Joint Transnational Call for Investigator-Initiated Clinical Studies

(JTC IICS) – 2025

"Fostering Pragmatic Comparative-Effectiveness Trials in Non-communicable Diseases" (EffecTrial)

Call Text

DEADLINES

January 28th, 2025 (16:00 CET) - SUBMISSION OF PRE-PROPOSALS

June 17th, 2025 (16:00 CEST) - SUBMISSION OF INVITED FULL PROPOSALS

Link to the electronic proposal submission:

https://ptoutline.eu/app/EffecTrial

The submission system will be open by November 28th, 2024

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

or contact the Joint Call Secretariat (JCS):

Institute of Health Carlos III (ISCIII)

Astrid Valencia Quiñónez / Sara García-Rodríguez

+34 918 222 227 / +34 918 222 868

EffecTrial@isciii.es

History of modifications :

27/11/2024 :

- Updated information for HRB's eligibility criteria regarding the Maximum/ Minimum funding per grant awarded to a clinical study partner.
- Updated information for FR-MOH's eligibility criteria (Annex I).
- Inclusion of the link to the electronic proposal submission (PT-Outline).
- Removal of the mention «*Pending for official confirmation*» for NCBR Funding Organisation.

03/12/2024:

- Removal of the mention «*Pending for official confirmation*» for IT-MOH Funding Organisation.

11/12/2024:

- Updated information for FR-MOH's eligibility criteria (Annex I).

Content

Definitions

Types of clinical studies:

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

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

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

Implementation clinical studies are scientific studies of methods to promote the uptake of research findings into routine healthcare.

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

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

Low intervention clinical trial means a clinical trial on medicinal product (or other types of medical interventions) which fulfils all of the following conditions: (a) the investigational medicinal products, excluding placebos, are authorised; (b) according to the protocol of the clinical trial, (i)the investigational medicinal products are used in accordance with the terms of the marketing authorisation; or (ii) the use of the investigational medicinal products or medical interventions are evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products in any of the Member States concerned; and (c) the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned (Source: Clinical Trial Regulation, EU 536/2014)

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

Pilot studies are small-scale studies conducted in preparation for a larger investigation.

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

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

Roles in the consortium and other definitions:

Associated partner is a recruitment site who has a collaboration agreement or a subcontract with one of the partners of the IICS consortium.

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

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.

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

Recruitment/recruiting site – facility where potential participants/patients are identified for and enrolled in clinical trials.

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

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

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

Aim and ambition of ERA4Health

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

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

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

ERA4Health has 4 specific objectives:

- SO1. Support relevant medical research including 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 IICS at European scale,
- SO4. Implement and advance the practice of Responsible Research and Innovation (RRI) across the breadth of the programme.

Rationale

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

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

Taking advantage of Europe's half-billion population size, its medical expertise, high quality healthcare systems, harmonised regulatory framework and scientific potential, enhanced multinational cooperation in clinical studies would boost clinical research in Europe. Additionally,

[1] https://era4health.eu/wp-content/uploads/2022/11/ec_rtd_he-partnerships-era-for-health-1.pdf

European studies allow rapid patient recruitment and spread best practices, thus enhancing Europe competitiveness and healthcare equity for the benefit of patients and of healthcare systems.

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

Comparative-effectiveness studies are a particularly important type of IICS.

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

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

In addition, comparative effectiveness studies can be conducted in a very pragmatic way. Pragmatic clinical studies enable investigation of whether a treatment works in the clinical setting, preferably on all types of relevant patients. In a pragmatic clinical study, only the necessary data will be collected, resulting in lower cost even with a high number of patients.

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

Aim of the call

The aims of the call are:

- to support randomised, interventional and **pragmatic comparative-effectiveness multi-country Investigator-Initiated Clinical Studies (IICS).**
- to encourage and enable **transnational collaboration** between clinical/public health research teams (from hospital/ public health, healthcare settings and other healthcare organisations) that conduct comparative-effectiveness multi-country IICS.

Proposals should address all the 4 following points :

1) **Be a pragmatic comparative effectiveness trial, designed as randomised interventional trial**.
2) Compare the use of currently approved healthcare interventions either to each other or to the current standard of care.

3) **They shall consider healthcare interventions** which could include but would not be limited to: diagnostic, screening, prevention and treatment interventions. The interventions can be pharmacological as well as non-pharmacological procedures like nutrition and/or lifestyle interventions, surgery, prognosis methods, use of medical devices, eHealth and digital interventions and other health interventions. [2]
4) These interventions shall have high public relevance only in the **fields of these specific diseases or conditions** (that are of equal importance):
    - Cardiovascular diseases
    - Metabolic disorders
    - Nutrition and lifestyle-related diseases
    - Non-communicable respiratory diseases

The focus of the multi-country Investigator-Initiated Clinical Studies should primarily address at least one of the abovementioned principal diseases/conditions, although the proposals can also address several of the mentioned diseases/conditions and/or other related comorbidities.

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

Requirements:

- Proposals must clearly demonstrate the potential health and/or economic impact(s) as well as the added value of transnational clinical collaboration.
- Proposals must include an early involvement of 'end users' (e.g. patients, care providers, healthcare professionals, etc.) in the design of the study (integrating patient valued outcomes) and in the research process. This is to ensure acceptability of the healthcare intervention and utility of the studies' knowledge for healthcare decision making. Patient organisations or other end-users can participate as partners (if eligible for funding by a national/regional funding organisation), as collaborators (participation with own budget) or as part of an advisory board.
- Special consideration must be given to fulfilling all ethical requirements (See ethical requirements and clearance section in the call documents, including reference to Reference to EU Regulation 2021/695 and ethical self-assessment).
- The consortia shall ensure the management of research data according to FAIR data principles (Findability, Accessibility, Interoperability and Reuse) and in compliance with the General Data Protection Regulation (GDPR).
- The proposed research shall consider sex and gender aspects, whenever applicable.
- Partners in the consortia, especially the coordinating PI, should have a proven track record in delivery of clinical trials to ensure the feasibility of the clinical trial.

[2] Please note that proposals that include a partner applying for funding from BMBF/DLR (Germany) are **only eligible if the comparison includes the use of at least one nutritional and/or lifestyle intervention**. The comparison of e.g. two pharmacological interventions would not be eligible in this case and would lead to an immediate exclusion of this proposal without further review. Please note that dietary supplements in pharmacological doses are not considered a nutritional intervention.

