European Joint Programme on Rare Diseases (EJP RD)

Call for Proposals 2019

"Transnational research projects to accelerate diagnosis and/or explore disease progression and mechanisms of rare diseases"

Preliminary Announcement

The content and procedures of the call described in this pre-announcement may be subject to changes and are not legally binding to the funding organizations.

The ERA-Net E-Rare has successfully implemented ten Joint Transnational Calls for rare disease research projects since 2006. This effort is now continued in the frame of the European Joint Programme on Rare Diseases (EJP RD) that has been established to further help in coordinating the research efforts of European, Associated and non-European countries in the field of rare diseases and implement the objectives of the International Rare Disease Research Consortium (IRDiRC).

The following funding organisations:

- Austrian Science Fund (FWF), Austria
- Research Foundation Flanders (FWO), Belgium, Flanders
- Fund for Scientific Research - FNRS (F.R.S.-FNRS), Belgium, Wallonia
- Canadian Institutes of Health Research – Institute of Genetics (CIHR-IG), Canada
- Fonds de recherche du Québec-Santé (FRQS), Québec (Canada)
- Ministry of Education, Youth and Sports (MEYS), Czech Republic
- Ministry of Social Affairs of Estonia (MoSAE), Estonia
- Academy of Finland (AKA), Finland
- French National Research Agency (ANR), France
- French Foundation for Rare Diseases (FFRD), France
- Federal Ministry of Education and Research (BMBF), Germany
- German Research Foundation (DFG), Germany
- General Secretariat for Research and Technology (GSRT), Greece
- National Research, Development and Innovation Office (NKFIH), Hungary
- Health Research Board, (HRB), Ireland
- Chief Scientist Office of the Ministry of Health (CSO-MOH), Israel
intend to open the first EJP RD Joint Transnational Call (JTC 2019) for funding multilateral research projects on rare diseases together with the European Commission (EC) under the EJP-COFUND mechanism. The call is expected to be opened simultaneously by the above-mentioned funding organisations in their respective countries/regions.

### 1. AIM OF THE CALL

The aim of the call is 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 benefit for patients.

**Topic: Research projects to accelerate diagnosis and/or explore disease progression and mechanisms of rare diseases.**

Transnational research proposals must cover at least one of the following areas, which are equal in relevance for this call:

a. Research to accelerate diagnosis, e.g:
   - New schemes for finding diagnosis for undiagnosed patients;
   - Improved annotation and interpretation of variants and development of diagnostic tests for the more prevalent variants;
   - Novel modalities of functional analysis of candidate variants through in vitro, cell, tissue or animal studies.
   - -omic or multi-omic integrated approaches for discovery of disease causes and mechanisms including development of relevant bioinformatic tools;

b. Research to explore disease progression and mechanisms, e.g:
• Natural history studies and patient registries (also for clinical trial readiness). Whenever possible these should include development and use of patient reported outcome measures. In addition, the exploration of the use of standardized M-Health-based surveillance instruments and of patient entered data to gather information for natural history studies is welcome;
• Identification of clinical biomarkers, clinical outcome measures and surrogate endpoints;
• Identification of novel pathophysiological pathways in appropriate disease models that effectively mimic the human condition.

