ERDERA European Rare Diseases Research Alliance

ERDERA

European Rare Diseases Research Alliance

ERDERA Clinical Trial Call 2026

Call Text

Version 3.0 | 1st July 2026

This call text may be subject to minor revisions. Applicants are responsible for regularly verifying that they are consulting the latest available version.

Submission deadline for Expressions of Interest: 10 September 2026
Submission deadline for Short Proposals: 29 October 2026
Contact-Scientific Secretariat
ERDERA Clinical Trial Call
Email: ctc.secretariat@erdera.org

ERDERA HAS RECEIVED FUNDING FROM THE EUROPEAN UNION'S HORIZON EUROPE RESEARCH AND INNOVATION PROGRAMME UNDER GRANT AGREEMENT N°101156595.

ERDERA HAS RECEIVED FUNDING FROM THE EUROPEAN UNION'S HORIZON EUROPE RESEARCH AND INNOVATION PROGRAMME UNDER GRANT AGREEMENT N°101156595.

ERDERA HAS RECEIVED FUNDING FROM THE EUROPEAN UNION'S HORIZON EUROPE RESEARCH AND INNOVATION PROGRAMME UNDER GRANT AGREEMENT N°101156595.

European Rare Diseases
Research Alliance

1. Background

There are approximately 7,000 distinct rare diseases (RDs), 80% of which are of genetic origin. Although individually rare, taken together RDs affect up to 30 million people in Europe. They represent a major public health challenge: many have an early or very early onset and/or lead to a significant decrease in life expectancy. Most cause chronic illnesses with profound impacts on patients, families, and healthcare systems. Current treatments are predominantly supportive or symptomatic rather than disease-modifying, leaving the majority of patients with considerable unmet medical needs.

The rare diseases landscape in Europe has evolved significantly over the past decade. The European Joint Programme on Rare Diseases (EJP RD, 2019–2024) advanced basic and clinical research, fostered patient engagement, and enabled important international collaborations. Building on this legacy, the European Rare Diseases Research Alliance (ERDERA) commenced its work in September 2024, with an estimated budget of €380 million until 2031, co-funded by the European Commission (EC) under the Horizon Europe PARTNERSHIP-COFUND mechanism (Grant Agreement N°101156595), Member States, Associated Countries, and other partners.

ERDERA positions itself in a dynamic EU context where clinical research and clinical trials in particular-are at the heart of health research priorities, as evidenced by recent initiatives including ERA4Health, ACT-EU, the Strategy for European Life Sciences, and the EU Biotech Act. Providing funding for high-quality clinical research is a core element of ERDERA's strategy to transform the rare disease research landscape in Europe.

Conducting clinical trials in rare diseases presents unique challenges. The small and geographically dispersed patient populations necessitate multinational collaboration to achieve the required sample sizes. The ERDERA Clinical Trial Call (ECTC) is designed precisely to address these challenges by supporting multi-national clinical trials as a single, coordinated funding effort. Up to €30 million of the ERDERA budget is dedicated to this call. UK Department of Health and Social Care (DHSC) is participating as a funding organisation in this call, marking the first time the UK contributes funding to an ERDERA call. UK contributions are integrated into the ERDERA central funds under a single set of rules, ensuring full harmonisation across all funded partners while enabling UK teams to be supported as part of multinational consortia.

Co-funded by the European Union

ERDERA has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement N°101156595.
Views and opinions expressed are those of the author(s) only and do not necessarily reflect those of the European Union or any other granting authority, who cannot be held responsible for them.

In addition to the ERDERA budget, a dedicated national funding envelope ($CAD 3.75 million) is provided by the Canadian Institutes of Health Research (CIHR) to support the participation of Canadian partners in funded consortia. CIHR funding is awarded to eligible Canadian partners in accordance with its national rules, with a parallel funding mechanism ensuring that Canadian participation is fully integrated within the overall multinational clinical trial framework.

2. Governance and Management Structures

⚑ **Key difference from JTC calls:** Unlike ERDERA Joint Transnational Calls (JTCs), where a Call Steering Committee (CSC) represents multiple national and regional funding organisations, each funding their own national applicants, the ERDERA Clinical Trial Call is governed by a single, centralised management structure. Funding flows from the European Commission to ERDERA and is distributed centrally by Fondazione Telethon (FTELE) on behalf of the ERDERA consortium. There are no parallel national funding processes and no national/regional funding organisations involved in the selection or distribution of funds. An exception applies to Canada, where the Canadian Institutes of Health Research (CIHR) provides funding to eligible Canadian partners through a parallel national mechanism aligned with the ERDERA process.

The management of the ERDERA Clinical Trial Call (ECTC) involves the following bodies:

Secretariat of the Clinical Trial Call (S-CTC)

The Scientific Secretariat is responsible for the day-to-day management of the call, including applicant communication, formal eligibility checks, organisation of the evaluation process, and coordination of the interview procedure. The Secretariat is hosted by Fondazione Telethon (FTELE). The S-CTC provides a Single Point of Contact for each consortium admitted to Stage 2, supporting applicants throughout the application preparation process. Contact: ctc.secretariat@erdera.org.

Clinical Trial Scientific Committee (CTSC)

The CTSC is the independent body responsible for the scientific evaluation of all proposals. It is composed of internationally recognised experts in clinical trial methodology, biostatistics, pharmacology, clinical medicine in rare diseases, patient/public involvement, and regulatory sciences. CTSC members must sign a confidentiality agreement and a conflict-of-interest declaration. CTSC members are not permitted to submit or participate in any proposal within this call. The CTSC establishes the scientific ranking of proposals and formulates funding recommendations to the ERDERA Board of Funders (BoF). The CTSC is also responsible for

the scientific assessment of funded projects at the Stage 4/Stage 5 transition, in accordance with the procedures described in Section 6.6.

ERDERA Coordination Office

The ERDERA Coordination Office provides strategic oversight and ensures alignment of the ECTC with ERDERA's overall scientific strategy and the obligations of the ERDERA Grant Agreement with the EC. It provides administrative support to the Call Secretariat and contributes to the organisation and oversight of the call process.

Board of Funders (BoF)

The Board of Funders is the final decision-making body for the ECTC. It reviews and formally approves the list of projects recommended for funding by the CTSC. The BoF fulfils, within the specific governance of the ECTC, a role analogous to the Call Steering Committee (CSC) in a typical ERDERA Joint Transnational Call. The BoF is composed of one representative from each funding organisation participating in ERDERA, and one representative of the European Commission. The BoF takes its final funding decisions on the basis of the scientific recommendations issued by the CTSC and in compliance with the ERDERA Grant Agreement with the EC.

Fondazione Telethon (FTELE)-Funding Administrator

FTELE acts as the central funding administrator for the ECTC on behalf of ERDERA . FTELE is responsible for the financial management of awarded grants, including the signature of Award Agreements with successful consortia, fund disbursement, financial reporting, and audit liaison with the European Commission. FTELE's role as funding body is distinct from the scientific evaluation, which remains the sole responsibility of the CTSC.

Canadian Institutes of Health Research (CIHR)

CIHR acts as the national funding organisation for Canadian partners participating in the ECTC on behalf of Canada. CIHR is responsible for the funding of eligible Canadian partners, in accordance with its national rules, eligibility criteria, and financial administration requirements. CIHR provides a dedicated budget for Canadian participation ($CAD 3.75 million in total), which will be allocated to top-ranked consortia including a Canadian component until the available CIHR funds are exhausted. If CIHR budget is fully committed, additional Canadian

partners in the selected projects may be funded through the ERDERA central fund, with FTELE acting as funding administrator under its applicable financial rules.

3. Aim of the Call

The aim of the ERDERA Clinical Trial Call (ECTC) is to fund multi-national, sponsor-led, GCP-compliant Phase I/II interventional clinical trials on rare diseases, generating data of sufficient quality and regulatory relevance to support future EMA regulatory filings, where appropriate. The call specifically targets areas of high unmet medical need where centrally coordinated; multinational funding offers a decisive advantage over individual national efforts.

3.1 In Scope

Study proposals must meet all of the following criteria:

- Address a rare disease within the meaning of Regulation (EC) No 141/2000 on orphan medicinal products-defined as a condition affecting not more than five in 10,000 persons in the European Community-as classified by Orphanet.
- Address a clearly defined, high unmet medical need in a severe, debilitating, or life-threatening condition in the relevant patient population. “Unmet medical need” is understood in accordance with the definition adopted by EMA/CHMP (EMA/CHMP/ICH/280/1995 as further elaborated in EMA guideline EMA/CHMP/0000054446/2022): a disease or condition where no satisfactory method of diagnosis, prevention, or treatment is authorised, or where, even if such a method exists, the proposed intervention provides substantial clinical benefit compared to existing therapies for patients with an unmet need.
- Target diseases with no satisfactory or sufficiently effective therapeutic option currently available, or with substantial residual unmet need despite existing treatment.
- Consists of multi-national Phase I, Phase I/II, or Phase II interventional clinical trials conducted in accordance with Good Clinical Practice (GCP) as per ICH E6(R3) guidelines and applicable EU regulations (EU Clinical Trial Regulation No. 536/2014).

Priority areas for this call

While proposals on all eligible rare diseases are welcome (excluding cancer and others, please refer to the 3.2 section below), the call particularly encourages applications addressing the following disease categories, where the need for coordinated multinational funding is most acute:

Paediatric rare diseases - conditions in which the relevant patient population is predominantly paediatric, as classified by Orphanet (see definition in Section 3.3).

Rapidly progressive rare diseases - conditions characterised by swift clinical deterioration over a short timeframe, creating heightened urgency for access to investigational therapies (see definition in Section 3.3).

Conditions lacking approved therapeutic options - rare diseases for which no medicinal product has received marketing authorisation in the EU, or for which existing authorised treatments provide only partial or insufficient clinical benefit (see definition in Section 3.3).

These priority areas are not eligibility criteria. However, where two or more proposals are of otherwise equivalent scientific quality, alignment with the above priority areas will be taken into account in the final strategic prioritisation.

