

ERDERA
European Rare Diseases Research Alliance

ERDERA Clinical Trial Call 2026

Guidelines for Applicants

Short Proposal

Version 1.1 | 18th September 2026

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

Submission deadline for Short Proposals: 29th October 2026 – 5 PM CEST

Contacts

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These Guidelines for Applicants 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 multinational, 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, 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 charge, 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.

Short proposals (in English) must be submitted via the electronic submission system no later than **October 29th, 2026 at 5:00 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.

All the documents regarding the ECTC 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](#).

Only the **Coordinating Investigator**, identified in the system portal as the **Lead Applicant**, is responsible for creating and completing the Application. Applicants should carefully read 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

The System allows the creation of an account associated with **ONLY** one email. Therefore, Applicants who have registered to the System are kindly asked to use the same credentials used for the EOI submission.

If needed, Applicants can request 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

5.2. Personal Details

Before starting a New Application, the Applicant can 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 allows Applicants to access draft applications, monitor the status of their submissions, and view 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 awaiting activation.

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

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

Locked – This tab shows Applications that were not successfully submitted and therefore are not eligible for evaluation.

6. Application Guidelines

6.1 Create an Application

On the Home Page, by 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 CTC 2026 – Short Proposal** 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.

To complete the submission, Applicants MUST click on the *Submit* button; until this step is completed, the Application will not be considered submitted.

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 Short Proposal

- **PROJECT DATA**

- Expression of Interest (EOI) Reference Number
- Project Title
- Project Acronym
- Horizon Europe keywords
- Disease Area
- Disease Name
- ORPHA Number
- Targeted Population
- Number of Patients
- Intervention Type
- Phase of the Proposed Study
- Study Duration (months)

- **SYNOPSIS**

- **COORDINATING INVESTIGATOR**

- First Name
- Last Name
- Affiliation / Institution
- Country
- Position
- PIC Number
- ERN
- Contacts email & phone number
- Other affiliation(s) & appointment(s) (if any)

- **SPONSOR**

- First Name
- Last Name
- Affiliation / Institution
- Country

- Position
- PIC Number
- ERN
- Contacts email & phone number
- Other affiliation(s) & appointment(s) (if any)
- Information for co-sponsorship
- Information for Canadian Sponsor
- **PARTNERS**
- **COLLABORATORS**
- **BIOSKETCH**
- **BUDGET**
- **NOTE**
 - Notes
 - Supporting Documents
- **DECLARATIONS**
 - Declarations

PROJECT DATA

This section comprises general information regarding the project.

Expression of Interest (EOI) Reference Number – Enter the Reference Number associated with the submitted EOI

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. The title may differ from the one provided in the EOI.

Acronym (max 250 characters) – Short alphanumeric abbreviation identifying the project throughout the application process and subsequent reporting. The acronym may differ from the one provided in the EOI.

Horizon Europe keywords— Select from the dropdown menu a maximum of 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.

Disease Name (max 200 characters) – Indicate the name of the disease. The disease **MUST** be the same as indicated at the EOI stage.

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, separated by a semicolon. If not available, please indicate “n.a.”.

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

Number of Patients — The total number of participants to be enrolled in the study, across all participating sites.

Intervention Type — The nature of the investigational intervention among those eligible.

Phase of the Proposed Study — The clinical development phase of the proposed study (Phase 1, Phase 1a, Phase 1b, Phase 2, Phase ½ or N-of-1).

Study Duration (months) — 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.

Abstract (max 2,000 characters) – Provide the following information:

- Background/Rationale
- Overall objectives and specific clinical trial objectives
- Research design and methods
- Anticipated outcomes

SYNOPSIS

The Clinical Trial Synopsis must be uploaded as one .pdf file in A4 format containing all the sections described below (max size 50 MB). Please use the “Template_ECTC_Synopsis”, available to download from the header of the online Application form. The uploaded file will be renamed to: ECTSP1_Synopsis.

Please use Calibri as the text font, minimum size 11.

IMPORTANT NOTICE: The file must not exceed **12 pages** (figures/tables included; GANTT Chart and Cited Literature excluded) and must contain all the sections below. Failure to comply with these requirements will result in automatic exclusion from the Call.

