CARDIOMAN
COMMUNICATION SHEET

Patient Name: _____ **CARDIOMAN study ID:** | | |

Date and time	Name	Message	Action

CARDIOMAN

A1

PATIENT DETAILS / TRIAL ELIGIBILITY

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

PATIENT DETAILS

Trust number **T** ☐☐☐☐☐☐☐

Date of Birth __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

Patient type: *Non-transplant* ☐ *Transplant* ☐

If Transplant patient, have statins been stopped
Statins must be stopped 2 weeks prior to study treatment

Yes ☐ *No* ☐ If yes date stopped: __ __ /__ __ /__ __ __ __

TRIAL ELIGIBILITY

	YES	NO
Male age ≥ 6 years old	☐	☐
Barth syndrome	☐	☐
Abnormal L4-cardiolipin/ monolysocardiolipin ratio	☐	☐
Mutation in tafazzin gene	☐	☐
Under care of Barth Syndrome Service	☐	☐
Stable cardiac condition	☐	☐
Able to swallow bezafibrate tablets (similar size to ibuprofen tablets)	☐	☐
Known photoallergic or phototoxic reactions to fibrates.	☐	☐
Known hypersensitivity to bezafibrate, to any component of the product or to other fibrates	☐	☐
Hepatic dysfunction and/or liver function tests greater than 2x normal	☐	☐

	YES	NO
A shortening fraction of <25 (or a significant drop in shortening fraction in the previous year)	☐	☐
Documented atrial or ventricular arrhythmia (atrial/ventricular tachycardia or atrial/ ventricular fibrillation) that has not been stabilised with treatment	☐	☐
Renal impairment (creatinine clearance (eGFR) < 90 mL/min)	☐	☐
Pre-existing known gallbladder disease	☐	☐
Recent unspecified significant deterioration in general health	☐	☐
Prisoner	☐	☐
Adult lacking capacity to provide informed consent	☐	☐
Already participating in another interventional research study	☐	☐

IF ANY OF THE ☐ ARE TICKED THE PATIENT IS NOT ELIGIBLE FOR THE TRIAL

I CONFIRM THE ABOVE NAMED PATIENT IS ELIGIBILE TO PARTICIPATE IN THE CARDIOMAN STUDY

(This must be signed by a medically qualified doctor)

SIGNED _____ PRINT _____ DATE __ __ /__ __ /__ __ __ __

PATIENT/PARENT/GUARDIAN INFORMATION

Date PIL sent/given to the patient and/or parent/guardians? __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

Version(s) of PIL sent/given?

Under 11yrs ☐ *v.* ___ *11-15 years* ☐ *v.* ___

16+ years ☐ *v.* ___ *Parent/guardian* ☐ *v.* ___

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

A2a

TRIAL ASSENT/CONSENT

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

PARENT/PATIENT CONSENT/ASSENT

	Patient ≤10 years	Patient 11-15 years	Patient 16+ years
Study explained to patient by parents/ clinician as appropriate?	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____
Was the patient or parents/guardians asked to give consent?	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____
Did the parents/ guardians consent to participate?	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____ If **YES**, date copy of consent form given to parents/guardians: __ __ /__ __ /__ __ __ __ *d d m m y y y y*	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____ If **YES**, date copy of consent form given to parent/guardians: __ __ /__ __ /__ __ __ __	
Was the patient asked to give assent?		*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____	
Did the patient assent to participate?		*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____ If **YES**, date copy of assent form given to patient: __ __ /__ __ /__ __ __ __	
Patient in agreement with the consent decision?	*Yes* ☐ *No* ☐ *NK* ☐		
Did the patient consent to participate?			*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____ If **YES**, date copy of consent form given to patient: __ __ /__ __ /__ __ __ __
Patient/guardian agree to donate samples for future research?		*Yes* ☐ *No* ☐	*Yes* ☐ *No* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

A2b

TRIAL ASSENT/CONSENT (CONTINUED)

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

PATIENT/PARENT CONSENT TO USE EXISTING SAMPLES ***(ONLY CURRENT 973 PATIENTS)***

	Patient 0 –15 years	**Patient 16+ years**
Was the patient or parents/guardians asked to give consent?	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____
Did the patient consent to participate?		*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____ If **YES**, date copy of consent form given to patient: __ __ /__ __ /__ __ __ __ *d d m m y y y y*
Did the parent/ guardian consent to participate?	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____ If **YES**, date copy of consent form given to parent/guardian:	

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

A2c

TRIAL ASSENT/CONSENT (CONTINUED)

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

PATIENT/PARENT ASSESNT/CONSENT TO TAKE PART IN QUALITATIVE INTERVIEWS

	Patient <14 years (parent to be interviewed)	Patient 14-15 years (patient to be interviewed)	Patient 16+ years (patient to be interviewed)
Was the patient or parents/guardians asked to give consent?	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____
Did the parents/ guardians consent to participate?	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____ If **YES**, date copy of consent form given to parents/guardians: __ __/__ __/__ __ __ __ (d d / m m / y y y y)	*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____ If **YES**, date copy of consent form given to parent/guardian: __ __/__ __/__ __ __ __	
Was the patient asked to give assent?		*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____	
Did the patient assent to participate?		*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____ If **YES**, date copy of assent form given to patient: __ __/__ __/__ __ __ __	
Did the patient consent to participate?			*Yes* ☐ *No* ☐ If **NO**, reason: _____ _____ If **YES**, date copy of consent form given to patient: __ __/__ __/__ __ __ __

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

A3

PATIENT CONTACT DETAILS AND RANDOMISATION

(ONLY COMPLETE FOR CONSENTED PATIENTS)

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Please complete the patient details below or apply addressograph NHS number: ☐☐☐☐☐☐☐☐☐☐

Patient address: _____

_____

_____

Patient postcode: _____

Would the patient like to receive a summary of the trial results at the end of the trial? *Yes* ☐ *No* ☐

Would the patient like to know their allocation order at the end of the trial? *Yes* ☐ *No* ☐

PATIENT CONTACT DETAILS (COMPLETE FOR PATIENTS 16YRS+)

Patient's mobile number: _____ Alternative phone number (if applicable): _____

Can answer machine messages be left on landline: *Yes* ☐ *No* ☐

Best time of day/week to contact patient _____

PARENT/GUARDIAN DETAILS

Name(s): _____ Relationship to child: _____

Address: _____

Parent/guardians mobile number: _____ Alternative phone number (if applicable): _____

Can answer machine messages be left on landline: *Yes* ☐ *No* ☐

Best time of day/week to contact parent/guardian _____

Would the parents/guardians like to receive a summary of trial results at the end of the trial? *Yes* ☐ *No* ☐

Would the parents/guardians like to know the trial allocation order at the end of the trial? *Yes* ☐ *No* ☐

GP DETAILS

GP name _____ GP practice _____

GP address _____

GP postcode _____ Date GP Letter sent: __ __ /__ __ /__ __ __ __

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

A4

DOCUMENTATION CHECKLIST

Patient Name: _____

CARDIOMAN study ID: ☐☐

DOCUMENTATION	*Please tick*		
Main study			
Original signed consent form (main study) filed in patient's CRF folder	☐		
Original signed patient assent form (main study) filed in patient's CRF folder	☐	*N/A*	☐
Copy of the signed consent form (main study) uploaded to electronic patient notes	☐		
Copy of the signed patient assent form (main study) filed in electronic patient notes	☐	*N/A*	☐
Copy of the signed consent form (main study) given to the parent/guardian/patient	☐		
Copy of the signed patient assent form (main study) given to the patient	☐	*N/A*	☐
Copy of the Patient Information Leaflet uploaded to electronic patient notes	☐		
Copy of completed A1 CRF uploaded to patient electronic notes	☐		
Copy of the GP letter filed in patient's CRF folder	☐		
Copy of the GP letter uploaded to electronic patient notes	☐		
Study inclusion details uploaded to electronic notes	☐		
Do not destroy details uploaded to electronic notes	☐		
Data entered on to EDGE	☐		
Existing samples			
Original signed consent form (existing samples) filed in patient's CRF folder	☐	*N/A*	☐
Copy of the signed consent form (existing samples) uploaded to electronic patient notes	☐	*N/A*	☐
Copy of the signed consent form (existing samples) given to the parent/guardian/ patient	☐	*N/A*	☐
Qualitative interview			
Original signed consent form (interview) filed in patient's CRF folder	☐	*N/A*	☐
Original signed patient assent form (interview) filed in patient's CRF folder	☐	*N/A*	☐
Copy of the signed consent form (interview) uploaded to electronic patient notes	☐	*N/A*	☐
Copy of the signed patient assent form (interview) filed in electronic patient notes	☐	*N/A*	☐
Copy of the signed consent form (interview) given to the parent/guardian/patient	☐	*N/A*	☐
Copy of the signed patient assent form (main study) given to the patient	☐	*N/A*	☐

CARDIOMAN
MEDICAL HISTORY

B1

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

HOSPITAL ADMISSIONS

Has the patient been admitted to hospital for an overnight stay in the last 6 months? *Yes* ☐ *No* ☐

If yes, how many times? ☐☐ *(please complete details below)*

Admission 1

Reason for admission: _____ Duration in days? ☐☐

Admission 2

Reason for admission: _____ Duration in days? ☐☐

If patient reports more than three admissions print and complete another B1 form.

SICK LEAVE

Has the patient missed school/work in the last 6 months? *Yes* ☐ *No* ☐

If yes, total duration of time off sick?

1 week ☐ 2-4 weeks ☐ 4 weeks + ☐

ANTIBIOTIC USE

Has the patient been prescribed any **additional** antibiotics in the last 6 months? *Yes* ☐ *No* ☐

If yes, name of drug? _____

If yes, name of indication? _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
MEDICAL HISTORY (CONTINUED)

B2

Patient Name: ______________________________ **CARDIOMAN study ID:** ☐☐

NEUTROPENIA

Please complete blood results for last 12 months?

Date	Neutrophils *(10^9/L)*	Monocytes *(10^9/L)*	Peak or Trough count	
__ __/__ __/__ __ __ __ *d d m m y y y y*	☐☐.☐☐	☐☐.☐☐	Peak ☐	Trough ☐
__ __/__ __/__ __ __ __	☐☐.☐☐	☐☐.☐☐	Peak ☐	Trough ☐
__ __/__ __/__ __ __ __	☐☐.☐☐	☐☐.☐☐	Peak ☐	Trough ☐
__ __/__ __/__ __ __ __	☐☐.☐☐	☐☐.☐☐	Peak ☐	Trough ☐
__ __/__ __/__ __ __ __	☐☐.☐☐	☐☐.☐☐	Peak ☐	Trough ☐
__ __/__ __/__ __ __ __	☐☐.☐☐	☐☐.☐☐	Peak ☐	Trough ☐
__ __/__ __/__ __ __ __	☐☐.☐☐	☐☐.☐☐	Peak ☐	Trough ☐
__ __/__ __/__ __ __ __	☐☐.☐☐	☐☐.☐☐	Peak ☐	Trough ☐
__ __/__ __/__ __ __ __	☐☐.☐☐	☐☐.☐☐	Peak ☐	Trough ☐
__ __/__ __/__ __ __ __	☐☐.☐☐	☐☐.☐☐	Peak ☐	Trough ☐
__ __/__ __/__ __ __ __	☐☐.☐☐	☐☐.☐☐	Peak ☐	Trough ☐
__ __/__ __/__ __ __ __	☐☐.☐☐	☐☐.☐☐	☐	Trough ☐

Name of person completing form* (capitals): ______________________________

Signature of person completing form: ____________________ Date completed *(dd/mm/yyyy)*: __ __/__ __/__ __ __ __

Name of person entering data* (capitals) ______________________________

Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

AR1

AUDIO RECORDING INTERVIEWS *(INTERVIEWER TO COMPLETE)*

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

END OF PHASE 1

Name of interviewer: _____

Date of interview: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) Time: __ __ : __ __ (*24 hr clock*)

Place of interview: _____

Interviewee: Parent ☐ Patient ☐

If parent/guardian name of interviewee: _____

Audio recording taken: *Yes* ☐ *No* ☐

If yes, audio recording ref _____

If no reason: Patient/parent changed their mind *Yes* ☐ *No* ☐ Equipment reason: *Yes* ☐ *No* ☐