Furthermore, additional elements need to be considered in the application:
• The design of the study (sample collection, statistical power, interpretation, relevant models for hypothesis validation) must be well justified and has to be part of the proposal;
• For natural history studies and patient registries: strategies and timelines for patient recruitment, retention, assessment, and analysis must be included. Data supporting the proposed recruitment numbers is mandatory. The study design and objectives should take into consideration what information regarding the rare disease population would be needed in order to pursue clinical trials or other health care related studies in that rare disease. There always need to be clear research questions that are addressed in the study/registry. Clear plans for sustainability of the resources must be described. Consideration of common data elements as outlined in the recent publication “Set of Common Data Elements for RD Registration” (http://www.erare.eu/sites/default/files/SetCommonData-EU%20RD%20Platform_CDS%20_final.pdf) is highly recommended;
• Appropriate bioinformatics and statistical skills should constitute, whenever justified, an integral part of the proposal, and the relevant personnel should be clearly specified;
• The new research data resulting from the project should be treated permissible according to the FAIR\(^1\) principles, and deposited and shared, according to the national/regional rules of the countries involved. It is strongly advised to make data accessible through RD-Connect (http://rd-connect.eu/) - connecting databases, patient registries, biobanks and clinical bioinformatics data into a central resource for researchers worldwide) and through Elixir (https://www.elixir-europe.org/platforms/data/elixir-deposition-databases - compiling a list of resources for the deposition of experimental, biomolecular data). To make research data findable, accessible, interoperable and re-usable (FAIR), a data management strategy for the proposed full project is mandatory in the full proposal stage. Some countries involved in EJP RD JTC 2019 will also ask for a data management plan (DMP) at national level at the stage of full proposal or after granting of the project.
• To ensure that the needs and priorities of rare disease patients are adequately addressed, they or their representatives should be appropriately involved in all

\(^1\) FAIR: Findable, Accessible, Interoperable, Reusable (for more information: see “The FAIR Guiding Principles for scientific data management and stewardship” (https://www.nature.com/articles/sdata201618)
projects wherever relevant. For examples, inclusion and involvement of patient representatives includes but is not restricted to natural history studies / registries where patients should be involved in the governance of the registry. Please consult the INVOLVE website for information on various ways to involve patients: http://www.invo.org.uk/resource-centre/resource-for-researchers/. For additional guidance and practical advice on patient involvement in research studies, please consult also the JPND guidelines: http://www.neurodegenerationresearch.eu/wp-content/uploads/2013/11/JPND-guide-for-Patient-and-Public-Involvement.pdf.

The following approaches and topics are excluded from the scope of this call:

- Approaches concerning rare infectious diseases or rare cancers;
- Approaches concerning rare adverse drug events/medical complications in treatments of common diseases;
- Studies that focus on pre-clinical therapy development and/or validation in cellular or animal models. These will be addressed in future calls;
- Intervventional clinical trials;
- Rare neurodegenerative diseases, which are within the main focus of the Joint Programming Initiative on Neurodegenerative Disease Research (JPND; http://www.neurodegenerationresearch.eu/). These concern: Alzheimer’s disease and other dementias; Parkinson’s disease (PD) and PD-related disorders; Prion disease; Motor Neuron Diseases; Huntington’s disease; Spinal Muscular Atrophy and dominant forms of Spinocerebellar Ataxia. Interested researchers should refer to the relevant JPND calls. Not excluded through this specification are childhood dementias/neurodegenerative diseases.

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. Applicants are encouraged to assemble groups of rare diseases based on solid criteria and commonalities if this leverages added value in sharing resources or expertise and has the capacity to elucidate common disease mechanisms and therapeutic targets.

The research projects submitted within this call must be based on novel ideas stemming from consolidated previous results or preliminary data and must be clearly endowed with benefit for the patients, i.e. studies allowing a rapid implementation into public health-related decisions or into the clinics. To achieve this goal, the necessary expertise and resources should be brought together from academia, clinical/public health sector and private companies whenever relevant. The research teams within a consortium should include investigators from complementary scientific disciplines, research areas and expertise necessary to achieve the proposed objectives.

The research proposals must demonstrate complementary and synergistic interaction among the partner teams. There should be clear added value in the transnational collaboration over the individual projects, in terms of:
Gathering a critical mass of subjects/patients and or subjects/patients databases and corresponding biological materials that would not be possible otherwise;

Sharing of resources (biobanks, models, databases, diagnostic tools, etc.), of specific know-how and/or innovative technologies including “-omics”, and of expertise. The projects should clearly demonstrate the potential health impact.

2. GENERAL CONDITIONS FOR APPLICATION

Joint research proposals may be submitted by applicants belonging to one of the following categories (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 organisations);
- Enterprise (all sizes of private companies). Participation of small and medium-size enterprises (SMEs) is encouraged when allowed by national/regional regulations;
- Patient advocacy organisations (PAOs - see more information below and refer to the INSERM contact point).

