

NOTE: Enrollment- see below

**Demographics**

**1** Date of birth: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ **DOB** **DEMOG (TYPE 1)**  
day month year

**2** Sex:  Male  Female **SEX<XGENDR>**

**3** Ethnicity (check only one):  Hispanic or Latino **ETHNIC<XETHN>**  
 Not Hispanic or Latino

**4** Race (check all that apply):  American Indian or Alaska Native  Native Hawaiian or other Pacific Islander **NATHWN<XYES>**  
**AMERIND<XYES>**  Asian  White/Caucasian **WHITE<XYES>**  
 Black **ASIAN<XYES>**  
**BLACK<XYES>**

**Eligibility**

Did the subject meet all eligibility criteria? **INCL1<I:3>** **INCL2<I:3>** **INCL3<I:3>** **ELIGIBLE (TYPE 1)**  
 No → If No: Inclusion criteria not met: # \_\_\_\_\_, # \_\_\_\_\_, # \_\_\_\_\_  
 Exclusion criteria present: # \_\_\_\_\_, # \_\_\_\_\_, # **EXCL1<I:3>** **EXCL2<I:3>** **EXCL3<I:3>**  
 Was a waiver granted for all of the above exceptions?  
**ELIGCRIT<XYESNO>**  No **WAIVER <XYESNO>**  
 Yes

**Hospitalization**

Date and time of initial presentation to acute care facility: **PRESENTD<DATE>** \_\_\_\_\_ **PRESENTM<DATETIME>** \_\_\_\_\_ **INITHOSP (TYPE 1)**  
day month year 00:00 to 23:59  
**DIURETIC (TYPE 4) PS**

**7-Day Prior Oral Diuretics**

	<b>Medication</b> <b>DIUMEDS&lt;HFDIUR&gt;</b>	<b>DIURANS&lt;HFRESP&gt;</b>	<b>Average Total Daily Dose</b>	<b>Units</b>
1=	<b>1</b> Furoseamide	<input type="checkbox"/> No <input type="checkbox"/> Yes → <b>0=NO</b>	<b>DIURDOSE&lt;F:9:3&gt;</b> _____	mg
2=	<b>2</b> Torsemide	<input type="checkbox"/> No <input type="checkbox"/> Yes → <b>1=YES</b> <b>2=YES,DAILY</b> <b>3=YES,PRN</b>	_____	mg
3=	<b>3</b> Bumetanide	<input type="checkbox"/> No <input type="checkbox"/> Yes →	_____	mg
4=	<b>4</b> Metolazone	<input type="checkbox"/> No <input type="checkbox"/> Yes, daily <input type="checkbox"/> Yes, PRN →	_____	mg
5=	<b>5</b> HCTZ	<input type="checkbox"/> No <input type="checkbox"/> Yes, daily <input type="checkbox"/> Yes, PRN →	_____	mg

6=CHLOROTHIAZIDE (P. 15,16 ONLY) **Enroll panel will contain:**  
**SUBJNO:** derived from 'DS'II INVSITE II '-II PATID  
**INITIALS V:3**  
**RANDTM<DATETIME>**  
**RANDDT<DATE>**  
**HMDIUDOS <I:3>**

**Clinical History**

1 Estimated date of initial diagnosis of heart failure: **DIAGHFM** **DIAGHFY** **MEDHIST1(TYPE 1)**  
 **<ZMONTH>** /  **<I:4>** / \_\_\_\_\_  
month year

2 Total number of cardiovascular hospitalizations within prior 12 months: **CVHSP<I:2>**  
 \_\_\_\_\_

3 Number of hospitalizations within prior 12 months with primary diagnosis of heart failure: **HFHSP<I:2>**  
 \_\_\_\_\_

4 Has LV function been assessed?  
**LVASSESS<XYESNO>**  
 No  
 Yes → If Yes: Date of last LVEF: **LVAASDT**  
 \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
day month year

Value of last LVEF: **LVEF<I:2>** EF \_\_\_\_\_ % OR Check only one:  **1** Normal **LVEFSTAT<HFLVEF>**  
 **2** Mild dysfunction  
 **3** Moderate dysfunction  
 **4** Severe dysfunction

