

Joint Transnational Call for Investigator-Initiated Clinical Studies (JTC IICS) – 2027

**“Multi-national Investigator-Initiated Clinical Studies in Cardiovascular,
Autoimmune, Metabolic, and Non-Communicable Respiratory Diseases,
including Underrepresented Populations” (IICS4all 2027)**

Call Text

DEADLINES

January 14th, 2027 (12:00 CET) - SUBMISSION OF PRE-PROPOSALS

June 14th, 2027 (12:00 CEST) - SUBMISSION OF INVITED FULL PROPOSALS

Link to the electronic proposal submission:

<https://ptoutline.eu/app/IICS4all>

The submission system will be open by October 27th, 2026

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

or contact the Joint Call Secretariat (JCS):

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Definitions

TYPES OF CLINICAL STUDIES OF THIS CALL

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.

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, diagnostics, behavioural treatments, process-of-care changes, preventive care, etc. Clinical trials may also be referred to as interventional trials.

Randomized controlled trials (RCT) are clinical trials, in which participants are randomly assigned to one or more intervention groups or to a control group, allowing researchers to compare outcomes and determine the effect of the intervention while minimizing bias.

Drug repurposing studies investigate new uses for approved medicines, in indications outside the scope of the original approval. Within this call, drug repurposing studies are limited to off-patent medicinal products, including biological medicinal products and biosimilars. These also include 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). These may include new therapeutic uses for existing medicines, different formulations of the same medicine, and/or creating new combinations of medicines or medicines with medical devices.

Comparative effectiveness studies generate and synthesise high-quality evidence to compare the benefits and harms of alternative methods for preventing, diagnosing, treating, or monitoring clinical conditions, or for improving care delivery. These patient-centred, outcome-based studies compare various interventions—such as approved therapies, surgical protocols, or lifestyle changes—to directly inform clinical and policy decision-making

Trial within cohorts (TwICs) study designs using the infrastructure of an observational (non-interventional) cohort study to conduct a randomized controlled trial (interventional) within that cohort by selecting eligible participants for specific interventions.

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.

ROLES IN THE CONSORTIUM

Associated partner: a recruitment site or another type of entity required for the development or implementation of the clinical trial, which has a collaboration agreement or a subcontract with one of the partners of the IICS consortium.

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

Coordinating Investigator/ Coordinator: 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.

Partner: Institution eligible to request funding from one of the funding organisations participating to the call.

Principal Investigator (PI): Each partner of a consortium is represented by a single Principal Investigator.

Recruitment/recruiting site: Facility where potential participants are identified and enrolled in clinical trials

Service provider: an external entity responsible for cross-cutting activities who will provide all recruitment sites with specific expertise in these activities. In this call, this service provider can be either the European Clinical Research Infrastructure Network (ECRIN)¹ or an entity subcontracted by ECRIN.

Sponsor: not-for-profit, legal institution or organisation which takes overall 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: for this Call, an approved or existing health care intervention is defined as follows:

- Medication or medical device approved by the European authorities for medicines and, if applicable, authorities of other countries outside the EU/ EEA involved in the respective consortium or;
- non-pharmacological health interventions, currently already developed and implemented in routine clinical practice.

The definition does not cover new health interventions that are not yet routinely implemented in clinical practice.

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, equity, environmental or ethical complexities of research and innovation. Further information can be found in [ERA4Health's Guidelines for RRI](#).

¹ A public, non-profit organisation that facilitates and supports the setup and management of multinational clinical trials in Europe. In this call, ECRIN provides and manages cross-cutting trial management services. www.ecrin.org

1 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)². To achieve this, a comprehensive network is created which aims at strengthening and expanding the existing conducive eco-system.

In this context, 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.

2 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.^{3 4 5}

In addition, in the last decades, common metabolic disorders, 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.⁶

Therefore, the impact of CVD and metabolic disorder 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.⁷

² [ec_rtd_he-partnerships-era-for-health-1.pdf](#)

³ [Cardiovascular diseases statistics - Statistics Explained - Eurostat](#)

⁴ [EHN-heart-failure-paper_final_180419.pdf](#)

⁵ [https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-\(cvds\)](https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds))

⁶ <https://doi.org/10.1093/eurheartj/ehac779.131>

⁷ [Eur Heart J. 2023 Dec 1;44\(45\):4752-4767. doi: 10.1093/eurheartj/ehad583](#)

Autoimmune diseases 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.^{8,9} Importantly, autoimmune diseases are associated with an increased risk of cardiovascular disease, further highlighting the interconnection between these disease areas¹⁰.

Among non-communicable diseases, chronic respiratory diseases (CRD) account for a substantial burden and premature mortality worldwide. Global Burden of Diseases 2019 reported 4.0 million deaths in 2019 caused by CRDs being the third leading cause of mortality globally. Beyond mortality risks, the breathlessness, restricted physical activity, and sleep disturbance can negatively affect CRD patients' quality of life. Furthermore, CRD management's substantial financial requirements often impose significant economic burdens on the patients, their families, and society.¹¹

Across all these disease areas, sex- and gender-related factors, as well as age, ethnicity and potential further aspects of diversity influence disease susceptibility, clinical presentation, disease progression, treatment response and long-term outcomes. Ensuring that these factors are appropriately considered in clinical research is essential to generate evidence that is applicable to the diverse populations encountered in routine healthcare.^{12,13}

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. The high burden and increasing evidence of interconnections between cardiovascular, metabolic, autoimmune and chronic respiratory diseases further reinforce the need for clinical research across these disease areas.

Investigator-Initiated Clinical Studies (IICS) are usually driven by scientific opportunities and pressing public health needs with high societal value. While they represent almost half of clinical research activities in Europe, IICSs are currently mostly conducted in a single country.

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. There is therefore a specific need for supporting high quality, multi-national IICS, given the added value that they can provide compared to single country ones.

Comparative-effectiveness studies compare two or more diagnostic tests, treatments, treatment combinations, interventions or care delivery systems that are already available in routine healthcare. A key objective of these studies is to provide stakeholders (e.g. patients, caregivers, providers) and key decision-makers with useful knowledge about respective benefits and/or risks.

Comparative effectiveness studies are considered to be low risk intervention studies as they compare approved interventions and therefore should pose no more than a minimal additional safety risk or burden to participants compared to usual clinical practice. They can be conducted as pragmatic

⁸ <https://doi.org/10.1016/j.autrev.2023.103410>

⁹ <https://doi.org/10.1016/j.autrev.2023.103326>

¹⁰ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)01349-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01349-6/fulltext)

¹¹ <https://link.springer.com/article/10.1007/s11739-025-04149-1>

¹² [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31561-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31561-0/fulltext)

¹³ <https://doi.org/10.1111/cts.70407>

clinical studies where necessary data will be collected mostly in routine clinical care. This results in lower costs even with a high number of patients.

Drug repurposing clinical studies can leverage existing pharmacological knowledge and clinical knowledge to accelerate the development of new indications for authorised medicinal products, including biological medicinal products and biosimilars. These types of studies can address unmet medical needs, reducing development costs and potentially improving patient access to new therapeutic uses of treatments. Drug repurposing constitutes a dynamic field of drug development that can offer real benefits to patients and healthcare systems.

3 Aim of the call

The aim of the call is to support **pragmatic, phase III, randomised controlled, multi-national interventional Investigator-Initiated Clinical Studies (IICS)**

(1) that are designed as following **study types**:

- comparative-effectiveness studies and/or
- drug repurposing studies of off-patent drugs

Applicants can make use of existing cohorts, e.g. for designing Trials within Cohorts (TwICs).¹⁴

(2) that have a high public relevance **in the fields of the following diseases or conditions** (that are of equal importance):

- Cardiovascular diseases
- Metabolic disorders¹⁵
- Autoimmune diseases¹⁶
- Non-communicable respiratory diseases

The IICS should primarily address at least one of the abovementioned diseases/conditions, although a proposal can also address several of the mentioned diseases/conditions and/or in combination with related comorbidities.

(3) that ensure **inclusivity and diversity in the study population** and also include **sex/gender-sensitive, age-specific or other diversity-related aspects**, if reasonable.

OUT OF SCOPE

- Clinical studies conducted for direct commercial purposes
- For drug repurposing studies: a drug still on patent in one of the participating countries. This criterion also applies to biological medicinal products and biosimilars.
- Phase I and Phase II studies: Studies in which a treatment is used in humans for the first time, or which are aimed exclusively at assessing tolerability, safety or dose determination

¹⁴ [E4H booklet on TWICs](#)

¹⁵, ¹⁶ Proposals focusing on type 1 diabetes should contact the Breakthrough T1D funding organisation, which can fund partners from different countries, also from countries not participating in the call (see chapter 5 “Participating countries and respective funding organisations”).

- Proposals focused on observational studies, non-interventional cohort studies, implementation studies, translational/clinical approval studies, creation of large databases, systematic reviews and meta-analysis. Non-randomised studies.
- Studies in **medical areas other than the ones mentioned above**. Particularly, **cancer is out of the scope of this call**, even if it concerns one of the eligible diseases/conditions (cardiovascular diseases, metabolic disorders, autoimmune diseases and non-communicable respiratory diseases).
- Basic and pre-clinical biomedical research and research involving animals or animal tissue
- Development of a new healthcare intervention
- Medicinal products without marketing authorization in Europe and in non-EU/EEA countries involved in the respective consortium and medical devices without CE mark.
- For comparative-effectiveness studies, the use of placebo is restricted to blinding of the interventions being compared. Any other use of placebo in comparative effectiveness studies is out of the scope. For drug repurposing trials, this restriction does not apply: the inclusion of placebo is permitted, but not mandatory.
- Topics not eligible for Horizon Europe funding: 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).

4 General conditions and requirements

The maximum funding duration is 48 months.

Applicants shall not apply at the same time to different calls for the same research activities. **Double funding is not allowed.**

REQUIREMENTS

Regarding the **selected study type and trial design** the following requirements apply:

- 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) and must be well justified in the proposal.
- The clinical study design and objectives must take into consideration the population that would be needed to reach the objective of the study. Strategies for recruitment, retention, assessment, and analysis must be included.
- **For comparative effectiveness studies**, these must compare the use of currently approved or existing healthcare interventions (see definition), used in clinical practice, either to each other or to the current standard of care.

These healthcare interventions 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, for example 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.

- **For drug repurposing trials**, a new indication of an approved off-patent medication should be explored. 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 eligible. Drug repurposing trials need to have an upfront plan to ensure patient's access to the drugs in the different countries.

The following requirements apply to ensure that proposals address **inclusivity and diversity in the study population** and also **address gender-sensitive and age-specific or other diversity-related aspects**:

- The proposed needs to address sex and gender aspects in alignment with the European Commission Roadmap for Women's Rights as well as with the Gender Equality Strategy 2026-2030 stating that women and girls' physical and mental health needs to be improved and the gender health gap needs to be closed by evidence-based information and gender-sensitive medical research, clinical trials, diagnostics and treatments.
Age-related aspects also need to be taken into account where relevant to the disease area and research question. These considerations should be reflected throughout the proposed study, including study design, conduct, statistical analysis, and interpretation of the results. Proposals should aim, where relevant, address sex/gender-sensitive, age-specific or other diversity-related knowledge gaps in one of the included disease areas (e.g. women in cardiovascular disease).
- The study population needs to adequately reflect the population for whom the intervention is intended, taking into account sex, gender and age. Studies should not exclude pregnant and breast-feeding women by default, any exclusion should be based on justified reasons.
- The applicants need to clearly justify in their proposal, where the inclusion of underrepresented groups or investigation of sex/gender-sensitive, age-specific or other diversity-related aspects is deemed not feasible. The justification should be evidence-based and explain the underlying scientific reasons, as well as the potential implications for the interpretation of and generalisability of the study results.

