ERDERA
European Rare Diseases
Research Alliance

Call for Proposals 2025

"Pre-clinical therapy studies for rare diseases using small molecules and biologicals – development and validation"

Call Text

For further information,
An information webinar will be held on December 17th, 2024, 14.00-16.00 (CET). Register to participate in the webinar here:
ERDERA JTC 2025 Information Webinar Registration

Visit us on the web:
ERDERA

Submission deadline for pre-proposals: February 13th, 2025 at 2 PM (CET)

Contact Joint Call Secretariat

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1. Background

There are at least 7000 distinct rare diseases, the great majority being of genetic origin. Although individually rare, taken together rare diseases affect at least 26-30 million people in Europe. Moreover, they represent a major issue in health care: many of these diseases have an early or very early onset and/or lead to a significant decrease in life expectancy. Moreover, most of them cause chronic illnesses with a large impact on quality of life and the health care system.

Research on rare diseases is needed to provide knowledge for prevention, diagnosis, better care and everyday life improvement for patients. Yet, research is hampered by lack of resources at several levels: (1) few scientists work on any given disease, (2) there are few patients per disease and they are scattered over large geographic areas, causing difficulties to assemble the necessary cohorts, (3) existing databases and bio-material collections are usually local, small, and not accessible or standardized, (4) the complex clinical phenotypes of these diseases require interdisciplinary cooperation to improve research and treatment outcomes.

The specificities of rare diseases - limited number of patients per disease, scarcity of relevant knowledge and expertise, and fragmentation of research - single them out as a distinctive domain with very high potential for an added-value through a European collaboration. Rare diseases are a prime example of a research area that necessitates collaboration/coordination on a transnational scale.

In this context, the European Rare Diseases Research Alliance (ERDERA) 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). These actions follow the five Joint Transnational Calls for rare diseases research projects launched previously by the European Joint Programme on Rare Diseases (EJP RD) since 2019.

2. Participating Organisations

Several national and regional funding organisations will participate in the ERDERA Joint Transnational Call (JTC) 2025 and will fund research projects on rare diseases. The call opens simultaneously with the involvement of the following funding organisations in their respective countries/regions:

- Austrian Science Fund (FWF), Austria
- Research Foundation Flanders (FWO), Belgium, Flanders
- Fund for Scientific Research - FNRS (F.R.S.-FNRS), Belgium, French speaking community
- Public Service of Wallonia (SPW), Belgium, Wallonie
- Bulgarian National Science Fund (BNSF), Bulgaria
- Canadian Institutes of Health Research – Institute of Genetics (CIHR-IG), Canada
- The Research and Innovation Foundation (RIF), Cyprus
- Ministry of Health (MZCR) / Czech Health Research Council (AZVCR), Czech Republic
- Innovation Fund Denmark (IFD), Denmark
- Estonian Research Council (ETAG), Estonia

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- French National Research Agency (ANR), France
- Foundation For Rare Diseases (FFRD), France
- Federal Ministry of Education and Research (BMBF), Germany
- German Research Foundation (DFG), Germany
- National Research, Development and Innovation Office (NKFIH), Hungary
- The Icelandic Centre for Research (RANNIS), Iceland
- 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 (MUR), Italy
- Fondazione Telethon (FTELE), Italy
- Regional Foundation for Biomedical Research (FRRB), Lombardy (Italy)
- Tuscany Region (RT/TuscReg), Tuscany (Italy)
- Latvian Council of Science (LZP), Latvia
- Research Council of Lithuania (LMT), Lithuania
- National Research Fund (FNR), Luxembourg
- The Research Council of Norway (RCN), Norway
- 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
- Vinnova, Sweden
- Swiss National Science Foundation (SNSF), Switzerland
- Netherlands Organisation for Health Research and Development (ZonMw), The Netherlands
- The Scientific and Technological Research Council of Türkiye (TUBITAK), Türkiye

3. Management and Evaluation Structures

Two boards, the Call Steering Committee (CSC) and the Scientific Evaluation Committee (SEC), will manage the evaluation process of the call with support of the Joint Call Secretariat (JCS) (DLR-PT, Germany). SEC and CSC members are not allowed to submit or participate in proposals within this call. The process includes the evaluation procedure of pre- and full proposals, the final selection and the award of research projects.

The Call Steering Committee (CSC) is composed of representatives from each country/region's funding organisation that participates in the JTC 2025. The CSC will supervise the progress of the call and the evaluation of proposals. The CSC will make the final funding recommendation to the national/regional funding organisations on the proposals to be funded, based on the final ranking list provided by the SEC. All decisions concerning the call procedures will be made by the CSC.

The Scientific Evaluation Committee (SEC) is a panel of internationally recognized, independent, scientific experts responsible for the evaluation of submitted proposals. SEC members must sign a confidentiality form and a statement to confirm that they do not have any conflicts of interest.

