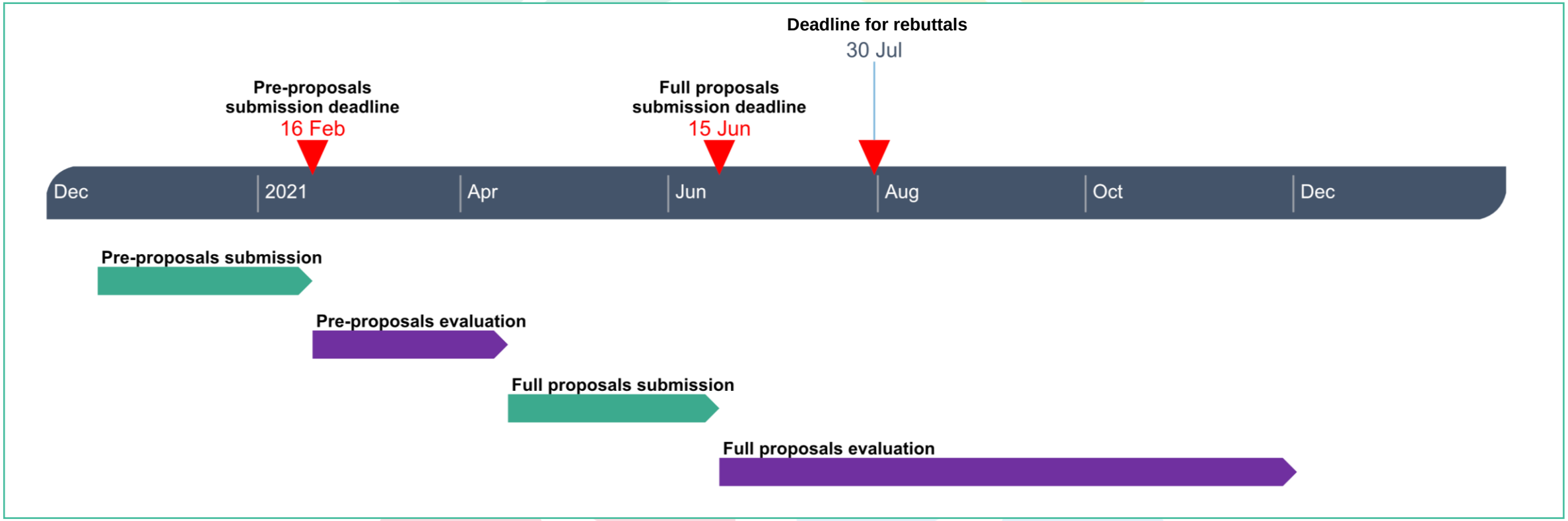
Call Timeline

Two-stage submission procedure for joint applications: pre-proposals and full proposals.



TIPS!

Contact your national /regional agency to validate eligibility/budget rules

Read carefully the preproposal form and all call documents

Register on the submission platform to submit your application:

https://ptoutline.eu/app/ejprd21

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Applications – project description

Pre-proposal application will describe in a 5-page document

- Background, rationale, present state of the art in the SSH research field, preliminary results
- Objectives and hypothesis
- Soundness and pertinence, originality, social care and public health interest
- Workplan & methodology *(highlighting feasibility)*
- Ethical and legal issues, data management
- Work packages, timeline and budget
- Responsibilities and workloads, complementarity of participants, management plan
- Impact of expected results, benefits and implementation in care
- Valorization, measures to exploit and disseminate the results, possible actions in social, health and/or socio-economic care, translatability and sustainability

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Evaluation criteria and procedure

At the pre-proposal stage, applicants should focus on presenting the scientific **idea/hypothesis** and supporting preliminary results, studies or data.

The proposal should describe the project, starting from an **unmet need**, and follow through to the expected end-point of the study.
Pre-proposals will be evaluated **by SSH and rare diseases experts**.

Evaluation criteria (5 points scale)

- **Excellence**

Objectives, methodology, feasibility

- **Impact**

Expected results for relevant application, innovative potential, benefit to patients, their families and carers

- **Quality and efficiency of the implementation**

Coherence and effectiveness of the work plan, complementarity of the participants

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Thank you for your attention!

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