



# 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



- Italian Ministry of Health (MoH-IT), Italy
- Ministry of Education, Universities and Research (MIUR), Italy
- Regional Foundation for Biomedical Research (FRRB), Lombardy (Italy)
- Tuscany Region (RT/TuscReg), Tuscany (Italy)
- Research Council of Lithuania (RCL), Lithuania
- National Research Fund (FNR), Luxembourg
- National Centre for Research and Development (NCBR), Poland
- The Foundation for Science and Technology (FCT), Portugal
- Slovak Academy of Sciences (SAS), Slovakia
- National Institute of Health Carlos III (ISCIII), Spain
- Swedish Research Council (SRC), Sweden
- Vinnova, Sweden
- Swiss National Science Foundation (SNSF), Switzerland
- Netherlands Organization for Health Research and Development (ZonMw), The Netherlands
- 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),

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](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<sup>1</sup> 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

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<sup>1</sup> 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;
- Interventional 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:



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- 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».

<b>Number of research partners requesting national/regional funding</b>	<b>Possible number of Additional Research Partners with own funding</b>
4	2
5	
6	
7 (only possible with inclusion of 1 partner from usually underrepresented countries)	1
8 (only possible with inclusion of 2 partners from usually underrepresented countries)	0

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



EJP RD JTC 2019: Preliminary announcement 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](http://www.e-rare.eu)

and the website of the EJP RD

[www.ejprarediseases.org](http://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](mailto:EJPRD2019@dlr.de)

or individually:

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For questions regarding national eligibility criteria and requirements please contact the national contact person listed below



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#### 4. NATIONAL CONTACT POINTS

Country/Region	Institution	Website	National/regional contact
Austria	FWF	<a href="http://www.fwf.ac.at">www.fwf.ac.at</a>	Stephanie Resch Phone: +43 (1) 505 67 40-8201 Email: <a href="mailto:stephanie.resch@fwf.ac.at">stephanie.resch@fwf.ac.at</a>  Anita Stürtz Phone: +43 (1) 505 67 40-8206 E-mail: <a href="mailto:anita.stuertz@fwf.ac.at">anita.stuertz@fwf.ac.at</a>
Belgium/Flanders	FWO	<a href="http://www.fwo.be">www.fwo.be</a>	Alain Deleener Phone: +32 2 550 15 95 Email: <a href="mailto:eranet@fwo.be">eranet@fwo.be</a>  Toon Monbaliu Phone: +32 2 550 15 70 Email: <a href="mailto:eranet@fwo.be">eranet@fwo.be</a>
Belgium/French speaking community	FNRS	<a href="http://www.frs-fnrs.be/">www.frs-fnrs.be/</a>	Florence Quist Phone: +32 2 504 93 51 Email: <a href="mailto:florence.quist@frs-fnrs.be">florence.quist@frs-fnrs.be</a>  Joël Groeneveld Phone: +32 2 504 92 70 E-mail: <a href="mailto:joel.groeneveld@frs-fnrs.be">joel.groeneveld@frs-fnrs.be</a>
Canada	CIHR-IG	<a href="http://www.cihr-irsc.gc.ca">www.cihr-irsc.gc.ca</a>	Ilana Gombos Phone: +1 613 952 0819 Email: <a href="mailto:ilana.gombos@cihr-irsc.gc.ca">ilana.gombos@cihr-irsc.gc.ca</a>
Canada (Québec)	FRQS	<a href="http://www.frqs.gouv.qc.ca">www.frqs.gouv.qc.ca</a>	Fonds de recherche du Québec-Santé (FRQS)  Maxime Beaudoin Phone: +1 514 873 2114, ext 1369 Email: <a href="mailto:maxime.beaudoin@frq.gouv.qc.ca">maxime.beaudoin@frq.gouv.qc.ca</a>



Country/Region	Institution	Website	National/regional contact
Czech Republic	MEYS	<a href="http://www.msmt.cz">www.msmt.cz</a>	Ministry of Education Youth and Sports Daniel Hanšpach (MSMT) Phone: +420 234 811 360 E-mail: <a href="mailto:Daniel.Hanspach@msmt.cz">Daniel.Hanspach@msmt.cz</a>
Estonia	MoSAE	<a href="https://www.sm.ee/en">https://www.sm.ee/en</a>	Ministry of Social Affairs (MoSAE)  Heli Paluste Phone : +372 626 9127 E-mail: <a href="mailto:Heli.Paluste@sm.ee">Heli.Paluste@sm.ee</a>  Angela Ivask Phone : +372 626 9735 E-mail: <a href="mailto:Angela.Ivask@sm.ee">Angela.Ivask@sm.ee</a>
Finland	AKA	<a href="http://www.aka.fi">www.aka.fi</a>	Heikki Vilen Phone: +358 29 5335 135 Email: <a href="mailto:heikki.vilen@aka.fi">heikki.vilen@aka.fi</a>
France	ANR	<a href="http://www.agence-nationale-recherche.fr">www.agence-nationale-recherche.fr</a>	Florence Guillot Phone: + 33 (0)1 78 09 80 01 Email: E- <a href="mailto:RareCalls@agencerecherche.fr">RareCalls@agencerecherche.fr</a>  Agence Nationale de la Recherche – ANR Health & Biology Department 50 Avenue Daumesnil 75012 Paris, France
France	FFRD	<a href="https://fondation-maladiesrares.org/eng/">https://fondation-maladiesrares.org/eng/</a>	Ingrid Zwaenepoel Phone : + 33 (0) 1 58 14 22 85 Diana Désir-Parseille Phone : + 33 (0) 1 58 14 22 81 Email: <a href="mailto:aap-bio@fondation-maladiesrares.com">aap-bio@fondation-maladiesrares.com</a>  Fondation Maladies Rares Plateforme Maladies rares 96 rue Didot - 75014 Paris, France



