

HEART FAILURE									
Protocol Identifier	Subject Identifier		Visit Description						
	<table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>								Treatment Period Visit XYZ

PAST MEDICAL HISTORY

Has the subject had a prior episode of heart failure? [Y] Yes [N] No

Does the subject have a prior history of exposure to cardiotoxins, such as anthracyclines? [Y] Yes [N] No

URGENT HEART FAILURE VISIT

Did heart failure lead to an unplanned visit to an emergency department or health care clinic? [Y] Yes [N] No

If Yes, complete the following:

If Yes, admission date and time:

Day		Month		Year						

Discharge date and time

Day		Month		Year	Hrs: Mins		(00:00-23:59)			

HOSPITALISATION

Did the subject's clinical status at the time of presenting with the event reported as heart failure lead to admission to the hospital? [Y] Yes [N] No

If Yes, complete the following:

If Yes, admission date and time:

Day		Month		Year	Hrs: Mins		(00:00-23:59)			

Discharge date and time:

Day		Month		Year	Hrs: Mins		(00:00-23:59)			

Did subject have evidence of an arrhythmia at time of presentation? [Y] Yes [N] No
If Yes, fill out Arrhythmia eCRF.

Did subject have evidence of acute coronary syndrome? [Y] Yes [N] No
If Yes, fill out Myocardial Infarction / Unstable Angina eCRF

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VITAL SIGNS AT PRESENTATION (will add appropriate unit fields prior to Dec. mtg)

Systolic Blood Pressure

Diastolic Blood Pressure

Heart Rate

Respiratory Rate

Temperature

NYHA SCORE at Presentation (✓ only one)						
Class	Functional Status					
<input type="checkbox"/> I	No symptoms and no limitation in ordinary physical activity.					
<input type="checkbox"/> II	Mild symptoms and slight limitation during ordinary activity.					
<input type="checkbox"/> III	Marked limitation in activity due to symptoms, even during less-than ordinary activity. Comfortable only at rest.					
<input type="checkbox"/> IV	Severe limitations. Experiences symptoms even while at rest.					
Criteria committee, New York Heart Association, Diseases of the heart and blood vessels. Nomenclature and criteria for diagnosis, 9 th ed. Boston: Little, Brown, 1994						
LABORATORY RESULT DATA						
Enter 'NR' if the laboratory results are not available to report or if a lab error occurred.						
Laboratory Name _____ Address _____ _____					Lab ID	
Date	Time	Test	Result	Normal Ranges		
				Low	High	Unit
Day Month Year	Hr: Min 00:00-23:59					
e.g. 01 JAN 2012	13:25	Serum Creatinine	83	62	115	umol/l

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		Brain natriuretic peptide				
		N-terminal pro-Brain natriuretic peptide				

Atrial natriuretic peptide

		Troponin				
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List all labs available. Add lines for serial values of the same lab as needed.

HEART FAILURE (continued)

CURRENT CLINICAL SIGNS AND SYMPTOMS OF HEART FAILURE

Symptoms (✓ all that apply)

Dyspnea

- Dyspnea with exertion
- Dyspnea at rest
- Orthopnea
- Paroxysmal Nocturnal Dyspnea

Decreased exercise tolerance

Fatigue

Other symptoms of worsened end-organ perfusion or volume overload (must be specified and described by the protocol): list: _____

Signs (✓ all that apply)

Peripheral edema

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<input type="checkbox"/> Increasing abdominal distention or ascites (in the absence of primary hepatic disease) <input type="checkbox"/> Pulmonary rales / crackles / crepitations <input type="checkbox"/> Increased jugular venous pressure <input type="checkbox"/> Hepatojugular reflex <input type="checkbox"/> S3 cardiac gallop <input type="checkbox"/> Clinically significant or rapid weight gain thought to be related to fluid retention <input type="checkbox"/> Tachypnea with respiratory rate > 20 breaths / minute

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HEART FAILURE (continued)

ECHOCARDIOGRAPHY

Was an Echocardiogram performed? [Y] Yes [N] N

If Yes, complete the following:

Date and time of Echocardiogram:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Day	Month	Year	Hrs:Mins		
			(00:00-23:59)		

Ejection Fraction Assessment (systolic function)? [Y] Yes [N] N

If Yes, record percentage %

Evidence of diastolic dysfunction? [Y] Yes [N] N

Evidence of significant valvular disease? [Y] Yes [N] N

Evidence of cardiac dilatation? [Y] Yes [N] N
If Yes, indicate which chamber(s) [A] Atrial [V] Ventricular

Evidence of regional wall motion abnormality? [Y] Yes [N] N

Was a prior Echocardiogram performed? [Y] Yes [N] N

If Yes, complete the following:

Date and time of prior Echocardiogram:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Day	Month	Year	Hrs:Mins	
			(00:00-23:59)	

Prior Ejection Fraction Assessment (systolic function)? [Y] Yes [N] N

If Yes, record percentage %

Prior evidence of diastolic dysfunction? [Y] Yes [N] N

Evidence of significant valvular disease? [Y] Yes [N] N

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Evidence of cardiac dilatation? [Y] Yes [N] N
 If Yes, indicate which chamber(s) [A] Atrial [V] Ventricular
 Evidence of regional wall motion abnormality? [Y] Yes [N] N

RIGHT HEART CATHETERIZATION

Was a right heart catheterization performed? [Y] Yes [N] N

Did RHC demonstrate Pulmonary Capillary Wedge Pressure \geq 18 mmHg [Y] Yes [N] N

Did RHC demonstrate Cardiac output $<$ 2.2 l/min/m²? [Y] Yes [N] N

CHEST XRAY

Was a Chest Xray performed? [Y] Yes [N] N

If Yes, complete the following:

Date and time of Chest Xray:

Day		Month		Year		Hrs:Mins	

(00:00-23:59)

Evidence of Pulmonary Edema [Y] Yes [N] N

Pleural Effusion [Y] Yes [N] N

Evidence of Cardiomegaly [Y] Yes [N] N

HEART FAILURE (continued)

MUGA

Was a Multiple Gated Acquisition Scan (MUGA) performed? [Y] Yes [N] N

If Yes, complete the following:

Date and time of MUGA:

Day		Month		Year		Hrs:Mins	

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Hrs:Mins

(00:00-23:59)

Ejection Fraction Assessment?

		%
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— box for “not done”

Evidence of wall motion abnormalities?

[Y] Yes [N] N

Was a prior Multiple Gated Acquisition Scan (MUGA) performed?

[Y] Yes [N] N

If Yes, complete the following:

Day		Month		Year	

Hrs:Mins			

Date and time of prior MUGA:

(00:00-23:59)

Prior Ejection Fraction Assessment?

[Y] Yes [N] N

If Yes, record percentage

		%
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Evidence of wall motion abnormalities?

[Y] Yes [N] N

ACUTE THERAPY FOR HEART FAILURE EPISODE

Were any acute changes to the subject’s treatment for heart failure required to treat their acute episode of heart failure during their clinic or emergency room visit or hospitalization?

[Y] Yes [N] N

If Yes, complete the following:

Escalation of chronic cardiovascular medication (not including diuretics)

[Y] Yes [N] N

Increase in oral diuretics

[Y] Yes [N] N

Uptitration of IV therapy if already on therapy

[Y] Yes [N] N

New class of medication added (e.g., beta blocker, ACE inhibitor /Angiotensin Receptor Blocker, Aldosterone receptor blocker, morphine sulfate)

[Y] Yes [N] N therapy: _____

Intravenous diuretics

[Y] Yes [N] N

Inotropes (e.g., dobutamine, milrinone)

[Y] Yes [N] N therapy: _____

Intravenous vasodilators (e.g., nitroglycerin, nitroprusside, nesiritide)

[Y] Yes [N] N therapy: _____

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Mechanical assisted device

[Y] Yes [N] N

If Yes, complete the following:

Intra-aortic balloon placement

[Y] Yes [N] N

Ventricular assist device insertion

[Y] Yes [N] N

[Y] Yes [N] N

Mechanical fluid removal

If Yes, complete the following:

Ultrafiltration

[Y] Yes [N] N

Hemofiltration

[Y] Yes [N] N

Dialysis

[Y] Yes [N] N

Others

[Y] Yes [N] N

DISCHARGE

Were the symptoms of heart failure resolved at the time of discharge?

[Y] Yes [N] N

If yes, indicate degree

[P] Partially

[Y] Completely

BNP / NT-pro BNP at discharge: result: _____

Send Discharge Summary

HEART FAILURE (continued)

FINAL PRIMARY DIAGNOSIS

(✓ only one)

Arrhythmia

Acute coronary syndrome

Ischemic cardiomyopathy

Dilated cardiomyopathy

Hypertrophic cardiomyopathy

Restrictive cardiomyopathy

Arrhythmogenic right ventricular cardiomyopathy

Unclassified cardiomyopathies

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Myocarditis

Other, specify _____

“Additional Supplemental information (to what has already been highlighted in yellow in the form): Source documents for data requested in the eCRF (e.g., labs, CXR) as well as admission History and Physical, ECG tracings at baseline and at time of event(s) and Discharge Summary”.

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