In addition, the following **general requirements** apply:

- To exclude clinical studies with direct commercial purposes, the protocol and study design must be described in a very clear and transparent manner. In the case of the involvement of any private for-profit entity, the consortia need to duly justify their role in the proposal and ensure that no commercial purpose or benefit exists.
- Partners in the consortia, especially the Coordinating Investigator, need to have a proven track record in delivery of clinical trials to ensure feasibility of the clinical trial. Further, all relevant expertise (including trial biostatistical expertise) needs to be included in the trial team to conduct high-quality clinical trials. The individual partners should be complementary in their expertise.
- Any IICS must clearly demonstrate the added value of transnational collaboration. Proposals must show how the outcomes of the trial could generate further health, economic and/or policy 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.

- 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)¹⁷ where they exist or justify their lack of use¹⁸.
- Proposals must follow the principles of **Responsible Research and Innovation (RRI)**. All Consortia must demonstrate a commitment to investigating and addressing social, political, equity, environmental or cultural dimensions of the proposed research. The guideline for applicants and the [ERA4Health Responsible Innovation Journey Guide](#) further support you on how RRI and complementary sets of ideas can be approached.
- 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 study outcomes for healthcare decision making to pursue a high implementation potential for the benefit of end-users/patients/citizens.
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.
- Inclusiveness aspects in patient recruitment (minorities, social-economic aspects, ethnical aspects) must be ensured by including underrepresented and vulnerable populations. Issues of particular relevance for the target population, for example, sex and gender specificities, age, multimorbidity, complex chronic conditions, polypharmacy, substance misuse, vaccine efficacy, compliance, and diseases with high societal burden need to be considered.
- Consortia are encouraged to promote gender balance in their overall team composition and to ensure equitable opportunities for participation in leadership roles and responsibilities.
- 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.
- It is strongly recommended to use appropriate statistical techniques that can account for variations among countries in a trial.
- Proposals shall address the scalability from the regulatory perspective for each of the involved countries.
- IICS supported by ERA4Health must respect fundamental ethical principles (see section ethical clearance). 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 ¹⁹). All funded partners must respect the fundamental principle of research integrity — as set out in the European Code of Conduct for Research Integrity²⁰. IICS involving human embryonic stem cells (hESC) or human embryos (hE) may not start without prior ethics review carried out by

¹⁷ 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.

¹⁸ <https://www.comet-initiative.org/>

²⁰ [The European Code of Conduct for Research Integrity - ALLEA](#) (All European Academies)

the European Commission and subsequent decision of the Horizon Europe Programme Committee.²¹

- 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).
- 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

The following recommendations should be considered:

- Consortia are encouraged, where appropriate, to build on or collaborate with existing and financially sustained multinational networks, infrastructures or platforms in the respective medical field to enhance the feasibility and efficient conduct of the trial.
- Applicants could make use of existing biobanks, existing cohorts (e.g. trials within cohorts), information from previous observational studies, systematic reviews, metadata repositories or routine healthcare data (e.g. for designing interventional real world evidence studies) as long as the proposed trial aligns with the above stated formal requirements.
- Where the Coordinating Investigator, the main PIs of the research teams or other responsible persons (e.g. biostatistician) of the research consortium are emeritus personnel, it should be clearly mentioned in the proposal and strongly justified that they will be able to hold and deliver the responsibilities associated to their role in the research consortium.
- Early Career Researchers (ECR) (e.g post-docs, medical doctors, clinician scientists) are encouraged to participate as additional team members in the consortium in accordance with applicable national/regional definitions and requirements. All PIs are asked to encourage ECR who will be involved in the research projects to actively engage in the [ERA4Health Early Career Network \(ECN\)](#). To facilitate participation of the ECR in the ECN, the Coordinating Investigator and PIs should (I) include travel costs for the project’s ECR dedicated to the ECN activities in the proposal and (II) allow the ECR to dedicate a small amount of their working time to the ECN.
- Any assessment or testing not linked to secondary endpoints should be optional for patients, in order to keep the study as pragmatic as possible.

5 Expected Impact

Practice-oriented, publicly funded multi-national clinical studies can provide answers to highly relevant health research questions, which are less likely to be answered by trials funded by the pharmaceutical and other health industries. By jointly conducting studies across different countries

²¹ [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021C0512\(01\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021C0512(01)&from=EN)

and healthcare settings, they can generate robust and transferable evidence on the clinical effectiveness and cost effectiveness of interventions. Comparison with the current standard of care can further increase the impact of the findings on public policies and healthcare systems.

Comparative-effectiveness studies 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, publicly funded drug repurposing clinical studies can leverage existing knowledge and clinical data accelerating the development of new indications that can address unmet medical needs, reduce costs and improve patients' access to new treatments.

By addressing cardiovascular, metabolic, autoimmune or respiratory diseases, clinical studies are expected to generate robust evidence, in disease areas associated with a substantial burden for patients and healthcare systems. Conducting the studies across Europe can facilitate faster patient recruitment, increase diversity and representativeness of study populations, and improve the transferability of results across different clinical practices and healthcare settings.

The appropriate consideration of sex, gender and age ensures that relevant differences in treatment effectiveness and safety are identified, and the generated evidence is applicable to the populations affected by the disease. Along with that, early and active involvement of patients or patient representatives in the clinical studies will ensure that the patient's needs in those medical areas will be adequately addressed leading to 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.

6 Participating countries/regions and respective funding organisations

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

Table 1: Participating funding organisations

Country	Funding organisation	Acronym	Contribution
Austria	Austrian Science Fund	FWF	1 400 000 €
Belgium	Belgian Health Care Knowledge Centre	KCE	1 500 000 €
Czech Republic	Ministry of Health of the Czech Republic	MZ CR (AZV CR)*	500 000 €
Egypt	Academy of Scientific Research and Technology	ASRT	300 000 €
France	French Ministry of Health	FR MOH**	1 500 000 €
Germany	Federal Ministry of Research, Technology and Space (BMFTR) / DLR Project Management Agency (DLR)	BMFTR/DLR	3 000 000 €
Ireland	Health Research Board	HRB	1 500 000 €

Israel	Ministry of Health	CSO-MOH	280 000 €
Italy	Regional Foundation for Biomedical Research (Lombardy Region)	FRRB	1 010 000 €
Latvia	Latvian Council of Science	LCS	800 000 €
Lithuania	Research Council of Lithuania	LMT	1 000 000 €
Norway	The Research Council of Norway	RCN	1 300 000 €
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	500 000 €
Spain	Department of Health of Catalunya	DS-CAT	700 000 €
Spain	Institute of Health Carlos III	ISCIII	2 400 000 €
Spain	Regional Ministry of Presidency, Healthcare and Emergencies of Andalusia	CPSEJA	250 000 €
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. 4 767 180 €)
Global organisation	Breakthrough T1D	BT1D	1 000 000 €

** MZ CR acts as funder in this call, while AZV CR acts as service agency to administer the call at national level. The project duration for the Czech partner differs from that of the other consortium partners, please see national annex I of Czech Republic*

***Participation pending as of 27 October 2026.*

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). Breakthrough T1D can fund partners from European countries under the Clinical Trial Regulation (see Annex I), as long as the study topic is type 1 diabetes, in alignment with the [Breakthrough T1D Research Strategy](#).

Understanding the challenges and complexities with multi-national IICS, an additional budget of up to 15% of the total budget can be requested to support cross cutting activities provided by ECRIN (see section 7 – “additional management budget” for further details). ECRIN may participate in the consortium solely as a Service Provider and not as a Partner or Collaborator.

7 Application

Eligibility criteria

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

Applicants seeking funding from **Breakthrough T1D** should likewise **contact the designated Breakthrough T1D contact point** to confirm their eligibility and applicable funding conditions before submission.

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. The maximum number of countries can be increased to 6 (six) if Slovakia is included in the consortium as underrepresented country.
- C. Depending on the funding organisation there are two different possibilities to include national partners (see Annex I and table in the funding mechanism section from the guidelines for applicants):
 - i. For funding organisations that restrict funding to **a single partner per country/region**: Only one national/regional partner may join the consortium. This partner may allocate budget to other eligible national recruiting sites through subcontracting or collaboration agreements (these sites are considered 'associated partners'). If patient recruitment underperforms, initial recruiting sites may be replaced by additional ones, subject to the national/regional regulations of the respective funding agency
 - ii. For funding organisations that fund **multiple partners per country/region**: A maximum of 3 (three) eligible partners from that country/region may join the consortium. They will be funded individually and manage separate budgets. They collectively count as one country toward the consortium's maximum country limit.
- D. No more than two funding organisations from the same country may participate in a single consortium. If a consortium includes partners applying to different funders within the same country, those partners must still adhere to the maximum partner limits (detailed in point C) established by their respective funding organisations. Please check national guidelines for specific details.

- E. Consortia may include a maximum of 3 (three) **Collaborators**. Collaborators are self-funded partners who do not request funds from any of the participating funding organisations (e.g., partners from non-funding countries or those ineligible for regional/national funding). 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.
 - A Collaborator cannot be the sponsor of the study.
 - In the case that the Collaborator is a private for-profit entity, it is required that the consortia duly justify this involvement in the proposal and that there is no commercial purpose for this collaboration.

Table 2: Possible composition of consortium

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 (irrespective of countries)	3	3	3

Each consortium must nominate a **clinical study Coordinator** among its partners (this CANNOT be 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.

Usually, the institution that hosts the Coordinating Investigator acts as the **Sponsor** of the study. The following conditions apply for Sponsors:

- Only a single sponsor per consortium is allowed
- A PI of one proposal cannot act as a sponsor representative of another proposal
- The sponsor can only be located in one of the participating countries of a consortium.
- The sponsor cannot be a collaborator of the consortium (i.e. self-funded partner)

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

A partner search tool, called **PartFinder**, is available on the [ERA4Health website](#) to help finding suitable consortium partners (filter by choosing the call name “ERA4Health JTC9 IICS4all”).

Financial and legal modalities

Each consortium partner will be funded by its respective 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 shall be implemented in compliance with applicable national rules and regulations, where applicable, EU/EEA (European Economic Area) State Aid rules (http://ec.europa.eu/competition/state_aid/overview/index_en.html) as well as 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 required to contact their national/regional funder contact points to check their national/regional eligibility rules before submission (see Annex I). Please note in some countries/regions this **may be mandatory**.

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.

Additional Management 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 authorisations, Investigational Medicinal Product (IMP) or medical device purchase, labelling and distribution, safety and data management under the responsibility of the sponsor through collaboration with ECRIN (www.ecriin.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 should 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). ECRIN provides services for multinational clinical trials with single sponsors. To guarantee that the collaboration is well established and with enough time, the consortium must **inform ECRIN representatives (Eucos)** as soon as possible and before this **deadline: 30th of November 2026** that they are preparing an application.

