ERA4Health Partnership

Co-funded by the European Union

# Joint Transnational Call for Investigator-Initiated Clinical Studies (JTC IICS) – 2026

## "Multi-country Investigator-Initiated Clinical Trials in Cardiovascular, Autoimmune and Metabolic diseases" (Trials4Health 2026)

## Call Text

## DEADLINES

Month (January) 27th, 2026 (16:00 CET) - SUBMISSION OF PRE-PROPOSALS

Month (June), 17th, 2026 (16:00 CEST) - SUBMISSION OF INVITED FULL PROPOSALS

Link to the electronic proposal submission:

Link

The submission system will be open by November 13th, 2025

For further information, please visit us on the website: https://era4health.eu/

or contact the Joint Call Secretariat (JCS):

Instituto de Salud Carlos III (ISCIII)

Astrid Valencia Quiñónez

+34 918 222 227

Trials4Health@isciii.es

Funded by the European Union under the Horizon Europe Framework Programme. Grant Agreement Nº: 101095426.

## History of modifications:

18/12/2025:

- Updated information for FRRB's eligibility criteria (Annex I).
- Updated information for BMFTR's eligibility criteria (represented by DLR) (Annex I).
- Updated information for IT-MOH's eligibility criteria (Annex I).

# Content

# Definitions

**Types of clinical studies:**

**Clinical study** refers to any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It may include investigation on medicinal products, clinical investigation and clinical evaluation on medical devices, performance studies and performance evaluation on in vitro diagnostic medical devices (Source: Information on clinical studies (HE): V4.1 –13.05.2022).

**Clinical trial** is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care. Clinical trials may also be referred to as interventional clinical studies.

**Comparative effectiveness studies** are defined as the generation of high-quality evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition or to improve the delivery of care. These include comparisons of interventions that are already being used in everyday clinical practice, such as approved therapies, different surgical protocols or lifestyle changes and comparisons between these different interventions. Those studies are patient-centred and outcome-based trials will compare benefits and risks of therapeutic interventions to inform clinical and/or policy decision making.

**Drug repurposing**, which is the process of identifying new uses for existing approved medicines in indications outside the scope of the original approval. It refers also to the process of allowing a medicinal product to broaden its position in a relevant market (excluding the extension of an authorized indication to those of a new age group or to another genetic mutation). It includes new therapeutic uses for existing medicines, different formulations of the same medicine, and/or creating new combinations of medicines or medicines with medical devices.

**Interventional clinical studies**, also called experimental studies, are those where the researcher intervenes at some point throughout the study. These evaluate the effects of the interventions on biomedical or health-related outcomes, and include early phase (up to phase II), phase II-phase III, and phase IV. The most common and strongest interventional study design is a randomized controlled trial.

**Investigator-Initiated Clinical Study (IICS)**, is a clinical study conceived, initiated, conducted and sponsored under the full responsibility of a non-industrial body as sponsor, such as an individual investigator, research performing institution, university, collaborative group, cooperative group or association.

**Low intervention clinical study** means a clinical study on medicinal product (or other types of medical interventions) which fulfils all of the following conditions: (a) the investigational medicinal products, excluding placebos, are authorised; (b) according to the protocol of the clinical trial, (i)the investigational medicinal products are used in accordance with the terms of the marketing authorisation; or (ii) the use of the investigational medicinal products or medical interventions are evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products in any of the Member States concerned; and (c) the additional

diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned (Source: Clinical Trial Regulation, EU 536/2014 )

**Non-interventional study/observational clinical study** is a type of study in which individuals are observed, or certain outcomes are measured. No attempt is made to affect the outcome by the investigator (for example, no treatment is given) (US National Institutes of Health -NIH- definition). Observational studies include case reports and case series, ecological studies, cross-sectional studies, case-control studies and cohort studies.

**Pragmatic trials** are designed to evaluate the effectiveness of interventions in real-life routine practice conditions. Clinical trials that are considered "pragmatic" are designed to study a health intervention in a real-world setting that is similar or identical to the one in which the intervention will be implemented.

**Randomised Controlled Trial:** The most common and strongest interventional study design is a randomized controlled trial. In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators. These interventions may be medical products, such as drugs or devices; cell or other biological products; procedures; preventive care; or changes to participants' behavior, such as diet. Clinical trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention.

**Roles in the consortium:**

**Associated partner** is a recruitment site or another type of entity needed for the development or implementation of the clinical trial who has a collaboration agreement or a subcontract with one of the partners of the IICS consortium.

**Collaborator** is a self-funded partner that does not request funds from any of the participating funding organisations.

**Coordinating investigator**: the person who takes primary responsibility for the design, conduct and reporting of the study and who will be responsible for the overall project coordination.

**Principal Investigator** (PI): each partner organisation is represented by a Principal Investigator who is the responsible leader of a team of investigators who conduct a clinical study at a clinical trial site.

**Recruitment/recruiting site** facility where potential participants/patients are identified for and enrolled in clinical trials (recruiting sites) and sites where patients are identified and referred elsewhere for recruitment (Patient Identification Centre (PIC) sites).

**Service provider:** an external entity responsible for cross-cutting activities who will provide all recruitment sites with specific expertise in these activities.

**Sponsor** will mean the non-for-profit institution or organisation which takes responsibility for the initiation, the management and setting up the financing of the clinical trial. For IICS, usually the sponsor is the institution that hosts the coordinating investigator.

**Other definitions:**

**Approved or existing health care intervention**: in this call text we consider an approved or existing health care intervention as following:

- Medication or medical device approved by the relevant national authorities for medicines or;
- non-pharmacological health interventions, currently already developed and implemented in routine clinical practice.

The definition does not cover new health interventions.

**Core outcome set (COS)** is an agreed, standardized collection of clinical outcomes that should be measured and reported in all clinical trials for a specific health condition. It aims to ensure consistency across studies, improve comparability of results, and enhance the relevance of research for patients, clinicians, and policymakers. Proposals should aim at including COS when appropriate.

**Cross-cutting activities:** activities that have to be managed transnationally because they go beyond the national boundaries, such as financing of intervention/study drug, trial authorization, data collection and management, statistical analysis, safety, study design and protocol development and the overall management activities.

**Responsible Research and Innovation (RRI)** is the process of engaging with the social, political, environmental or ethical complexities of research and innovation. Further information can be found in ERA4Health's Guidelines for RRI.

## Aim and ambition of ERA4Health

The Partnership "Fostering a European Research Area for Health" (ERA4Health) aims at establishing a flexible and effective coordination between funding organisations in the European Research Area (ERA) for Health and Well-being. This Partnership brings the opportunity to increase European transnational collaborative research funding by creating a funding body for joint programming in priority areas addressing European Public Health needs.

The general objective of ERA4Health is to reach an effective joint approach and generate knowledge and products (e.g. preventive guidelines, medical protocols) in the identified research areas as outlined in ERA4Health Strategic Research and Innovation Agenda (SRIA)[1]. To achieve this, a comprehensive network is created which aims at strengthening and expanding the existing conducive eco-system.

In this light, ERA4Health gathers public funders of health research in the European Research Area including the European Commission that jointly identify and implement a common funding strategy in priority areas to advance health research and develop innovation.

ERA4Health has 4 specific objectives:

- SO1. Support relevant medical research including different clinical fields and intervention areas (prevention, diagnosis, treatment),
- SO2. Improve the utilisation of existing health technologies in clinical practice,
- SO3. Build capacity, in particular in conducting Investigator-initiated Clinical Studies (IICS) at European scale,
- SO4. Implement and advance the practice of Responsible Research and Innovation (RRI) across the breadth of the programme.

## Rationale

Cardiovascular diseases (CVD) are the leading cause of death worldwide, causing over 3.9 million deaths per year in Europe and over 1.7 million deaths per year in the European Union (EU), representing 45% and 33% of total deaths, respectively. Cardiovascular diseases are also responsible for 20% of all premature deaths (before 65) in the EU and are expected to remain the largest cause of death over the next 20 years. [2] [3] [4]

In addition, in the last decades, common metabolic disorders (MD), such as type 2 diabetes mellitus, type 1 diabetes mellitus, obesity, hypercholesterolemia, hypertension and metabolic dysfunction-associated to fatty liver disease have become a major public health burden worldwide. [5]

[1] ec_rtd_he-partnerships-era-for-health-1.pdf
[2] Cardiovascular diseases statistics - Statistics Explained - Eurostat
[3] EHN-heart-failure-paper_final_180419.pdf
[4] https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds)
[5] https://doi.org/10.1093/eurheartj/ehac779.131

Therefore, the impact of CVD and metabolic diseases in health care systems and society, causing disability and premature mortality is highly significant. These chronic diseases imply a very high economic burden as well. In Europe, CVD is estimated to cost €282 billion annually, including health and long-term care.[6]

Autoimmune diseases (AD) affect approximately 10% of the population worldwide with an increasing incidence and also pose a huge health and economic burden to society. The chronic and debilitating nature of these autoimmune disorders have a major impact on patients' quality of life. The elevated medical costs associated with the treatment of these disorders pose a major challenge for health care systems in Europe. [7] [8]

The importance to further develop clinical research on these conditions remains high. It is particularly relevant in these medical fields, to promote Investigator-Initiated Clinical Studies which have a high impact in public health, society's quality of life and global economy.

**Investigator-Initiated Clinical Studies (IICS)**, also referred to as non-commercial, academic or independent clinical studies, are studies initiated by investigators. They address important research questions that would not normally be of strong commercial interest to private industry. They are usually driven by scientific opportunities and pressing public health needs with high societal value, such as: cardiovascular, metabolic and autoimmune diseases. IICS are led by investigators, who conceive the research, develop the protocol and can be supported by public funding.

Whereas they represent almost half of clinical research activities in Europe, IICS are mostly conducted in a single country. Therefore, there is a specific need for supporting multi-country IICS, given the added value that they can provide compared to single country ones.

Taking advantage of Europe's half-billion population size, its medical expertise, high quality healthcare systems, harmonised regulatory framework and scientific potential, enhanced multinational cooperation in clinical studies would boost clinical research in Europe. Additionally, European studies allow rapid patient recruitment and spread best practices, thus enhancing Europe's competitiveness and healthcare equity for the benefit of patients and of healthcare systems.

Multi-country IICS require appropriate public or charity funding, and a multinational trial management capacity as the European legislation requires a sponsor for such trials in Europe. For IICS, academic institutions (usually the Institution of the principal investigator) act as the sponsor (academic-sponsored trials).

Comparative-effectiveness studies are a particularly important type of clinical studies. In clinical practice, many treatments have not been thoroughly evaluated, making it unclear whether a patient with a specific condition would benefit from a given treatment or if another might be more effective. In comparative-effectiveness studies, the benefits and side-effects of different methods to prevent, diagnose, treat and/or monitor a clinical condition are compared.

[6] Eur Heart J. 2023 Dec 1;44(45):4752-4767. doi: 10.1093/eurheartj/ehad583
[7] https://doi.org/10.1016/j.autrev.2023.103410
[8] https://doi.org/10.1016/j.autrev.2023.103326

A key objective of these studies is to provide stakeholders (patients, caregivers, providers, payers, policy makers) with useful knowledge to make an informed decision between two or more diagnostic tests, treatments, treatment combinations, interventions, care delivery systems or policies.

In addition, comparative effectiveness studies can be conducted in a very pragmatic way. Pragmatic clinical studies enable investigation of whether a treatment works in the real-world clinical setting, preferably on all types of relevant patients. In a pragmatic clinical study, necessary data will be collected mostly in routine clinical care and will imply less burden for the patients than in an explanatory trial. This results in lower costs even with a high number of patients.

Comparative effectiveness studies are considered to be low intervention studies (see definition) as they will compare approved interventions that are already being used in everyday clinical practice and in accordance with the marketing authorization. These studies should pose no more than a minimal additional safety risk or burden to participants compared to usual clinical practice.

In addition, drug repurposing clinical studies can leverage existing pharmacological knowledge and clinical data accelerating the development of new indications that can address unmet medical needs, reducing the costs and improving patient access to new treatments. Drug repurposing constitutes a dynamic field of drug development that can offer real benefits to patients.

## Aim of the call

The aims of the call are:

- to support randomised interventional multi-country Investigator-Initiated Clinical Studies that are designed as **pragmatic comparative-effectiveness studies** and/or **drug repurposing studies.** The clinical trial design should be appropriate to answer the research question, and its selection shall be fully justified in the proposal. To exclude clinical studies with direct commercial purposes, the protocol and study design must be described in a very clear and transparent manner.

- to encourage and enable **transnational collaboration** between clinical/public health research teams (from hospital/ public health, healthcare settings and other healthcare organisations) that conduct multi-country IICS, either comparative-effectiveness or drug repurposing studies.

Please take in note that clinical studies conducted for direct commercial purposes are excluded from support by the ERA4Health programme. In the case of the involvement of any private for-profit entity, it is needed that the consortia duly justify their role in the proposal and that there is no commercial purpose or benefit.

Proposals should take into account the following points that apply according to the selected clinical trial design:

1) The proposed study needs to be **a pragmatic comparative effectiveness trial and/or a drug repurposing trial, designed as Phase III randomised interventional trial**. The clinical design should be appropriate and justified. Cluster randomisation could be considered in the clinical trial design if justified.

2) **In case of comparative effectiveness trials**, these must compare the use of currently approved or existing healthcare interventions (see definition), used in clinical practice in Europe, either to each other or to the current standard of care.
3) **In case of comparative effectiveness trials, these must consider existing, approved healthcare interventions** (see definition) which could include but would not be limited to: diagnostic, screening, prevention and treatment interventions. The interventions can be pharmacological as well as non-pharmacological procedures like well-defined, reproducible and targeted nutritional and lifestyle interventions, surgery, prognosis methods, use of medical devices, nano and advanced health technologies, eHealth and digital interventions and other health interventions.
4) **In case of drug repurposing trials**, the aim shall be to explore a new indication of an approved off-patent medication. Given that this call is supported by public funding, clinical studies with a commercial purpose are excluded, therefore only off-patent drug repurposing trials are allowed.
5) These interventions shall have high public relevance in at least one of **these specific diseases or conditions** (that are of equal importance):
    - Cardiovascular diseases
    - Metabolic disorders
    - Autoimmune diseases (including antibody-based autoimmune diseases and/or also other Immune-mediated inflammatory diseases)

The focus of the multi-country Investigator-Initiated Clinical Studies is cardiovascular, metabolic or autoimmune disorders as primary causes of illness. Proposals may focus on a single cardiovascular, metabolic or autoimmune disease, or they may explore these conditions in combination with comorbidities.

Beyond the research topics, the following requirements and recommendations should be considered, including approaches to Responsible Research and Innovation (RRI) (see RRI guidelines and Guidelines for applicants document). Requirements:

- Proposals must clearly demonstrate the potential health and/or economic impact(s) as well as the added value of transnational clinical collaboration.
- Proposals shall use validated instruments and methods for determining the burden of disease and for evaluating the effects of the interventions where they exist.
- Proposals must include an early involvement of 'end users' (patients, care providers, healthcare professionals, etc.) in the design and development of the study (integrating patient relevant outcomes, selection of patient-relevant study endpoints, feasibility /acceptability of the study and trial assessments) and a continued involvement of patients through the lifecycle of the research project. This is to ensure acceptability of the healthcare intervention and utility of the studies' knowledge for healthcare decision making. A clear description of patient involvement needs to be included in the proposal. Patient organisations or other end-users can participate as partners (if eligible for funding by a national/regional funding organisation), as collaborators (participation with their own budget) or as part of a Patient Advisory Board.
- Special consideration must be given to fulfilling all ethical requirements (See ethical requirements and clearance section in the call documents, including reference to Reference to EU Regulation 2021/695 and ethical self-assessment).

- The consortia shall ensure the management of research data and biological samples collected during the projects, according to FAIR data principles (Findability, Accessibility, Interoperability and Reuse) and in compliance with the General Data Protection Regulation (GDPR).
- In alignment with the European Commission Roadmap for Women's Rights stating that women's and girls' physical and mental health needs to be improved by evidence-based information and gender-sensitive medical research, clinical trials, diagnostics and treatments, the proposed research needs to consider sex and gender aspects. Furthermore, the gender balance of the patients recruited in the clinical study need to be adequate and duly justified to ensure the evidence of the results in all sexes. Proposals that aim to address a gender-related knowledge gap in one of the included disease areas (e.g. women in cardiovascular disease) will be welcomed. Studies should not exclude pregnant and breast-feeding women by default, any exclusion should be based on justified reasons.
- The consortia must ensure inclusiveness aspects in patient recruitment (minorities, social-economic aspects, ethnical aspects…), to include underrepresented and vulnerable populations that could be specifically relevant in a certain medical area and consider issues of particular relevance for the target population, for example, gender specificities, age, multimorbidity, complex chronic conditions, polypharmacy, substance misuse, vaccine efficacy, compliance, and diseases with high societal burden.
- The consortia should consider the gender balance in their overall team composition. Responsibilities should be equally shared between them.
- Partners in the consortia, especially the coordinating PI, need to have a proven track record in delivery of clinical trials to ensure feasibility of the clinical trial. Further, all relevant expertise (including biostatistical expertise) needs to be included in the trial team to conduct high quality clinical trials.
- For the chosen population, clinical and safety parameters, as well as health and socio-economic outcomes (e.g. quality of life, patient mortality, (co)morbidity, costs, and performance of the health system) should be assessed. Proposals must include Core outcome sets (COS) where they exist or justify their lack of use.
- Additionally, proposals should take into account the diversity of health systems and the choice of the comparator in different regions of Europe to allow large-scale uptake.
- Proposals shall address the scalability from the regulatory perspective. They shall include a plan to address the different regulatory requirements in each of the countries.
- Applicants invited to submit a full proposal must demonstrate that they have explored the "freedom to operate" (FTO) aspects of their proposed study and are aware of the relevant regulatory requirements. Applicants should consult with their legal advisors or technology transfer office (TTO) early in the process to ensure that implementation of the study is not restricted by intellectual property rights (e.g., primary or secondary patents) or regulatory requirements.

Recommendations:

- Additionally, proposals are encouraged to show how the outcomes of the trial could generate further impact in the future (e.g. through a socioeconomic evaluation and to demonstrate how the evidence gathered by the comparative-effectiveness clinical trial

could be valuable for future Health Technology Assessments (HTA). They should consider the path to impact both if an effect is shown and if an effect cannot be shown.

