



Paediatric clinical Research Infrastructure Service Model

PRISM call for proposals on paediatric multinational investigator-initiated clinical studies

Call text and application guidelines

Deadlines:

Submission of Letter of Intent: December 31, 2026, at 5:00 PM CET

Submission of invited proposals: June 30, 2027, at 5:00 PM CET

Link to the online submission portal:

[PRISM TNA1 Call Application Link](#)

For further information, please visit the website: <https://prismeu.org/calls.html>

Or contact the Joint Call Secretariat (JCS)

call2026@prismeu.org

Version history

Version	Date of publication	Changes made
1.0	Sept 25, 2026	-

Definitions

Investigator-Initiated Study: A clinical study driven, designed, and led by an academic, non-commercial investigator or institution, where the initiating entity acts as or appoints the sponsor and retains full scientific independence, data ownership, and editorial control over research outputs.

Principal Investigator (PI): The qualified healthcare professional responsible for the operational conduct, safety monitoring, ethics compliance, and scientific oversight of the clinical study at a specific study site.

Coordinating investigator: The lead principal investigator designated by the sponsor to coordinate trial activities, communication, and scientific direction across all participating international sites.

Non-commercial sponsor: An academic, medical, and/or non-commercial institution or organization taking ultimate legal, operational, and administrative responsibility for the initiation, management, and financial oversight of the clinical study, in accordance with applicable regulatory frameworks.

Sponsor representative: A legal entity established within the EU, designated by a Sponsor located outside EU to act on the Sponsor's behalf and ensure full compliance with European regulatory obligations and applicable clinical trial legislation.

Or, a legal entity established within Canada, Switzerland or UK, designated by a sponsor located outside these countries to act on the Sponsor's behalf and ensure full compliance with applicable regulatory obligations and clinical trial legislation.

Study duration: The total operational timeframe of the project encompassing all phases from study start-up (regulatory and ethical submissions) through trial conduct and patient follow-up, up to the completion of the final close-out visit (COV).

Aim and ambition of PRISM

PRISM (Paediatric Clinical Research Infrastructure Service Model) is a European consortium aiming to strengthen multinational paediatric clinical research by providing **infrastructure**, **operational expertise**, and **innovative clinical study** support to paediatric investigator-initiated clinical studies across Europe* and Canada.

Rationale and aim of the call

While paediatric investigator-initiated clinical studies address pressing public health needs, they face significant operational and regulatory hurdles when expanding across borders. Funded by Horizon Europe (GA 101292607), PRISM addresses this capacity gap by selecting paediatric studies and delivering coordinated, innovative, end-to-end trial management services. By leveraging cutting-edge infrastructure services and operational expertise, PRISM ensures feasibility, regulatory compliance, and achievement of recruitment target and planned study objectives for multinational investigator-initiated studies.

General conditions for application

Eligible projects include paediatric pragmatic comparative effectiveness¹ trials, optimisation studies, repurposing trials and prospective observational studies in all paediatric disease areas **except cancer and rare diseases**.

Studies should involve 3 to 6 countries in Europe* and Canada. Maximum study duration: 2.5 years (30 months), covering all phases from study start-up to completion of the close-out visit (COV). A single non-commercial experienced sponsor is required. If the sponsor is located outside of the European Union, it is necessary to designate a sponsor representative with a location within the EU for clinical sites in the EU. If the sponsor is located outside of Canada, Switzerland or UK it is necessary to designate a sponsor representative with a location for clinical sites within these countries.

Eligible study populations include preterm and term neonates, infants, children and adolescents until the age of 18. Maternal-infant studies are eligible if the intervention targets the infant.

Where applicable, interventions must comply with European regulatory frameworks (such as [CT Regulation 536/2014](#), [Medical Device Regulation MDR](#), [ISO 14155](#), and the [EU AI Act](#) where digital or AI-driven tools are utilized) and Health Canada regulations when clinical sites are planned in Canada.