Eligible therapeutic interventions include:

- Small molecules-both new chemical entities (NCEs) and repurposed drugs (i.e., existing authorised substances proposed for a new indication).
- Advanced Therapy Medicinal Products (ATMPs) - provided that the manufacturing process has been developed and validated under GMP conditions appropriate for Phase I/II use. (See Section 4 for specific provisions on manufacturing cost coverage)
- Biologics and New Biological Entities (NBEs) - i.e., biological substances not previously authorised as a medicinal product in the EU.
- Repurposed biologics.

3.1.1 Specific Requirements for Repurposed Drugs and Repurposed Biologics

Proposals involving repurposed drugs or repurposed biologics must demonstrate, at Stage 2, that both (i) uninterrupted IMP supply for the full duration of the trial and (ii) a credible pathway towards patient access following successful trial completion are secured or realistically achievable. Unlike new chemical entities or ATMPs, where the applicant controls manufacturing and development, repurposed products may depend on third-party Marketing Authorisation Holders (MAHs), manufacturers, or suppliers whose commercial decisions are independent of the funded project. Failure to address these risks may compromise both trial completion and the translation of positive results into clinical practice. Accordingly, applicants must provide all of the following as part of the Full Proposals

(a) A letter of intent, supply agreement, or documented alternative supply strategy demonstrating that the required quantity of IMP can be obtained for the planned trial duration;
(b) A contingency plan addressing the risk of supply disruption, product discontinuation, withdrawal from the market, or change in manufacturing arrangements during the trial;
(c) A post-trial access strategy for participants, specifying either:
(i) a named pathway (e.g. off-label prescribing framework, compassionate use programme, managed access programme, or Marketing Authorisation application) through

which participants who benefit from the intervention may continue to receive treatment after trial completion; or
(ii) a clear statement that post-trial access falls outside the scope of the funded activity, accompanied by an ethical transition plan for participants, in accordance with ICH E6(R3) GCP and the Declaration of Helsinki;

(d) A translation and implementation strategy describing how positive trial results could be advanced towards broader patient access and clinical adoption. Applicants must identify the organisation(s) expected to support the next regulatory, manufacturing, reimbursement, implementation, or dissemination steps following trial completion. Where relevant, evidence of engagement with the MAH, manufacturer, intellectual property holder, generic or biosimilar manufacturer, patient organisation, public authority, or other relevant stakeholder should be provided.

For products subject to intellectual property rights, regulatory exclusivities, proprietary manufacturing know-how, or other legal restrictions that could affect trial conduct or future implementation, applicants must demonstrate that these issues have been identified and that an appropriate mitigation strategy is in place.

Proposals that do not adequately address points (a), (b), (c), and (d) above may be considered incomplete and may be downgraded or declared ineligible during evaluation.

3.2 Out of Scope

The following are explicitly excluded from the scope of this call:

- Non-clinical studies (in vitro, in silico, animal studies, preclinical work).
- Studies of medical devices, food supplements, radiological or surgical procedures, or behavioural/rehabilitation interventions without any investigational medicinal product.
- Phase III and Phase IV clinical trials.
- Pharmacovigilance studies (Phase IV).
- Rare infectious diseases and rare cancers. Important note: tumour-predisposition syndromes and non-malignant or low-grade tumour manifestations within a rare genetic disease are not excluded and remain eligible.
- Rare adverse drug events or secondary outcomes in the treatment of non-rare diseases.
- Projects where the primary objective is a health economic assessment without an interventional component.

Note: A project will be considered ineligible if its primary objective falls outside the above scope, even if secondary objectives are within scope. All proposals are evaluated by the Clinical Trial Scientific Committee (CTSC). The decision as to whether to submit a borderline case rests entirely with the applicant.

3.3 Definitions

All key terms used in this call text are defined in Annex I (Definitions). Applicants MUST consult Annex I before preparing their proposal. Failure to comply with the definitions set out in Annex I may result in ineligibility or downgrading during evaluation. In case of any discrepancy between a term as used in the call text and the definition provided in Annex I, the definition in Annex I shall prevail.

4. Funding Mechanism

4.1 Central Funding via Fondazione Telethon (FTELE)

⚑ **Key difference from JTC calls:** In ERDERA Joint Transnational Calls (JTCs), each participating national or regional funding organisation funds the applicants from its own country independently, according to national rules. Applicants in JTCs must comply with their respective national/regional funding requirements and submit parallel national applications. This is NOT the case for the ERDERA Clinical Trial Call. In the ECTC, all funding is provided centrally from the European Commission's contribution to ERDERA and is administered and distributed by Fondazione Telethon (FTELE). There is a single set of funding rules applicable to all participants, regardless of their country of origin. No parallel national submissions are required.

The ERDERA Clinical Trial Call (ECTC) is financed through ERDERA's European Partnership budget, which receives funding from the European Commission under the Horizon Europe PARTNERSHIP-COFUND mechanism (Grant Agreement N°101156595). On behalf of the ERDERA consortium, FTELE serves as the sole funding body for this call.

This centralised model reflects both the nature of clinical trial funding-which requires a coordinated and unified financial structure-and the specific governance arrangements within ERDERA. It ensures that all partners within a funded consortium operate under identical financial terms, eliminates disparities arising from differing national funding rules, and provides a streamlined contracting process.

4.2 National funding for Canadian Partners via Canadian Institutes of Health Research (CIHR)

Canadian partners participating in the ECTC are primarily funded through the Canadian Institutes of Health Research (CIHR), which provides a dedicated national budget to support eligible Canadian partners. CIHR funding is awarded to the institution of the Nominated Principal Applicant and is managed in accordance with CIHR national rules and financial administration requirements, with funds transferred directly to the Nominated Principal Applicant's institution in Canada.

In the event that the CIHR budget is fully committed, additional Canadian partners may be funded through the ERDERA central fund. In such cases, FTELE acts as the funding administrator, and ERDERA financial rules apply, with funds transferred via the consortium's EU legal Sponsor in accordance with the applicable funding arrangements.

4.3 Total Budget Envelope and Per-Project Budget

Up to €30 million of the ERDERA budget is available to fund projects under this call. A portion of this envelope is reserved for the support of the selected short proposals (see section 6.3). The exact number of projects funded will depend on the scientific quality and feasibility of the proposals, as well as the budgets requested.

CIHR provides a dedicated budget for Canadian participation ($CAD 3.75 million in total).

The requested budget for each project should be adequate for the needs of the proposed work. Budgets are expected to be in the range of €1 million to €5 million per project. Projects outside this range are eligible but must provide adequate justification.

Eligible costs include:

- Personnel costs of clinical and research staff at all participating sites.
- Costs of the investigational medicinal product (IMP), including for ATMPs, manufacturing costs up to and including Phase I/II batch production (GMP-compliant). Phase III-scale manufacturing costs are not eligible.
- Clinical site costs: screening, monitoring, data collection, patient visits.
- **Regulatory costs:** Ethics committee submissions and Clinical Trial Authorisation (CTA) fees are eligible for all projects. EMA scientific advice fees: EMA provides fee waivers for certain categories of applicants and products, including paediatric studies (under the Paediatric Regulation), products with Orphan Drug Designation (ODD), and academic/non-commercial sponsors. Applicants who qualify for a waiver are expected to apply for it; the corresponding costs will not be eligible for ECTC funding. For applicants that do not qualify for any EMA fee waiver (e.g. SME sponsors without ODD or paediatric designation), EMA scientific advice fees are eligible and must be included in the project budget.
- Data management and biostatistics, including costs associated with the central data collection and management service designated by the ERDERA programme (see mandatory requirement below).
- Patient and Public Involvement and Engagement (PPIE) activities: costs associated with patient partner participation, including PAO staff time, travel and

subsistence, translation and interpretation, reimbursement of out-of-pocket expenses, and costs of developing patient-facing materials. PPIE costs must be adequately budgeted and described in the Patient Involvement Plan.

- Costs of multinational clinical trial management support structure: consortia are required to include or contract an organisation with proven experience in multinational trial coordination (see mandatory requirement below). Example of clinical trial management support structures (non-exhaustive list): ECRIN, CVBF or equivalent.

- Project management and coordination costs, including costs of the Sponsor institution for fulfilling its regulatory and legal obligations.

- Dissemination and open access publication costs.

- Costs relating to subcontracting of activities.

- Overhead/indirect costs as per the applicable rate defined in the Award Agreement with FTELE.

- **Eligible costs for Canadian applicants**: please refer to the Tri-Agency Guide on Financial Administration for guidance on the appropriate use of grant funds.

Mandatory budget requirements:

- **Multinational clinical trial management partner:** All funded consortia are required to include, or demonstrate a formal access arrangement with, an organisation with proven experience in coordinating multinational clinical trials (e.g. ECRIN, c4c, CVBF, or equivalent). This entity must be identified in the consortium at Full Proposal stage. Its costs must be included in the project budget. Applicants are strongly encouraged to initiate contact with such an organisation at the earliest possible stage-no later than Stage 2-in order to integrate them meaningfully into the consortium.

- **Central data collection and management service:** Funded projects will be required to use the central data collection and management service designated by the ERDERA programme in order to promote harmonised, interoperable and regulatory-quality data collection across the portfolio. Applicants must therefore foresee an appropriate budget allocation for these services within their proposal. As an indication, costs are expected to range between approximately €80,000 and €150,000 depending on study complexity, duration and data requirements. The designated service provider will be communicated to shortlisted applicants at Stage 2.

SME Funding Provisions

Small and medium-sized enterprises (SMEs), as defined in Commission Recommendation 2003/361/EC, are eligible to participate in this Call as beneficiaries, consortium partners, or Sponsors, provided that they meet all applicable eligibility requirements and can fulfil the responsibilities assigned to them within the project.
Funding rates for SMEs are subject to applicable State aid rules. For this Call, the maximum funding rates are:

- Small enterprises: up to 70% of eligible costs;
- Medium-sized enterprises: up to 60% of eligible costs.