Method of assessment of LV function (check only one):  **1** Radionuclide ventriculogram **LVMETH<HFMETH>**  
 **2** Left ventriculogram  
 **3** Echocardiogram  
 **4** MRI  
 **98** Other

5 Does the subject have a documented history of ischemic heart disease?  
 No **ISCHEMIC<XYESNO>**  
 Yes → If Yes: Specify (check all that apply):  
 Angina pectoris: **ANGINA<XYES>**  
 Myocardial infarction (MI) → Date of most recent: **MIDT**  
 \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
day month year  
**MI<XYES>** **LTCATH<XYES>**  Left heart catheterization before randomization → Date of most recent: **LTCATHDT**  
 \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
day month year  
**LM<XYES>** **LAD<XYES>** **LCX<XYES>** **RCA<XYES>**  
**PTCI<XYES>**  Percutaneous transluminal coronary intervention (PTCI) → Date of most recent: **PTCJDT**  
 \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
day month year  
**CABG<XYES>**  Coronary artery bypass graft (CABG) → Date of most recent: **CABGDT**  
 \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
day month year

6 Does the subject have evidence of non-ischemic cardiomyopathy?  
 No **NONISCH<XYESNO>**  
 Yes → If Yes: Specify contributors (check all that apply):  
 Alcoholic **ALCOHOLC<XYES>**  
 Cytotoxic drug therapy **CYTOTOXC<XYES>**  
 Familial **FAMILIAL<XYES>**  
 Hypertensive **HYPERTEN<XYES>**  
 Idiopathic dilated cardiomyopathy **DILATED<XYES>**  
 Idiopathic restrictive cardiomyopathy **RESTRICT<XYES>**  
 Peripartum **PERIPAR<XYES>**  
 Valvular **VAL<XYES>**  
 HCM **HCM<XYES>**  
 Other/uncertain (specify): \_\_\_\_\_ **OTHCONT<XYES>** **OTHCONSP<V:50>**

**Clinical History** (continued)

**Does the subject have a documented history of any of the following?** MEDHIST2 (TYPE1)

**7 Valvular heart disease:**  
 No VALVULAR<XYESNO>  
 Yes → If Yes: Specify: ALL BELOW CODE< HFVALV> EXCEPT PRIOR VALVULAR SURGERY  
**MSTENOS** Mitral stenosis → Check one:  None/Trivial  Mild  Moderate  Severe  Unknown  
**MREGURG** Mitral regurgitation → Check one:  None/Trivial  Mild  Moderate  Severe  Unknown  
**ATSTENOS** Aortic stenosis → Check one:  None/Trivial  Mild  Moderate  Severe  Unknown  
**AREGURG** Aortic regurgitation → Check one:  None/Trivial  Mild  Moderate  Severe  Unknown  
**TSTENOS** Tricuspid stenosis → Check one:  None/Trivial  Mild  Moderate  Severe  Unknown  
**TREGURG** Tricuspid regurgitation → Check one:  None/Trivial  Mild  Moderate  Severe  Unknown  
 Prior valvular surgery → Check all that apply:  None  Mitral  Aortic  Tricuspid  Pulmonic

**8 Hypertension:** HYPRTESN<XYESNO>  No  Yes  
 NONSURG, MITSURG, AORSURG, TRISURG, PULSURG  
 All <XYES>

**9 TIA:** TIA<XYESNO>  No  Yes

**10 Stroke:** STROKE<XYESNO>  No  Yes

**11 Arrhythmia:** ARRHYTHM <XYESNO>  
 No  
 Yes → If Yes: Specify (check all that apply):  
**ATRIALFB<XYES>** Atrial fibrillation/flutter → Check one:  New onset  Paroxysmal  Persistent  Permanent  
**SUSVTVF<XYES>** Sustained VT or VF  
**ARREST<XYES>** Cardiac arrest (etiology unclear)  
 FIBFLUTR<HFFIBF>  
 PACETYPE<HFCHBR>

