Clinical Study Final Report

Clinical Study

CS/XX/X/XXXXX

Section 1 - Study details

Date of award

Date response

Start Date

Date response

End Date

Date response

Award value (original at award)

Value

Awarded Duration

Please enter the duration of award in months (original at award)

Text response

Was the grant extended and/or received a supplement?

Yes/No

If answer to above is Yes

Please provide the following for each extension and/or supplement request:

Date of request, Additional time granted if applicable (months), Additional funds granted if applicable (£).

Text response

Final award value

£0.00

Final award duration in months

Text response

Name of Sponsor

Text response

Name of Clinical Trials Unit

Text response

Date of HRA submission

Date response

Date of HRA approval

Date response

Date of ethics approval

Date response

Date of MHRA approval (if applicable)

Date response

Date of portfolio adoption

Date response

UKCRN Study ID

Text response

Clinical trials registry number (include EUDRA-CT no and/or Clinical trials.gov no and/or ISRCTN Registry no.)

Text response

Date of last update of the registry

Date response

Do you have a plan in place to update the registry annually or sooner until the trial is completed?

Please note that BHF guidelines for researchers conducting clinical trials require that:

- Registry records are updated to include final enrolment numbers achieved and the date of primary study completion (defined as the last data collection time point for the last subject for the primary outcome measure).

- Once available, the full study protocol and analysis plan must be uploaded

to or linked on the registry.

- Summary results from clinical trials (whether neutral, positive or negative) are made publicly available on the trial registry **within 12 months** of primary study completion. Any publications should also be linked to the registry record.

Yes/No

If answer to above is Yes
Please provide brief details.

Text response
If answer to above is No
Please explain why.

Text response

Did you set up a Trial Steering Committee?

Yes/No

If answer to above is Yes
Please provide the name of the TSC chair.

Text response
If answer to above is No
Please explain why.

Text response

Did you set up a Data Monitoring Committee?

Yes/No

If answer to above is Yes
Please provide the name of the DMC chair.

Text response
If answer to above is No
Please explain why.

Text response

Has the protocol been published or made publicly available?

Yes/No

If answer to above is Yes

Please provide details – including date of publication and where the study protocol is available.

Text response

If answer to above is No

Please explain why.

Text response

Does the study have a data management plan for making trial data more widely available after completion?

Yes/No

If answer to above is Yes

Please provide brief details.

Text response

If answer to above is No

Please explain why.

Text response

Section 2 - Study aims, recruitment and outcomes

Please provide a brief overview of study aims and design.

Include Aim/s, Setting, Design, Population, Intervention & Comparator (if applicable), Duration of intervention (if applicable), Outcome measures, Follow up duration.

Text response (500 words max)

Have your aims and objectives changed? If so, explain in what way and why.

Text response (500 words max)

Was the power calculation revised during the award? If so, summarise the changes and their rationale.

Text response

What was the original recruitment target at application?

Number

What was the revised recruitment target (if applicable?)

Number

Please provide the total number of participants actually recruited into the study.

Number

Please provide the total number of sites from which participants were recruited.

Number

Were participants recruited in the UK only?

Yes/No

If answer to above is No

Please provide the number of participants recruited in the UK.

Number

Please provide the number of UK study sites.

Number

Please list the countries in which recruitment took place.

Text response

Please provide the number of participants recruited outside of the UK.

Number

Please provide the number of study sites outside the UK.

Number

If you did not recruit to target, please explain why.

No Response

Demographics of participants

Please provide information on the overall demographics of the participants recruited (such as age, sex, ethnicity, and any other relevant characteristics) versus expected demographics of the population that is affected by the condition being studied or that needs the healthcare intervention. Please outline any actions that were taken to improve diversity of the participants recruited if relevant.

Text response

Summary of your findings (outcomes)

Text response (1000 words max)

How will these outcomes contribute to the fight against cardiovascular disease?

Text response (500 words max)

Lay Summary

Please also provide a brief summary of the outcomes in lay/simple language. Please note that we may publish a summary of the study and its findings on our website. We will contact you for final sign off before publishing.