- The consortia should consider the gender balance in their composition and to balance the responsibilities between them.
- Additionally, proposals should take into account the diversity of health systems in different regions of Europe to allow large-scale uptake.
- The consortia are requested to ensure inclusiveness aspects in patient recruitment (minorities, ethnical aspects…), to include underrepresented and vulnerable populations that could be specifically relevant in a certain medical area and consider issues of particular relevance for the target population, for example, gender specificities, age, multimorbidity, complex chronic conditions, polypharmacy, substance misuse, vaccine efficacy, compliance, and diseases with high societal burden.
- 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. Consider using new instruments and methods for determining the burden of disease and for evaluating the effects of the interventions. Low-cost innovations should also be considered.

Recommendations:

- Additionally, proposals are encouraged to show how the outcomes of the trial could generate further impact in the future (e.g. through a socioeconomic evaluation and to demonstrate how the evidence shown by the comparative-effectiveness clinical trial could be very valuable for future Health Technology Assessments (HTA).
- The consortia are encouraged to take into consideration existing multinational networks, platforms or existing cohorts in the respective medical field that they have access to ensure the feasibility of the trial.
- Applicants could make use of existing biobanks, existing cohorts, information from previous observational studies, systematic reviews, and/or metadata repositories, although their clinical studies should not be based only on this type of approaches.

Out of scope:

- Studies in **other medical areas different from the ones mentioned above** (cardiovascular diseases, metabolic disorders, nutrition and lifestyle-related diseases and non-communicable respiratory diseases).
- Particularly, those clinical trials that are focused on **rare diseases, cancer and/or infectious diseases are out of the scope of this call**, even if these diseases are studied with one of the eligible diseases/conditions
- Proposals focused on observational studies, cohort studies, translational/clinical approval studies, creation of large databases, systematic reviews and meta-analysis.
- Basic biomedical research
- Development of a new healthcare intervention
- Phase I and phase II studies
- Placebo randomized controlled trials

Expected Impact

Pragmatic practice-oriented comparative-effectiveness publicly funded clinical studies can provide answers to highly relevant health research questions, both in terms of clinical effectiveness and cost-effectiveness of interventions, which are less likely to be answered by trials funded by the pharmaceutical and other health industry. In case of comparison with the current standard of care, the impact on the public policies and the healthcare systems will be enhanced.

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

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

General conditions for application

The initial duration of the clinical studies will be 48 months.

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

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

IICS supported by ERA4Health must respect fundamental ethical principles. Applicants must fill an ethical grid 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/Europe [3]).

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

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

[3] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

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

Please take in note that clinical studies conducted for direct commercial purposes are excluded from support by the ERA4Health programme.

Participating countries and respective funding organisations

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

Country	**Funding organisation**	**Acronym**	**Contribution (€)**
Austria	Austrian Science Fund	FWF	2.000.000
Czech Republic	Ministry of Health / Czech Health Research Council	MZCR /AZVCR	500.000
France	Ministry of Health	Fr-MoH	2.000.000
Germany	Federal Ministry for Education and Research (BMBF)/DLR Project Management Agency (DLR)	BMBF/DLR	2.000.000
Ireland	Health Research Board	HRB	1.200.000
Israel	Ministry of Health	CSO-MOH	320.000
Italy	Ministry of Health	IT MOH	2.000.000
Latvia	Latvian Council of Science	LCS	800.000
Lithuania	Research Council of Lithuania	LMT	1.000.000
Norway	Research Council of Norway	RCN	900.000
Poland	National Centre for Research and Development	NCBR	2.500.000
Slovakia	Slovak Academy of Sciences	SAS	240.000

Spain	Institute of Health Carlos III	ISCIII	3.000.000
Spain	Regional Ministry of Health and Consumer Affairs of Andalusia [4]	CSCJA [4]	250.000

Table 1: Participating funding organisations

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).

Application

ELIGIBILITY CRITERIA

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

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

Size 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. A minimum of 3 (three) and a maximum of 5 (five) countries should be represented in the consortium (the countries of the collaborators (see below) are not considered in this number)

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

[4] *During the lifetime of this call, funding authority CSCJA could be replaced (Partial Takeover) by the new entity Instituto de Salud de Andalucía / Andalusian Health Institute (created by Law 1/2024 of June 21) which, in such case, would assume CSCJA's rights and obligations by means of the corresponding amendment to the Grant Agreement 101095426.*

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

D. The maximum number of countries can be increased to 6 (six) or 7 (seven) if they include 1 (one) or 2 (two) countries, respectively, from the following list: Czech Republic, Latvia.

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

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

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

Table 3: Possible composition of consortium

Each study consortium must nominate **a clinical study coordinato**r among its partners (NOT a collaborator). The clinical study coordinator cannot be an enterprise. The representative of the clinical study coordinator, the **coordinating investigator,** will represent the consortium externally,

will act as contact person for the Joint Call Secretariat (JCS) and will be responsible during the entire process for the internal scientific management such as controlling, overseeing intellectual property rights (IPR) issues, overseeing the work of a service provider responsible for the transversal activities of the study (i.e. clinical study management activities at consortium level) as well as reporting to the JCS.

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

Financial and legal modalities

Clinical study partners will be funded by their relevant national/regional funding organisations. 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.

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

In addition, and with the respect of specific conditions detailed in the guidelines for applicants, an additional budget representing up to 15% of the total budget requested to the national/regional funders could be requested for covering the conduction of cross-cutting management activities (i.e. clinical study management activities at consortium level) such as trial authorizations, drug, safety and data management under the responsibility of the coordinating investigator and his/her legal entity. See section "Funding Mechanism" in the guidelines for applicants for more details.

Please note that if a partner is found to be non-eligible at any step of the process by one of the funding organisations, the entire proposal could be rejected without further review. Therefore, please make sure to carefully read and follow the respective national/regional regulations in Annex I.

Submission of joint proposals

There will be a two-step submission and evaluation procedure for joint applications, i.e. pre-proposals, with invitation of successful consortia to submit a full proposal. In addition, the full proposal review process will be complemented by a rebuttal phase and an interview jointly with the coordinating investigator and a representative of the sponsor. The representative from the sponsor that will be interviewed 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 able 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:

20 November, 2024	**Publication of EffectTrial call**
27 November, 2024	**Webinar Info Day**
28 January, 2025	**Deadline for pre-proposal submission**
15 April, 2025	Communication of the results of the pre-proposal assessment (invitation for full proposal)
17 June, 2025	**Deadline for full proposal submission**
25 August – 5 September, 2025	**Rebuttal stage**
25 August – 5 September, 2025	**Interview to assess the study feasibility**
End of October, 2025	Communication of the funding decisions to the applicants
January – May 2026	**Expected project start** (subject to national procedures)

Table 1: Timeline application process

The pre-proposal template is available on the ERA4Health website (https://era4health.eu/pre-announcement-of-effectrial-call/).