The remaining costs must be covered from the SME's own resources or from other funding sources that are compatible with the applicable funding and State aid rules.
Applicants must declare any other public funding, grants, subsidies, or aid received or requested for the same project activities or eligible costs. The same eligible costs may not be funded more than once.
SMEs established in Canada are not eligible to receive funding from ERDERA or CIHR.
The funding rates set out above apply only to funding provided through the ERDERA common pot.
Where necessary for the implementation of the project, beneficiaries may procure specific commercial services or products from external providers, provided that such services or products are necessary for the project, are obtained in accordance with applicable procurement principles, and do not constitute core project activities.
The SME funding provisions of this Call are established in accordance with the applicable State aid framework, including Article 25 (Aid for research and development projects) of Commission Regulation (EU) No 651/2014, as amended.

4.4 Award Agreement Key Terms

Successful consortia will enter into a single Award Agreement directly with FTELE. This Award Agreement will be signed by the Sponsor institution, on behalf of the entire consortium, following the model applied under Horizon Europe funded projects. Partner institutions will accede to the Award Agreement by signing an Accession Form. The Award Agreement will set out the Sponsor's obligation to distribute funding to all consortium partners in accordance with the approved budget, in line with the milestone-based disbursement schedule. Internal consortium financial and governance arrangements must be further governed by a Consortium Funding Agreement, which shall address intellectual property, data management, publication rights, and liability distribution among partners. The key features of this arrangement are as follows:

- Single Award Agreement: One contract is signed between FTELE and the Sponsor institution. The Sponsor is financially and legally responsible to FTELE for the entire project budget, including funds allocated to all consortium partners.
- Fund redistribution: The Sponsor is responsible for redistributing funds to consortium partners in accordance with the budget plan approved in the Award Agreement. Internal

consortium financial arrangements shall be governed by a Consortium Funding Agreement signed by all partners.

- Financial reporting: All financial reporting is directed to FTELE as the funding body. FTELE in turn reports to the European Commission as required by the ERDERA Grant Agreement. Partners must provide the Sponsor with the necessary financial documentation to enable consolidated reporting to FTELE.
- Audit rights: FTELE, ERDERA, and the European Commission retain the right to audit the use of funds at any level of the consortium, including at individual partner institutions.
- Applicable rules: The financial rules applicable to the ECTC grants derive from the ERDERA Grant Agreement with the EC (Horizon Europe rules) as operationalised by FTELE. These rules apply uniformly to all partners, regardless of their country of origin. Partners are expected to comply with these rules in addition to any applicable national legislation (e.g. ethics, data protection, and clinical trial authorisation requirements in their country).
- No national co-funding requirement: Unlike in JTC calls, partners in the ECTC are not required to secure national or regional co-funding. The full requested budget, within the eligible limits defined in this call, will be provided centrally through FTELE for partners from ERDERA full member countries.
- Milestone-based disbursement: Funding will be disbursed in instalments linked to the achievement of pre-agreed milestones (see Section 6 for the phased funding approach).

Exception-Canada: participate with dedicated additional national contributions managed directly by CIHR. Funding for Canadian partners will be distributed by CIHR, not by FTELE. CIHR disbursement schedule must be aligned with the milestone-based payments administered by FTELE. Reporting remains consolidated: all partners must report through the Sponsor, which submits a single consolidated financial and scientific report to FTELE. Specific conditions applicable to Canadian partners are set out in the dedicated Award Agreement.
In Canada, a Canadian sub-sponsor or equivalent institutional structure must be identified; further details are provided in Section 5.3.2.

5. Eligibility Criteria

5.1 Eligible Countries

⚑ **Key difference from JTC calls:** Unlike JTC calls, where only institutions from countries with a participating national funding organisation are eligible, the ECTC is open to institutions from all ERDERA member countries and regions. Applicants do not need to verify whether their national funding organisation is participating, as funding is provided centrally by FTELE. The eligible countries list is also provided in Annex II.

The following countries are currently eligible to participate in the ECTC as funded partners: Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Georgia, Greece, Hungary, Island, Ireland, Israel, Italy, Latvia, Lithuania,

Luxembourg, Morocco, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, The Netherlands, Türkiye and UK (England, Northern Ireland, Scotland and Wales).

Institutions from countries NOT listed above may participate only as self-funded collaborators (see Section 5.3.3) and are not eligible for ECTC funding. There are no country-specific budget caps at the individual project level. However, partners from Canada may be subject to additional, specific funding conditions set out in their national funding agreement (see Section 4.3). All eligible partner institutions must comply with applicable national and EU legislation, including ethics regulations, data protection (GDPR), and clinical trial authorisation requirements in each country where a trial site is located. These are regulatory obligations that are independent of the centralized funding mechanism.

5.2 Eligible Applicants and Organisations

Research proposals must be multinational (see Section 5.3) and may be submitted by applicants belonging to one or more of the following categories:

- Academia-research teams working in universities, higher education institutions, or research institutes.
- Clinical centres-research teams working in hospitals, clinical research organisations, or other healthcare settings, regardless of their legal status or profit nature.
- Patient Advocacy Organisations (PAOs).
- Small and Medium Enterprises (SMEs), eligible as funded partners and may act as Sponsor (see Section 4.2 and Annex I for the SME definition and applicable State aid provisions). SMEs from Canada are not eligible to receive funding from CIHR or ERDERA.
- Non-profit research organisations or foundations.

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

5.3 Consortium Composition Requirements

5.3.1 Multinational Requirement

Only multinational clinical trials will be funded.
Each consortium must involve a minimum of three independent eligible-for-funding partner institutions from at least three different ERDERA member countries. Partners from the same country may participate, provided that the multinational requirement is fulfilled and the participation of each partner is scientifically justified.
The consortium must designate a Clinical Trial Sponsor and a Coordinating Investigator and include at least one funded patient partner represented by a Patient Advocacy Organisation (PAO) or another organised patient group. In addition, the consortium must include, or

demonstrate a formal access arrangement with, a qualified multinational Clinical Trial Management Organisation (CTMO) in accordance with the requirements set out in this Call.
Patient Advocacy Organisations (PAOs) participating in Patient and Public Involvement and Engagement (PPIE) activities do not count towards the minimum consortium composition requirement of three partners from three different countries. However, a PAO acting as the Clinical Trial Sponsor may be counted towards the minimum consortium composition requirement, provided that it fulfils all Sponsor eligibility and capacity requirements specified in this Call.
CTMOs providing trial management support do not count towards the minimum consortium composition requirement unless they participate as full consortium partners contributing directly to the scientific conduct and implementation of the clinical trial.

5.3.2 Clinical Trial Sponsor

Each proposal must identify a Clinical Trial Sponsor. The Sponsor is the legal entity that assumes full responsibility for the initiation, management, conduct, and financial accountability of the clinical trial in accordance with Regulation (EU) No. 536/2014 and applicable national legislation. The Sponsor must be established in an EU Member State or Norway.
Any eligible legal entity participating in the consortium may act as Sponsor, including academic institutions, clinical centres, non-profit foundations, Patient Advocacy Organisations (PAOs), and SMEs. Private for-profit companies other than SMEs are not eligible to act as Sponsor.
The Sponsor assumes all legal and regulatory responsibilities associated with the clinical trial, including submission and maintenance of the Clinical Trial Application through CTIS, pharmacovigilance reporting, safety oversight, trial monitoring, quality management, and fulfilment of Good Clinical Practice (GCP) obligations across all participating clinical sites. The Sponsor remains ultimately responsible for ensuring compliance with all applicable regulatory and GCP requirements, irrespective of any delegation of activities or support provided by consortium partners or external service providers.
The Sponsor and the Coordinating Investigator may belong to the same institution or to different consortium partners. Where they are different entities, the proposal must clearly describe their respective roles and responsibilities, as well as the arrangements in place to ensure effective coordination between scientific leadership and Sponsor oversight.
Applicants must demonstrate that the Sponsor possesses, either directly or through formalised arrangements with qualified third parties, the expertise, infrastructure, and operational capacity required to fulfil the Sponsor role for a multinational Phase I/II clinical trial. The proposal must describe the Sponsor's arrangements for regulatory oversight, pharmacovigilance, monitoring, quality assurance, data management, and oversight of subcontracted or outsourced activities, where applicable. Applicants should provide evidence of relevant experience in the conduct, management, or sponsorship of interventional clinical trials, or otherwise demonstrate access to the expertise and support structures necessary to ensure compliant trial delivery.
The Sponsor must be clearly identified in the proposal, together with a clear intellectual property (IP) strategy where the owner of the IP, Orphan Drug Designation (ODD), investigational product, or other relevant rights is not part of the consortium. Where the Sponsor is not the owner of the IP, ODD, investigational product, or associated background

data, the proposal must demonstrate that the consortium has secured the necessary rights, agreements, and legal access required for the conduct of the trial and the implementation of its results. The Sponsor institution will sign the Award Agreement with FTELE on behalf of the consortium and will serve as the primary contractual contact for administrative, financial, and regulatory matters related to the funded project.

For consortia including a Canadian partner, A Canadian sub-sponsor or equivalent institutional structure must be identified for the Canadian component of the trial. This entity will provide a coordination function for the Canadian component, including support for obtaining regulatory and ethics approvals, as needed and as appropriate. Note that this could be the institution paid for the Canadian Nominated Principal Applicant (NPA), and agreements must be established with the European Sponsor and CTMO. These agreements will be developed between the Canadian Sponsor/CTMO and their European counterparts. Canadian investigators may serve as the Coordinating Investigator; however, an EU Member State or Norway–based Sponsor and CTMO are still required.

For Canadian partners funded through FTELE, funds are transferred to the consortium's EU legal Sponsor, which is responsible for redistributing funding to all consortium partners, including Canadian institutions, and for ensuring that funding to Canadian partners is transferred in accordance with the applicable funding arrangements.

5.3.3 Coordinating Investigator

Each consortium must nominate one Coordinating Investigator from among the Principal Investigators of the consortium partners. The Coordinating Investigator is responsible for the scientific leadership and coordination of the project and serves as the primary scientific contact for ERDERA programme management.
The Coordinating Investigator and the Sponsor may belong to the same institution or to different consortium partners (see Section 4.2). Entities from EU countries, Norway, the United Kingdom or Canada may provide the Coordinating Investigator. Where the Sponsor and the Coordinating Investigator belong to the same institution, that institution must be established in an EU Member State or Norway.

