GCRFF/23/270144

Section 1 - Investigator information

PRIMARY APPLICANT DETAILS

Title
Name
Surname
Organisation
Tel (Mobile)
Email (Work)
Address

Other investigator information

Provide the name, job title, department, institution and country for each co-applicant. Separate each entry with a line break.
The GCRFF encourages diversity in investigator teams, including the trial leadership.

Section 2 - Trial summary

Project title

The title should be concise and accurately reflect the overall aim of the proposed research. You can include special characters.

You can enter a maximum of 50 words.

Scientific Abstract

You can enter a maximum of 200 words.

Plain English Summary

You can enter a maximum of 200 words.

Estimated start date of trial

The start date of the trial will be dependent on the processes of individual funders so please bear this in mind when estimating.

No Response

Estimated end date of trial

No Response

Duration (in years and months)

X years, X months

Estimated total amount to be requested for the whole study (in pounds sterling)

£0.00

Is this a resubmission?

Select **Yes** if you have previously submitted the same proposal, or a closely related one, to the GCRFF Multinational Clinical Trials Initiative.

⊙ Yes

Resubmission of (Case Reference)

Please refer to your decision email for the relevant case reference number.

If answer is Yes to Is this a resubmission?

Explain how the Expression of Interest has changed from the previous submission.

If answer is Yes to Is this a resubmission?

Upload a PDF copy of the summary comments and individual reviews you received on your previous Expression of Interest (from the decision email). You can also include a one page (A4) response to the panel's comments. We suggest you focus on responding to the panel's summary comments – it is not expected that you respond to each individual reviewer comment.

No Response

A statement of the research question(s), aims and objectives

No Response

Explain why a multinational study is needed

You can enter a maximum of 300 words.

No Response

Study design in PICO format

- Population (include inclusion and exclusion criteria)
- Intervention and Comparator. Include whether the treatments will be blinded. State whether the trial will be placebo controlled.
- Outcome measures: primary and secondary outcome measures. State the main outcomes only.
- Time of measurement of primary and secondary outcomes (duration of follow up).
- Clinical setting in which participants will be identified and invited to participate (e.g. general practice, hospital outpatients, ambulance service users).

You can enter a maximum of 1500 words.

Sample size and recruitment targets

- State the proposed total sample size.

- Provide a sample size calculation, describing the event rate (which should be based on contemporary data) and explaining how it was estimated. **It is important to justify the event rate, estimated effect size, power and type 1 error rate** (referring where appropriate to published literature – please add any relevant references to the **References** section at the end of Section 3).

- **The GCRFF would usually expect a multinational trial to be designed with ~90% power to increase the likelihood of a definitive result**.

- Give details of the proposed recruitment targets in each country (total numbers and proportion of the total sample size to be recruited from each country).

You can enter a maximum of 1500 words.

Sex analysis and under-represented groups

The GCRFF encourages diversity in trial participation. Demographic characteristics that can limit inclusion in research include sex/gender, ethnicity, socioeconomic status, and living in rural/remote areas.

Are you intending to perform a sex/gender stratified analysis? If not, justify why such an analysis is not required.

Outline briefly the strategies you will use to recruit a diverse group of participants that represents the population affected by the condition or needing the health intervention, including how your recruitment and retention methods will engage with any relevant under-represented groups.

You can enter a maximum of 200 words.

Evidence of feasibility

Explain how you have assessed the feasibility of the study, giving details of any pilot work to establish numbers of available participants, numbers of interested sites, trial methods and the existence of equipoise for the study question.

You can enter a maximum of 400 words.

Vanguard phase

The GCRFF would usually expect a multinational clinical trial to include a 'vanguard' phase to establish trial deliverability.

If you are planning a vanguard phase to establish deliverability of the trial, list the countries in which you are planning to include a vanguard phase, and provide brief details of the vanguard phase. If you are not planning a vanguard phase, justify why not.

You can enter a maximum of 400 words.

Study logistics and management

- Provide a brief overview of arrangements for management of the study across the collaborating countries, including the name of the overall study lead.
- State who will be the overall international sponsor for the study, and whether there will be distributed country level sponsors.

- Include the location of any international co-ordinating centre.

You can enter a maximum of 200 words.

Section 3 - Rationale for the trial

Brief description of the health problem being addressed

You can enter a maximum of 200 words.

No Response

Explain why the research is important to people affected by, or at risk of, cardiovascular disease

You can enter a maximum of 200 words.

No Response

Describe briefly what is already known about the topic (include how previous studies, meta-analyses or systematic reviews support the proposal)

You can enter a maximum of 400 words.

No Response

Explain why the study is needed now, what it will add and how it is novel

You can enter a maximum of 300 words.

No Response

Outline what will be the impact of the proposed study if successful. Are there any implementation challenges that might arise if it is successful?

You can enter a maximum of 200 words.

No Response

Describe briefly how patient and public involvement has informed and/or influenced the development of the study

You can enter a maximum of 200 words.

No Response

References

List a **maximum of 10** key references relevant to the proposal, including any publications on which the sample size is based. Provide publications in the following format: Lead author(s), publication title, journal name, year published.

Please do not include references anywhere else in the application form.

You can enter a maximum of 400 words.

Section 4 - Partnership details

Summary of costs

When completing the cost table below please do the following:

- Provide indicative total amounts requested from each country specific funder (or funders).
- Use the full funder name, rather than abbreviations.
- Specify the amount of funding requested in the Estimated amount requested boxes in both the local country specific currency and in pounds sterling.
- When entering the local currency amount, please provide the 3-letter abbreviation for the currency in brackets after the value. For example: 1,000,000 (EUR).
- You can add additional rows to the table for more funders if needed.

Name of funder	**Country**	**Estimated enrolment**	**Estimated amount requested (in pounds sterling)**	**Estimated amount requested (in local currency)**
British Heart Foundation	United Kingdom	750	£1,000,000.00	£1,000,000 (GBP)
Dutch Heart Foundation	Netherlands	500	£500,000.00	€575,275.00 (EUR)
Institute of Circulatory and Respiratory Health, Canada	Canada	250	£250,000.00	$425,000 (CAD)
		Total cost of trial (in pounds sterling, automatically calculated).	**£** 1,750,000.00	

Contact with national funders

- **Outline any discussions that have taken place between the trial team and prospective funders and the outcome of these discussions.**
- **Please note that we are also asking for your permission to discuss your expression of interest with other funders.**

Investigators are encouraged to informally discuss their trial proposal with the relevant national funders before submitting a proposal to the GCRFF Multinational Clinical Trials Initiative. **If you plan to apply to the DZHK for funding**, you should submit a short pre-application to the DZHK Clinical Study Group before submitting to the GCRFF

You can enter a maximum of 400 words.

Previous or parallel applications

- **Tell us about any previous applications for funding for elements of the study, where you have received a decision. Give details of the funders name, funding scheme, decision, grant reference number if awarded, amount awarded and date of decision.**
- **Provide details about any formal applications for funding that have been submitted, but where a result is awaited. Give the details of the funders name, funding scheme and the date when a decision will be reached.**

You can enter a maximum of 500 words.

Non academic collaborators

- **Give the name and type of contribution from any potential non academic collaborator (including commercial collaborators, e.g. drug company) if relevant.**

You can enter a maximum of 400 words.