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4. 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 the expected impact being future use of the results to benefit patients.

Projects should focus on a group of rare diseases or a on a single rare disease if there is no valid rationale/evidence for the benefit of grouping diseases. If focusing on a single rare disease, applicants must clearly specify why working on a group of rare diseases is not appropriate. The classification of rare diseases follows 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.

Only a few rare diseases benefit from treatment options, but possible commonalities exist between groups of rare diseases (i.e., common disease biological pathways, clinical symptoms and/or clinical phenotypes and importantly the combination of those common features). Therefore, with the view of offering more options for more patients suffering from different rare diseases, applicants are strongly encouraged to work on groups of rare diseases with commonalities and assemble criteria of meaningful grouping of the rare diseases under study, based on state-of-the-art scientific discoveries and clinical practice.

Topic: "Pre-clinical therapy studies for rare diseases using small molecules and biologicals – development and validation"

❖ 4.1 Topics List

Research studies on therapies using small molecules, small non-coding chemically synthesized nucleic acid-based therapies, repurposed drugs or biologicals (e.g., antibodies or proteins such as enzymes, immune modulators or growth factors etc.). Proposals must cover at least two of the following areas:

1. development of novel therapies in a pre-clinical setting through cell, organoid and animal disease model studies, and/or use of *in silico* or artificial intelligence models to accelerate the success rate of the pre-clinical stage
2. development of predictive and pharmacodynamics biomarkers correlated to the efficiency of the therapy in a preclinical setting that could serve as surrogate endpoints
3. replication of pre-clinical studies in an independent lab to increase validity of exploratory findings
4. pre-clinical proof of concept studies for evidence of pharmacological activity *in vitro* and *in vivo*, pharmaco-kinetics and pharmaco-dynamics of the investigational drug (i.e., small molecule(s) and/or biologic) and first toxicology and safety data as well as studies to support readiness for initiating clinical trial authorization conforming to regulatory requirements

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Translatability into humans should be the key focus of the project, and applicants should demonstrate access to relevant scientific or regulatory expertise (e.g., through innovation task forces or competent national authorities).

❖ 4.2 Excluded Approaches and Topics

The following approaches and topics are excluded from the scope of the JTC 2025:

- ATMP therapies (gene therapy medicinal product (including mRNA-based therapies), somatic cell therapy medicinal product, tissue engineered product, according to EMA definition).
- Development of new cell/organoid/animal models, which should already be established.
- Set-up or extension of natural history studies / patient registries.
- Interventional clinical trials to prove efficacy of drugs/treatments/surgical procedures/medical procedures. This includes studies comparing efficacy, e.g., two surgical techniques or therapies, and projects whose main objective is the implementation of a clinical phase IV pharmacovigilance study.
- Projects focusing only on rare neurodegenerative diseases that are within the focus of the Joint Programming Initiative on Neurodegenerative Disease Research (JPND). These are: Alzheimer's disease and other dementias; Parkinson's disease (PD) and PD-related disorders; Prion diseases; Motor Neuron Diseases; Huntington's disease; Spinal Muscular Atrophy and dominant forms of Spinocerebellar Ataxia. Interested researchers should refer to the relevant JPND calls. However, childhood dementias/neurodegenerative diseases are eligible.
- Rare infectious diseases, rare cancers and rare adverse drug events in treatments of common diseases. Rare diseases with a predisposition to cancer are eligible.

❖ 4.3 General Considerations

The following additional elements should be considered in the application:

Projects should focus on rare diseases or disease groups with high unmet medical need, high disease burden, and no currently approved therapeutic options in Europe (European marketing authorisation). Preferably, they should address group(s) of rare diseases with commonalities such as, but not exclusively, shared molecular etiologies and/or clinical symptoms, such that the same drug and/or drug combinations could be used for clinical trials of multiple diseases (see corresponding article).

Existing knowledge from multiple sources (natural history studies/registries, real-world data/evidence, multi-omics, medical imaging, etc.) should be used to underpin the therapeutic hypothesis and therapeutics development.

Studies should be based on rigor, quality and transparency to achieve reproducibility of results. This includes specification of protocols ahead of time, adequate sample size and implementing active laboratory management practice.