- The consortia are encouraged to take into consideration existing and financially sustained multinational networks / infrastructures, platforms or existing cohorts in the respective medical field that they have access to ensure the feasibility of the trial.
- Applicants could make use of existing biobanks, existing cohorts, information from previous observational studies, systematic reviews, and/or metadata repositories, although their clinical studies should not be based only on these types of approaches.
- It is strongly recommended to use appropriate statistical techniques that can account for variations among countries in a pragmatic trial.

  Drug repurposing trials should have an upfront plan to ensure patient's access to the drugs in the different countries. Where the coordinating PI, the main PIs of the research teams or other responsible persons (e.g. biostatistician) of the research consortium are emeritus personnel, it should be strongly justified in the proposal that they will be able to hold and deliver the responsibilities associated to their role in the research consortium.

**Out of scope:**

- Clinical studies conducted for direct commercial purposes.
- Studies in **other medical areas different from the ones mentioned above** (cardiovascular diseases, metabolic disorders and autoimmune diseases).
- Particularly, those clinical trials that are focused on **cancer are out of the scope of this call**, even if this is studied with one of the eligible diseases/conditions.
- Proposals focused on observational studies, cohort studies, translational/clinical approval studies, creation of large databases, systematic reviews and meta-analysis. Non-randomised studies.
- Basic biomedical research and research involving animals or animal tissue.
- Development of a new healthcare intervention.
- Drugs without marketing authorization in Europe, medical devices without CE mark. However, off-label use that is well established in usual care is accepted.
- Phase I and phase II studies
- In comparative-effectiveness studies, the use of placebo will only be allowed for blinding of the interventions that will be compared. Otherwise, the use of placebo in those studies will be out of the scope. In the case of drug repurposing trials, this exclusion would not apply, and these studies could include placebo, albeit it would not be mandatory to include it.
- Topics excluded from Horizon Europe: research which aims at human cloning for reproductive purposes, modifying the genetic heritage of human beings which could make such modifications heritable, creating human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer, or leading to the destruction of human embryos (for example, for obtaining stem cells).

## Expected Impact

Pragmatic practice-oriented comparative-effectiveness publicly funded clinical studies can provide answers to highly relevant health research questions, both in terms of clinical effectiveness and cost-

effectiveness of interventions, which are less likely to be answered by trials funded by the pharmaceutical and other health industry. In case of comparison with the current standard of care, the impact on the public policies and the healthcare systems will be enhanced.

These types of pragmatic trials are a key element for Health Technology Assessments (HTA) and to assist decision-makers from health ministries and other public institutions, to promote value-based health care, evidence-based health policies and prioritize health interventions that have a substantial public health impact.

Additionally, drug repurposing of publicly funded clinical studies can leverage existing pharmacological knowledge and clinical data accelerating the development of new indications that can address unmet medical needs, reduce the costs and improve patient access to new treatments.

Through the early and active involvement of patients or patient representatives in the clinical studies the patient's needs in those medical areas will hopefully be adequately addressed and will ensure better acceptability and adherence to the healthcare interventions. This will further contribute to the patient-centred decision-making process and to enhance the societal impact and transfer of clinical research. Overall, the patients' quality of life will be improved.

## General conditions for application

The duration of the clinical studies will be 48 months.

**Any IICS must clearly demonstrate the potential health, economic, and/or policy impacts,** as well as **the added value of transnational collaboration**.

Applicants shall not apply to different calls for the same research activities. **Double funding is not allowed. Proposals should follow the principles of Responsible Research and Innovation (RRI).**

Consortia must show how they will engage with and address the relevant social, political, equity, environmental or cultural dimensions of the proposed research. The proposal template and ERA4Health RRI Guidelines further elaborate on how RRI dimensions can be approached (see our recommendation in the guidelines for applicants).

IICS supported by ERA4Health must respect fundamental ethical principles. Applicants must fill an ethical grid as part of their proposal and describe any potential ethical aspects of the work to be carried out, and how the clinical study will fulfil applicable requirements in institutional, national and European Union legislation (including the ethical standards and guidelines of Horizon 2020/ Horizon Europe [9]). All funded partners must respect the fundamental principle of research integrity — as set out in the European Code of Conduct for Research Integrity[10]. IICS involving human embryonic stem cells (hESC) or human embryos (hE) may not start without prior ethics review carried out by the European Commission and subsequent decision of the Horizon Europe Programme Committee.[11]

The individual partners of the joint applications should be complementary in their expertise, and the proposed work should pursue a high implementation potential for the benefit of end-users/patients/citizens.

[9] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf
[10] The European Code of Conduct for Research Integrity - ALLEA (All European Academies)
[11] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021C0512(01)&from=EN

Furthermore, additional aspects need to be considered in the application:

- The design of the clinical study must be appropriate to answer the research question (population, sample collection, statistical power, statistical analysis, interpretation, relevant models for hypothesis validation) must be well justified and should be part of the proposal.
- Strategies for recruitment, retention, assessment, and analysis must be included. The clinical study design and objectives should take into consideration the population that would be needed to reach the objective of the study.
- Gender equality as well as inclusiveness of the diversity of the population in the recruitment.
- Involvement of patient/patients' representatives and other relevant users in the co-creation and implementation of the tasks

## Participating countries and respective funding organisations

The following participating funding organisations have agreed to fund this call for transnational clinical studies:

| Country | Funding organisation | Acronym | Contribution |
|---|---|---|---|
| Austria | Austrian Science Fund | FWF | 1 400 000€ |
| Belgium | Belgian Health Care Knowledge Centre | KCE | 2 000 000€ |
| Czech Republic | Czech Republic Ministry of Health | MZ CR<br>(AZV CR)* | 500 000€ |
| France | French Ministry of Health | FR MOH | 2 000 000€ |
| Germany | Federal Ministry of Research, Technology and Space (BMFTR)/DLR Project Management Agency (DLR) | BMFTR/DLR | 3 000 000€ |
| Italy | Italian Ministry of Health | IT MOH | 2 000 000 € |
| Italy | Regional Foundation for Biomedical Research (Lombardy Region) | FRRB | 1 500 000€ |
| Latvia | Latvian Council of Science | LCS | 800 000€ |
| Lithuania | Research Council of Lithuania | LMT | 1 000 000€ |
| Norway | The Research Council of Norway | RCN | 1 200 000€ |
| Norway | South Eastern Norway regional Health Authority | HSØRHF | |

| | | | |
|---|---|---|---|
| Poland | The National Centre for Research and Development | NCBR | 2 840 000€ |
| Romania | Executive Agency for Higher Education, Research, Development and Innovation Funding | UEFISCDI | 1 000 000€ |
| Slovakia | Slovak Centre of Scientific and Technical Information | CVTI SR | 600 000€ |
| Spain | Regional Ministry of Health and Consumer Affairs of Andalusia | CSCJA | 250 000€ |
| Spain | Institute of Health Carlos lll | ISCIII | 2 400 000€ |
| Spain | Department of Health of Catalunya | DS-CAT | 700 000 € |
| Sweden | Swedish Research Council | SRC | 1 500 000 € |
| Türkiye | Health Institutes of Türkiye | TÜSEB | 600 000€ |
| UK | Department of Health and Social Care | DHSC-NIHR | 4 000 000 £ (approx. 4 400 000 €) |
| Global organisation | Breakthrough T1D | BT1D | 2 500 000€ |

*Table 1: Participating funding organisations.*
**For clarification in this call MZ CR acts as funder in this call, while AZV CR acts as service agency to administer the call at national level.*

The partners will be funded by their relevant national/regional funding organisations. Eligible costs and funding rules vary between the respective funding organisations (see Annex I). In the case of Breakthrough T1D funder, they can fund partners from different countries (see Annex I), but its funding it is type 1 diabetes specific, in alignment with its Breakthrough T1D Research Strategy

# Application

## ELIGIBILITY CRITERIA

Applicants must demonstrate that the research team contains the necessary breadth and depth of expertise in all the methodological areas required to deliver the proposed study.

PIs should demonstrate experience and expertise in the conduct and delivery of clinical trials.

### Size and composition of the consortium

The number of participants and their research contribution should be appropriate for the aims of IICS and be reasonably balanced in terms of international participation. Each IICS should represent the

critical mass to achieve ambitious scientific goals and should clearly demonstrate an added value from working together.

Only transnational studies will be funded. The following conditions apply to the composition of consortia:

A. The project must be a transnational project **involving eligible research partners from a minimum of 3 (three) and a maximum of 5 (five) different countries** participating in the call. In addition, in each consortium **at least two eligible partners (independent legal entities) must be from different EU Member States or Horizon Europe Associated Countries** participating in the call.

B. If a partner is eligible by a funding organisation, which will grant a single partner (see Annex I and table in the funding mechanism section from the guidelines for applicants), only one national partner should be part of the consortium. This partner will have the opportunity to establish a collaboration agreement with other eligible additional national recruiting sites and allocate a budget to the recruitment sites. Those recruitment sites will be considered associated partners to the consortium. If actual patient recruitment is lower than expected during the runtime of the clinical study, initial recruiting sites may be substituted by additional ones, if it is possible under the national/regional regulations of the respective national funding agency for that specific partner.

C. If there are partners eligible by a funding organisation, which will fund several partners for this country/region in the consortium, the consortium can be composed with a maximum of 3 (three) partners eligible by this funding organisation. In this case, there will be no collaboration agreement between those partners, and they will all be granted individually by the funding organisation and have their own budget. These 3 partners will be counted as 1 (one) country for the maximum number of countries represented in the consortia.

D. The maximum number of countries can be increased to 6 (six) or 7 (seven) if 1 (one) or 2 (two) countries, respectively, from the following list will be included in the consortium: **Slovakia, Czech Republic.**

E. The maximum number of funding organisations from the same country represented in each research consortium will be 2 (two). If in the same consortium are participating eligible applicants applying funding each of them to a different funding organisation from the same country, they should respect the maximum number of partners, stated in bullet point B and C according to the financial mode of those 2 (two) funding organisations. Please see national guidelines for details.

F. A maximum of 3 (three) collaborators per consortium is allowed. Collaborators are self-funded partners: i.e., partners that do not request funds from any of the participating funding organisations (i.e., partners from non-funding countries or partners which are not fundable according to national/regional regulations of the participating funding organisations). The following conditions apply for collaborators:
    - Clear added value for the IICS should be demonstrated in the proposal.
    - Secure their own funding for participation with clear evidence in the proposal.
    - A letter of commitment of the collaborator(s) needs to be included as an annex to the pre-proposal / full proposal.
    - A collaborator cannot be a work package leader.
    - A collaborator cannot be a recruitment site for the study.

- In the case that the collaborator is a private for-profit entity, it is needed that the consortia duly justify this involvement in the proposal and that there is no commercial purpose for this collaboration.

| | | | |
|---|---|---|---|
| Number of countries in the consortium | **3-5** | **6** | **7** |
| Number of underrepresented countries in the consortium | No constraints | At least 1 | At least 2 |
| Maximum number of collaborators (be aware it corresponds to organisations not countries) | 3 | 3 | 3 |

*Table 3: Possible composition of consortium*

Each study consortium must nominate **a clinical study coordinato**r among its partners (NOT a collaborator). The clinical study coordinator cannot be a commercial enterprise or for-profit organisation. The representative of the clinical study coordinator, the **coordinating investigator,** will represent the consortium externally, will act as contact person for the Joint Call Secretariat (JCS) and will be responsible during the entire process for the internal scientific management such as controlling, overseeing intellectual property rights (IPR) issues, overseeing the work of a service provider responsible for the transversal activities of the study (i.e. clinical study management activities at consortium level) as well as reporting to the JCS.

Each Principal Investigator can submit only **1** (**one) pre-proposal as coordinator or as simple partner** (i.e. the coordinator or the partner of a proposal cannot be a partner in another proposal).

## Financial and legal modalities

Each clinical study partner will be funded by its relevant national/regional funding organisation. Therefore, eligible costs, funding rules and other specific aspects allowed may vary between the respective funding organisations (see Annex I). Due to these differences, it is recommended that each clinical study partner defines its own budget in accordance with the funding rules of its own country/region.

This call for proposals must be practised in compliance with the national applicable (EU/EEA (European Economic Area) State Aid rules (http://ec.europa.eu/competition/state_aid/overview/index_en.html) and in compliance with the principles of Transparency, Non-discrimination and Sound financial management.

For information on the specific funding rules and eligibility criteria of the national/regional funding organization, please carefully read Annex I and the national/regional announcements of the call and the guidelines for applicants. Applicants will be informed about any call updates through the ERA4Health website.

**Applicants are consequently strongly encouraged to contact their national/regional contact points to check their national/regional eligibility rules before submission (see Annex I).** Please note in some countries/regions this **may be mandatory.**

**ADDITIONAL BUDGET**: an additional budget of a maximum up to 15% of the total budget requested to the national/regional funders can be requested for covering the conduction of cross-cutting management activities (i.e. clinical study management activities at consortium level) such as trial authorizations, drug, safety and data management under the responsibility of the coordinating investigator and his/her legal entity through collaboration with ECRIN (www.ecrin.org). This additional budget will be directly allocated to ECRIN to perform cross-cutting trial management activities.

To request this additional budget in the pre-proposal, the consortium shall closely collaborate with ECRIN during the pre-proposal phase to define the details of the service provision (either directly performed by ECRIN or by an entity subcontracted by ECRIN, in the case that ECRIN cannot provide these services). To guarantee that the collaboration is well established and with enough time, the consortium must **inform ECRIN representatives** as soon as possible and before this **deadline: 30th November 2025** that they are preparing an application**.**

To establish this contact with ECRIN, the consortium must contact the Euco from the country to which the coordinator/sponsor is located (contact details of Euco can be found at: https://ecrin.org/ecrin-staff selecting the sponsor country) or in the case of coordinator/sponsor from non-ECRIN member countries, the consortium must contact ECRIN Core Team contact point (https://ecrin.org/contacts/sareema-javaid).

Once the collaboration between ECRIN and the applicants will be agreed, it will be formalized through a **written letter signed by ECRIN** representatives that must be **included as Annex of the pre-proposal** application. The letter will describe the agreed service provision for the additional budget.

Applicants shall be aware that this additional budget, allocated for cross-cutting management activities, may not be sufficient to cover all such activities required for conducting the clinical trial. Therefore, it may be necessary to request additional funding from national/regional funding organisation(s) to ensure full coverage of these cross-cutting management needs (the type of activities eligible for funding will vary between the respective funding organisation, please see Annex I).

See section "Funding Mechanism" in the guidelines for applicants for more details.

**Please note that if a partner is found to be non-eligible at any step of the process by one of the funding organisations, the entire proposal could be rejected without further review.**

**Therefore, please make sure to carefully read and follow the respective national/regional regulations in Annex I.**

### Submission of joint proposals

There will be a two-step submission and evaluation procedure for joint applications, i.e. pre-proposals, with invitation of successful consortia to submit a full proposal. In addition, the full proposal review process will be complemented by a rebuttal phase and an interview jointly with the coordinating investigator and a representative of the sponsor. The representative from the sponsor shall be the person responsible for the implementation of clinical studies in the sponsor organisation and shall be identified by the consortia in the full proposal. This representative shall be aware of the

responsibilities of the sponsor in clinical trials and how the sponsor guarantees the compliance with Good Clinical Practice and applicable regulation, as well as ability to provide information regarding the previous experience of the institution as sponsor.

For both submission steps, one joint proposal document (in English) shall be prepared by the partners of a transnational consortium following a pre-defined template and must be submitted to the JCS by uploading it on the electronic submission system by the coordinating investigator.

The two-step application process will have the following timeline:

| | |
|---|---|
| **6th November, 2025** | **Publication of Trials4Health call** |
| **13th November, 2025** | **Webinar Info Day** |
| **27th January, 2026** | **Deadline for pre-proposal submission** |
| 17th April, 2026 | Communication of the results of the pre-proposal assessment (invitation for full proposal) |
| **17th June, 2026** | **Deadline for full proposal submission** |
| **24th August – 4th September, 2026** | **Rebuttal stage** |
| **24th August – 4th September, 2026** | **Interview to assess the study feasibility** |
| End of October, 2026 | Communication of the funding decisions to the applicants |
| **January – May 2027** | **Expected project start** (subject to national procedures) |

*Table 1: Timeline application process*

The pre-proposal template is available on the ERA4Health website (Link).

An application template for the full proposal stage will be sent to the coordinating investigator by the JCS with the invitation to submit a full proposal.

The pre-proposals or full proposals submitted without using the relevant template will be declared non-eligible. In addition, the page limits on the length of each of the different sections of the template should be strictly respected.

For applicants from specific countries/regions it might be mandatory to submit an additional national/regional proposal and/or other information, in some cases before the deadline of this call, directly to the national/regional funding organisations. Therefore, applicants are strongly advised to check their funding organisations specific regulations. See Annex I for more details.

For the submission of full proposals, **the widening concept** will be applied. It will therefore be possible, but not mandatory, to add a new partner that is eligible for funding by certain funding organisations (with a low number of eligible applicants at the first step). The widening process consists of the inclusion of one new partner of one of the underrepresented funding organisations/countries of the list provided, while respecting the maximum number of countries. The inclusion of this new partner should be relevant for your proposal, and the new partner should be well integrated in your consortium. The list of the underrepresented funding organisations/countries

will be provided by the JCS to coordinators in the letter with invitation to the second step. The maximum of 7 countries within the consortium should still be respected. Finally, **it is mandatory for the new partner included in the widening process to contact its national funding organization and obtain approval before the submission of the full proposal** (see contact details in Annex I of the call text).

If invited to submit a full application, no changes (including to the budget) are permitted to the full proposal, unless the changes address specific requirements/ guidance identified by reviewers. Any fundamental change between the two-stage evaluation, e.g. concerning the composition of the consortium or the objectives of the study must be communicated to the JCS and to the national/regional involved funding organisations. In exceptional cases, these changes may be approved if detailed justification is provided and if they are accepted by the CLSC. The requested budget at pre-proposal stage cannot be modified for the full proposal, unless there is a strong justification, the change is in response to requirements/guidance provided by the external reviewers after review of the pre-proposal. Any proposed change in budget must be submitted by the applicants to the relevant involved national/regional funding organisation and submitted notification about the budget modification to the JCS. Written approval for the revised budget from the funder must be in place before submission of the full proposal.