Fill in all the following mandatory sections, ensuring that the original sections’ titles remain unchanged:

A. CLINICAL TRIAL SYNOPSIS - A short summary of the key points of the clinical trial.

1. Background and rationale - Background, main features of the rare disease and current standard therapy, referring to relevant publications, evidence supporting the objective of the proposed trial (current state of the art, references to literature and data that are relevant to the trial). Highlight any prior work related to the proposal and any relevant preliminary results.

In case of a first-in-human trial, please indicate which non-clinical data exist or would need to be generated to support the proposed clinical trial (please refer to guidelines for FIH and ODD)

Description of the **unmet medical**, societal and public health need, knowledge gap, and/or technical or implementation challenge that is addressed by the proposed trial. “Unmet medical need” is understood in accordance with the definition adopted by EMA/CHMP: 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.

Preliminary description of the work plan including the methodology, highlighting the novelty, originality, and feasibility of the project.

2. Objectives - Describe the specific primary and secondary objectives of the study.

3. Study design - Study design (e.g. single arm, randomised trial, basket/umbrella/platform trial, etc.) and specific methods (e.g. for type of randomisation, blinding, etc). Please describe and justify the appropriateness of the selected design and suitability of methodological approach and how this affects the feasibility of the trial. Indicate if and how dedicated methodology expertise for designing the trial has been used.

4. Population - Add information on target population and inclusion/exclusion criteria. Please also include if and how any biomarker tests/kits and their status (e.g., CE mark, hospital use, etc.) are to be used (Applicants can find guidance at the following links: [MDCG 2022-10](#) or [EMA](#)).

5. Endpoints - Outcome measures and proposed statistical analysis. Provide a schematic diagram that describes the timing for trial procedures (e.g., screening for eligibility), interventions, and outcome measurement.

6. Sample size and statistical justification - Provide the sample size and the underlying statistical assumptions/justification

7. Description of the investigational product - Name and description of the investigational product. Include mode of action, chemical structure and pharmacological classification, where appropriate. Specify the intended indication, posology, and any special precautions or recommendations for use of the product (including a possible risk management strategy). Include dosage, route of administration, and treatment duration.

8. Visit schedule/overall study duration - Outline the anticipated visit schedule (screening, treatment/intervention and follow-up visits) and the overall expected duration of the study, from first patient enrolled to last patient's last visit and data lock.

9. Safety monitoring plan - Describe the planned approach to safety monitoring and oversight, including adverse event, serious adverse event and reporting procedures, any planned interim safety reviews or stopping rules.

10. Outline of the statistical analysis plan - Provide a preliminary outline of the statistical analysis strategy, including the analysis populations (e.g. intention-to-treat, per-protocol, safety), the planned approach to primary and secondary endpoint analyses, any interim analyses, and how missing data and dropouts will be handled.

11. Preliminary study plan – Preliminary plan of the study, including milestones (please refer to the Call Text) and timeline as diagram

12. Cited Literature – Please list all references. The list must include the name of all authors, year of publication, title, book or journal, volume number and page numbers. Applicants are encouraged to consult the Nature Guide to Authors and follow the reference format used in Nature journals.

B. BASIC READINESS - Indicate which elements are already secured or secured-in-principle, such as drug supply, initial site feasibility and realistic recruitment potential. Please comment on each topic below:

1. Progress with drug supply
2. Progress with sites (number of planned countries and sites)
3. Outline of recruitment potential
4. Progress with other essential elements of the trial (diagnostics, assessments)
5. To what extent are eligibility criteria and outcome assessments ready for regulatory review?
6. Progress with dosing
7. Status of pivotal (GLP) nonclinical safety/ toxicology studies (completed or not)

C. PRELIMINARY PLAN FOR PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT (PPIE)

Describe the level of involvement and participation of patients in the planning, conduct and dissemination of the results of the proposed trial.