* European Union, Norway, Switzerland, and United Kingdom

Eligibility criteria

- Investigator-initiated paediatric clinical study
- Study population age: from birth to 18 years
- Study recruitment: to take place in 3 to 6 countries (Europe¹ and Canada)
- Sponsor: A single Sponsor located in Europe* or Canada with a designated sponsor representative in other countries as required (**see sponsor representative definition**).
- Sites: Maximum 15 sites per study (except for cluster randomized controlled trials)
- Maximal requested budget: EUR 2.0 million (*for details refer to section Financing and contribution*)
- Maximal study duration: 2.5 years, covering all phases from study start-up to completion of the close-out visit (COV).
- Types of study:
 - Interventional studies: pragmatic, investigator-initiated randomised controlled trials with the objective of comparing/optimising healthcare strategies
 - Types of intervention: therapeutic (with or without health products), diagnostic or preventive intervention
 - Observational studies: prospective cohorts
- One primary outcome and a maximum of two secondary outcomes
- Use of clinical operations and Data Management services from PRISM service package is mandatory.
- Apart from the mandatory services, selection of at least one service from the PRISM package is expected (see specific chapter)

Out of scope

- Commercial, industry-sponsored clinical studies
- Clinical studies focusing on
 - Oncology
 - Rare diseases (*prevalence lower than 5 per 10 000 people*¹)
 - Patient populations during the transition of care (from paediatric to adult care)
 - Seasonal diseases with transient recruitment windows unless robust risk mitigation strategies for recruitment fluctuations are provided
- Basic research, pre-clinical research and phase I studies
- Already running studies

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¹ https://health.ec.europa.eu/rare-diseases-and-european-reference-networks/rare-diseases_en

Financing and contribution

Indicative requested budget ranges: EUR 1.0–2.0 million for interventional studies and a maximum of EUR 1.0 million for observational studies.

Costs eligible within the requested budget include investigational costs allocated to recruiting sites (examples: per patient costs, study drug, pharmacy cost), project management cost allocated to the sponsor, and cost of PRISM service package. Co-funding from non-commercial grants or industry in-kind contributions is permissible (only when it is already available or agreed). Expansion of ongoing studies is not eligible.

Indicative requested budget should be included in the Letter of Intent (LoI) covering the projected budget of the study (cost of investigation, cost of sponsor activities and regulatory, monitoring, vigilance, and data management activities). Budget will be refined after the stage I with the selected candidates and the PRISM service providers.

PRISM service package

Through this call, selected clinical research projects receive direct operational support and comprehensive end-to-end trial management services throughout the study lifecycle.

Beyond standard trial coordination, this call incorporates cutting-edge digital and methodological solutions to modernise paediatric trials. Applicants are expected to select at least one service (or service module) apart from the mandatory services from the ECRIN Coordinated Service Package tailored to their study design within their initial application.

Proposals shortlisted after stage 1 will enter an interactive support and consultation phase prior to stage 2. During this collaboration period, the PRISM team will engage with applicants to review protocol requirements, identify additional PRISM services of potential value, address operational bottlenecks, and optimize trial feasibility and design.

PRISM services include:

- **Mandatory Services:** ECRIN coordinated service packages
- **Other services:**
 - International collaboration with Canada
 - Epidemiological/statistical analysis
 - Decentralised elements in paediatric trials
 - Digital patient-reported outcome measures
 - GenAI-enhanced eCRF for study execution

Details on these above-mentioned services are available in Annex I.

Application and evaluation procedure and timelines

The application process follows a two-stage procedure. An informational **launch webinar** will take place on **Oct 8, 2026, at 4:00 PM CET** to guide potential applicants through the call requirements and the PRISM Service Package. [Registration details](#) are available on the PRISM website.

Stage 1 (Letter of Intent - Lol): September 30, 2026 – December 31, 2026

High-level submission detailing clinical need, objectives, study design (PICO – Population, Intervention, Comparison, and Outcome), and geographical footprint of the consortium.

The Lol must be submitted as a template-based PDF file to the [PRISM call submission platform](#) by the **December 31, 2026, at 5:00 PM CET**. The template for the Lol is downloadable from [PRISM call submission platform](#). In addition, part of the required information must be completed through an online questionnaire available on the platform.

