ERDERA launches Clinical Trial Call 2026 to advance early-phase clinical trials for rare diseases

ERDERA (the European Rare Diseases Research Alliance) has opened its Clinical Trial Call to support multinational early-phase clinical trials in rare diseases. The call will fund studies designed to generate robust clinical evidence, strengthen regulatory readiness and make rare disease trials more feasible across countries.

Paris, 1 July 2026 – ERDERA, the European Rare Diseases Research Alliance, has opened its Clinical Trial Call, a new funding opportunity for multinational early-phase interventional clinical trials in rare diseases.

The call is intended for sponsor-led Phase I, Phase I/II and Phase II clinical trials of medicinal products, conducted in accordance with Good Clinical Practice. It is focused on studies that can generate robust clinical evidence and, where appropriate, data of regulatory relevance to guide the next steps in therapeutic development.

Up to €30 million of the ERDERA budget is dedicated to this call. Individual project budgets are expected to be broadly in the range of €1 million to €5 million, with flexibility where adequately justified. Unlike ERDERA Joint Transnational Calls, the Clinical Trial Call uses a centralised funding model administered by Fondazione Telethon on behalf of the ERDERA consortium, with one common funding framework rather than parallel national funding processes.

From promising therapies to reliable clinical evidence

Rare diseases affect up to 30 million people in Europe. Many begin early in life, reduce life expectancy or cause long-term disability, yet most still lack disease-modifying treatments. In many conditions, care remains supportive or symptomatic rather than able to alter the course of disease.

For rare disease patients, researchers and clinicians, one of the hardest steps is **moving from a plausible therapeutic approach to a trial that can produce reliable evidence**.

The Clinical Trial Call is aimed at projects ready to enter that demanding clinical stage. It is not a discovery or preclinical funding scheme. It is for clinical studies in humans evaluating investigational medicinal products with a clear therapeutic rationale, a defined patient population and a credible development path.

"When patients are few, knowledge is scattered and every data point matters, the quality of the study depends on whether the right expertise, sites, patient communities and regulatory questions are brought together early enough.

This call is designed around that reality. It supports trials that do not lower the evidence bar because a disease is rare, but instead build the conditions needed to reach it: multinational recruitment, careful methodology, patient-relevant outcomes, regulatory thinking and data that can be used beyond a single project. That is where ERDERA can add value — by helping transform fragmentation into a structured path towards evidence."

***Daria Julkowska**, ERDERA Scientific Coordinator*

What can be funded

The call covers multinational interventional trials in rare diseases. Phase I studies primarily examine safety, tolerability, pharmacokinetics, pharmacodynamics or dose. Phase I/II studies combine safety questions with early efficacy or proof-of-concept objectives. Phase II studies examine therapeutic activity, dosing, further safety or preliminary efficacy in a defined patient population.

Eligible interventions are medicinal products. These may be new or repurposed small molecules; new or repurposed biological therapies; and Advanced Therapy Medicinal Products, provided the manufacturing process has been developed and validated under Good Manufacturing Practice conditions appropriate for early-phase clinical use.

In practice, this could include a medicine already authorised for another indication and now being tested in a rare disease, a biological product reaching early clinical development, or an advanced therapy with sufficient manufacturing and evidence readiness for a Phase I or Phase I/II trial.

For repurposed drugs and biologics, applicants must also show that the investigational product can be supplied throughout the trial and that there is a credible route towards patient access or further development if results are positive.

The call does not fund non-clinical work, including in vitro, in silico, animal or other preclinical studies. It also excludes Phase III and Phase IV trials, pharmacovigilance studies, rare infectious diseases, rare cancers, and interventions without an investigational medicinal product, such as standalone medical device, surgical, radiological, behavioural or rehabilitation studies.

Priorities and trial readiness

The call is open to eligible rare diseases within its scientific and regulatory scope, although ERDERA encourages proposals in three areas where multinational early-phase trials may be especially difficult, urgent or valuable: paediatric rare diseases, rapidly progressive rare diseases, and conditions with no approved therapy or only limited benefit from existing options.

These three areas are not eligibility filters; a proposal outside them may still apply and be competitive if it meets the call requirements. Their role is to guide strategic prioritisation only when proposals are otherwise comparable in scientific quality, feasibility, patient relevance and implementation capacity. In practical terms, ERDERA is signalling particular interest in trials where the scarcity of patients, the speed of disease progression or the absence of effective treatment makes coordinated European action especially important.