Include details on the role of PPIE in preparing the proposal (Who, how, when, what did PPI input say, impact of PPI input on the application)

D. INITIAL REGULATORY DEVELOPMENT PLAN

An initial regulatory development plan, including the following information:

1. **Orphan Drug Designation (ODD) status** – Indicate the current ODD status: obtained/applied for/not yet initiated. If not yet initiated, please outline the intended timeline and strategy
2. **Regulatory pathway envisaged** – Please include the following:
 - i) Type of regulatory interaction planned (EMA Scientific Advice, Protocol Assistance, ITF briefing, national Competent Authority advice)
 - ii) Where applicable, request verification of eligibility for the EMA Scientific Advice fee waiver
 - iii) Indicative timeline for initiating such interaction. Justify how the timing of your Scientific Advice request fits within the overall development and regulatory strategy
 - iv) Anticipated pathway for patient access, reimbursement and/or market authorisation following trial completion, and any relevant activities planned to pursue this pathway (e.g. early dialogue with HTA bodies or payers, market access strategy).
3. **Anticipated CTA/CTIS submission** – Outline an indicative timeline for Clinical Trial Application submission via CTIS. Identification of the Sponsor and country of submission
4. **Paediatric-specific element (if applicable)** – Status of any Paediatric Investigation Plan (PIP), or justification if not applicable
5. **Repurposed drug/biologic-specific element (if applicable)** – Preliminary indication of IMP supply/access route. How will you ensure the product ultimately reaches patients, from trial through to registration and access (including who will apply for Marketing Authorisation)?

COORDINATING INVESTIGATOR

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 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, as it appears in official institutional and regulatory records.

Last Name — Legal last name of the Coordinating Investigator, 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 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.

Contact 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.

Other affiliation(s) & appointment(s) (if any) — please indicate institution and role/position

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. A Sponsor representative should be designated, considering that will eventually participate in the final Interview Phase with a panel of Clinical Trial Scientific Committee (CTSC) experts (Section 7.4 of the Call Text).

For consortia including a Canadian partner, A **Canadian sub-sponsor** or equivalent institutional structure must be identified for the Canadian component of the trial. Please refer to the Call Text and to the “Annex IV - Guidelines for Canadian Partners” for further information.

Do the Sponsor and the Coordinating Investigator belong to the same institution or organization? Select the appropriate option:

- **Yes**, if the Coordinating Investigator and the Sponsor are affiliated with the same institution or organization. In this case, the Sponsor information already provided does not need to be entered again.

- **No**, if the Coordinating Investigator and the Sponsor are affiliated with different consortium partners. In this case, the Sponsor information below must be completed:

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

Last Name — Legal last name of the Coordinating Sponsor, 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 Sponsor 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.

Contact 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.

Other affiliation(s) & appointment(s) (if any) - please indicate institution and role/position

Co-sponsorship - Select the appropriate option:

- **Yes**, if a co-sponsor is included in the consortium. In this case, the co-sponsor information must be completed
- **No**, if no co-sponsor is included in the consortium

Does the consortium include a Canadian partner? Select the appropriate option:

- **Yes**, if the consortium includes a Canadian partner, a Canadian Sponsor must be identified and all the relevant general information requested must be completed.
- **No**, if no Canadian partners are included in the consortium

PARTNERS

[Eligible-for-funding](#)

Please list all consortium **partners eligible for ERDERA funding** other than the Coordinating Investigator and the Sponsor.

Please consider that the consortium must 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.

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.

Commercial CROs/CTMOs can be used. Depending on the role, they may be included as full consortium partners or subcontractors/service providers. A CTMO providing trial management support does not count toward the minimum three-country consortium composition unless it participates as a full consortium partner contributing directly to the scientific conduct and implementation of the trial.

For consortia including a Canadian partner, a **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.

Please refer to the ECTC Call Text for more details.

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

Role in the consortium: Select from the dropdown menu whether the role is “Partner”, “PAO”, “CTMO”, “subcontracted CTMO”, or “Canadian CTMO”

A **Letter of Commitment** is mandatory at this stage for each Partner included in the consortium. Please use the "Template_ECTC_Letter_of_Commitment," available for download from the header of the online Application form. Each uploaded file will be renamed to: ECTSP1_LetterOfCommitment_"

"Please click 'Yes' in the 'Uploaded Letter of Commitment' column to display the upload box. As more than one Letter of Commitment is required, each one must be uploaded as a separate file.

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.