**12 Pacemaker without ICD:** PACEMAKR<XYESNO>  No  Yes → Check one:  Single  Dual  Biventricular

**13 ICD:** ICD<XYESNO>  No  Yes → Check one:  Single  Dual  Biventricular

**14 Peripheral vascular disease:** PVD<XYESNO>  No  Yes ICDTYPE<HFCHBR>

**15 Chronic obstructive pulmonary disease:**  No  Yes COPD<XYESNO>

**16 Diabetes:** DIABETES<XYESNO>  No  Yes → Check one:  Insulin treated  
 DIABTYPE<HFDIAB>  Non-insulin medically treated  
 Diet only

**17 Gout:** GOUT<XYESNO>  No  Yes

**18 Hepatic disease:** HEPATIC<XYESNO>  No  Yes

**19 Malignancy (past 5 years, other than skin):**  No  Yes MALIGNCY<XYESNO>

**20 Depression (treated with prescription medications):**  No  Yes DEPRESS<XYESNO>

**21 Chronic alcohol use:**  No  Yes ALCOHOL<XYESNO>

**22 Cigarette smoking (check only one):** CIGARETT<HFCIGP>  Current  Quit < 6 months ago  Quit ≥ 6 months ago  Never

**23 Heart transplant status (check only one):** TRANSPLT<HFTRAN>  
 Ineligible  
 No evaluation planned  
 Active evaluation  
 Currently listed  
 Post → Date of transplant: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
 TRANSPDT

**24 Hyperlipidemia:** LIPIDEMA<XYESNO>  No  Yes

**ECG** (Record results of ECG closest to time of randomization.)

**1** Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ OR  Not done **ECG (TYPE 1)**  
day month year **ECGNOTDN<XYES>**

**2** Rate: \_\_\_\_\_ bpm  
**ECGHRATE<I:3>**

**3** Rhythm (check only one): <sub>1</sub> Sinus bradycardia <sub>2</sub> Normal sinus rhythm <sub>3</sub> Sinus tachycardia  
<sub>4</sub> Atrial fibrillation/flutter <sub>99</sub> Other **ECGRHYTH<HFECGR>**