Stage 2 (Full Application): February 22, 2027 – September 01, 2027

After the Stage 1 review, shortlisted applicants will be notified by **Feb 22, 2027**, and will receive dedicated PRISM infrastructure support to refine their protocol and **project proposal** before submitting the full proposal.

A full proposal must be submitted via the PRISM submission platform by **June 30, 2027, at 5:00 PM CET**. In addition to the initial Lol contents, the full proposal (template will be available after Stage 1) must contain a fully developed clinical study protocol, a granular itemized budget and co-funding breakdown, a comprehensive recruitment and risk mitigation plan, an initial Data Management Plan (DMP), and an integrated PRISM service delivery roadmap.

A final selection will be based on the evaluation of the full proposal, followed by an interview with an independent jury focusing on operational aspects and project risks. The evaluation and interview process will take place during **July and August 2027**.

Selected projects will be announced on **Sept 1, 2027**.

Evaluation criteria for the Lol

Proposals will be evaluated by independent expert reviewers across three standard Horizon Europe criteria, with strong emphasis on scientific quality, operational feasibility, risk mitigation, and strategic alignment with the PRISM infrastructure:

1. Excellence



- **Medical & public health relevance:** High clinical need, clear potential to optimize paediatric healthcare strategies, and strong scientific alignment with the call objectives.
- **Scientific quality & methodology:** Methodological rigor, sound study design (PICO), clear primary and secondary outcomes, and a robust data analysis plan.
- **Innovation & PRISM service package:** Use of innovative and cost-effective trial methodologies or technologies, with a clear rationale for applying to the PRISM competitive call. Precise identification and justification of the PRISM services required for the project.

2. Impact

- **Clinical, paediatric and public health impact:** Direct, tangible outcomes for paediatric patients, families, and healthcare providers, ensuring long-term healthcare improvement.
- **Patient & public involvement (PPI):** Meaningful early engagement of patients, families, caregivers, healthcare professionals or other interested parties, along with population diversity and inclusiveness.
- **Geographical footprint:** Multinational collaboration involving eligible countries across Europe* and Canada.

3. Quality and efficiency of the implementation

- **Operational feasibility & readiness:** High trial readiness, realistic recruitment projections, compliance with requested budget limits, confirmation of secured co-funding (where applicable), and demonstrated capability to initiate study start-up upon project selection and execute the project within the maximum 30-month study duration.
- **Risk management:** Identification of critical project risks (e.g., recruitment fluctuations, logistical bottlenecks, regulatory approval delays) alongside concrete, actionable risk mitigation strategies.

* European Union, Norway, Switzerland, and United Kingdom

- **Consortium & sponsor track record:** Operational capacity and expertise of the sponsor, coordinating and principal investigators, and participating sites.
- **Ethics, regulatory & data governance:** Compliance with applicable EU and Canada regulatory frameworks, Horizon Europe standards, GDPR, and FAIR data principles.

Ethical clearance

All studies must comply with fundamental ethical principles, Horizon Europe ethics standards, EU Regulation 536/2014, the Declaration of Helsinki, and national regulatory approval requirements and where applicable Health Canada regulations. Formal ethics clearance needs to be obtained after acceptance of the full proposal and prior study initiation.

Legal and financial conditions

By submitting a Letter of Intent (Stage 1), applicants acknowledge and agree to comply with the legal and financial framework of the PRISM project. Applicants invited to stage 2 (Full application) commit to providing all required legal, administrative, and financial disclosures during the full proposal development phase. Submission at Stage 1 implies acceptance that funding disbursements will be tied to the successful achievement of project milestones and operational deliverables.

Redress procedure

Coordinating investigators may lodge a formal appeal regarding procedural irregularities or manifest errors within 7 calendar days of receiving eligibility or evaluation results. Appeals do not re-evaluate scientific judgment by the independent evaluation panel or jury, but focus on verifying whether procedural rules, administrative checks, and evaluation criteria were applied correctly and fairly. To submit a redress request, the Coordinating Investigator must send a formal appeal by email to the PRISM Joint Call Secretariat at call2026@prisme.eu.org.

