European Rare Diseases
Research Alliance

ERDERA
European Rare Diseases Research Alliance

ERDERA Clinical Trial Call 2026

Guidelines for Applicants

Expression of Interest (EOI)

Version 1.0 | 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: 10th September 2026
Submission deadline for Short Proposals: 29th October 2026

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These Guidelines for Applicants are intended to support the preparation and submission of applications via the electronic platform at this link. Applicants must also carefully consult the official Call Text, which provides the complete description of the call, including scope, funding rules, evaluation procedures, and detailed requirements.

1. 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.

2. Funding Mechanism

Funding for the ERDERA Clinical Trial Call is centrally managed by Fondazione Telethon (FTELE) on behalf of the ERDERA consortium, under a single set of rules applicable to all funded partners. Unlike ERDERA Joint Transnational Calls (JTCs), no parallel national submissions are required. An exception applies to Canada, where the Canadian Institutes of Health Research (CIHR) provides funding to eligible Canadian partners through a dedicated national funding mechanism aligned with the ERDERA process. Applicants are encouraged to consult the specific guidelines applicable to Canadian partners.

3. Eligibility Criteria

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.

Only interventional clinical trials (Phase I, Phase I/II or Phase II) involving investigational medicinal products are eligible under this call.

Non-clinical studies, Phase III/IV trials, studies without a medicinal product (e.g. devices, behavioural interventions), and studies outside the scope of rare diseases are not eligible.

3.1. Eligible Countries

Institutions from the following countries are currently expected to be eligible as funded partners: Austria, Belgium, Bulgaria, Canada* (see specific Canadian guidelines at this link), 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.

* Canada participates in the call through a dedicated national funding mechanism managed by the Canadian Institutes of Health Research (CIHR). Additional procedures may apply at later stages of the application process for Canadian applicants.

3.2. Eligible Applicants and Organisations

Research proposals must be multinational 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. Canadian SMEs are not eligible to receive funding.
- 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.

3.3. Eligible Interventions

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.
- Biologics and New Biological Entities (NBEs)-i.e., biological substances not previously authorised as a medicinal product in the EU.
- Repurposed biologics.

4. Application Process

There will be a four-stage submission procedure for joint applications: **Stage 0 – Expression of Interest (EOI)**, **Stage 1 – Short Proposal**, **Stage 2 – Support Stage (Preparation of Study Services, PSS)**, and **Stage 3 – Full Proposal**. Stage 2 is a stage, free of charges, for shortlisted applicants and does not constitute a submission or evaluation stage of the application process. In all cases, one document (in English) shall be prepared by the participants of the study and must be submitted by the Coordinating Investigator via the electronic submission system to Fondazione Telethon (FTELE) which acts as the central funding administrator for the ECTC on behalf of the ERDERA consortium.

EOI (in English) must be submitted via the electronic submission system no later than September 10th, 2026 at 1:00 p.m. Central European Time (CET).

Short proposals (in English) must be submitted via the electronic submission system no later than October 29th, 2026 at 1:00 p.m. Central European Time (CET).

Full proposals (in English) must be submitted in English through the electronic submission system by the end of September 2027; the exact deadline will be announced in due course.

Guidelines for short and full proposals will be published online in due course. Please, check the ERDERA website: https://erdera.org/call/ctc2026/

5. General Instructions

The Application form is available on the *Fondazione Telethon Grant Management* system portal at this **link**.

The Coordinating Investigator in charge of creating and completing the Application is identified as **Lead Applicant** in the system portal. Applicants should pay attention to these Guidelines, **as an Application failing to meet the requirements will be rejected**. An accurate Application will facilitate the review process. Use **English** language only. For abbreviations and acronyms not universally known, spell out the term the first time it is used, with the appropriate abbreviation in parentheses; the abbreviation should then be used thereafter. Some special characters/symbols may not be read by the platform. The text must be single-spaced, not exceeding the specified character or word number limitations. **The maximum number of characters in the different sections includes spaces.**

5.1. Applicant Account

Registered Users in TETRA (the former Grant Management system)

Applicants who have already registered in TETRA – the former *Fondazione Telethon Grant Management* system – are **kindly asked NOT to create a new account**.

Please click on ***Forgot Password?*** and follow the instructions for setting a New Password, then enter the portal at this link. Please note that the System allows the creation of an account associated with **ONLY** one email. Therefore, if the Applicant already has an account, he/she is kindly requested NOT to register with a different email, but to ask for a password change (by clicking on ***Forgot Password?*** - below the ***Login*** button).