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Consortia performing preclinical development of therapeutics are strongly advised to engage or consult experts in the various stages of product development to ensure that the data generated is suitable for future regulatory filings such as for application of receiving orphan designation and/or clinical trial preparedness for regulatory advice and authorisation. The aim should be to establish one or more of the following:

a) Target validation: strong link between target and disease, pharmacological basis of expected clinical benefit (e.g., understanding target engagement requirements), available and predictive biomarkers.
b) Suitable formulation and route-of-administration: for the proposed preclinical studies as well as a plausible path to translate into a practical clinical-stage drug product.
c) Right Tissue: adequate bioavailability and tissue exposure, definition of pharmacodynamics biomarkers, clear understanding of preclinical pharmacokinetics.
d) Right safety profile: differentiated and clear safety margins (either in models for new drugs or in humans if a clinical-stage or approved drug is repurposed), understanding of secondary pharmacology risk which consists of evaluating the potential off-target or unintentional effects of a drug, including understanding of reactive metabolites, genotoxicity, drug–drug interactions, and off-target liability. These studies are important in predicting potential toxicities and demonstrating the safety of a therapy.
e) Right patient: identification of the most responsive patient population, with a risk–benefit analysis.
f) Readiness for clinical trial application (CTA)-directed studies: exploratory studies to establish the basis for GMP manufacturing and/or GLP toxicology and safety pharmacology studies to support regulatory clearance for first-in-human studies. Examples include pilot scale-up studies for drug substance manufacturing and exploratory dose-range finding studies for toxicology.

For the development of novel therapies or pre-clinical proof-of-principle studies, the following issues should be addressed in the proposal:

- Orphan medicine designation (OD) planning: has an OD been granted or is being planned? If so, please explain. The path to drug development outside the OD incentives should be described (including target product profile for therapy development).
- EMA Scientific Advice Working Party (SAWP) and/or Innovation Task Force (ITF) early engagement: has the novel therapy received EMA support e.g. scientific advice or protocol assistance? If not, has scientific advice/protocol assistance, including the qualification of innovative methodologies be planned? The reasons for not applying should be mentioned in the project description.
- For projects developing a new target (not extensively described in the literature), target validation in relevant preclinical disease and/or mechanism models should be a first step in the project.

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Validation or development of predictive and pharmacodynamics biomarkers (predictive biomarkers are important to help guide patient selection; pharmacodynamics biomarkers can provide information on the pharmacologic effects of a drug on its target):

- Development of surrogate biomarker(s) for drug efficacy (pre-clinical, clinical). This will generally be limited to primary genetic defects in rare diseases.
- Biomarkers of dose/response to de-risk a program and provide dose finding. These will generally be strongly linked to disease molecular pathophysiology, correlated to clinical efficacy (if possible) and will aid the sponsor to de-risk the program, but may be viewed as exploratory by competent authorities.
- Robust analytical procedures: any biomarker should have analytical procedures that are adequate to support the context of use. If planned as a surrogate biomarker, the assays should adhere to regulatory guidelines for acceptance as a primary or secondary outcome in clinical trials.
- Ensure in the first stage of the project that the biomarker (signature) undergoes analytical validation using high quality samples from an independent collection (different from the collection in which the signal was discovered), which have been collected and stored under quality-controlled conditions and following international standards.
- Validation should follow a risk-based approach wherein depending on potential confounding variables such as genetic diversity, multiple biobanks from multiple regions may be utilised. Sample size and number should reflect such risk.

Applicants should describe and justify the use of disease models (animal or otherwise) described in the proposal:

- How the model replicates the pathology or human condition (aetiology, pathophysiology, symptomatology and response to therapeutic intervention) and how the model could potentially be used in other rare diseases with similar pathology or pathways;
-
- Whether the model replicates aspects of the therapy target including expression, distribution and primary structure, pharmacodynamics, metabolism and other pharmacokinetic aspects;
- Sound scientific justification for the use of animals (if applicable), including an explanation of why there are no realistic alternatives, and demonstration that the numbers proposed will allow meaningful results to be obtained from the research, while respecting the 3R principles on animal studies.
- Availability of the model and feasibility of breeding programs to achieve sufficient numbers of animals for robust and well-controlled pre-clinical efficacy studies (sex and age-matched, blinded groups of sufficient [well-powered] numbers);
- Primary endpoints and/or surrogate markers for measuring efficacy/safety, including sample size calculations for determination of drug effect, and;
- Describe how the proposed pre-clinical work correlates and aligns with any planned future stages of the research in humans. Describe those future stages as well as potential collaborators.

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The following additional elements need to be considered in all proposals:

- The design of the study (sample collection, statistical power, interpretation, relevant models for hypothesis validation) must be well justified and should be part of the proposal.
- Appropriate bioinformatics and statistical methods, whenever included and justified, should constitute, an integral part of the proposal, and the relevant personnel should be clearly specified. These personnel should either be an eligible partner of the consortium, part of the research group of an eligible partner or involved as direct contractors of an eligible partner. They cannot be external collaborators that participate with their own funding. Their responsibilities must be clearly described and align with the requested resources and a CV must be provided.
- The project team is expected to include at least one patient partner (patient/caregiver/family member) or a patient advocacy organisation (PAO) in the role of Principal Knowledge User (PKU), Knowledge User (KU) or Co-Applicant as appropriate. Details must be provided regarding the patient partner involvement plan and the consideration given to patient compensation must be explicit in the proposed budget.
- Preliminary data should be described in a manner that would allow a skilled peer to replicate the data, including positive and negative controls, and suitable n values for statistical analysis. All data points should be included in the analysis and presented with error bars where relevant.
- Risk management should be considered including the identification of possible bottlenecks and go/no go contingencies.
- Feasibility of the project given requested resources (budget) and schedule must be demonstrated: timelines should be realistic, and lead times should be accounted for (e.g., regulatory or scientific advice).
- If relevant, the consortium should identify technology transfer institutions responsible for intellectual property (IP) management. The project plan should include innovation management activities (e.g., ongoing monitoring, expert panels to identify research results with a high potential for exploitation), and may describe post-grant follow-on funding and/or draft study/business plans for further clinical development of promising research results (with relevant stakeholders including patient groups and/or companies for potential co-development).
- The analysis of IP status, freedom to operate and access to therapeutic molecules for development should be clearly described.
- Applicants should include information about other ongoing development work on the target/indication (if applicable) and explain why their approach should be supported.
- Study design, preclinical models and reagents should be selected to facilitate approval in human trials and future clinical grade manufacturing.

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- Proposals are expected to consider how sex and/or gender might shape research activities. Applicants are encouraged to visit the European Commission, Directorate-General for Research and Innovation, Horizon Europe, gender equality , and CIHR's Sex, Gender and Health Research resource page for more information on key considerations for the appropriate integration of sex and gender in their proposal.
- Data generated or newly collected for the project must be made ready for reuse. This should be achieved by contributing to the creation of the ERDERA Data Hub, a collaborative responsibility of the ERDERA partnership. This will result in data that are Findable, Accessible, Interoperable and Reusable in accordance with the FAIR Guiding Principles, enabling automated applications across multiple data and knowledge sources. Effort and budget must be earmarked for FAIR data stewardship and a milestone should be included to mark the contribution. The stewardship effort includes the identification and use of appropriate data repository services, exchange formats, access protocols and policies, ontology-based data and metadata models for describing the project's datasets, data elements and access conditions, and, importantly, the establishment of interoperability with other sources connected to the ERDERA Data Hub. A full description of the contribution to the ERDERA Data Hub, which encompasses the implementation of FAIR Data Principles, is not necessary. A concrete commitment to FAIR data stewardship and collaboratively delivering the ERDERA Data Hub are sufficient. If FAIR expertise is not present in the project consortium, then a FAIR partner can be added during the run time of the project.
- Research including Indigenous people should also adhere to the CARE (Collective benefits, Authority to control, Responsibility, Ethics) Principles for Indigenous Data Governance.
- Some countries involved in ERDERA JTC 2025 may also request a data management plan (DMP) at the national level during the full proposal stage or after granting of the project.

❖ 4.4 Project Description

Applicants should describe and justify the following elements (see "Guidelines for Applicants" section 3 – Project Description for complete information on the content of pre- and full proposal templates):

- Background, present state of the art in the research field
- Objectives and hypothesis
- Soundness and pertinence
- Workplan and methodology *(highlighting feasibility)*
- Impact
- Valorization, translation to practice
- Patient engagement/involvement/partnership
- Ethical and legal issues, data management
- Work packages, timeline and budget

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- Responsibilities and workloads

5. Funding and Eligibility Criteria

❖ 5.1 Funding

The maximum duration of the project is three years.

Double funding of research projects is not permitted. The JCS and national/regional funding organisations may perform cross-checks of submissions against other funding initiatives managed by the same organisations (both national/regional calls and Joint Transnational Calls, e.g. NEURON, JPND, or European Partnerships such as ERA4Health, EP PerMed, THCS etc.). Partners may not apply for funding for the same research activities in different calls. In addition, there can be no double funding for activities already funded by EC H2020 and Horizon Europe calls.

Consortia of projects funded in previous Joint Transnational Calls of the EJP RD can apply for funding for an extension of their cooperation in a new project, but only for new research activities not yet funded under the previous Call. These consortia must clearly demonstrate the success of the past/current project and innovative scientific aims for their future collaboration. Their applications will compete with applications for new research projects.

❖ 5.2 Categories of Partners

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

❖ 5.3 Countries and Region-specific Guidelines

Although applications will be submitted jointly by applicants from several countries, individual groups will be funded by their respective regional/national funding organisation. Applicants therefore must contact their respective funding organisations and confirm eligibility in advance of applying (see section 10). The adherence to the national/regional regulations in the "Guidelines for Applicants" document is mandatory. The inclusion of a non-eligible partner in a proposal will lead to the rejection of the entire proposal without further review. For additional information, please contact the JCS. Note that a parallel proposal submission is required by some regional/national funding organisations.