Other, please specify *Yes* ☐ *No* ☐ _____

Name of interviewer: _____

Date of interview: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) Time: __ __ : __ __ (*24 hr clock*)

Place of interview: _____

Interviewee: Parent ☐ Patient ☐

If parent/guardian name of interviewee: _____

Audio recording taken: *Yes* ☐ *No* ☐

If yes, audio recording ref _____

If no reason: Patient/parent changed their mind *Yes* ☐ *No* ☐ Equipment reason: *Yes* ☐ *No* ☐

Other, please specify *Yes* ☐ *No* ☐ _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

AR2

AUDIO RECORDING INTERVIEWS *(INTERVIEWER TO COMPLETE)*

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

END OF PHASE 2

Name of interviewer: _____

Date of interview: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) Time: __ __ : __ __ (*24 hr clock*)

Place of interview: _____

Interviewee: Parent ☐ Patient ☐

If parent/guardian name of interviewee: _____

Audio recording taken: *Yes* ☐ *No* ☐

If yes, audio recording ref _____

If no reason: Patient/parent changed their mind *Yes* ☐ *No* ☐ Equipment reason: *Yes* ☐ *No* ☐

Other, please specify *Yes* ☐ *No* ☐ _____

Name of interviewer: _____

Date of interview: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) Time: __ __ : __ __ (*24 hr clock*)

Place of interview: _____

Interviewee: Parent ☐ Patient ☐

If parent/guardian name of interviewee: _____

Audio recording taken: *Yes* ☐ *No* ☐

If yes, audio recording ref _____

If no reason: Patient/parent changed their mind *Yes* ☐ *No* ☐ Equipment reason: *Yes* ☐ *No* ☐

Other, please specify *Yes* ☐ *No* ☐ _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

Needed by __ : __ on __ / __ / __
- Researcher to collect [ ]
- Patient to collect [ ]
- To post [ ]

University Hospitals Bristol NHS
NHS Foundation Trust

CARDIOMAN Study (Eudract No.2015-001382-10)
CLINICAL TRIAL PRESCRIPTION CHART

Chief Investigator: G Pieles

N.B. ALWAYS REFER TO THE CURRENT PROTOCOL WHEN PRESCRIBING

PHASE: (please circle) 1 or 2

PATIENT NAME	PATIENT TRIAL NO.							
HOSPITAL NUMBER								
DATE OF BIRTH	ALLERGIES							
CONSULTANT	BLOOD RESULTS Date:							
	Hb	WBC	Plts.	Neuts	Cr	eGFR	ALT	ALP

BEZAFIBRATE / Placebo PRESCRIBING INFORMATION:

- Children aged 6-9 years: Commence on 100mg OD for the first month and if well tolerated increase to 100mg BD for the remaining 3 month treatment period
- Children aged 10-17 years: commence on 200mg OD for the first month and if well tolerated increase to 200mg BD for the remaining 3 month treatment period
- Adults (≥ 18 years): 200mg BD

PLEASE DISPENSE STUDY MEDICATION AS FOLLOWS:

Please dispense _____ month's supply of:

BEZAFIBRATE 100mg or PLACEBO tablets (according to the randomisation list)

_____ tablets to be taken _____ times a day for 1 month
And then continue / increase to

_____ tablets to be taken _____ times a day for 3 months (as advised)

PRESCRIBER:

Sign: _____ Name: _____ Date: _____ Bleep: _____

PHARMACY USE:

Clinical check by / date	Quantity dispensed	Dispensed by / date	Checked by / date
	Bezafibrate 100mg /Placebo tablets x _____		

COLLECTED / POSTED BY:

Sign: _____ Name: _____ Date: _____ Time: __ __

DOCUMENTATION CONTROL	VERSION: 3.0	ISSUED BY:	CHECKED BY:	APPROVED BY:
ISSUE DATE: 04/07/2019	SIGNATURE:		williams	
REVIEW DATE: 03/01/2020				

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ / __ __ / __ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
VISIT 1 - INVESTIGATION CHECKLIST

V1a

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

INVESTIGATION CHECKLIST

CONSENT	☐	ECHO DURING EXERCISE	☐
MEDICAL INFORMATION	☐	MRI	☐
MEDICAL EXAMINATION	☐	QUESTIONNAIRE	☐
ECG AT REST	☐	PRESCRIPTION INSTRUCTIONS DISCUSSED	☐
ECG DURING EXERCISE	☐	UP TO DATE RECORD OF CONTACT DETAILS, INFORMATION AS TO BEST TIME TO CALL & REMINDER FOLLOW UP CALLS COME FROM WITHELD NUMBER	☐
ECHO AT REST	☐		

BLOODS

Blood samples taken? *Yes* ☐ *No* ☐ If ***NO,*** reason: _____

If ***YES,*** date and time taken __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) __ __ : __ __ (*24 hr clock*)

UHBristol Laboratory:

Time samples sent to UHBristol lab: __ __ : __ __ (*24 hr clock*)

Adults:
- 1 x 3.0ml PST tube ☐
- 1 x PST microtainer (min 0.5ml needed) ☐
- 1 x 2ml EDTA tube ☐

Total - 5.5mls

Children:
- 2 x PST microtainer ☐
- 1 x paediatric EDTA microtainer (min 0.7ml needed to complete FBC) ☐

Total - 1.9mls

UoB Laboratory (please liaise with trial coordinator who will arrange delivery):

Any blood taken for UoB labs? *Yes* ☐ *No* ☐

(Up to 20mls can be taken for CARDIOMAN. Any remaining blood should be put in EDTA tubes)

If yes, number tubes sent: ☐☐

If yes, time samples sent to UoB lab: __ __ : __ __ (*24 hr clock*)

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN V1b

MEDICAL INFORMATION & EXAMINATION - VISIT 1

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

ANTHROPOMETRICS

Height ☐☐☐ *cm* Weight ☐☐☐.☐ *kg* Fat mass ☐☐☐.☐ *kg*

Skin fold measurements

Tricep ☐☐☐.☐ *mm* Sub scapula ☐☐☐.☐ *mm* Supra iliac ☐☐☐.☐ *mm*

Bicep ☐☐☐.☐ *mm*

MEDICAL EXAMINATION

Resting measurements:

O_2 saturations _____ % BP / Heart rate _____ bpm Respiratory rate_____ breaths per min

Heart sounds normal? *Yes* ☐ *No* ☐ Pulses regular? *Yes* ☐ *No* ☐

Signs of heart failure? *Yes* ☐ *No* ☐

If yes, which ones: Respiratory distress *Yes* ☐ *No* ☐ Ascites *Yes* ☐ *No* ☐

Hepatomegaly *Yes* ☐ *No* ☐ Pitting oedema *Yes* ☐ *No* ☐

Pulmonary auscultation findings *Yes* ☐ *No* ☐

MEDICAL QUESTIONS

Has the patient fainted in the last four months? *Yes* ☐ *No* ☐

If yes, was this related to exercise? *Yes* ☐ *No* ☐

If yes, please give details? _____

Has the patient experienced dizziness in the last four months? *Yes* ☐ *No* ☐

If yes, was this related to exercise (i.e. before/after/during)? *Yes* ☐ *No* ☐

If yes, please give details? _____

Has the patient had palpitations in the last four months? *Yes* ☐ *No* ☐
(palpitations are feeling a regular unexpected quickening of your heart rate)

If yes, please give details? _____

Has the patient had chest pain or tightness of the chest in the last four months? *Yes* ☐ *No* ☐

If yes, when did it happen? Before exercise ☐ During exercise ☐ After exercise ☐

If yes, please give details? _____

Has the patient's exercise capacity or fitness level decreased unexpectedly in last four months? *Yes* ☐ *No* ☐

If yes, please give details? _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

V1c

MEDICATIONS—VISIT 1

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

CARDIAC DRUG USAGE

Is the patient taking any cardiac medications? *Yes* ☐ *No* ☐ If ***YES***, please specify:

Medication	**YES**	**NO**	**If *YES*, Dose**	**If *YES*, Units** *(circle)*	**If *YES*, Units** *If 'other', specify*	**If *YES*, Frequency** *(circle)*	**If *YES*, Frequency** *If 'other' or PRN, specify*
Amlodipine	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Aspirin	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Atorvastatin	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Bisoprolol	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Captopril	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Carvedilol	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Digoxin	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Enalapril	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Furosemide	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Lisinopril	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Pravastatin	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Propanolol	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Ramipril	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Spironolactone	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Other, specify: _____	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Other, specify: _____	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Other, specify: _____	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____

Please refer to the protocol for advice on concomitant medications/treatments.

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

V1d

MEDICATIONS—VISIT 1

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

GENERAL SUPPORTIVE CARE DRUGS

Is the patient taking any supportive care drugs? *Yes* ☐ *No* ☐ If ***YES***, please specify:

Medication	**YES**	**NO**	**If *YES*, Dose**	**If *YES*, Units** *(circle)*	*If 'other', specify*	**If *YES,* Frequency** *(circle)*	*If 'other' or PRN, specify*
Citalopram	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Folic Acid	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Forceval	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Gaviscon	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Glycozade	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Lactulose	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Lansoprazole	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Movical	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Multivitamins	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Omeprazole	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Pantothenate	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Pizotifen	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Ranitidine	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Seravit	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Sertraline	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Sytron	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Thiamine	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Other, specify: _____	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Other, specify: _____	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN V1e

MEDICATIONS—VISIT 1

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

OTHER DRUGS

Is the patient taking any other medications? *Yes* ☐ *No* ☐ If ***YES***, please specify:

Medication type	**Medication**	**YES**	**NO**	**If *YES*, Dose**	**If *YES*, Units** *(circle)*	**If *YES*, Units** *If 'other', specify*	**If *YES*, Frequency** *(circle)*	**If *YES*, Frequency** *If 'other' or PRN, specify*
Transplant related drugs	Ciclosporin	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
	MMF	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
	Prednisolone	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
	Sirolimus	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
	Tacrolimus	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
	Other, specify: _____	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
	Other, specify: _____	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
Drugs used in infection prophylaxis	Amoxicillin	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
	Azithromycin	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
	Cotrimoxazole	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
	G-CSF	☐	☐	_____	mcg / mg / g other	_____	3 times per week/ alternate daily/ once every 1 to 3 weeks/ intermittently/ other	_____
	Penicillin	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
	Other, specify: _____	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	
	Other, specify: _____	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	
OTHER	Specify: _____	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
	Specify: _____	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
	Specify: _____	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____
	Specify: _____	☐	☐	_____	mcg / mg / g other	_____	OD / BD / TDS QDS / PRN / other	_____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN V1f

VISIT 1- ECHO AT REST *(ECHO TECHNICIAN TO COMPLETE)*

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Date of echo: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) Time: __ __ : __ __ (*24 hr clock*) Name of technician: _____

LV function *Good* ☐ *Mildly impaired* ☐ *Moderately impaired* ☐ *Severely impaired* ☐ *Not stated* ☐

Fraction shortening *(Teichholz)* ☐☐ %

Biplane ejection fraction ☐☐ %

LV Myocardial performance index ☐☐.☐☐

Mitral annular plane systolic excursion (MAPSE) - lateral ☐☐ *mm*

Mitral annular plane systolic excursion (MAPSE) - septal ☐☐ *mm*

Tissue Doppler (pulsed wave)