### Further information

For additional information, please contact the JCS, or your national/regional funding organisation Contact Person (see Annex I).

## Evaluation and decision

### Eligibility check and evaluation procedure

#### Formal check and evaluation of pre-proposal

After submission, the JCS will check all pre-proposals to ensure that they meet the call's formal criteria (date of submission; number of participating countries; inclusion of all necessary information in English; appropriate limits on length). In parallel, the JCS will give access to the pre-proposals to the national/regional funding organisations, which will perform an administrative check for compliance with national/regional regulations.

The pre-proposal of each consortium passing the eligibility check (JCS and country/region) will be evaluated by external reviewers. Evaluation of a pre-proposal will be made by three reviewers with a scientific/clinical background. One of these three reviewers will have specific expertise in clinical trial methodology and biostatistics. Potential conflicts of interests of the evaluators will be taken into consideration during the allocation of the proposals. The reviewers will perform the assessment of the pre-proposals and complete a written evaluation form with scores and comments for the evaluation criteria that they should evaluate. The evaluation will include an eligibility check that the

proposal is included in the call scope (e.g. disease area, type of trial, etc). Based on the scores in the written evaluations, a ranking list will be established. The Clinical Study Steering Committee (CLSC) members will meet to decide which proposals will be invited to submit a full proposal based on the reviewers' recommendations and to ensure a reasonable balance of requested and available national/regional budgets. Pre-proposals which do not pass this assessment will not be invited for the full proposal stage. All consortia will receive the full evaluation reports, excluding the evaluation scores.

## Formal check and evaluation of full proposals

After submission, the JCS will check the full proposals to ensure that they meet the call's formal criteria and have not changed substantially from the respective pre-proposals before sending them to the reviewers.

Each full proposal will be allocated to three reviewers with a scientific/clinical background and taking into consideration the potential conflicts of interest between the reviewers and the applicants. One of these three reviewers will have specific expertise in clinical trial methodology and biostatistics. The reviewers will perform the assessment of the full proposal and complete a written evaluation form with scores and comments for each criterion (see evaluation criteria below).

Additionally, a Patient Advocacy Committee will assess the patient involvement and relevance for patient needs in the full proposals and will complete a written review.

Each coordinator is provided with the opportunity of getting acquainted with the assessments and commenting on the arguments and evaluations of the reviewers (see section "Rebuttal") before the Peer Review Panel (PRP) members meet to discuss each **full proposal** in a PRP meeting.

In addition, an online interview of the coordinator and the person responsible for the implementation of clinical studies in the sponsor organisation, according to the organisation's legal structure, authorised to speak on behalf of the sponsor and identified by the consortia in the full proposal, will take place. This interview will evaluate the capacity of the sponsor and the coordinator to implement the clinical study. Apart from the coordinator and the representative of the sponsor, a maximum of three other additional representatives of the research consortium can attend this online interview, in case that their specific expertise is needed to demonstrate the capacity to implement the clinical study (e.g. biostatistician of the research consortium).

During the PRP meeting, the reviewers and interviewers will discuss all proposals and produce a ranking list of proposals recommended for funding. Representatives of the Patient Advocacy Committee will be invited to take part in the discussion and present their assessment of the patient involvement of each proposal during the PRP meeting. They will have voting rights similar to the scientific evaluators attending the PRP, in case that a voting procedure is needed to take the final decision.

### Evaluation Criteria

Proposals not relevant to the call topic and objectives (out of the scope) will be declared ineligible and will not be funded and forwarded to full proposal stage independently of their scientific quality.

## Pre-proposal

### 1. Excellence

- Scientific relevance, scientific quality and target of an unmet clinical need.
- Previous research and evidence, supporting the objective of the trial and the estimated effect size (i.e. background, state of the art); adequacy of search strategy to identify previous research evidence.

### 2. Impact

- Impact on patient benefit, clinical practice, and the healthcare system (e.g. socio-economic impact)
- Added value of transnational collaborative study compared to a national/regional study
- Involvement of patients and other relevant stakeholders in the design and execution of the IICS and the dissemination of its results.
- Quality of the approach to RRI in realising the scientific and clinical objectives.

### 3. Quality and efficiency of the implementation

- Appropriateness of the study design, suitability of methodological approach
- Ethical acceptability, feasibility of the project
- Quality of the research team (complementarity of expertise, expertise in relation to the project, expertise in multicentric clinical studies).

## Full proposal

### 1. Excellence

- Innovation and scientific relevance of the study and how it will contribute to extend the knowledge beyond the state of the art, potential to change the current medical/clinical practice.
- Relevance to meeting patient needs.
- Scientific quality and pertinence of the objectives
- Soundness of the evidence presented (supported by an adequate search strategy) in support of the medical need, the study rationale, and the estimated effect size; including presentation of other existing trials addressing a comparable question (if applicable) and documentation of clinical safety of the agent(s), if applicable.

### 2. Impact

- Added value of transnational collaboration
- Expected impact of the study at short-term and long-term level related to the overall duration and budget. Potential of the expected results in terms of potential impact for: patients, public health, clinical practice and/or other socio-economic health relevant applications and potential commercial exploitation.

- Effectiveness of proposed measures to exploit and disseminate the study results (including engagement with patients and other public groups) and to manage research data
- Substantive involvement of pertinent patient organisations or patient representatives or other relevant stakeholders (in planning and execution of the trial, and dissemination of the results).
- Appropriate integration of RRI dimensions within the study design.

**3. Quality and efficiency of the implementation**

- Adequacy, coherence and feasibility of the study design to verify the hypothesis(es) and to respond to the medical need
- Feasibility of the study according to the planned duration and available budget
- Coherence and effectiveness of the work plan and study design (appropriateness of the allocation of tasks, resources, timeframe, infrastructural support to the clinical trial).
- Feasibility of recruitment (Feasibility of recruitment rates; Feasibility of the trial in the proposed population/time frame; Adequateness of the site selection criteria; Adequateness of the documented feasibility of the recruitment by the recruiting centres).
- Appropriateness of the management structures and procedures, including risk and innovation management and the communication flow among partners and among the different boards/committees.
- Description of potential risks, including the recruitment risks, and adequate pre-planned counter measures, including involvement of and charter for independent data monitoring and safety committee where relevant
- Adequacy of resources, staff and activities dedicated to RRI, including ELSI (Ethical, Legal and Social Issues) aspects, in design and implementation of the clinical study.
- Consideration of sex/gender aspects in the clinical study design, study implementation and study recruitment.
- Adequacy of the plan for compliance with regulatory requirements and international standards (GCP, Declaration of Helsinki, CONSORT-Statement).
- Management of research data according to FAIR data principles and where relevant, adequateness of planned strategies for long-term accessibility and potential re-use of study data.

**4. Competence of the research team and quality of research environment**

- Competence and experience of participating partners (previous work in the field, specific technical expertise, proven track record in multicentre clinical trials)
- Complementarity and completeness of skills within the consortium (clinical, methodological, biostatistical expertise)
- Meaningful links to multinational networks and existing infrastructures.

**5. Methods and Design of the clinical trial**

- Relevance and adequateness of the outcome measures with respect to the overall objectives of the trial; Relevance of chosen primary and secondary outcomes for patients.
- Adequacy of the target and study population and of the controls and/or comparators
- Adequacy of the consideration of the potential clinical and epidemiological consequences of the trial results

- Adequacy of randomisation criteria
- Adequacy of methods against bias and the proposed strategy for statistical and biostatistical analysis and sample size calculation
- Impact of non-compliance and missing values on the sample size.

**A consortium will not be funded if the sponsor does not present the capacity to implement a transnational clinical study, independently of the scientific quality of its proposal.**

### Scoring system

Evaluation scores will be awarded for each main criterion. Each criterion will be scored out of five. The weight of each main criterion is equal.

**0 = Failure.** The proposal fails to address the criteria or cannot be assessed due to missing or incomplete information.
**1 = Poor.** The criteria are inadequately addressed, or there are serious inherent weaknesses.
**2 = Fair.** The proposal broadly addresses the criteria, but there are significant weaknesses.
**3 = Good.** The proposal addresses the criteria well, but a number of shortcomings are present.
**4 = Very Good.** The proposal addresses the criteria very well, but a small number of shortcomings are present.
**5 = Excellent.** The proposal successfully addresses all relevant aspects of the criteria. Any shortcomings are minor.

Only integer values are accepted.

The maximum scoring for pre-proposals will be 15 points and for full proposals 25 points.

**Full proposal will be considered fundable if the threshold average score for individual criterion is 3 points and the overall score is at least 17 points.**

### Rebuttal stage

Before the PRP members meet to discuss the full proposals in a PRP meeting, each coordinator is provided with the complete reviewers' assessments. This stage allows applicants to comment on factual errors or misunderstandings that may have occurred in the review process and to reply to reviewers' questions. However, issues not related to reviewers' comments or questions cannot be addressed and the work plan cannot be modified at this stage.

The applicants will have **up to 12 calendar days** (24th August to 4th September, 2026) for this optional response to the reviewers' comments. Answers sent after the notified deadline, or not related with reviewers' comments or questions will be disregarded.

### Interview of the sponsor

The coordinating investigator and the representative of the sponsor will be jointly interviewed by an interview committee (formed by 3 experts that will be part of the PRP) to determine the capacity of

the coordinator to implement the proposed clinical study and of the sponsor to oversee and manage it. The JCS will attend the interviews as observers.

During the interview, a qualitative assessment of the feasibility of the trial will be performed, taking into account:

- The previous experience of the coordinating investigator and the sponsor in conducting multicentre and/or multinational clinical trials
- Daily management and operational aspects of the study
- Risk identification and planned mitigation measures
- the governance and communication flows among the committees that they will put in place to ensure the feasibility of the trial

All PRP members will receive the feedback of the interview committee (which will be a qualitative gradual assessment of the feasibility of the study) which will be considered during the PRP discussion in the PRP meeting.

### PRP meeting

The JCS will give the PRP members access to all full proposals, reviews and rebuttals, outcomes of the interview of the coordinators and sponsors, avoiding any conflicts of interest. The PRP will meet to discuss each proposal and, after consideration of the evaluation criteria, external reviews (patient representatives), rebuttals, interview outcomes, their own reviews and discussions, the PRP will assign final scores, make a classification of the proposals, and rank proposals recommended for funding. The final summary review report prepared by the PRP members will be sent to the respective coordinating investigators.

### Ethical clearance

After the PRP meeting, ethics experts will remotely check the full proposals, which are recommended for funding by the PRP and selected for funding by the CLSC, for alignment with ethical norms and regulations[12]. A meeting will also be organised for a discussion between the different ethics experts, if necessary. The ethics experts may ask the consortium for clarifications on the ethical points related to the proposed research approaches. The Ethics experts may highlight some vigilance points that need to be monitored during the implementation of the funded clinical study. Only those proposals approved by both the scientific evaluation and ethical assessment (complying with all central Horizon Europe and regional/national ethical requirements), will be funded.

### Clinical study selection and reconfiguration process

A first selection of the clinical studies for funding identified as the main list will be made by the national/regional funding organisations based on the ranking list established by the PRP, available funding and the ethical clearance outcomes.

[12] Reference to EU Regulation 2021/695 and how-to-complete-your-ethics-self-assessment_en.pdf (europa.eu)

After the establishment of the main list, additional clinical studies that have been assessed to be of good quality by the evaluation process could be invited to restructure their consortia, if there is any remaining funding budget. Research consortia will be provided 15 calendar days for this reconfiguration process.

Restructuring may take place with the following boundary conditions:

- Invitation for restructuring will take place only when availability of certain national/regional funding is the limiting factor
- Restructuring is possible only in cases where changes affect only one partner of the clinical study consortium; and in this step only a partner that serves as recruiting site of the clinical study or a service provider can be partly/ fully replaced.
- Restructuring cannot lead to the change of the coordinating investigator.
- The central eligibility criteria of at least 3 funded partners from 3 different countries is respected
- Restructuring can take effect either through non-funded participation of the partner (this partner would act as a self-funded collaborator, being possible to increase to a maximum number of 4 collaborators in the consortium at this stage, in case that there are already 3 collaborators involved) or through finding a replacement partner eligible for funding from a funding organisation that still has funds available.

The clinical studies that are invited to resubmit their proposal with a restructured consortium must still meet the eligibility criteria of the call. In principle, the JCS will check the restructuring process. Only if needed, it will be checked by an independent expert(s) or PRP member(s) to ensure that there is no loss of quality in the proposal. The selection of the clinical studies to be funded among the resubmitted proposals will be guided by the outcome of the evaluation process and the availability of national budgets. After the approval of the CLSC, a second selection of studies for funding can be established.

**IMPORTANT:** If at any point of the proposal selection phase, or the clarification and negotiation phase, a clinical study partner or collaborator with a crucial role in the study (e.g. to ensure the number of patient recruitment, drug/intervention provider) withdraws from the clinical study, is ineligible or not able to fulfil its commitment as stated in the proposal, the proposal is irrevocably disqualified without the opportunity of restructuring. Furthermore, if at any point, the coordinating investigator withdraws from the clinical study, is ineligible or not able to fulfil its commitment as stated in the proposal, the clinical study proposal is irrevocably disqualified without the opportunity of restructuring. **In any case, a restructuring of the consortium can lead to a re-evaluation of the proposal**.

Coordinating investigators having submitted an eligible proposal will be informed about the funding recommendation regarding their proposal by the JCS. Coordinating investigators are responsible to communicate this information to their clinical study partners. ERA4Health will publish in its website the information regarding the co-funded projects by the call, once that the call procedure has completely finalised.

## Redress procedure

Applicants can appeal against the evaluation outcome if they suspect a breach in the application of the evaluation and selection procedures. This redress procedure only covers the procedural aspects of the evaluation and/or central formal eligibility checks.

Requests for redress on national/regional eligibility decisions will not be handled by the JCS and need to be addressed to the responsible national contact point. A mere disagreement with peer reviewers or panel members' comments are not grounds for an appeal. The redress procedure will not call into question the scientific or technical judgement of appropriately qualified experts.

In this case the applicants shall submit their appeal to the JCS via email (Trials4Health@isciii.es) up to 7 calendar days after the date of the eligibility check or evaluation outcome email notifications by the call secretariat at the end of each step (eligibility check, first or second evaluation stage).

Admissibility of appeals

For an appeal to be admissible the following conditions must be met:

- The appeal must be submitted by the coordinator of the proposal to which the appeal relates
- Only one appeal per proposal can be submitted after each step
- The appeal must be submitted via email within the 7 calendar days deadline. The appeal must contain the following minimum information:
    - The name of the call for proposals
    - The proposal acronym
    - The title of the proposal
    - A description of the alleged shortcomings of the evaluation procedure

The appeal must demonstrate a procedural irregularity, factual or manifest errors in the evaluation process, misuse of powers, or a conflict of interests. Appeals that do not meet the above conditions, or do not deal with the evaluation of a specific proposal or express mere disagreement with the result or the reasoning of the evaluation will be judged as not suitable for redress.

### Procedure

Upon receipt of an appeal, an acknowledgement of receipt will be sent by the call secretariat as soon as the email is read. The acknowledgement shall report the redress process and the anticipated date by which a decision on the appeal will be communicated to the appellant.
All appeals received by the 7 calendar days deadline will be processed together by a designated Redress Committee and the decision will be communicated to the appellant **within 10 calendar days** after the deadline for submitting the appeals.

# Responsibilities, Reporting requirements and Dissemination

## Consortium Agreement

The coordinating investigator will be responsible for drawing up a Consortium Agreement (CA) suitable to the study partners to manage the delivery of the study activities, finances, Intellectual Property Rights (IPR), to handle confidential data (e.g. patient data) and to avoid disputes which might be detrimental to the completion of the study. Within a funded consortium, partners must grant each other access - under fair and reasonable conditions — to background needed for exploiting their results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to restrictions. The consortium is strongly encouraged to sign this CA before the official study start date, and in any case the CA should be signed in the first 6 months of the clinical study**.** Please note that national regulations may apply concerning the requirement for a CA (e.g. certain funding organisations may need the signed CA to release some funds). Further instructions will be provided by the JCS to the coordinators of the clinical studies selected for funding.

## Open Science

Importantly, all funding recipients must ensure that all outcomes (publications, etc.) of transnational ERA4Health-funded clinical studies are published with Open Access. Clinical studies funded by ERA4Health are eligible to publish on **Open Research Europe (ORE)**, the Platform of the EC [13] at no cost.

Any clinical study funded within this call needs to be registered in a publicly accessible WHO primary clinical trial registry. Furthermore, the protocol of the clinical study and the results of the clinical studies will need to be published with open access and additionally made available in a publicly accessible registry (WHO primary registry).

The new research data resulting from the study should be treated according to the FAIR [14] principles, and deposited and shared, according to the national rules of the countries involved. To make research data findable, accessible, interoperable and re-usable (FAIR), a Data Management strategy for the full proposals is mandatory in the second evaluation stage. Studies selected to receive funding in the current call, will be requested to present a more detailed Data Management Plan (DMP) before month 6 from the official start of the study and an update of the DMP will be asked at the end of the clinical studies.

## Monitoring

Project coordinators are required upon notification to deliver a scientific abstract and lay summary of their project suitable for communication and dissemination purposes.

[13] https://open-research-europe.ec.europa.eu/
[14] https://www.nature.com/articles/sdata201618

The coordinating investigator is required to submit an annual scientific progress report on behalf of the consortium to the JCS in March of each year following a pre-defined template, detailing how the study is progressing in relation to planned objectives, with an additional progress report at month 6 of the project. In this 6-month progress report detailed information about the recruitment (total recruitment and recruitment broken down for all partners by trial site) must be included.