The Coordinating Investigator will:

- Represent the consortium in scientific interactions with the Scientific Secretariat, the CTSC, and FTELE.
- Be responsible for the scientific leadership and internal coordination of the project, including scientific reporting and communication with evaluation bodies.
- Ensure timely submission of all scientific deliverables, milestone reports, and other documents required by the Scientific Secretariat and FTELE.
- Coordinate scientific activities and serve as the primary interface with the Scientific Secretariat, the CTSC, and FTELE on scientific and project implementation matters.

Each partner institution will be represented by a single Principal Investigator (PI). Coordination workload should be adequately reflected in the budget.

5.3.4 Patient Advocacy Organisation (PAO)

Each consortium must include at least one Patient Advocacy Organisation (PAO) or, where no disease-specific PAO exists, another organised patient group representing the target patient population.

The PAO must participate as a funded consortium partner and receive appropriate financial support for its contribution to the project. Funding for PAO activities, including personnel costs, travel, meeting participation, training, and out-of-pocket expenses, is eligible under the ECTC and should be included in the project budget. The requested funding must be proportionate to the tasks and responsibilities assigned to the PAO and clearly justified in the proposal.

The role and responsibilities of the PAO must be clearly described in the proposal and reflected in the work plan, governance structure, and budget.

Importantly, PAOs participating in Patient and Public Involvement and Engagement (PPIE) activities do not count towards the minimum consortium composition requirement of three partners from three different countries. The only exception is a PAO acting as the Clinical Trial Sponsor, which may be counted towards the minimum composition requirement, provided it fulfils all Sponsor eligibility and capacity requirements specified in this Call.

5.3.5 Multinational Clinical Trial Management Organisation (CTMO)

Each consortium must include, or demonstrate a formal access arrangement with, a qualified organisation with proven experience in coordinating multinational clinical trials (e.g., ECRIN, c4c, CVBF, or equivalent).
For consortia including a Canadian component, an additional Canadian CTMO must be identified, or access to such an organisation must be demonstrated, in line with the overall consortium requirements for multinational trial management. Agreements must be established with the European Sponsor and CTMO. These agreements will be developed between the Canadian Sponsor/CTMO and their European counterparts.

The CTMO must be identified in the Full Proposal, and its role, responsibilities, and budget must be clearly described. Applicants are strongly encouraged to engage with the proposed CTMO at the earliest possible stage, and no later than Stage 2, in order to ensure meaningful integration into trial planning and implementation.
The CTMO may support the consortium in areas such as trial management, regulatory coordination, monitoring, quality assurance, site management, vendor oversight, study start-up activities, and other operational functions required for the conduct of a multinational clinical trial.
The proposal must clearly describe the division of responsibilities between the Sponsor, the Coordinating Investigator, the CTMO, and any other entities involved in trial delivery. The use of a CTMO does not transfer the legal responsibilities of the Sponsor under applicable legislation.

5.3.6 Collaborators and subcontractors

Consortia may include collaborators and subcontractors.
Collaborators (self-funded participants) are entities that participate in the project but do not receive ECTC funding. They cover their own costs of participation from their own resources or other funding sources. Collaborators must demonstrate clear scientific added value to the clinical study, provide evidence that funding for their participation is secured, and submit a signed letter of commitment. Collaborators may contribute to project activities but may not act as Sponsor, Coordinating Investigator, work package leader, or beneficiary responsible for project deliverables or milestones. Collaborators from non-ERDERA countries are permitted, provided their participation is scientifically justified and they do not receive ECTC funding.

Subcontractors are third parties contracted by a funded consortium partner to carry out specific, clearly defined tasks or services. Subcontractors are remunerated from the ECTC budget of the contracting partner and must be selected in accordance with the applicable procurement and value-for-money principles. Subcontracting must be clearly described and justified in the proposal. Core scientific, regulatory, Sponsor, Coordinating Investigator, may not be subcontracted.

Clinical sites whose sole role is to recruit and follow study participants, collect study data or biological samples, or perform protocol-specified procedures, and which are not included as funded consortium partners, may participate as subcontractors under an appropriate contractual arrangement within the consortium. Such sites receive payment from the project budget but do not sign the Consortium Funding Agreement and are not party to the Award Agreement. These arrangements must be clearly described in the work plan and budget.

The use of subcontracted clinical sites does not alter the Sponsor's responsibilities under applicable clinical trial legislation, GCP requirements, or the trial protocol. Appropriate contractual, oversight, and monitoring arrangements must be in place to ensure compliance at all participating sites.

5.4 Patient and Public Involvement and Engagement (PPIE)

Meaningful Patient and Public Involvement and Engagement (PPIE) is a mandatory requirement of the ERDERA Clinical Trial Call. Patient engagement must be integrated throughout the design, conduct, oversight, and dissemination of the proposed study and must go beyond a purely advisory or consultative role. Patient involvement should be substantive, meaningful, and documented throughout the clinical trial lifecycle. Tokenistic involvement of patient representatives will not be considered sufficient.
PPIE activities should be integrated across the full spectrum of trial activities, including, where relevant:

- Protocol design and selection of patient-relevant outcomes;
- Recruitment and retention strategies;
- Informed consent procedures and patient-facing documentation;
- Feasibility assessment and identification of barriers to participation;
- Dissemination of trial results to participants, patient communities, and the wider public;

- Participation in governance and oversight structures, such as Trial Steering Committees and other advisory bodies, where appropriate;
- Development of post-trial access, implementation, and dissemination strategies.

The proposal must include a detailed Patient Involvement Plan describing:

- The identity, expertise, and role of the patient partner(s) throughout the study;
- How patient input has informed, or will inform, the study design, selection of outcome measures, site selection, feasibility assessment, and participant experience;
- How patient partners will participate in governance and oversight structures;
- How findings will be communicated back to trial participants and the broader patient community;
- The expected impact of patient involvement on study design, trial conduct, participant experience, and implementation of results.

The Patient Involvement Plan will be assessed as part of the scientific evaluation and should demonstrate how patient perspectives have been incorporated into key trial design and implementation decisions. Applicants should provide evidence that patient engagement activities are appropriately planned, resourced, and integrated into the overall project governance structure.

Applicants seeking to identify suitable patient partners may consult relevant patient organisations and networks, including:

- Orphanet patient organisation directory (www.orpha.net);
- EURORDIS – Rare Diseases Europe (www.eurordis.org);
- European Reference Networks (ERNs) (www.ern-net.eu);
- European Patients' Forum (www.eu-patient.eu).

PPIE requirements: patient and family experience principles

All funded projects must address the following patient and family experience principles in their Patient Involvement Plan and trial protocol, where applicable to the study design:

- **Transparency and information sharing:** Applicants must describe how trial results, relevant safety information, and interim updates will be communicated to participants and their families in a timely, accessible, and comprehensible manner. Protocols must include formal mechanisms for information exchange between trial clinicians and local care teams at key milestones to ensure continuity of care.

- **Minimising trial burden:** Protocol design must avoid duplication of assessments and minimise the physical and logistical burden on participants. For paediatric studies, protocols must be adapted to paediatric realities-including the length of hospital visits and the impact of participation on the child's daily life.

- **Protected spaces for child participants:** In paediatric trials, the protocol must include provision for dedicated space and support time for child participants (e.g. play facilities, child life specialists) during periods when adults are engaged in clinical discussions or procedures.

- **Hybrid and decentralised follow-up:** Where clinically and scientifically feasible, protocols should incorporate provisions for remote or locally conducted follow-up visits to reduce the need for extended stays abroad and the associated burden on families. Applicants must describe how they have considered decentralised trial elements in their study design.

- **Language support and daily life assistance:** For multinational trials requiring participants to attend sites abroad, the budget and participant support plan must include provisions for interpretation, translation of patient-facing documents, and practical daily-life support. Families and patient organisations must be consulted in the design of these support mechanisms.

- **Responsible communication of critical changes:** The protocol must include a communication procedure ensuring that participants and their families are informed directly and without delay of any significant change to the trial (including suspension or discontinuation), prior to any public announcement. Participants are primary stakeholders and must be treated as such.

- **Cross-border financial and logistical support:** Proposals must include explicit provision for cross-border travel, accommodation, and related expenses for participants from countries other than the trial site. The budget must reflect the realistic cost of enabling participation for geographically dispersed families.

- **Patient and family involvement in protocol design:** Patients and caregivers must be involved from the earliest stages of protocol development. Their input is essential in the identification and definition of unmet medical needs and in key protocol design decisions-including endpoint selection, study procedures, and outcome measures-to ensure the feasibility and patient-centricity of the study.

5.5 Additional Recommendations

To strengthen the scientific, operational, and regulatory readiness of the proposed clinical trial, applicants are encouraged to address the following elements, where relevant to the proposed intervention and development strategy:

- Demonstrate a robust understanding of the natural history of the targeted rare disease(s);
- Provide evidence of access to appropriate patient identification and recruitment resources, such as patient registries, databases, natural history studies, ERNs, expert centres, or equivalent mechanisms;
- Describe the anticipated recruitment capacity of participating sites and the basis for recruitment projections;
- Describe the anticipated regulatory, clinical development, and patient access pathway following completion of the proposed study;

- Describe plans for communicating study results to participants, patient organisations, and the broader patient community;
- Demonstrate access to the investigational medicinal product and the manufacturing and supply arrangements necessary to support the proposed trial and subsequent development activities, where applicable.

Applicants are furthermore encouraged to engage early with relevant regulatory authorities and development pathways, including, where appropriate:

- Orphan Drug Designation (ODD) in the European Union;
- EMA Scientific Advice, Protocol Assistance, or Innovation Task Force (ITF) briefing meetings;
- Scientific advice procedures offered by national competent authorities;
- Paediatric Investigation Plans (PIPs) for paediatric development programmes.

