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NEWSFLASH

November 21st, 2024

EffecTrial: Fostering Pragmatic Comparative-Effectiveness Trials in Non-communicable Diseases

ERA4Health is excited to announce the launch of EffecTrial.

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.
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 requirements and recommendations should be considered (check the Call text for further information).
Please note that **additional conditions** might apply at **national level**.

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

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 pre-proposal

template and the ERA4Health RRI Guidelines further elaborate on how RRI dimensions can be approached (check the Guidelines for Applicants for more information).

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).

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:

- 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.

Call timeline and further information

INFO DAY

Informative online session for EffecTrial applicants

November 27th, 2024

14:30 – 16:30

Online

Further details will be published in the ERA4Health website

For more latest news and events, follow the following links

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Thank you for showing interest in this Partnership. We greatly value your support and participation. If you have any questions, comments, or research insights you would like to share, we encourage you to reach out.

Sincerely,
ERA4Health

Reach out

If your organisation is interested in being involved in the ERA4Health network and activities, please contact Cristina Nieto,

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