ERDERA
European Rare Diseases
Research Alliance

## ERDERA Clinical Trial Call 2026 – Pre-announcement

The European Rare Diseases Research Alliance (ERDERA) is pleased to announce the upcoming launch of the ERDERA Clinical Trial Call 2026 (ECTC), expected to open on **1 July 2026**.

The ECTC aims to support multinational, GCP-compliant Phase I, Phase I/II and Phase II interventional clinical trials in rare diseases, generating robust clinical evidence and, where appropriate, data of regulatory relevance to support future interactions with regulatory authorities and subsequent clinical development.

The call is specifically designed to address the challenges of conducting clinical trials in rare diseases, where patient populations are often small and geographically dispersed, making multinational collaboration essential.

### Priority Areas

While applications addressing all eligible rare diseases are welcome, the call particularly encourages proposals targeting:

- Paediatric rare diseases;
- Rapidly progressive rare diseases;
- Rare diseases lacking approved therapeutic options or with substantial residual unmet medical need despite existing treatments.

These priority areas are not eligibility criteria but may be considered during strategic prioritisation where proposals are otherwise of equivalent scientific quality.

### Eligible Applicants

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.
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Eligible organisations include:

- Universities, higher education institutions and research institutes;
- Hospitals and clinical centres;
- Non-profit research organisations and foundations;
- Patient Advocacy Organisations (PAOs);
- Small and Medium Enterprises (SMEs), subject to the specific funding provisions applicable under the Call.

Each consortium must designate:

- A Clinical Trial Sponsor;
- A Coordinating Investigator;
- At least one patient partner represented by a PAO or other organised patient group;
- Access to a qualified multinational Clinical Trial Management Organisation (CTMO).

**Eligible Interventions**

Eligible interventions include:

- Small molecules, including repurposed drugs;
- 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);
- Repurposed biologics.

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## Eligible Countries

Institutions from the following countries are currently expected to be eligible as funded partners:

Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Slovakia, Spain, Sweden, The Netherlands, Türkiye and the United Kingdom.

Please note that, in accordance with the current draft call provisions, the Clinical Trial Sponsor must be established in an EU Member State or Norway.

## Indicative Application Process

The ECTC is expected to follow a multi-stage process:

- **Stage 0 – Expression of Interest (EOI)** (mandatory)
- **Stage 1 – Short Proposal Stage**
- **Stage 2 – Support Stage**
- **Stage 3 – Full Proposal Stage**
- **Stage 4 – Initial Trial Execution**
- **Stage 5 – Conditional Continuation Funding**

## Indicative Key Dates

- **Information Webinar:** 6 July 2026, 15:00–17:00 CEST

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- **Stage 0 – Expression of Interest (EOI):** 1 July – 10 September 2026
- **Stage 1 – Short Proposal Stage:** 15 September – 29 October 2026
- **Stage 2 – Support Stage:** January – July 2027
- **Stage 3 – Full Proposal Stage:** July – September 2027
- **Funding Decisions:** February 2028

Commented [CF1]: I changed the full proposal timeline because it will most likely closing beginning of september.

An information webinar for prospective applicants will be held on **6 July 2026 (15:00–17:00 CEST)** and will provide an overview of the call objectives, eligibility requirements, evaluation process and indicative timeline.

**Important Notice**

This pre-announcement and all related documents currently made available by ERDERA are provided for information purposes only.

The ERDERA Clinical Trial Call 2026 documentation is currently in preparation and has not yet been formally adopted by the relevant ERDERA governance bodies. Consequently, all information contained in this pre-announcement, including the scope, eligibility criteria, funding conditions, budget, timelines, evaluation procedures and governance arrangements, is provisional, non-binding and subject to change.

Only the official Call Text and associated application documents published at the time of call launch will constitute the authoritative and legally applicable version of the Call.

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