

Call for proposals 2027

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

Preliminary announcement

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) in priority areas addressing European Public Health Needs. This Partnership brings the opportunity to increase European transnational collaborative research funding by creating a funding body for joint programming.

Under this umbrella, ERA4Health is glad to pre-announce the launch of its 9th Joint Transnational Call (JTC) which will be dedicated to funding multi-country Investigator-Initiated Clinical Studies (IICS): “Multi-national Investigator-Initiated Clinical Studies in Cardiovascular, Autoimmune, Metabolic, and Non-Communicable Respiratory Diseases, including Underrepresented Populations” (IICS4all 2027).

1. Aim of the call

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

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

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

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

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

- Cardiovascular diseases
- Metabolic disorders¹
- Autoimmune diseases²
- Non-communicable respiratory diseases

The multi-national 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 in combination with related comorbidities.

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

OUT OF SCOPE

- Clinical studies conducted for direct commercial purposes
- For drug repurposing studies: a drug still on patent in one of the participating countries. This criterion also applies to biological medicinal products and biosimilars.
- Phase I and Phase II studies: Studies in which a treatment is used in humans for the first time, or which are aimed exclusively at assessing tolerability, safety or dose determination
- Proposals focused on observational studies, non-interventional cohort studies, implementation studies, translational/clinical approval studies, creation of large databases, systematic reviews and meta-analysis. Non-randomised studies.
- Studies in **other medical areas which are not mentioned above** (cardiovascular diseases, metabolic disorders, autoimmune diseases and non-communicable respiratory diseases). Particularly, those clinical studies that are focused on **cancer are out of the scope of this call**, even if this is studied with one of the eligible diseases/conditions.
- Basic biomedical research and research involving animals or animal tissue
- Development of a new healthcare intervention
- Medicinal products without marketing authorization in Europe and in other countries outside the EU/EEA involved in the respective consortium. Medical devices without CE mark.

^{1, 3} Proposals focusing on type 1 diabetes should contact the Breakthrough T1D funding organisation, which can fund partners from different countries, also from countries not participating in the call.

- In comparative-effectiveness studies, the use of placebo will only be allowed for blinding of the interventions that will be compared. Otherwise, the use of placebo in those studies will be out of the scope. In the case of drug repurposing trials, this exclusion would not apply, and these studies could include placebo, albeit it would not be mandatory to include it.
- Topics excluded from Horizon Europe: research which aims at human cloning for reproductive purposes, modifying the genetic heritage of human beings which could make such modifications heritable, creating human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer, or leading to the destruction of human embryos (for example, for obtaining stem cells).

REQUIREMENTS

The maximum funding duration is 48 months.

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

- The design of the clinical study must be appropriate to answer the research question (population, sample collection, statistical power, statistical analysis, interpretation, relevant models for hypothesis validation) and must be well justified in the proposal.
- The clinical study design and objectives must take into consideration the population that would be needed to reach the objective of the study. Strategies for recruitment, retention, assessment, and analysis must be included.
- **For comparative effectiveness studies**, these must compare the use of currently approved or existing healthcare interventions (see definition), used in clinical practice, either to each other or to the current standard of care.
These healthcare interventions could include but would not be limited to: diagnostic, screening, prevention and treatment interventions. The interventions can be pharmacological as well as non-pharmacological procedures, for example well-defined, reproducible and targeted nutritional and lifestyle interventions, surgery, prognosis methods, use of medical devices, nano and advanced health technologies, eHealth and digital interventions and other health interventions.
- **For drug repurposing trials**, a new indication of an approved off-patent medication should be explored. Given that this call is supported by public funding, clinical studies with a commercial purpose are excluded, therefore only off-patent drug repurposing trials are eligible. Drug repurposing trials need to have an upfront plan to ensure patient's access to the drugs in the different countries.

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

- In alignment with the [European Commission Roadmap for Women's Rights](#) stating that women and girls' physical and mental health needs to be improved by evidence-based information and gender-sensitive medical research, clinical trials, diagnostics and treatments, the proposed research needs to address sex and gender aspects.
Age-related aspects also need to be taken into account where relevant to the disease area and research question. These considerations should be reflected throughout the proposed study, including study design, conduct, statistical analysis, and interpretation of the results. Proposals

should aim, where relevant, address sex/gender-sensitive, age-specific or other diversity-related knowledge gaps in one of the included disease areas (e.g. women in cardiovascular disease).