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❖ 5.4 Consortium Makeup

5.4.1 Limit number of partners

Only transnational projects will be funded. Each consortium submitting a proposal must involve four to six eligible principal investigator partners (referred to as partners below) from at least four different participating countries (see list in section 2). One of these four to six partners must be an Early Career Researcher (ECR; see section 5.6). In specific cases this number of consortium partners can be increased to eight partners (see below). No more than two eligible partners from the same country can be present in each consortium; further national/regional limits may apply, see "Guidelines for Applicants". Patient advocacy organisations (PAOs) requesting funding do not count toward the total.

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

1. The inclusion of partners from participating countries usually underrepresented in projects (UR: Czech Republic, Estonia, Latvia, Lithuania, Slovakia, Türkiye), OR
2. The inclusion of an additional ECR as full partner (see section 5.6).

Number of research partners requesting national/regional funding	Inclusion of UR partner	Inclusion of ECR partner
4	Not mandatory	1 mandatory
5		
6		
7 (only possible with inclusion of one partner from UR countries or additional ECR)	1	1 additional ECR partner
8 (only possible with inclusion of two partners either from UR countries or additional ECRs)	1-2	1-2 additional ECR partners

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

To be considered as an eligible partner, a group must contribute substantially to at least one of the project's work packages. If the only role of a group is to provide patient access, data or samples for the study, they will not be considered as partners of the consortium, but can be included otherwise, via cooperation agreements (as collaborators) or subcontracting.

Consortia may include collaborators that secure their own funding. Collaborators cannot be work package leaders, and their contribution to the consortium must be described. As they do not receive funding as part of this call, they do not count toward the limit of 8 partners requesting research funding (nor is there a limit of collaborators per country, as long as their participation is justified). Collaborators must supply a letter of intent and a CV as well as be entered in the online submission system.

If necessary, to implement the research activity, consortia may also include sub-contractors according to country/regional regulations. Sub-contractors may cover only a limited part of the research activity, and their contribution to the consortium must be described. They do not count toward the limit of 8 partners requesting research

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funding (nor is there a limit of subcontractors per country, as long as their participation is justified and if subcontracting is possible according to national/regional funding rules).

5.4.3 Consortium organisation

Each transnational proposal must nominate a project consortium coordinator among the project partner principal investigators. The coordinator must be an eligible project partner from an ERDERA JTC 2025 funding country/region. The project coordinator will represent the consortium externally to the JCS and to CSC, and will be responsible for its internal scientific management (such as controlling, reporting, and intellectual property rights issues). This workload should be considered in the estimation of the budget of the coordinator. A single principal investigator will represent each project partner. Within a joint proposal, the principal investigator of each project partner will be the contact person for the relevant country/regional funding organisation.

❖ 5.5 Patient Advocacy Organisations and Patient Involvement/Partnership

Consortia are expected to include and actively engage patient partners (patients/caregivers/family members) and/or patient advocacy organisations (PAOs) from the start when preparing their proposals. For information on where to find patient partners and PAOs willing to be involved in research, please see:

- Orphanet portal for rare diseases and drugs patient organisation directory
- Rare Diseases Europe (EURORDIS)
- European Reference Networks (ERNs)
- European Patient's Academy on Therapeutic Innovation (EUPATI)
- European Patients' Forum https://www.eu-patient.eu/
- Research Patient Partnership resources (CIHR-IG)

The consortia should clearly describe the role and responsibilities of the patient partners and PAOs, how they will operate, at what levels and stages of the research, and provide justifications for allocated resources in a patient involvement plan. It is highly encouraged that patient partners and PAOs are involved in all levels of the proposed work, including in project design, by advising on prioritization, sitting on advisory groups, and/or being a member of the consortium steering group or the governance group. Patient partners and PAOs may be part of institutional scientific boards to discuss the proposal and subsequent study on issues such as:

- the research idea, for relevance to patient concerns;
- possible outcomes;
- informed consent;
- patient input on appropriate outcome measures;
- possible patient intervention in the project;
- review of the data collected;
- dissemination of research findings;
- plain language summaries, and;
- review of data use conditions and access procedures within and outside of the project consortium, within and beyond the runtime of the project.

For more information on patient-centered care and strategies to involve patient partners and PAOs in your research project, please consult:

- EJP RD Short guide on patient partnerships in rare diseases research projects

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- INVOLVE Briefing Notes for Researchers and cost calculator,
- Recommendations for Successful Patient Involvement in Scientific Research (de Witt et al., 2016),
- Measuring what matters to rare disease patients (Morel & Cano, 2017),
- CIHR's Institute of Genetics Patient Partnership resources.

Funding for PAOs through the central funding mechanism administered by ZonMw is limited to a total of 25,000 € over 3 years and per project regardless of the number of participating PAOs (see "Guidelines for Applicants" for eligibility rules). In addition, PAOs can also be involved through national/regional funding or subcontracting depending on the proposed tasks and national/regional funding rules.