Consortia must show that the trial can be **delivered responsibly across borders** as each proposal must bring together at least **three independent eligible-for-funding partner institutions** from at least three different eligible ERDERA member countries. It should also designate a **Clinical Trial Sponsor**, nominate a **Coordinating Investigator**, include at least **one funded patient partner** through a **Patient Advocacy Organisation** or another organised patient group, and secure access to a **qualified multinational Clinical Trial Management Organisation**.

The Sponsor holds legal and regulatory responsibility for the trial, including Good Clinical Practice oversight, pharmacovigilance, monitoring, quality management and trial authorisation. The Coordinating Investigator provides scientific leadership and internal project coordination; and the CTMO may support trial management, regulatory coordination, monitoring, quality assurance, site management, vendor oversight, study start-up and other operational functions, without transferring the Sponsor's legal responsibilities.

Patient involvement built into the trial

Meaningful Patient and Public Involvement and Engagement is mandatory. Patient partners must be involved in the design, conduct, oversight and dissemination of the trial, with a role that goes beyond consultation.

Applicants **must provide a Patient Involvement Plan** explaining how patient perspectives have shaped, or will shape, the study design, outcome measures, recruitment and retention strategy, informed consent materials, feasibility assessment, governance and communication of results.

The call also asks applicants to address the practical conditions of participation, including trial burden, language support, cross-border travel and accommodation, remote or local follow-up where feasible, and timely communication with participants and families if important changes occur during the study.

For rare disease trials, these requirements are not separate from feasibility. A protocol that does not reflect the realities of patients and families may struggle to recruit, retain participants or collect outcomes that are meaningful in daily life.

"Patient involvement is often described as a question of representation, but in a rare disease clinical trial it is also a question of evidence quality. If a protocol overlooks how families travel, how symptoms fluctuate, what outcomes matter in daily life, or what makes participation possible across borders, those omissions can affect recruitment, retention and the usefulness of the results.

The call encourages applicants to integrate patient partnership into trial design and governance. From a funding perspective, this approach helps ensure that selected projects are not only scientifically robust but also feasible, transparent, and better positioned to generate meaningful results that are relevant, interpretable, and ultimately usable in real-world settings."

***Carmen Fotino**, Clinical Trial Call Secretariat*

Application process and support

- → Stage 0 – Expression of Interest: open from 1 July to 10 September 2026.
- → Stage 1 – Short Proposal: planned from 15 September to 29 October 2026.
- → Stage 2 – Support Phase: planned from January to July 2027.
- → Stage 3 – Full Proposal: planned for July to September 2027.
- → Funding decisions: currently expected in February 2028.

An information webinar for prospective applicants will take place on 6 July 2026, from 15:00 to 17:00 CEST, covering the call objectives, eligibility requirements, evaluation process and indicative timeline.

Who can apply

Eligible applicants include universities, higher education institutions and research institutes; hospitals and clinical centres; non-profit research organisations and foundations; Patient Advocacy Organisations; and SMEs, subject to the specific funding provisions of the call.

Private for-profit pharmaceutical industry companies other than SMEs are not eligible to receive ERDERA funding as beneficiaries or funded partners.

Institutions from the following countries are currently eligible as funded partners: Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Slovakia, Spain, Sweden, The Netherlands, Türkiye and the United Kingdom.

Institutions from countries not listed may participate only as self-funded collaborators, where scientifically justified. Under the current call provisions, the Clinical Trial Sponsor must be established in an EU Member State or Norway.

Canadian institutions are eligible as funded partners and may provide the Coordinating Investigator; Canadian partners are primarily funded through CIHR

under its national rules, although SMEs established in Canada are not eligible to receive CIHR funding.

Applicants should consult the official Clinical Trial Call 2026 page for the authoritative call text, application documents, national and regional information, webinar registration and contact details. The mandatory Expression of Interest stage remains open until **10 September 2026**.

For scientific queries, applicants may contact the Clinical Trial Call Scientific Secretariat at ctc.secretariat@erdera.org.

Media Resources Available

- → ERDERA Clinical Trial Call webpage with detailed information on each project.
- → ERDERA Media Hub ERDERA's active campaigns and key messages, tailored for media.
- → ERDERA Clinical Trial Call 2026 Media Kit Press materials for this specific Call.
- → Press Contacts:

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