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

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

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

For the submission of full proposals, **the widening concept** will be applied. It will therefore be possible, but not mandatory, to add partners that are eligible for funding by certain funding organisations (with low number of eligible applicants at the first step). The inclusion of new partner(s) should be relevant for your proposal, and the new partner(s) should be well integrated in your consortium. The list of the participating funding organisations/countries will be provided by the JCS when the results of the first step will be communicated to the coordinators. The maximum of 7 countries within the consortium should still be respected. Finally, **it is mandatory for the new partner(s) to contact her/his national funding organizations and obtain approval before the submission of the full proposal** (see contact details in Annex I of the call text).

Further information

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

Evaluation and decision

Eligibility check and evaluation procedure

Formal check and evaluation of pre-proposal

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

The pre-proposal of each consortium passing the eligibility check (JCS and country/region) will be evaluated by external reviewers. Evaluation of a pre-proposal will be made by three reviewers with a scientific/clinical background. Potential conflicts of interests of the evaluators will be taken into consideration during the allocation of the proposals. The reviewers will perform the assessment of the pre-proposals and complete a written evaluation form with scores and comments for the evaluation criteria that they should evaluate. The evaluation will include an eligibility check that the proposal is included in the call scope (e.g. disease area, type of trial, etc). Based on the scores in the written evaluations, a ranking list will be established. The Clinical Study Steering Committee (CLSC) members will meet to decide which proposals will be invited to submit a full proposal based on the reviewers' recommendations and to ensure a reasonable balance of requested and available national/regional budgets. Pre-proposals which do not pass this assessment will not be invited for the full proposal stage. All consortia will receive the full evaluation reports, excluding the evaluation scores.

Formal check and evaluation of full proposals

After submission, the JCS will check the full proposals to ensure that they meet the call's formal criteria and have not changed substantially from the respective pre-proposals before sending them to the reviewers. Any fundamental change between the two-stage evaluation, e.g. concerning the composition of the consortium, the objectives of the study or the requested budget must be communicated to the JCS and to the national/regional involved funding organisations. In exceptional cases, these changes may be approved if detailed justification is provided and if they are accepted by the CLSC.

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

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

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

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

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

Evaluation Criteria

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

Pre-proposal

1. **Excellence**

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

2. **Impact**

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

3. Quality and efficiency of the implementation

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

Full proposal

1. Excellence

- Innovation and scientific relevance of the study and how it will contribute to extend the knowledge beyond the state of the art, potential to change the current medical/clinical practice.
- Relevance for 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 with the 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 manage research data
- Substantive involvement of pertinent patient organisations or patient representatives or other relevant stakeholders (in planning and execution of the trial, and dissemination of the results).
- Appropriate integration of RRI dimensions within the study design.

3. Quality and efficiency of the implementation

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

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

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

5. Methods and Design of the clinical trial

- Relevance and adequateness of the outcome measures with respect to the overall objectives of the trial; Relevance of chosen primary and secondary outcomes for patients.
- Adequacy of the target and study population and of the controls and/or comparators
- Adequacy of the consideration of the potential clinical and epidemiological consequences of the trial results
- Adequacy of randomisation criteria
- Adequacy of methods against bias and the proposed strategy for statistical and biostatistical analysis and sample size calculation
- Impact of non-compliance and missing values on the sample size.

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

Scoring system

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

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

Only integer values are accepted.

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

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

Rebuttal stage

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

The applicants will have **up to 12 calendar days** (25th August to 5th September, 2025) for this optional response to the reviewers' comments. Answers sent after the notified deadline, or not related with reviewers' comments or questions will be disregarded.

Interview of the sponsor

The coordinating investigator and the representative of the sponsor will be jointly interviewed by an interview committee (formed by 3 experts that will be part of the PRP) to determinate the capacity of the coordinator to implement the proposed clinical study and of the sponsor to manage it. The JCS will attend the interviews as observer.

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

- The previous experience of the coordinating investigator and the sponsor in conducting multicentre and/or multinational clinical trials
- Daily management and operational aspects of the study

- Risk identification and planned mitigation measures
- the governance and communication flows among the committees that they will put in place to ensure the feasibility of the trial

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

PRP meeting

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

Ethical clearance

After the PRP meeting, ethics experts will remotely check the full proposals, which are recommended for funding by the PRP and selected for funding by the CLSC, for alignment with ethical norms and regulations[5]. A meeting will also be organised for a discussion between the different ethics experts, if necessary. The ethics experts may ask the consortium for clarifications on the ethical points related to the proposed research approaches. The Ethics experts may highlight some vigilance points that need to be monitored during the implementation of the funded clinical study. Only those proposals approved by both the scientific evaluation and ethical assessment (complying with all central Horizon Europe and regional/national ethical requirements), will be funded.

Clinical study selection and reconfiguration process

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

After the establishment of the main list, additional clinical studies that have been assessed to be of good quality by the evaluation process could be invited to restructure their consortia, if there is any remaining funding budget. Research consortia will be provided 10 calendar days for this reconfiguration process.

Restructuring may take place with the following boundary conditions:

- Invitation for restructuring will take place only when availability of certain national/regional funding is the limiting factor

[5] Reference to EU Regulation 2021/695 and how-to-complete-your-ethics-self-assessment_en.pdf (europa.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 replaced.
- Restructuring cannot lead to the change of the coordinating investigator
- The central eligibility criteria of at least 3 funded partners from 3 different countries is respected
- Restructuring can take effect either through non-funded participation of the partner (this partner would act as a self-funded collaborator, being possible to increase to a maximum number of 4 collaborators in the consortium at this stage, in case that there are already 3 collaborators involved) or through finding a replacement partner eligible for funding from a funding organisation that still has funds available.

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

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

Coordinating investigators having submitted an eligible proposal will be informed about the funding recommendation regarding their proposal by the JCS. Coordinating investigators are responsible to communicate this information to their clinical study partners.

Redress procedure

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

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

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

Admissibility of appeals

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

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

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

Procedure

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

Responsibilities, Reporting requirements and Dissemination

Consortium Agreement

The coordinating investigator will be responsible for drawing up a Consortium Agreement (CA) suitable to the study partners to manage the delivery of the study activities, finances, Intellectual Property Rights (IPR), to handle confidential data (e.g. patient data) and to avoid disputes which might be detrimental to the completion of the study. The consortium is strongly encouraged to sign this CA before the official study start date, and in any case the CA should be signed in the first 6 months of the clinical study**.** Please note that national regulations may apply concerning the requirement for a CA (e.g. certain funding organisations may need the signed CA to release some funds). Further instructions will be provided by the JCS to the coordinators of the clinical studies selected for funding.

Open Science

Importantly, all funding recipients must ensure that all outcomes (publications, etc.) of transnational ERA4Health-funded clinical studies are published with Open Access. Clinical studies funded by ERA4Health are eligible to publish on **Open Research Europe (ORE)**, the Platform of the EC [6] at no cost.