❖ 5.6 Early Career Researchers

At least one Early Career Researcher (ECR) must join a consortium as a full research partner and is therefore subject to the same eligibility criteria as other partners. ECRs must demonstrate independence and scientific excellence, and should be clearly identified in the proposal and their CV. A definition of ECRs is provided in "Guidelines for Applicants", section 4.1.

6. Registration and Submission

Research consortia who intend to submit a transnational project proposal should register as soon as possible via the electronic proposal system: https://funding.erdera.org

There will be a two-stage submission procedure for joint applications: a pre- and full proposal stage. In both cases, one joint proposal document (in English) shall be prepared by the partners of a joint transnational proposal and must be submitted by the coordinator only to the JCS via the electronic submission system. Proposals must be prepared using the templates provided in the electronic system. Proposals not conforming to template instructions will be rejected.

Call Timeline

10th December 2024	Launch of the call
17th December 2024	Information webinar for potential applicants
13th February 2025	Pre-proposal submission deadline
3rd March 2025	Pre-proposal eligibility check
Early May 2025	Invitation to full proposal
6th May 2025	Information webinar for applicants invited to submit a full proposal
9th July 2025	Full proposal submission deadline
18th July 2025	Full proposal eligibility check
December 2025	Notification of funding decision

Full proposals will be accepted only from those applicants who were explicitly invited by the JCS to submit them.

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In general, fundamental changes between the pre- and full proposals concerning the composition of the consortia, objectives of the project, or requested budget can only be applied with a detailed justification provided to the JCS for consideration by the CSC. Potential justifications may include advice gathered on the feasibility of the project indicating the need for additional expertise and/or resources, or the addition of partner(s) through the widening scheme. However, the national/regional regulations on eligible partners and budget caps will still apply and the budget change needs to be pre-approved by relevant national/regional funding organisation(s).

Further information on how to submit pre-proposals and full proposals electronically (including "Guidelines for Applicants" and submission templates) is available at the ERDERA website.

7. Evaluation Process

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 endpoint of the study.

At the full proposal stage, in addition to the scientific content, a full description of the patient engagement plan, data management, statistical methods, and ethical and legal issues will be required in compliance with EC requirements. Applicants should anticipate these requirements and ensure that they have consulted relevant experts to verify the feasibility of the project, and that the proposal can be completed within the defined timelines and budget (considering budget limits listed in the "Guidelines for Applicants").

❖ 7.1 Evaluation Criteria

Evaluation scores will be awarded according to specific evaluation criteria that are in line with Horizon Europe rules (see below), using a common evaluation form.

7.1.1 Scoring system

0: Failure: The proposal fails to address the criterion in question or cannot be judged because of missing or incomplete information.
1: Poor: The proposal shows serious weaknesses in relation to the criterion in question.
2: Fair: The proposal generally addresses the criterion, but there are significant weaknesses that need corrections.
3: Good: The proposal addresses the criterion in question well, but certain improvements are necessary.
4: Very good: The proposal addresses the criterion very well, but small improvements are possible.
5: Excellent: The proposal successfully addresses all aspects of the criterion in question.

7.1.2 Criteria

1. Excellence (0-5)

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a. Clarity and pertinence of the objectives;
b. Credibility of the proposed approach and methodology;
c. Soundness of the concept;
d. Innovative potential: description of existing development landscape, relationships with technology transfer offices, plan for ongoing development, involvement of industry partners;
e. Competence of participating research partners in the field(s) of the proposal (e.g., previous work in the field, specific expertise), and;
f. **Active and meaningful participation of PAOs and patient partners in the project (including in the design and definition of research priorities, interpretation and implementation of results, their dissemination, and communication) as well as clarity of the patient partner involvement plan.

2. Impact (0-5)
   a. *Potential and readiness of the expected results to be translatable for future clinical applications for diseases without approved treatment options in Europe;
   b. *Benefit to patients, their families, and carers;
   c. *Added value of transnational collaboration: gathering a critical mass of patients/material, sharing of expertise and resources, harmonisation of data, sharing of specific know-how and/or innovative solutions, and;
   d. **Effectiveness of the proposed measures to exploit and disseminate the project results (including management of intellectual property rights (IPR)), to communicate the project, and to manage research data. A data management strategy in the full proposal is mandatory.

3. Quality and efficiency of the implementation (0-5)
   a. Feasibility of the project (coherence and effectiveness of the work plan, including appropriateness of the allocation of tasks, resources and timeframe, access to data and material);
   b. Complementarity of the participants within the consortium, including the integration of PAOs or patient partners;
   c. **Appropriateness of the management structures and procedures, including risk management, contingency plans and innovation management, and;
   d. **Plan for sustainability of infrastructures or resources initiated by the project.