LV S' wave velocity ☐☐.☐☐ *cm/s*

LV E' wave velocity ☐☐.☐☐ *cm/s*

LV A' wave velocity ☐☐.☐☐ *cm/s*

LV IVA ☐☐☐.☐☐ *m/s²*

LV E/E' ☐☐.☐☐

LV E wave velocity ☐☐.☐☐ *cm/s*

LV A wave velocity ☐☐.☐☐ *cm/s*

LV Deceleration time ☐☐.☐☐ *ms*

LV E/A ratio ☐☐ ☐☐

LV IVS S' wave velocity ☐☐.☐☐ *cm/s*

LV IVS E' wave velocity ☐☐.☐☐ *cm/s*

LV IVS A' wave velocity ☐☐.☐☐ *cm/s*

LV IVS IVA ☐☐☐.☐☐ *m/s²*

LV mean systolic longitudinal strain ☐☐ %

LV lateral basal ☐☐ %

LV lateral mid ☐☐ %

LV lateral apical ☐☐ %

LV septal basal ☐☐ %

LV septal mid ☐☐ %

LV septal apical ☐☐ %

LV mean systolic circumferential strain ☐☐ %

LV anterior septal ☐☐ %

LV anterior ☐☐ %

LV lateral ☐☐ %

LV posterior ☐☐ %

LV inferior ☐☐ %

LV septal ☐☐ %

LV mean systolic longitudinal strain rate ☐☐ %

LV 3-D mean systolic strain ☐☐ %

LV mean systolic circumferential strain rate ☐☐ %

LV Wall Motion Abnormalities *Yes* ☐ *No* ☐

If yes, what type? normal ☐ mild hypokinesia ☐

severe hypokinesia ☐ dyskinesia ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN V1g

VISIT 1- ECHO AT REST (continued)

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

RV function *Good* ☐ *Mildly impaired* ☐ *Moderately impaired* ☐ *Severely impaired* ☐ *Not stated* ☐

RV Wall Motion Abnormalities *Yes* ☐ *No* ☐

If yes, what type? normal ☐ mild hypokinesia ☐ severe hypokinesia ☐ dyskinesia ☐

TR peak velocity given? *Yes* ☐ *No* ☐

If ***YES***, TR peak velocity ☐☐.☐☐ *m/s*

TAPSE ☐☐ *mm*

RV myocardial performance index ☐☐.☐☐

RV fractional area of change ☐☐ *%*

RV mean systolic longitudinal strain ☐☐ *%* RV mean systolic longitudinal strain rate ☐☐ *%*

RV lateral basal ☐☐ *%*

RV lateral mid ☐☐ *%*

RV lateral apical ☐☐ *%*

Tissue Doppler (pulsed wave)

RV S' wave velocity ☐☐.☐☐ *cm/s*

RV E' wave velocity ☐☐.☐☐ *cm/s*

RV A' wave velocity ☐☐.☐☐ *cm/s*

RV IVA ☐☐☐.☐☐ *m/s²*

RV E/E' ☐☐.☐☐

RV E wave velocity ☐☐ ☐☐ *cm/s*

RV A wave velocity ☐☐.☐☐ *cm/s*

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN V1h

VISIT 1- EXERCISE ECHO

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

EXERCISE HISTORY

Exercise hrs / week: ☐☐ Self assess exercise capacity (1 = low, 10= elite) ☐☐

Motivation: *Low* ☐ *Average* ☐ *High* ☐

EXERCISE TEST

Time/work rate, Min/W	HR (bmp)	BP sys/dias	SpO_2 (%)	Symptoms Comments	ECG Comments	NIRS (%)
Baseline Pre-exercise		/				
0W		/				
20W		/				
40W		/				
60W		/				
80W		/				
100W		/				
120W		/				
140W		/				
160W		/				
Recovery (2 min post)		/				
Recovery (6 min post)		/				

Exercise duration (min:sec) ☐☐.☐☐ Achieved work rate ☐☐ W

Cause of cessation: _____

Comment on cessation: _____

Perceived exercise effort - Borg scale at end of exercise (1-10). ☐☐ Peak heart rate (bpm) ☐☐☐

Blood pressure peak (mmHg) : systolic ☐☐☐ diastolic ☐☐☐

Mean blood pressure during exercise (mmHg): systolic ☐☐☐ diastolic ☐☐☐

Comments vital data: _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN V1i

VISIT 1- EXERCISE ECHO (CONTINUED)

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Stage	Borg score	MV E cm/s	LV PSMLS %	LV PSMCS %	LV S' cm/s	LV E' cm/s	RV PSMLS %	TR m/s	RV S' cm/s	*RV E' cm/s*
Rest										
0 W										
20 W										
40 W										
60 W										
80 W										
100W										
120W										
140W										
160W										
180W										
2 min rec										
6 min rec										

Anaerobic threshold: ☐☐ % O2 pulse: ☐☐ ml/beat

RER: ☐☐ METs: ☐☐

<u>VO_2 measurement (PRIMARY OUTCOME MUST BE COMPLETED):</u>

Baseline VO_2: ☐☐ ml/kg/min

Peak exercise VO_2: ☐☐ ml/kg/min

2 min recovery VO_2: ☐☐ ml/kg/min

6 min recovery VO_2: ☐☐ ml/kg/min

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN V1j

VISIT 1– ECG

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

ECG AT REST

Heart rate _____ bpm

Baseline rhythm:

Sinus rhythm *Yes* ☐ *No* ☐ Atrial fibrillation/flutter *Yes* ☐ *No* ☐

Heart block *Yes* ☐ *No* ☐ Paced *Yes* ☐ *No* ☐

P wave normal? *Yes* ☐ *No* ☐ P - axis ☐☐ °

PR-interval ☐☐☐ ms

QRS-axis ☐☐☐ ° QRS-duration ☐☐☐ ms

Left ventricular hypertrophy *Yes* ☐ *No* ☐ Right ventricular hypertrophy *Yes* ☐ *No* ☐

ST-segments normal ☐ abnormal ☐ ST depression: *Yes* ☐ *No* ☐

TWI *Yes* ☐ *No* ☐

T axis ☐☐ °

QTc: ☐☐☐ ms

ECG DURING EXERCISE

Rhythm changes during exercise: *Yes* ☐ *No* ☐

If yes, new rhythm?

Sinus rhythm *Yes* ☐ *No* ☐ Atrial fibrillation/flutter *Yes* ☐ *No* ☐

Heart block *Yes* ☐ *No* ☐ Paced *Yes* ☐ *No* ☐

Arrhythmia during exercise? *Yes* ☐ *No* ☐

If arrhythmia (what, when, progression, resolving): _____

_____

ST-changes during exercise? *Yes* ☐ *No* ☐

If ST-changes (what, amount [mm], progression, resolving): _____

_____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
VISIT 1- CARDIAC MRI

V1k

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

CARDIAC MRI SUMMARY

Date of scan __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) Time of scan ___ ___ : ___ ___ (*24 hr*)

Name of scan operator _____

LEFT VENTRICULAR FUNCTION

Wall motion abnormalities? *Yes* ☐ *No* ☐

If yes, what type? normal ☐ mild hypokinesia ☐ severe hypokinesia ☐ dyskinesia ☐

If yes, where? _____

Structure? normal ☐ wall thinning ☐ wall thickening (hypertrophy) ☐

	LV (Absolute)	LV (Indexed)
Ejection fraction (%)		
End diastolic volume (ml/m^2)		
End systolic volume (ml/m^2)		
Stroke volume (ml)		
Cardiac output (l/min)		
Cardiac index (l/min/m^2)		
Mass (g/m^2)		

RIGHT VENTRICULAR FUNCTION

Wall motion abnormalities? *Yes* ☐ *No* ☐

If yes, what type? normal ☐ mild hypokinesia ☐ severe hypokinesia ☐ dyskinesia ☐

If yes, where? _____

Structure? normal ☐ wall thinning ☐ wall thickening (hypertrophy) ☐

	RV (Absolute)	RV (Indexed)
Ejection fraction (%)		
End diastolic volume (ml/m^2)		
End systolic volume (ml/m^2)		
Stroke volume (ml)		
Cardiac output (l/min)		
Cardiac index (l/min/m^2)		

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
VISIT 2 - INVESTIGATION CHECKLIST

V2a

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

INVESTIGATION CHECKLIST

MEDICAL INFORMATION	☐	MRI	☐
MEDICAL EXAMINATION	☐	MRS	☐
ECG AT REST	☐	QUESTIONNAIRE	☐
ECG DURING EXERCISE	☐	REMINDER OF PRESCRIPTION PROCESS	☐
ECHO AT REST	☐	UP TO DATE RECORD OF CONTACT DETAILS	☐
ECHO DURING EXERCISE	☐	QUALITATIVE INTERVIEW *Yes* ☐ *No* ☐	

BLOODS

Blood samples taken? *Yes* ☐ *No* ☐ If ***NO,*** reason: _____

If ***YES,*** date and time taken __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) __ __ : __ __ (*24 hr clock*)

UHBristol Laboratory:

Time samples sent to UHBristol lab: __ __ : __ __ (*24 hr clock*)

Adults:
- 1 x 3.0ml PST tube ☐
- 1 x PST microtainer (min 0.5ml needed) ☐
- 1 x 2ml EDTA tube ☐

Total - 5.5mls

Children:
- 2 x PST microtainer ☐
- 1 x paediatric EDTA microtainer (min 0.7ml needed to complete FBC) ☐

Total - 1.9mls

UoB Laboratory (please liaise with trial coordinator who will arrange delivery):

Any blood taken for UoB labs? *Yes* ☐ *No* ☐

(Up to 20mls can be taken for CARDIOMAN. Any remaining blood should be put in EDTA tubes)

If yes, number tubes sent: ☐☐

If yes, time samples sent to UoB lab: __ __ : __ __ (*24 hr clock*)

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN V2b

MEDICAL INFORMATION & EXAMINATION - VISIT 2

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

ANTHROPOMETRICS

Height ☐☐☐ *cm* Weight ☐☐☐.☐ *kg* Fat mass ☐☐☐.☐ *kg*

Skin fold measurements

Tricep ☐☐☐.☐ *mm* Sub scapula ☐☐☐.☐ *mm* Supra iliac ☐☐☐.☐ *mm*

Bicep ☐☐☐.☐ *mm*

MEDICAL EXAMINATION

Resting measurements:

O_2 saturations _____ % BP / Heart rate _____ bpm Respiratory rate_____ breaths per min

Heart sounds normal? *Yes* ☐ *No* ☐ Pulses regular? *Yes* ☐ *No* ☐

Signs of heart failure? *Yes* ☐ *No* ☐

If yes, which ones: Respiratory distress *Yes* ☐ *No* ☐ Ascites *Yes* ☐ *No* ☐

Hepatomegaly *Yes* ☐ *No* ☐ Pitting oedema *Yes* ☐ *No* ☐

Pulmonary auscultation findings *Yes* ☐ *No* ☐

MEDICAL QUESTIONS

Has the patient fainted since their last visit? *Yes* ☐ *No* ☐

If yes, was this related to exercise? *Yes* ☐ *No* ☐

If yes, please give details? _____

Has the patient experienced dizziness since their last visit? *Yes* ☐ *No* ☐

If yes, was this related to exercise (i.e. before/after/during)? *Yes* ☐ *No* ☐

If yes, please give details? _____

Has the patient had palpitations since their last visit? *Yes* ☐ *No* ☐
(palpitations are feeling a regular unexpected quickening of your heart rate)

If yes, please give details? _____

Has the patient had chest pain or tightness of the chest since their last visit? *Yes* ☐ *No* ☐

If yes, when did it happen? Before exercise ☐ During exercise ☐ After exercise ☐

If yes, please give details? _____

Has the patient's exercise capacity or fitness level decreased unexpectedly since their last visit? *Yes* ☐ *No* ☐

If yes, please give details? _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN V2c

MEDICAL INFORMATION & EXAMINATION (CONTINUED) - VISIT 2

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Has the patient changed their diet (i.e. had cornstarch or overnight feeds added) or deliberately tried to lose weight since the start of the study treatment? *Yes* ☐ *No* ☐

If YES, please describe: _____

_____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

MEDICATIONS—VISIT 2

V2d

Patient Name: ____________________________________ **CARDIOMAN study ID:** ☐☐

PREVIOUSLY REPORTED MEDICATIONS (PLEASE USE MULTIPLE SHEETS WHERE REQUIRED)

Medication at last visit: Name	Dose	Units *(circle)*	Frequency	Still taking medication?	If NO, date stopped	If still taking medication, still taking same dose?	If NO, date changed	Dose	Units (circle)	Frequency (circle)	If **OTHER OR PRN**, specify:
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	

Name of person completing form* (capitals): ____________________________________

Signature of person completing form: ________________________ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) ________________________