Furthermore, a final scientific report must be sent to the JCS within a period of two months after the study has ended. In addition to the reports, information related to some indicators related to the study may be collected on a platform/survey. The project coordinator is requested to justify the accomplishment of several critical milestones that will ensure the correct performance of the clinical study. Periodic reporting will be required on the following milestones that have to be defined in the full proposal (including an update on M1 milestones when all approvals and agreement are in place to facilitate First Patient First Visit (FPFV)):

| | |
|---|---|
| M1: The Project has obtained all administrative and regulatory authorisations | Milestone 1.1. Proof of registration |
| | Milestone 1.2. Final approved version of the study protocol (referring to the one that will be submitted to National Competent Authorities (NCA) and EC / the one that will be sent for publication) |
| | Milestone 1.3. Final approved version of the Data Management Plan |
| | Milestone 1.4. Establishment of Governance Boards, including Data Safety Monitoring Board |
| | Milestone 1.5. Data Management System |
| | Milestone 1.6. Agreements in place* |
| M2: First Patient First Visit (FPFV) | |
| M3: 25% final target recruitment | |
| M4: 50% final target recruitment | |
| M5: 75% final target recruitment | |
| M6: 100 % final target recruitment | |
| M7: Last Patient Last Visit (LPLV) | |
| M8: Analysis of results | |
| M9: Publication of results | |

*Including:

- Sponsor-site agreements with all participating recruiting sites
- Sponsor-vendor agreements, including drug supplier, drug distributor and all other applicable (Contract Research Organization -CROs-, Clinical Trials Unit -CTUs- for monitoring, data and/or project management and vigilance) agreements

- Insurance (if applicable)

The description of status and dates for all agreements in all countries should be stated.

National funding organisations may also request additional financial and/or scientific annual progress reports and/or a final report on the study from the partners from their respective country.

In addition, the coordinators of each consortium may be asked to participate in a kick-off meeting and present two progress updates, one mid-term and one final status symposium organised by ERA4Health. An appropriate travel budget should be included and justified in the financial plan of the proposal. In the case that some of the events are organised as an online conference, all partners of the consortia will be encouraged to participate.

### Communication

The coordinating investigator will represent the consortium externally and will be responsible for all communication with the relevant ERA4Health bodies. The coordinator must promptly inform the JCS in case of any significant changes in the work plan or the consortium's composition. The JCS will inform the relevant funding organisations, who will decide upon the proper action to be taken.

Coordinating investigators, upon notification, are required to deliver an abstract of their study suitable for communication and dissemination purposes.

For the effective contribution of the study to the objectives of the ERA4Health, the coordinating investigator should be available to participate in meetings/workshops with the aim of:

- Exchanging study results
- Developing a joint strategy to coordinate and facilitate integration of the planned activities of ERA4Health
- Communicating results across ERA4Health

Importantly, all funding recipients must ensure that all outcomes (publications, etc.) of transnational ERA4Health funded studies include proper acknowledgement of the ERA4Health partnership and the respective funding partner organisations.

"*This study received funding from [name of funding organisations, or an acknowledgment as requested by your national/regional funding organisations] under the umbrella of the Partnership Fostering a European Research Area for Health (ERA4Health) (GA N° 101095426 of the EU Horizon Europe Research and Innovation Programme).*"

## Confidentiality

The Clinical Study Steering Committee (CLSC, composed of one representative from each funding organisation participating in the call) and the JCS will take all lawful steps to ensure confidentiality of the information and documents obtained during the evaluation and selection procedure of the joint call.

In selecting the international experts for the PRP, the ethical experts and the patient representatives, the JCS shall endeavour to avoid any possible Conflicts of Interest (CoI).

Each expert will have to sign a declaration of confidentiality and absence of conflict of interest. In case of a CoI, the reviewer will be withdrawn from evaluating the respective proposal. Conflicts of interest are managed and recorded throughout the evaluation process.

## General Data Protection Regulation

The following Data Privacy Notice applies:

By submitting an application, the applicants consent to the use, processing and retention of their personal data[15], in accordance with article 6.1 (e) and (c) of the General Data Protection Regulation (GDPR) (2016/679) and 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 organisations relationship with them
- Analysing and evaluating the call
- Providing aggregate data to national and European surveys and analyses on the funded clinical studies
- Complying with audits that may be initiated by the funding organisations and the European Commission (or its agencies).

The members of the CLSC 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 CLSC may link the data that funding recipients provide in the application with national, bibliographic or external research funding data which are available through public subscription-based databases (e.g. Scopus, Web of Science, etc.) or other national / open datasets.

[15] Last name, first name of the researchers, date of birth, professional contact information, degree(s), position (current and previous), fields of activity, place of work, organisation, address(es), curriculum vitae, ORCID number, name and reference of studies, LoIs, study proposals (scientific document, administrative and financial appendix).

# ANNEX I

| | |
|---|---|
| **Country** | Austria |
| **Funding organisation** | FWF – Austrian Science Fund |
| **National contact person** | Christoph Gross, christoph.gross(at)fwf.ac.at, +43 676 83487 8910 Stefanie Schagginger, stefanie.schagginger(at)fwf.ac.at, +43 676 83487 8213 |
| **Funding commitment** | 1.400.000€ |
| **Anticipated number of fundable proposals** | 3-4 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | The FWF generally does not have any minimum limit. The maximum limit is 450.000 €. |
| **Funding mechanism** | The Austrian subprojects must have a thematic focus on clinical/translational research with patient-oriented approaches, whereby the elucidation of disease mechanisms is desirable and cooperation between clinicians and basic researchers should be intensified. All participating organisations will be granted and should be part of the clinical study consortium. A maximum of 3 partners are authorised.<br><br>If the following option is intended, please contact the FWF office: Only one organisation will be granted and this organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement. |
| **Eligibility of partners** | All Austrian research institutions are eligible to apply if they are registered in the FWF's research institution portal. Applications are to be submitted by the research institution where the project is to be carried out. |
| **Eligibility of costs, types and their caps** | Project-specific costs are eligible for funding. These include personnel and non-personnel costs that are needed to carry out the project and that are not included in the infrastructure provided by the research institution. The FWF does not finance the infrastructure or basic equipment of research institutions. The research institution must provide the necessary infrastructure. Personnel costs for administrative tasks cannot be funded by the FWF. The current FWF Personnel Costs and Salary Rates indicates the salaries that may be requested. The FWF grants an annual salary adjustment to compensate for inflation, which is applied automatically to all contracts of employment in Principal Investigator projects that are valid when the adjustment takes effect. Please refer to the FWF Application Guidelines. |
| **Duration of the clinical study** | Funding requested for FWF Principal Investigator Projects is limited to a maximum of 48 months. |
| **Specific rules for potential extensions** | A cost-neutral extension of up to 12 months is possible and must be applied for at the FWF before the official end date of the project. |

| | |
|---|---|
| **Submission of the proposal at the national level** | In addition to the application at the ERA4Health level, administrative data (in accordance with the FWF Guidelines for Principal Investigator Projects) must be submitted online to the FWF at https://elane.fwf.ac.at/. This is required already at the pre-proposal stage via the programme category "PIK – International Projects preproposal" no later than 14:00 CET the day following the EUP deadline for submission of pre-proposals (FWF Deadline: Wednesday 28th January 2026, 14:00 CET). For the full proposal stage applicants must choose the programme category "KIN– International – Multilateral Initiatives" and submit no later than 14:00 CET the day following the EUP deadline for submission of full proposals (FWF Deadline: Wednesday =17th June 2026, 14:00 CET). **Both steps are mandatory.**<br><br>All proposals must be submitted using the elane online portal. Project funding is administered through the research institution (PROFI mode); for this reason, the submission must be approved in the application portal both by the applicant and by the respective research institution before the respective deadlines (see above).<br><br>Please note that the number of ongoing/approved projects in which one researcher can serve as principal investigator is limited to three in the Stand-Alone Projects Programme, International Programmes, Clinical Research and Arts-Based Research Programmes. Information on the limit of the number of ongoing/approved projects and the limit of applications that can be submitted can be found here.<br><br>See for further information. |
| **Submission of other information at the national level** | See above. |
| **Submission of financial and scientific reports at the national level** | Annual Status Report:<br>The principal investigators of ongoing projects are required to report published research results on an annual basis. For further information, please refer to the information on Annual Status Reports.<br><br>Final Project Report:<br>After completion of the project, in addition to the research results, information on statistical and program-specific issues as well as any changes to the project as originally planned are also documented in Researchfish. Principal investigators are notified by email and provided with initial information about Researchfish and their reporting obligations. The FWF requests annual updates to include subsequently published results for up to 5 years after the end of the project. |
| **Starting date of the clinical study** | The FWF expects the start of the project within six months from the date of approval notification. Any further delays of up to 12 months |

| | |
|---|---|
| | after notification must be justified, otherwise the funding approval may be rescinded. |
| **Further guidance** | The principal investigator's publication record over the last five years must be internationally visible and commensurate with the expected career path in their field. The following criteria apply for the assessment of an applicant's publication record and initiation of the review process:<br><br>Quality assurance: Most relevant in assessing the applicant's publication record are those publications that have been subject to a quality assurance procedure in line with international standards (peer review or an equivalent procedure; in the natural and life sciences, peer review is expected). Journals must usually be listed in Web of Science, Scopus, or the Directory of Open Access Journals (DOAJ). For journals not listed in those databases, or for monographs, edited volumes, contributions to edited volumes, or other publication types, the applicant must provide a link to the publisher's website which contains a description of the applicable quality assurance procedure. Should no such description be available on the website, it is the applicant's responsibility to provide evidence that the publication has been subject to a quality assurance procedure in accordance with the standards of the field.<br><br>International visibility: The majority of the applicant's publications must have a wider than national reach. In the natural sciences, life sciences, and social sciences, most of the publications listed must be in English.<br><br>Number/scope and quality of the publications must commensurate with the researcher's expectable career path and the respective discipline. At least two publications must be quality-assured and internationally visible publications with a substantial and independent contribution by the applicant. At least one publication with first, last, or corresponding authorship is required, with the exception of publications in journals (or disciplines) that rank authors alphabetically. If any such publications are included in the required document PI_publication.pdf, the applicant's contribution must be specified.<br><br>If there is any uncertainty about general application requirements or about accounting for career interruptions, the FWF recommends contacting the FWF Office or the FWF Equal Opportunities and Diversity in Research Funding unit well before submitting the application to confirm that all requirements are met and that any career interruptions can be accounted for. In cases of doubt, the appropriate decision-making bodies of the FWF shall decide on applicants' eligibility. |

# ANNEX I

| | |
|---|---|
| **Country** | Belgium |
| **Funding organisation** | Belgian Health Care Knowledge Centre (KCE) |
| **National Programme** | KCE Trials |
| **National contact person** | Renate Zeevaert / France Vrijens<br>trials@kce.fgov.be<br><br>Prior the submitting of the proposal, it is highly recommended to get in touch with the national contact persons to clarify the specific requirements of this call. |
| **Funding commitment** | Up to a maximum of 2.000.000 €. |
| **Anticipated number of fundable proposals** | KCE anticipates funding several projects (2-4), subject to the volume of applications received and the specific role of the Belgian partner within each consortium (either as sponsor or as Belgian Coordinating Centre - BCC). |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | KCE will provide funding up to:<br>- a maximum of 1.000.000 € for projects where the Belgian partner acts as sponsor of the trial. This amount includes both sponsor-related costs and sites costs within Belgium.<br>- a maximum of 500.000 € per project where the Belgian partner acts as Belgian Coordinating Center of the trial. This amount includes costs for sponsor-delegated tasks to BCC and site costs within Belgium. |
| **Funding mechanism** | **Single lead applicant:** Only one Belgian partner may act as the lead applicant per proposal. This lead applicant will be the sole recipient of KCE funding and is responsible for the appropriate distribution of funds to Belgian recruiting sites and associated partners. The lead applicant must establish a consortium/collaboration agreement or site contracts with all involved partners.<br><br>**No double funding:** Eligible costs covered by KCE funding under the conditions of Appendix I may only be funded once. Double funding from other sources (including via the Belgian compulsory health insurance) for the same cost items is strictly prohibited.<br><br>**Additional funding and in-kind support**: Supplementary funding and/or in-kind contributions for items not otherwise covered are permitted only if they align with KCE's national terms and conditions (see KCE Trials ERA4Health webpage Calls). In particular, commercial exploitation of the clinical trial data and results is prohibited unless prior written approval is granted by KCE and all data and results generated in Belgium must be shared with KCE upon request. |

| | |
|---|---|
| **Eligibility of partners** | To be considered eligible, the Belgian partner, whether acting as Sponsor or Belgian Coordinating Center (BCC), must be a Belgian non-profit institution or research organisation with proven expertise in conducting non-commercial multicentre clinical trials.<br><br>Specifically:<br>- If the partner acts as sponsor, it must have successfully completed a KCE Trials sponsor capacity assessment.<br>- If the partner acts as BCC, it must, depending on the tasks it is committed to conduct, demonstrate sufficient operational support from a clinical trial centre (CTC) or equivalent.<br><br>Regardless of the role (Sponsor or BCC), the Belgian partner must:<br>- Agree in writing to the KCE Trials terms and conditions (as implemented in the KCE Trials contract templates) and submit the following documentation to KCE Trials by the ERA4Health call deadline.<br>➢ If the Belgian partner is the Sponsor: a signed sponsor letter of commitment.<br>➢ If the Belgian partner is the BCC: two signed letters of commitment (one by the BCC, one by the international sponsor), confirming acceptance of the KCE Trials terms and conditions.<br>➢ If there is an entity offering additional funding and/or in-kind support to the trial in Belgium, a signed letter of commitment from such party at the time of the application.<br>- Declare no conflicts of interest, in accordance with the *General principles for the declaration of interests by applicants and the management of (potential) conflicts of interest in KCE-funded clinical trials*.<br><br>All those documents have to be submitted using the KCE Trials templates, which can be found on the KCE Trials ERA4Health dedicated webpage (Calls). |

| | |
|---|---|
| **Specific requirements for clinical studies** | The Belgian partner must secure a formal commitment to participate in the trial from at least one recruiting centre in each Belgian region (Flanders, Wallonia, and Brussels). Exceptions to this requirement will be allowed only if centralized care hampers the participation of one recruiting site in each region. This must be clearly justified within the proposal.<br><br>All identified recruiting sites must be explicitly listed in the application. |
| **Eligibility of costs, types and their caps** | **Eligible Costs**: All project-specific costs are eligible for funding, provided they are justified and related tasks are well described in the budget template.<br><br>These costs include:<br>- Personnel and non-personnel costs essential to the execution of the project<br>- Costs not covered by the infrastructure of the Belgian partner institution<br>Note: Sponsors eligible costs might be covered but KCE will not cover costs already included in the tasks allocated to ECRIN or its subcontractor, (cross-cutting tasks).<br><br>**Overhead policy**: KCE permits a maximum overhead rate of 17% on costs not delivered by third-party providers (e.g. subcontractors, drug or equipment purchase). Overhead on site costs must be fully transferred to the sites (and detailed in the "Overhead" section of the requested budget template).<br><br>**Site fees**<br>Sites should be compensated for their study related work. Those costs should be mentioned in the "subcontracting" section of the requested ERA4Health budget template. VAT on site costs should be taken into account, if applicable. |
| **Duration of the clinical study** | Funding requested is limited to a maximum of 48 months in accordance with ERA4Health call conditions. |
| **Specific rules for potential extensions** | Under exceptional circumstances, a cost-neutral extension is possible and must be applied for and accepted by KCE and all other project funders before the official end date of the project in accordance with ERA4Health call conditions. |

| | |
|---|---|
| **Submission of the proposal at the national level** | To be considered a valid application, in addition to ERA4Health call requirements, applicants must submit all required documents via email to KCE Trials (at trials*at*Kce.fgov.be) no later than the ERA4Health deadline.<br><br>The required documents include:<br>➢ If the Belgian partner is the Sponsor: a signed sponsor letter of commitment.<br>➢ If the Belgian partner is the BCC: two signed letters of commitment (one by the BCC, one by the international sponsor), confirming acceptance of the KCE Trials terms and conditions.<br>➢ If there is an entity offering additional funding and/or in-kind support to the trial in Belgium, a signed letter of commitment from such party at the time of the application.<br><br>All documents have to be submitted using the KCE Trials templates, which can be found on the KCE Trials ERA4Health dedicated webpage (Calls). |
| **Submission of other information at the national level** | NA |
| **Submission of financial and scientific reports at the national level** | If the study is selected for funding, KCE will require the provision of additional financial and scientific information beyond what is outlined in the ERA4Health call text. These requirements will be detailed in the contract between KCE and the Belgian partner, as specified in the official KCE contract templates (available on the KCE website).<br><br>**Progress Reviews**<br>The Belgian Sponsor or Belgian Coordinating Centre (BCC), and KCE will conduct regular update meetings to review and discuss the conduct and progress of the Study (in Belgium). In addition, recruitment progress per Belgian site will be entered monthly into the web-based KCE Trials dedicated platform.<br><br>**Clinical Study Report submission**<br>If the Belgian partner is the Sponsor, they are responsible for preparing a Clinical Study Report (CSR) in accordance with the CONSORT statement guidelines.<br><br>If the Belgian partner is a Belgian Coordinating Centre (BCC) and a CS is available, the BCC must either:<br>- Submit the CSR directly to KCE, or<br>- Ensure that the Sponsor submits it to KCE. |

| | |
|---|---|
| **Starting date of the clinical study** | KCE expects that the clinical trial will be submitted to the competent national Ethics Committee and/or national competent authority within six months following the official ERA4Health approval notification.<br><br>If submission is delayed beyond this six-month window, an extension of up to 12 months may be accepted, but only if a clear and justified explanation is provided. Failure to comply with this timeline may result in the withdrawal of funding approval. |
| **Requirements on data and repositories** | As a public funder KCE has, after trial completion and upon request, access to all the (pseudonymised) data generated by the trial in Belgium and an unlimited, irrevocable and transferable right to use the data, only for research and health policy related purposes (*see more details in KCE contract templates*).<br><br>Researchers funded by KCE must follow the KCE *Trials policy on Research transparency*. |
| **Use of Research infrastructures and platforms** | NA |
| **Acknowledgements** | Any publication, presentation, database, product, or event—whether protected by intellectual property rights (IPR) or not—that results from the granted project must include the following acknowledgment:<br><br>"*Funded by the Belgian Health Care Knowledge Centre (KCE) under the KCE Trials Programme (ref KCE id) and under the umbrella of the Partnership Fostering a European Research Area for Health (ERA4Health) (GA N° 101095426 of the EU Horizon Europe Research and Innovation Programme).*" |