*Sub-criteria 2a, 2b and 2c will be prioritized for assessing the impact of proposals (pre- and full proposal stage).
**Sub-criteria 1f, 2d, 3c, 3d will only be assessed as part of the full proposal evaluation step.

❖ 7.2 Pre-proposal Review

Eligibility check
The JCS will check all pre-proposals to ensure that they meet the call's formal criteria (completeness of information in submission platform, general eligibility criteria). The JCS will forward the proposals to the CSC members who will perform a check for compliance to country/regional eligibility rules. Please note that proposals not meeting

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the formal criteria or the national/regional eligibility criteria and requirements will be declined without further review.

Peer review of pre-proposals
Pre-proposals that pass the eligibility check will be forwarded to the SEC members with biomedical expertise for a first evaluation (see evaluation criteria above). These SEC members will perform the assessment of the pre-proposal and fill the evaluation forms with scores and comments for each criterion. Each pre-proposal will be assessed by 2 SEC members. The SEC members will then meet online to establish a ranking of the pre-proposals. This ranking will be used by the CSC to decide which pre-proposals will be accepted for full proposal submission. Applicants will receive their individual consensus review report and corresponding SEC recommendations regarding full proposal submission.

Scoring rules
Each criterion will be scored out of five (5). The weighting factor for the Excellence criterion will be two. Therefore, the maximum overall score for each proposal will be 20 points. To be approved for the full proposal stage, the application must receive a minimum threshold score of 3 (out of 5) for each individual evaluation criterion; in addition, the application must receive a minimum overall score of 15 points per expert vote.

Widening
At the end of this stage research teams of underrepresented or undersubscribed countries may join successful pre-proposals after approval by the relevant funding organizations (see 5.2 in "Guidelines for Applicants" for more details).

ERDERA support services
Applicants that are invited to submit a full proposal are strongly encouraged to make use of the ERDERA support services for FAIR data, translational mentoring and regulatory advice (see 5.3 in "Guidelines for Applicants" for more details).

❖ 7.3 Full Proposal Review

Formal criteria check
The JCS will check the full proposals to ensure that they meet the call's formal criteria with the help of the CSC.

SEC meeting evaluation
The JCS will send full proposals to the SEC members. The SEC will meet to discuss the proposals, assign their final scores and create a ranking list with proposals that are recommended for funding. The final summary review report for each consortium will be prepared by the SEC members and sent to respective applicants.

Scoring rules

Each proposal will be evaluated by three biomedical reviewers (including methodological reviewers) and one patient reviewer.

For biomedical SEC members, each criterion will be scored out of five. The weighting factor for the criterion excellence will be two. Therefore, the maximum overall score will

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be 20 points. The threshold for an individual criterion is three, with an overall threshold of 15 points per expert vote.

In addition, the full proposals will be reviewed by a patient reviewer according to the relevant evaluation criteria listed above (see 7.1.2; subcriteria 1f, 2b, 3b). The maximum score per patient expert is 15 points with a threshold of 10 points. Patient reviewers will be present at the SEC meeting to discuss proposals and provide their feedback.

Based on the above, the overall maximum score that can be given to a consortium, through the addition of individual expert scores, is 75 points. The minimum threshold to be considered for funding will be 55 points, with each expert meeting their respective threshold as described above.

Ethical evaluation
After the second SEC meeting, full proposals recommended for funding by the SEC will be remotely evaluated by independent experts in ethics. These experts will report on the feasibility of a given proposal to comply with the ethical requirements. If necessary, they will list those tasks to be done and documents to be submitted by the consortium in order to receive approval for funding from an ethics standpoint. Only those proposals approved by both the scientific and ethical evaluations (complying with all central Horizon Europe and regional/national ethical requirements), will be funded.

❖ 7.4 Funding Decision

Based on the ranking list established by the SEC, the ethical evaluation and available funding, the CSC decides on the list of projects recommended for funding.
Each CSC member organisation makes the final decision on its funding contribution according to its respective regulations, calendar and legal frameworks.

If necessary, the CSC will determine a priority order for funding proposals which have been awarded the same score within a ranked list. Prioritization will be based on (in descending order):

- Availability of national/regional funding;
- Maximization of use of national/regional funding;
- Proposals with participation of underrepresented or undersubscribed countries;
- Proposals that address diseases not otherwise covered by more highly ranked proposals.

The JCS will notify all project coordinators of the final funding decision and disseminate the SEC consensus report.

8. Redress Procedure

Applicants can appeal against the evaluation outcome if they suspect a breach in the application of the evaluation and selection procedures. This redress procedure only covers the procedural aspects of the call. The redress will not call into question the scientific or technical judgement of appropriately qualified experts/evaluators.
Applicants may submit their appeal to the ERDERA coordination up to seven (7) calendar days following the dispatch of the evaluation outcome notification by the JCS at the end of each stage (first or second step). The proposal outcome email containing the results

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of the evaluation will include information on the appeals procedure, which is described below.