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Version 3.0 03/07/2019

** Names must appear on the site signature & delegation log*

CARDIOMAN

V2e

VISIT 2 - ECHO AT REST (*ECHO TECHNICIAN TO COMPLETE)*

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Date of echo: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) Time: __ __ : __ __ (*24 hr clock*) Name of technician: _____

LV function *Good* ☐ *Mildly impaired* ☐ *Moderately impaired* ☐ *Severely impaired* ☐ *Not stated* ☐

Fraction shortening *(Teichholz)* ☐☐ %

Biplane ejection fraction ☐☐ %

LV Myocardial performance index ☐☐.☐☐

Mitral annular plane systolic excursion (MAPSE) - lateral ☐☐ *mm*

Mitral annular plane systolic excursion (MAPSE) - septal ☐☐ *mm*

Tissue Doppler (pulsed wave)

LV S' wave velocity ☐☐.☐☐ *cm/s*

LV E' wave velocity ☐☐.☐☐ *cm/s*

LV A' wave velocity ☐☐.☐☐ *cm/s*

LV IVA ☐☐☐.☐☐ m/s^2

LV E/E' ☐☐.☐☐

LV E wave velocity ☐☐.☐☐ *cm/s*

LV A wave velocity ☐☐.☐☐ *cm/s*

LV Deceleration time ☐☐.☐☐ *ms*

LV E/A ratio ☐☐ ☐☐

LV IVS S' wave velocity ☐☐.☐☐ *cm/s*

LV IVS E' wave velocity ☐☐.☐☐ *cm/s*

LV IVS A' wave velocity ☐☐.☐☐ *cm/s*

LV IVS IVA ☐☐☐.☐☐ m/s^2

LV mean systolic longitudinal strain ☐☐ %

LV lateral basal ☐☐ %

LV lateral mid ☐☐ %

LV lateral apical ☐☐ %

LV septal basal ☐☐ %

LV septal mid ☐☐ %

LV septal apical ☐☐ %

LV mean systolic circumferential strain ☐☐ %

LV anterior septal ☐☐ %

LV anterior ☐☐ %

LV lateral ☐☐ %

LV posterior ☐☐ %

LV inferior ☐☐ %

LV septal ☐☐ %

LV mean systolic longitudinal strain rate ☐☐ %

LV 3-D mean systolic strain ☐☐ %

LV mean systolic circumferential strain rate ☐☐ %

LV Wall Motion Abnormalities *Yes* ☐ *No* ☐

If yes, what type? normal ☐ mild hypokinesia ☐

severe hypokinesia ☐ dyskinesia ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
VISIT 2- ECHO AT REST (continued)

V2f

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

RV function *Good* ☐ *Mildly impaired* ☐ *Moderately impaired* ☐ *Severely impaired* ☐ *Not stated* ☐

RV Wall Motion Abnormalities *Yes* ☐ *No* ☐

If yes, what type? normal ☐ mild hypokinesia ☐ severe hypokinesia ☐ dyskinesia ☐

TR peak velocity given? *Yes* ☐ *No* ☐

If ***YES***, TR peak velocity ☐☐.☐☐ *m/s*

TAPSE ☐☐ *mm*

RV myocardial performance index ☐☐.☐☐

RV fractional area of change ☐☐ *%*

RV mean systolic longitudinal strain ☐☐ *%* RV mean systolic longitudinal strain rate ☐☐ *%*

RV lateral basal ☐☐ *%*

RV lateral mid ☐☐ *%*

RV lateral apical ☐☐ *%*

Tissue Doppler (pulsed wave)

RV S' wave velocity ☐☐.☐☐ *cm/s*

RV E' wave velocity ☐☐.☐☐ *cm/s*

RV A' wave velocity ☐☐.☐☐ *cm/s*

RV IVA ☐☐☐.☐☐ *m/s²*

RV E/E' ☐☐.☐☐

RV E wave velocity ☐☐ ☐☐ *cm/s*

RV A wave velocity ☐☐.☐☐ *cm/s*

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

VISIT 2- EXERCISE ECHO

V2g

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

EXERCISE HISTORY

Exercise hrs / week: ☐☐ Self assess exercise capacity (1 = low, 10= elite) ☐☐

Motivation: *Low* ☐ *Average* ☐ *High* ☐

EXERCISE TEST

Time/work rate, Min/W	HR (bmp)	BP sys/dias	SpO_2 (%)	Symptoms Comments	ECG Comments	NIRS (%)
Baseline Pre-exercise		/				
0W		/				
20W		/				
40W		/				
60W		/				
80W		/				
100W		/				
120W		/				
140W		/				
160W		/				
Recovery (2 min post)		/				
Recovery (6 min post)		/				

Exercise duration (min:sec) ☐☐.☐☐ Achieved work rate ☐☐ W

Cause of cessation: _____

Comment on cessation: _____

Perceived exercise effort - Borg scale at end of exercise (1-10). ☐☐ Peak heart rate (bpm) ☐☐☐

Blood pressure peak (mmHg) : systolic ☐☐☐ diastolic ☐☐☐

Mean blood pressure during exercise (mmHg): systolic ☐☐☐ diastolic ☐☐☐

Comments vital data: _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

VISIT 2- EXERCISE ECHO (CONTINUED)

V2h

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Stage	Borg score	MV E cm/s	LV PSMLS %	LV PSMCS %	LV S' cm/s	LV E' cm/s	RV PSMLS %	TR m/s	RV S' cm/s	*RV E' cm/s*
Rest										
0 W										
20 W										
40 W										
60 W										
80 W										
100W										
120W										
140W										
160W										
180W										
2 min rec										
6 min rec										

Anaerobic threshold: ☐☐ % O2 pulse: ☐☐ ml/beat

RER: ☐☐ METs: ☐☐

VO_2 measurement (PRIMARY OUTCOME MUST BE COMPLETED):

Baseline VO_2: ☐☐ ml/kg/min

Peak exercise VO_2: ☐☐ ml/kg/min

2 min recovery VO_2: ☐☐ ml/kg/min

6 min recovery VO_2: ☐☐ ml/kg/min

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

VISIT 2- – ECG

V2i

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

ECG AT REST

Heart rate _____ bpm

Baseline rhythm:

Sinus rhythm *Yes* ☐ *No* ☐ Atrial fibrillation/flutter *Yes* ☐ *No* ☐

Heart block *Yes* ☐ *No* ☐ Paced *Yes* ☐ *No* ☐

P wave normal? *Yes* ☐ *No* ☐ P - axis ☐☐ °

PR-interval ☐☐☐ ms

QRS-axis ☐☐☐ ° QRS-duration ☐☐☐ ms

Left ventricular hypertrophy *Yes* ☐ *No* ☐ Right ventricular hypertrophy *Yes* ☐ *No* ☐

ST-segments normal ☐ abnormal ☐ ST depression: *Yes* ☐ *No* ☐

TWI *Yes* ☐ *No* ☐

T axis ☐☐ °

QTc: ☐☐☐ ms

ECG DURING EXERCISE

Rhythm changes during exercise: *Yes* ☐ *No* ☐

If yes, new rhythm?

Sinus rhythm *Yes* ☐ *No* ☐ Atrial fibrillation/flutter *Yes* ☐ *No* ☐

Heart block *Yes* ☐ *No* ☐ Paced *Yes* ☐ *No* ☐

Arrhythmia during exercise? *Yes* ☐ *No* ☐

If arrhythmia (what, when, progression, resolving): _____

_____

ST-changes during exercise? *Yes* ☐ *No* ☐

If ST-changes (what, amount [mm], progression, resolving): _____

_____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
VISIT 2- CARDIAC MRI

V2j

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

CARDIAC MRI SUMMARY

Date of scan __ __ /__ __ /__ __ __ __ Time of scan ___ ___ : ___ ___
d d m m y y y y *(24 hr)*

Name of scan operator _____

LEFT VENTRICULAR FUNCTION

Wall motion abnormalities? *Yes* ☐ *No* ☐

If yes, what type? normal ☐ mild hypokinesia ☐ severe hypokinesia ☐ dyskinesia ☐

If yes, where? _____

Structure? normal ☐ wall thinning ☐ wall thickening (hypertrophy) ☐

	LV (Absolute)	LV (Indexed)
Ejection fraction (%)		
End diastolic volume (ml/m^2)		
End systolic volume (ml/m^2)		
Stroke volume (ml)		
Cardiac output (l/min)		
Cardiac index (l/min/m^2)		
Mass (g/m^2)		

RIGHT VENTRICULAR FUNCTION

Wall motion abnormalities? *Yes* ☐ *No* ☐

If yes, what type? normal ☐ mild hypokinesia ☐ severe hypokinesia ☐ dyskinesia ☐

If yes, where? _____

Structure? normal ☐ wall thinning ☐ wall thickening (hypertrophy) ☐

	RV (Absolute)	RV (Indexed)
Ejection fraction (%)		
End diastolic volume (ml/m^2)		
End systolic volume (ml/m^2)		
Stroke volume (ml)		
Cardiac output (l/min)		
Cardiac index (l/min/m^2)		

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
VISIT 2—MRS

V2k

Patient Name: _____ **CARDIOMAN study ID:** | |

CARDIAC MRS

Date of scan __ __ /__ __ /__ __ __ __ *d d m m y y y y*

Time of scan ___ ___ : ___ ___ *(24 hr)*

Name of scan operator _____

PLEASE ATTACH THE MRS PRINT OUT TO THIS SHEET

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
VISIT 3 - INVESTIGATION CHECKLIST

V3a

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

INVESTIGATION CHECKLIST

MEDICAL INFORMATION	☐	MRI	☐
MEDICAL EXAMINATION	☐	MRS	☐
ECG AT REST	☐	QUESTIONNAIRE	☐
ECG DURING EXERCISE	☐	UP TO DATE RECORD OF CONTACT DETAILS	☐
ECHO AT REST	☐	QUALITATIVE INTERVIEW *Yes* ☐ *No* ☐	
ECHO DURING EXERCISE	☐		

BLOODS

Blood samples taken? *Yes* ☐ *No* ☐ If ***NO,*** reason: _____

If ***YES,*** date and time taken __ __ /__ __ /__ __ __ __ __ __ : __ __
d d m m y y y y (24 hr clock)

UHBristol Laboratory:

Time samples sent to UHBristol lab: __ __ : __ __
(24 hr clock)

Adults:
- 1 x 3.0ml PST tube ☐
- 1 x PST microtainer (min 0.5ml needed) ☐
- 1 x 2ml EDTA tube ☐

Total - 5.5mls

Children:
- 2 x PST microtainer ☐
- 1 x paediatric EDTA microtainer (min 0.7ml needed to complete FBC) ☐

Total - 1.9mls

UoB Laboratory (please liaise with trial coordinator who will arrange delivery):

Any blood taken for UoB labs? *Yes* ☐ *No* ☐

(Up to 20mls can be taken for CARDIOMAN. Any remaining blood should be put in EDTA tubes)

If yes, number tubes sent: ☐☐

If yes, time samples sent to UoB lab: __ __ : __ __
(24 hr clock)

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN V3b

MEDICAL INFORMATION & EXAMINATION - VISIT 3

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

ANTHROPOMETRICS

Height ☐☐☐ *cm* Weight ☐☐☐.☐ *kg* Fat mass ☐☐☐.☐ *kg*

Skin fold measurements

Tricep ☐☐☐.☐ *mm* Sub scapula ☐☐☐.☐ *mm* Supra iliac ☐☐☐.☐ *mm*

Bicep ☐☐☐.☐ *mm*

MEDICAL EXAMINATION

Resting measurements:

O_2 saturations _____ % BP / Heart rate _____ bpm Respiratory rate_____ breaths per min

Heart sounds normal? *Yes* ☐ *No* ☐ Pulses regular? *Yes* ☐ *No* ☐

Signs of heart failure? *Yes* ☐ *No* ☐

If yes, which ones:

Respiratory distress *Yes* ☐ *No* ☐ Ascites *Yes* ☐ *No* ☐

Hepatomegaly *Yes* ☐ *No* ☐ Pitting oedema *Yes* ☐ *No* ☐

Pulmonary auscultation findings *Yes* ☐ *No* ☐

MEDICAL QUESTIONS

Has the patient fainted since their last visit? *Yes* ☐ *No* ☐

If yes, was this related to exercise? *Yes* ☐ *No* ☐

If yes, please give details? _____

Has the patient experienced dizziness since their last visit? *Yes* ☐ *No* ☐

If yes, was this related to exercise (i.e. before/after/during)? *Yes* ☐ *No* ☐

If yes, please give details? _____

Has the patient had palpitations since their last visit? *Yes* ☐ *No* ☐
(palpitations are feeling a regular unexpected quickening of your heart rate)

If yes, please give details? _____

Has the patient had chest pain or tightness of the chest since their last visit? *Yes* ☐ *No* ☐

If yes, when did it happen? Before exercise ☐ During exercise ☐ After exercise ☐

If yes, please give details? _____

Has the patient's exercise capacity or fitness level decreased unexpectedly since their last visit? *Yes* ☐ *No* ☐

If yes, please give details? _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN V3c

MEDICAL INFORMATION & EXAMINATION (CONTINUED) - VISIT 3

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Has the patient changed their diet (i.e. had cornstarch or overnight feeds added) or deliberately tried to lose weight since the last visit ? *Yes* ☐ *No* ☐

If YES, please describe: _____

_____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

V3d

MEDICATIONS—VISIT 3

Patient Name: ____________________

CARDIOMAN study ID: ☐☐

PREVIOUSLY REPORTED MEDICATIONS (PLEASE USE MULTIPLE SHEETS WHERE REQUIRED)

Medication at last visit: Name	Dose	Units *(circle)*	Frequency	Still taking medication?	If NO, date stopped	If still taking medication, still taking same dose?	If NO, date changed	Dose	Units (circle)	Frequency (circle)	If **OTHER OR PRN**, specify:
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	

Name of person completing form* (capitals): ____________________

Signature of person completing form: ____________________ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) ____________________

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

VISIT 3 - ECHO AT REST

V3e

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Date of echo: __ __ /__ __ /__ __ __ __ (d d m m y y y y) Time: __ __ : __ __ (24 hr clock) Name of technician: _____

LV function *Good* ☐ *Mildly impaired* ☐ *Moderately impaired* ☐ *Severely impaired* ☐ *Not stated* ☐

Fraction shortening *(Teichholz)* ☐☐ %

Biplane ejection fraction ☐☐ %

LV Myocardial performance index ☐☐.☐☐

Mitral annular plane systolic excursion (MAPSE) - lateral ☐☐ *mm*

Mitral annular plane systolic excursion (MAPSE) - septal ☐☐ *mm*

Tissue Doppler (pulsed wave)

LV S' wave velocity ☐☐.☐☐ *cm/s*

LV E' wave velocity ☐☐.☐☐ *cm/s*

LV A' wave velocity ☐☐.☐☐ *cm/s*

LV IVA ☐☐☐.☐☐ m/s^2

LV E/E' ☐☐.☐☐

LV E wave velocity ☐☐.☐☐ *cm/s*

LV A wave velocity ☐☐.☐☐ *cm/s*

LV Deceleration time ☐☐.☐☐ *ms*

LV E/A ratio ☐☐ ☐☐

LV IVS S' wave velocity ☐☐.☐☐ *cm/s*

LV IVS E' wave velocity ☐☐.☐☐ *cm/s*

LV IVS A' wave velocity ☐☐.☐☐ *cm/s*

LV IVS IVA ☐☐☐.☐☐ m/s^2

LV mean systolic longitudinal strain ☐☐ %

LV lateral basal ☐☐ %

LV lateral mid ☐☐ %

LV lateral apical ☐☐ %

LV septal basal ☐☐ %

LV septal mid ☐☐ %

LV septal apical ☐☐ %

LV mean systolic circumferential strain ☐☐ %

LV anterior septal ☐☐ %

LV anterior ☐☐ %

LV lateral ☐☐ %

LV posterior ☐☐ %

LV inferior ☐☐ %

LV septal ☐☐ %

LV mean systolic longitudinal strain rate ☐☐ %

LV 3-D mean systolic strain ☐☐ %

LV mean systolic circumferential strain rate ☐☐ %

LV Wall Motion Abnormalities *Yes* ☐ *No* ☐

If yes, what type? normal ☐ mild hypokinesia ☐

severe hypokinesia ☐ dyskinesia ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN V3f

VISIT 3- ECHO AT REST (continued)

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

RV function *Good* ☐ *Mildly impaired* ☐ *Moderately impaired* ☐ *Severely impaired* ☐ *Not stated* ☐

RV Wall Motion Abnormalities *Yes* ☐ *No* ☐

If yes, what type? normal ☐ mild hypokinesia ☐ severe hypokinesia ☐ dyskinesia ☐

TR peak velocity given? *Yes* ☐ *No* ☐

If ***YES***, TR peak velocity ☐☐.☐☐ *m/s*

TAPSE ☐☐ *mm*

RV myocardial performance index ☐☐.☐☐

RV fractional area of change ☐☐ *%*

RV mean systolic longitudinal strain ☐☐ *%* RV mean systolic longitudinal strain rate ☐☐ *%*

RV lateral basal ☐☐ *%*

RV lateral mid ☐☐ *%*

RV lateral apical ☐☐ *%*

Tissue Doppler (pulsed wave)

RV S' wave velocity ☐☐.☐☐ *cm/s*

RV E' wave velocity ☐☐.☐☐ *cm/s*

RV A' wave velocity ☐☐.☐☐ *cm/s*

RV IVA ☐☐☐.☐☐ *m/s²*

RV E/E' ☐☐.☐☐

RV E wave velocity ☐☐ ☐☐ *cm/s*

RV A wave velocity ☐☐.☐☐ *cm/s*

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

VISIT 3 - EXERCISE ECHO

V3g

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Exercise hrs / week: ☐☐ Self assess exercise capacity (1 = low, 10= elite) ☐☐

Motivation: *Low* ☐ *Average* ☐ *High* ☐

EXERCISE TEST

Time/work rate, Min/W	HR (bmp)	BP sys/dias	SpO_2 (%)	Symptoms Comments	ECG Comments	NIRS (%)
Baseline Pre-exercise		/				
0W		/				
20W		/				
40W		/				
60W		/				
80W		/				
100W		/				
120W		/				
140W		/				
160W		/				
Recovery (2 min post)		/				
Recovery (6 min post)		/				

Exercise duration (min:sec) ☐☐.☐☐ Achieved work rate ☐☐ W

Cause of cessation: _____

Comment on cessation: _____

Perceived exercise effort - Borg scale at end of exercise (1-10). ☐☐ Peak heart rate (bpm) ☐☐☐

Blood pressure peak (mmHg) : systolic ☐☐☐ diastolic ☐☐☐

Mean blood pressure during exercise (mmHg): systolic ☐☐☐ diastolic ☐☐☐

Comments vital data: _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

VISIT 3 - EXERCISE ECHO (CONTINUED)

V3h

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Stage	Borg score	MV E cm/s	LV PSMLS %	LV PSMCS %	LV S′ cm/s	LV E′ cm/s	RV PSMLS %	TR m/s	RV S′ cm/s	*RV E′ cm/s*
Rest										
0 W										
20 W										
40 W										
60 W										
80 W										
100W										
120W										
140W										
160W										
180W										
2 min rec										
6 min rec										

Anaerobic threshold: ☐☐ % O2 pulse: ☐☐ ml/beat

RER: ☐☐ METs: ☐☐

VO_2 measurement (PRIMARY OUTCOME MUST BE COMPLETED):

Baseline VO_2: ☐☐ ml/kg/min

Peak exercise VO_2: ☐☐ ml/kg/min

2 min recovery VO_2: ☐☐ ml/kg/min

6 min recovery VO_2: ☐☐ ml/kg/min

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

VISIT 3 – ECG

V3i

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

ECG AT REST

Heart rate _____ bpm

Baseline rhythm:

Sinus rhythm *Yes* ☐ *No* ☐ Atrial fibrillation/flutter *Yes* ☐ *No* ☐

Heart block *Yes* ☐ *No* ☐ Paced *Yes* ☐ *No* ☐

P wave normal? *Yes* ☐ *No* ☐ P - axis ☐☐ °

PR-interval ☐☐☐ ms

QRS-axis ☐☐☐ ° QRS-duration ☐☐☐ ms

Left ventricular hypertrophy *Yes* ☐ *No* ☐ Right ventricular hypertrophy *Yes* ☐ *No* ☐

ST-segments normal ☐ abnormal ☐ ST depression: *Yes* ☐ *No* ☐

TWI *Yes* ☐ *No* ☐

T axis ☐☐ °

QTc: ☐☐☐ ms

ECG DURING EXERCISE

Rhythm changes during exercise: *Yes* ☐ *No* ☐

If yes, new rhythm?

Sinus rhythm *Yes* ☐ *No* ☐ Atrial fibrillation/flutter *Yes* ☐ *No* ☐

Heart block *Yes* ☐ *No* ☐ Paced *Yes* ☐ *No* ☐

Arrhythmia during exercise? *Yes* ☐ *No* ☐

If arrhythmia (what, when, progression, resolving): _____

_____

ST-changes during exercise? *Yes* ☐ *No* ☐

If ST-changes (what, amount [mm], progression, resolving): _____

_____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
VISIT 3- CARDIAC MRI

V3j

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

CARDIAC MRI SUMMARY

Date of scan __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) Time of scan ___ ___ : ___ ___ (*24 hr*)

Name of scan operator _____

LEFT VENTRICULAR FUNCTION

Wall motion abnormalities? *Yes* ☐ *No* ☐

If yes, what type? normal ☐ mild hypokinesia ☐ severe hypokinesia ☐ dyskinesia ☐

If yes, where? _____

Structure? normal ☐ wall thinning ☐ wall thickening (hypertrophy) ☐

	LV (Absolute)	LV (Indexed)
Ejection fraction (%)		
End diastolic volume (ml/m^2)		
End systolic volume (ml/m^2)		
Stroke volume (ml)		
Cardiac output (l/min)		
Cardiac index (l/min/m^2)		
Mass (g/m^2)		

RIGHT VENTRICULAR FUNCTION

Wall motion abnormalities? *Yes* ☐ *No* ☐

If yes, what type? normal ☐ mild hypokinesia ☐ severe hypokinesia ☐ dyskinesia ☐

If yes, where? _____

Structure? normal ☐ wall thinning ☐ wall thickening (hypertrophy) ☐

	RV (Absolute)	RV (Indexed)
Ejection fraction (%)		
End diastolic volume (ml/m^2)		
End systolic volume (ml/m^2)		
Stroke volume (ml)		
Cardiac output (l/min)		
Cardiac index (l/min/m^2)		

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
VISIT 3—MRS

V3k

Patient Name: _____ **CARDIOMAN study ID:** | |

CARDIAC MRS

Date of scan __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) **Time of scan** ___ ___ : ___ ___ (*24 hr*)

Name of scan operator _____

PLEASE ATTACH THE MRS PRINT OUT TO THIS SHEET

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

RESEARCH BLOOD TESTS

C1

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

	VISIT 1 (baseline)	VISIT 2	VISIT 3
Date	__ __ /__ __ (d d m m)	__ __ /__ __ (d d m m)	__ __ /__ __ (d d m m)
Creatine Kinase (U/L)	☐☐☐	☐☐☐	☐☐☐
Hb *(g/L)*	☐☐☐	☐☐☐	☐☐☐
WBC *(10^9/L)*	☐☐☐.☐	☐☐☐.☐	☐☐☐.☐
Platelets *(10^9/L)*	☐☐☐	☐☐☐	☐☐☐
Neutrophils *(10^9/L)*	☐☐.☐☐	☐☐.☐☐	☐☐.☐☐
Lymphocytes *(10^9/L)*	☐☐.☐☐	☐☐.☐☐	☐☐.☐☐
Monocytes *(10^9/L)*	☐☐.☐☐	☐☐.☐☐	☐☐.☐☐
Creatinine *(µmol/L)*	☐☐.☐	☐☐.☐	☐☐.☐
eGFR *(mL/min)*	< 90 ☐ > 90 ☐	< 90 ☐ > 90 ☐	< 90 ☐ > 90 ☐
Urea *(mmol/L)*	☐☐.☐	☐☐.☐	☐☐.☐
Sodium *(mmol/L)*	☐☐☐	☐☐☐	☐☐☐
Potassium *(mmol/L)*	☐.☐	☐.☐	☐.☐
Bircarbonate (mEq/L)	☐☐	☐☐	☐☐
Calcium (mmol/L)	☐.☐☐	☐.☐☐	☐.☐☐
Bilirubin *(µmol/L)*	☐☐	☐☐	☐☐
Alk Phos *(IU/L)*	☐☐☐	☐☐☐	☐☐☐
ALT *(U/L)*	☐☐	☐☐	☐☐
Total protein *(g/L)*	☐☐☐	☐☐☐	☐☐☐
Albumin *(g/L)*	☐☐☐	☐☐☐	☐☐☐
Plasma arginine	☐☐☐	☐☐☐	☐☐☐
Plasma cysteine	☐☐☐	☐☐☐	☐☐☐
Brain natriuretic peptide	☐☐☐	☐☐☐	☐☐☐
Total cholesterol	☐.☐	☐.☐	☐.☐
HDL - cholesterol	☐.☐	☐.☐	☐.☐
Triglycerides	☐.☐	☐.☐	☐.☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