Applicants are strongly encouraged to have obtained, applied for, or initiated preparations for obtaining Orphan Drug Designation (ODD), where the proposed intervention and target indication are eligible for such designation. Where ODD has not yet been obtained, applicants should describe their intended strategy and timeline for pursuing ODD during the subsequent development of the product, where relevant.

For proposals targeting paediatric rare diseases, applicants are encouraged to describe the status of any Paediatric Investigation Plan (PIP) or provide justification where a PIP is not applicable.

⚠ Orphan Drug Designation (ODD):

Orphan Drug Designation (ODD) is a regulatory status granted by the European Commission, following a positive opinion from the European Medicines Agency (EMA), for medicinal products intended for the diagnosis, prevention, or treatment of rare diseases. ODD is designed to support the development of therapies for conditions affecting no more than 5 in 10,000 people in the European Union, or where the return on investment would otherwise be insufficient to stimulate development.
ODD provides several incentives to developers, including access to protocol assistance, eligibility for fee reductions or waivers for certain regulatory procedures, and the possibility of obtaining market exclusivity following marketing authorisation, subject to the applicable regulatory requirements.
For medicinal product development programmes targeting rare diseases, ODD may facilitate interactions with regulatory authorities and support the overall development strategy. Applicants are therefore encouraged to consider the potential relevance of ODD to their proposed intervention and target indication, where applicable.
Further information on ODD and eligibility criteria is available from the EMA: https://www.ema.europa.eu/en/human-regulatory-overview/orphan-designation-overview

6. Application Process

The ECTC follows a multi-stage application process, designed to support applicants progressively towards a full clinical trial protocol while ensuring that only scientifically sound and operationally feasible projects advance to full funding. The stages are described below.

Overview of the Application Process:

Stage 0-Expression of Interest (EOI): mandatory gating step

Stage 1-Short Proposal: initial scientific evaluation

Stage 2-Support Phase: mandatory regulatory, methodological and PPIE support (free to applicants, ~6 months)

Stage 3-Full Proposal: complete protocol, feasibility, budget

Stage 4-Grant Award: clinical execution-safety and early efficacy (~2–3 years)

Stage 5-Grant Extension (Conditional): continuation upon positive Stage 4 outcomes (~2–3 years)

6.1 Stage 0 – Expression of Interest (EOI)

Stage 0 constitutes a mandatory preliminary notification stage for all applicants intending to submit a Short Proposal under the ERDERA Clinical Trial Call. The purpose of the EOI is to enable the Scientific Secretariat to estimate the expected number, scope, therapeutic areas, and support needs of future applications, and to plan the evaluation and proposal support processes accordingly.
Submission of an EOI is mandatory for any applicant intending to submit a Short Proposal at Stage 1. Proposals for which no EOI has been submitted by the applicable deadline will not be eligible to proceed to Stage 1. Submission of an EOI does not commit the applicant to submit a Short Proposal and does not constitute a formal application for funding.
Applicants must provide the following information in the EOI:

- Preliminary information on consortium partners;
- Disease area and disease name;
- European Reference Network (ERN) covering the disease, where applicable;
- Orphanet/ORPHA code;
- Target population, including age range where applicable, and indication of whether the proposal addresses one or more of the priority areas described in Section 3.1 (paediatric rare disease; rapidly progressive rare disease; condition lacking approved therapeutic options; disease requiring multinational patient recruitment);
- Description of the unmet medical need;
- Type of intervention (small molecule, ATMP, biologic, repurposed drug, repurposed biologic);
- Intended development phase for the trial (Phase I, Phase I/II, or Phase II);

- Confirmation of preliminary readiness, including anticipated access to investigational product supply, initial site feasibility considerations, and expected patient recruitment potential;
- Anticipated countries in which the trial will be conducted;
- Expected need for regulatory and/or PPIE support during Stage 2;
- Estimated budget request.

EOI submissions will be reviewed by the Scientific Secretariat for planning purposes only. Applicants may be contacted for clarification where necessary. Following the closure of the EOI stage, applicants will receive confirmation that their EOI has been registered and information regarding the next stage of the application process.

For Canadian applicants, no separate submission to CIHR is required at Stage 0, as proposals are submitted exclusively to ERDERA through FTELE grant tracking platform at this **link**.

6.2 Stage 1 – Short Proposal

Only applicants who submitted an EOI in Stage 0 may submit a Short Proposal.
The purpose of the Short Proposal is to demonstrate that the proposed project is scientifically sound, suitable for a multinational Phase I, Phase I/II, or Phase II clinical trial, and sufficiently mature to benefit from the structured support provided during Stage 2. The Short Proposal should enable the Clinical Trial Scientific Committee (CTSC) to assess the scientific merit, feasibility, and development potential of the proposed study.
The Short Proposal should include:

- Scientific rationale and initial evidence supporting the proposed clinical trial;
- Information on the investigational medicinal product, including preliminary evidence of access to the product and anticipated supply arrangements;
- A preliminary study concept (not a full protocol);
- Evidence of site feasibility, anticipated recruitment strategy, and potential patient recruitment capacity;
- An initial regulatory development plan, including orphan designation status, planned regulatory interactions, and anticipated CTA submission timeline;
- A preliminary Patient and Public Involvement and Engagement (PPIE) plan;
- Proposed consortium composition, including the Sponsor, Coordinating Investigator, patient partner, CTMO, and participating countries;
- A preliminary budget.

Short Proposals will be evaluated by the CTSC according to the evaluation criteria described in Section 7.2. Based on this evaluation, a selected number of short proposals will be invited to participate in Stage 2. Applicants will receive written feedback from the evaluation process. Participation in Stage 2 is by invitation only. Stage 1 evaluates not only scientific excellence but also the likelihood that the project can realistically reach a fundable Full Proposal after six months of support.

For Canadian applicants, no separate submission to CIHR is required at Stage 2, as applications continue to be submitted exclusively to ERDERA through FTELE grant tracking platform at this **link**.

6.3 Stage 2 – Support Stage: Preparation of Study Services (PSS)

Stage 2 is a mandatory structured proposal maturation and optimisation phase of approximately six months for all consortia selected following Stage 1 evaluation to submit a full proposal. Participation in Stage 2 is compulsory. Stage 2 is provided free of charge to applicants; all support costs are borne by ERDERA.

The objective of Stage 2 is to strengthen and optimise selected short proposals prior to submission of the Full Proposal through structured expert support in regulatory strategy, methodology, and Patient and Public Involvement and Engagement (PPIE). The aim is to maximise scientific quality, regulatory readiness, protocol feasibility, patient relevance, and the overall likelihood of successful trial implementation and subsequent development. Support is delivered through the Preparation of Study Service (PSS), structured around three pillars: regulatory alignment (EMA), methodological support, and PPI. Input is provided by independent experts (under confidentiality), coordinated centrally.

Each consortium will be assigned a Single Point of Contact (SPoC) within the PSS. The SPoC will coordinate all support activities and serve as the primary interface between the consortium and the PSS throughout Stage 2. Support includes an initial needs assessment, recommendations by Month 2, and continued feedback over the six-month period, including an optional final review. Experts provide comments on submitted materials only and do not contribute to writing proposals. All input is provided on a best-efforts basis and should be considered by applicants, with justification where recommendations are not followed.

Pillar 1 – Alignment with Regulators (EMA)

All shortlisted consortia will receive structured regulatory support coordinated through the PSS and delivered in collaboration with regulatory experts.

At the start of Stage 2, each proposal will undergo a regulatory scoping assessment to identify the most appropriate regulatory pathway and advisory mechanisms. This may include EMA Scientific Advice, Protocol Assistance, ITF interactions, or advice from national Competent Authorities. Where relevant, an early coordination step with EMA will be facilitated to guide this process.

Pillar 1 focuses on supporting access to the EMA's Scientific Advice procedure, with the objective of strengthening the regulatory relevance of each proposal and its contribution to future decision-making (e.g. towards Marketing Authorisation or regulatory requirements such as PIPs).

The PSS will support consortia in preparing for these interactions, with a primary focus on the preparation of the briefing package required to request EMA Scientific Advice. This includes guidance on requirements, review of draft materials, and access to independent experts. The full EMA procedure remains external to the PSS and follows standard timelines.

Pillar 2 – Methodological Support

The PSS will provide expert support on key methodological aspects of each proposal, including study objectives, trial design, eligibility criteria, endpoint selection, outcome measures, statistical methodology, sample size justification, feasibility, and operational aspects of multinational clinical trials.

At the start of Stage 2, each proposal will undergo a methodological scoping assessment to identify its specific needs and define the scope of support.

Pillar 2 aims to provide access to state-of-the-art methodological expertise to strengthen the scientific quality and robustness of each application, ensuring that the proposed design is appropriate for the stage of development and regulatory objectives of the project. Support will be tailored to each consortium and delivered by independent, conflict-free methodological experts, appointed and coordinated by the Pillar 2 Secretariat, and matched to the specific needs of each application.

The process will be structured around a limited number of key interactions, including an initial scoping phase, an expert review with recommendations, and a follow-up phase to support the integration of methodological improvements. Continuous advice may also be provided throughout the PSS via written exchanges or meetings, as appropriate.

Pillar 3 – Patient and Public Involvement and Engagement (PPIE)

Each consortium will be assigned a PPIE coordinator and at least two independent, conflict-free PPI experts.

The PSS will provide structured support to strengthen patient and public involvement (PPI) across proposals, including engagement with patient organisations and individuals with lived experience, integration of patient perspectives into study design and endpoints, review of patient-facing materials, and improvements to recruitment, retention, and communication strategies.
At the start of Stage 2, a scoping phase will assess existing PPI approaches and identify gaps. Support will then focus on providing tailored recommendations to improve the relevance, feasibility, and inclusiveness of each proposal, as well as its overall impact. The process will be organised around a limited number of key interactions, including a scoping meeting, a recommendations meeting, and an optional follow-up session to support integration of PPI improvements. Continuous advice may also be provided throughout the PSS, as appropriate.