To register, Applicants should click on the ***Register Here*** button, enter their email address and follow the online instructions.

Institution Information

Please enter the full name of the Applicant's Institution. If the name of the Institution is already registered in the System, it will be shown in a dropdown menu. Only if the Institution has not been registered yet, Applicants have to register it by clicking on Register New Institution and following the instructions.

Contact Information

Please note that the System allows the creation of an account associated with **ONLY** one email. Therefore, if the Applicant already has an account, he/she is kindly requested NOT to register with a different email, but to ask for a password change (by clicking on ***Forgot Password?*** - below the ***Login*** button). In case the email address is no longer valid, the Applicant is kindly asked to contact our IT Admin (telethonscience@fondazionetelethon.it) to update it.

For questions concerning the Application, it is possible to send an email to: telethonscience@fondazionetelethon.it.

Please note that, once the Applicant has registered on the portal for the first time, it is necessary to update the Profile Information by clicking on the dedicated shortcut ***Update/Edit Profile*** in the dashboard. Please fill in all the mandatory fields.

5.2. Personal Details

Before starting a New Application, the Applicant must update the **My Profile** – **General and Biosketch** sections by clicking on the dedicated shortcut ***Update/Edit Profile*** in the dashboard.

The **My Profile – General** section contains the information entered during the first registration on the portal and can be updated/modified at any time. This section automatically reports the Institution Information entered during the first registration on the portal. If you need to update the **Department/Institute**, use the lookup tool to filter the Applicant's **Host Institution**, and all the departments associated with it will be listed for selection. If the Applicant does not have a department or the department is not available among those listed, please enter only the Host Institution, and email it to telethonscience@fondazionetelethon.it. At the end, click on ***Submit profile*** so that all this information will automatically populate the Application relevant fields.

In the **My Profile – Biosketch** section (**not mandatory**), the Applicant can update the following items: *Education/Training, Personal Statement, Positions, Contributions to Science, Relevant Publications, Patents, Companies*.

Of note: keep the My Profile section updated. Please ensure to click on ***Submit Profile*** before creating a New Application, so that the information contained in the My Profile sections will be automatically incorporated in the relevant fields of the New Application.

5.3. Application status

In the **My Applications** section on the Home Page the Applicant can find draft Applications, check the status of the Applications and find submitted Applications and active grants (once available on the new platform).

In the **My Applications** section, accessible from the left-hand side of the Home Page, the following tabs are available:

In progress –This tab displays draft Applications. To edit an Application, select the one you wish to change. **Submitted** – This tab displays submitted Applications.

Under Review – This tab displays Applications in Under Review status.

Post Review – This tab shows a list of Applications for which the post-review decision remains pending. While an Application is in this status, it cannot be accessed by the Applicant.

Pending activation – This tab shows the list of Applications that are waiting to be activated.

Active grants – This tab shows the list of Application that have been activated.

Historical Grants – This tab displays the Application history (e.g. declined or closed applications).

Locked – This tab shows Applications that are locked because the Call closed before completion.

6. Application Guidelines

6.1 Create an Application

On the Home Page, clicking on the ***Funding Opportunities*** shortcut on the dashboard, the Applicant can access the page listing all the available Calls.

Select, within the Call list **ERDERA Clinical Trial Call 2026 - EOI** and then click ***Apply*** to create a New Application form. The Applicant may read/download the related Guidelines and Privacy Policies. The Application ID will be assigned to the newly created Application project once the Applicant reads and agrees with the Privacy Policies.

6.1 Fill in the Application

After clicking ***Apply***, the system will ask the Applicant to read the **Privacy Policies** and agree to them. It is now possible to access the Application form by clicking on the ***Begin Application*** button. Please refer to the **Application sections** paragraph on page 6 for details on how to fill each field in the Application form.

Ensure that you save the draft Application to allow for continued work at different times. **Please be aware that certain fields will only populate after selecting the *Save Draft* option. It is recommended to save the draft Application regularly, particularly upon completion of each section**.

The Back and ***Next*** buttons enable the Applicant to navigate through the Application, and the ***Save Draft*** button saves all changes and activates important functionalities within the Application without leaving the current page. To exit the Application page, click on the left-hand arrow at the top of the page to return to the Application list. It is possible to delete the Application by clicking on the ***Delete*** button at the bottom of the Application page. Please note that the Application may be withdrawn by clicking on the **Withdrawal** tab only when the Application is in *Pending Signature* status.