COLLABORATORS

Self-funded

Collaborators 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 from non-ERDERA countries are permitted, provided their participation is scientifically justified and they do not receive ECTC funding.

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

A **Letter of Commitment** is mandatory at this stage for each Partner included in the consortium. Please use the "Template_ECTC_Letter_of_Commitment," available for download from the header of the online Application form. Each uploaded file will be renamed to: ECTSP1_LetterOfCommitment_

"Please click 'Yes' in the 'Uploaded letter of collaboration' column to display the upload box. As more than one Letter of Commitment is required, each one must be uploaded as a separate file.

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.

BIOSKETCH

All participants in the consortium (partners and collaborators) are requested to complete a **Biosketch**. All the biosketches will have to be uploaded in the dedicated box as .pdf files (one per participant) in A4 format containing all the mandatory sections described below. Please refer to the "Template_ECTC_Biosketch", available to download from the header of the online application form. Please keep the .pdf size below 100 MB.

The Biosketch may not exceed **5 pages**, including the table at the top of the first page, excluding relevant publications. Figures, tables, or graphics are not allowed. Please ensure to complete the following items that are required for the submission of the Application:

ID Researcher Platform and Personal Author ID – the Applicant must indicate one of the Researcher Platforms and provide their personal author ID. In case the Applicant does not have one, we suggest generating an ORCID ID (<http://orcid.org/>).

Education/Training – click on the Edit button and fill in the requested details. Begin with the baccalaureate or other initial professional education. Include postdoctoral, residency, and clinical fellowship training, as applicable, listing each separately. For each entry provide:

- the name and location of the institution
- the degree received (if applicable)
- the month and year of end date (or expected end date)

- the field of study (for residency entries, the field of study should reflect the area of residency training)

Personal Statement – briefly describe why the applicant is well-suited for his/her role(s) in the project. Relevant factors may include aspects of his/her training; previous experimental work on the specific topic or related topics; technical expertise; collaborators or scientific environment; past performance in the field or in related fields, including ongoing and completed research projects from the past three years that the applicant wants to draw attention to.

Positions, Scientific Appointments, and Honors – list in reverse chronological order all current positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary). List any relevant academic and professional honors.

Contributions to Science – briefly describe up to five of the applicant's most significant contributions to science. The description of each contribution should be no longer than one-half

BUDGET

Indicate the total budget requested for the entire study, in **euros (€)** in the dedicated text box.

The Budget must be uploaded as one .xls or .xlsx file (max size 50 MB). Please use the "Template_ECTC_Budget", available to download from the header of the online Application form. The uploaded file will be renamed to: ECTSP1_Budget.

A budget amount must be provided for each **Cost Category** listed in the template, and every Cost Category must be justified in the "**Task attributed to the budget**" column and clearly related to the execution of the project. For each cost category, please provide a *Low* and a *High estimate* reflecting the plausible cost range at this early stage of project development.

Please note that the budget must refer to the consortium as a whole and should not be broken down by individual Partner. The budget may be revised after the Support Stage 2, and a final detailed and justified budget will be required only at the Full Proposal Stage.

Personnel — Costs of clinical and research staff time at all participating sites (e.g., investigators, research nurses, project staff, etc.). Please avoid duplicating the same staff cost under both this line and a more specific category (e.g., Investigator Site, Project Management).

Study Design and Protocol — Costs associated with developing the study protocol and its amendments (e.g., protocol writing, rare disease expert board consultation, clinical development plan).

IMP / Therapeutic Intervention — Costs of the investigational medicinal product (IMP) up to and including GMP-compliant Phase I/II batch production. This includes manufacturing or supply, storage and distribution (e.g., cold chain, hospital pharmacy), clinical trial insurance, and IMP traceability systems. Phase III-scale manufacturing costs are not eligible.

Project Management — Costs of coordinating and managing the consortium as a whole, including the Sponsor institution's costs for fulfilling its regulatory and legal obligations (e.g., senior clinical project manager, investigator meetings, trial master file/eTMF maintenance, overall reporting).

Investigator Site — Costs incurred directly by participating clinical sites, including site set-up and closure, screening and follow-up visit costs, logistics for biological sampling, etc.