Completion of Stage 2

Shortlisted applicants are expected to carefully consider the recommendations provided through the different pillars of the Proposal Support Service (PSS) when developing their full

proposals. While applicants are not obliged to implement all recommendations, they should provide a rationale for any recommendations that are not taken forward. The recommendations, together with the applicants' responses, may be made available to the full proposal evaluators as additional contextual information.

6.4 Stage 3 – Full Proposal

The Full Proposal constitutes the definitive application on the basis of which final funding decisions will be made. Only consortia explicitly invited following the successful completion of Stage 2 may submit a Full Proposal.
The Full Proposal must demonstrate that the proposed clinical trial is scientifically robust, operationally feasible, regulatory-ready, and supported by an appropriate consortium and implementation plan. It must include:

- A detailed clinical trial protocol synopsis;
- The regulatory strategy and current regulatory status, including relevant regulatory interactions undertaken during Stage 2 and how resulting recommendations have been incorporated into the proposed development plan;
- Confirmed site feasibility, including letters of commitment from all principal recruiting sites;
- A fully justified and detailed budget;
- Explicit Go/No-Go criteria governing the transition between Stage 4 and Stage 5;
- A complete Patient Involvement Plan;
- A Data Management Plan (DMP) describing data governance, data sharing, long-term preservation, interoperability, and FAIR compliance;
- Ethical and regulatory compliance documentation, or a clear plan and timeline for obtaining the necessary approvals;
- A description of how recommendations received during Stage 2 have been considered and incorporated into the proposal, where appropriate.

Applicants should note that the Full Proposal is expected to evolve as a result of the Stage 2 support process. Modifications to the study design, methodology, outcome measures, regulatory strategy, patient involvement approach, operational arrangements, or consortium composition that arise from Stage 2 recommendations will not be penalised and are encouraged where they improve the quality, feasibility, regulatory readiness, or patient relevance of the proposed trial.
Where substantial modifications have been introduced following Stage 2, applicants should provide a brief summary of the principal changes and their rationale. Fundamental changes that alter the primary objective, target disease, investigational product, or overall scope of the proposed trial may require prior notification to the Scientific Secretariat and may be reviewed for continued eligibility.

For Canada, a distinct parallel process will be in place only for applicants invited to submit a full application (Stage 3). Canadian applicants must apply directly through FTELE Platform for Stages 0–2, with CIHR-specific procedures applying only at the later stage. At Stage 3, Canadian applicants invited to submit a full application must submit the full application to ERDERA through the FTELE platform and a short proposal and detailed budget (in Canadian dollars) to CIHR and a detailed budget to CIHR, in accordance with CIHR requirements. Further information will be provided through ResearchNet.

6.5 Stage 4 – Grant Award and Initial Trial Execution

Stage 4 covers the initial execution phase of the funded clinical trial. Its objective is to generate early evidence of safety, feasibility, and preliminary clinical activity, as appropriate for the development stage of the investigational product. The expected duration of Stage 4 is approximately 2 to 3 years.
Funding will be provided through an Award Agreement between FTELE and the Sponsor institution. The implementation plan will include predefined milestones and Go/No-Go criteria agreed during the grant preparation process.
For each funded project, key milestones will typically include:

- Regulatory and ethics approvals required to initiate the clinical trial (e.g. CTA authorisation and ethics committee approval), 20% of the awarded budget;
- First Participant First Visit (FPFV), 20% of the awarded budget;
- Last Participant First Visit (LPFV), 25% of the awarded budget;
- Last Participant Last Visit (LPLV), 15% of the awarded budget;
- Clinical study report, 15% of the awarded budget;
- Entry of the study results in the clinical trial registry, 5% of the awarded budget.

FTELE will monitor milestone achievement in close collaboration with the Scientific Secretariat. Failure to achieve agreed milestones within the expected timelines will be reviewed on a case-by-case basis. Where delays or deviations materially affect the feasibility or scientific validity of the project, FTELE may suspend, modify, or terminate funding in accordance with the terms of the Award Agreement.

Funding Model

FTELE intends to implement a lump-sum funding model based on principles similar to those used in Horizon Europe Lump Sum Grants.
Under this model, funding is awarded for the completion of predefined project activities, work packages, milestones, and deliverables rather than on the basis of actual costs incurred. Payments will therefore be linked to the satisfactory completion of agreed project phases and associated outputs, as specified in the Award Agreement.
Applicants will be required to submit a detailed budget and implementation plan at Full Proposal stage. The final lump-sum structure, payment schedule, and associated reporting requirements will be defined during grant preparation and incorporated into the Award Agreement.
Additional guidance on the implementation of the lump-sum funding model will be provided to applicants invited to Stage 3.

For Canadian partners funded by CIHR, CIHR funds will be administered in accordance with CIHR Application Administration Guide and the Tri-agency Guide on Financial Administration.

6.6 Stage 5 – Conditional Continuation Funding

Stage 5 provides continuation funding for projects that successfully meet the predefined Go/No-Go criteria established during Stage 3 and incorporated into the Award Agreement.

The purpose of Stage 5 is to support the continued clinical development of interventions that have demonstrated sufficient promise during Stage 4 and warrant further evaluation.
At the conclusion of Stage 4, the CTSC will review the results generated by the project against the pre-agreed Go/No-Go criteria. These criteria may include safety, feasibility, recruitment performance, pharmacodynamic or biomarker evidence, preliminary efficacy signals, or other study-specific endpoints appropriate to the stage of development and therapeutic modality.
Based on this assessment, the CTSC will determine whether the project has successfully met the predefined criteria for progression to Stage 5.
The expected duration of Stage 5 is approximately 2 to 3 years. The combined duration of Stages 4 and 5 may not exceed seven years.
Where a project is approved for continuation, FTELE will implement the CTSC decision through an amendment to the original Award Agreement. The amendment will define the scope of Stage 5 activities, the corresponding budget, the implementation plan, and any additional milestones, deliverables, or reporting requirements.
FTELE will continue to manage the grant during Stage 5 under the same principles and procedures applicable to Stage 4, including monitoring of milestone achievement, contractual management, reporting, and payment administration. Stage 5 will constitute a separate implementation phase with its own agreed lump-sum budget and payment schedule, as specified in the Award Agreement amendment.

7. Evaluation Process

7.1 Evaluation Structure

The evaluation process is managed by the Scientific Secretariat and conducted by the Clinical Trial Scientific Committee (CTSC).
The evaluation comprises two scientific assessment stages:

- Short Proposal evaluation (Stage 1), open only to applicants who submitted an Expression of Interest (EOI) in Stage 0;
- Full Proposal evaluation (Stage 3), open only to consortia that successfully completed Stage 2 and were invited to submit a Full Proposal.

Formal and Eligibility Checks – Short Proposals

The Scientific Secretariat will verify that each Short Proposal complies with the formal requirements of the Call, including submission deadlines, completeness of the application, page limits, eligibility of participating entities, consortium composition requirements, and compliance with the scientific scope of the Call.
Proposals that fail to satisfy these requirements will not proceed to scientific evaluation. Applicants will be informed of the reasons for rejection.

Scientific Evaluation – Short Proposals

Short Proposals that pass the formal and eligibility checks will be evaluated by a panel of at least five reviewers appointed by the CTSC. The panel will include:

- At least two scientific experts with relevant expertise in the disease area, therapeutic modality, or clinical development pathway;
- One patient expert with relevant lived experience or patient advocacy expertise;
- One expert in clinical trial methodology and/or biostatistics;
- One regulatory expert with experience relevant to rare disease medicinal product development.

The purpose of the Stage 1 evaluation is to identify proposals with sufficient scientific merit, feasibility, development potential, regulatory maturity, and patient relevance to benefit from the structured support provided during Stage 2.
Reviewers will complete written evaluation reports, including scores and comments. Based on the reviewer assessments and subsequent discussion, the CTSC will establish a ranked list and determine which proposals will be invited to participate in Stage 2.
Applicants will receive the written reviewer comments without numerical scores.

Conflict of Interest Management

Potential conflicts of interest will be assessed and managed before proposal allocation.
All experts involved in Stage 2 support activities, proposal evaluation, interviews, ethics review, or Stage 4/Stage 5 progression assessments must declare any actual, potential, or perceived conflicts of interest.
Conflicts of interest will be assessed and managed at the level of individual experts rather than participating organisations. The participation of an organisation in proposal support activities, evaluation processes, clinical trial management services, patient engagement activities, or funded projects does not automatically create a conflict of interest for other individuals affiliated with that organisation.
Experts who have participated in Stage 2 support activities for a proposal may also contribute to subsequent assessment processes where their expertise is considered valuable. In such cases, the Scientific Secretariat and CTSC will ensure that the overall assessment remains balanced, independent, and based on multiple sources of expert opinion.
Experts shall not participate in the evaluation or assessment of a proposal where they have a direct personal, professional, financial, or institutional interest that could compromise, or reasonably be perceived as compromising, their independence and impartiality.
The Scientific Secretariat will implement appropriate measures to ensure the confidentiality, independence, and integrity of all support, evaluation, and assessment procedures.

Formal and Eligibility Checks – Full Proposals

The Scientific Secretariat will verify that each Full Proposal complies with the formal requirements of the Call and that any substantial modifications introduced since Stage 1 are adequately justified and consistent with the recommendations received during Stage 2.

Scientific Evaluation – Full Proposals

Full Proposals will be evaluated by a panel of three to five independent reviewers appointed by the CTSC. Collectively, the evaluation panel will provide expertise in the relevant disease area, medicinal product development, clinical trial methodology and/or biostatistics, patient involvement, and regulatory development.
The evaluation will assess the scientific quality, methodological robustness, regulatory readiness, feasibility, patient relevance, implementation capacity, and overall development potential of the proposed clinical trial.
Reviewers will complete written evaluation reports, including scores and comments. Based on these assessments, the CTSC will establish a preliminary ranking of proposals.
The CTSC will not recommend funding for any consortium that fails to demonstrate adequate scientific, operational, regulatory, and management capacity to conduct the proposed multinational clinical trial, including appropriate Sponsor oversight, scientific leadership, clinical trial management, pharmacovigilance, and regulatory support arrangements, irrespective of the scientific quality of the proposal.