The new research data resulting from the study should be treated according to the FAIR [7] principles, and deposited and shared, according to the national rules of the countries involved. To make research data findable, accessible, interoperable and re-usable (FAIR), a Data Management strategy for the full proposals is mandatory in the second evaluation stage. Studies selected to receive funding in the current call, will be requested to present a more detailed Data Management Plan (DMP) before month 6 from the official start of the study and an update of the DMP will be asked at the end of the clinical studies.

Monitoring

Project coordinators are required upon notification to deliver an abstract of their project suitable for communication and dissemination purposes.

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

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

M1: The Project has obtained all administrative and regulatory authorisations	Milestone 1.1. Proof of registration
	Milestone 1.2. Final approved version of the study protocol (referring to the one that will be submitted to National Competent Authorities (NCA) and EC / the one that will be sent for publication)
	Milestone 1.3. Final approved version of the Data Management Plan

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

	Milestone 1.4. Establishment of Governance Boards, including Data Safety Monitoring Board
	Milestone 1.5. Data Management System
	Milestone 1.6. Agreements in place*
M2: First Patient First Visit (FPFV)	
M3: 25% final target recruitment	
M4: 50% final target recruitment	
M5: 75% final target recruitment	
M6: 100 % final target recruitment	
M7: Last Patient Last Visit (LPLV)	
M8: Analysis of results	
M9: Publication of results	

*Including:
- Sponsor-site agreements with all participating recruiting sites
- Sponsor-vendor agreements, including drug supplier, drug distributor and all other applicable (Contract Research Organization -CROs-, Clinical Trials Unit -CTUs- for monitoring, data and/or project management and vigilance) agreements
- Insurance (if applicable)
The description of status and dates for all agreements in all countries should be stated.

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

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

Communication

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

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

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

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

Importantly, all funding recipients must ensure that all outcomes (publications, etc.) of transnational ERA4Health funded studies include proper acknowledgement of the ERA4Health partnership and the respective funding partner organisations.
"*This study received funding from [name of funding organisations, or an acknowledgment as requested by your national/regional funding organisations] under the umbrella of the Partnership Fostering a European Research Area for Health (ERA4Health) (GA N° 101095426 of the EU Horizon Europe Research and Innovation Programme).*"

Confidentiality

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

The proposals will be handled confidentially by the JCS and by the national/regional funding organisations. In selecting the international experts for the PRP, the ethical experts and the patient representatives, the JCS shall endeavour to avoid any possible Conflicts of Interest (CoI).

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

General Data Protection Regulation

The following Data Privacy Notice applies:

By submitting an application, the applicants consent to the use, processing and retention of their personal data[8], in accordance with article 6.1 (e) and (c) of the General Data Protection Regulation (GDPR) (2016/679) and for the purposes of:

[8] 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 studys, LoIs, study proposals (scientific document, administrative and financial appendix).

- Processing and evaluating the application where processing shall be lawful only if and to the extent that processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller
- Administering any subsequent funding award
- Managing the funding organisations relationship with them
- Analysing and evaluating the call
- Providing aggregate data to national and European surveys and analyses on the funded clinical studies
- Complying with audits that may be initiated by the funding organisations and the European Commission (or its agencies).

The members of the CLSC may share applicant's data with third parties (some of which may be based outside the European Economic Area) in relation to the above activities including evaluators, auditors and the European Commission (or its agencies).

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

ANNEX I

Country	**Austria**
Funding organisation	**Austrian Science Fund (FWF)** www.fwf.ac.at
National contact person	Markus Kubicek Tel.: +43 1 505 67 40 - 8202 E-Mail: markus.kubicek@fwf.ac.at Stefanie Schagginger Tel.: +43 1 505 67 40 - 8213 E-Mail: stefanie.schagginger@fwf.ac.at
Funding commitment	€ 2.000.000€,00
Anticipated number of fundable proposals	The FWF anticipates funding of 5 projects, given an average amount of funding per partner of approx. 400.000.
Maximum/ Minimum funding per grant awarded to a clinical study partner	The FWF generally does not have any minimum or maximum limits but, given the limited nature of the financial commitment of the FWF to this Call (see above), we do expect Austrian participations not to exceed the average range of an FWF stand-alone Project (typically € 300.000 to €450.000).
Funding mechanism	For the FWF, 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 FWF office for a detailed clarification which approach would be the most appropriate for your proposal.
Eligibility of partners	The proposed research must be carried out in Austria under the auspices of the Austrian lead research institution The principal investigator must be employed at the Austrian research institution applying for funding at the time the project is scheduled to begin. All Austrian research institutions are eligible to apply if they are registered in the FWF's research institution portal. Applications are to be submitted by the research institution where the project is to be carried out. Neither a specific academic degree nor Austrian citizenship is required to act as principal investigator. The principal investigator must, however, have appropriate scientific qualifications (see section 1.4) and sufficient time resources to carry out the proposed research. The research institution must provide the necessary infrastructure. Please refer to the general FWF Application Guidelines and the respective Application and project number limit
Eligibility of costs, types and their caps	Project-specific costs are eligible for funding. These include personnel and non-personnel costs that are needed to carry out the project and that are not included in the infrastructure provided by the research institution. The FWF does not finance the infrastructure or basic equipment of research institutions.

	The current FWF Personnel Costs and Salary Rates scale indicates the salaries that may be requested. The FWF grants an annual salary adjustment to compensate for inflation, which is applied automatically to all contracts of employment in Principal Investigator projects that are valid when the adjustment takes effect. Please refer to the FWF Application Guidelines
Duration of the clinical study	Funding requested for FWF Principal Investigator Projects is limited to a maximum of 48 months.
Specific rules for potential extensions	A cost-neutral extension of up to 12 months is possible and must be applied for at the FWF before the official end date of the project.
Submission of the proposal at the national level	In addition to the application at the ERA4Health level, administrative data (in accordance with the FWF Guidelines for Principal Investigator Projects) must be submitted online to the FWF at https://elane.fwf.ac.at/ This is required already at the pre-proposal stage via the programme category "PIK – International Projects preproposal" no later than January 29, 2024, 14:00 CET. For the full proposal stage applicants must choose the programme category "PIN– International Projects" (Deadline June 18, 2024, 14:00 CET. **Both steps are mandatory.** All proposals must be submitted using the elane online portal. Project funding is administered through the research institution (PROFI mode); for this reason, the submission must be approved in the application portal both by the applicant and by the respective research institution before the respective deadlines (see above). Please note that the number of ongoing/approved projects in which one researcher can serve as principal investigator is limited to three in the Stand-Alone Projects Programme, International Programmes, Clinical Research and Arts-Based Research Programmes. Information on the limit of the number of ongoing/approved projects and the limit of applications that can be submitted can be found at project_number_limit.pdf (fwf.ac.at) For information on submitting an application from abroad please refer to he the FWF Website Applying from Abroad.
Submission of other information at the national level	See above
Submission of financial and scientific reports at the national level	Annual Status Report: The principal investigators of ongoing projects are required to report published research results on an annual basis. For further information, please refer to the information on Annual Status Reports. Final Project Report: After completion of the project, in addition to the research results, information on statistical and program-specific issues as well as any changes to the project as originally planned are also documented in Researchfish. Principal investigators are notified by email and provided with initial information about Researchfish and their reporting obligations.