Admissibility of appeals

For an appeal to be admissible the following conditions must be met:

- The appeal must be submitted by the coordinator of the proposal to which the appeal relates;
- Only one appeal per proposal will be considered;
- The appeal must be submitted via email within the seven (7) calendar days deadline. The appeal must contain the following minimum information:
  - The name of the call for proposals;
  - The proposal acronym;
  - The title of the proposal;
  - A description of the alleged shortcomings of the evaluation procedure.

The appeal must demonstrate a procedural irregularity or a factual error. Appeals that do not meet the above conditions, or do not relate to the evaluation of a specific proposal or express mere disagreement with the result or the reasoning of the evaluation will be judged as not suitable for redress.

Procedure

Upon receipt of an appeal, an acknowledgement of receipt will be sent by the ERDERA coordination within seven (7) calendar days. The acknowledgement shall report the redress process and the anticipated date by which a decision on the appeal will be communicated to the appellant. All appeals received by the seven (7) calendar days deadline will be processed together, and the decision of the CSC will be communicated to the appellant by the JCS within seven (7) calendar days after the decision has been made.

9. Responsibilities, Reporting Requirements and Dissemination

The Joint Call Secretariat (JCS) is the DLR Projektträger (DLR-PT, Germany) to assist the CSC and the national/regional funding bodies during the implementation of the call. The JCS will be responsible for the administrative management of the call. It will be the primary contact point between the research consortia, the funding organisations, and peer reviewers with regard to call procedures. The project coordinator is the point of contact for the consortium during the application procedure and is responsible for forwarding relevant information from the JCS to the consortium members. CSO-MOH, Israel, will be responsible for the monitoring phase until the funded research projects have ended.

The coordinators of all funded projects must submit annual scientific project reports and a final scientific project report (due within three months of the end of the project). All reports must be in English and must be filled out online and use the reporting templates provided. The research partners are jointly responsible for delivery of the reports. Only reports delivered on behalf of the consortium, via the project coordinator, will be accepted.

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If required, each beneficiary should submit financial and scientific reports to their national/regional funding organisations, according to national/regional regulations. The progress and final results of each individual contract/letter of grant will be monitored by the respective national/regional funding organisations.

The coordinators and national/regional group leaders will be asked to present the progress and results of their projects at an intermediate status symposium organized by ERDERA. The onsite presence of at least one representative (coordinator and/or partner) per project will be mandatory. Therefore, the coordinator and respective partners must budget a sufficient amount for the expenses related to this event.

Please read the "Guidelines for Applicants" document for further information including national/regional information and eligibility requirements.

10. Contacts and Further Information

Further information on ERDERA, the Call, and follow-up is available at the ERDERA website (https://erdera.org/).

Call Contacts

Role	Organisation	Contact Details
Joint Call Secretariat	DLR-Projektträger	Dr. Katarzyna Saedler Dr. Michaela Fersch Dr. Ralph Schuster +49228-38212453 SelteneErkrankungen@dlr.de

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11. National and Regional Contacts

Applicants should refer to the guidelines document for country-specific information including national/regional rules that may apply. Applicants are strongly advised to contact the national/regional contact person to ensure eligibility before submitting their projects.

Country/ Region	Funding Organisation	Contact Details
Austria	Austrian Science Fund (FWF)	Dr. Doris Lucyshyn Doris.lucyshyn@fwf.ac.at DI Anita Stürtz Anita.stuertz@fwf.ac.at
Belgium	Fund for Scientific Research – FNRS (F.R.S.-FNRS)	Dr. Maxime Bonsir +32 2 504 9236 Dr. Florence Quist +32 (0)2 504 9351 International@frs-fnrs.be
Belgium	Research Foundation Flanders (FWO)	Toon Monbaliu (FO) +32 (0)2 550 15 70 Kristien Peeters (SBO) +32 (0)2 550 15 95 europe@fwo.be
Belgium	Public Service of Wallonia (SPW)	Dr. Cédric Morana Cedric.morana@spw.wallonie.be Dr. Fleur Roland Fleur.roland@spw.wallonie.be
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Czech Republic	The Ministry of Health of the Czech Republic (MZCR), Czech Health Research Council (AZVCR)	Olga Laaksonen Phone: + 420 604 786 141 Email: olga.laaksonen@mzcr.cz Monika Kocmanova Phone: +420 606 273 871 Email: monika.kocmanova@azvcr.cz

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France	Foundation For Rare Diseases (FFRD)	Dr. Pauline Nauroy aap-bio@fondation-maladiesrares.com
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