To establish this contact with ECRIN, the consortium must contact the Euco (European Correspondent) from the country to which the Coordinating Investigator/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 Coordinating Investigator/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 has been 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).

If applicants do not request the additional funding for cross-cutting management activities, they should clearly outline how these types of cross-cutting activities will be supported/funded in the study.

Submission of joint proposals

Joint applications will follow a two-step procedure: consortia first submit pre-proposals for evaluation. Successful consortia are then invited to submit a full proposal. In addition, the full proposal review process will be complemented by a rebuttal phase and a dedicated written feasibility check. 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:

Table 3: Timeline application process

27 th October 2026	Publication of IICS4all call
10th November 2026	Online info session for applicants. Registration link: https://events.teams.microsoft.com/event/c3dcc787-cfdd-4da2-8067-7f1d3ce16250@fb1d50ca-b2da-4b61-afb4-068ca84158be?source=copyLinkLegacyShareLinkDialog
30th November 2026	Deadline to contact ECRIN representative for cross-cutting management activities
14th January 2027 12:00 CET	Deadline for pre-proposal submission
Mid-April 2027	Communication of the results of the pre-proposal assessment (invitation for full proposal)
14th June 2027 12:00 CEST	Deadline for full proposal submission
23th August – 3rd September 2027	Rebuttal stage
End of October 2027	Communication of the funding decisions to the applicants
January – May 2028	Expected project start (subject to national procedures)

The pre-proposal template is available on the ERA4Health website (<https://era4health.eu/calls/iics4all2027.php>).

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.

Any pre-proposals or full proposals submitted without using the relevant template will be declared ineligible. 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.

Widening concept

For the submission of full proposals, the widening concept will be available. It is possible, but not mandatory, to add a new partner that is eligible for funding by certain funding organisations (where there are a low number of eligible applicants at the first step). The widening process consists of the inclusion of one new partner from one of the underrepresented funding organisations/countries from 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 Coordinating Investigators 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 obtain approval from their national funding organisation before the submission of the full proposal** (see contact details in Annex I of the call text). For this, the new partner needs to **contact their national funding organization no later than calendar 10 days prior to the full proposal submission deadline**.

Changes between pre- and full proposals

If invited to submit a full proposal, no increase of the total requested budgets per partner is permitted.

In exceptional cases well-justified changes can be considered:

- minor budget changes will need to be agreed with the national/regional involved funding organisations prior to submission of the full proposal;
- changes of the consortium composition, e.g. widening concept or inclusion of an additional Collaborator, need to be communicated to the JCS and will need to be agreed by the Clinical Study Steering Committee (CLSC, composed of one representative from each funding organisation participating in the call);
- changes to the study design are only permitted if the changes address specific requirements identified by reviewers.

These changes need to be communicated and agreed with the JCS and the involved national funding organisation no later than calendar 10 days prior to the full proposal submission deadline.

Further information

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

8 Evaluation and funding decision

Eligibility check and evaluation procedure

Formal check and evaluation procedure of pre-proposal

After submission, the JCS will perform a formal eligibility check (e.g. date of submission; consortium composition; appropriate limits on length, signatures) and the funding organisations will perform a national/regional eligibility check.

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 trial 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 according to the evaluation criteria (as defined below). The evaluation will include an eligibility check that the proposal is included in the call scope (e.g. disease area, study type, etc). Based on the scores in the written evaluations, a ranking list will be established. The CLSC members will 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 procedure of full proposals

After submission, the JCS will perform a formal eligibility check, and the funding organisations will perform a national/regional eligibility check.

Each eligible full proposal will be allocated to three reviewers with a scientific/clinical background and taking into consideration the potential conflicts of interest. 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 according to the evaluation criteria for full proposals (see evaluation criteria below) including a dedicated feasibility assessment.

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

Each Coordinating Investigator 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.

During the PRP meeting, the reviewers will discuss all proposals and produce a ranking list of proposals recommended for funding. Representatives of the Patient Advocacy Committee will present their assessment of the patient involvement of each proposal during the PRP meeting. They will have the same voting rights as 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 (i.e. out of the scope) will be declared ineligible and will not proceed to full proposal assessment stage and, independent of their scientific quality, will not be considered for funding.

Pre-proposal

1. Excellence

- Scientific relevance, scientific quality and target of an unmet clinical need or evidence gap.
- 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 guidelines, and the healthcare system (e.g. socio-economic impact, evidence-based health policy decisions)
- 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 study conduct

- Appropriateness of the study design, suitability of methodological approach
- Adequate consideration of diversity and inclusion e.g. sex-, gender-, age-related or other diversity-related aspects in the clinical study design, implementation, analysis and study recruitment
- Ethical acceptability, feasibility of the project
- Adequacy of the budget: appropriate distribution of resources in relation to project plan and duration
- Quality of the research team (complementarity of expertise, expertise in relation to the conduct of the study, expertise in conducting 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 study conduct

- Appropriateness, coherence and feasibility of the study design and methodology 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 as well as access to underrepresented populations).
- 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/appropriateness of resources, staff and activities dedicated to RRI, including ELSI (Ethical, Legal and Social Issues) aspects, in design and implementation of the clinical study.
- Adequate consideration of sex-, gender, age-related or other diversity-related aspects in the clinical study design, implementation, analysis and study recruitment.
- Adequacy of the plan for compliance with regulatory requirements and international standards (GCP, Declaration of Helsinki, CONSORT-Statement) as well as applicable EU and national legislation, including Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use.
- 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 in accordance with applicable ethical, legal and data protection requirements.

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 conducting multicentre clinical trials)
- Complementarity and completeness of skills and expertise within the consortium (clinical, methodological, trial biostatistical expertise, diversity of the team)
- 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
- Adequacy of trial design to inform on diversity and inclusion aspects e.g. sex-, gender-, age- or other diversity-related aspects

A consortium will not be funded if the sponsor does not demonstrate 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 on a scale of 1 to 5 (whole numbers only). 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 there are a number of shortcomings.

4 = Very Good. The proposal addresses the criteria very well, but there are a small number of shortcomings.

5 = Excellent. The proposal successfully addresses all relevant aspects of the criteria. Any shortcomings are minor.

The maximum possible score is 15 points for pre-proposals and 25 points for full proposals.

Full proposals will be considered fundable if an average score of at least 3 points on each individual criterion and a total score of at least 17 points is achieved.

Rebuttal stage

Before the PRP members meet to discuss the full proposals in a PRP meeting, each Coordinating Investigator 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** (23rd August to 3rd September 2027) to provide an optional response to the reviewers' comments. Answers sent after the notified deadline, or which are not related with reviewers' comments or questions will be disregarded.

Assessment of study feasibility

To ensure the feasibility of the proposed study, the capacity of the Coordinating Investigator to implement the proposed clinical study and of the sponsor to oversee and manage the clinical study will be assessed at the full proposal stage in two stages. In the first stage, the Coordinating Investigator and the sponsor of the study will be requested to address the following points in writing within the annex of the full proposal. To provide details of:

- Previous experience of the Coordinating Investigator and the sponsor in conducting multicentre and/or multinational clinical trials;
- Risk identification and planned mitigation measures;
- Daily management, quality assurance and operational aspects of the study;
- Governance and communication flows among the committees that they will put in place to ensure the feasibility of the trial.

In the second stage, the reviewers evaluating the full proposals will have the opportunity to pose specific follow-up questions to the sponsor and Coordinating Investigator regarding the feasibility as part of their written evaluation. These questions will be forwarded to the sponsor and the Coordinating Investigator and they will need to be answered as part of the rebuttal letter.

PRP meeting

The JCS will give the PRP members access to all full proposals, reviews including specific follow up questions to sponsor and CI and rebuttals, whilst 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, 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 regulations²². A meeting will be organised for a discussion between the various ethics experts if serious or complex ethics issues are identified in at least one full proposal. If necessary, the ethics experts may ask the consortium for clarifications on ethical points related to the proposed research approaches and documents such as the patient consent form. The Ethics experts may highlight some points that need to be monitored during the implementation of the funded project. Only the proposals approved by both the scientific evaluation and ethical assessment (complying with all central Horizon Europe and regional/national ethical requirements), will be funded. In addition, projects involving human embryonic stem cells (hESC) or human embryos (hE) cannot start without receipt of prior ethics review carried out by the European Commission and subsequent decision of the Horizon Europe Programme Committee.

Clinical study selection and reconfiguration process

National /regional funding organisations will first select the main list of funded clinical studies based on the PRP ranking, available budget, and ethical clearance outcomes. If funding budget remains after this list is established, additional high-quality proposals may be invited to restructure their consortia, i.e. adjust their partner composition to meet the availability of remaining funds from the participating funding organisations. If invited, these research consortia will have 15 calendar days to complete the optional reconfiguration process.

Restructuring may take place with the following boundary conditions:

- Invitation for restructuring will only be considered when availability of certain national/regional funding is the limiting factor.

²² Reference to EU Regulation 2021/695 and how-to-complete-your-ethics-self-assessment_en.pdf ([europa.eu](https://europea.eu))

- 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 will be 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. Reconfiguration shall not alter the scientific objectives, methodology, budgetary basis or ranking-relevant elements of the proposal, except to the extent strictly necessary to replace the affected partner. The selection of 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 for communicating this information to their clinical study partners. ERA4Health will publish the information regarding the co-funded projects by the call on its website, once that the call procedure is completely finalised.

9 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 is 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 via the Coordinating Investigator to the JCS (iics4all@dlr.de) 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 Coordinating Investigator 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.

10 Responsibilities, Reporting requirements and Dissemination

Consortium Agreement

The Coordinating Investigator will be responsible for putting a Consortium Agreement (CA) in place 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 IP needed for exploiting their results, unless the beneficiary that holds the background IP has — before acceding to the Agreement — informed the other beneficiaries that access to its background IP 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 within 6 months of the start of the grant. 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 Coordinating Investigators 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](#) and [Zenodo](#) at no cost.

Any clinical study funded within this call is required 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 must be published with open access and additionally made available in a publicly accessible registry (WHO primary registry).

New research data resulting from the study should be treated according to the [FAIR](#)²³ principles, and deposited and shared, according to the national rules of the countries involved. Further information can be found in the ERA4Health “[Guidelines for data sharing of investigator-initiated clinical studies](#)”. 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) within 6 month of the official start of the funding and an update of the DMP will be required at the end of the projects.

Monitoring

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 after the start 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 two months after the funding period. In addition to the reports, information related to some indicators related to the study may be collected on a platform/survey. The Coordinating Investigator 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)):

Table 4: Overview on Milestones

M1: The Project has obtained all required administrative and regulatory authorisations	Milestone 1.1 Signed declaration by trial sponsor and conduct of the clinical trial according to ICH-GCP
	Milestone 1.2. Proof of registration on a publicly assessable clinical trials database
	Milestone 1.3. 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)

²³ <https://www.nature.com/articles/sdata201618>

	Milestone 1.4. Final approved version of the Data Management Plan
	Milestone 1.5. Establishment of Governance Boards, including Data Safety Monitoring Board
	Milestone 1.6. Data Management System
	Milestone 1.7. 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 completed	
M9: Publication of results	

*Including:

- Sponsor-site agreements with all participating recruiting sites. ERA4Health provides a template for the Clinical Site Agreement that can be found [here](#).
- 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 Coordinating Investigators of each consortium will 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 Coordinating Investigator 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).”

