

GLOBAL CARDIOVASCULAR RESEARCH FUNDERS FORUM

MULTINATIONAL CLINICAL TRIALS INITIATIVE

About the GCRFF

The Global Cardiovascular Research Funders Forum (GCRFF) has been established as a forum for dialogue and collaboration between major international cardiovascular research funders. Founding members include:

- The American Heart Association
- The British Heart Foundation
- The Danish Heart Foundation,
- The Dutch Heart Foundation,
- The German Centre for Cardiovascular Research,
- The Leducq Foundation,
- The Heart and Stroke Foundation of Canada,
- The Institute of Circulatory and Respiratory Health, Canadian Institutes of Health Research, Canada,
- The National Heart Foundation of Australia,
- The National Heart Foundation of New Zealand
- The Swedish Heart Lung Foundation

The mission of the group is to advance global cardiovascular health by catalysing, supporting and promoting transformational international research efforts in heart, stroke and circulatory diseases.

The **Multinational Clinical Trials sub-group** of GCRFF aims to support this mission by facilitating the coordinated consideration of investigator-led multinational clinical trials by national funders. Current membership of the Multinational Clinical Trials sub-group is:

- British Heart Foundation
- Dutch Heart Foundation
- German Centre for Cardiovascular Research
- Institute of Circulatory and Respiratory Health, Canada
- National Heart Foundation of Australia
- National Heart Foundation of New Zealand

The GCRFF Multinational Clinical Trials Initiative

The GCRFF Multinational Clinical Trials Initiative aims to facilitate the coordinated consideration of investigator-led multinational clinical trials by national funders.

The GCRFF is committed to promoting and facilitating better international collaboration and coordination in the conduct of cardiovascular clinical trials, in recognition of the following advantages:

- The findings are more generalisable
- Trials can be delivered much faster, with higher power and stronger evidence
- Sharing the financial burden can make them more affordable
- They have the power to improve health for people around the world in a more equitable way

The GCRFF Multinational Clinical Trials Initiative provides a mechanism through which researchers can submit a single proposal for a multinational cardiovascular trial, for timely consideration by individual research funders. Each national funder can then decide whether they wish to consider an application to fund the element of the trial in their jurisdiction through their normal processes, with a full understanding of the wider components of trial design and funding. The aim is to deliver the following benefits:

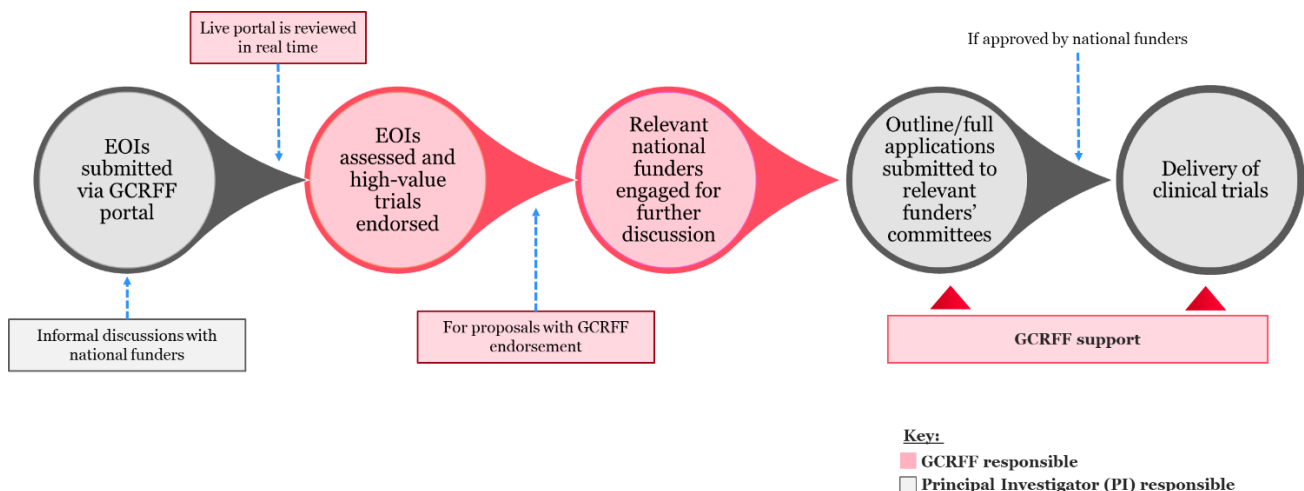
- Help researchers in different countries to collaborate more effectively and plan ambitious, practice-changing clinical trials for successful delivery from the outset.
- Allow individual research funders to input into the trial design at the outset, in contrast to the current situation, where additional funders are often approached late after initial support for the trial has been secured from one funder, and the trial has already started.
- Reduce the risk to the funder(s) because there is greater assurance that the trial will be deliverable and costs are spread.