C2a

SAFTEY BLOOD TESTS

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

BLOOD TESTS

	Week 2 (phase1) Only creatinine Transplant patients	**Month 1 (phase 1)** *Time window (week 2-3)*	**Month 2 (phase 1)** *Time window (week 6-7)*
Date	__ __ /__ __ *d d m m*	__ __ /__ __	__ __ /__ __
Creatine Kinase (U/L)		☐☐☐	☐☐☐
Hb *(g/L)*		☐☐☐	☐☐☐
WBC *(10^9/L)*		☐☐☐.☐	☐☐☐.☐
Platelets *(10^9/L)*		☐☐☐	☐☐☐
Neutrophils *(10^9/L)*		☐☐.☐☐	☐☐.☐☐
Lymphocytes *(10^9/L)*		☐☐.☐☐	☐☐.☐☐
Monocytes *(10^9/L)*		☐☐.☐☐	☐☐.☐☐
Creatinine *(µmol/L)*	☐☐.☐	☐☐.☐	☐☐.☐
eGFR *(mL/min)*		< 90 ☐ > 90 ☐	< 90 ☐ > 90 ☐
Urea *(mmol/L)*		☐☐.☐	☐☐.☐
Sodium *(mmol/L)*		☐☐☐	☐☐☐
Potassium *(mmol/L)*		☐.☐	☐.☐
Bircarbonate (mEq/L)		☐☐	☐☐
Calcium *(mmol/L)*		☐.☐☐	☐.☐☐
Bilirubin *(µmol/L)*		☐☐	☐☐
Alk Phos *(IU/L)*		☐☐☐	☐☐☐
ALT *(U/L)*		☐☐	☐☐
Total protein *(g/L)*		☐☐☐	☐☐☐
Albumin *(g/L)*		☐☐☐	☐☐☐
Total cholesterol		☐.☐	☐.☐
LDL-cholesterol		☐.☐	☐.☐
Triglycerides		☐.☐	☐.☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

C2b

SAFTEY BLOOD TESTS

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

BLOOD TESTS

	Month 3 (phase 1) *Time window (week 10-11)*	**Washout (phase 2)** *Time window (week 17-18)*	**Week 2 (phase 2), only creatinine** **Transplant patients** *Time window (week 21)*
Date	__ __ /__ __ (d d m m)	__ __ /__ __	
Creatine Kinase (U/L)	☐☐☐	☐☐☐	
Hb *(g/L)*	☐☐☐	☐☐☐	
WBC *(10^9/L)*	☐☐☐.☐	☐☐☐.☐	
Platelets *(10^9/L)*	☐☐☐	☐☐☐	
Neutrophils *(10^9/L)*	☐☐.☐☐	☐☐.☐☐	
Lymphocytes *(10^9/L)*	☐☐.☐☐	☐☐.☐☐	
Monocytes *(10^9/L)*	☐☐.☐☐	☐☐.☐☐	
Creatinine *(µmol/L)*	☐☐.☐	☐☐.☐	☐☐.☐
eGFR *(mL/min)*	< 90 ☐ > 90 ☐	< 90 ☐ > 90 ☐	
Urea *(mmol/L)*	☐☐.☐	☐☐.☐	
Sodium *(mmol/L)*	☐☐☐	☐☐☐	
Potassium *(mmol/L)*	☐.☐	☐.☐	
Bircarbonate (mEq/L)	☐☐	☐☐	
Calcium *(mmol/L)*	☐.☐☐	☐.☐☐	
Bilirubin *(µmol/L)*	☐☐	☐☐	
Alk Phos *(IU/L)*	☐☐☐	☐☐☐	
ALT *(U/L)*	☐☐	☐☐	
Total protein *(g/L)*	☐☐☐	☐☐☐	
Albumin *(g/L)*	☐☐☐	☐☐☐	
Total cholesterol	☐.☐	☐.☐	
LDL-cholesterol	☐.☐	☐.☐	
Triglycerides	☐.☐	☐.☐	

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

C2c

SAFTEY BLOOD TESTS

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

BLOOD TESTS

	Month 6 (phase 2) *Time window (week 21-22)*	**Month 7 (phase 2)** *Time window (week 25-26)*	**Month 8 (phase 2)** *Time window (week 29-30)*
Date	__ __ /__ __ (d d m m)	__ __ /__ __	__ __ /__ __
Creatine Kinase (U/L)	☐☐☐	☐☐☐	☐☐☐
Hb *(g/L)*	☐☐☐	☐☐☐	☐☐☐
WBC *(10^9/L)*	☐☐☐.☐	☐☐☐.☐	☐☐☐.☐
Platelets *(10^9/L)*	☐☐☐	☐☐☐	☐☐☐
Neutrophils *(10^9/L)*	☐☐.☐☐	☐☐.☐☐	☐☐.☐☐
Lymphocytes *(10^9/L)*	☐☐.☐☐	☐☐.☐☐	☐☐.☐☐
Monocytes *(10^9/L)*	☐☐.☐☐	☐☐.☐☐	☐☐.☐☐
Creatinine *(µmol/L)*	☐☐.☐	☐☐.☐	☐☐.☐
eGFR *(mL/min)*	< 90 ☐ > 90 ☐	< 90 ☐ > 90 ☐	< 90 ☐ > 90 ☐
Urea *(mmol/L)*	☐☐.☐	☐☐.☐	☐☐.☐
Sodium *(mmol/L)*	☐☐☐	☐☐☐	☐☐☐
Potassium *(mmol/L)*	☐.☐	☐.☐	☐.☐
Bircarbonate (mEq/L)	☐☐	☐☐	☐☐
Calcium *(mmol/L)*	☐.☐☐	☐.☐☐	☐.☐☐
Bilirubin *(µmol/L)*	☐☐	☐☐	☐☐
Alk Phos *(IU/L)*	☐☐☐	☐☐☐	☐☐☐
ALT *(U/L)*	☐☐	☐☐	☐☐
Total protein *(g/L)*	☐☐☐	☐☐☐	☐☐☐
Albumin *(g/L)*	☐☐☐	☐☐☐	☐☐☐
Total cholesterol	☐.☐	☐.☐	☐.☐
LDL-cholesterol	☐.☐	☐.☐	☐.☐
Triglycerides	☐.☐	☐.☐	☐.☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN D1

COMPLICATIONS (to be completed at visits and during follow up calls)

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

DISEASE RELATED EXPECTED EVENTS

Has the patient experienced any **disease related** events listed on CRF D2? *Yes* ☐ *No* ☐ If ***YES*,** specify:

[1] *Select an **event code** from CRF D2 (disease related events). These are all 'anticipated' and **only require an SAE form to be completed if they are** **deemed related to bezafibrate.***

[2] *Please tick 'YES' to **SAE** if the event fits any of the following criteria: **i) caused hospital admission, ii) increased length of hospital admission, iii) is/was life threatening, iv) persistent or significant disability, v) resulted in death***

[3] ***Relatedness** of SAEs to the study intervention should be determined by PI and coded as follows:*
1= not related, 2= unlikely to be related, 3= possibly related, 4= probably related, or 5= definitely related

[4] *Outcome should be coded as follows: A= Resolved, no sequelae; B= Resolved with sequelae; C= Ongoing; D= Died*

[5] ***End date** = date resolved. Not required if outcome = C or D (unless related)*

EVENT CODE[1]	SPECIFY (if required)	ONSET / START DATE	SAE [2]		RELATED[3] (if SAE)		PI INITIALS	OUTCOME [4]	END DATE[5]
			YES	NO	YES	NO			
☐☐☐	_____	__ __/__ __/__ __ __ __ (d d m m y y y y)	☐	☐	☐	☐	☐☐	☐	__ __/__ __/__ __ __ __
☐☐☐	_____	__ __/__ __/__ __ __ __	☐	☐	☐	☐	☐☐	☐	__ __/__ __/__ __ __ __
☐☐☐	_____	__ __/__ __/__ __ __ __	☐	☐	☐	☐	☐☐	☐	__ __/__ __/__ __ __ __

EXPECTED EVENTS OF BEZAFIBRATE

Has the patient experienced any **expected Bezafibrate** events listed on CRF D3? *Yes* ☐ *No* ☐ If ***YES*,** specify:

[6] *Select an **event code** from CRF D3 (expected events of bezafibrate)*

EVENT CODE[6]	SPECIFY (if required)	ONSET / START DATE	SAE[2]		RELATED[3] (if SAE)		PI INITIALS	OUTCOME [4]	END DATE[5]
			YES	NO	YES	NO			
☐☐☐	_____	__ __/__ __/__ __ __ __	☐	☐	☐	☐	☐☐	☐	__ __/__ __/__ __ __ __
☐☐☐	_____	__ __/__ __/__ __ __ __	☐	☐	☐	☐	☐☐	☐	__ __/__ __/__ __ __ __
☐☐☐	_____	__ __/__ __/__ __ __ __	☐	☐	☐	☐	☐☐	☐	__ __/__ __/__ __ __ __

*If criteria for an SAE [2] met , complete an **SAE form, (CRF S0 - S2) for each event***

OTHER UNEXPECTED ADVERSE EVENTS

*List any 'other/unexpected' adverse events that are **not listed on CRFs D2 or D3** (including death) in this section.*

Has the patient experienced any **OTHER** events **NOT** listed on CRFs D2 or D3? *Yes* ☐ *No* ☐ If ***YES*,** specify:

SPECIFY	ONSET / START DATE	SAE [2]		RELATED[3] (if SAE)		PI INITIALS	OUTCOME [4]	END DATE[5]
		YES	NO	YES	NO			
_____	__ __/__ __/__ __ __ __	☐	☐	☐	☐	☐☐	☐	__ __/__ __/__ __ __ __
_____	__ __/__ __/__ __ __ __	☐	☐	☐	☐	☐☐	☐	__ __/__ __/__ __ __ __
_____	__ __/__ __/__ __ __ __	☐	☐	☐	☐	☐☐	☐	__ __/__ __/__ __ __ __

*If criteria for an SAE [2] met , complete an **SAE form, (CRF S0 - S2) for each event***

Multiple copies of this CRF can be used

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
ANTICIPATED EVENTS

D2

Patient Name: _____ **CARDIOMAN study ID:** | | |

DISEASE RELATED EVENTS

101) Small changes of dilated cardiomyopathy (DCM) (change in EF of <15%)

102) Left ventricular non-compaction (LVNC)

103) Prolonged corrected QT interval

104) Proximal myopathy/weakness/fatigue

105) Exercise intolerance

106) Neutropaenia

107) Aphthous ulcers and sore gums

108) Bacterial skin infections

109) Hypocholesterolaemia

110) Hypoglycaemia (primarily in infants)

111) Episodic or chronic diarrhoea

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
EXPECTED EVENTS OF BEZAFIBRATE