National/regional funding organisations may require additional acknowledgements.

11 Confidentiality

The CLSC 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.

12 General Data Protection Regulation

The following Data Privacy Notice applies:

By submitting an application, applicants acknowledge that their personal data²⁴ will be used, processed and retained in accordance with the applicable data protection legislation and the relevant lawful basis, including article 6.1 (e) and (c) of the General Data Protection Regulation (GDPR) (2016/679) with 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;

²⁴ 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, Lols, study proposals (scientific document, administrative and financial appendix).

- 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). Any transfer of personal data to Third Countries²⁵ will be carried out in accordance with the applicable data protection legislation and subject to the required safeguards for international data transfers.

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.

²⁵ [Data protection adequacy for non-EU countries](#)

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
Maximum/minimum funding per grant awarded to a clinical study partner	The FWF generally does not have any minimum limit. The maximum limit per project submitted to the FWF is €450.000. Projects requesting funding above this upper limit will not be eligible.
Funding mechanism	The eligibility criteria for the Austrian research institution and its appointed principal investigator are described in sections 1.3 and 1.4 of the FWF Application Guidelines and the restrictions on the number of projects. 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. If the following option is intended, please contact the FWF office before the submission deadline: 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	Austrian research institutions must be registered in the FWF's Research Institution Portal before the submission of the pre-proposal. The proposed research must be carried out in Austria under the auspices of the Austrian lead research institution. Applications are submitted by the research institution where the project will be carried out. Please refer to section 1.3.1-1.3.2 of the FWF Application Guidelines for more details.
Eligibility of costs, types and their caps	The budget specified in the national submission must correspond to this consortium partner's budget submitted to the EP and be calculated on the basis of the applicable FWF personnel cost rates at the time of submission in both the pre-proposal and full proposal stages. Minor deviations resulting from updated FWF personnel cost rates between

	stages are permissible. To ensure consistency, project costs should be calculated on elane (FWF) prior to inclusion in the consortium proposal. The FWF does not fund institutional or indirect overhead costs. The “General Project Costs” automatically calculated in the elane cost breakdown on the basis of the requested FWF cost categories are an FWF-specific flat rate and may be reported under the “Overheads” heading in the EP budget forms for technical reasons, even though they do not constitute overheads in the FWF sense. 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 (see section 2.3 of the FWF Application Guidelines). The FWF does not finance the infrastructure or basic equipment of research institutions. In addition, funding may be requested for project-specific work at the associated research partner’s institution (if already registered in the FWF’s Research Institution Portal). Associated research partners are researchers working on a project-specific basis at other Austrian research institutions (associated research institutions) and who are making a significant scientific/scholarly contribution to the project. Please refer to section 1.5 of the FWF Application Guidelines for more details.
Duration of the clinical study	As specified by the EP ERA4Health.
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 to the Call Secretariat, <u>administrative data must be submitted online to the FWF on elane (user manual) for both the pre-proposal and the full proposal stages</u> before each specific deadline. When <u>submitting pre-proposals to the FWF</u>, applicants must choose the program category “PIK – International Projects Pre-Proposal” (<u>deadline January 15th 2027, 2:00 pm CET, local time</u>) and upload the following documents as individual annexes: • CV of the FWF principal investigator (pursuant to the FWF Application Guidelines, section 2.2.3, Annex 3). • Proof of publication output of the FWF principal investigator (pursuant to FWF Application Guidelines, section 2.2.4). IMPORTANT: Please note that applications are only valid once they have been approved for submission by the research institution (PROFI) in the submission portal in due time before the specified deadline. For the full proposal stage, applicants must choose the program category “KIN– International Projects” (deadline June 15th 2027, 2:00 pm CET, local time). The FWF will contact applicants invited to submit a full proposal with further information.

	Please note that it is not necessary to upload the proposal itself as this document is provided to the FWF by the Call Secretariat.
Submission of other information at the national level	For the submission to the FWF see section “Submission of the proposal at the national level”.
Submission of financial and scientific reports at the national level	For funded projects, this information is communicated as part of the Grant Agreement.
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 provisions set out in this national annex are binding for all FWF applicants and apply in addition to the requirements of the respective European Partnership. FWF applications must meet all eligibility criteria at both the pre-proposal and full proposal stages. *It is recommended to reach out to the FWF contact if you have questions regarding the national project. *Projects that do not comply with the FWF submission guidelines will be declared ineligible. *Applicants are required to submit the necessary documents to the FWF for both the pre-proposal and the full proposal stage. *Detailed budget planning should be first performed in elane. *Overheads are not eligible costs for FWF-funded projects (see section “Eligibility of costs, types and their caps”).

	Belgium
Funding organisation	Belgian Health Care Knowledge Centre (KCE) – KCE Trials Programme
National contact person	Renate Zeevaert / France Vrijens trials@kce.fgov.be Prior the submitting of the proposal, it is required to get in touch with the national contact persons to clarify the specific requirements of this call.
Funding commitment	Up to a maximum of 1.500.000 €.
Anticipated number of fundable proposals	KCE anticipates funding several projects (2-6), 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: - a maximum of 800.000 € for projects where the Belgian partner acts as sponsor of the trial. This amount includes both sponsor-related costs and sites costs within Belgium. - a maximum of 400.000 € per project where the Belgian partner acts as Belgian Coordinating Center of the trial. This amount includes costs for sponsor-delegated tasks to BCC, where applicable, and site costs within Belgium. It is not anticipated that coordination fees will exceed site fees.
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. 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. 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. Specifically: - If the partner acts as <u>sponsor</u>, it must have successfully completed a KCE Trials sponsor capacity assessment. - If the partner acts as <u>BCC</u>, it must, depending on the tasks it is committed to conduct, demonstrate sufficient operational support from a Belgian clinical trial centre (CTC) or equivalent. Regardless of the role (Sponsor or BCC), the Belgian partner must: - 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. ➤ If the Belgian partner is the <u>Sponsor</u>: a signed sponsor letter of commitment. ➤ If the Belgian partner is the <u>BCC</u>: two signed letters of commitment (one by the BCC, one by the international sponsor), confirming acceptance of the KCE Trials terms and conditions. ➤ 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. - Declare no conflicts of interest, in accordance with the <i>General principles for the declaration of interests by applicants and the management of (potential) conflicts of interest in KCE-funded clinical trials</i>. 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 <u>from at least one recruiting centre in each Belgian region</u> (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. All 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. The general budgeting principles outlined in the KCE Trials budget tool and guidance will be followed. Applicants are encouraged to use the KCE Trials budget tool as an aid to build their budget. KCE Trials will perform a check of submitted budgets against this tool. These costs include: - Personnel and non-personnel costs essential to the execution of the project - Costs not covered by the infrastructure of the Belgian partner institution Ineligible costs include: - Costs already included in the tasks allocated to ECRIN or its subcontractor or another partner (cross-cutting tasks). - Costs solely related to other countries (e.g. buying, labeling and distributing drugs in other countries. Tasks can be organized by a single country but other countries should contribute pro-rata to the costs). - Costs related to translational research and exploratory endpoints (e.g. biobanking..). Site fees 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. If there are medical interventions, imaging, laboratory analysis or (day)hospitalisations that are not performed and reimbursed in the usual way (standard of care), the corresponding INAMI-RIZIV nomenclature number should be mentioned and the corresponding rate applied. 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
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 trialsatKce.fgov.be) no later than the ERA4Health deadline. The required documents include: ➤ If the Belgian partner is the <u>Sponsor</u>: a signed sponsor letter of commitment. ➤ If the Belgian partner is the <u>BCC</u>: two signed letters of commitment (one by the BCC, one by the international sponsor), confirming acceptance of the KCE Trials terms and conditions. ➤ 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. 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). Progress Reviews 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. Clinical Study Report submission If the Belgian partner is the Sponsor, they are responsible for preparing a Clinical Study Report (CSR) in accordance with the CONSORT statement guidelines. If the Belgian partner is a Belgian Coordinating Centre (BCC) and a CS is available, the BCC must either: - Submit the CSR directly to KCE, or - 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. 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 and in Belgium and an unlimited, irrevocable and transferable right to use the data, only for research and health policy related purposes (<i>see more details in KCE contract templates</i>). Data access also includes the possibility for KCE to use the coded national registry number of Belgian participants to allow data linkage for public health purposes. Researchers funded by KCE must follow the <i>KCE Trials policy on Research transparency</i>.
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: <i>“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).”</i>

Country	Czech Republic
Funding organisation	Ministry of Health of the Czech Republic (MZCR)
National contact person	Monika Kocmanova National coordinator on Health-related European Partnerships (AZVCR) Phone : +420 778 973 186 Email : monika.kocmanova@azvcr.cz Olga Laaksonen Head of the Science, Research, and Subsidies for Education Unit (MZCR) Phone : +420 224 972 755 Email : olga.laaksonen@mzd.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. 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	IMPORTANT: The Czech applicant can only participate as a project partner, not as a coordinator under this call. Research Organisations, Enterprises, Patient Organisations. All eligibility rules and criteria can be found on the Czech Health Research website (ERA4Health Výzva 2027 – AZV ČR). It is strongly recommended to contact the responsible person at the Czech Health Research Council (prior to submission regarding the eligibility criteria). • Conditions for PO funding – Patients 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 criteria for the Principal Investigator: The PI must hold a Ph.D. degree (for more information, please refer to the national document "<i>Podmínky pro zapojení českého uchazeče do výzvy</i>",

	available on the AZV CR website). MZCR/AZVCR sets a criterion for the maximum workload, which must not exceed 1.00 FTE within a single submitted project. There is no minimum workload requirement for the PI in relation to European Partnerships (EP) in health-care area imposed by the national funding authority (MZCR). However, the allocated FTE must correspond to the actual workload required for the project. Within the EP, the assigned FTE is subject to verification by the institution or organisation employing the PI. Therefore, the provisions of Act No. 262/2006 Coll., the Labour Code, must be respected. AZV CR does not impose any additional FTE-related restrictions within the framework of the EP. • Definition of ECR - A natural person engaged in research who, in the year of submission of the Project proposal to the call for proposals, has received their Ph.D. academic title or its equivalent in the past 8 years, or has obtained it no later than the date of conclusion of the Contract/issuance of the Project Decision. If the Proposer has been on maternity or parental leave, has suffered a long-term illness, or has interrupted his/her scientific career for similar objective reasons, the time limit of 8 years from the award of the academic degree of Ph.D. or its equivalent is increased by this period. These facts (award of the degree, parental leave, etc.) shall be documented by the Applicant by means of a Sworn Statement.
Eligibility of costs, types and their caps	All eligibility of costs, types and their caps can be found on the Czech Health Research Council (ERA4Health Výzva 2027 – AZV ČR). It is strongly recommended to contact the responsible person at the Czech Health Research Council (prior to submission regarding the eligibility criteria).
Duration of the clinical study	For the Czech applicants: 36 months. IMPORTANT: All projects will be funded under the Programme for the Support of Applied Health Research for the Years 2024–2030 and <u>must therefore start on 1 January 2028 and be completed no later than 31 December 2030, as the programme itself ends at the end of that year.</u>
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.
Submission of the proposal at the national level	Prior to submission of the <u>pre-proposal</u> to EP ERA4Health, Czech researchers need to submit to the Czech Health Research Council the following documents: 1. Sworn Statement of a Legal Entity / Natural Person (mandatory) 2. Sworn Statement for a Research Organisation (if relevant) 3. Sworn Statement of composition consortium (only if SMEs or industry are involved in the project proposal from the Czech side)