	The FWF requests annual updates to include subsequently published results for up to 5 years after the end of the project.
Staring date of the clinical study	The FWF expects the start of the project within six months from the date of of approval notification. Any further delays of up to 12 months after notification must be justified, otherwise the funding approval may be rescinded.
Further guidance	The principal investigator's publication record over the last five years must be internationally visible and commensurate with the expected career path in their field. The following criteria apply for the assessment of an applicant's publication record and initiation of the review process: Quality assurance: Most relevant in assessing the applicant's publication record are those publications that have been subject to a quality assurance procedure in line with international standards (peer review or an equivalent procedure; in the natural and life sciences, peer review is expected). Journals must usually be listed in Web of Science, Scopus, or the Directory of Open Access Journals (DOAJ). For journals not listed in those databases, or for monographs, edited volumes, contributions to edited volumes, or other publication types, the applicant must provide a link to the publisher's website which contains a description of the applicable quality assurance procedure. Should no such description be available on the website, it is the applicant's responsibility to provide evidence that the publication has been subject to a quality assurance procedure in accordance with the standards of the field. International visibility: The majority of the applicant's publications must have a wider than national reach. In the natural sciences, life sciences, and social sciences, most of the publications listed must be in English. Number/scope and quality of the publications must be commensurate with the researcher's expectable career path and the respective discipline. At least two publications must be quality-assured and internationally visible publications with a substantial and independent contribution by the applicant. At least one publication with first, last, or corresponding authorship is required, with the exception of publications in journals (or disciplines) that rank authors alphabetically. If any such publications are included in the required document PI_publication.pdf, the applicant's contribution must be specified. If there is any uncertainty about general application requirements or about accounting for career interruptions, the FWF recommends contacting the FWF Office or the FWF Equal Opportunities and Diversity in Research Funding unit in good time before submitting the application to confirm that all requirements are met and that any career interruptions can be accounted for. In cases of doubt, the appropriate decision-making bodies of the FWF shall decide on applicants' eligibility.

Country	**Czech Republic**
Funding organisation	**Ministry of Health of the Czech Republic**
National contact person	Monika Kocmanova
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.** However, the final decision about the maximum funding per grant will depend on the number of proposals submitted to the pre-proposal stage or the number of proposals with Czech participation recommended for funding by the international evaluation committee. In the case of only one Czech project proposal being recommended for funding, the amount of finance support per project may be increased.
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	Research Organisations, Enterprises. All eligibility rules and criteria can be found on the Czech Health Research website (AZV ČR – Agentura pro zdravotnický výzkum České republiky (azvcr.cz). It is **recommended** to contact the responsible person at the Czech Health Research Council (prior to submission regarding the eligibility criteria).
Eligibility of costs, types and their caps	All eligibility of costs, types and their caps can be found on the Czech Health Research website (AZV ČR – Agentura pro zdravotnický výzkum České republiky (azvcr.cz)). It is **recommended** to contact the responsible person at the Czech Health Research Council prior to submission regarding the eligibility criteria.
Duration of the clinical study	48 months
Specific rules for potential extensions	An optional cost-neutral extension of 1 year if needed
Submission of the proposal at the national level	NO
Submission of other information at the national level	**Prior to submission of the pre-proposal to IICS, Czech researchers need to submit to the Czech Health Research Council the following documents:** 1. **Sworn statement** 2. **Sworn statement of composition consortium** 3. **Application form** **All these documents are available on the website at the Czech Health Research Council** AZV ČR – Agentura pro zdravotnický výzkum České republiky (azvcr.cz).

	Prior to submission of the full proposal to IICS, Czech researchers need to submit to the Czech Health Research Council the following documents: 1. **Ethics documents** 2. **Updated budget table** **More information about ethics documents is available on the website of the Czech Health Research Council** AZV ČR – Agentura pro zdravotnický výzkum České republiky (azvcr.cz); and **also part of the document "Methodology for European Partnerships in Health" in the chapter 7.2.1 Eligibility requirement for applicants.** In case the projects of Czech participants are recommended for funding based on the results of the international evaluation and after the approval of the representatives of the funding authorities of the countries participating in IICS, the Ministry of Health of the Czech Republic / the Czech Health Research Council may ask the successful Czech participants to submit additional documents in order to issue a decision on the provision of purpose-special support according to the rules established by the Ministry of Health of the Czech Republic/ the Czech Health Research Council.
Submission of financial and scientific reports at the national level	Submission of scientific and financial reports will be required according to the national rules. All necessary information is part of the document called "Methodology for European Partnerships in Health," available on the website.
Starting date of the clinical study	In line with the start date of the project as stated in the "Contract" or "Decision" on the provision of support or the issuance of a decision.
Further guidance	AZV ČR – Czech Health Research Agency (azvcr.cz)

Country	FRANCE
Funding organisation	FR MOH – Ministry of Health
National contact person	Cecile.fragny@sante.gouv.fr
Funding commitment	2.000.000 €
Anticipated number of fundable proposals	3 to 4
Maximum/ Minimum funding per grant awarded to a clinical study partner	700.000 € Maximum
Funding mechanism	Only one organisation will be granted and this organisation will establish a collaboration with other recruitment sites via subcontracting or a collaboration agreement
Eligibility of partners	Eligible institutions: French ministry of Health (Fr MoH) funds French healthcare institutions defined by public health regulation articles L.611-1 and further, L.6141-1 and further, L6161-1 and further (établissements de santé), L6133-1 to 8 (groupements de coopération sanitaire), L6323-3 (maisons de santé) and L6323-1 (centres de santé) of the Code de la Santé Publique. 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 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.
Duration of the clinical study	48 months
Specific rules for potential extensions	Extension is not automatic. A report explaining the project extension request must be submitted to the FR MOH with all supporting documents at least 6 months before the project end date. The extension may not exceed 1 year and cannot give rise to additional funding payments. The extension cannot exceed the end date of the partnership.