ANNEX I

| | |
|---|---|
| **Country** | Czech Republic |
| **Funding organisation** | Ministry of Health of the Czech Republic |
| **National contact person** | **Monika Kocmanova**<br>Coordinator of the European Partnerships for Health (AZVCR)<br>Phone: +420 778 973 186<br>Email: monika.kocmanova@azvcr.cz<br><br>**Rachel Hengalova**<br>European Partnerships for Health Officer (AZVCR)<br>Phone: + 420 778 880 697<br>Email: rachel.hengalova@azvcr.cz<br><br>**Olga Laaksonen**<br>Head of the Science, Research, and Subsidies for Education Unit (MZCR)<br>Phone : +420 224 972 755<br>Email : olga.laaksonen@mzcr.gov.cz |
| **Funding commitment** | 500 000 EUR |
| **Anticipated number of fundable proposals** | 2 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | **The maximum funding per grant awarded to a clinical study partner is 250,000 EUR.**<br><br>The requested budget from pre-proposal stage to full proposal stage can be slightly modified. This change must be approved by MZCR/AZVCR and also communicated to the JCS. Final budget must not exceed the maximum allocated amount per project. |
| **Funding mechanism** | Only one organisation will be granted, and this organisation will establish a collaboration with other co-applicant(s) via subcontracting or a collaboration agreement. |
| **Eligibility of partners** | Research Organisations, Enterprises. All eligibility rules and criteria can be found on the Czech Health Research website (Výzva 2026 – AZV ČR). It is **recommended** to contact the responsible person at the Czech Health Research Council (prior to submission regarding the eligibility criteria).<br><br>Conditions for PO funding – Patient organisations can receive direct funding if they take an active role in the project's research activities. This means they must contribute to specific research objectives (for example, by being involved in one or more work packages) and these types of research activities must be clearly described in their **statutes**. |
| **Eligibility of costs, types and their caps** | Eligibility of all costs, types and their caps can be found on the Czech Health Research website (Výzva 2026 – AZV ČR). It is **recommended** to contact the responsible person at the Czech Health Research Council prior to submission regarding the eligibility criteria. |

| | |
|---|---|
| **Duration of the clinical study** | 48 months<br><br>Duration of the clinical study is 48 months. However, all projects funded under the Programme for the Support of Applied Health Research for the period 2024-2030 must be completed no later than **31 December 2030**, as the Programme itself concludes at the end of that year. |
| **Specific rules for potential extensions** | Under this call, project extensions are not possible, as all projects funded through the Programme for the Support of Applied Health Research for the period 2024-2030 must be completed **by the end of 2030**, when the Programme itself comes to an end. **Applicants are therefore strongly advised to start their projects on 1 January 2027 at the latest.** |
| **Submission of the proposal at the national level** | NO |
| **Submission of other information at the national level** | Prior to submission of the pre-proposal to EP ERA4Health, Czech researchers need to submit to the Czech Health Research Council the following documents:<br><br>1. **Sworn Statement of a Legal Entity /Natural Person (mandatory)**<br>2. **Sworn Statement of a Research Organisation (if relevant)**<br>3. **Sworn Statement of a consortium composition (only if SMEs or industry are involved in the project proposal from the Czech side)**<br>4. **Application form**<br><br>Czech partners are required to complete a **national Application Form**, providing basic information about the applicant and any co-applicant(s), if applicable, including their respective budgets. It is necessary to list all national institutions involved in the project due to funding requirements.<br><br>All these documents are available on the website at the Czech Health Research Council (Výzva 2026 – AZV ČR).<br><br>Prior to submission of the full proposal to EP ERA4Health, Czech researchers need to submit to the Czech Health Research Council the following documents:<br><br>1. **Documents** related to **professional competence**, depending on the nature of the project, must be provided in the form of a **Sworn Statement**, which is available on the website of the Czech Health Research Council AZV ČR – Výzva 2026 – AZV ČR.<br>2. **Updated Application Form**<br><br>Czech partners are required to complete the **updated national Application Form**, providing basic information about the applicant and any co-applicant(s), if applicable, including their respective budgets. It is necessary to list all national institutions involved in the project due to funding requirements. |

| | |
|---|---|
| | According to Czech regulations, the main Czech applicant will sign a grant agreement with the national funding authority (MZCR) and, if there are any other Czech co-applicant(s), will subsequently enter into a cooperation agreement with them.<br><br>At the international level (pre- or full proposal), it is preferable to list only one Czech partner – the main applicant. If needed, it is possible to list more than one partner (in accordance with the call rules); however, at the national level, there will be one main Czech applicant while the remaining national institutions will act as co-applicants. Together, they must share the allocated project budget among themselves. The total project budget must not exceed EUR 250,000.<br><br>In case the projects of Czech participants are recommended for funding based on the results of the international evaluation and after the approval of the representatives of the funding authorities of the countries participating in IICS, the Ministry of Health of the Czech Republic / the Czech Health Research Council may ask the successful Czech participants to submit additional documents in order to issue a decision on the provision of purpose-special support according to the rules established by the Ministry of Health of the Czech Republic/ the Czech Health Research Council. |
| **Submission of financial and scientific reports at the national level** | Submission of scientific and financial reports will be required according to the national rules. All necessary information is part of the document called "Methodology for European Partnerships in Health," available on the Czech Health Research Council website - Výzva 2026 – AZV ČR. |
| **Staring date of the clinical study** | In line with the start date of the project as stated in the "Contract" or "Decision" on the provision of support or the issuance of a decision. |
| **Further guidance** | Výzva 2026 – AZV ČR |

# ANNEX I

| | |
|---|---|
| **Country** | FRANCE |
| **Funding organisation** | French ministry of Health |
| **National contact person** | melanie.fisher@sante.gouv.fr<br>cecile.fragny@sante.gouv.fr<br>era4health@sante.gouv.fr |
| **Funding commitment** | 2.000.000 M€ |
| **Anticipated number of fundable proposals** | 3 to 5 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | Funding Scenarios<br>- Case 1: A maximum of €500,000 per project may be granted.<br>- Case 2: A maximum of €300,000 may be granted if the clinical study is already funded by the French Ministry of Health through a national call for proposals (notably PHRC-N). In this case, eligible costs are strictly limited to cross-cutting activities at the European level, provided they are not already covered by ECRIN. These activities may include: Data management, Comparative analyses between countries, Dissemination of results.<br>Important Note:<br>These two funding scenarios are mutually exclusive. The French Ministry of Health does not allow double funding for the same activities. |
| **Funding mechanism** | Only one organisation will be granted and this organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement |
| **Eligibility of partners** | Eligible institutions: French ministry of Health (Fr MoH) funds French healthcare institutions defined by public health regulation articles L.611-1 and further, L.6141-1 and further, L6161-1 and further (établissements de santé), L6133-1 to 8 (groupements de coopération sanitaire), L6323-3 (maisons de santé) and L6323-1 (centres de santé) of the Code de la Santé Publique.<br>A partner must be composed of a physical leader and of a health care institution, which manages the financing.<br>The physical leader must be contractually linked to a healthcare institution and get its approval to be part of the project. For example, leaders can be private health professionals if they have a binding agreement with a French healthcare institution.<br>Minimum funding per awarded to a partner: 10 000 €<br>Fr MoH will avoid double funding and will not finance projects or parts of projects that have been funded through other calls. |
| **Eligibility of costs, types and their caps** | Funds are reserved for the exclusive use of French healthcare institutions involved in the project. Transfer for part of these funds to |

| | |
|---|---|
| | other French structures, organisations or physical or legal person may be allowed provided they are not eligible for funding by another financing body of the partnership. The healthcare institution would also have to demonstrate that they do not have the necessary skills. If so, public tenders rules including call of bides applies.<br><br>Investment expenses giving rise to depreciation are not eligible.<br><br>Management costs up to 10% of personal expenses are eligible. |
| **Duration of the clinical study** | Max 4 years |
| **Specific rules for potential extensions** | A one-year extension may be requested. No additional funding will be granted. |
| **Submission of the proposal at the national level** | **Proposal Submission**:<br><br>A pre-proposal and a full proposal must be submitted electronically on the partnership website dedicated to the call for projects, in accordance with the terms and procedures defined in the call text. No proposal will be accepted through any other channel.<br><br>**Additional administrative and budgetary documents** must be submitted to the FR MOH (DGOS) in parallel with the pre-proposal submission, via the Démarches Simplifiées platform:<br><br>- A signed submission certificate (to be valid, the document must bear at least three of the required signatures)<br><br>- A budget grid<br><br>These documents will be available for download on the website of the French Ministry of Health:<br>https://sante.gouv.fr/systeme-de-sante/innovation-et-recherche/l-innovation-et-la-recherche-clinique/article/partenariat-era4health<br><br>The link to the Démarches Simplifiées platform for submitting the documents will be available as soon as the application submission phase opens. |
| **Submission of other information at the national level** | A report on expenses is submitted to FR MOH each year by the funded institutions. The expenses reported must be in direct relation with the project. They must be necessary for project implementation and conform to the selected project. |
| **Submission of financial and scientific reports at the national level** | |
| **Starting date of the clinical study** | First semester of 2027. |
| **Further guidance** | Funds delegation will be performed through budgetary circulars of the Fr MoH. Funds will be allowed regarding project progression. |

# ANNEX I

| | |
|---|---|
| **Country** | Germany |
| **Funding organisation** | **Federal Ministry of Research, Technology and Space (BMFTR) represented by the Programme Management Agency in the German Aerospace Centre (DLR Projektträger)** |
| **National contact person** | Name : Dr. Dorothea Bayer-Kusch<br>Dr. Svenja Krebs<br>Dr. Eva Müller-Fries<br><br>Phone: +49 228 3821 2567<br><br>E-mail: era4health@dlr.de<br><br>Address: DLR Projektträger, on behalf of the BMFTR<br>Heinrich-Konen-Str. 1<br>53227 Bonn<br>Germany<br><br>Prior the submitting of the proposal, it is **highly recommended** to get in touch with the national contact persons to clarify the specific requirements of this call. |
| **Funding commitment** | Up to 3.0 Mio € |
| **Anticipated number of fundable proposals** | 6 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | Up to 500.000 € for regular German partners; up to 750.000 € for German partners in the role of the sponsor (overhead costs included). Only one German partner per consortium is allowed. The applicants (PI) are not allowed to participate in more than one research proposal. The number of recruitment sites in Germany depends on the intended sample size and the structure of the consortium and is not restricted. |
| **Funding mechanism** | Only one German partner per proposal will be granted and this organisation will establish a collaboration with other German recruitment sites via case payments based on collaboration agreements. |
| **Eligibility of partners** | Eligible applicants are researchers or research groups from German universities, German university hospitals and German non-university research institutes. Enterprises in the commercial sector are only eligible to apply in exceptional cases if they are also a healthcare organisation. The projects must be clearly defined in terms of subject, time frame, and budget; they must not have been started [yet]. For specific conditions see also link to German version of the call below. |
| **Eligibility of costs, types and their caps** | The following costs are eligible for funding (details see German version of the call):<br>- Personnel (e.g. project management, clinical project management, coordination and quality assurance); |

| | |
|---|---|
| | - case payments;<br>- patient and target group involvement;<br>- materials;<br>- Fees and Insurance;<br>- Travel & networking costs;<br>- Communication, Dissemination and Publication costs;<br>- Overhead costs ("Projektpauschale").<br><br>Overheads are eligible according to standard BMFTR regulations.<br>Funding rates for universities, university hospitals and non-university research institutes can be up to 100% of their costs. |
| **Duration of the clinical study** | Up to 48 months |
| **Specific rules for potential extensions** | Cost neutral extensions can only be granted in exceptional cases. |
| **Submission of the proposal at the national level** | On request in case of a positive funding recommendation. |
| **Submission of other information at the national level** | On request in case of a positive funding recommendation. |
| **Submission of financial and scientific reports at the national level** | On request in case of a positive funding recommendation. |
| **Staring date of the clinical study** | March 2027 (the earliest) |
| **Further guidance** | https://www.gesundheitsforschung-bmbf.de/de/18975.php |

# ANNEX I

| | |
|---|---|
| **Country** | Italy |
| **Funding organisation** | IT-MoH |
| **National contact person** | Grazia Papagni - int-dgric@sanita.it |
| **Funding commitment** | € 2.000.000,00 |
| **Anticipated number of fundable proposals** | 3 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | Max 650.000 per project. |
| **Funding mechanism** | Simultaneous PI participation in different 2026 JTCs funded by the Ministry of Health is not allowed. No more than two Italian PIs (Principal Investigators) are eligible to apply for the same project. Italian PAOs can be funded as a sub-contractor of an IRCCS if they fulfil the eligibility criteria of the EC. The maximum amount eligible for a subcontract is < **10% of the total budget** (from the IRCCS Budget). Italian PAOs can still participate in Consortia as "Collaborators" with their own funds. |
| **Eligibility of partners** | Only IRCCS (Istituti di Ricovero e Cura a Carattere Scientifico) researchers are eligible to apply. Universities, other research Institutes, companies are excluded from funding.<br>**In order for a Private IRCCS to act as Coordinators of clinical studies under this JTC2026, the Ministry of Health will require that these private entities sign a declaration confirming that the study does not have a commercial purpose along with the pre-elegibility form.** |
| **Eligibility of costs, types and their caps** | **Direct Costs:**<br>• Personnel (only temporary contracts or permanent contracts for the amount of hours dedicated to the project, **≤60%**);<br>• Consumables/Supplies;<br>• Animals/Model costs;<br>• Equipment (only on leasing or rent);<br>• Travel ( **≤ 30%**);<br>• Dissemination activities (**≤ 1%**);<br>• Publication costs: < 2%; open access < 5%;<br>• Patients recruitment costs;<br>• IT Services and Data Bases;<br>• Coordination costs<br>**Indirect Costs:**<br>• Overhead (**≤ 10%**, included in the total); |

| | |
|---|---|
| | Other indirect costs are not eligible.<br><br>Transfer of eligible funds abroad is not allowed.<br><br>**Subcontracts are allowed only upon approval, by presenting via Workflow – code ER, a request together with the National preelegibility form, the latest 20 days before the deadline of the pre-proposal submission.** |
| **Duration of the clinical study** | Up to 48 months |
| **Specific rules for potential extensions** | At max one-year extension |
| **Submission of the proposal at the national level** | In order to expedite the eligibility check process, the Ministry of Health will grant an eligibility clearance to the applicant prior to the submission of the proposals. To this end, it is mandatory that the applicants fill out and return to the IT-MoH a pre-submission eligibility check form through their IRCCS, using WFR System-> ER communication code, before submitting their proposal to the Joint Call Secretariat.<br>It is strongly recommended that the form, completed and duly signed, is returned at least 10 working days before the proposal submission deadline. Applicants will be sent written notification of their eligibility status. Changes in acronyms and budgets provided in the pre-submission eligibility check are not allowed. The pre-eligibility form can be downloaded here:<br><br>www.salute.gov.it/imgs/C_17_pagineAree_4441_0_file.pdf |
| **Submission of other information at the national level** | |
| **Submission of financial and scientific reports at the national level** | Submission of annual scientific and financial reports at the national level will be required according to the rules of the Ministry of Health (Ricerca Finalizzata). |
| **Staring date of the clinical study** | |
| **Further guidance** | Further information on the rules of the Ministry of Health can be requested to the national contact persons. |

ANNEX I

| | |
|---|---|
| **Country** | Italy |
| **Funding organisation** | **Fondazione Regionale per la Ricerca Biomedica (Lombardy Region)** |
| **Regional contact person** | Giulia Maria Rossignolo giuliamaria.rossignolo@frrb.it (Phone: +39 02 6765 0159)<br><br>bandi@frrb.it |
| **Funding commitment** | 1,500,000.00€ |
| **Anticipated number of fundable proposals** | 2 proposals |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | 750,000.00€ |
| **Funding mechanism** | **Maximum ONE PARTNER from Lombardy PER PROJECT**<br><br>**Only one organisation will be granted. This organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement.**<br><br>Italian PAOs are not eligible for funding. They can still participate in Consortia as "Collaborators" with their own funds. |
| **Eligibility of partners** | Eligible institutions<br><br>1. Public or Private Italian IRCCS (Scientific Institutes for Health Research, Hospitalization and Health Care) 2. Public Health Care Providers (ASST) 3. Agenzie di Tutela della Salute (ATS) 4. Azienda Regionale Emergenza Urgenza (AREU) 5. Universities - only in partnership with one of the organizations above (1,2,3,4) located in Lombardy and requesting funding to FRRB 6. Research Institutes - only in in partnership with one of the organizations above (1,2,3,4) located in Lombardy and requesting funding to FRRB. Please note: All applicants must be located in Lombardy and their activities should take place in Lombardy. Enterprises and for-profit Organisations are NOT eligible |

| | |
|---|---|
| **Eligibility of costs, types and their caps** | Direct costs:<br><br>• **Personnel** (for public IRCCS and ASST, ATS, AREU, Universities and Research Centres).<br><br>The specific details will be set out in the reporting manual, to be issued by FRRB in due time.<br><br>• **Consumables:** reagents/animal purchase, etc..<br><br>• **Equipment** (eligible amortization rate).<br><br>• **Travel**: max 10% of the total direct costs (overheads and subcontracting costs excluded)<br><br>• **Publications** (only Open Access): max 5% of the total direct costs (overheads and subcontracting costs excluded). • **Other direct costs:** please insert under this category any other costs, including those related to patient involvement (insurance, etc.).<br><br>•**Subcontracting:** max 30% of the total direct costs (overheads costs excluded).<br><br>• **Overheads:** 20% flat rate calculated on direct costs (subcontracting costs excluded from this calculation).<br><br>FRRB will require the submission of a financial audit certificate together with the final financial report. This cost, to be included under the "Subcontracting" category will be eligible up to a maximum of € 8.000. Only costs generated over the lifetime of the project will be considered eligible. |
| **Duration of the clinical study** | 48 months |
| **Specific rules for potential extensions** | Maximum 12 months |
| **Submission of the proposal at the national level** | According to internal procedures, FRRB will grant an eligibility clearance to the potential applicants prior to the submission of the pre-proposals. This eligibility check will be based on the verification of a dedicated form ("Eligibility check form"), available on FRRB platform, to be completed by the Principal Investigator at least 10 working days before the pre-<br><br>proposal submission deadline. FRRB will provide feedback on the "Eligibility check form" ONLY in case of major non-eligibility issues.<br><br>**A Principal Investigator (PI) cannot simultaneously hold more than one FRRB active grant.** |

| | |
|---|---|
| **Submission of other information at the regional level** | For clinical trials or interventional studies, PIs are required to submit an approvals package to confirm all ethical and regulatory approvals, and contractual agreements are in place before patient recruitment commences. |
| **Submission of financial and scientific reports at the regional level** | Submission of annual scientific and financial reports at the regional level will be required according to the rules of FRRB. |
| **Starting date of the clinical study** | N/A |
| **Further guidance** | N/A |

