Trial number: ☐☐☐☐

CONFIDENTIAL WHEN COMPLETE

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

CALIBRE

FOLLOW-UP FORM – TWO WEEKS SAFETY VISIT (CARVEDILOL ARM)

IDENTIFYING DETAILS

Trial No.: ☐☐☐☐	Initials: ☐☐☐☐
Site Name: ……	
Date of appointment: D D / M M M / Y Y Y Y	

HOW THE VISIT WAS CONDUCTED

Please state how the visit was conducted:

Face to Face ☐	Remote ☐

*Guidance: If a face to face visit is required **following** a remote visit, please only complete the CRF at face to face visit.*

CONFIRMATION OF CONSENT

Does the participant wish to continue taking part in the CALIBRE trial? No ☐ Yes ☐

If no, please complete a Change of Status Form.

If yes, please continue to GP Visits.

GP VISITS

Since CALIBRE Trial entry, has the participant visited their GP in relation to liver cirrhosis/ oesophageal varices? No ☐ Yes ☐

If yes, how many times did the participant visit their GP? ☐☐

Please include the total for all GP visits that were required due to liver cirrhosis/oesophageal varices, since CALIBRE Trial visit:

INTERVENTION START DATE

Date first dose of carvedilol prescribed: D D / M M M / Y Y Y Y

VITAL SIGNS

Were vital signs taken? No ☐ Yes ☐ N/A ☐

Blood pressure: ☐☐☐ / ☐☐☐ mmHg	Pulse: ☐☐☐ bpm

ADVERSE EVENTS

Since CALIBRE trial entry, has the participant experienced any serious adverse events that are not defined as 'expected' (i.e. are recognised complications/ consequences of cirrhosis and oesophageal varices) in the protocol? **If yes, please complete a CALIBRE SAE FORM and return to the CALIBRE Trial Office within 24 hours** No ☐ Yes ☐

PARTICIPANTS RANDOMISED TO THE CARVEDILOL ARM

Since CALIBRE trial entry, has the participant experienced/ been diagnosed with: *Please tick all that apply*

	Yes		Yes
Gastrointestinal upset	☐	Blurred vision	☐
Dizziness	☐	Lethargy	☐
Rash	☐	Headache	☐
Swelling in the feet or hands	☐	Upper respiratory tract infection	☐
Shortness of breath	☐	Sexual dysfunction	☐
Other (please specify)	☐	……	

I confirm that all above items have been considered and only those ticked were present No ☐ Yes ☐

Has the participant been put onto either a split or reduced dose of carvedilol because of adverse events? No ☐ Yes ☐

If no, please continue to the question regarding stopping carvedilol.

If yes, complete the following questions and rest of form.

Tick if not applicable

Date carvedilol dose was split: D D / M M M / Y Y Y Y ☐

Date carvedilol was reduced: D D / M M M / Y Y Y Y ☐

Please indicated which adverse events led to the dose of carvedilol being split or reduced: *Please tick all that apply*

	Yes		Yes
Gastrointestinal upset	☐	Blurred vision	☐
Dizziness	☐	Lethargy	☐
Rash	☐	Headache	☐
Swelling in the feet or hands	☐	Upper respiratory tract infection	☐
Shortness of breath	☐	Sexual dysfunction	☐
Other (please specify)	☐	……	

I confirm that all above items have been considered and only those ticked were present No ☐ Yes ☐

Has the participant stopped taking carvedilol because of adverse events? No ☐ Yes ☐

If no, please continue to the question regarding alternative treatment commenced

If yes, complete the following questions.

Date carvedilol was stopped: D D / M M M / Y Y Y Y

Please indicated which adverse events have led to carvedilol being stopped: *Please tick all that apply*

	Yes		Yes
Gastrointestinal upset	☐	Blurred vision	☐
Dizziness	☐	Lethargy	☐
Rash	☐	Headache	☐
Swelling in the feet or hands	☐	Upper respiratory tract infection	☐
Shortness of breath	☐	Sexual dysfunction	☐
Other (please specify)	☐	……	

I confirm that all above items have been considered and only those ticked were present No ☐ Yes ☐

Has an alternative treatment been commenced? No ☐ Yes ☐

If no, please continue to the question regarding other reason for alternative treatment commenced

If yes, please complete following question.

Which alternative treatment has been commenced?

Propranolol ☐ Nadolol ☐ Variceal band ligation ☐

Other (please specify) ☐ ……

Tick if not available

Date alternative treatment commenced: D D / M M M / Y Y Y Y ☐

CRF completed by:

You **must** have signed the CALIBRE site training log and CALIBRE delegation log

Name: ……..
(please print)

Date: D D / M M M / Y Y Y Y **Signature:** ……..