ERA4Health Partnership

Co-funded by the European Union

Call for proposals 2025

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

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 a first Joint Transnational Call (JTC) in multi-country Investigator-Initiated Clinical Studies (IICS) on "Fostering Pragmatic Comparative-Effectiveness Trials in Non-communicable Diseases" (EffecTrial).

1. 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 <u>all</u> the 4 following points:

1) **Be a pragmatic comparative effectiveness trials, designed as randomised interventional trials**.

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. [1]

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 taken into account, including approaches to Responsible Research and Innovation (RRI).

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 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.
- 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,

[1] 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 nutrition 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 nutrition intervention.

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 abovementioned** (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.

2. Time schedule

There will be a two-step submission and evaluation procedure for joint applications. The full proposal review process will be complemented by an online interview of the investigating coordinator and a representative of the sponsor, and a rebuttal stage. 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 project coordinator. The two-step application process will have the following timetable:

20 November, 2024	**Publication of EffectTrial call**
27 November, 2024	**Webinar Infoday**
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**
End of October, 2025	Communication of the funding decisions to the applicants
January – May 2026	**Expected project start** (subject to national procedures)

3. Participating countries/regions and respective funding organisations

Country	Funding organisation	Acronym
Austria	Austrian Science Fund	FWF *
Czech Republic	Ministry of Health	MZCR
France	Ministry of Health	Fr-MoH
Germany	Federal Ministry for Education and Research (BMBF) represented by DLR Project Management Agency (DLR-PT)	BMBF/DLR
Ireland	Health Research Board	HRB
Italy	Ministry of Health	IT MOH
Latvia	Latvian Council of Science	LCS
Lithuania	Research Council of Lithuania	LMT
Norway	Research Council of Norway	RCN
Poland	National Centre for Research and Development	NCBR
Slovakia	Slovak Academy of Sciences	SAS
Spain	Institute of Health Carlos III	ISCIII
Spain	Regional Ministry of Health and Consumer Affairs of Andalusia	CSCJA

** Pending for official confirmation.*

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.*