	4. Application Form 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. All these documents are available on the website at the Czech Health Research Council AZV ČR – ERA4Health Výzva 2027 – AZV ČR. Prior to submission of the <u>full proposal</u> to EP ERA4Health, Czech researchers need to submit to the Czech Health Research Council the following documents: 1. Documents related to <u>professional competence</u>, depending on the nature of the project, must be provided in the form of a Sworn Statement, which will be available on the website at the Czech Health Research Council AZV ČR – ERA4Health Výzva 2027 – AZV ČR. 2. Updated Application Form 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.
Submission of other information at the national level	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. 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 the EP ERA4Health calls, 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 / 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,” and detailed

	information will be available on the Czech Health Research Council website - AZV ČR – Czech Health Research Agency .
Starting date of the clinical study	In line with the start date (1 January 2028) of the project as stated in the “Contract” or “Decision” on the provision of support or the issuance of a decision.
Further guidance	ERA4Health Výzva 2027 – AZV ČR Please note: the Call is administered by the Czech Health Research Council (AZV CR) at the national level but the Ministry of Health of the Czech Republic (MZ CR) is the funding organisation. IMPORTANT: In the Consortium Agreement, it must be stated that due to national funding conditions applicable to Czech partner, the project duration for the Czech partner differs from that of the other consortium partners. The Czech partner must start its project activities on 1 January 2028 and complete them no later than 31 December 2030.

Country	Egypt
Funding organisation	Academy of Scientific Research and Technology (ASRT)
National contact person	Asmaa Abdellah and Amr Radwan Email: innov@sti.sci.eg; engasmaa2005@gmail.com; radwan.amro@gmail.com Telephone: +20 2 2792 0126 Address: 101 Kasr Al-Ainy Street, 6th Floor, Cairo 11516, Egypt
Funding commitment	EUR 300,000
Anticipated number of fundable proposals	3 (indicative, subject to the scientific ranking, national eligibility and available budget)
Maximum/minimum funding per grant awarded to a clinical study partner	Maximum ASRT contribution to the Egyptian participation in one clinical study consortium: • Up to EUR 100,000 where the Egyptian participant(s) participate as partner(s). • Up to EUR 130,000 where an eligible Egyptian legal entity acts as the clinical study coordinator. Where more than one Egyptian partner participates, the applicable ceiling is shared among all ASRT-funded Egyptian partners.
Funding mechanism	Only one Egyptian organisation will be funded per proposal. ASRT will contract directly with this organisation, which will establish collaboration agreements with other additional national recruiting sites.
Eligibility of partners	• Eligible applicants are Egyptian legal entities established in Egypt, including public or private universities, research institutes, university hospitals and other healthcare or research institutions, non-profit organisations, SMEs and enterprises, provided that they can perform the proposed work and sign a national grant/contract with ASRT. • Participation of a private for-profit entity must be duly justified. A commercial enterprise or other for-profit organisation may not act as the clinical study coordinator. • All central ERA4Health eligibility and clinical-study requirements apply. Each Egyptian partner must have the expertise and institutional capacity required for its role; an Egyptian coordinator and/or sponsor must demonstrate capacity for multi-country study oversight, ethics, regulatory compliance and Good Clinical Practice. • At the time of national contracting, the Egyptian PI may not hold more than two ongoing ASRT-funded projects as PI or coordinator.

Eligibility of costs, types and their caps	Funding rates - Universities, public research bodies and public hospitals: up to 100% of eligible costs, subject to the national ceilings above. - Other legal entities (e.g., non-profits, SMEs, enterprises) able to carry out the work and sign a national grant/contract with ASRT. Applicants of other legal forms can contact ASRT before submission to confirm the applicable funding rate and any national conditions. General conditions - Costs must be necessary, reasonable, directly related to the approved work plan, appropriately documented and not financed from another source.
Eligibility of costs, types and their caps (continued)	Eligible cost categories - Personnel: PI, researchers, clinicians, data managers, technical and support staff assigned to the project. Time records are required. Personnel costs are capped at 25% of the ASRT-requested contribution for each Egyptian applicant. - Consumables and project materials: laboratory consumables, kits, study materials and small supplies required for the approved activities. - Other direct clinical-study costs essential to achieve the objectives, such as sample processing, storage and shipment; access to specialised facilities, databases and software; patient and public involvement; data curation and repositories; regulatory or ethics-related fees; study insurance; monitoring; data management; biostatistical support; publication and intellectual-property costs; and external services that are not core scientific tasks. Such costs must be specifically justified. - Equipment: eligible only where directly required for the study and fully justified in relation to the proposed activities. - Travel and subsistence: in accordance with the applicable rules of the Ministry of Higher Education and Scientific Research and the host institution; economy class only; travel must directly serve the work plan, including justified consortium and ERA4Health meetings. - Meetings and events: reasonable organisational costs for scientific meetings, workshops and consortium meetings directly linked to the study. - Patient and Public Involvement (PPI) and FAIR data-management costs: eligible where relevant, including patient or user engagement, data curation and use of appropriate repositories. - Indirect costs (overheads): 5% of eligible direct costs. Not eligible or capped - Activities primarily supporting teaching programmes, stand-alone website launches, or the design or development of original teaching tools are collectively capped at 15% of the Egyptian applicant's requested budget. Research communication and dissemination remain eligible where directly linked to the study. - Costs related to activities with a direct commercial purpose, and costs

	not necessary for the approved clinical study are not eligible.
Duration of the clinical study	Up to 48 months. The exact contractual start and end dates will be defined in the ASRT grant agreement in accordance with the final call arrangements.
Specific rules for potential extensions	Potential extensions are exceptional and subject to prior written approval by ASRT. Any request must be submitted before the contractual end date and supported by a clear scientific, operational and financial justification. Approval of an extension does not entail an automatic increase in ASRT funding.
Submission of the proposal at the national level	No separate national proposal is required at the pre-proposal or full-proposal stage. The joint proposal must be prepared in English and submitted by the coordinating investigator through the ERA4Health electronic submission system in accordance with the call text.
Submission of other information at the national level	No additional national documentation is required at the initial submission stage. During the national eligibility check and grant-preparation stage, ASRT may request supporting legal, administrative, financial, ethical and regulatory documentation.
Submission of financial and scientific reports at the national level	ASRT-funded partners must submit periodic and final scientific and financial reports in accordance with the national grant/contract and applicable ASRT policies, in addition to the reporting required by ERA4Health and the Joint Call Secretariat. Reports must document progress against the work plan, milestones and recruitment targets, where applicable, and include statements of expenditure and supporting records.
Starting date of the clinical study	Expected within six months following the official ERA4Health approval notification, subject to completion of national grant preparation and the applicable ethical and regulatory approvals. 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.
Further guidance	

Country	FRANCE
Funding organisation	French Ministry of Health
National contact person	melanie.fisher@sante.gouv.fr cecile.fragny@sante.gouv.fr
Funding commitment	1.500.000 M€
Anticipated number of fundable proposals	3 to 4
Maximum/ Minimum funding per grant awarded to a clinical study partner	<u>Funding Scenarios</u> - Case 1: A maximum of €500,000 per project may be granted. - 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. <u>Important Note:</u> 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 funding 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. A partner must be composed of a physical leader and of a health care institution, which manages the financing. The physical leader must be contractually linked to a healthcare institution specified above 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. Minimum funding per awarded to a partner: 10 000 € 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. Investment expenses giving rise to depreciation are not eligible.

	Management costs up to 10% of personal expenses are eligible. Further information and questions pertaining to specific eligible costs can be found in the rules and FAQ detailed in the budget grid.
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: 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. Additional administrative and budgetary documents must be submitted to the FR MOH (DGOS) in parallel with the pre-proposal submission, via the Démarches Numériques platform: - A signed submission certificate (to be valid, the document must bear at least three of the required signatures) - A budget grid Submission Date: Same as the deadline for submission of pre-proposal These documents will be available for download on the website of the French Ministry of Health: https://sante.gouv.fr/systeme-de-sante/innovation-et-recherche/l-innovation-et-la-recherche-clinique/article/partenariat-era4health The link to the Démarches Numériques platform for submitting the documents will be available as soon as the application submission phase opens.
Submission of other information at the national level	
Submission of financial and scientific reports at the national level	Each funded institution is required to submit a report on expenses to FR MOH each civil year. The expenses reported must be in direct relation with the project. They must be necessary for project implementation and conform to the selected project.
Starting date of the clinical study	First semester of 2027.
Further guidance	The delegation of funds will be performed through budgetary circulars of the Fr MoH. Funds will be allowed regarding project progression.

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. Svenja Krebs Dr. Eva Müller-Fries Phone: +49 228 3821 2567 E-mail: era4health@dlr.de Address: DLR Projektträger, on behalf of the BMFTR Heinrich-Konen-Str. 1 53227 Bonn Germany 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	5
Maximum/ Minimum funding per grant awarded to a clinical study partner	Up to 600.000 € for regular German partners; up to 800.000 € 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): - Personnel (e.g. project management, clinical project management, coordination and quality assurance); - case payments; - patient and target group involvement; - materials;

	- Fees and Insurance; - Travel & networking costs; - Communication, Dissemination and Publication costs; - Overhead costs ("Projektpauschale"). Overheads are eligible according to standard BMFTR regulations. 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. Only investigator initiated, prospective and randomised interventional clinical phase III studies can be funded. Not eligible for funding are studies involving healthy individuals (with the exception of pregnant women), studies on issues relating to primary prevention, studies aimed at investigating a diagnostic procedure without subsequent intervention and observational studies.
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	March 2028 (the earliest)
Further guidance	https://www.gesundheitsforschung-bmftr.de/de/20075.php