**4** Are there two or more paced beats? <sub>0</sub> No <sub>1</sub> Yes **ECGPACED<XYESNO>**

**5** QRS duration: \_\_\_\_\_ msec OR  Not done **ECGQRSND<XYES>**

**ASSESSMT(TYPE 3)**

**Heart Failure Clinical Assessment** At Randomization

Assessment	Not Done	Provide Details
<b>1</b> Heart rate (sitting or resting): <b>HRNOTDN&lt;XYES&gt;</b> <input type="checkbox"/>		<b>HRATE&lt;I:3&gt;</b> _____ bpm
<b>2</b> Blood pressure (sitting or resting): <b>BPNOTDN&lt;XYES&gt;</b> <input type="checkbox"/>		<b>BPSYS &lt;I:3&gt; BPDIA&lt;I:3&gt;</b> ____/____ mm Hg <small>systolic diastolic</small>
<b>3</b> SpO <sub>2</sub> : <b>SPNOTDN&lt;XYES&gt;</b> <input type="checkbox"/>		<b>SPO2&lt;I:3&gt;</b> _____ %
<b>4</b> Height: <b>HTNOTDN&lt;XYES&gt;</b> <input type="checkbox"/>		<b>HEIGHT &lt;F:9:3&gt; HTUNITS&lt;XHGTU&gt;</b> _____ . ____ <input type="checkbox"/> <sub>1</sub> in <input type="checkbox"/> <sub>2</sub> cm
<b>5</b> Weight: <b>WTNOTDN&lt;XYES&gt;</b> <input type="checkbox"/>		<b>WEIGHT &lt;F:9:3&gt; WTUNITS&lt;XWGTU&gt;</b> _____ . ____ <input type="checkbox"/> <sub>1</sub> lb <input type="checkbox"/> <sub>2</sub> kg
<b>6</b> Jugular venous pressure (check only one): <b>JVPNOTDN&lt;XYES&gt;</b> <input type="checkbox"/>		<b>JVP&lt;HFJVP&gt;</b> <input type="checkbox"/> <sub>1</sub> < 8 cm <input type="checkbox"/> <sub>2</sub> 8-12 cm <input type="checkbox"/> <sub>3</sub> 13-16 cm <input type="checkbox"/> <sub>4</sub> > 16 cm
<b>7</b> Rales (check only one): <b>RASNOTDN&lt;XYES&gt;</b> <input type="checkbox"/>		<b>RALES&lt;HFRALE&gt;</b> <input type="checkbox"/> <sub>0</sub> None <input type="checkbox"/> <sub>1</sub> < 1/3 <input type="checkbox"/> <sub>2</sub> 1/3-2/3 <input type="checkbox"/> <sub>3</sub> > 2/3
<b>8</b> S3 auscultation: <b>AUSNOTDN&lt;XYES&gt;</b> <input type="checkbox"/>		<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes <b>AUSCULTN&lt;XYESNO&gt;</b>
<b>9</b> Hepatomegaly: <b>HEPNOTDN&lt;XYES&gt;</b> <input type="checkbox"/>		<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes <b>HEPATOM&lt;XYESNO&gt;</b>
<b>10</b> Ascites: <b>ASCNOTDN&lt;XYES&gt;</b> <input type="checkbox"/>		<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes <b>ASCITES&lt;XYESNO&gt;</b>
<b>11</b> Peripheral edema (check only one): <b>PEDNOTDN&lt;XYES&gt;</b> <input type="checkbox"/>		<b>PEREDEMA&lt;HFEDEM&gt;</b> <input type="checkbox"/> <sub>0</sub> None <input type="checkbox"/> <sub>1</sub> Trace <input type="checkbox"/> <sub>2</sub> Moderate <input type="checkbox"/> <sub>3</sub> Severe
<b>12</b> Current NYHA heart failure classification (check only one): <b>NYNOTDN&lt;XYES&gt;</b> <input type="checkbox"/>		<input type="checkbox"/> <sub>1</sub> I <input type="checkbox"/> <sub>2</sub> II <input type="checkbox"/> <sub>3</sub> III <input type="checkbox"/> <sub>4</sub> IV <b>NYHA&lt;XKCLAS&gt;</b>
<b>13</b> Orthopnea (check only one): <b>ORTNOTDN&lt;XYES&gt;</b> <input type="checkbox"/>		<input type="checkbox"/> <sub>0</sub> None <input type="checkbox"/> <sub>1</sub> One pillow (10 cm) <b>ORTHOPNEA&lt;HFORTH&gt;</b> <input type="checkbox"/> <sub>2</sub> Two pillows (20 cm) <input type="checkbox"/> <sub>3</sub> Three or more pillows <input type="checkbox"/> <sub>4</sub> Not evaluable