- The study population needs to adequately reflect the population for whom the intervention is intended, taking into account sex, gender and age. Studies should not exclude pregnant and breast-feeding women by default, any exclusion should be based on justified reasons.
- The applicants need to clearly justify in their proposal, where the inclusion of underrepresented groups or investigation of sex/gender-sensitive, age-specific or other diversity-related aspects is deemed not feasible. The justification should be evidence-based and explain the underlying scientific reasons, as well as the potential implications for the interpretation of and generalisability of the study results.

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

- To exclude clinical studies with direct commercial purposes, the protocol and study design must be described in a very clear and transparent manner. In the case of the involvement of any private for-profit entity, the consortia need to duly justify their role in the proposal and ensure that no commercial purpose or benefit exists.
- Partners in the consortia, especially the Coordinating Investigator, need to have a proven track record in delivery of clinical trials to ensure feasibility of the clinical trial. Further, all relevant expertise (including trial biostatistical expertise) needs to be included in the trial team to conduct high-quality clinical trials. The individual partners should be complementary in their expertise.
- Any IICS must clearly demonstrate the added value of transnational collaboration. Proposals must show how the outcomes of the trial could generate further health, economic and/or policy impact in the future (e.g. through a socioeconomic evaluation and to demonstrate how the evidence gathered by the comparative-effectiveness clinical trial could be valuable for future Health Technology Assessments (HTA). They should consider the path to impact both if an effect is shown and if an effect cannot be shown.
- For the chosen population, clinical and safety parameters, as well as health and socio-economic outcomes (e.g. quality of life, patient mortality, (co)morbidity, costs, and performance of the health system) should be assessed. Proposals must include Core outcome sets (COS)³ where they exist or justify their lack of use⁴.
- 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).
- Proposals must include an **early involvement of ‘end users’** (patients, care providers, healthcare professionals, etc.) in the design and development of the study (integrating patient-relevant outcomes, selection of patient-relevant study endpoints, feasibility /acceptability of the study and trial assessments) and a continued involvement of patients through the lifecycle

³ Core outcome set (COS) is an agreed, standardized collection of clinical outcomes that should be measured and reported in all clinical trials for a specific health condition. It aims to ensure consistency across studies, improve comparability of results, and enhance the relevance of research for patients, clinicians, and policymakers. Proposals should aim at including COS when appropriate.

⁴ <https://www.comet-initiative.org/>

of the research project. This is to ensure acceptability of the healthcare intervention and utility of the study outcomes for healthcare decision making to pursue a high implementation potential for the benefit of end-users/patients/citizens.

Patient organisations or other end-users can participate as partners (if eligible for funding by a national/regional funding organisation), as Collaborators (participation with their own budget) or as part of a Patient Advisory Board.

- Inclusiveness aspects in patient recruitment (minorities, social-economic aspects, ethnical aspects...) must be ensured by including underrepresented and vulnerable populations. Issues of particular relevance for the target population, for example, sex and gender specificities, age, multimorbidity, complex chronic conditions, polypharmacy, substance misuse, vaccine efficacy, compliance, and diseases with high societal burden need to be considered.
- Consortia are encouraged to promote gender balance in their overall team composition and to ensure equitable opportunities for participation in leadership roles and responsibilities.
- Proposals should take into account the diversity of health systems and the choice of the comparator in different regions of Europe to allow large-scale uptake.
- It is strongly recommended to use appropriate statistical techniques that can account for variations among countries in a trial.
- Proposals shall address the scalability from the regulatory perspective for each of the involved countries.
- IICS supported by ERA4Health must respect fundamental ethical principles (see section ethical clearance). Applicants must fill an ethical grid as part of their proposal and describe any potential ethical aspects of the work to be carried out, and how the clinical study will fulfil applicable requirements in institutional, national and European Union legislation (including the ethical standards and guidelines of Horizon 2020/Horizon Europe ⁵). All funded partners must respect the fundamental principle of research integrity — as set out in the European Code of Conduct for Research Integrity⁶. IICS involving human embryonic stem cells (hESC) or human embryos (hE) may not start without prior ethics review carried out by the European Commission and subsequent decision of the Horizon Europe Programme Committee.⁷
- The consortia shall ensure the management of research data and biological samples collected during the projects, according to FAIR data principles (Findability, Accessibility, Interoperability and Reuse) and in compliance with the General Data Protection Regulation (GDPR).
- Applicants invited to submit a full proposal must demonstrate that they have explored the “freedom to operate” (FTO) aspects of their proposed study and are aware of the relevant regulatory requirements. Applicants should consult with their legal advisors or technology transfer office (TTO) early in the process to ensure that implementation of the study is not restricted by intellectual property rights (e.g., primary or secondary patents) or regulatory requirements.