Mandatory fields are indicated by red stars. To successfully submit an Application, all mandatory fields must be completed. Any item missing before submission is listed in a box that is shown at the top of the page, once the Applicant clicks on the ***Submit*** button.

A submitted Application cannot be further modified; if the Applicant needs to make some amendments before the Call deadline date, an email should be sent to telethonscience@fondazionetelethon.it.

7. Application sections for EOI

- **Project Data**

  - Project Title
  - Project Acronym
  - Horizon Europe keywords
  - Disease Area
  - ORPHA Number
- **Project Description**
  - Unmet Medical Need
  - Target Population
  - Intervention Type
  - Orphan Drug Designation (ODD)
  - Intended Trial Development Phase
  - Estimated Number of Participants
  - Estimated Duration of the Study
  - Confirmation of Basic Readiness
  - EMA Scientific Advice or National Regulatory Bodies
- **Coordinating Investigator / Sponsor**
  - First Name
  - Last Name
  - Affiliation / Institution
  - Country
  - Position
  - PIC Number
  - ERN
  - Contacts
- **Partners**
- **Budget**
  - Estimated Total Budget Request (€)
- **Declarations**
  - Notes
  - Supporting Documents
- **Declarations**
  - Declarations

Project Data

This section comprises general information regarding the project.

Project Title (max 250 characters) – Enter the full title of the proposed clinical study. In case of title changes, the Applicant can modify it at any time before final submission.

Acronym (max 250 characters) – Short alphanumeric abbreviation identifying the project throughout the application process and subsequent reporting.

Horizon Europe keywords— Select from the dropdown menu maximum 3 keywords characterising the proposed clinical study, selected in line with the Horizon Europe classification system.

Disease Area — Select the rare disease(s) or disease group(s) addressed by the proposed clinical study. Maximum 3.

ORPHA Number — The unique identifier assigned to the target rare disease in the Orphanet classification system (https://www.orpha.net/consor/cgi-bin/index.php?lng=EN). Where multiple conditions are addressed, all relevant codes should be provided separating them with a semicolon. If not available, please indicate "n.a.".

Project Description

Unmet Medical Need — A concise description of the current therapeutic or diagnostic gap for the target disease, including the absence or limitations of existing approved treatments and the impact on patients.

Target Population — Indicate of the intended study population, whether it will be paediatric, adult or both.

Intervention Type — The nature of the investigational intervention.

Orphan Drug Designation (ODD) — Indicate whether the investigational product has obtained, or has applied for, orphan drug designation from the EMA, providing the relevant reference number where available.

Intended Trial Development Phase — The clinical development phase of the proposed study (Phase I, Phase II, or Phase I/II).

Estimated Number of Participants — The estimated projected total number of participants to be enrolled in the study, across all participating sites.

Estimated Duration of the Study — The expected total duration of the clinical study from the regulatory and ethics approvals to entry of study results in the clinical trials registry, expressed in months.

Confirmation of Basic Readiness — Declaration by the applicant that the essential preconditions for the proposed clinical study are in place, including drug supply, initial site feasibility and realistic recruitment potential.

EMA Scientific Advice or National Regulatory Bodies — Indicate whether the applicant has received formal scientific advice from the EMA or a national competent authority in relation to the proposed study, specifying the regulatory body, type of procedure, and current status of the interaction.

Coordinating Investigator / Sponsor

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. Entities from EU countries, Norway, the United Kingdom or Canada may provide the Coordinating Investigator.

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.

The Coordinating Investigator and the Sponsor may belong to the same institution or to different consortium partners.

Please, refer to the ECTC text for more details.

First Name — Legal first name of the Coordinating Investigator/Sponsor/Partner, as it appears in official institutional and regulatory records.

Last Name — Legal last name of the Coordinating Investigator/Sponsor/Partner, as it appears in official institutional and regulatory records.

Affiliation / Organization — Full legal name of the organization at which the Coordinating Investigator/Sponsor/Partner holds their primary appointment.

Country — Country in which the Coordinating Investigator/Sponsor/Partner organization has its registered office.

Position — Current institutional role or title of the Coordinating Investigator/Sponsor/Partner (e.g., Principal Investigator, Clinical Research Director, Chief Executive Officer, etc).

PIC Number — The Participant Identification Code assigned to any organization registered in the EU Funding & Tenders Portal. Registration is mandatory. To register an organization, please visit the Eu Funding & Tenders Portal at this link.