Country/Region	Institution	Website	National/regional contact
Germany	BMBF/ PT-DLR	<a href="http://www.gesundheitsforschung-bmbf.de">www.gesundheitsforschung-bmbf.de</a>	<p>Katarzyna Saedler Phone: +49 (0)228 3821 1947 Email: <a href="mailto:Katarzyna.Saedler@dlr.de">Katarzyna.Saedler@dlr.de</a></p> <p>Michaela Fersch Phone: +49 (0)228 3821 1268 Email: <a href="mailto:Michaela.Fersch@dlr.de">Michaela.Fersch@dlr.de</a></p> <p>Ralph Schuster Phone: +49 (0)228 3821 1233 Email: <a href="mailto:Ralph.Schuster@dlr.de">Ralph.Schuster@dlr.de</a></p> <p>Project Management Agency of the German Aerospace Centre (PT-DLR) -Health Research</p>
Germany	DFG	<a href="http://www.dfg.de">www.dfg.de</a>	<p>Dr. Katja Großmann Email: <a href="mailto:katja.grossmann@dfg.de">katja.grossmann@dfg.de</a> Phone: +49 (0) 228 885 2565 Fax: +49 (0) 228) 885 2777 Kennedyallee 40 53175 Bonn</p>
Greece	GSRT	<a href="http://www.gsrt.gr">www.gsrt.gr</a>	<p>Sofia DIMITROPOULOU Phone: +30 2107 458 187 Email: <a href="mailto:s.dimitropoulou@gsrt.gr">s.dimitropoulou@gsrt.gr</a> Ministry of Education, Research &amp; Religious Affairs General Secretariat for Research &amp; Technology International S&amp;T Cooperation Directorate Division of Bilateral &amp; Multilateral Relations</p>



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Italy	MoH-It	<a href="http://www.salute.gov.it">www.salute.gov.it</a>	<p>Dr.Giselda Scalera Phone: +39 065994 2596 Email: <a href="mailto:g.scalera@sanita.it">g.scalera@sanita.it</a> <a href="mailto:research.EU.dgric@sanita.it">research.EU.dgric@sanita.it</a></p> <p>Head Office 5 (Health Research IRCCS), Directorate General for Research and Innovation in Healthcare Ministry of Health, Viale Giorgio Ribotta, 5 -00144 Rome, Italy</p>
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Country/Region	Institution	Website	National/regional contact
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Portugal	FCT	<a href="https://www.fct.pt/index.phtml.en">https://www.fct.pt/index.phtml.en</a>	<p>Anabela Isidro            Phone: +351 213 911 552            Email: <a href="mailto:anabela.isidro@fct.pt">anabela.isidro@fct.pt</a></p> <p>Rita Cavaleiro            Phone: +351 213 911 541            Email: <a href="mailto:rita.cavaleiro@fct.pt">rita.cavaleiro@fct.pt</a></p>
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Sweden	SRC	<a href="http://www.vr.se">www.vr.se</a>	<p>Malin Eklund            Swedish Research Council            Department of Research policy            Phone: +46 (0)76 526 72 56            E-mail : <a href="mailto:malin.eklund@vr.se">malin.eklund@vr.se</a></p>



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Switzerland	SNSF	<a href="http://www.snf.ch">www.snf.ch</a>	<p>Christoph Meier            Division Biology and Medicine            Swiss National Science Foundation            Phone: +41 31 308 23 62            Email: <a href="mailto:christoph.meier@snf.ch">christoph.meier@snf.ch</a></p>
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Turkey	TUBITAK	<a href="http://www.tubitak.gov.tr">www.tubitak.gov.tr</a>	<p>Jale Şahin            Phone: +90- 312- 298 17 96            Email: <a href="mailto:jale.sahin@tubitak.gov.tr">jale.sahin@tubitak.gov.tr</a></p> <p>The Scientific and Technological Research Council of Turkey (TUBITAK)            International Cooperation Department            Division of Bilateral and Multilateral Relations</p>
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