Progress Report Form Clinical Study

For submission to BHF via the Grants Management System (GMS)

Contact for queries: gurungd@bhf.org.uk

BHF Grant No	
Name of Principal Investigator	
Title of project	
Host institution	
Award value	
Award duration	

Sponsor	
Clinical Trials Unit	

Date of Award			
Award start date	*dd/mm/yyyy*	**Award end date (current)**	*dd/mm/yyyy*
Date of report	*dd/mm/yyyy*	**Report number**	
Period covered by report	*dd/mm/yyyy to dd/mm/yyyy*	**% of grant duration completed**	

Details of extensions or supplements		
Requested date	**Additional funds granted (£)**	**Additional time granted (months)**
Extension/supplement totals		

Trial Steering Committee (if applicable)		YES (X)		NO (X)	
Name of Chair					
Last mtg date	*dd/mm/yyyy*	**Next mtg date**	*dd/mm/yyyy*		

Data Monitoring Committee (if applicable)		YES (X)		NO (X)	
Name of Chair					
Last mtg date	*dd/mm/yyyy*	**Next mtg date**	*dd/mm/yyyy*		

Date of HRA submission		**Date of HRA approval**	
Date of ethics approval		**Date of MHRA approval (if applicable)**	
Date of portfolio adoption		**UKCRN Study ID**	
Clinical trial registry name		**Clinical trials registry number (include EUDRA-CT no and/or Clinical trials.gov no and/or ISRCTN Registry no.**	

Have you reviewed the registry (and updated if appropriate) in the last 12 months?	YES (X)		NO (X)	
***Note**: The registry must be updated after each substantial protocol amendment or major milestone (e.g., end of vanguard phase, end of recruitment) and reviewed at least annually until the trial is completed. See BHF clinical study guidelines.*				
Date of last update of the registry	*dd/mm/yyyy*			
***Note**: Please see **Information about the protocol** on BHF clinical study guidelines for our expectations about making your protocol publicly available, and formally publishing the protocol and analysis plan.*				

PROJECT OUTLINE/BRIEF ABSTRACT (max 1 side A4 page)
Include Aim/ Setting/ Design / Population, Intervention, Comparator, Outcome measures, Duration of intervention, Follow up duration.

POWER CALCULATION
Include ***a brief summary*** of the power calculation and sample size estimation. Please include ***a brief summary*** of any revised power calculation.

STUDY PREPARATION

Outline progress on preparations for the trial. Include details of:
-establishment and membership of the Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) (if applicable)
-appointment of staff
-any delays in approvals (including HRA approvals, ethics approvals, MHRA approval etc).

STUDY PROGRESS

SUMMARY OF STUDY RECRUITMENT

If the report is for the UK arm of an international study, please include information about recruitment for the overall trial as well as the UK arm, where appropriate.

Target recruitment *(original at application and current target if revised)*	*xxx participants*	**Planned duration of recruitment** *(original at application. If an extension has been awarded, also include planned duration of recruitment after the latest approved extension)*	*xx months*
Number of planned study sites overall *(specify overall number of sites, UK sites, international sites)*	*xx sites overall* *xx UK sites* *xx international sites*	**Number of study sites currently open to recruitment**	*xx sites overall* *xx UK sites* *xx international sites*
First subject first visit date		**First subject last visit date**	
Last subject first visit date *(predicted if recruitment is ongoing)*		**Last subject last visit date** *(predicted if recruitment is ongoing)*	

Total number of participants recruited to	*xx participants recruited vs*	**Total duration of recruitment to date**	*xx months*

