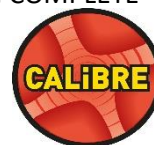


Trial number:

CONFIDENTIAL WHEN COMPLETE

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BIRMINGHAM



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

### IDENTIFYING DETAILS

Trial No.:

Initials:

Site Name: .....

Date of appointment:  /  /

### 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:  /  /

### VITAL SIGNS

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

Blood pressure:  /  mmHg Pulse:  bpm

Trial number: 

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**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	<input type="checkbox"/>	Blurred vision	<input type="checkbox"/>
Dizziness	<input type="checkbox"/>	Lethargy	<input type="checkbox"/>
Rash	<input type="checkbox"/>	Headache	<input type="checkbox"/>
Swelling in the feet or hands	<input type="checkbox"/>	Upper respiratory tract infection	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>	Sexual dysfunction	<input type="checkbox"/>
Other (please specify)	<input type="checkbox"/>		

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:  /  /  ☐

Date carvedilol was reduced:  /  /  ☐

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

	Yes		Yes
Gastrointestinal upset	<input type="checkbox"/>	Blurred vision	<input type="checkbox"/>
Dizziness	<input type="checkbox"/>	Lethargy	<input type="checkbox"/>
Rash	<input type="checkbox"/>	Headache	<input type="checkbox"/>
Swelling in the feet or hands	<input type="checkbox"/>	Upper respiratory tract infection	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>	Sexual dysfunction	<input type="checkbox"/>
Other (please specify)	<input type="checkbox"/>		

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

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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:   /    /

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

	Yes		Yes
Gastrointestinal upset	<input type="checkbox"/>	Blurred vision	<input type="checkbox"/>
Dizziness	<input type="checkbox"/>	Lethargy	<input type="checkbox"/>
Rash	<input type="checkbox"/>	Headache	<input type="checkbox"/>
Swelling in the feet or hands	<input type="checkbox"/>	Upper respiratory tract infection	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>	Sexual dysfunction	<input type="checkbox"/>
Other (please specify)	<input type="checkbox"/>	.....	

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:   /    /     ☐

### CRF completed by:

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

Name: .....  
(please print)

Date:   /    /

Signature: .....