7.2 Evaluation Criteria

Short Proposal Assessment Criteria

1. Scientific Quality

- Scientific relevance and quality of the proposed study and the extent to which it addresses an unmet medical need;
- Quality of the preliminary evidence supporting the study rationale and objectives;
- Appropriateness of the proposed development pathway for the investigational medicinal product.

2. Impact

- Potential impact on patients, clinical practice, and healthcare systems;
- Transnational added value beyond what would be achievable through a national or regional study;
- Potential contribution to future clinical development and patient access;
- Planned involvement of patients and patient representatives in study design, conduct, and dissemination.

3. Quality and Feasibility of Implementation

- Adequacy of the proposed study concept and methodology;
- Feasibility of patient recruitment and site participation;
- Preliminary regulatory readiness and development strategy;
- Feasibility of delivering the project within the anticipated timeframe and budget;
- Quality, complementarity, and appropriateness of the proposed consortium.

Full Proposal Assessment Criteria

1. Scientific Excellence

- Innovation and scientific relevance;
- Contribution beyond the current state of the art;
- Potential to improve clinical practice and inform future research;
- Relevance to patient needs;
- Clarity and pertinence of the research question and study objectives;
- Robustness of the scientific evidence supporting the medical need, study rationale, investigational medicinal product, and sample size justification;
- Adequacy of available safety information supporting clinical investigation.

2. Impact

- Added value of transnational collaboration;
- Expected short- and long-term impact for patients and healthcare systems;
- Potential impact on public health, clinical practice, future research, and socio-economic outcomes;
- Credibility of plans for exploitation, dissemination, implementation, and patient access;
- Data sharing and long-term data stewardship plans;
- Quality of patient and stakeholder involvement.

3. Quality and Feasibility of Implementation

- Feasibility of conducting the proposed study within the planned timeframe and budget;
- Readiness to initiate the clinical trial within the proposed timelines;
- Quality and coherence of the implementation plan;
- Appropriateness of governance structures, management arrangements, communication flows, and decision-making processes;
- Feasibility of patient recruitment and site activation;
- Adequacy of risk identification and mitigation measures;
- Adequacy of plans for trial monitoring, data quality assurance, pharmacovigilance, and participant safety;
- Appropriateness of the proposed CTMO support arrangements;
- Consideration and incorporation of relevant recommendations arising from Stage 2.

4. Competence of the Consortium and Environment

- Competence and experience of the Sponsor, Coordinating Investigator, and consortium partners;
- Experience in multinational clinical trials and rare disease research;
- Adequacy of regulatory, methodological, operational, and clinical expertise;
- Complementarity and completeness of the consortium;
- Access to relevant networks, infrastructures, and patient communities;
- Robustness of patient engagement arrangements and contingency measures for continued patient involvement.

5. Clinical Trial Design and Statistical Methodology

- Appropriateness of study design and control strategy;
- Relevance and adequacy of endpoints and outcome measures;
- Use of validated or standardised outcome measures where appropriate;
- Adequacy of randomisation, blinding, and bias mitigation measures where applicable;
- Quality of the statistical analysis plan;
- Adequacy of sample size justification;
- Strategies to address missing data, protocol deviations, and participant non-compliance;
- Consideration of the implications of study findings for future clinical development, clinical practice, and regulatory decision-making.

For proposals involving repurposed drugs or repurposed biologics, the adequacy and credibility of the IMP supply strategy (including any MAH commitment or equivalent arrangements), the robustness of the supply contingency plan, and the appropriateness of the post-trial access strategy will be assessed under Criterion 3 (Quality and feasibility of implementation).

7.3 Scoring System

Evaluation scores will be awarded using the following scale:

Score	Description
0-Failure	The proposal fails to address the criterion or cannot be assessed due to missing or incomplete information.
1-Poor	The criterion is inadequately addressed, or there are serious inherent weaknesses.
2-Fair	The proposal broadly addresses the criterion, but there are significant weaknesses.
3-Good	The criterion is addressed well, but several shortcomings are present.
4-Very Good	The criterion is addressed very well, but a small number of shortcomings are present.
5-Excellent	All relevant aspects of the criterion are successfully addressed; any shortcomings are minor.

The maximum score for Short Proposals is 15 points (3 criteria × 5).
The maximum score for Full Proposals is 25 points (5 criteria × 5).
Full Proposals will not be considered fundable if any individual criterion receives a score below 3, or if the total score is below 18 points.

7.4 Rebuttal Phase and Interview

Rebuttal Phase

Before the final CTSC funding meeting, each consortium submitting a Full Proposal will receive the complete set of reviewer assessments.
The rebuttal phase allows applicants to respond to reviewer comments and questions. It is not intended to permit modifications to the work plan, study design, consortium composition, or budget.
Applicants will have 7 calendar days to submit an optional written response. Responses submitted after the deadline or addressing matters unrelated to reviewer comments may be disregarded.
Rebuttal responses will be considered by the CTSC during final deliberations.

Interview with the Coordinating Investigator and Sponsor

The Coordinating Investigator and a designated representative of the Sponsor institution will participate in an interview conducted by a panel of three CTSC experts. The Scientific Secretariat will attend as an observer.
The interview serves as a qualitative assessment of the consortium's readiness to implement the proposed clinical trial and may cover:

- Previous experience of the Coordinating Investigator, Sponsor, and key consortium partners in conducting interventional clinical trials;
- Sponsor oversight arrangements and delegation of responsibilities;
- Clinical trial management arrangements, including the role of the CTMO where applicable;
- Regulatory, pharmacovigilance, monitoring, and quality management arrangements;
- Risk identification and mitigation strategies;
- Governance structures and communication flows across the consortium.

The interview panel's assessment will be shared with the CTSC and considered during the final funding deliberations.
The CTSC will not recommend funding for any consortium that fails to demonstrate adequate scientific, operational, regulatory, or management capacity to deliver the proposed trial, irrespective of the scientific quality of the proposal.

Stage 4/Stage 5 Progression Assessment

In addition to its role in proposal evaluation, the CTSC is responsible for assessing funded projects at the conclusion of Stage 4 in accordance with the procedures described in Section 6.6.
The CTSC will review the results generated during Stage 4 against the predefined Go/No-Go criteria established in the Award Agreement and determine whether the project has successfully met the conditions for progression to Stage 5.
This assessment constitutes a scientific continuation review and is distinct from the proposal evaluation procedures described above.

8. Programme-Level Ethics Review

Full Proposals selected for funding by the Board of Funders (BoF), subject to successful completion of the programme-level ethics review, will undergo a programme-level ethical and regulatory readiness assessment conducted by ERDERA ethics experts. The objective of this assessment is to support the ethical robustness, multinational readiness, and alignment of funded projects with ERDERA and Horizon Europe ethical expectations, particularly in the context of rare disease clinical research involving vulnerable populations and cross-border data and sample sharing, post-trial access arrangements, and long-term follow-up.

The review may identify ethical, operational, or procedural elements requiring clarification, adaptation, or completion before project activation. Where applicable, applicants may be requested to provide additional documentation, implementation plans, or evidence that identified requirements have been addressed within an agreed timeframe.
This programme-level review is complementary to, and does not replace, any approvals, authorisations, or regulatory procedures required under applicable European and national legislation, including approvals from Ethics Committees, Competent Authorities, and procedures conducted through the Clinical Trials Information System (CTIS) under Regulation (EU) No. 536/2014.
Applicants remain fully responsible for obtaining all required ethics approvals, clinical trial authorisations, and regulatory clearances in each participating country before trial initiation.
Signature of the Award Agreement does not constitute authorisation to initiate the clinical trial. Confirmation that all required approvals are in place remains a prerequisite for activation of the clinical trial and release of the funding instalment linked to the First Participant First Visit (FPFV) milestone.

9. Redress Procedure

Applicants may request a redress review if they have reasonable grounds to believe that a procedural irregularity or factual error may have affected the outcome of an eligibility check or evaluation process.
The redress procedure is limited to procedural aspects of the evaluation process and formal eligibility checks. Disagreement with the scientific, technical, methodological, ethical, regulatory, or strategic judgement of reviewers, interview panels, ethics experts, or the CTSC does not constitute grounds for redress. The scientific and technical assessments made by qualified experts are not subject to appeal.

9.1 Admissibility Conditions

For a request for redress to be admissible, all of the following conditions must be met:

- The request must be submitted by the Coordinating Investigator on behalf of the consortium;
- Only one request for redress may be submitted per proposal following each evaluation stage;

- The request must be submitted by email to the Scientific Secretariat ctc.secretariat@erdera.org within 7 calendar days of notification of the relevant eligibility or evaluation outcome;
- The request must clearly identify the call, proposal acronym, proposal title, and provide a detailed description of the alleged procedural irregularity or factual error.

9.2 Procedure

Upon receipt of a request for redress, the Scientific Secretariat will acknowledge receipt and inform the applicant of the anticipated timeline for review.
Admissible requests will be examined by an independent Redress Committee that was not involved in the original evaluation of the proposal.
The Redress Committee will assess only whether a procedural irregularity or factual error occurred and whether it may have materially affected the outcome. The Committee will not reassess the scientific, technical, methodological, ethical, regulatory, or strategic merits of the proposal.
If the Redress Committee concludes that no procedural irregularity or factual error occurred, the original evaluation outcome will stand.
If the Redress Committee concludes that a procedural irregularity or factual error may have materially affected the outcome, the proposal may be referred for partial or full re-evaluation, as appropriate. The Redress Committee will not modify evaluation scores, rankings, or funding recommendations directly.
The decision of the Redress Committee will be communicated to the applicant within 10 calendar days of the redress submission deadline.
Requests that do not satisfy the admissibility conditions, or that merely express disagreement with the scientific or technical evaluation, will be declared inadmissible and will not be examined further.