| | |
|---|---|
| **Country** | **Latvia** |
| **Funding organisation** | **Latvian Council of Science** |
| **National contact person** | Maija Bundule<br>E-mail: Maija.Bundule@lzp.gov.lv<br>Tel: +371- 26514481<br><br>Uldis Berkis<br>E-mail: Uldis.Berkis@lzp.gov.lv<br>Tel.: +371-29472349 |
| **Funding commitment** | 0,8M EUR |
| **Anticipated number of fundable proposals** | 2 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | Maximum funding for a funded partner is 100.000 EUR per year<br>Funding rates under Regulation EC 651/2014 shall be respected in case of state aid<br>Maximum 2 Latvian partners per proposal allowed, they must be fully independent on legal, financial and personnel basis<br>Maximum duration of a funded project – 4 years |
| **Funding mechanism** | The funded Latvian partner must be in possession of necessary resources, and can use subcontracting up to the established maximum rate, following the public procurement laws. Subcontracting shall not exceed 25% of the total direct costs. There are no exemptions to this rule. Subcontracting to members of the consortium is not funded by LCS. All study sites must undergo public procurement procedure.<br><br>Maximum 2 funded Latvian partners per proposal allowed, they must be fully independent on legal, financial and personnel basis.<br><br>Any kind of business enterprise can be supported only according to the regulations for state aid. LCS is not using de-minimis aid. |
| **Eligibility of partners** | Only the following **legal persons** are eligible:<br><br>1) Research institutions registered in the Latvian Registry of Scientific Institutions, e.g.<br>- Research Institutes<br>- Universities<br>And must have the status of Research and knowledge dissemination organization (Regulation EC 651/2014)<br><br>2) Business enterprises entered into the Latvian Commercial registry as companies, assumed they are eligible to do the specific research and have specific capacity and resources to do the research in Latvia and have their main activity in Latvia. Limitations of EU legislation apply (R651/2014) together with financial reporting requirements, in this case this is state aid. Two previous statements with sworn auditor's approval should be provided and they must reflect the correspondence to the regulation as well as prove the evidence of previous scientific activity and presence of capacity.<br>Enterprises not having closed two annual financial periods (years) are not eligible. |

| | |
|---|---|
| **Eligibility of costs, types and their caps** | • Personnel costs incl. taxes;<br>• Consumables;<br>• Subcontracts (up to 25% of direct costs), needs detailed justification, includes all external services, project core activities cannot be subcontracted;<br>• Equipment (only depreciation costs during project directly attributable to project tasks);<br>• Replaceable and fully consumable during project elements of equipment (e.g. electrodes);<br>• Travels (according to travel plan);<br>Indirect costs (up to 25% of direct costs excluding subcontracting).<br><br>Any type of clinical trials is experimental development according to the Art. 25 of the Regulation EC 651/2014. Therefore, maximum aid intensity according to the part 4. of the aforementioned article is 25%. This value of aid intensity can be increased by up to 25% if the conditions of part 6., (d) are fulfilled. According to part 6. (a) aid intensity can be increased further by 10 percentage points for medium-sized enterprises and by 20 percentage point for small enterprises. Total state aid intensity can not exceed 70% for small enterprises, 60% for medium-sized and 50% for large enterprises provided all requirements are fulfilled.<br><br>LCS funding is not allowed to create additional demand in the healthcare system, nor to cover standard healthcare costs, nor to reduce waiting lines. The funding for LCS is only for the research going outside of the normal healthcare services provided in the case of a specific ailment.<br><br>Direct costs can not be share of total costs, it always requires evidence of really occurring costs and expenses.<br><br>Funding by LCS is operated only via a Latvian banking account.<br><br>Business enterprises can claim only reimbursement of their incurred eligible costs, not an advance payment.<br><br>LCS is not funding postmarket activities. LCS is not funding any activity beyond experimental development. |
| **Duration of the clinical study** | Maximum 4 years |
| **Specific rules for potential extensions** | Extensions can be without funding only and not beyond of the planned final calendar year. |
| **Submission of the proposal at the national level** | Not at the application phase |
| **Submission of other information at the national level** | Applicants for State aid must send before the call deadline (both 1st and 2nd stages) to the e-mail address lzp@lzp.gov. lv, stating the acronym and the title of the project, applicant name and registration number, the following document: a certification that the applying entity does not correspond to the criteria laid down in laws and regulations to be subject |

| | |
|---|---|
| | to insolvency proceedings at the request of the creditor. It must be electronically signed by valid legal representative (s).<br><br>Upon request applicants for State aid must provide all requested documents to evaluate the financial situation and financial viability. Undertakings in difficulty are not eligible for funding. (Regulation 651/2014)<br><br>In case of State aid the undertakings are assessed for eligibility at each of the application stages and at the conclusion and during execution of the contract with LCS for project funding. If the eligibility criteria are not fulfilled, project funding can not be approved or continued. |
| **Submission of financial and scientific reports at the national level** | To receive funding by LCS, Consortium agreement duly signed should be presented. Enterprises shall provide audited statements of 2 previous closed financial periods on request.<br>Final audit according to the LCS regulations.<br><br>Annual or in some cases half-annual financial and scientific reporting is mandatory. |
| **Staring date of the clinical study** | Application for the state aid must be submitted **before** the start of the project which is stated in the consortium agreement |
| **Further guidance** | Support is provided according to Provisions Nr 259, 26.05.2015 of the Latvian Cabinet of Ministers (http://likumi.lv/ta/id/274671-atbalsta-pieskirsanas-kartiba-dalibaistarptautiskas-sadarbibas-programmas-petniecibas-un-tehnologiju-joma)<br>These provisions should be respected without exceptions. The maximum rates should respect the Provisions. The requirements in the provisions to specific applicant groups must be respected.<br>LCS cannot fund implementation support, nor training activities.<br>LCS is funding only research<br>The project must respect national regulations for clinical trials, including the biomedical ethics permission from an authorised ethical committee for clinical trials |

# ANNEX I

| | |
|---|---|
| **Country** | Lithuania |
| **Funding organisation** | Research Council of Lithuania |
| **National contact person** | Živilė Ruželė |
| **Funding commitment** | 1 Mln Eur |
| **Anticipated number of fundable proposals** | 2 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | Within a single project proposal, the maximum funding can be up to EUR 500 000 |
| **Funding mechanism** | Only one organisation will be granted, and this organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement (as associated project partner, see section "Eligibility of partners") |
| **Eligibility of partners** | Eligible for funding institutions are Lithuanian research and higher education institutions that are included in the Register of Education and Research institutions, public healthcare institutions, university hospitals. Eligible beneficiary institution (grant holder) manages the state budget funds allocated to the project following the rules stated in the legal acts, as well as representing the associated project partners (if applicable 'project partner' means public or private legal entity that, together with the eligible institution, created the conditions for project implementation).<br>Principal Investigator must be a PhD holder.<br>Principal investigators from Lithuania cannot be involved in more than 1 proposal submitted to this call.<br>The beneficiary institution employs the principal investigator to work on the project, and his workload must be at least 20 hours multiplied by the number of months to execute the project. Hourly rates approved by the Chairman of the Lithuanian Research Council must be applied for the personnel costs. All other general rules for competitive funding of Research Council of Lithuania apply:<br>https://www.e-tar.lt/portal/lt/legalAct/0a8bead0577611e9975f9c35aedfe438/asr |
| **Eligibility of costs, types and their caps** | All costs mentioned in the Call text as Investigational costs are eligible: site costs (personnel, clinical procedure, site services, patient/participant renumeration), country management sites (site selection and coordination at the country level), and clinical study management costs at national or regional level (e.g. monitoring and insurance).<br>Additional cross-cutting trial management costs can also be eligible if some of the sponsor's tasks are delegated to Lithuanian team.<br>Only costs generated during the lifetime of the project, related to the project, are eligible. Eligible cost types: personnel, consumables, subcontracting, equipment and instruments, other direct costs, costs for |

| | |
|---|---|
| | dissemination of results, data handling and analysis, overheads (up to 20 % from direct costs).<br>More details about eligibility of costs: https://www.e-tar.lt/portal/lt/legalAct/0a8bead0577611e9975f9c35aedfe438/asr |
| **Duration of the clinical study** | 48 Months |
| **Specific rules for potential extensions** | During the implementation of the project, the reasoned amendments of the agreement may be initiated, including extensions. Amendments to the agreement shall be made in accordance with the procedures and within the time limits specified in the agreement. |
| **Submission of the proposal at the national level** | The submission of the proposal at the national level is not required. |
| **Submission of other information at the national level** | Following funding decision, grant signing institution and the PI must complete and submit the national document (the template can be found following this link) containing this information: more detailed planed budget, foreseen dissemination and communication activities and expected outputs from clinical study results with the granted research team contribution (scientific papers, patents, etc.) |
| **Submission of financial and scientific reports at the national level** | Midterm and final scientific reports nationally are required as well as the yearly financial reports. |
| **Starting date of the clinical study** | It must be in 2027, preferably no later than the common start date of the study agreed upon by the consortium partners. |
| **Further guidance** | For any information, please refer to contact person. All information about the call is published on LMT website under Calls webpage.<br><br>General information for applicants submitting proposals to European Partnerships calls can be found here |

# ANNEX I

| | |
|---|---|
| **Country** | Norway |
| **Funding organisation** | The Research Council of Norway (RCN) and South-Eastern Norway Regional Health Authority (HSØ) |
| **National contact person** | Henrietta Blankson<br>hbl@rcn.no<br>+ 47 922 33 762<br><br>Torunn Berge<br>Torunn.Berge@helse-sorost.no<br>+47 414 17 665 |
| **Funding commitment** | Total national funding is 1 200 000 EUR of which 900 000 EUR is provided by RCN and 300 000 EUR is provided by HSØ.<br><br>Projects will be co-funded by the two funding organisations with 75 % from RCN and 25 % from HSØ. HSØ is providing these funds on behalf of the National programme for clinical therapy research (KLINBEFORSK) following a decision to participate in the co-fund from the KLINBEFORSK board.<br><br>Depending on the quality and number of eligible projects, available funding may be increased by up to 25 % to fund additional projects on the ranking list. |
| **Anticipated number of fundable proposals** | 2-3 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | For a single project, the maximum grant awarded can be up to 450 000 EUR. If the participant has a coordinator role, the maximum grant can be raised up to 500 000 EUR. |
| **Funding mechanism** | Funding will be awarded to one institution only, which will act as coordinating institution responsible for establishing subcontracting or collaboration agreements with other recruitment sites. |
| **Eligibility of partners** | Approved Norwegian research organizations, hospitals or a private, non-profit hospitals eligible for the regional health authorities' research funds. |
| **Eligibility of costs, types and their caps** | Payroll expenses, consumables and operating costs, networking/study meetings and expenses relating to user involvement and dissemination.<br><br>PhD fellowships are not eligible within the national funding. For postdoctoral fellowships, duration of the support is limited to a minimum of three years and a maximum of four years. Any overhead costs may be included in the rates for personnel.<br><br>For funded projects, the contractual budget will be in NOK using the exchange rate (European Central Bank) from the pre-proposal deadline. |

| | |
|---|---|
| **Duration of the clinical study** | Max 48 months |
| **Specific rules for potential extensions** | A cost-neutral extension based on a written request with justification and an agreement within the whole project consortium may be considered. |
| **Submission of the proposal at the national level** | If the proposal is granted, information about national project registration will be given. |
| **Submission of other information at the national level** | On request in case of a positive funding recommendation. |
| **Submission of financial and scientific reports at the national level** | On request in case of a positive funding recommendation. |
| **Starting date of the clinical study** | From January 2027 |
| **Further guidance** | Patients should preferentially be recruited from all health regions across Norway.<br><br>Requirements and guidelines for registration and disclosure of medical and health-related studies involving human participants must be followed, please see Requirements and guidelines for registration and disclosure of medical and health-related studies involving human participants |

# ANNEX I

| | |
|---|---|
| **Country** | Poland |
| **Funding organisation** | National Centre for Research and Development (NCBR) |
| **National contact person** | Magdalena Krzystyniak<br>M: +48 571 226 675<br>era4health@ncbr.gov.pl |
| **Funding commitment** | 2 840 000 € |
| **Anticipated number of fundable proposals** | 1 – 6 (all within available funding commitment) |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | Maximum 500 000 € |
| **Funding mechanism** | **Only one organisation will be granted.** The funded organization will establish cooperation with other recruitment services through subcontracting or a cooperation agreement. |
| **Eligibility of partners** | Following entities are eligible to apply:<br><br>**Research organization** (research and knowledge-dissemination organisations)[1].<br><br>Entities must be established as a legal person[2] and must conduct its business, R&D or any other activity on the territory of the Republic of Poland, confirmed by an entry into the relevant register[3]. |
| **Eligibility of costs, types and their caps** | **<u>The eligible costs shall be the following</u>:**<br>**1. personnel costs**<br>**2. consumables**<br>**3. equipment**<br>**4. travel**<br>**5. other direct costs**<br>**6. subcontracting** – used exclusively for the research activity; this cost category shall not exceed 70% of all eligible costs of a project<br>**7. additional overheads** – incurred indirectly as a result of the research project; That costs should account 25% of all eligible direct costs and are counted as a multiplication by percentage given above (called x%) and the rest of direct costs for research organizations, excluding subcontracting (6); It means 7 = (1+2+3+4+5)*25% |

[1]Defined in Commission Regulation (EU) No 651/2014;
[2]Legal person (juridical person) - an entity that is capable of having and amend legal rights and obligations within a certain legal system, such as to enter into contracts, sue, and be sued, excluding natural persons;
[3]if applicable. Does not apply to legal persons that are not obliged to register in a relevant Polish official register according to Polish law.

<table>
<tr><td></td><td>
<table>
<tr><th></th><th>Research organization</th></tr>
<tr><td>Fundamental/Basic Research</td><td>Not eligible</td></tr>
<tr><td>Industrial/Applied Research</td><td>Not eligible</td></tr>
<tr><td>Experimental Development</td><td>Up to 100 %</td></tr>
</table>
<br>Please note that only Experimental Development is eligible for funding. Fundamental/Basic research or Industrial/Applied research are not eligible for funding.<br><br>As part of the project implementation, key tasks related to coordination, management and dissemination are eligible for funding.<br><br>For more details on eligible costs, applicants are advised to check cost eligibility guide (przewodnik kwalifikowalności kosztów) in the call announcement on NCBR webpage.
</td></tr>
<tr><td>Duration of the clinical study</td><td>up to 48 months</td></tr>
<tr><td>Specific rules for potential extensions</td><td>-</td></tr>
<tr><td>Submission of the proposal at the national level</td><td>Participants from Poland will be informed and invited to submit a national application once the international evaluation and the ranking list have been established.<br><br>Only projects recommended for funding will be asked to submit a national application form (NAF).</td></tr>
<tr><td>Submission of other information at the national level</td><td>All entities invited to submit Polish full proposal are obliged to use European Central Bank’s exchange rate in force on the day the call is opened.</td></tr>
<tr><td>Submission of financial and scientific reports at the national level</td><td>Annual scientific reports are obligatory.</td></tr>
<tr><td>Starting date of the clinical study</td><td>-</td></tr>
<tr><td>Further guidance</td><td>Sample documents are available at:<br>https://www.gov.pl/web/ncbr/wniosek-krajowy<br><br>We encourage you to learn about and use our "PartFinder" (Partner Search Tool), which allows you to match science and industry entities from around the World with each other. The search engine is available at:<br>https://partfinder.ncbr.gov.pl/</td></tr>
</table>

| | |
|---|---|
| | <u>Relevant documents</u><br>All proposals must be aligned with national regulations, inter alia:<br>• The Act of 20 July 2018 - Law on Higher Education and Science;<br>• The Act of 30 April 2010 on the National Centre for Research and Development;<br>• The Regulation of the Minister of Science and Higher Education of 17 September 2010 on the detailed mode of performance of tasks of the National Centre for Research and Development. |

# ANNEX I

| | |
|---|---|
| **Country** | ROMANIA |
| **Funding organisation** | Executive Agency for Higher Education, Research, Development and Innovation Funding |
| **National contact person** | Mihaela Manole<br>E-mail: mihaela.manole@uefiscdi.ro<br>Phone: +40 21 302 38 63<br><br>Nicoleta Dumitrache<br>E-mail: nicoleta.dumitrache@uefiscdi.ro<br>Phone: +40 21 302 38 86 |
| **Funding commitment** | 1.000.000 euro |
| **Anticipated number of fundable proposals** | 4-5 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | Funding rates vary in accordance with state aid legislation.<br>For more information :<br>https://uefiscdi.gov.ro/parteneriate-si-misiuni-europene<br>• 250.000 euro for all romanian partners in case a Romanian institution is the Coordinator;<br>• 200.000 for all romanian partners in case a Romanian institution is not the Coordinator. |
| **Funding mechanism** | For UEFISCDI, both options are theoretically possible:<br>- All participating organisations will be granted and should be part of the clinical study consortium. A maximum of 3 partners are authorised.<br>- Or only one organisation will be granted and this organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement<br>Please contact the UEFISCDI NCP for a detailed clarification which approach would be the most appropriate for your proposal. |
| **Eligibility of partners** | Eligible entities for funding are universities, public institutions, R&D national institutions, joint-stock companies, SME's and Large companies, NGOs (associations, foundations, etc.), others. |
| **Eligibility of costs, types and their caps** | a. Staff costs;<br>b. Logistics expenses<br>- Capital expenditure;<br>- Expenditure on stocks - supplies and inventory items;<br>- Expenditure on services performed by third parties cannot exceed 25 % of the funding from the public budget. The subcontracted parts should not be core/substantial parts of the project work;<br>c. Travel expenses;<br>d. Overhead (indirect costs) is calculated as a percentage of direct costs: staff costs, logistics costs (excluding capital costs and cost for subcontracting) and travel expenses. Indirect costs will not exceed 25 % of direct costs. |

| | |
|---|---|
| **Duration of the clinical study** | Up to 48 months, max. until December 2030 |
| **Specific rules for potential extensions** | Cost neutral runtime extensions can only be granted until December 2030 |
| **Submission of the proposal at the national level** | no |
| **Submission of other information at the national level** | no |
| **Submission of financial and scientific reports at the national level** | yes |
| **Staring date of the clinical study** | Not specified |
| **Further guidance** | https://uefiscdi.gov.ro/parteneriate-si-misiuni-europene |