Country	Ireland
Funding organisation	Health Research Board (HRB)
National contact person	Dr Fiona Manning Dr Shannon Lee Email: EUTrials@hrb.ie
Funding commitment	€1,500,000
Anticipated number of fundable proposals	2-3
Maximum/minimum funding per grant awarded to a clinical study partner	Up to a maximum of €650,000 per project, including overhead contribution of 30% of Total Direct Modified Costs (TDMC excludes sub-contracting, equipment and capital building costs). Overheads are applied in accordance with the HRB Policy on Usage of Overheads .
Funding mechanism	HRB will contract with a single Host Institution (Lead Applicant). Additional national recruiting sites (Associated Partners) are permitted to join the consortium. The Lead Applicant will be responsible for appropriate distribution of funds to the Associated Partner(s) via collaboration and/or consortium agreements. The HRB does not have a limit on the number of associated partners that will act as clinical study sites. Partners classed as 'Enterprise' cannot be in receipt of HRB funding as Partners or Collaborators. Third Party Organisations providing specific services to the Project can be paid by the Host Institution via sub-contracting costs, subject to the relevant Procurement and other relevant requirements and regulations.
Eligibility of Partners	Please refer to the IICS4All scheme page on HRB's website for detailed guidance on eligibility for applicants based in Ireland. (https://www.hrb.ie/funding-scheme/era4health-partnership-2027/)
Eligibility of costs, types and their caps	Please refer to the IICS4All scheme page on HRB's website for detailed guidance on eligible/ineligible costs (https://www.hrb.ie/funding-scheme/era4health-partnership-2027/)
Duration of the clinical study	48 months
Specific rules for potential extensions	12-month no cost extension (NCE) permissible in line with HRB Policy on No -Cost Extensions .
Submission of the proposal at the national level	The Host Institution must send the pre-application to EUTrials@hrb.ie within three working days following the submission deadline, along with the completed Host Institution sign off form (available on HRB's call webpage (https://www.hrb.ie/funding-scheme/era4health-partnership-2027/)). Additional requirements apply for new applicants to JTC calls (Lead Applicant Eligibility Form) and researchers who do not have a permanent

	position (HI Letter of Support for LA in a contract position / Adjunct Professors not directly employed by the HI). These must be emailed to EUTrials@hrb.ie before the pre-proposal submission deadline. Please refer to the IICS4All scheme page on HRB webpage for further information: https://www.hrb.ie/funding-scheme/era4health-partnership-2027/
Submission of other information at the national level	At Full Application stage, applicants from Ireland must submit details of their budget and the key milestones and deliverables to HRB. Templates will be sent to applicants after invitation to submit a full Proposal. Completed deliverable and budget details must be returned to HRB no later than 3 days after the deadline for submission of the Full Proposals.
Submission of financial and scientific reports at the national level	HRB grant holders are required to submit grant reports as outlined in their grant contracts and the most recent HRB General Terms and Conditions for Research Awards . The PI must submit an Approvals Package to confirm all ethical and regulatory approvals, and contractual agreements are in place before patient recruitment commences. The PI must notify the HRB of the first patient first visit (FPFV) and thereafter furnish quarterly recruitment updates during the recruitment phase. The HRB should be notified of the date of the last patient last visit (LPLV). In addition, the PI must submit an annual activity report for the duration of the grant. Financial reports must be submitted annually.
Starting date of the clinical study	January - May 2028
Further guidance	HRB will not support activities for the development of an intervention. HRB recommends applicants to liaise with their local Sponsorship Office (or equivalent) and regulatory authority where relevant, to confirm local sponsorship/regulatory requirements All Irish Partners who are undertaking clinical interventional studies must adhere to the HRB Clinical Trial and Interventions Research Governance Policy. Applicants should contact the HRB with any queries regarding the requirements of this policy.

Country	Israel
Funding organisation	CSO-MOH
National contact person	Dr. Irit Allon irit.allon@moh.health.gov.il +972 (0)2 5082167 Netta Koren netta.koren@moh.health.gov.il +972 (0) 545889393
Funding commitment	Up to 280,000 €, depending on budget availability
Anticipated number of fundable proposals	1-2
Maximum/minimum funding per grant awarded to a clinical study partner	Up to 140,000 €
Funding mechanism	
Eligibility of partners	Researchers will only be able to participate as partners in consortia, not as a coordinating investigator. Coordinators will be considered and approved only in exceptional cases where funding is secured from other sources. Position in a university, research center or hospital. Research authority must approve position prior to submission. PI should hold a Ph.D., M.D., D.M.D., D. Sc or equivalent degree and employed by an eligible institution. Research will not be funded simultaneously by CSO-MOH on more than one grant (Era-NET or national). Researchers can not apply for more than one grant from any ERA-NET funded by CSO-MOH or submit more than one proposal for any programme.
Eligibility of costs, types and their caps	Materials and consumables; Travel and hosting (up to 5%); No salaries for applicants; No heavy equipment, Institutional overhead 10%.
Duration of the clinical study	Up to 4 years
Specific rules for potential extensions	See national guidelines
Submission of the proposal at the national level	Prior to submission, researchers will submit to CSO-MOH an abstract approved by their research authority including budget distribution. No submission of abstract can result in declaration of the consortium as ineligible.

Submission of other information at the national level	Bioethics approvals must be submitted with the application or up to 4 months later.
Submission of financial and scientific reports at the national level	Yes
Starting date of the clinical study	NA
Further guidance	Please see detailed instructions of application at the national level and reporting at https://www.gov.il/he/service/era-net-instructions-for-israeli-researchers

Country	Italy
Funding organisation	Fondazione Regionale per la Ricerca Biomedica (Lombardy Region)
National contact person	Giulia Maria Rossignolo, giuliamaria.rossignolo@frrb.it (Phone: +39 02 6765 0159) Fabio Rondini, fabio.rondini@frrb.it (Phone: +39 02 6765 0163) bandi@frrb.it
Funding commitment	1,010,000.00€
Anticipated number of fundable proposals	2 proposals
Maximum/minimum funding per grant awarded to a clinical study partner	500,000.00€
Funding mechanism	Maximum ONE eligible organisation from Lombardy PER PROJECT Only one Lombardy organisation will be granted. In order for the organisation to apply and receive funding, it is mandatory to establish agreements (e.g. subcontracting) with one or more recruiting sites. The recruiting sites must be located in the Lombardy region territory. Italian PAOs are not eligible for funding. They can still participate in Consortia as “Collaborators” with their own funds.
Eligibility of partners	Eligible institutions 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). Please note: all applicants and all recruiting sites must be located exclusively in Lombardy, and their activities must take place in Lombardy. Private IRCCSs will be required to submit a self-declaration confirming the non-commercial nature of the clinical trials carried out as part of the Era4Health project. Universities and Research Organisations may participate only as subcontractors. Enterprises and for-profit Organisations are NOT eligible.
Eligibility of costs, types and their caps	Direct costs: • Personnel (only for personnel to be recruited <i>ad hoc</i> for the project). The specific details will be set out in the reporting manual, to be issued by FRRB in due time.

	• Consumables: reagents/animal purchase, etc.. • Equipment (eligible amortization rate). • Travel: max 10% of the total direct costs (overheads and subcontracting costs excluded) • 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.). • Subcontracting: a maximum of 30% of the total direct costs, excluding overheads, may be allocated to this category. In exceptional circumstances, this ceiling may be increased to 40%. FRRB reserves the right to assess and approve such exceptions on a case-by-case basis, taking into account factors such as the number of recruiting sites and patients involved. • Overheads: 20% flat rate calculated on direct costs (subcontracting costs excluded from this calculation). FRRB will require the submission of a financial audit certificate together with the final financial report. The cost of this audit certificate, had to be included under the “Subcontracting” category. 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 its internal procedures, FRRB will assess the eligibility of potential applicants prior to the submission of pre-proposals. The eligibility check will be based on a dedicated “Eligibility Check Form”, available on the FRRB website. The form must be completed and uploaded to the FRRB platform by the Principal Investigator (PI) at least five working days before the pre-proposal submission deadline. FRRB will provide feedback on the “Eligibility Check Form” only in the event of major eligibility issues that may prevent the applicant from submitting a pre-proposal. A Principal Investigator (PI) may not simultaneously hold more than one active FRRB grant.
Submission of other information at the national level	For clinical trials or interventional studies, PIs are required to submit an approval package confirming that all necessary ethical and regulatory approvals have been obtained and that the relevant contractual agreements are in place before patient recruitment begins.

Submission of financial and scientific reports at the national level	Annual scientific and financial reports must be submitted to FRRB in accordance with its applicable rules and procedures.
Starting date of the clinical study	N/A
Further guidance	Please refer to the information available on the dedicated FRRB website

Country	Latvia
Funding organisation	Latvian Council of Science
National contact person	Maija Bundule E-mail: Maija.Bundule@lzp.gov.lv Tel: +371- 26514481 Uldis Berkis E-mail: Uldis.Berkis@lzp.gov.lv 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 Funding rates under Regulation EC 651/2014 shall be respected in case of state aid Maximum 2 Latvian partners per proposal allowed, they must be fully independent on legal, financial and personnel basis 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. Maximum 2 funded Latvian partners per proposal allowed, they must be fully independent on legal, financial and personnel basis. 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: 1) Research institutions registered in the Latvian Registry of Scientific Institutions, e.g. - Research Institutes - Universities And must have the status of Research and knowledge dissemination organization (Regulation EC 651/2014) 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. Enterprises not having closed two annual financial periods (years) are not eligible.
Eligibility of costs, types and their caps	• Personnel costs incl. taxes; • Consumables; • Subcontracts (up to 25% of direct costs), needs detailed justification, includes all external services, project core activities cannot be subcontracted; • Equipment (only depreciation costs during project directly attributable to project tasks); • Replaceable and fully consumable during project elements of equipment (e.g. electrodes); • Travels (according to travel plan); Indirect costs (up to 25% of direct costs excluding subcontracting). 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. 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. Direct costs can not be share of total costs, it always requires evidence of really occurring costs and expenses. Funding by LCS is operated only via a Latvian banking account. Business enterprises can claim only reimbursement of their incurred eligible costs, not an advance payment. 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). 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) 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 latest 6 month after the starting date. Enterprises shall provide audited statements of 2 previous closed financial periods on request. Final audit according to the LCS regulations. Annual or in some cases half-annual financial and scientific reporting is mandatory.
Starting 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) 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. LCS cannot fund implementation support, nor training activities. LCS is funding only research The project must respect national regulations for clinical trials, including the biomedical ethics permission from an authorised ethical committee for clinical trials

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. Principal Investigator must be a PhD holder. Principal investigators from Lithuania cannot be involved in more than 1 proposal submitted to this call. 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: https://www.e-tar.lt/portal/lt/legalAct/Oa8bead0577611e9975f9c35aedfe438/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 remuneration), 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). Additional cross-cutting trial management costs can also be eligible if some of the sponsor’s tasks are delegated to Lithuanian team. 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). More details about eligibility of costs: https://www.e-tar.lt/portal/lt/legalAct/Oa8bead0577611e9975f9c35aedfe438/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 planned 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 2028, 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. General information for applicants submitting proposals to European Partnerships calls can be found here

Country	Norway
Funding organisation	The Research Council of Norway (RCN) and South-Eastern Norway Regional Health Authority (HSØ)
National contact person	Henrietta Blankson hbl@rcn.no +47 922 33 762 Torunn Berge Torunn.Berge@helse-sorost.no +47 414 17 665
Funding commitment	900 000 EUR + 400 000 EUR Total national funding is 1 300 000 EUR of which 900 000 EUR is provided by RCN and 400 000 EUR is provided by HSØ. Projects will be co-funded by the two funding organisations with 69 % from RCN and 31 % 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. 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 550 000 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. 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. 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 2028
Further guidance	Patients should preferentially be recruited from all health regions across Norway. 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

Country	Poland
Funding organisation	National Centre for Research and Development (NCBR)
National contact person	Marcin Chmielewski era4health@ncbr.gov.pl +48 571 226 666
Funding commitment	2 840 000 EUR
Anticipated number of fundable proposals	1-4
Maximum/minimum funding per grant awarded to a clinical study partner	700 000 EUR
Funding mechanism	Only one organisation will be granted. The funded organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement.
Eligibility of partners	The following entities are eligible to apply: Research organisations¹. Entities must be established as a legal person ² and must conduct its 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	The eligible costs shall be the following: 1. personnel costs 2. consumables 3. equipment 4. travel 5. other direct costs 6. subcontracting – used exclusively for the research activity; this cost category shall not exceed 70% of all eligible costs of a project 7. additional overheads – incurred indirectly as a result of the research project. These costs are counted by multiplying direct costs (excluding subcontracting [6]) by 25%. It means $7 = (1+2+3+4+5) \cdot 25\%$ For research organizations, Industrial/Applied Research and Experimental Development are eligible for funding at an intensity of 100%. Please note that Fundamental/Basic research is entirely ineligible for funding. As part of the project implementation, key tasks related to coordination, management and dissemination are eligible for funding.