D3

Patient Name: _____ **CARDIOMAN study ID:** | | |

Expected adverse events of Bezafibrate	
Body system	**Adverse Event**
Blood and lymphatic system disorders	201) pancytopenia, 202) thrombocytopaenic purpura
Immune system disorders	203) hypersensitivity reactions including anaphylactic reactions.
Metabolism and nutrition	204) decreased appetite.
Psychiatric disorders	205) depression 206) insomnia
Nervous system disorders	207) dizziness 208) headache 209) peripheral neuropathy 210) paraesthesia
Respiratory, thoracic and mediastinal disorders	211) interstitial lung disease
Gastrointestinal disorders	212) gastrointestinal disorders 213) abdominal distension 214) diarrhoea 215) nausea 216) abdominal pain 217) constipation 218) dyspepsia 219) pancreatitis
Hepatobiliary disorders	220) cholestasis. 221) cholelithiasis.
Skin and subcutaneous tissue disorders	222) pruritus 223) urticaria 224) photosensitivity reaction 225) alopecia 226) rash 227) Erythema multiforme 228) Stevens-Johnson syndrome 229) toxic epidermal necrolysis
Musculoskeletal and connective tissue disorders	230) muscular weakness 231) myalgia 232) muscle cramp. 233) rhabdomyolysis
Renal and urinary disorders	234) acute renal failure
Reproductive system and breast disorders	235) erectile dysfunction NOS
Investigations	236) increased blood creatinine phosphokinase 237) blood creatinine increased 238) decreased gamma- glutamyl transferase and in parallel alka-line phosphatase 239) haemoglobin decreased 240) platelet increased 241) white blood cell count decreased 242) gamma- glutamyl transferase increased 243) transaminase increased

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

F1

TELEPHONE FOLLOW UP LOG

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Phase 1: 1 week after initiated study drug

Safety bloods taken *Yes* ☐ *No* ☐

Safety bloods results received *Yes* ☐ *No* ☐

Telephone contact attempts

Attempt	Date	Time	Contact successful?
1	__ __ /__ __ /__ __ __ __ *d d m m y y y y*	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
2	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
3	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
4	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
5	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
6	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
7	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
8	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
9	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐

Telephone Follow up

Is the patient happy to continue participating in the trial *Yes* ☐ *No* ☐ If no, please complete a **withdrawal form**

Any missed doses of study medication *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Any days where incorrect dose has been taken *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Patient experienced any adverse events *Yes* ☐ *No* ☐ If yes, please complete **D1** and **SAE** forms where appropriate

Changes to concomitant medications *Yes* ☐ *No* ☐ If yes, please complete details of changes on **F11 & F12**

Reminded patient to send back used bottles in pre-paid envelopes *Yes* ☐ *No* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
TELEPHONE FOLLOW UP LOG

F2

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Phase 1: Month 1

Safety bloods taken *Yes* ☐ *No* ☐

Safety bloods results received *Yes* ☐ *No* ☐

Telephone contact attempts

Attempt	Date	Time	Contact successful?
1	__ __ /__ __ /__ __ __ __ *d d m m y y y y*	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
2	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
3	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
4	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
5	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
6	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
7	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
8	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
9	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐

Telephone Follow up

Is the patient happy to continue participating in the trial *Yes* ☐ *No* ☐ If no, please complete a **withdrawal form**

Any missed doses of study medication *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Any days where incorrect dose has been taken *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Patient experienced any adverse events *Yes* ☐ *No* ☐ If yes, please complete **D1** and **SAE** forms where appropriate

Changes to concomitant medications *Yes* ☐ *No* ☐ If yes, please complete details of changes on **F11 & F12**

Reminded patient to send back used bottles in pre-paid envelopes *Yes* ☐ *No* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
TELEPHONE FOLLOW UP LOG

F3

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Phase 1: Month 2

Safety bloods taken *Yes* ☐ *No* ☐

Safety bloods results received *Yes* ☐ *No* ☐

Telephone contact attempts

Attempt	Date	Time	Contact successful?
1	__ __ /__ __ /__ __ __ __ *d d m m y y y y*	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
2	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
3	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
4	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
5	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
6	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
7	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
8	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
9	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐

Telephone Follow up

Is the patient happy to continue participating in the trial *Yes* ☐ *No* ☐ If no, please complete a **withdrawal form**

Any missed doses of study medication *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Any days where incorrect dose has been taken *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Patient experienced any adverse events *Yes* ☐ *No* ☐ If yes, please complete **D1** and **SAE** forms where appropriate

Changes to concomitant medications *Yes* ☐ *No* ☐ If yes, please complete details of changes on **F11 & F12**

Reminded patient to send back used bottles in pre-paid envelopes *Yes* ☐ *No* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
TELEPHONE FOLLOW UP LOG

F4

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Phase 1: Month 3

Safety bloods taken *Yes* ☐ *No* ☐

Safety bloods results received *Yes* ☐ *No* ☐

Telephone contact attempts

Attempt	Date	Time	Contact successful?
1	__ __ /__ __ /__ __ __ __ *d d m m y y y y*	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
2	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
3	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
4	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
5	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
6	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
7	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
8	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
9	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐

Telephone Follow up

Is the patient happy to continue participating in the trial *Yes* ☐ *No* ☐ If no, please complete a **withdrawal form**

Any missed doses of study medication *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Any days where incorrect dose has been taken *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Patient experienced any adverse events *Yes* ☐ *No* ☐ If yes, please complete **D1** and **SAE** forms where appropriate

Changes to concomitant medications *Yes* ☐ *No* ☐ If yes, please complete details of changes on **F11 & F12**

Reminded patient to send back used bottles in pre-paid envelopes *Yes* ☐ *No* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
TELEPHONE FOLLOW UP LOG

F4

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Washout period: Month 5

Safety bloods taken *Yes* ☐ *No* ☐

Safety bloods results received *Yes* ☐ *No* ☐

Telephone contact attempts

Attempt	Date	Time	Contact successful?
1	__ __ /__ __ /__ __ __ __ *d d m m y y y y*	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
2	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
3	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
4	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
5	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
6	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
7	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
8	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
9	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐

Telephone Follow up

Is the patient happy to continue participating in the trial? *Yes* ☐ *No* ☐ If no, please complete a **withdrawal form**

Patient experienced any adverse events *Yes* ☐ *No* ☐ If yes, please complete **D1** and **SAE** forms where appropriate

Changes to concomitant medications *Yes* ☐ *No* ☐ If yes, please complete details of changes on **F11 & F12**

Reminded patient about the date they should start taking medication for phase 2? *Yes* ☐ *No* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

F5

TELEPHONE FOLLOW UP LOG

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Phase 2: 1 week after initiated study drug

Safety bloods taken *Yes* ☐ *No* ☐

Safety bloods results received *Yes* ☐ *No* ☐

Telephone contact attempts

Attempt	Date	Time	Contact successful?
1	__ __ /__ __ /__ __ __ __ *d d m m y y y y*	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
2	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
3	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
4	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
5	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
6	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
7	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
8	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
9	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐

Telephone Follow up

Is the patient happy to continue participating in the trial *Yes* ☐ *No* ☐ If no, please complete a **withdrawal form**

Any missed doses of study medication *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Any days where incorrect dose has been taken *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Patient experienced any adverse events *Yes* ☐ *No* ☐ If yes, please complete **D1** and **SAE** forms where appropriate

Changes to concomitant medications *Yes* ☐ *No* ☐ If yes, please complete details of changes on **F11 & F12**

Reminded patient to send back used bottles in pre-paid envelopes *Yes* ☐ *No* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

F6

TELEPHONE FOLLOW UP LOG

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Phase 2: Month 6

Safety bloods taken *Yes* ☐ *No* ☐

Safety bloods results received *Yes* ☐ *No* ☐

Telephone contact attempts

Attempt	Date	Time	Contact successful?
1	__ __ /__ __ /__ __ __ __ *d d m m y y y y*	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
2	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
3	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
4	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
5	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
6	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
7	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
8	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
9	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐

Telephone Follow up

Is the patient happy to continue participating in the trial *Yes* ☐ *No* ☐ If no, please complete a **withdrawal form**

Any missed doses of study medication *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Any days where incorrect dose has been taken *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Patient experienced any adverse events *Yes* ☐ *No* ☐ If yes, please complete **D1** and **SAE** forms where appropriate

Changes to concomitant medications *Yes* ☐ *No* ☐ If yes, please complete details of changes on **F11 & F12**

Reminded patient to send back used bottles in pre-paid envelopes *Yes* ☐ *No* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

F7

TELEPHONE FOLLOW UP LOG

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Phase 2: Month 7

Safety bloods taken *Yes* ☐ *No* ☐

Safety bloods results received *Yes* ☐ *No* ☐

Telephone contact attempts

Attempt	Date	Time	Contact successful?
1	__ __ /__ __ /__ __ __ __ *d d m m y y y y*	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
2	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
3	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
4	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
5	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
6	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
7	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
8	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
9	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐

Telephone Follow up

Is the patient happy to continue participating in the trial *Yes* ☐ *No* ☐ If no, please complete a **withdrawal form**

Any missed doses of study medication *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Any days where incorrect dose has been taken *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Patient experienced any adverse events *Yes* ☐ *No* ☐ If yes, please complete **D1** and **SAE** forms where appropriate

Changes to concomitant medications *Yes* ☐ *No* ☐ If yes, please complete details of changes on **F11 & F12**

Reminded patient to send back used bottles in pre-paid envelopes *Yes* ☐ *No* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN
TELEPHONE FOLLOW UP LOG

F8

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Phase 2: Month 8

Safety bloods taken *Yes* ☐ *No* ☐

Safety bloods results received *Yes* ☐ *No* ☐

Telephone contact attempts

Attempt	Date	Time	Contact successful?
1	__ __ /__ __ /__ __ __ __ *d d m m y y y y*	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
2	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
3	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
4	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
5	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
6	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
7	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
8	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐
9	__ __ /__ __ /__ __ __ __	__ __ : __ __ ***(24 hr clock)***	*Yes* ☐ *No* ☐

Telephone Follow up

Is the patient happy to continue participating in the trial *Yes* ☐ *No* ☐ If no, please complete a **withdrawal form**

Any missed doses of study medication *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Any days where incorrect dose has been taken *Yes* ☐ *No* ☐

If yes, how many ☐☐

Reason _____

Patient experienced any adverse events *Yes* ☐ *No* ☐ If yes, please complete **D1** and **SAE** forms where appropriate

Changes to concomitant medications *Yes* ☐ *No* ☐ If yes, please complete details of changes on **F11 & F12**

Reminded patient to send back used bottles in pre-paid envelopes *Yes* ☐ *No* ☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

F10

TELEPHONE FOLLOW UP LOG

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

End of trial— one month follow up

Telephone contact attempts

Attempt	Date	Time	Contact successful?
1	__ __ /__ __ /__ __ __ __ *d d m m y y y y*	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
2	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
3	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
4	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
5	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
6	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
7	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
8	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐
9	__ __ /__ __ /__ __ __ __	__ __ : __ __ *(24 hr clock)*	*Yes* ☐ *No* ☐

Telephone Follow up

Patient experienced any adverse events *Yes* ☐ *No* ☐ If yes, please complete **D1** and **SAE** forms where appropriate

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

CHANGES TO MEDICATIONS

F11

Patient Name: ______________________________ **CARDIOMAN study ID:** ☐☐

PREVIOUSLY REPORTED MEDICATIONS (PLEASE USE MULTIPLE SHEETS WHERE REQUIRED)

Medication at last visit: Name	Medication at last visit: Dose	Medication at last visit: Units *(circle)*	Medication at last visit: Frequency	Still taking medication?	If NO, date stopped	If still taking medication, still taking same dose?	If NO, date changed	Dose	Units (circle)	Frequency (circle)	Frequency: If **OTHER OR PRN**, specify:
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	
		mcg / mg / g other	OD / BD / TDS QDS / PRN / other	*Yes* ☐ *No* ☐		*Yes* ☐ *No* ☐			mcg / mg / g other, specify:	OD / BD / TDS QDS / PRN / OTH	

Name of person completing form* (capitals): ______________________________

Signature of person completing form: ____________________ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) ______________________ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

F12

CHANGES TO MEDICATIONS - CONTINUED

Patient Name: ______________________ **CARDIOMAN study ID:** [ ][ ]

NEW MEDICATIONS PRESCRIBED (PLEASE USE MULTIPLE SHEETS WHERE REQUIRED)

Medication	Dose	Units		Frequency	
		(circle)	*If 'other', specify*	*(circle)*	*If 'other' or PRN, specify*
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________
		mcg / mg / g other	________	OD / BD / TDS QDS / PRN / other	________

Please refer to the protocol for advice on concomitant medications/treatments.