Submission of the proposal at the national level	The certificate and budget grid available on Fr MoH website page must be fulfilled and sent before submission deadline. See online for further instructions.
Submission of other information at the national level	
Submission of financial and scientific reports at the national level	A report on expenses is submitted to FR MOH each year by the funded institutions. The expenses reported must be in direct relation with the project. They must be necessary for project implementation and conform to the selected project.
Starting date of the clinical study	The project begins as soon as possible after the results of the Call have been confirmed. The official project start date must be communicated to the FR MOH by the funded institution as soon as it is known.
Further guidance	Funds delegation will be performed through budgetary circulars of the Fr MoH. Funds will be allowed regarding project progression.

Country	**Germany**
Funding organisation	**Federal Ministry for Education and Research (BMBF) represented by the Programme Management Agency in the German Aerospace Centre (DLR-PT)**
National contact person	Name : Dr. Svenja Finck Dr. Kristina Foterek Phone: +49 228 3821 1877 +49 228 3821 1161 E-mail: era4health@dlr.de Address: DLR PT, on behalf of the BMBF 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 2.0 Mio € Only consortia whose research question includes at least the use of one nutrition and/or lifestyle interventions are eligible for funding from BMBF/DLR-PT. The comparison of e.g. two pharmacological interventions cannot be funded by BMBF/DLR-PT. Please note that dietary supplements in pharmacological doses are not considered a nutrition intervention.
Anticipated number of fundable proposals	4-5
Maximum/ Minimum funding per grant awarded to a clinical study partner	Up to 350.000 € for regular German partners; up to 500.000 € 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. 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 BMBF 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 runtime extensions can only be granted in exceptional cases.
Submission of the proposal at the national level	On request in case of a positive funding recommendation.
Submission of other information at the national level	On request in case of a positive funding recommendation.
Submission of financial and scientific reports at the national level	On request in case of a positive funding recommendation.
Starting date of the clinical study	April 2026 (the earliest)
Further guidance	https://www.gesundheitsforschung-bmbf.de/de/18037.php

Country	**Ireland**
Funding organisation	**Health Research Board**
National contact person	Dr Karen Crowley Dr Fiona Manning Email: EUTrials@hrb.ie
Funding commitment	€1,200,000 (inclusive of overhead contribution)
Anticipated number of fundable proposals	1-2
Maximum/ Minimum funding per grant awarded to a clinical study partner	**Maximum funding is:** Up to €1,000,000 including overhead contribution of 30% of Total Direct Modified Costs (TDMC). Please see HRB's dedicated scheme page on HRB's funding page for further Guidance and FAQ specific to applicants based in Ireland.
Funding mechanism	HRB will contract with a single Host Institution (Lead Applicant). Additional national recruiting sites (associate 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.
Eligibility of partners	Lead Applicants (Principal Investigators) based in Ireland must be from a recognised HRB Host Institution in the Republic of Ireland (Policy on Approval of HRB Host Institutions). Partners classed as 'Enterprise' cannot be in receipt of HRB funding. Please see HRB's dedicated scheme page on HRB's funding page for Guidance and FAQ specific to eligibility for applicants based in Ireland.
Eligibility of costs, types and their caps	Funding available is inclusive of overheads and pension contributions Salary related costs Direct running costs, including patient-related costs and costs to support interventional studies Patient and Public Involvement (PPI) costs Small equipment costs (€10,000) Travel FAIR data management costs Dissemination and knowledge exchange costs For more information please see HRB's guidance on the dedicated scheme page on HRB's funding page.
Duration of the clinical study	48 months
Specific rules for potential extensions	12-month no cost extension (NCE) permissible

Submission of the proposal at the national level	No additional requirements
Submission of other information at the national level	Applicants will have to complete HRB's Budget and Deliverables templates. These will be supplied after submission. Applicants must submit a short information form at submission to provide details on PI's track record for eligibility checks.
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. For clinical trials or interventional studies, PIs are required to submit an approvals package to confirm all ethical and regulatory approvals, and contractual agreements are in place before patient recruitment commences. The PI must notify the HRB that the first patient first visit (FPFV) has occurred and subsequently furnish a three-month recruitment report. Thereafter, the PI must submit bi-annual progress reports for the duration of the grant. Financial reports must be submitted annually. A final report must be submitted at the end of the grant.
Starting date of the clinical study	Jan - May 2026
Further guidance	All Irish partners who are undertaking interventional studies must adhere to the HRB Clinical Trial and Interventions Research Governance Policy. All 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 320,000 €, depending on budget availability
Anticipated number of fundable proposals	1-2
Maximum/ Minimum funding per grant awarded to a clinical study partner	Up to 160,000 €
Funding mechanism	All participating organisations will be granted and should be part of the clinical study consortium. A maximum of 3 partners are authorised.
Eligibility of partners	Researchers will only be able to participate as partners in consortia. Sponsors 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
Staring date of the clinical study	NA
Further guidance	Please see detailed instructions of application at the national level and reporting at http://www.health.gov.il/research-fund

Country	**Italy**
Funding organisation	**Italian Ministry of Health (IT MoH)**
National contact person	Chiara Ciccarelli – c.ciccarelli@sanita.it Francesca Turco – f.turco@sanita.it
Funding commitment	€ 2.000.000,00
Anticipated number of fundable proposals	3
Maximum/ Minimum funding per grant awarded to a clinical study partner	Max. € 650.000 per project
Funding mechanism	Simultaneous PI participation in different 2025 JTCs funded by the Ministry of Health is not allowed. No more than two Italian PIs (Principal Investigators) are eligible to apply for the same project. Italian PAOs can be funded as a sub-contractor of an IRCCS if they fulfil the eligibility criteria of the EC. The maximum amount eligible for a sub-contract is < 10% of the total budget (from the IRCCS Budget). Italian PAOs can still participate in Consortia as "Collaborators" with their own funds.
Eligibility of partners	Only IRCCS (Istituti di Ricovero e Cura a Carattere Scientifico) researchers are eligible to apply.
Eligibility of costs, types and their caps	**Direct Costs:** • Personnel (only temporary contracts or permanent contracts for the amount of hours dedicated to the project, **≤ 60%**); • Consumables/Supplies; • Animals/Model costs; • Equipment (only on leasing or rent); • Travel (**≤ 30%**); • Dissemination activities (**≤ 1%**); • Publication costs: < 2%; open access < 5%; • Patients recruitment costs; • IT Services and Data Bases; • Coordination costs