¹Research organisation - an entity defined in Article 2(83) of Commission Regulation (EU) No 651/2014, and in Article 37(1) of the Act of 30 April 2010 on the National Centre for Research and Development (Polish Journal of Laws 2024, item 1170 as amended), in conjunction with Article 7(1)(1, 2, 4, 5, 6, 6a, 6b, 6c, 8) Act of 20 July 2018 of the Law on Higher Education and Science (Polish Journal of Laws 2024, item 1571 as amended);

²Legal person - an entity other than a natural person that has the legal capacity to hold and to exercise legal rights and obligations within a certain legal system, such as to enter into contracts, sue and be sued.

³if applicable. Does not apply to legal persons that are not obliged to register in a relevant Polish official register according to Polish law (e.g. KRS).

	For more details on eligible costs, applicants are advised to check cost eligibility guide (przewodnik kwalifikowalności kosztów) in the call announcement on NCBR webpage.
Duration of the clinical study	Up to 48 months
Specific rules for potential extensions	The Polish participant must notify the NCBR about the project extension and submit a formal request to amend the national contract.
Submission of the proposal at the national level	Participants from Poland will be informed and invited to submit a national application form (NAF) once the international evaluation and the ranking list have been established. Only projects recommended for funding will be asked to submit a NAF.
Submission of other information at the national level	All entities invited to submit national application form (NAF) are obliged to use European Central Bank's exchange rate in force on the day the call is opened.
Submission of financial and scientific reports at the national level	Annual scientific reports are obligatory.
Starting date of the clinical study	-
Further guidance	Sample documents are available at: https://www.gov.pl/web/ncbr/wniosek-krajowy-w-lsi 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: https://partfinder.ncbr.gov.pl/ <u>Relevant documents</u> All proposals must be aligned with national regulations, inter alia: • The Act of 20 July 2018 - Law on Higher Education and Science; • The Act of 30 April 2010 on the National Centre for Research and Development; • 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. In light of the European Commission's ongoing work on a regulation intended to replace Regulation (EU) No 651/2014, the National Centre for Research and Development (NCBR) informs that the conditions governing the provision of support set out in this documentation may be amended following the entry into force of the new European Commission regulation. NCBR may enter into a project contract provided that the participating entity: 1) is not excluded from applying for funding on the basis of:

	a) Article 207(4) of Act of 27 August 2009 on Public Finance (Polish Journal of Laws 2025, item 1483 as amended); b) Article 12(1)(1) of the Act of 15 June 2012 on the consequences of entrusting work to foreigners staying illegally in the territory of the Republic of Poland (Polish Journal of Laws 2025, item 1567 as amended); c) Article 9(1)(2a) of the Act of 28 October 2002 on the liability of collective entities for acts prohibited under penalty (Polish Journal of Laws 2024, item 1822 as amended); 2) is not an entity subject to an obligation to repay aid because the European Commission has declared such aid unlawful and incompatible with the internal market, 3) is not in arrears with payments of public dues or with social security and health insurance contributions, 4) is not an undertaking in difficulty within the meaning of EU state aid rules and is not under receivership, 5) is not subject to exclusion from applying for funding due to sanctions.
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Country	ROMANIA
Funding organisation	Executive Agency for Higher Education, Research, Development and Innovation Funding
National contact person	Mihaela Manole E-mail: mihaela.manole@uefiscdi.ro Phone: +40 21 302 38 63 Nicoleta Dumitrache E-mail: nicoleta.dumitrache@uefiscdi.ro 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. For more information : https://uefiscdi.gov.ro/parteneriate-si-misiuni-europene • 250.000 euro for all romanian partners in case a Romanian institution is the Coordinator; 200.000 for all romanian partners in case a Romanian institution is not the Coordinator.
Funding mechanism	For UEFISCDI, both options are theoretically possible: - All participating organisations will be granted and should be part of the clinical study consortium. A maximum of 3 partners are authorised. - Or only one organisation will be granted and this organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement 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. Funding rates vary in accordance with state aid legislation https://uefiscdi.gov.ro/pncdi-iv-program-8
Eligibility of costs, types and their caps	a. Staff costs; b. Logistics expenses - Capital expenditure; - Expenditure on stocks - supplies and inventory items; - 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; c. Travel expenses; 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
Starting date of the clinical study	Not specified
Further guidance	https://uefiscdi.gov.ro/parteneriate-si-misiuni-europene

Country	Slovakia
Funding organisation	Centrum vedecko-technických informácií Slovenskej republiky / Slovak Centre of Scientific and Technical Information (CVTI SR)
National contact person	- Contact: Marek Babušiak, PhD., European Partnerships Coordinator Email: marek.babusiak@cvtisr.sk, tel.: 00421 948 855 449 - Contact: Libuša Ďaďová, European Partnerships Coordinator, Email: libusa.dadova@cvtisr.sk, tel.: 00 421 915 808 814
Funding commitment	500 000 EUR
Anticipated number of fundable proposals	1-2
Maximum/minimum funding per grant awarded to a clinical study partner	The maximum funding amount is 300 000 EUR per Slovak partner, or 400 000 EUR if a Slovak partner acts as the project coordinator or if there are two Slovak partners participating in a single project. These amounts may be further increased by up to 15 000 EUR if a Slovak partner submits a patent, trademark, or design application, and/or publishes project results in an internationally indexed (peer-reviewed) scientific journal (e.g., WoS/Scopus). The minimum funding amount per Slovak project partner is 100 00 EUR.
Funding mechanism	All participating organisations will be granted and should be part of the clinical study consortium. A maximum of 3 partners is authorised.
Eligibility of partners	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. - Research institutions (e.g. the Slovak Academy of Sciences and its institutes) - Academic sector (e.g. universities and higher education institutions) - Non-governmental non-profit organizations - Cluster organizations - Private sector entities (entrepreneurial/business sector) Public administration bodies, including local and regional government authorities, are eligible to participate; however, they are not eligible to receive funding and therefore cannot have a budget allocated to them.
Eligibility of costs, types and their caps	Only direct costs that are essential to the project implementation and are directly related to its activities and timeline are eligible. No indirect costs/overheads will be funded. All costs must be fully utilized and accounted for by the end of 2029. Eligible costs:

	• 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; • Costs of instruments and equipment; • 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. General eligibility rule: All expenditures incurred by Slovak project participants must comply with: • 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 co-operation in the field of research, development and innovation; • The provisions of the State Aid Scheme to Support Partnerships in the Field of Research, Development and Innovation under the Programme Slovakia; • Strategy for Financing the ERDF, ESF+, CF, FST, and ENRAF 2021–2027. Slovak applicants are advised to thoroughly familiarize themselves with the Guide for Applicants in European Co-funded Partnerships and Guide to Eligibility of Expenses under the Programme Slovakia, as the planned co-financing will be provided through this programme. It is further recommended that at least 30% of the Slovak applicant's total budget be dedicated to the actual performance of research activities.
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	January-May 2028 (subject to national procedures)
Submission of the proposal at the national level	Submission of pre-proposal and full proposal to the ERA4Health JTC9 IICS Call Secretariat only.
Submission of other information at the national level	Following the receipt of the formal international funding recommendation, applicants will be required to submit a separate application for national funding via the national submission platform. This serves as the final formal step, with the official funding decision issued by CVTI SR once the project has been successfully recommended by the Partnership.
Submission of financial and scientific reports at the national level	Yes, yearly.

Starting date of the clinical study	Based on the agreement between partners.
Further guidance	The proposed research activities must be carried out in Slovakia, and their results must be applicable and utilized within the Slovak Republic's environment. The proposed project activities must be in line with the priorities defined in Programme Slovakia 2021-2027, 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. All Slovak entities must have their contractual financial matters settled with CVTI SR by the end of 2029. All Slovak applicants are strongly advised to contact the CVTI SR's contact points before submitting their proposals. No change of the applicant institution is allowed between the stages. The information given in the pre-proposal is binding and no major changes regarding the proposal's content or objectives are allowed between the pre-proposals and full proposals (if invited to stage 2) including the proposed budget. However, a limited number of minor administrative changes including small budget reshuffles may be allowed. Any modification must ensure that the total funding requested in the full proposal does not exceed the amount declared in the pre-proposal stage. Useful links: Programme Slovakia SK RIS3 2021+ Strategy for Financing the ERDF, ESF+, CF, FST, and ENRAF 2021–2027 State Aid Scheme to Support Partnerships in the Field of Research, Development and Innovation under the Programme Slovakia

Country	Spain
Funding organisation	Departament de Salut – Generalitat de Catalunya (DS-CAT)
National contact person	Carme Pérez 935566103 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) - Max. 300.000,00 € per project (if not coordinator) (Including overheads)
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.
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 Consumables Core facilities Travel Other (direct costs). It is compulsory to include the cost of a financial audit certificate up to a maximum of € 2,000 Overhead (Flat rate 21% calculated on direct costs) Equipment is not eligible
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

Country	Spain
Funding organisation	Institute of Health Carlos III (ISCIII)
National contact person	Ana García Sacristán and Beatriz Rubio Cuesta anagarcia@isciii.es and b.rubio@isciii.es
Funding commitment	2.400.000,00 €
Anticipated number of fundable proposals	3-4
National Programme	The Strategic Action in Health (Strategic Lines of Health Research 2024–2027, hereinafter AES 2027). (Pending to be published).
Maximum/ Minimum funding per grant awarded to a clinical study partner	Maximum funding from ISCIII <u>per awarded Spanish project</u>: • 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. • If a Spanish Partner requesting funding to the ISCIII IS NOT the Coordinator (at international level) of the clinical study: Max. 600.000,00 € per project. Overheads according to the national programme AES 2027: 25% 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. 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 2027). 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 2027 as ineligible to receive funds by ISCIII.
Eligibility of PI and team members	• Principal Investigators (PI) shall mandatory have PhD degree. • Principal Investigators (PI) can only participate in one project proposal per call. • Principal Investigators (PIs) belonging to an Accredited Health Research Institutes (IIS), even if they are also

	affiliated with another institution, must apply ONLY through the IIS as applicant Institution. • The Principal Investigator (PI) and all members of the research group must belong to the eligible institutions in the call. • PIs that have an ongoing International Collaboration (PCIN) project of the same initiative and purpose that this call (EfecTrial, Trials4Health call) and that the project has an ending date after the 31st of December 2027 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. • For additional incompatibilities please review AES 2027. EXCLUDED personnel as Principal Investigator (PI): • Those undergoing a postgraduate training in Health Specialization (MIR, EIR, FIR, QIR, BIR, PIR, RFIR) • Those undergoing research training (e.g. PhD students, or “Río Hortega” contracts). • Those undergoing postdoctoral training (e.g. “Sara Borrell” or “Juan de la Cierva” contracts). • 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. - 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: - Personnel costs will be eligible for contracts with the professional category needed (Superior technician, BSc

	(Grado), MSc (Máster), PhD (Doctor) for project development according to the published salary tables in ISCIII's webpage/ AES 2027. Personnel cost will be precisely adhered to the salary tables; no other amount will be considered, either upper or lower. - Contracts for PhD students will be made in the framework of National Subprogramme for Training (scholarships are not eligible). - 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 2027) either employed by the beneficiary entities or belonging to the research team. - 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 2027 for eligible personnel costs, for contracts framed under the Law 17/2022, 5 September, article 23bis in the specified Entities of Public sector. • 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 2027, that can be justified as necessary to carry out the proposed activities. • Overheads, according to AES 2027 (25%). • 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 2027.
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 2027. Due to administrative and legal regulations, the Institute of Health Carlos III establishes the end of October 2027 (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 2027 (probably September/October 2027).