# ANNEX I

| | |
|---|---|
| **Country** | Slovakia |
| **Funding organisation** | Centrum vedecko-technických informácií Slovenskej republiky / Slovak Centre of Scientific and Technical Information |
| **National contact person** | Erika Jankajová, Contact Point EU Missions / European Partnerships Coordinator<br>email: erika.jankajova@cvtisr.sk, tel.: +421 904 859 228<br><br>Magdaléna Švorcová, European Partnerships Coordinator<br>email: magdalena.svorcova@cvtisr.sk, tel.: +421 917 733 493 |
| **Funding commitment** | 600 000 EUR |
| **Anticipated number of fundable proposals** | 1 - 2 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | The maximum funding amount requested by all Slovak partners in each international project is 400 000 EUR.<br>The minimum funding amount is 100 000 EUR per project. |
| **Funding mechanism** | All participating organisations will be granted and should be part of the clinical study consortium. A maximum of 3 partners are allowed. |
| **Eligibility of partners** | CVTI SR can fund only Principal Investigator (PI), not a Coordinating Investigator in this call.<br><br>Legal entities established in the Slovak Republic, such as public or private research and academic institutions, higher education institutions, SMEs, public sector entities, and other relevant organizations actively involved in research, development, and innovation.<br><br>• Research institutions (e.g. the Slovak Academy of Sciences and its institutes)<br>• Academic sector (e.g. universities and higher education institutions)<br>• Public administration bodies and organizations established by them, including local and regional government authorities<br>• Non-governmental non-profit organizations<br>• Cluster organizations<br>• Private sector entities |
| **Eligibility of costs, types and their caps** | • Personnel costs (salaries of researchers, technicians and other support staff employed by the beneficiary, to the extent that they are directly involved in the project, salaries of project management personnel and other essential positions necessary for the implementation and coordination of the project;<br>• Costs of instruments and equipment;<br>• Costs for contract research, technical knowledge and patents purchased or licensed from external sources under market conditions, |

| | |
|---|---|
| | as well as costs for consultancy and equivalent services used exclusively for the project.<br><br>General eligibility rule:<br><br>All expenditures incurred by Slovak project participants must comply with:<br><br>• Programme Slovakia, specifically Priority 1P1 Science, Research and Innovation, Specific objective RSO1.1: Development and enhancement of research and innovation capacities and the uptake of advanced technologies, Measure 1.1.3: Support for international cooperation in the field of research, development and innovation<br>• The provisions of the State Aid Scheme to Support Partnerships in the Field of Research, Development and Innovation under the Programme Slovakia;<br>• Strategy for Financing the ERDF, ESF+, CF, FST, and ENRAF 2021–2027. |
| **Duration of the clinical study** | 48 months; Important notice: All Slovak entities must have their contractual financial matters settled with CVTI SR by the end of 2029. |
| **Specific rules for potential extensions** | N/A |
| **Submission of the proposal at the national level** | Submission of pre-proposal and full proposal to the ERA4Health JTC7 IICS Call Secretariat only. |
| **Submission of other information at the national level** | After having been informed about the international funding decision, CVTI SR will require also submission of separate application for national funding into the national submission platform. The final formal funding decision is made by CVTI SR and only after the project was recommended for funding by the Partnership. |
| **Submission of financial and scientific reports at the national level** | Yes, yearly. |
| **Staring date of the clinical study** | Based on the agreement between partners. |
| **Further guidance** | The proposed research activities must be carried out in Slovakia. All Slovak applicants are strongly advised to contact the CVTI SR's contact points before submitting their proposals.<br><br>The proposed project activities must be in line with the priorities defined in the Research and Innovation Strategy for Smart Specialisation of the Slovak Republic 2021-2027 (SK RIS3 2021+), which serves as the strategic framework for research, development and innovation investments in Slovakia.<br><br>All Slovak entities must have their contractual financial matters settled with CVTI SR by the end of 2029. |

| | |
|---|---|
| | Relevant national documents:<br><br>Programme Slovakia, Research and Innovation Strategy for Smart Specialisation of the Slovak Republic 2021-2027 (SK RIS3 2021+), State Aid Scheme to Support Partnerships in the Field of Research, Development and Innovation under the Programme Slovakia.<br><br>Useful links:<br>Programme Slovakia<br>SK RIS3 2021+<br>Strategy for Financing the ERDF, ESF+, CF, FST, and ENRAF 2021–2027 |

# ANNEX I

| | |
|---|---|
| **Country** | **Spain** |
| **Funding organisation** | **Andalusian Regional Ministry of Health and Consumer Affairs (CSCJA)** |
| **National contact person** | Alicia Milano Curto<br>Tel : +34 955 04 04 50<br>ep.fps@juntadeandalucia.es |
| **Funding commitment** | 250.000 € |
| **Anticipated number of fundable proposals** | 1-2 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | 125.000€, 250.000€ if coordinator (including 21% indirect costs) |
| **Funding mechanism** | A maximum of 1 coordinator or 2 partners per proposal are allowed. |
| **Eligibility of partners** | Eligible organisation must be Andalusian Non-profit entities registered as Agents of the Andalusian Knowledge System (Registro de Agentes Andaluces del Conocimiento) with research and innovation activity in Biomedicine and Health Sciences, ie: Research managing foundations of the Andalusian Public Health System.<br><br>Eligibility criteria established in Orden de 10 de agosto de 2023 de la Consejería de Sanidad, Presidencia y Emergencias de la Junta de Andalucía de la Junta de Andalucía.<br><br>• Principal investigators must be linked through a civil servant, statutory or labour relationship with the applicant or performing centre. For Health Research Institutes (Institutos de Investigación Sanitaria, IIS), the link may be with any of the public or private law entities that are part of the IIS provided that the entity meets all the specific requirements determined in each action, and, in any case, be personnel assigned to the IIS.<br><br>• More than one partner from Andalusia may participate in the same project<br><br>• A PI can only participate in one application per call.<br><br>• For receiving regional funding, the final funding decision issued by the corresponding program's decision-making body must be accredited. |

| | |
|---|---|
| | • The duration of the projects shall be determined by the corresponding JTC. In any case, this period shall be stated in the award resolution. |
| **Eligibility of costs, types and their caps** | a) **Goods and services**: consumables, bibliographic material, equipment rentals, software licenses and external services.<br><br>b) **Personnel costs**: specifically hired for the project, including salaries, employer Social Security contributions, legally established compensation and other duly justified expenses derived.<br><br>c) **Travel, accommodation and subsistence** according to the maximum amounts of compensation for service established in Decree 54/1989, of March 21, on compensation for service of the Junta de Andalucía, exclusively for people who are part of the research group or hired under the funded project. Exceptionally, any expense outside these amounts, or for people other than those listed before, must be authorised by the granting body.<br><br>d) **Registration fees for congresses or conferences** for the presentation and dissemination of the results. Publication costs<br><br>e) **Other expenses** duly justified and necessary for carrying out the project.<br><br>f) **Indirect costs** 21%<br><br>g) **Subcontracting costs**: cannot exceed 50% of the funding and need prior authorization from the granting body. Nor Scientific aspects nor the management of the project should be subcontracted.<br><br>The following are not considered eligible expenses<br>• Equipment or Equipment repair and maintenance<br>• Items or amounts that, after analysis, are not considered justified<br>• Amounts paid to persons participating in the project, except for expenses necessary for special attention to patients that involve compensation for their participation in the project not derived from an employment relationship.<br><br>The sum of the funding or income received for the same purpose may in no case exceed the cost of the funded activity. |
| **Duration of the clinical study** | The duration of the projects shall be determined by the corresponding Call. In any case, this period shall be stated in the award resolution |
| **Specific rules for potential extensions** | The maximum extension is limited to half of the initial duration of the project. |

| | |
|---|---|
| **Submission of the proposal at the national level** | • The deadline for the submission of regional applications will be established in the regional call and will be informed through the website of the Regional Ministry of Health and Consumer Affairs.<br>• Regional applications must be submitted to the General Secretariat of Public Health and R&D&I in Health exclusively by telematic means (please see section 10.c Orden de 10 de agosto de 2023) |
| **Submission of other information at the national level** | • Beneficiaries must submit financial and scientific reports to Consejería de Sanidad, Presidencia y Emergencias de la Junta de Andalucía (please see section 22.b) 3º and 25.f) 1º Orden de 10 de agosto de 2023)<br>• Additionally, for projects involving invasive procedures on human beings, their biological material and/or clinical data, a favourable report or a document accrediting the request for its evaluation by the Biomedical Research Ethics Committee must be provided. The documents to be provided are detailed in section 14 of the Orden de 10 de agosto de 2023. |
| **Submission of financial and scientific reports at the national level** | Beneficiaries must submit financial and scientific reports to Consejería de Sanidad, Presidencia y Emergencias de la Junta de Andalucía (please see section 22.b) 3º and 25.f) 1º Orden de 10 de agosto de 2023) |
| **Staring date of the clinical study** | The starting date will be stated in the award resolution. |
| **Further guidance** | The projects must respect the fundamental principles established in national and international declarations, protocols and conventions on research ethics, as well as respect the requirements established in national and regional legislation in the field of biomedical research, development and innovation, personal data protection and bioethics.<br><br>When the results are not susceptible to protection of industrial or intellectual property rights, the scientific publications resulting from the funding granted must be made available in open access, in accordance with article 37 of Law 14/2011, of June 1. |

# ANNEX I

| | |
|---|---|
| **Country** | Spain |
| **Funding organisation** | **Institute of Health Carlos III (ISCIII)** |
| **National contact person** | **Astrid Valencia Quiñónez / Cristina Nieto García**<br>Trials4Health@isciii.es |
| **Funding commitment** | **2.400.000,00 €** (*pending of approval of Spanish State Budget*) |
| **Anticipated number of fundable proposals** | 3-4 |
| **National Programme** | The Strategic Action in Health (Strategic Lines of Health Research 2024–2027, hereinafter **AES 2026**) |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | **Maximum funding from ISCIII per awarded Spanish project:**<br>• If a Spanish Partner requesting funding to the ISCIII **IS** the Coordinator (at international level) of the clinical study: **Max. 1.000.000,00 € per project.**<br>• If a Spanish Partner requesting funding to the ISCIII **IS NOT** the Coordinator (at international level) of the clinical study: **Max. 750.000,00 € per project.**<br>**Overheads** according to the national programme AES 2026: 25%<br>The level of funding will take into account the evaluation of the collaborative proposal, the scientific quality of the Spanish group, the added value of the international collaboration, and the financial resources available. |
| **Funding mechanism** | **Only ONE eligible partner (represented by one PI) can request funds to ISCIII per consortium.**<br>It can be a multicentric study but only with one beneficiary entity requesting funds to ISCIII. The beneficiary entity must be the Institution to which the PI belongs (according to the rules established by AES 2026).<br>This partner will have the opportunity to establish a collaboration agreement with other additional national recruiting sites and allocate a budget to the recruitment sites. These additional national recruiting sites need to be specified in the proposal. |
| **Eligibility of partners** | The involvement of Spanish primary health care centers in the clinical studies is encouraged if relevant for the clinical research. |

**Eligible Institutions (including associated partners/recruiting sites):**

- **Accredited Health Research Institutes (Institutos de Investigación Sanitaria acreditados, IIS).** Accredited according to the RD 279/2016 (These institutions may manage research via a foundation regulated according to the Spanish Act 50/ 2002, of December 26th). See the list of IIS in this link.

- Hospitals, primary health care or public health administration of the Spanish **National Health System (SNS).** These institutions may manage research via a foundation regulated in accordance to the Spanish Act 50/2002, of December 26th (a copy of the foundation's statutes may be submitted).

- **CIBER:** Only one PI can be eligible by ISCIII per consortium, fulfilling that the team members applying to the call must be from at least two groups belonging to CIBER in two different home institutions and one of these two should be a hospital, primary health care or public health administration of the Spanish National Health System (SNS) or Accredited Health Research Institutes (Institutos de Investigación Sanitaria acreditados, IIS). Please contact CIBER (pai@ciberisciii.es) for more information related to CIBER's eligibility.

- **Public R&D Centres legally constituted on a monographic basis** and which are **exclusively working in the field of the priority medical areas included in the call** (cardiovascular diseases, metabolic disorders, autoimmune diseases).

**NOT eligible institutions:**

- Applicants not related with the National Health System from non-profit research organizations such **Public Research Institutions (OPIs)** as defined in article 47 of Law 14/2011, of 1 June, in accordance with the provisions of Royal Decree 202/2021, of 30th March and **other public R&D centers** that are not monographic and exclusively working in the field of the priority medical areas of the call**,** private health entities and institutions and public and private **universities**, **technological centres** and other **private non-profit institutions performing RDI activities** in Spain.

- Those declared by AES 2026 as ineligible to receive funds by ISCIII.

| | |
|---|---|
| **Eligibility of PI and team members** | • Principal Investigators (PI) shall mandatory have **PhD degree.**<br>• Principal Investigators (PI) can only participate **in one project proposal** per call.<br>• Principal Investigators (PIs) belonging to an **Accredited Health Research Institutes (IIS) could apply ONLY from the IIS as applicant Institution.**<br>• The Principal Investigator (PI) and all members of the research group must belong to the **eligible institutions** in the call.<br>• PIs that has an ongoing International Collaboration (PCIN) project of the same initiative and purpose that this call (EfecTrial call) and that the project has an ending date after the 31st December 2026 will not be able to apply for this call. This incompatibility will affect only to the PI, and this incompatibility will not apply in the case that the PI participates as coordinator in the new application or in the ongoing project.<br>• For additional incompatibilities please review AES 2026.<br>**Excluded** personnel as Principal Investigator (PI):<br>• Those undergoing a postgraduate training in Health Specialization (MIR, EIR, FIR, QIR, BIR, PIR, RFIR)<br>• Those undergoing research training (e.g. PhD students, or "Río Hortega" contracts).<br>• Those undergoing postdoctoral training (e.g. "Sara Borrell" or "Juan de la Cierva" contracts).<br>• Researchers contracted by a RICORs and platforms funded by ISCIII. |
| **Specific requirements for clinical studies** | - In case of a **Spanish group coordinating at international level** the clinical trial and applying funding to ISCIII, it must involve a member from from one of the Clinical Trial Units (CTUs) of the **Spanish Clinical Trials Network (SCReN)**. If no SCReN CTU exists in their institution, they must contact the SCReN Technical Secretariat for the allocation of a CTU.<br>- In case of a **Spanish group not coordinating at international level** the clinical trial and applying funding to ISCIII, it is strongly recommended to involve a member from one of the Clinical Trial Units (CTUs) of the Spanish Clinical Trials Network (**SCReN**). If not available in their institution, |

| | |
|---|---|
| | applicants should contact the SCReN Technical Secretariat to facilitate the involvement. |
| **Eligibility of costs, types and their caps** | • **Personnel costs:**<br>- Personnel costs will be eligible for contracts with the needed professional category (superior technician, BSc (grado), MSc (máster), PhD (doctor) for the project development accordingly to the published salary tables in ISCIII's webpage/ AES 2026. Personnel cost will **precisely adhere to the salary tables**, no other amount will be considered, either upper nor lower.<br>- Contracts for PhD students will be done in the framework of National Subprogramme for Training (scholarships are not eligible).<br>- Personnel costs will NOT be eligible when they correspond to civil servants or the equivalent personnel (as specified in the art. 3.4 of AES 2026) either employed by the beneficiary entities or belonging to the research team.<br>- The hiring of permanent personnel already belonging to the beneficiary entity or members of the research team will not be considered eligible expenses, unless that applies the exception stated in AES 2026 for eligible personnel costs, for contracts framed under the Law 17/2022, 5 September, article 23bis in the specified Entities of Public sector.<br>• **Other eligible costs:** Current costs, small scientific equipment, disposable materials, travelling expenses, complementary expenses (use of central and general research support services of the beneficiary entity), publication and dissemination of results, costs of external service providers directly involved in the development of the clinical study, specific clinical studies related costs (e.g. administrative fees for civil responsibility insurance, taxes for regulatory approvals, clinical study monitoring costs) and other costs as included in AES 2026, that can be justified as necessary to carry out the proposed activities.<br>• **Overheads,** according to AES 2026 (**25%**).<br>• **Double funding** of the same concept is not allowed. |
| **Duration of the clinical study** | The duration of the clinical studies will be **48 months**. |
| **Specific rules for potential extensions** | Potential extensions could be provided according to the national Regulation and AES 2026. |

| | |
|---|---|
| **Submission of the proposal at the national level** | **National phase**: national applications will be required by ISCIII to the full proposal applicants according to the timeline established in AES 2026.<br><br>Due to administrative and legal regulations, the Institute of Health Carlos III establishes the **end of October 2026** (tentatively date) as the national deadline for the decision on fundable project consortia which includes Spanish partners to be funded by ISCIII, which must present their national application in the period stated in AES 2026 (probably September/October 2026).<br><br>Any concerned applicant in a proposal for which no final decision has been made by the deadline of **end of October 2026** (tentatively date), could be declared not fundable by ISCIII.<br><br>Submission of financial and scientific reports as specified by the call text at international level and additionally at the national level as specified by ISCIII's instructions (please check ISCIII's webpage).<br><br>**Additional clause regarding the available grant**: After the evaluation process, depending on its budgetary availability, of the requested funding of the selected projects, and giving priority to projects requesting funding from ISCIII, ISCIII and other Spanish funding agencies may exchange applicants with each other in order to optimize the available funds, provided that the respective eligibility rules are met. Such applicants must submit their application to the national phase of ISCIII, in time and form. |
| **Submission of other information at the national level** | As specified by AES 2026.<br><br>In order to expedite the eligibility check process, it is mandatory that all the applicants submit the CVA-ISCIII of the PI.<br><br>This document shall be submitted by the PI by electronic email before the pre-proposal submission deadline to: Trials4Health@isciii.es |
| **Submission of financial and scientific reports at the national level** | As specified by ISCIII's instructions (please check ISCIII's webpage). |
| **Starting date of the clinical study** | The starting date of the grant for the clinical study will be established in the national grant resolution (most probably will be beginning of 2027). |
| **Requirements on data and repositories** | • Researchers funded by ISCIII must make public the human genomic data, as well as relevant data (phenotype and exposition data) generated inside the funded project and will use open access repositories. Researchers must also make public all the necessary information for the interpretation of these genomic data, including lab protocols, data instruments survey tools. Regarding genomic |

| | |
|---|---|
| | data it is understood: association of complete genomes (GWAS), matrixes of polymorphism of a single nucleotide (SNP) and sequence of genome, and transcriptomic, metagenomic, epigenomic and gene expression data. The researchers whose projects are funded by ISCIII are recommended to store their scientific data at the "ELIXIR Core Data Resources", or if non-European repositories or data bases are to be used they must be certified by ELIXIR or the US National Center for Biotechnology Information (NCBI).<br><br>• ISCIII may not fund any project that may require a repository and/or a data base without a plan ensuring sustainability and decommissioning after the end of funding |
| **Use of Research infrastructures and platforms** | Researchers funded by ISCIII are encouraged to make use of the resources available through the European Research Infrastructures and the Spanish Platforms funded by ISCIII for supporting the biomedical and health R&I. |
| **Acknowledgements** | Any publication, data base, product or event protected with IPR or not, resulting from the granted project must acknowledge "Award no. XX by Instituto de Salud Carlos III (ISCIII) through AES 2026 and within the ERA4Health Partnership" even after the end of the project, including other specific acknowledgments that could be requested by ISCIII to the granted project. For more information please see ISCIII's ROR here. |