RECOMMENDATIONS

The following recommendations should be considered:

⁶ [The European Code of Conduct for Research Integrity - ALLEA](#) (All European Academies)

⁷ [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021C0512\(01\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021C0512(01)&from=EN)

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

2. Time schedule

There will be a two-step submission and evaluation procedure for joint applications.. In addition, the full proposal review process will be complemented by a rebuttal phase including a dedicated feasibility assessment. For both submission steps, one joint proposal document (in English) shall be prepared by the partners of a joint transnational proposal and must be submitted on the dedicated electronic submission system PT-Outline by the Coordinator Investigator. The two-step application process will have the following timetable:

27th October 2026	Publication of IICS4all call
10th November 2026	Online info session for applicants
14th January 2027 12:00 CET	Deadline for pre-proposal submission
Mid-April 2027	Communication of the results of the pre-proposal assessment (invitation for full proposal)
14th June 2027 12:00 CEST	Deadline for full proposal submission
23th August – 3rd September 2027	Rebuttal stage
End of October, 2027	Communication of the funding decisions to the applicants
January – May 2028	Expected project start (subject to national procedures)

3. Participating countries/regions and respective funding organisations

Country	Funding organisation	Acronym
Austria	Austrian Science Fund	FWF
Belgium	Belgian Health Care Knowledge Centre	KCE
Czech Republic	Ministry of Health of the Czech Republic	MZ CR (AZV CR)
Egypt	Academy of Scientific Research and Technology	ASRT
France	French Ministry of Health	FR MOH
Germany	Federal Ministry of Research, Technology and Space (BMFTR) / DLR Project Management Agency (DLR)	BMFTR/DLR
Ireland	Health Research Board	HRB
Israel	Ministry of Health	CSO-MOH
Italy	Regional Foundation for Biomedical Research (Lombardy Region)	FRRB
Latvia	Latvian Council of Science	LCS
Lithuania	Research Council of Lithuania	LMT
Norway	The Research Council of Norway	RCN
Norway	South Eastern Norway Regional Health Authority	HSØRHF
Poland	The National Centre for Research and Development	NCBR
Romania	Executive Agency for Higher Education, Research, Development and Innovation Funding	UEFISCDI
Slovakia	Slovak Centre of Scientific and Technical Information	CVTI SR
Spain	Department of Health of Catalunya	DS-CAT
Spain	Institute of Health Carlos III	ISCIII
Spain	Regional Ministry of Presidency, Healthcare and Emergencies of Andalusia	CPSEJA
Sweden	Swedish Research Council	SRC
Türkiye	Health Institutes of Türkiye	TÜSEB
UK	Department of Health and Social Care	DHSC-NIHR
Global organisation	Breakthrough T1D	BT1D

If you are interested in this call and are looking for potential consortium partners, please have a look at the partner search tool **PartFinder** that is available on the [ERA4Health website](https://era4health.eu/) (filter by choosing the call name “ERA4Health JTC9 IICS4all”).

More information will soon be available online:

<https://era4health.eu/>

Please note: The content of the call described in this pre-announcement is indicative and may be subject to changes and is not legally binding. Interested applicants are encouraged to initiate scientific contacts with potential project consortium partners for applications.