Responsibilities reporting requirements and dissemination

The coordinating investigator must submit annual progress reports, a 6-month operational report (tracking First Patient First Visit - FPFV), and a draft scientific report within two months of the COV. All study outcomes must be published open access.

Open science

Research data must adhere to FAIR principles (Findable, Accessible, Interoperable, Reusable). To maximize long-term scientific impact, funded projects are expected to enable and facilitate the secondary use of pseudo-anonymized research data for future health research under controlled, GDPR-compliant access frameworks. An initial Data Management Plan (DMP), including provisions for data sharing is required at stage 2 and must be fully established by Month 6.

Communication

All publications, presentations, and dissemination materials must explicitly acknowledge funding from the European Union's Horizon Europe programme under the PRISM grant agreement No 101292607.

Confidentiality

The Joint Call Secretariat, peer reviewers, and panel experts bound by strict non-disclosure agreements will handle all submission data confidentially.

GDPR

Processing of personal data for applicants and trial participants must strictly comply with [EU Regulation 2016/679](#) as well as applicable national data protection laws. Special attention must be given to child data protection, ensuring robust technical and organizational safeguards appropriate for paediatric populations, including clear assent and consent management frameworks.

Further information

For technical and administrative queries, applicants may contact the PRISM Joint Call Secretariat (call2026@prismeu.org) and refer to official guidelines published on prismeu.org.

Annex 1: Description of PRISM services

ECRIN coordinated service package (mandatory)

Service partner: European Clinical Research Infrastructure Network (ECRIN)

ECRIN is a [European research infrastructure](#) that facilitates sponsors and investigators to set up and conduct multinational clinical studies in Europe. ECRIN does this by linking with national European Correspondents, the national networks of clinical trial units (CTU), and through its services and tools. All CTUs involved in ECRIN projects are selected based on the location of the investigation sites, their competencies/expertise, and the availability of resources.

More specifically, ECRIN coordinated service package includes:

- Study management and coordination: development and maintenance of study documents, organisation of the communication flow and study meetings, global coordination and reporting with a quality management system
- Regulatory & ethical approvals: management of the regulatory and ethical submissions in all participating countries until the approval. Management of all subsequent modifications and notifications until the end of the study
- Study monitoring: training of the monitors, on-site visits, reporting & communication with clinical sites
- Vigilance: central vigilance for clinical studies/clinical investigations and adverse events reporting
- Data management provided by ECRIN-certified data management centres, which are compliant with ECRIN standards
- Data sharing

International collaboration with Canada

Service partner: Maternal Infant Child and Youth Research Network (MICRYN)

MICRYN is a national not-for-profit clinical research network that supports investigators, institutions, and partners across Canada through comprehensive Academic Research Organization (ARO) and clinical trial support services. MICRYN provides expertise throughout the research lifecycle, including study design and protocol optimization, grant development, regulatory and ethics submissions, project management, quality assurance and monitoring, data management, biostatistics, and Data Safety Monitoring Board coordination. Through its national network of paediatric and maternal-child health research centres and experts, MICRYN facilitates multicentre clinical trials and collaborative research initiatives. Additional services include patient and family engagement, knowledge translation and communications support, governance and administrative coordination, research pharmacy resources, and consultation services. MICRYN's experienced team helps investigators navigate complex regulatory, operational, and compliance requirements while promoting high-quality, efficient, and patient-centred research. By providing scalable support tailored to the needs of each project, MICRYN enables researchers to advance innovative studies that improve health outcomes for children, youth, pregnant individuals, and families across Canada.