Please note that the inclusion of a non-eligible research partner (principle investigator) in a proposal leads to the rejection of the entire proposal without further review. Whilst applications will be submitted jointly by applicants from several countries/regions, individual groups will be funded by the individual funding organisation of their country/region that is participating in the EJPRD JTC 2019. The applications are therefore subjected to eligibility criteria of individual funding organisations. Applicants are strongly advised to contact their corresponding national/regional representative and confirm eligibility with their respective funding organisations in advance of submitting an application (see national/regional contact details).

Only transnational projects will be funded. Each consortium submitting a proposal must involve a minimum of four eligible and a maximum of six eligible research partners from at least four different countries participating to the call (see list above). No more than two eligible research partners from the same country participating in the call will be accepted in one consortium.

The Joint Call Secretariat and national/regional funding organisations will perform cross-checks in parallel submissions to other joint transnational calls (e.g. NEURON, JPND, EuroNanoMed, ERA PerMed and others) and national calls. Applicants shall avoid applying for same research activities to different calls. Double funding is not allowed.

The consortium coordinator must always be eligible to receive funding from the funding organisations participating in the call and cannot be a partner that joins only with their own funding. Only groups that contribute substantially to at least one of the work packages are considered as partners and should be indicated in the project.
Applicants are encouraged to include research partners from participating countries usually underrepresented in projects (Czech Republic, Slovakia, Estonia, Hungary, Lithuania, Poland, and Turkey). If they include such research partners, the maximum number of research partners can be increased to eight (see tables below).

Consortia are also encouraged to include Early Career Scientists as principal investigators in their proposal. Early career PIs must prove that they are scientifically excellent and independent, for example that they lead or have led a research group or project. They also must clearly be eligible according to national/regional funding regulations. Early Career Scientists should be clearly identified in the proposal and their CV.

Additional research partners that secure their own funding may join consortia. However, their number is limited to two and depends on the number of research partners requesting funding (see table below). These additional research partners can only come from countries that are not involved in the EJPRD JTC 2019 funding or are not eligible for the respective funding organization due to national/regional rules. These research partners must state clearly in the proposal if these funds are already secured or if not, how they plan to obtain funding in advance of the project start, as well as what the concrete amount of contributed funding will be. It will be required to document the availability of their funds before October 1, 2019. In the (pre)proposal form these research partners are mentioned in the category «Associated research partners not asking for funding».

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<th>Number of research partners requesting national/regional funding</th>
<th>Possible number of Additional Research Partners with own funding</th>
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<td>4</td>
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<td>5</td>
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<td>6</td>
<td>2</td>
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<td>7 (only possible with inclusion of 1 partner from usually underrepresented countries)</td>
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<tr>
<td>8 (only possible with inclusion of 2 partners from usually underrepresented countries)</td>
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To collect the necessary patient data and/or samples for the proposed study, a consortium may need to collaborate with other centres. If the unique role of those centres is providing patients data and/or samples for the study only, they will not be considered as research partners of the consortium but can be included otherwise, e.g. via cooperation agreements or subcontracting.

In addition, the inclusion of patient advocacy organizations (PAO) in the proposal is highly encouraged. These can be involved in all levels of the proposed work including helping to develop the research question or patient centred tools, advising on prioritisation, being involved in advisory groups, being a member of the consortium steering group or the governance group of a registry, carrying out the research and disseminating the research.
findings. Therefore PAOs are also eligible to receive funding for their activities. If PAO involvement is not deemed appropriate within a specific research study, this should be explained and justified. The included PAO(s) will not be counted as a national/regional principal investigator research partner and therefore their inclusion does not influence the maximum number of research partners as described above.

3. TIMETABLE

There will be a two-stage submission procedure for joint applications: pre-proposals and full proposals. The call is scheduled to open on December 14, 2018. The indicative deadline for submitting the pre-proposals is foreseen for February 14, 2019. An independent international Scientific Evaluation Committee will carry out a scientific evaluation according to specific evaluation criteria. Based on this central evaluation, selected consortia will be invited to submit a full proposal by early May 2019 (indicative deadline for full proposals: June 11, 2019).

