SAE Ref.: ☐☐/☐☐☐☐ CONFIDENTIAL WHEN COMPLETE

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

CALIBRE

SAE FORM

To be completed by the site (PART 1)

SITE DETAILS

Site Name:	Name of PI:
.....	.....

PARTICIPANT DETAILS

Trial No.: ☐☐☐☐	Sex: Male ☐ Female ☐
Participants Initials: ☐☐☐☐	Participant Partial DoB: M M M / Y Y Y Y

REPORT TYPE (use BCTU allocated unique SAE number if this is a follow-up or final report)

Initial Report:	☐	
Follow-up Report:	☐ *Please insert unique SAE number*	☐☐/☐☐☐☐
Final Report:	☐ *Please insert unique SAE number*	☐☐/☐☐☐☐

EVENT INFORMATION

Signs and Symptoms:

.....

.....

.....

EVENT DIAGNOSIS

Diagnosis:

.....

.....

.....

Event Severity: Mild ☐ Moderate ☐ Severe ☐

SERIOUSNESS OF EVENT

Seriousness of event *(please provide a response to each question)*	No	Yes	Details
Death:	☐	☐	Date of death: DD / MMM / YYYY Cause of death: ……
Life threatening event:	☐	☐	
In-patient hospitalisation or prolongation of existing hospitalisation:	☐	☐	Initial ☐ Prolonged ☐ Date of discharge: DD / MMM / YYYY
Persistent or significant disability/incapacity:	☐	☐	
Congenital anomaly or birth defect:	☐	☐	
Other medical reason for reporting?	☐	☐	Please specify: ……

DETAILS OF EVENT

Date of Onset: DD / MMM / YYYY	Date Became Serious: DD / MMM / YYYY
Date Site Became Aware: DD / MMM / YYYY	Date resolved: DD / MMM / YYYY **OR** tick if ongoing ☐

TRIAL INTERVENTION SUMMARY							
List details of all trial interventions being received when the SAE started							
Intervention	**Intervention Received** (*Last date of last dose*)	**Route**	**Dose**	**Intervention Start Date**	**Action Taken** 1=None 2=Intervention Stopped 3=Intervention Delayed 4=Intervention Reduced	**Intervention Stopped Date**	**Causality Assessment** 1=Unrelated 2=Unlikely to be related 3=Possibly related 4=Probably related 5=Definitely related
Carvedilol	DD / MMM / YYYY	**Oral**		DD / MMM / YYYY	☐	DD / MMM / YYYY	☐
Variceal band ligation	DD / MMM / YYYY	**N/A**	**N/A**	DD / MMM / YYYY	☐	DD / MMM / YYYY	☐
Causality assessment undertaken by: (*This must be undertaken by a medically qualified doctor who has been delegated the task*)							

TRIAL TREATMENT			
Where drug interventions (IMP) have been stopped			
Did the event abate on stopping drug?	No ☐	Yes ☐	Not applicable ☐
If yes please provide details:	…….. ……..		
Did the event reappear after introduction of drug?	No ☐	Yes ☐	Not applicable ☐
If yes please provide details:	…….. ……..		

CONCOMITANT MEDICATIONS

Has the participant taken any other drugs which may interact with the intervention or influence the SAE? No ☐ Yes ☐ *If yes, please complete below*

Drug Name	Route 1=Oral 2=IV 3=Subcutaneous 4=Other (specify)	Dose (including units and frequency)	Start Date	Ongoing?		Stop Date (if relevant)
				No	Yes	
	☐		DD / MMM / YYYY	☐	☐	DD / MMM / YYYY
	☐		DD / MMM / YYYY	☐	☐	DD / MMM / YYYY
	☐		DD / MMM / YYYY	☐	☐	DD / MMM / YYYY
	☐		DD / MMM / YYYY	☐	☐	DD / MMM / YYYY
	☐		DD / MMM / YYYY	☐	☐	DD / MMM / YYYY
	☐		DD / MMM / YYYY	☐	☐	DD / MMM / YYYY
	☐		DD / MMM / YYYY	☐	☐	DD / MMM / YYYY
	☐		DD / MMM / YYYY	☐	☐	DD / MMM / YYYY
	☐		DD / MMM / YYYY	☐	☐	DD / MMM / YYYY
	☐		DD / MMM / YYYY	☐	☐	DD / MMM / YYYY
	☐		DD / MMM / YYYY	☐	☐	DD / MMM / YYYY
	☐		DD / MMM / YYYY	☐	☐	DD / MMM / YYYY