	<u>Indirect Costs:</u> • Overhead (**≤ 10%**, included in the total); Other indirect costs are not eligible. Transfer of eligible funds abroad is not allowed. **Subcontracts are allowed only upon approval, by presenting via Workflow – code ER, a request together with the National preelegibility form, the latest 20 days before the deadline of the pre-proposal submission.**
Duration of the clinical study	Up to 48 months.
Specific rules for potential extensions	Max 1 year
Submission of the proposal at the national level	In order to expedite the eligibility check process, the Ministry of Health will grant an eligibility clearance to the applicant prior to the submission of the proposals. To this end, it is mandatory that the applicants fill out and return to the IT-MoH a pre-submission eligibility check form through their IRCCS, using WFR System-> ER communication code, before submitting their proposal to the Joint Call Secretariat. It is strongly recommended that the form, completed and duly signed, is returned at least 10 working days before the proposal submission deadline. Applicants will be sent written notification of their eligibility status. Changes in acronyms and budgets provided in the pre-submission eligibility check are not allowed. The pre-eligibility form can be downloaded here: https://www.salute.gov.it/imgs/C_17_pagineAree_4441_0_file.pdf
Submission of other information at the national level	
Submission of financial and scientific reports at the national level	Submission of annual scientific and financial reports at the national level will be required according to the rules of the Ministry of Health (Ricerca Finalizzata). Further information on the rules of the Ministry of Health can be requested to the national contact persons
Staring date of the clinical study	
Further guidance	

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. 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 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. For pragmatic clinical trials the healthcare costs must be carried by the national healthcare system. 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 for the research going outside of the normal healthcare services provided in the case of a specific ailment. 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
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. 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.
Staring date of the clinical study	Application for the state aid must be submitted **before** the start of the project which is stated in the consortium agreement
Further guidance	Support is provided according to Provisions Nr 259, 26.05.2015 of the Latvian Cabinet of Ministers (http://likumi.lv/ta/id/274671-atbalsta-pieskirsanas-kartiba-dalibaistarptautiskas-sadarbibas-programmas-petniecibas-un-tehnologiju-joma) 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. Eligible beneficiary institution (grant holder) manages the state budget funds allocated to the project following the rules stated in the legal acts, as well as representing the associated project partners (if applicable 'project partner' means public or private legal entity that, together with the eligible institution, created the conditions for project implementation). 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 in 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/0a8bead0577611e9975f9c35aedfe438/asr
Eligibility of costs, types and their caps	All costs mentioned in the Call text as Investigational costs are eligible: site costs (personnel, clinical procedure, site services, patient/participant renumeration), country management sites (site selection and coordination at the country level), and clinical study management costs at national or regional level (e.g. monitoring and insurance). 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/0a8bead0577611e9975f9c35aedfe438/asr
Duration of the clinical study	48 Months
Specific rules for potential extensions	During the implementation of the project, the reasoned amendments of the agreement may be initiated, including extensions. Amendments to the

	agreement shall be made in accordance with the procedures and within the time limits specified in the agreement.
Submission of the proposal at the national level	The submission of the proposal at the national level is not required.
Submission of other information at the national level	Following funding decision, grant signing institution and the PI must complete and submit the national document (the template can be found following this link) containing this information: more detailed planed budget, foreseen dissemination and communication activities and expected outputs from clinical study results with the granted research team contribution (scientific papers, patents, etc.)
Submission of financial and scientific reports at the national level	Midterm and final scientific reports nationally are required as well as the yearly financial reports.
Starting date of the clinical study	It must be in 2026, 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**
National contact person	Henrietta Blankson hbl@rcn.no tel : +47 92233762
Funding commitment	900 000 EUR Depending on the volume of submitted and eligible projects, up to 25 % additional funding may be allocated to the call 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	Within a single project, the maximum funding can be up to 300 000 EUR. If the participant has a coordinator role, the maximum funding can be up to 450 000 EUR.
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	Principal investigators must come from an approved Norwegian research organization. User/patient organizations may participate under the umbrella of the principal investigator (with a collaboration agreement or subcontracting).
Eligibility of costs, types and their caps	Payroll expenses, consumables, operating expenses, network measures. PhD fellowships are not eligible within the RCN funding. For postdoctoral fellowships, duration of the support is limited to a minimum of three years and a maximum of four years. The overhead cost is 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 request with justification and an agreement in the whole project consortium may be considered.
Submission of the proposal at the national level	If the proposal is granted, information about national 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.
Staring date of the clinical study	From January 2026
Further guidance	For medical and health-related studies involving human participants, the Research Council stipulates special 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	Dr Marcin Chmielewski T: +48 22 39 07 109 M: +48 571 226 666 marcin.chmielewski@ncbr.gov.pl
Funding commitment	2 500 000 EUR
Anticipated number of fundable proposals	1-5
Maximum/ Minimum funding per grant awarded to a clinical study partner	Maximum 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.
Eligibility of partners	Following entities are eligible to apply: **Research organization** (research and knowledge-dissemination organisations)[1]. Entities must be established as a legal person[2] and must conduct its business, R&D or any other activity on the territory of the Republic of Poland, confirmed by an entry into the relevant register[3].
Eligibility of costs, types and their caps	The eligible costs shall be the following: 1. personnel costs 2. consumables 3. equipment 4. travel 5. other direct costs 6. subcontracting - this cost type cannot account for more than 70% of all eligible costs of a project 7. additional overheads incurred indirectly as a result of the research project; that costs are exactly 25% of eligible project costs and are counted as a multiplication by percentage given above and the rest of direct costs, excluding subcontracting (6); It means 7 = (1+2+3+4+5)*25%

[1] Defined in Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty (hereinafter referred to as “Commission Regulation (EU) No 651/2014”);

[2] Legal person (juridical person) - an entity that is capable of having and amend legal rights and obligations within a certain legal system, such as to enter into contracts, sue, and be sued, excluding natural persons;

[3] if applicable.

<table>
<tr><td></td><td>Please refer to cost eligibility guide (przewodnik kwalifikowalności kosztów) for details. Guide is available on the NCBR webpage: https://www.gov.pl/web/ncbr

<table><tr><th></th><th>Research organization</th></tr><tr><td>Fundamental/Basic Research</td><td>Not eligible</td></tr><tr><td>Industrial/Applied Research</td><td>Not eligible</td></tr><tr><td>Experimental development</td><td>Up to 100 %</td></tr></table>
Please note that only Experimental Development will be funded. Fundamental/Basic research or Industrial/Applied research are not eligible for funding.</td></tr>
<tr><td>Duration of the clinical study</td><td>Up to 48 months</td></tr>
<tr><td>Specific rules for potential extensions</td><td>-</td></tr>
<tr><td>Submission of the proposal at the national level</td><td>Polish Participants will be informed and invited to submit Polish proposal once the international evaluation and the ranking list will be established.</td></tr>
<tr><td>Submission of other information at the national level</td><td>After international evaluation of full proposals and the selection of projects to be funded, Polish participants will be invited to submit a National Application Form (NAF). The NAFs will be examined for the appropriateness of funding requested. The Polish participants are obliged to use the rate of exchange of the European Central Bank dated on the day of opening of the call.</td></tr>
<tr><td>Submission of financial and scientific reports at the national level</td><td>Annual scientific reports are obligatory.</td></tr>
<tr><td>Staring date of the clinical study</td><td></td></tr>
<tr><td>Further guidance</td><td>Sample documents are available at:
https://www.gov.pl/web/ncbr/wniosek-krajowy

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/

Relevant documents:
All proposals must be aligned with national regulations, inter alia:</td></tr>
</table>

	• 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.