# ANNEX I

| | |
|---|---|
| **Country** | Spain |
| **Funding organisation** | Departament de Salut – Generalitat de Catalunya (DS-CAT) |
| **National contact person** | Carme Pérez<br>935566103<br>peris@gencat.cat |
| **Funding commitment** | 700.000,00 € |
| **Anticipated number of fundable proposals** | 2 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | - Max. 400.000,00 € per project (if coordinator)<br>- Max. 300.000,00 € per project (if not coordinator)<br>(Including overheads) |
| **Funding mechanism** | Only one organisation will be granted and this organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement |
| **Eligibility of partners** | Foundations managing research activities of both SISCAT and Public health centres who carry out research activity in Catalonia, including accredited Health Research Institutes and CERCA institutions |
| **Eligibility of costs, types and their caps** | Personnel costs<br>Consumables<br>Core facilities<br>Travel<br>Other (direct costs). It is compulsory to include the cost of a financial audit certificate up to a maximum of € 2,000<br>Overhead (Flat rate 21% calculated on direct costs) |
| **Duration of the clinical study** | Up to 48 months |
| **Specific rules for potential extensions** | Potentially cost-neutral extensions could be provided, according to national regulation |
| **Submission of the proposal at the national level** | National applications will be required by DS-CAT to the fundable project consortia which includes Catalan partners to be funded by DS-CAT |
| **Submission of other information at the national level** | None |
| **Submission of financial and scientific reports at the national level** | Established in the national grant resolution |
| **Starting date of the clinical study** | Established in the national grant resolution (from January 2027) |
| **Further guidance** | peris@gencat.cat |

# ANNEX I

| | |
|---|---|
| **Country** | Sweden |
| **Funding organisation** | The Swedish Research Council (SRC) |
| **National contact person** | Abraham Mellkvist-Roos, abraham.mellkvist-roos@vr.se, +46 76 5257613 |
| **Funding commitment** | 1 500 000 € |
| **Anticipated number of fundable proposals** | 3-4 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | Maximum 5 700 000 SEK (approximately 500 000 €), minimum 3 420 000 SEK (approximately 300 000 €)<br>Please note that the exchange rate 1 EUR = 11.40 SEK shall be used to calculate actual amounts applied for in the application. |
| **Funding mechanism** | Only one organisation will be granted and this organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement |
| **Eligibility of partners** | The applicant must be an individual researcher holding a PhD. Only researchers at an administrating organisation approved by the Swedish Research Council may apply. Please refer to general applicant eligibility requirements found here. The applicant may not have any other project grant concerning the same project concept, funded by the Swedish Reseach Council, at the start of the grant period.<br><br>All Swedish applicants to the SRC must communicate with a SRC ERA4Health national contact person regarding their intention to participate in the call, before submission of the consortium application.<br><br>No funding of industrial partners.<br><br>You can only take part in one consortium within this call, either as coordinator or partner. |
| **Eligibility of costs, types and their caps** | The project grant may be used to fund all types of project-related costs, such as salaries (including your own salary, however no more than corresponding to the person's activity level in the project), running costs (such as consumables, travel including stays at research facilities, publication costs and minor equipment), premises and depreciation costs. The project grant may also be used to cover costs for patient advocacy organisations (PAO) part in the project. The costs that can be covered are the same as the above mentioned. Grants may not be used for scholarships. If a doctoral student participates, project funds may not be paid out as salary during teaching or other departmental duties. |
| **Duration of the clinical study** | Project period plus an availability period of one additional year. |

| | |
|---|---|
| **Specific rules for potential extensions** | The Swedish project leader must submit an application for an extension in the Swedish application system Prisma, in according to the instructions on the **SRC website**. |
| **Submission of the proposal at the national level** | All Swedish project leaders participating in the call for support from the Swedish Research Council shall also submit a parallel application according to the Swedish Research Council's instructions. The application form and instructions how to submit the parallel application can be reached from the call text at the SRC website.<br><br>Parallel application is a mandatory eligibility criterion. Failure to submit the parallel application to the Swedish Research Council before the deadline of the SRC call will result in the Swedish partner being declared ineligible. |
| **Submission of other information at the national level** | All Swedish applicants are must communicate with the ERA4Health national contact person regarding their intention to participate in the call, before submission of the consortium application. |
| **Submission of financial and scientific reports at the national level** | The Swedish partner must submit annual economic reports and final economic and scientific reports in the application system Prisma. |
| **Starting date of the clinical study** | January 1st, 2027 |
| **Further guidance** | See national call texts for all national requirements |

# ANNEX I

| | |
|---|---|
| **Country** | Türkiye |
| **Funding organisation** | Health Institutes of Türkiye |
| **National contact person** | Fatih KARADEMİR, Foreign Affairs Department, fatih.karademir@tuseb.gov.tr<br>Batuhan YEŞİLYURT, Head of Project Management and Support Department, batuhan.yesilyurt@tuseb.gov.tr |
| **Funding commitment** | 600.000 € |
| **Anticipated number of fundable proposals** | 2 project proposals |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | €300,000 per clinical study partner.<br>Support will be provided for 2 projects. |
| **Funding mechanism** | e.g. only one organisation will be granted, and this organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement<br><br>Only an institution or organization located in Turkey can receive funding from TÜSEB.<br><br>The primary organization (coordinator or partner) receiving funding may, if deemed necessary, work with other domestic research centers under subcontractor or collaboration protocols.<br><br>TÜSEB funds are not transferred to international partners. |
| **Eligibility of partners** | Within the scope of this call:<br><br>Higher education institutions covered by the Higher Education Law,<br><br>Training and research hospitals,<br><br>Public institutions and organizations,<br><br>Capital companies (private organizations) established in Turkey that create added value at the firm level and hold a trade registry certificate, regardless of sector or size.<br><br>Only researchers in Turkey will be funded. |
| **Eligibility of costs, types and their caps** | Personnel expenses (researchers, project personnel, scholarship holders)<br><br>Consumable expenses<br><br>Travel expenses |

| | |
|---|---|
| | Service purchases<br><br>Machinery and Equipment Expenses<br><br>Information Systems Purchases<br><br>TÜSEB national rules and budget guides apply. |
| **Duration of the clinical study** | Maximum 4 years |
| **Specific rules for potential extensions** | Upon justified request, an extension of up to 24 months is possible with TÜSEB approval; no additional budget will be provided. |
| **Submission of the proposal at the national level** | In addition to the international application submitted to the ERA4Health electronic application system, the national application must be submitted through the TÜSEB online project application system (tbys.tuseb.gov.tr). |
| **Submission of other information at the national level** | Ethics committee approval, institutional authorization letter and CVs of the research team must be uploaded to the national system. |
| **Submission of financial and scientific reports at the national level** | Annual progress and financial reports should be prepared in TÜSEB format and uploaded to the TÜSEB system. |
| **Staring date of the clinical study** | The project must be started within 3 months at the latest after the signing of the fund agreement. |
| **Further guidance** | TÜSEB's national call announcement and guide will be published at https://www.tuseb.gov.tr.<br>Applicants should review national eligibility requirements and contact their national contact point before applying.<br>Call details will be published in TÜSEB's national call announcement. |

ERA4Health Partnership

Co-funded by the European Union

# ANNEX I

| | |
|---|---|
| **Country** | United Kingdom |
| **Funding organisation** | DHSC (funding via NIHR) |
| **National contact person** | Sarah Puddicombe, sarah.puddicombe@nihr.ac.uk or Yessica?<br>cc: internationalapplications@nihr.ac.uk |
| **Funding commitment** | £4,000,000 (approx €4,400,000) |
| **Anticipated number of fundable proposals** | 2-5 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | Max €1,500,00 for a project. Applicants must justify that the budget requested is appropriate and proportionate to the outlined research plans and ensures value for money. |
| **Funding mechanism** | NIHR issues research contracts to lead UK contractor organisation within the consortium who will need to establish agreements with other eligible collaborators or recruitment sites via collaboration or subcontracting agreements. The contracting organisation must be able to meet these NIHR contract terms without amendments in any way.<br><br>Example contracts are found here https://www.nihr.ac.uk/research-funding/application-support/signing-contract. Please familiarise yourself with them. The Lead Applicant will be responsible for appropriate distribution of funds to any other UK collaborators via collaboration, Service level and/or consortium agreement. See guidance on Intellectual Property and Commercial partners https://www.nihr.ac.uk/about-us/who-we-are/policies-and-guidelines/intellectual-property-and-commercialisation-guidance as background and foreground IP arrangements will be required to be detailed as part of the contract. |
| **Eligibility of partners** | Academic Higher Education institutions/ Research Institutes, NHS bodies and providers of services,local authorities, industry, charities, social care organisations in England, Scotland, Wales and Northern Ireland ( check individual NIHR programme remits) |
| **Eligibility of costs, types and their caps** | **In Scope:**<br>Costs for research and recruitment in the UK aligned to the most relevant NIHR domestic programme for this call and which meet NIHR finance requirements<br>**Out of scope:**<br>● NIHR does not fund research involving animals or animal tissue. |

| | |
|---|---|
| | • See NIHR finance guidance for applicants :<br><br>https://www.nihr.ac.uk/research-funding/application-support/guidance/finance-guidance-for-applicants#tab-375156.<br><br>This includes costs for Research training, mobility and academic career development for early career researchers is a key priority for NIHR in supporting the next generation of research leaders.<br><br>NIHR further supports open access for publications. NIHR will pay reasonable fees required by a publisher to effect publication in line with the criteria of the NIHR Open Access policy see guidance https://www.nihr.ac.uk/nihr-open-access-publications-funding-guidance |
| **Duration of the clinical study** | 4yrs |
| **Specific rules for potential extensions** | No-cost and cost extensions may be requested and considered on a case by case basis where well justified. |
| **Submission of the proposal at the national level** | NIHR will require applications for UK based research components to be submitted through the NIHR awards management system. This is only required once the proposal submitted to the EU is recommended for funding. NIHR will then require full budget details for assessment as part of the precontracting processes.<br><br>All applicants are required to register on the NIHR Awards Management system and provide an ORCID. Anonymous EDI data collection will be requested on submission of your application. |
| **Submission of other information at the national level** | **In scope:** Applied health and care research in scope of the ERA4Health IICS call and within remit of a relevant NIHR programme from attainment of proof of concept onwards. For clinical studies of phase 2b to phase 3/4 or from TLR3/TLR4 to TLR8. The NIHR programme most closely aligned to this call is the Health Technology Assessment Programme: Funding research into the clinical and cost-effectiveness of treatments and tests. Funded studies often compare a new technology's existing evidence with the current method in the UK. Followed by the Efficacy Mechanisms and Evaluation programme which funds clinical trials, and other robustly designed studies that test the efficacy of interventions which have the potential to improve patient care or benefit the public. Interventions must have sufficient evidence that the intervention might work in humans, i.e. that there is 'proof of concept'.<br><br>If you have queries on the alignment of your project with our programmes |

| | |
|---|---|
| | please contact internationalapplications@nihr.ac.uk |
| **Submission of financial and scientific reports at the national level** | NIHR requires annual reporting of funding outcomes and impacts for a period of 5 years after the award ends. NIHR may request additional data or more frequent progress reports beyond the minimum of annual reporting ( as required by ERA4Health) on a case by case basis.<br><br>NIHR will retain 5% of the total UK award pending the submission and acceptance for publication of the primary research outcome in addition to the submission of a final report ( required by the HE partnership and NIHR) within two months of project end date.<br><br>Awards must comply with the NIHR Policy on clinical trial registration and disclosure of results- https://www.nihr.ac.uk/about-us/who-we-are/policies-and-guidelines/clinical-trial-registration-and-disclosure-of-results |
| **Starting date of the clinical study** | 1st of the Month ( approx 6 months after outcome notification) |
| **Further guidance** | Contact internationalapplications@nihr.ac.uk |

# ANNEX I

| | |
|---|---|
| **Country** | European countries under the scope of EU Clinical Trial Regulation |
| **Funding organisation** | Breakthrough T1D |
| **National contact person** | Carmen Hurtado del Pozo churtadodelpozo@breakthrought1d.org<br>Hilda Ahnstedt hahnstedt@breakthrought1d.org |
| **Funding commitment** | € 2.500.000,00 |
| **Anticipated number of fundable proposals** | 2-3 |
| **Maximum/ Minimum funding per grant awarded to a clinical study partner** | Max: € 800.000 |
| **Funding mechanism** | Only one organisation will be granted and this organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement |
| **Eligibility of partners** | Applicants must hold an MD, DMD, DVM, PhD, or equivalent, and have a faculty position (or equivalent) at a college, university, medical school, company, or other research facility. Applications may be submitted by non-profit, public, or private organizations such as colleges, universities, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government.<br>For this specific call, funding eligibility is restricted to institutions based in European countries under the scope of EU Clinical Trial Regulation.<br>Clinical projects must be aligned with the Breakthrough T1D Research Strategy. Approval from the Breakthrough T1D Board of Directors is required for the commitment of Breakthrough T1D funds. |
| **Eligibility of costs, types and their caps** | Direct Costs are defined as those costs falling within the following Breakthrough T1D budget categories: Salaries& Wages, Stipends, Supplies, Other Costs, Equipment and Travel.<br>• Salaries & Wages includes wages earned by an employee, and may include benefits, including insurance and retirement plans. Breakthrough T1D requires the Grantee Institution to have administrative and financial controls in place to allocate and track salaries and wages in realtime across a Breakthrough T1D-funded project.<br>• Fringe benefits in the form of employer contributions or expenses for social security, employee insurance, workers' compensation insurance, tuition or remission of tuition for individual employees are allowable, provided such benefits are granted in accordance with established educational institutional policies, and are distributed to all institutional activities on an equitable basis. Tuition benefits for family members other than the employee are unallowable. Any deductions other than the listed above are not allowable. Car insurance that is not a standard institutional benefit offered to all employees of comparable rank is unallowable. |

| | |
|---|---|
| | • Stipends are applied for Breakthrough T1D Postdoctoral andAdvanced Postdoctoral Fellowships inplace of Salary & Wages. Stipend levels are determined based on the fellow's years of postdoctoral experience.<br>• Supplies are general purpose consumable items that are used on a regularbasis and have a shorter life span in use than equipment and machines.<br>• Other costs might include items that are not consumable but are needed on a regularbasis, such as animal purchases and maintenance charges. Other costs should also include the cost of making publications completely open access, whenever possible (see 5.8).<br>• Salary and fringe for a statistician or other staff responsible for cleaning and entering data into the public repository, to comply with Breakthrough T1D's Data Sharing requirement (see 5.9), may be included as Direct Costs. • ResearchAllowances areprovidedfor Postdoctoral Fellowships only in the amountof USD$5,500per year. These can be used towards travel to scientific meetings, journal subscriptions, books, health insurance costs, etc.<br>• Travel may include anydomestic and/orinternational journeys by an employee related to the project and is limited to USD$2,000 per year on a grant unless otherwise approved by Breakthrough T1D.<br><br>Indirect costs are limited to 10% of direct costs. The Grantee Institution may request indirect costs less than 10%. Equipment, subcontract, contractual, and fee-for service costs are not eligible for inclusion in calculating indirect costs. In instances where there is a subcontract, the Subcontract Institution may also budget up to 10% of their direct costs to indirect costs. The Grantee Institution may notincur any indirect costs off the subcontract costs. |
| **Duration of the clinical study** | 48 months |
| **Specific rules for potential extensions** | Grants are eligible to request No Cost Extensions |
| **Submission of the proposal at the national level** | NO |
| **Submission of other information at the national level** | NO |
| **Submission of financial and scientific reports at the national level** | Breakthrough T1D scientific program manager will work with the PI requesting specific information in the quarterly and/or annual progress report. The Annual Progress Report requires submission of the Scientific Progress Report, Website Progress Report (Lay audience), and any associated Publications, Abstracts (Lay audience), or Presentations. For all grants, a Final Scientific Progress Report is required within 75 days after the end of the grant period. |

| | |
|---|---|
| **Starting date of the clinical study** | Max at three months after notification |
| **Further guidance** | Clinical Trial Registration and Requirements<br><br>Breakthrough T1D requires that all applicable clinical trials be registered in a recognized clinical trial registry (country-specific or international, e.g., ClinicalTrials.gov). Registration must occur no later than 21 days after the first subject is enrolled to ensure transparency and free access to information on Breakthrough T1D–funded trials within the T1D community.<br><br>The applicant is required to follow the laws pertaining to the need of applicable regulatory authority where the research is going to be conducted which for an international trial may vary from one country to another. The awardee must provide Breakthrough T1D with any such regulatory approval documentation.<br><br>Clinical trials funded by Breakthrough T1D must comply with ICH-GCP standards and all applicable regulatory requirements, including guidelines for safety reporting and the reporting of unanticipated problems. Investigators must inform the Breakthrough T1D Scientific Program Manager within 24 hours of notifying the IRB and/or relevant regulatory authority of any Serious Adverse Event (SAE).<br><br>Final Progress Reporting<br>If applicable, a comprehensive final progress report must be submitted upon completion of the trial. This report should include outcomes, safety data, and a summary of results consistent with regulatory and registry requirements. |