RELEVANT MEDICAL HISTORY (*provide narrative if relevant to diagnosis*)
Please provide a narrative if relevant to diagnosis. List any underlying **comorbidities or lab results and investigations that are relevant** (*where investigations or lab tests are appended, please ensure patient identifiers are replaced with trial number only*).
.....
.....
.....

UNRELATED EVENT	
If the event is unrelated, please provide details of an alternative explanation for the event:	....

DETAILS OF PERSON REPORTING			
Name of person reporting:	Job title of person reporting:		Date reported: DD / MMM / YYYY
Signature of person reporting: (*must appear on delegation log*)	.....	Date of signature:	DD / MMM / YYYY
Signature of PI:	.....	Date of PI signature:	DD / MMM / YYYY
Please return this form to the CALIBRE Trial Office at Birmingham Clinical Trials Unit			

To be completed by the Chief Investigator or named delegate (PART 2)			
Review of Causality			**Assessment of Expectedness**
Intervention	**Review of Causality** 1=Unrelated 2=Unlikely to be related 3=Possibly related 4=Probably related 5=Definitely related	**Dose**	This column should **only** be completed if causal relationship is classified as 3, 4 or 5 **(possibly, probably or definitely related)**. The expectedness assessment **must** be made with reference to the reference safety information (RSI).
Carvedilol	☐		Expected ☐
Variceal band ligation	☐	N/A	Unexpected ☐

CTCAE category:
Please refer to coded reference list below. ☐☐ CTCAE Term: ……

Coded Reference List

Common Terminology Criteria for Adverse Events (CTCAE Coded List)

Code	Category	Code	Category
1	Blood and lymphatic system disorders	**14**	Metabolism and nutrition disorders
2	Cardiac disorders	**15**	Musculoskeletal and connective tissue disorders
3	Congenital, familial and genetic disorders	**16**	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
4	Ear and labyrinth disorders	**17**	Nervous system disorders
5	Endocrine disorders	**18**	Pregnancy, puerperium and perinatal conditions
6	Eye disorders	**19**	Psychiatric disorders
7	Gastrointestinal disorders	**20**	Renal and urinary disorders
8	General disorders and administration site conditions	**21**	Reproductive system and breast disorders
9	Hepatobiliary disorders	**22**	Respiratory, thoracic and mediastinal disorders
10	Immune system disorders	**23**	Skin and subcutaneous tissue disorders
11	Infections and infestations	**24**	Social circumstances
12	Injury, poisoning and procedural complications	**25**	Surgical and medical procedures
13	Investigations	**26**	Vascular disorders

SIGNATURES

In signing this form the CI or delegate confirms the **Causality** and **Expectedness** of the event

Name of CI or delegate:	Signature of CI or delegate:	Date of CI or delegate signature:
……	……	DD / MMM / YYYY

FOR BCTU USE ONLY			
SAE Reference Number: ☐☐/☐☐☐☐			
Participants randomised to the carvedilol arm:			
Event Categorised as:	SAE ☐ SAR ☐		
	SUSAR ☐ (*fatal or life threatening*)	Date reported to CA, REC and Sponsor:	DD / MMM / YYYY
	SUSAR ☐ (*non-fatal or life threatening*)	Date reported to CA, REC and Sponsor:	DD / MMM / YYYY
Participants randomised to the variceal band ligation arm:			
Event Categorised as:	SAE ☐		
	Serious related and unexpected event ☐	Date reported to REC and Sponsor:	DD / MMM / YYYY
Completed by:			
Name: …….	Signature: …….	Date of signature: DD / MMM / YYYY	