date versus expected number for this timepoint	*xxx target no of participants*		
Planned recruitment start date *(original at application)*	*dd/mm/yyyy*	**Planned recruitment end date** *(original at start of study. If an extension has been awarded, also include planned recruitment end date after the latest approved extension)*	*dd/mm/yyyy (at start of study)* *dd/mm/yyyy (after extension approved in mm/yyyy)*
Actual start date of recruitment	*dd/mm/yyyy*	**Current predicted recruitment end date** *(this should reflect the current recruitment status of the trial)*	*dd/mm/yyyy*
Please provide dates of any COVID-19-related pausing and restart/planned restart.			
If the study has restarted, has activity recommenced at all sites?			
Recruitment rate prior to March 2020		xx participants per month from xxx sites *(N/A if the trial started recruiting after March 2020)*	
Current recruitment rate		xx participants per month from xxx sites	
Recruitment rate to reach target by planned end date (*Recruitment rate using either the original planned recruitment end date or the revised planned recruitment end date if an extension has been approved by BHF)*		xx participants per month from xxx sites	
Recruitment rate to reach target by predicted end date if different from above		xx participants per month from xxx sites	
Expected primary outcome event rate	*Please provide this information as used in the sample size estimation*	**Actual primary outcome event rate**	*Please provide the number of primary endpoints (unrefuted, or adjudicated) over total follow up time to date.*

Include a graph of actual/expected recruitment
Please include vertical lines to indicate where recruitment has been paused and/or restarted.

If the report is for the UK arm of an international study, please include a graph of actual/expected recruitment for the overall trial as well as the UK arm.

Site Specific Recruitment
Provide details of the sites recruiting with site-specific monthly recruitment figures (and the site-specific monthly and total target): include a table of the numbers of patients screened and randomised per month at each site, dating from first patient screened to the most recent. Include details of sites that are yet to be initiated and the estimated dates when they will commence screening. Where recruitment has been paused due to COVID-19, please indicate site-specific restart/planned restart dates. Please see example table for studies which **have not** been paused due to COVID-19 and example table for studies that **have** been paused due to COVID-19. The appropriate table can be provided as a separate Excel or PDF file.

If the study is under-recruiting, explain why there are problems with recruitment. Include details about unresolved problems with recruitment prior to COVID-19 and COVID-19 related issues.
Include a plan outlining steps you are taking to bring/keep recruitment on schedule.

Demographics of participants
Please provide information on the demographics of the participants recruited so far (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 taken to improve diversity of the participants recruited if relevant.

Please note: We do not expect a description of demographic characteristics by treatment group.

Milestone update
Please detail any formal milestones agreed with BHF and update on the study's progress against milestones.

Loss to follow up and crossovers
Please note the number of participants lost to follow up, and the number of crossovers between arms (if appropriate). Outline any impacts of COVID-19 on participant follow up and how this has been/will be mitigated.

Cost mitigation
Please outline any actions you have taken to mitigate costs on the grant in light of any COVID-19-related or other delays and/or suboptimal recruitment.

Please outline any changes to project staff since your last report (including whether any staff have been furloughed/redeployed)

Adverse events

Have there been any adverse events since your last progress report which are reportable to a regulatory body?	*Yes/No*
If 'Yes', were any of these a SUSAR?	*Yes/No*
If 'Yes' to either of the above please provide a description	
Have these events been reported to the appropriate body?	*Yes/No*
If 'Yes' please provide the identity of the regulatory body	
If 'No' briefly explain why	

Project Oversight

Project Oversight Group name	Date of last meeting
Trial Steering Committee	
Data Monitoring Committee	
Please list any major actions recommended by the project oversight group and your response	

Please outline any major changes to the protocol since your last report.

Intellectual property

Please tell us about any changes or updates to Intellectual Property and/or commercialisation with relation to your study (for example if there are any plans for filing of a regulatory submission by any parties that pertain to the study). *You should discuss IP with your institution's Technology Transfer Office, or equivalent when completing this section.*

Timeline
Include details of the original study timeline, and indicate whether the study is on track to achieve this. Outline any impacts of Covid-19 on the study timelines and if necessary please include a revised timeline.

Other COVID-19-related Issues
Please notify us of any other significant impacts/potential impacts of COVID-19 on the study not covered in other sections. Please provide details about any changes to the study that have been/will be implemented to mitigate these impacts.

Other Issues
Please notify us of any other significant issues affecting the study or changes that have taken place. This may include changes to the CTU, ethics, PPI or any other issues not covered in other sections.

PLEASE NOTE: THIS REPORT SHOULD NOT BE USED TO REQUEST AN EXTENSION OR SUPPLEMENTARY FUNDING, WHICH SHOULD BE DISCUSSED WITH THE BHF OFFICE.

Principal Investigator's Signature: _____ Date: _____