Please note: the GCRFF Multinational Clinical Trials Initiative provides a mechanism to support better coordination of consideration of multinational trial funding. It does not fund trials directly, nor does it guarantee funding by individual funders. Individual members of the Expert Advisory Panel assessing Expressions of Interest should not be contacted by researchers directly.

Proposed funders do not need to be members of the GCRFF.

How it works:

Triallists wishing to participate in the GCRFF Multinational Clinical Trials Initiative will follow the following process:



Researchers can submit initial expressions of interest (EOIs) for multinational trials through a [dedicated portal](#). Please note that EOIs must meet specified criteria – see below for details on how to submit.

Members of the GCRFF and their advisory group will then assess the EOI, endorse trials considered to have merit, and convene and facilitate discussion by relevant national funders accordingly.

Following these discussions, investigators in each country can prepare coordinated but individual applications to their national funders requesting support for that component of the trial, in the knowledge that those funders are already aware of the proposal, and the GCRFF's endorsement. The scientific rationale and trial design would be expected to be uniform across all applications.

Knowing from the offset where the trial will be conducted, its full sample size, and the totality of funding requested will help national funders make informed decisions on whether to support the final application. Furthermore, funders can make their decision conditional on the trial being funded in sufficient countries to make it viable.

If sufficient funders are prepared to support the trial, the trial can begin at or near the same time in different countries making it more likely to succeed and be delivered in a timely fashion.

Criteria for submitting an Expression of Interest

- The principal investigator should be a senior researcher working in an established and eligible research institution in a GCRFF member country. They must have a strong track record of grant support, and an internationally recognised research profile.
- The trial should plan to test specific interventions or pathways of care for the prevention, diagnosis or treatment of heart and circulatory diseases. Interventions include drugs, surgery, devices, psychological, physical and educational interventions.
- The trial should address an unmet clinical need of importance to people affected by, or at risk of, cardiovascular disease. Its results should have the potential to change clinical practice.
- There should be a clear need for a *multinational trial* to answer the clinical question.
- It should be clear why the trial should be considered for support by the national cardiovascular funders and not by others (e.g. pharma) - although we encourage applicants to explore co-funding beyond the GCRFF members.
- The triallists should have initiated discussions about the trial with relevant funding bodies in the countries where the majority of participants are planned to be recruited.

How to submit an EOI

The portal to access and submit an EOI can be found here - <https://researchgrants.bhf.org.uk/>.

- The first step involves a review by the GCRFF of an expression of interest (EOI) for the trial. The EOI must be submitted online through the portal linked above. New users will need to register for an account before they can submit an EOI.
- Sign in to the application portal and select 'My Applications' from the top right of the screen. Select 'Available grants' from the menu on the left and scroll down to GCRFF Multinational Clinical Trials Expression of Interest. Click 'Start' to begin an EOI.
- If not already recorded on their portal profile, applicants will be asked to provide contact information and institution details. All pages of the form will then need to be completed - clicking 'Submit application' on the summary page will then submit the EOI for consideration by the GCRFF.
- Submission receipt will be acknowledged by email automatically and followed up with a further email indicating when an outcome of the application can be expected.