ERN — In case of affiliation of an organization with a European Reference Network(s) applicants should indicate the relevant ERN by name, selecting it from the dropdown menu.

Contacts email and **phone number** — Institutional contact details for official correspondence relating to the application. These details will be used for all formal communications during the evaluation and project implementation phases.

Partners

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.

Please, refer to the ECTC text for more details.

At this stage, Partners may be provisional and can be changed before short-proposal submission.

Use the icon  to add Partners and provide all required information, as for the Coordinating Investigator and Sponsor.

To remove Partners, click on  and then on ✕ icons displayed next to their names in the list.

Please, remember to save the draft through the ***Save Draft*** button.

Budget

Indicate the estimated total budget requested for the entire study, in euros (€). This is a preliminary estimate and may be revised later; a final detailed and justified budget will be required only at the full-proposal stage.

Notes

Notes (max 5,000 characters) - Any personal comments, details, or additional information the Applicant wishes to add to any specific section of the Application can be inserted here. The Applicant must indicate which section they are referring to and the reasons for including more information.

Supporting documents - Please attach any supporting documentation (if any). It is possible to upload .pdf files and .jpg files.

Declarations

Declarations - The Applicant is required to certify that all information contained in the Application is accurate and complete, that they possess the authority and/or entitlement to disclose any information provided therein, and that they adhere to the terms and conditions established by Fondazione Telethon ETS.

I have read the above information and:

☐ I hereby certify that all information submitted in the online application form is accurate and complete.

☐ If I am awarded funding for this project, I will accept the conditions set by Fondazione Telethon ETS.

☐ I authorise the processing of personal data, in compliance with the European General Data Protection Regulation, Reg (EU) 2016/679 for the specific purpose they are collected (any communication of personal data to private or public subject will be allowed only for the specific purpose they are collected).

☐ I authorise the use of my personal data to be contacted by the ERDERA services program.

☐ I authorise to be contacted for involvement in future collaborative initiatives, which might fall within the scope of my research activity.

☐ I authorise to be contacted for dissemination and communication activities (e.g. newsletters, invitations to meetings).

8. Application Submission

The deadline for online submission is **September 10th, 2026, at 5 pm**.

Once the Application has been completed in all its parts by the Lead Applicant, clicking on the ***Submit*** button placed at the bottom-right of the page will initiate the submission procedure.

Please note that if there are sections that need completion or are wrongly completed, these will be shown in a tab at the top of the Application page during this phase: complete/correct all the highlighted fields before sending for signature again.

The submitted Application will be automatically shown in the **Submitted** tab in the **My Applications** Home Page, and it cannot be further modified. Should the Applicants need to make some amendments before the Call deadline date, they are asked to write an email to telethonscience@fondazionetelethon.it.

Before final submission, Applicants are invited to download the PDF of their Application to check all the sections. Please note that Applicants are liable for the contents and quality of the Application in its final version.

Fondazione Telethon ETS holds the responsibility and authority to make the final decision on the Application's completeness and eligibility.

9. General Data Protection Regulation

The following Data Privacy Notice applies

By applying to the ERDERA Clinical Trial call 2026, applicants consent to the use, processing and retention of their data for the purposes of:

- processing and evaluating the application where processing shall be lawful only if and to the extent that processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
- administering any subsequent funding award;
- managing the Funding Party's relationship with them;
- analysing and evaluating the call;
- reporting to the European Commission/ European Health and Digital Executive Agency (HADEA) on the Co-funded call;
- Collecting additional information and analysing the provided project advancement annual reports for reporting purposes of ERDERA, including impact performance indicators;
- providing aggregate data to national and European surveys and analyses;
- complying with audits that may be initiated by F T E L E and the European Commission (or its agencies);
- collecting information and feedback from the applicants and funded researchers for the purpose of improvement of call processes.

The members of the ERDERA consortium may share applicant's data with third parties (some of which may be based outside the European Economic Area) in relation to the above activities including evaluators, auditors and the European Commission (or its agencies).

The members of the ERDERA consortium may link the data that applicants provide in the application with national, bibliographic or external research funding data which is available through public subscription-based databases (e.g., Scopus, Web of Science, etc.) or other national/open datasets. The members of the ERDERA consortium may also link the data that applicants provide in their application with future data that applicants provide as part of the ongoing management and reporting on a call award which may be awarded to them.

Milan July 1st, 2026 FONDAZIONE TELETHON ETS