Text response (200 words max)

Do you envisage that additional important outcomes resulting from this grant will appear in the months ahead?

Please note that BHF guidelines for researchers conducting clinical trials require that:

- Summary results from clinical trials (whether neutral, positive or negative) are made publicly available on the trial registry **within 12 months** of primary study completion (defined as the last data collection time point for the last subject for the primary outcome measure). Posting results to the registry should not prevent subsequent publication in a journal.

- The main findings are published in peer-reviewed journal or platform **within 24 months** of primary study completion.

Yes/No

If answer to above is Yes

Outline what these will be and when they are anticipated.

Text response (500 words max)

Section 3 - Patient and public involvement

Please provide an overview of how patients and the public have been involved in the design and conduct of the study. See our website for examples**.**

Text response

Please explain how patients and the public have been/will be involved in the dissemination of results.

Text response

How have you/will you be sharing results with participants?

Text response

As part of publishing the study details and results on our website**, we aim to include the perspectives of one or more participants in the study where possible. Would you be able to put us in contact with any participants who may be interested in contributing?**

If yes, we will follow up with you directly for details.

Yes/No

Section 4 - Publications and other outputs

Publications resulting directly from work of this grant

Do not include publications that are unrelated to the research funded through this grant. We expect all primary research articles reported to comply with our Open Access policy. **The grant reference number should have been acknowledged in all research articles. The study's unique registry number should be included in publications.**

Number of published or in press papers

Number

List of published or in press papers resulting directly from the work of this grant

Please list your publications in the following format - Lead author(s), publication title, journal name, year published, DOI/PMID. Please specify whether each paper is published or in press.

Text response

Number of papers in preparation or submitted

Text response

List of papers in preparation or submitted resulting directly from the work of this grant

Please list your publications in the following format - Lead author(s), publication title, journal name. Please specify whether each paper is

submitted or in preparation. **A reminder - the grant reference number should be acknowledged in all research articles.**

Text response

Other outputs resulting directly from work of this grant

For example, contributions to guidelines or policies, or technologies, tools, databases or other resources created.

Text response

Other publications/outputs that have been facilitated or supported by this grant

Please list any other publications or outputs that have been indirectly supported by this grant, indicating for publications whether they are in preparation, submitted, in press or published.

Text response

Dissemination of results

List where and by whom your findings have been disseminated. This may include conferences and workshops, but may also include other engagement events, for example related to patient & public involvement.

Text response

Section 5 - Intellectual property and commercial collaborators

Did your application indicate that protectable intellectual property and/or commercially exploitable technology would arise directly from the research funded by this grant?

Yes/No

Regardless of your answer above, please complete the sections below.

If protectable intellectual property and commercialisation activity has resulted directly from the research funded by this grant, or there is an intent to pursue commercialisation from data arising from the grant, please provide details (e.g. regulatory filings), patents filed, licenses, other commercial activity).

Text response

If no protectable intellectual property and commercialisation activity has resulted directly from the research funded by this grant, please tell us why.

Text response

Were any commercial collaborators involved with the study?

Yes/No

If answer to above is Yes

Please provide the names of the company/companies involved, their contribution to the project and expectations moving forward.

No Response

Section 6 - Staff contributions

Please provide details of staff who were employed at 100% FTE on the grant at any point during the award, with start and end dates and what they have contributed.

Text response

Section 7 - Signatures

Please download this attachment **and then either:**

- **Print and sign the document as appropriate, scan the document back onto your computer and upload it in the file upload box below, or,**
- **Paste your electronic signature as an image into the document, save it and upload it in the file upload box.**

Please note – final reports must be countersigned by the Head of Department.

File upload

Please note – in addition to completing this report, it is a condition of most grants that you will also need to continue to report on outcomes through Researchfish for five years from the end of the grant. Where appropriate, we will ask you to submit BHF-related grant outputs and impact data once a year, during a defined submission period.