Country	**Slovakia**
Funding organisation	**Slovak Academy of Sciences (SAS)**
National contact person	Katarina BIBOVA bibova@up.upsav.sk Silvia KECEROVÁ kecerova@up.upsav.sk
Funding commitment	240.000€
Anticipated number of fundable proposals	1
Maximum/ Minimum funding per grant awarded to a clinical study partner	240.000€
Funding mechanism	SAS allows the 1st funding mechanism, which means, that 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	Only research Institutes of the Slovak Academy of Sciences are eligible organisations for funding by SAS (up to 100%). SAS can fund only Principal Investigator (PI), not a Coordinating Investigator in this call.
Eligibility of costs, types and their caps	Total eligible costs = Direct costs + Indirect costs (DC + IC) • Direct costs (DC): Personnel (max. 15% of DC for the Project Partner) • Consumables and Travel costs • Indirect costs (IC, Overheads): max. 20 % of DC. https://oms.sav.sk/wp-content/uploads/Financne-pravidla-na-udelovanie-grantov-SAV-na-medzinarodne-vyskumne-projekty-platne-na-vyzvy-zverejnene-od-1.12.2023.pdf
Duration of the clinical study	48 months
Specific rules for potential extensions	If necessary, the possibility of a cost-neutral extension based on a request with justification and an agreement in the whole project consortium.
Submission of the proposal at the national level	No
Submission of other information at the national level	Submission of the proposal at the national level will be required once the international evaluation has taken place and the ranking list has been endorsed by the Joint Call Steering Committee (CSC). The Slovak partner will be informed about recommendation for funding by the project consortium coordinator and invited by SAS to submit the national proposal form (MVTS form). The Presidium of SAS makes the final decision concerning the approval of funding (according to internal rules of SAS). Resolution of the SAS Presidency no. 936. C.
Submission of financial and scientific reports at the national level	On annual basis (financial and scientific)

Starting date of the clinical study	Based on the agreement in the consortium in the consortium agreement (CA)
Further guidance	133 Act of February 19, 2002 on the Slovak Academy of Sciences, Principles of allocation of funds for the institutes of SAS to support projects in the field of international scientific cooperation

Country	Spain
Funding organisation	**Institute of Health Carlos III (ISCIII)**
National contact person	**Astrid Valencia Quiñónez / Sara García-Rodríguez** 91 822 22 27 / 91 822 28 68 EffecTrial@isciii.es
Funding commitment	**3.000.000,00 €** (*pending of approval of Spanish State Budget*)
Anticipated number of fundable proposals	3-4
National Programme	**PEICTI 2024-2027 "Líneas Estratégicas de Investigación en Salud"**
Maximum/ Minimum funding per grant awarded to a clinical study partner	**Maximum funding from ISCIII per awarded Spanish project:** • 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. 750.000,00 € per project.** **Overheads** according to the national programme "Líneas Estratégicas de Investigación en Salud" 2025: 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 "Líneas Estratégicas de Investigación en Salud" 2025). 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:

- **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, nutrition and lifestyle-related diseases and non-communicable respiratory 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 "Líneas Estratégicas de Investigación en Salud" 2025 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) could apply ONLY from 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. • For additional incompatibilities please review "Líneas Estratégicas de Investigación en Salud" 2025. **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 their scientific node of the **Spanish Clinical Trials Network (SCReN)** or if it does not exist, a member from the personnel of their Clinical Research Supporting Platform of their institutions (UIC). - In case of a **Spanish group not coordinating at international level** the clinical trial and applying funding to ISCIII, it is considered necessary and recommended to involve a member from their scientific node of the **Spanish Clinical Trials Network (SCReN)** or if it does not exist, a member from the personnel of their Clinical Research Supporting Platform of their institutions (UIC).

Eligibility of costs, types and their caps	• **Personnel costs:** - Personnel costs will be eligible for contracts with the needed professional category (superior technician, BSc (grado), MSc (máster), PhD (doctor) for the project development accordingly to the published salary tables in ISCIII's webpage / "Líneas Estratégicas de Investigación en Salud" 2025. Personnel cost will **precisely adhere to the salary tables**, no other amount will be considered, either upper nor lower. - Contracts for PhD students will be done 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 "Líneas Estratégicas de Investigación en Salud" 2025) 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 "Líneas Estratégicas de Investigación en Salud" 2025 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 "Líneas Estratégicas de Investigación en Salud" 2025, that can be justified as necessary to carry out the proposed activities. • **Overheads,** according to "Líneas Estratégicas de Investigación en Salud" 2025 (**25%**). • **Double funding** of the same concept is not allowed.
Duration of the clinical study	The initial 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 "Líneas Estratégicas de Investigación en Salud" 2025.

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 "Líneas Estratégicas de Investigación en Salud" 2025. Due to administrative and legal regulations, the Institute of Health Carlos III establishes the **31st October 2025** 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 "Líneas Estratégicas de Investigación en Salud" 2025. Any concerned applicant in a proposal for which no final decision has been made by the deadline of **31/10/2025**, 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 "Líneas Estratégicas de Investigación en Salud" 2025. 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: EffecTrial@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 2026).
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 "Líneas Estratégicas de Investigación en Salud" 2025 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	**Andalusian Regional Ministry of Health and Consumer Affairs (CSCJA)**
National contact person	Alicia Milano Curto Tel: +34 955040450 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 and should be part of the clinical study consortium. A maximum of 3 partners are authorised.
Eligibility of partners	Eligible organisation must be Andalusian Non-profit entities registered as Agents of the Andalusian Knowledge System (Registro de Agentes Andaluces del Conocimiento) with research and innovation activity in Biomedicine and Health Sciences, ie: Research managing foundations of the Andalusian Public Health System. Eligibility criteria established in Orden de 10 de agosto de 2023 de la Consejería de Salud y Consumo de la Junta de Andalucía. • 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% **g. Subcontracting costs**: cannot exceed 50% of the funding and need prior authorization from the granting body. Nor Scientific aspects nor the management of the project should be subcontracted. 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 Call. In any case, this period shall be stated in the award resolution
Specific rules for potential extensions	The maximum extension is limited to half of the initial duration of the project.
Submission of the proposal at the national level	• The deadline for the submission of regional applications will be established in the regional call and will be informed through the website of the Regional Ministry of Health and Consumer Affairs. • 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 Salud y Consumo 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 Salud y Consumo 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.