Name of person completing form* (capitals): ______________________

Signature of person completing form: ______________ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) ______________________

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

NOTE TO FILE

N1

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

Please use this form to record details of important events to document breaches of GCP.

Does this note relate to a page in the CRFs? *Yes* ☐ *No* ☐ If **YES**, give page number (e.g. C1) ☐☐

Date and time of event (where applicable, or record NA):

__ __ /__ __ /__ __ __ __ (*y y y y*) *Date not applicable* ☐ __ __ : __ __ (*24 hr clock*) *Time not applicable* ☐

File note (include all relevant details of event)

FOR CTEU USE ONLY			
Sponsor informed? *(e.g. confidentiality, GCP, data integrity, patient safety breach)*	☐ *Yes*	☐ *No*	*If NO, reason:* _____
CAPA required? *(check with Sponsor if necessary)*	☐ *Yes*	☐ *No*	☐ *N/A*
Classification of the event:	☐ *Serious breach*	☐ *Non-serious breach/deviation*	☐ *No breach/deviation identified*

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

SAE MASTER FORM — CTIMP

S0

Sponsor Ref: CS/2015/4775
REC Ref: 15/SW/0228
EudraCT Ref: 2015-001382-10

CARDIOMAN study ID: ☐☐

An SAE report should be completed for any deaths or any events which are not listed on CRFs D2 (unless deemed related to bezafibrate) *and fit into any of the following criteria:*
i) causes hospitalisation, ii) increased length of hospital stay iii) life-threatening, iv) persistent or significant disability.
Complete one line in the table below and one initial report form (S1 and S2) for each event. The first follow-up report is due 5 days after the initial report. Subsequent reports should be completed as and when new information becomes available until the event is resolved or the patient had died.

SAE ref	Brief description of event	Onset date	Date of initial report	Date of follow-up 1	Date of follow-up 2	Date of follow-up 3	Less frequent follow-up agreed? (Tick)	Event resolved? (Tick)
1		__/__/____	__/__/____	__/__/____	__/__/____	__/__/____		
2		__/__/____	__/__/____	__/__/____	__/__/____	__/__/____		
3		__/__/____	__/__/____	__/__/____	__/__/____	__/__/____		
4		__/__/____	__/__/____	__/__/____	__/__/____	__/__/____		
5		__/__/____	__/__/____	__/__/____	__/__/____	__/__/____		
6		__/__/____	__/__/____	__/__/____	__/__/____	__/__/____		
7		__/__/____	__/__/____	__/__/____	__/__/____	__/__/____		
8		__/__/____	__/__/____	__/__/____	__/__/____	__/__/____		

Use the space below for details of any further follow-ups (use SAE reference):

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

CARDIOMAN

S1

SAE INITIAL REPORT FORM

Sponsor Ref: CS/2015/4775
IRAS: 170371
EudraCT Ref: 2015-001382-10

SAE ref ___ (for CTEU use only)

SAE report page ___ of ___

CARDIOMAN study ID: ☐☐

Date study team became aware of event: __ __ / __ __ / __ __ __ __

1. PARTICIPANT DETAILS

Patient initials ☐☐ Year of Birth __ __ __ __ (*y y y y*)

2. EVENT NAME

SAE ref (as listed on S0): ☐☐ Event name : _____

3. SAE CLASSIFICATION

	YES	NO		YES	NO
Prolonged an ongoing hospitalisation	☐	☐	Required hospitalisation	☐	☐
Resulted in persistent or significant disability / incapacity	☐	☐	Is / was life-threatening	☐	☐
Resulted in death	☐	☐	Other significant medical event	☐	☐

If **YES,** give date of death: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

If **YES,** specify: _____

4. DETAILS OF ONSET AND DURATION

Date and time of onset __ __ /__ __ /__ __ __ __ ___ ___ : ___ ___ (*24 hr clock*)

End date and time (if resolved) __ __ /__ __ /__ __ __ __ ___ ___ : ___ ___ (*24 hr clock*)

5. OUTCOME OF EVENT

Resolved, no sequelae ☐ *Resolved, with sequelae ** ☐ *Ongoing * (please complete and return follow-up report)* ☐ *Died * (give cause)* ☐

If **Resolved with sequelae, ongoing or **died,** please give details:*

6. FURTHER DETAILS OF EVENT

Maximum intensity of event (up until time of initial report)

***Mild**: an event easily tolerated by patient, causing minimal discomfort, not interfering with everyday activities** ☐

***Moderate**: an event interfering with normal everyday activities** ☐

***Severe**: an event that prevents normal everyday activities** ☐

(* 'interfering with everyday activities' refers to activities that the patient was previously capable of doing at that stage in their recovery)

Full description of event, including body site, reported signs and symptoms and diagnosis where possible

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

SAE INITIAL REPORT FORM

S2

Sponsor Ref: CS/2015/4775
IRAS: 170371
EudraCT Ref: 2015-001382-10

SAE ref ___ (for CTEU use only)

SAE report page ___ of ___

CARDIOMAN study ID: ☐☐

7. DETAILS OF RESEARCH INTERVENTION

Date intervention started: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

Intervention: Treatment (placebo/Bezafibrate) is given in two 4 month long phases with a minimum of one month washout period between these where no treatment is given.

Date and dose last taken: __ __ /__ __ /__ __ __ __ ☐☐☐ *mg*

Which phase of the study was the participant in at the time of onset of the SAE?

Phase 1 ☐ *Washout period* ☐ *Phase 2* ☐ *Follow up period* ☐

Treated according to protocol at the time of onset of the SAE: *Yes* ☐ *No* ☐ If ***NO,*** give details: _____

8. ACTION TAKEN AND FURTHER INFORMATION

Please describe action taken and record any other relevant information *(e.g. medical history, test results*)

9. WITHDRAWAL

Has the study medication been discontinued? *Yes* ☐ *No* ☐ *NA* ☐ If ***YES,*** date treatment withdrawn __ __ /__ __ /__ __ __ __

Has the patient been withdrawn from the study completely? *Yes* ☐ *No* ☐ If ***YES,*** date withdrawn __ __ /__ __ /__ __ __ __

10. UNBLINDING

Has the randomisation code been broken *Yes* ☐ *No* ☐

If ***YES,*** please provide details of randomisation *Bezafibrate* ☐ *Placebo* ☐

11. EXPECTEDNESS

Was the event expected of the study medication (see CRF D3)? *Yes* ☐ *No* ☐

If ***YES,*** enter event code from CRF D3: ☐☐☐ Specify, if required: _____

12. RELATEDNESS

In the opinion of the PI or delegated doctor, was the event related to the study intervention

Not related ☐ *Unlikely to be related* ☐ *Possibly related* ☐ *Probably related* ☐ *Definitely related* ☐

13. DETAILS OF PRINCIPAL INVESTIGATOR, OR DELEGATED DOCTOR

The completed SAE form must be signed off by the **PI or other delegated doctor** prior to sending to the sponsor.

I confirm that the contents of this form (pages S1 and S2) are accurate and complete.

Name: _____ Signature: _____ Date: __ __ /__ __ /__ __ __ __

If additional space is required to record further information, use CRF S4

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

SAE FOLLOW-UP REPORT FORM

S3

Sponsor Ref: CS/2015/4775
IRAS: 170371
EudraCT Ref: 2015-001382-10

SAE ref ___ (for CTEU use only)
SAE report page ___ of ___

CARDIOMAN study ID: ☐☐

1. PARTICIPANT DETAILS

Patient initials ☐☐ Year of Birth — — — —
y y y y

2. SAE DETAILS

Event name (as listed on S0 & S1): _____ SAE ref (as listed on S0 & S1): ☐☐

Date and time of onset __ __ /__ __ /__ __ __ __ ___ ___ : ___ ___
d d m m y y y y *(24 hr clock)*

3. NEW INFORMATION ABOUT EVENT

Maximum intensity of event (up until time of follow-up report)

***Mild**: an event easily tolerated by patient, causing minimal discomfort, not interfering with everyday activities** ☐

***Moderate**: an event interfering with normal everyday activities** ☐

***Severe**: an event that prevents normal everyday activities** ☐

(* 'interfering with everyday activities' refers to activities that the patient was previously capable of doing at that stage in their recovery)

Additional action taken and further information since initial report (e.g. medical history, test results etc)

4. OUTCOME OF EVENT

End date and time (if resolved) __ __ /__ __ /__ __ __ __ ___ ___ : ___ ___
(24 hr clock)

Resolved, no sequelae ☐ *Resolved, with sequelae** ☐ *Ongoing * (complete follow-up form within 5 days, unless otherwise agreed by sponsor)* ☐ *Died * (give cause)* ☐

If **Resolved with sequelae, ongoing or **died,** please give details:*

If a long term SAE and a new follow-up schedule has been agreed with the Sponsor, give date of next follow-up __ __ /__ __ /__ __ __ __

5. WITHDRAWAL

Has the study medication been discontinued? *Yes* ☐ *No* ☐ *NA* ☐ If ***YES,*** date treatment withdrawn — — /— — /— — — —

Has the patient been withdrawn from the study completely? *Yes* ☐ *No* ☐ If ***YES,*** date withdrawn __ __ /__ __ /__ __ __ __

6. UNBLINDING

Has the randomisation code been broken *Yes* ☐ *No* ☐

If ***YES,*** please provide details of randomisation *Bezafibrate* ☐ *Placebo* ☐

7. DETAILS OF PRINCIPAL INVESTIGATOR OR DELEGATED DOCTOR

The completed SAE form must be signed off by the **PI or other delegated doctor** prior to sending to the sponsor.
I confirm that the contents of this form are accurate and complete.

Name: _____ Signature: _____ Date: — — /— — /— — — —

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

S4

SAE ADDITIONAL INFORMATION FORM

Sponsor Ref: CS/2015/4775
IRAS: 170371
EudraCT Ref: 2015-001382-10

SAE ref ___ (for CTEU use only)

SAE report page ___ of ___

CARDIOMAN study ID: | | |

ADDITIONAL INFORMATION	
Section No	**Further Information**

Multiple copies of this CRF can be completed if required

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

CARDIOMAN

W1

WITHDRAWAL/CONTINUATION OF DATA COLLECTION

Patient Name: _____ **CARDIOMAN study ID:** ☐☐

WITHDRAWAL DETAILS

Date of withdrawal from study / study treatment __ __ /__ __ /__ __ __ __
d d m m y y y y

Was withdrawal: *Before randomisation* ☐ *After randomisation but before intervention* ☐ *During intervention* ☐ *During wash out period* ☐ *After intervention* ☐

REASON FOR WITHDRAWAL

Patient/Parent choice *Yes* ☐ *No* ☐ If ***YES***, select one option below:

- Patient/Parent changed their mind about ☐
- Patient did not give reason ☐
- Patient no longer wishes to do the trial assessments ☐
- Patient no longer wishes to take study medication ☐
- Other ☐
- If ***OTHER***, specify: _____

Clinician choice *Yes* ☐ *No* ☐ If ***YES***, , select one option below:

- Not willing to prescribe study medication ☐
- Patient no longer eligible ☐
- Other ☐
- If ***OTHER***, specify: _____

Name of clinician withdrawing patient: _____

Admin / logistical reasons *Yes* ☐ *No* ☐

If ***YES***, specify reason: _____

ADDITIONAL QUESTIONS

1. Is patient willing for data already collected to be used? *Yes* ☐ *No* ☐
2. Is patient willing for data routinely collected about them by the NHS (Medical records & NHS spine) to be used in this study? *Yes* ☐ *No* ☐
3. Is the patient willing to participate in follow-up *(please tick N/A if patient has not been randomised)?* *N/A* ☐ *Yes* ☐ *No* ☐

*If **NO** to questions **1, 2 and 3**, a **photocopy** of the **completed withdrawal form** should be **uploaded to the electronic medical notes.***

Additional information (only complete if relevant)

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*