- Study Design and Protocol Development
- Grant and Proposal Development Support
- Clinical Trial Project Management
- Regulatory Affairs and Health Canada Submissions
- Research Ethics Review Support
- Quality Assurance and Risk-Based Monitoring
- Bilingual Clinical Trial Monitoring (Remote and On-Site)
- Data Management and Validated Database Solutions
- Biostatistics and Statistical Analysis Support
- Data Safety Monitoring Board (DSMB) Coordination
- Patient and Family Engagement
- Knowledge Translation and Research Communications
- Research Pharmacy Network Services
- Financial Administration and Grant Management
- Canadian Sub-Sponsorship and Sponsor Support
- Multicentre Trial Coordination
- National and International Research Collaboration Support

Epidemiological/statistical analysis

Service partner: Swiss Clinical Trial Organisation (SCTO)/Kantonsspital Basel (USBL)

Experienced trial statisticians from the University of Basel will devise statistical analysis plans together with trial investigators and conduct statistical analyses of collected trial data using state-of-the-art methodology.

Decentralised elements in paediatric trials

Service partner: European Network of Living Labs (ENOLL)

This service supports the design and delivery of decentralised elements within paediatric clinical trials, helping study teams expand beyond hospital-based investigation sites while maintaining data quality and regulatory compliance. The offering covers decentralised trial components adapted to the specific needs of paediatric populations: online recruitment platforms, paediatric-adapted e-consent, home visits, video-consultations, IMP delivery and management, remote adverse event reporting, remote and risk-based monitoring, remote data collection (including via wearables and biosensors), and electronic PROMs.

As part of this offering, Living Labs can be integrated as a supporting infrastructure for decentralised trials, enabling patient follow-up and investigation outside traditional hospital settings, and offering a real-world alternative to hospital-based sites. Attention is given to key technical and methodological challenges, such as mapping wearable and biosensor data to clinical trial data standards.

Digital patient-reported outcome measures/clinical outcome assessment (ePRO/eCOA)

Service partner: Innovation Sprint Srl (iSPRINT)



[Healthentia](#) is offered as the PRISM digital patient-reported outcome service: a GxP compliant ePRO/eCOA and a certified Class IIa CE-marked medical device under EU MDR, dedicated to electronic patient-reported outcomes (ePRO), electronic Clinical Outcome Assessment (eCOA), and remote patient monitoring (RPM).

It is used by investigators, academic sponsors, clinical research infrastructures and top-5 pharmaceutical companies and is clinically validated and used in 45+ hospitals across 10+ countries.

Healthentia is built to make GCP audits for sponsors/investigators straightforward, through a validated system with complete audit trail, controlled user roles, electronic signatures, and qualification documentation a sponsor would need for its own audits. The software is also MDR certified as a Class IIa SaMD and audited by an independent Notified Body.

For PRISM, the service is adapted to paediatric and decentralised designs. It covers study-specific configuration of validated and custom PROMs and eDiaries without software development. It has multilingual interfaces with linked caregiver or proxy reporting, scheduled questionnaires with smart reminders and adherence tracking, data capture from wearables and sensors alongside self-report, adverse-event prompting, and real-time completeness dashboards for the investigator.

Data are exportable in standard formats, and Healthentia interoperates with eConsent, eCRF, remote monitoring and analytical components of PRISM. The service is delivered end-to-end: protocol-driven set-up and instrument translation, site and participant onboarding, training material, helpdesk support, continuous data-quality and completeness follow-up.

GenAI-enhanced eCRF for study execution

Service partner: AINIGMA Technologies (AINIGMA)

This service provides the electronic Case Report Forms (eCRF) that underpin remote and in-person data collection in paediatric trials, deployed and maintained throughout study execution. Interfaces are user-friendly and secure, tailored to the needs of paediatric studies and to young research participants, and incorporate (gen)AI tools. The eCRF is designed around regulatory requirements and full auditability, supporting compliant data capture across all participating sites. The study is built and conducted in a single platform: the visit schedule is set up with day windows and required or optional flags, forms are assigned to each visit, and multiple sites are configured with principal investigator and coordinator roles. Study teams follow progress through a subject-by-visit completion matrix showing which forms are complete, partial or overdue, raise and resolve data-clarification queries on individual fields, and consult a study-level activity log. The eCRF can be integrated with other digital systems used in the study, such as digital patient-reported outcome measures (PROMs), remote monitoring tools and biospecimen tracking tools. Support to study teams also includes platform updates, troubleshooting of technical issues and direct collaboration with site staff throughout the study.