Further information about the official publication of the call will soon be available on the E-Rare website
www.e-rare.eu
and the website of the EJP RD
www.ejprarediseases.org

For general questions regarding the joint call please contact the Joint Call Secretariat at DLR-PT, Germany:

E-Mail: EJPRD2019@dlr.de

or individually:

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Michaela Fersch
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+49 (0)228 3821 1268

Ralph Schuster
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+49 (0)228 3821 1233

For questions regarding national eligibility criteria and requirements please contact the national contact person listed below.
The content and procedures of the call described in this pre-announcement may be subject to changes and are not legally binding to the funding organizations.

## 4. NATIONAL CONTACT POINTS

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<th>Country/Region</th>
<th>Institution</th>
<th>Website</th>
<th>National/regional contact</th>
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<tr>
<td>Austria</td>
<td>FWF</td>
<td><a href="http://www.fwf.ac.at">www.fwf.ac.at</a></td>
<td>Stephanie Resch&lt;br&gt;Phone: +43 (1) 505 67 40-8201&lt;br&gt;Email: <a href="mailto:stephanie.resch@fwf.ac.at">stephanie.resch@fwf.ac.at</a>&lt;br&gt;Anita Stürtz&lt;br&gt;Phone: +43 (1) 505 67 40-8206&lt;br&gt;Email: <a href="mailto:anita.stuertz@fwf.ac.at">anita.stuertz@fwf.ac.at</a></td>
</tr>
<tr>
<td>Belgium/Flanders</td>
<td>FWO</td>
<td><a href="http://www.fwo.be">www.fwo.be</a></td>
<td>Alain Deleener&lt;br&gt;Phone: +32 2 550 15 95&lt;br&gt;Email: <a href="mailto:eranet@fwo.be">eranet@fwo.be</a>&lt;br&gt;Toon Monbaliu&lt;br&gt;Phone: +32 2 550 15 70&lt;br&gt;Email: <a href="mailto:eranet@fwo.be">eranet@fwo.be</a></td>
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<tr>
<td>Belgium/French speaking community</td>
<td>FNRS</td>
<td><a href="http://www.frs-fnrs.be/">www.frs-fnrs.be/</a></td>
<td>Florence Quist&lt;br&gt;Phone: +32 2 504 93 51&lt;br&gt;Email: <a href="mailto:florence.quist@frs-fnrs.be">florence.quist@frs-fnrs.be</a>&lt;br&gt;Joël Groeneveld&lt;br&gt;Phone: +32 2 504 92 70&lt;br&gt;Email: <a href="mailto:joel.groeneveld@frs-fnrs.be">joel.groeneveld@frs-fnrs.be</a></td>
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<tr>
<td>Canada</td>
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<tr>
<td>Canada (Québec)</td>
<td>FRQS</td>
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<th>Country/Region</th>
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| Italy         | FRRB        | [www.frrb.it](http://www.frrb.it) | Fondazione Regionale per la Ricerca Biomedica  
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Department for International Cooperation, Nowogrodzka Str. 47a, 00-695 Warsaw, Poland,  
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<td>Sweden</td>
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<td><a href="http://www.vinnova.se">www.vinnova.se</a></td>
<td>Frida Lundmark</td>
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<td>Division of health</td>
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<td></td>
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<td>Vinnova, Sweden’s innovation agency</td>
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<td>SNSF</td>
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<td>Christoph Meier</td>
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<td>Sonja van Weely</td>
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<td>TUBITAK</td>
<td><a href="http://www.tubitak.gov.tr">www.tubitak.gov.tr</a></td>
<td>Jale Şahin</td>
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<td>Email: <a href="mailto:jale.sahin@tubitak.gov.tr">jale.sahin@tubitak.gov.tr</a></td>
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<td><a href="http://www.inserm.fr">www.inserm.fr</a></td>
<td>Daria Julkowska</td>
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<td>Email: <a href="mailto:daria.julkowska@inserm.fr">daria.julkowska@inserm.fr</a></td>
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