	Any concerned applicant in a proposal for which no final decision has been made by the deadline of end of October 2027 (tentatively date), could be declared not fundable by ISCIII. 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). 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 2027. In order to expedite the eligibility check process, it is mandatory that all the applicants submit the CVA-ISCIII of the PI. This document shall be submitted by the PI by electronic email before the pre-proposal submission deadline to: anagarcia@isciii.es and b.rubio@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 2028).
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).

	• 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 2027 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.

Country	Spain
Funding organisation	Regional Ministry of Presidency, Healthcare and Emergencies of Andalusia-CPSEJA
National contact person	Alicia Milano Curto Tel : +34 955 04 04 50 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	All participating organisations will be granted. Given the amount of funding committed for this call, participation in the same project is limited to one coordinator or two partners.
Eligibility of partners	Eligibility criteria are established in Orden de 10 de agosto de 2023 : • 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. • 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. • More than one partner from Andalusia may participate in the same project • A PI can only participate in one application per call. • 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. b) Personnel costs: specifically hired for the project, including salaries, employer Social Security contributions, legally established compensation and other duly justified expenses derived. 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. d) Registration fees for congresses or conferences for the presentation and dissemination of the results. Publication costs e) Other expenses duly justified and necessary for carrying out the project. f) Indirect costs 21% f) 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. The following are not considered eligible expenses • Equipment or Equipment repair and maintenance • Items or amounts that, after analysis, are not considered justified • 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. 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 JTC. 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. • 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) • 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)
Starting 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. 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.

Country	Sweden
Funding organisation	Swedish Research Council (SRC)
National contact person	Abraham Mellkvist-Roos, abraham.mellkvist-roos@vr.se
Funding commitment	1 500 000 euro (indicative)
Anticipated number of fundable proposals	3-4
Maximum/minimum funding per grant awarded to a clinical study partner	Maximum 5 000 000 SEK (approximately 500 000 €), minimum 3 000 000 SEK (approximately 300 000 €) Please note that the exchange rate 1 EUR = 10 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 Research Council, at the start of the grant period. 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. No funding of industrial partners. Applicants from Sweden 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. Funds are reserved for the exclusive use of recruitment sites in Sweden. 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 Swedish Research Council's website .

Submission of the proposal at the national level	All project leaders in Sweden participating in the call with support from the Swedish Research Council must 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. A 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 applicants in Sweden 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	Januari 1 st , 2028.
Further guidance	See national call texts for all national requirements.

Country	TÜRKİYE
Funding organisation	Health Institutes of Türkiye (TÜSEB)
National contact person	Fatih Karademir Head of International Relations Department- fatih.karademir@tuseb.gov.tr
Funding commitment	600000 EURO
Anticipated number of fundable proposals	Up to 2 proposals are anticipated, subject to the requested budgets, final ranking and availability of TÜSEB funds.
Maximum/minimum funding per grant awarded to a clinical study partner	300000 EURO
Funding mechanism	Up to two eligible Turkish partners per consortium may receive individual funding from TÜSEB, subject to national eligibility requirements, the available funding budget and the final funding decision.
Eligibility of partners	Eligible applicants include universities, public and private hospitals, research institutes, and other healthcare and research organisations established in Türkiye that meet TÜSEB national funding requirements and have the scientific, legal, and operational capacity to conduct the proposed clinical study. Applicants must also comply with the general eligibility requirements of the ERA4Health IICS4all call. The Principal Investigator must have the relevant scientific qualifications and research experience and comply with applicable TÜSEB national eligibility criteria. For clinical trials subject to Turkish regulations requiring a medically qualified responsible investigator, this investigator must be a medical doctor or dentist with the specialist or doctoral qualifications required for the relevant clinical trial. Clinical studies must be conducted at eligible research sites, including university hospitals, public and private hospitals, research institutes, and other authorised healthcare and research facilities, with appropriate clinical infrastructure, qualified personnel, and necessary equipment.
Eligibility of costs, types and their caps	Eligible costs may include personnel costs, consumables/materials, equipment, subcontracting and other direct costs subject to TÜSEB national funding rules. The eligibility and applicable limits of each cost category will be assessed in accordance with TÜSEB rules and the national funding agreement.
Duration of the clinical study	48 months
Specific rules for potential extensions	No-cost extensions may be considered only in accordance with ERA4Health procedures and TÜSEB national rules. Extensions are not automatic and require prior approval by the relevant bodies/funder.
Submission of the proposal at the national level	No separate national proposal is required. Applicants requesting TÜSEB funding must comply with TÜSEB national funding rules, and TÜSEB may request revisions to the budget breakdown and/or additional documents where necessary.

Submission of other information at the national level	Turkish applicants must provide any additional documents requested by TÜSEB for national eligibility and, if selected for funding, for contracting (e.g. institutional/financial information, declarations and applicable ethics/regulatory documentation). Details will be communicated by TÜSEB. All required ethics committee approvals and regulatory authorisations must be obtained in accordance with applicable Turkish legislation before initiating clinical study activities that require such approvals or authorisations in Türkiye.
Submission of financial and scientific reports at the national level	No additional national reporting requirements are foreseen at the application stage. Any additional requirements that may be necessary will be announced by TÜSEB.
Starting date of the clinical study	January-May 2028 (subject to national procedures) The initiation of clinical study activities in Türkiye remains subject to applicable national ethics and regulatory requirements.
Further guidance	Applicants are strongly advised to contact TÜSEB before submission to confirm national eligibility and applicable funding rules. For National project applications: info@tuseb.gov.tr

Country	UNITED KINGDOM
Funding organisation	UK Department of Health and Social Care (via the National Institute for Health and Care Research (NIHR))
National contact person	Sarah Puddicombe and Emma Lofthouse sarah.puddicombe@nihr.ac.uk cc: internationalapplications@nihr.ac.uk
Funding commitment	£4,000,000 (approx €4,600,000)
Anticipated number of fundable proposals	Up to 4 proposals
Maximum/minimum funding per grant awarded to a clinical study partner	Up to £1,000,000 (or approximately €1,150,000) for a project. Applicants must justify that the budget requested is appropriate and proportionate to the outlined research plans and ensures value for money. For conversion to GBP, please use your institution's standard exchange rate; NIHR does not mandate a fixed exchange rate, and total costs must be within the max funding threshold per award.
Funding mechanism	NIHR issues research contracts to one 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. Public and Patient organisations may be partners to this call but are not eligible to act as the UK lead contracting organisation. 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	Eligible costs Costs for research and recruitment in the UK aligned to the most relevant NIHR domestic programme for this call and which meets NIHR finance requirements. In brief this means including only eligible UK investigational costs (staff time, study procedures, site services, participant expenses, and justified subcontracting), excluding NHS Support Costs, Treatment Costs and Excess Treatment Costs, and ensuring all costs are proportionate, deliverable and represent value for money.

	UK organisations are funded by NIHR for their UK-incurred costs only, and these are treated under NIHR domestic funding rules. UK HEIs are funded at 80% FEC, which may include indirect and estate costs in line with standard FEC methodology. UK NHS organisations are funded at 100% of eligible direct costs only. UK partners are not considered “international applicants” solely because the consortium is led or sponsored by a non-UK organisation. International costing rules (i.e. 100% direct costs only, no overheads) apply only where a UK applicant is requesting funding for activity undertaken outside the UK. Further information about costs can be found in the following publication Attributing the costs of health and social care research (AcoRD) N.B. NHS support costs and excess treatment costs are not supported through the NIHR research award funding. These are the responsibility of the NHS and should be funded through normal commissioning arrangements. 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. Costs may include Research training, mobility and academic career development for early career researchers which is a key priority for NIHR in supporting the next generation of research leaders. All financial costs associated with making the study inclusive (e.g., translators, accessible technology, community engagement, or transport) must be specified and explicitly costed. See NIHR finance guidance for applicants: https://www.nihr.ac.uk/research-funding/application-support/guidance/finance-guidance-for-applicants#tab-375156.
Duration of the clinical study	Up to 48 months
Specific rules for potential extensions	No-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 only request full applications for UK based research components to be submitted through the NIHR awards management system after receipt of a positive funding recommendation from the secretariat. NIHR will then require a copy of the application and full budget details for assessment as part of the precontracting processes. 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. For clinical studies phase 3/4 or from TLR5 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. Out of scope: NIHR does not fund research involving animals or animal tissue. Any project seeking UK support must email NIHR no less than 7 days prior to the preproposal submission deadline. Please provide the application number, title and UK lead partner details and clearly articulate the UK component of the research and how the findings will be relevant to inform national health or care practice /policy in the UK. This should be no more than 1 page of A4. The information will support national eligibility checks on all preproposal submissions after the deadline. 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. NIHR will retain 10% of the total UK award pending the submission of the agreed final contractual outputs, including submission and approval of the Final Statement of Expenditure due within two months of the project end date. 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

Funding acknowledgement

This study/project is funded by the NIHR [name of NIHR programme (NIHR unique award identifier)] 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).

"The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care."

Country	European countries under the Clinical Trial Regulation
Funding organisation	Breakthrough T1D
National contact person	Carmen Hurtado del Pozo churtadodelpozo@breakthrough1d.org
Funding commitment	€ 1.000.000,00
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. For this specific call, funding eligibility is restricted to institutions based in European countries (including Switzerland) and the United States. 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. • 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. • 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 and Advanced Postdoctoral Fellowships in place of Salary & Wages. Stipend levels are determined based on the fellow's years of postdoctoral experience.

	- Supplies are general purpose consumable items that are used on a regular basis and have a shorter life span in use than equipment and machines. - Other costs might include items that are not consumable but are needed on a regular basis, 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). - 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. - Research Allowances are provided for Postdoctoral Fellowships only in the amount of USD\$5,500 per year. These can be used towards travel to scientific meetings, journal subscriptions, books, health insurance costs, etc. - Travel may include any domestic and/or international 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. 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 not incur 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

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.

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.

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).

Final Progress Reporting

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.