10. Contacts

For all enquiries relating to the ERDERA Clinical Trial Call 2026, applicants should contact the Scientific Secretariat:

Scientific Secretariat-ERDERA Clinical Trial Call

Institution: Fondazione Telethon

Contact person(s): Carmen Fotino

Email: ctc.secretariat@erdera.org

Website: https://erdera.org

An information webinar for prospective applicants will be held on July 6th, 2026. Registration details will be published on the ERDERA website.

For financial and award agreement enquiries, applicants should contact FTELE's grants management team after the funding decision has been communicated:

Fondazione Telethon (FTELE)-Grant Management

Contact: Raffaella Pettorruso

Email: telethonscience@fondazionetelethon.it

For all enquiries relating to requirements for Canadian partners, please contact the Canadian Institutes of Health Research at:

Canadian Institute of Health Research (CIHR)

Email: PDD-IGStrategic-CEP-IGStrategique@cihr-irsc.gc.ca

Annex I. Definitions of Clinical Study Types and Key Roles

The following definitions are applicable to this Call and are based on Regulation (EU) No. 536/2014, ICH E6(R3), Horizon Europe clinical study guidance, and related European regulatory documents.

Clinical Study

Any investigation in relation to humans intended to discover or verify the clinical, pharmacological, or other pharmacodynamic effects of one or more medicinal products; identify adverse reactions; or study the absorption, distribution, metabolism, and excretion of one or more medicinal products, with the objective of ascertaining their safety and/or efficacy. Clinical studies may be interventional or non-interventional. (CC Research Ethics)

Clinical Trial (Interventional Clinical Trial)

A clinical study that fulfils the definition of a clinical trial under Regulation (EU) No. 536/2014 and in which participants are prospectively assigned to receive one or more investigational medicinal products in order to evaluate their safety, efficacy, pharmacokinetics, pharmacodynamics, or other health-related outcomes.

Low-Intervention Clinical Trial

A clinical trial on an authorised medicinal product where: (a) the investigational medicinal product is used in accordance with the terms of its marketing authorisation, or its use is evidence-based and supported by published scientific evidence on safety and efficacy; and (b) any additional diagnostic or monitoring procedures pose no more than minimal additional risk or burden to participants compared with normal clinical practice.

Phase I Trial

A clinical trial primarily designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, or dose characteristics of an investigational medicinal product. Phase I studies may also include early assessments of biological or clinical activity.

Phase I/II Trial

A combined clinical trial designed to assess both safety-related objectives (Phase I) and preliminary efficacy or proof-of-concept objectives (Phase II). Such designs are particularly relevant in rare diseases where patient populations are limited.

Phase II Trial

A clinical trial designed to evaluate the therapeutic activity, efficacy, optimal dose, regimen, or further safety profile of an investigational medicinal product in a defined patient population. This includes Phase IIa (exploratory or dose-finding) and Phase IIb (proof-of-concept) studies.

First-in-Human Trial

A clinical trial in which an investigational medicinal product is administered to human participants for the first time following completion of relevant non-clinical development activities.

Basket Trial

A clinical trial evaluating a single investigational medicinal product or therapeutic strategy across multiple diseases, indications, or patient populations that share a common molecular, genetic, mechanistic, or biomarker-defined characteristic.

Umbrella Trial

A clinical trial evaluating multiple investigational medicinal products or therapeutic strategies within a single disease population, where treatment allocation is based on specific molecular, genetic, or biomarker-defined subgroups.

Platform Trial

A clinical trial conducted under a master protocol that allows multiple investigational interventions to be evaluated simultaneously, with treatment arms added, modified, or discontinued over time according to predefined decision rules.

Randomised Controlled Trial (RCT)

A clinical trial in which participants are randomly assigned to one or more intervention groups and, where applicable, one or more control groups, in order to minimise selection bias and support robust comparisons between treatments.

Pilot or Feasibility Study

A small-scale study conducted to assess the feasibility, acceptability, recruitment strategy, operational procedures, or methodological aspects of a future clinical trial. Within this Call, pilot or feasibility components are eligible only where they are integrated into a broader Phase I, Phase I/II, or Phase II clinical trial programme.

Non-Interventional Study

A clinical study other than a clinical trial, as defined in Regulation (EU) No. 536/2014. In a non-interventional study, the medicinal product is prescribed in the usual manner in accordance with the terms of the marketing authorisation and no additional diagnostic or monitoring procedures are applied beyond routine clinical practice. Non-interventional studies are not eligible as the primary objective of proposals submitted under this Call.

Repurposed Drug

An authorised or previously developed medicinal product investigated for a therapeutic indication, patient population, route of administration, dosage regimen, or treatment context different from that for which it was originally developed or authorised.

Repurposed Biologic

A biological medicinal product investigated for a therapeutic indication, patient population, route of administration, dosage regimen, or treatment context different from that for which it was originally developed or authorised.

Sponsor

The individual, company, institution, or organisation that assumes responsibility for the initiation, management, and regulatory oversight of a clinical trial in accordance with Regulation (EU) No. 536/2014.
For projects funded under this Call, the Sponsor is responsible for ensuring compliance with applicable regulatory requirements, including Clinical Trial Application (CTA) submission and maintenance through CTIS, pharmacovigilance obligations, trial oversight, and Good Clinical Practice (GCP) compliance. The Sponsor acts as the signatory of the Award Agreement with FTELE and is responsible for the contractual coordination and financial management of the grant on behalf of the consortium.
The Sponsor and the Coordinating Investigator may belong to the same or different consortium entities. Any eligible legal entity, including academic institutions, hospitals, research organisations, non-profit foundations, Patient Advocacy Organisations (PAOs), and SMEs, may act as Sponsor provided that it fulfils the eligibility conditions established in this Call and demonstrates adequate operational, regulatory, and financial capacity.

Coordinating Investigator

The individual designated by the consortium to provide overall scientific leadership and coordination of the project and to act as the primary scientific contact with ERDERA, the Scientific Secretariat, the CTSC, and FTELE.
The Coordinating Investigator is responsible for coordinating the scientific conduct of the trial across participating sites and ensuring effective collaboration among consortium partners.

Principal Investigator (PI)

The investigator responsible for the conduct of the clinical trial at a participating site in accordance with the protocol, Good Clinical Practice, and applicable regulatory requirements. The Principal Investigator represents that site within the consortium.

Clinical Trial Management Organisation (CTMO)

An organisation with demonstrated expertise in the operational management of multinational clinical trials. A CTMO may provide support in areas including project management, monitoring, regulatory coordination, site management, quality assurance, vendor management, trial logistics, and operational oversight.

The CTMO does not assume the legal responsibilities of the Sponsor unless separately designated as Sponsor.

Patient Partner

A representative of a Patient Advocacy Organisation (PAO) or other organised patient group who contributes lived experience and patient perspectives to the design, conduct, oversight, dissemination, implementation, or evaluation of the clinical trial.

Small and Medium Enterprise (SME)

As defined in Commission Recommendation 2003/361/EC. An SME is an enterprise that employs fewer than 250 persons and whose annual turnover does not exceed EUR 50 million and/or whose annual balance sheet total does not exceed EUR 43 million.
Within the SME category, a small enterprise employs fewer than 50 persons and has an annual turnover and/or annual balance sheet total not exceeding EUR 10 million.
Applicants claiming SME status must self-certify compliance with this definition at submission and may be required to provide supporting evidence at grant signature.

Annex II. Eligible Countries

⚑ **Key difference from JTC calls:** In JTC calls, only countries with a participating national funding organisation are eligible, and applicants must comply with national/regional funding rules. In the ECTC, ERDERA member countries are eligible, and a single set of rules (those of FTELE/ERDERA) applies to all partners, regardless of nationality. Only Canada has specific rules for Canadian partners.

Institutions from all ERDERA member countries and associated regions are eligible to participate in the ECTC and receive funding through FTELE. The following countries are currently ERDERA members. For the most up-to-date list, consult the ERDERA website (https://erdera.org).

- Austria
- Belgium (Flanders)
- Belgium (French-speaking community)
- Belgium (Wallonie)
- Bulgaria
- Canada (Canadian Institutes of Health Research, CIHR)
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany

- Georgia
- Greece
- Hungary
- Iceland
- Ireland
- Israel
- Italy
- Latvia
- Lithuania
- Luxembourg
- Morocco
- Norway
- Poland
- Portugal
- Romania
- Serbia
- Slovakia
- Slovenia
- Spain
- Sweden
- Türkiye
- The Netherlands
- United Kingdom (England, Northern Ireland, Scotland and Wales)

Note: Participation of institutions from non-ERDERA countries may be accepted as self-funded collaborators only. They are not eligible for ECTC funding.

Annex III. Indicative Call Timeline

The following timeline is indicative and subject to change. The definitive timeline will be published on the ERDERA website and communicated to registered applicants. All deadlines are at 17:00 CET unless otherwise stated.

Phase	Activity	Indicative Date
—	Launch of the call (publication on ERDERA website)	June 3rd, 2026
—	Information webinar for prospective applicants	July 6th, 2026
Stage 0	Expression of Interest (EOI) submission deadline	September 10th, 2026
Stage 0	EOI review/check	By mid-September 2026
Stage 0	Notification to applicants	By mid-September 2026
Stage 1	Short Proposal submission deadline	October 29th, 2026
Stage 1	Formal and eligibility check	November 2026
Stage 1	Scientific evaluation (CTSC)	December 2026
Stage 1	Notification of results-invitation to Stage 2	January 2027
Stage 2	Support phase	January – July 2027
Stage 3	Full Proposal submission period	August - September 2027
Stage 3	Formal check, scientific evaluation, rebuttal, Sponsor interview	October – December 2027
Stage 3	Notification of funding decisions	February 2028
Phase 4	Award Agreement signature with FTELE; project start	[TBD]
Phase 4	CTSC assessment & Go/NO go decision	[TBD]
Phase 5	Upon the results of CTSC assessment & recommendation for further funding	[TBD]

Submissions outside of the published deadlines will not be accepted. The Scientific Secretariat does not accept requests for extensions except in exceptional and duly

documented circumstances, which must be notified at least 5 working days before the deadline.

Annex IV. Guidelines for Canadian Partners

Specific and centralized guidelines for Canadian partners can be found here.