Patient Recruitment & Retention — Costs of identifying and retaining patients in the study, including outreach through patient registries and advocacy networks, and support for participants (e.g., identification through registries/ERNs, patient advocacy outreach, reimbursement of patient travel/lodging expenses, remote follow-up tools, management of dropouts).

PPIE Activities — Costs of involving patients and the public throughout the trial's design, conduct, oversight, and dissemination, as described in the Patient Involvement Plan (e.g., PAO staff time, travel and subsistence, translation/interpretation, reimbursement of out-of-pocket expenses, development of patient-facing materials).

Lab Analyses (genomics, etc.) — Costs of specialised laboratory or genomic analyses supporting the trial (e.g., WGS/WES sequencing, trio sequencing, bioinformatics analysis, clinical interpretation of variants, biobanking, GDPR-compliant data infrastructure), where relevant to the study design.

Clinical Data Management — Costs of the systems and staff needed to collect, clean, and manage trial data, including the mandatory data collection and management service and the CDISC (Clinical Data Interchange Standards Consortium), as requested in the Call Text.

Monitoring & Pharmacovigilance — Costs of clinical monitoring and safety oversight of the trial (e.g., CRA monitoring visits, centralised/remote risk-based monitoring, pharmacovigilance activities such as SAE/SUSAR/DSUR management, an independent Data Safety Monitoring Board).

Regulatory Costs — Costs of regulatory and ethics submissions required to initiate and maintain the trial (e.g., competent authority/CTA submission, ethics committee submission and follow-up, EMA scientific advice fees where no fee waiver applies, amendments). Ethics committee and CTA fees are eligible for all projects; where an EMA fee waiver applies, the corresponding costs are not eligible for ECTC funding. Please, refer to the Call Text.

Statistics — Costs of statistical expertise applied to the trial, including interim/final statistical analysis, together with the Clinical Study Report.

Dissemination & Publication — Costs of communicating and publishing the trial's results (e.g., open-access publication fees, conference participation, dissemination materials).

Others – other costs not included in the above list

Institutional overheads — Indirect/overhead costs applied at the **EU-fixed 25% rate**. The amount will be calculated automatically in the Excel file as a percentage of the direct-cost lines above, excluding Subcontracting. Goods, works or services purchased to support a task that remains under a partner's own responsibility (e.g. outsourced lab analyses) count as purchase costs and, as stated under EU rules, remain included in the overhead base.

Person Months requested — The total effort, expressed in person-months, dedicated to the project across the consortium; reported alongside the Personnel line to reflect coordination and staff workload.

Subcontracting — Costs of a specific, clearly-defined task (or part of the trial workplan) that a funded consortium partner outsources to a third party responsible for its execution and delivery, under the partner's oversight, in line with applicable procurement and value-for-money principles. Core scientific, regulatory, Sponsor, and Coordinating Investigator functions may not be subcontracted. Unlike goods, works or services purchased to *support* a partner's own task (see Institutional overheads above), subcontracting covers activities that *are* the task itself, and — as stated under EU rules — is excluded from the overhead calculation base.

In-kind — Non-cash contributions provided by consortium participant in support of the project (e.g., existing infrastructure, IMP or staff time not charged to the ECTC budget), reported for transparency alongside the requested budget.

REVIEWERS

Please click on the Add/Edit button to add or update reviewers.

Suggested Reviewers – The Applicant may suggest reviewers who are experts in their fields of research and could competently review the Application. Co-authors in scientific publications and/or individuals who have been associated with the Applicants within the last 5 years will not be considered suitable. A reason for the suggestion may be provided. FTELE and ERDERA reserve the right to choose reviewers independently.

Click **Save** and **Save Draft** to update the suggested reviewers. This insertion will then be displayed in a dedicated table on the Reviewers tab within the Application.

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 **October 29th, 2026, at 5 p.m. (CET)**.

Once the Application has been completed in all its parts by the Coordinating Investigator, clicking on the **Submit** button placed at the bottom-right of the page to complete the submission.

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:

- 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 FTELE and the European Commission (or its agencies);
- collecting information and feedback from the applicants and funded researchers for improvement of call processes.

The members of the ERDERA consortium may share applicants 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, September 18th, 2026

FONDAZIONE TELETHON ETS