Subject ID: DS \_\_\_\_\_ Subject Initials: \_\_\_\_\_  
site # subject #

Labs				
	Assessment LABASSES<HFLAB>	Not Done	Value	Units LABS(TYPE 4)PS
1=	1 Sodium:	<input checked="" type="checkbox"/> LABND<XYES>	LABVALUE<F:9:3>	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>2</sub> mEq/L LABUNIT<HFLABU>
2=	2 Potassium:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>2</sub> mEq/L
3=	3 BUN/Urea:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>3</sub> mg/dL
4=	4 Bicarbonate:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>2</sub> mEq/L
5=	5 Creatinine:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>3</sub> mg/dL <input type="checkbox"/> <sub>4</sub> μmol/L
6=	6 Magnesium:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>2</sub> mEq/L <input type="checkbox"/> <sub>3</sub> mg/dL
7=	7 Glucose:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>3</sub> mg/dL
8=	8 Total cholesterol:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>3</sub> mg/dL
9=	9 AST/SGOT:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>5</sub> U/L <input type="checkbox"/> <sub>6</sub> IU/L
10=	10 ALT/SGPT:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>5</sub> U/L <input type="checkbox"/> <sub>6</sub> IU/L
11=	11 Alkaline phosphatase:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>5</sub> U/L <input type="checkbox"/> <sub>6</sub> IU/L
12=	12 Total bilirubin:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>3</sub> mg/dL <input type="checkbox"/> <sub>4</sub> μmol/L
13=	13 Albumin:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>7</sub> g/dL <input type="checkbox"/> <sub>8</sub> g/L
14=	14 Hemoglobin (Hgb):	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>7</sub> g/dL <input type="checkbox"/> <sub>8</sub> g/L <input type="checkbox"/> <sub>1</sub> mmol/L
15=	15 WBC:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>9</sub> 10 <sup>9</sup> /L OR 10 <sup>3</sup> /mm <sup>3</sup> <input type="checkbox"/> <sub>10</sub> /mm <sup>3</sup>
16=	16 Lymphocyte %:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>11</sub> %
17=	17 Red cell distribution (RDW):	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>11</sub> %
18=	18 BNP:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>12</sub> pg/mL <input type="checkbox"/> <sub>13</sub> ng/L
19=	19 NT-pro-BNP:	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>12</sub> pg/mL <input type="checkbox"/> <sub>13</sub> ng/L

**Subject Status**

Was assessment performed? **EVALUTE<XYESNO>** **SUBJSTAT<HFSUBJ>** **STATUS(TYPE 3)**  
 No → If No: Reason:  Subject discharged  Subject withdrew  Subject died  Other (specify): **STATUSSP**  
 Yes → If Yes: Assessment date and time: **EVALDT<DATE>** or **EVALTM<DATETIME>** **<V:50>**

**Clinical Assessment** from same daily assessment time

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	<input type="checkbox"/>	_____ bpm <b>ASSESSMT(TYPE 3)</b>
2 Blood pressure (sitting or resting):	<input type="checkbox"/>	_____ / _____ mm Hg <b>SEE ANNOTATION P.4</b>
3 SpO <sub>2</sub> :	<input type="checkbox"/>	_____ % <b>NOTE: Questions to suppress</b>
4 Weight:	<input type="checkbox"/>	_____ . _____ <input type="checkbox"/> lb <input type="checkbox"/> kg
5 Jugular venous pressure (check only one):	<input type="checkbox"/>	<input type="checkbox"/> < 8 cm <input type="checkbox"/> 8–12 cm <input type="checkbox"/> 13–16 cm <input type="checkbox"/> > 16 cm
6 Peripheral edema (check only one):	<input type="checkbox"/>	<input type="checkbox"/> None <input type="checkbox"/> Trace <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
7 Orthopnea (check only one):	<input type="checkbox"/>	<input type="checkbox"/> None <input type="checkbox"/> One pillow (10 cm) <input type="checkbox"/> Two pillows (20 cm) <input type="checkbox"/> Three or more pillows <input type="checkbox"/> Not evaluable

**Labs—Chemistry** from same daily assessment time

Assessment	Not Done	Value	Units
1 Sodium	<input type="checkbox"/>	_____	<input type="checkbox"/> mmol/L <input type="checkbox"/> mEq/L <b>LABS(TYPE 4)PS</b>
2 Potassium	<input type="checkbox"/>	_____	<input type="checkbox"/> mmol/L <input type="checkbox"/> mEq/L <b>SEE ANNOTATION P.5</b>
3 BUN/Urea	<input type="checkbox"/>	_____	<input type="checkbox"/> mmol/L <input type="checkbox"/> mg/dL <b>NOTE: 1-5 ONLY</b>
4 Bicarbonate	<input type="checkbox"/>	_____	<input type="checkbox"/> mmol/L <input type="checkbox"/> mEq/L
5 Creatinine	<input type="checkbox"/>	_____	<input type="checkbox"/> mg/dL <input type="checkbox"/> μmol/L <b>FLUID(TYPE 3)</b>

**24 Hour Fluid Intake/Output** from same daily assessment time

1 Total input: **TOTALIN <I:4>** \_\_\_\_\_ mL      2 Total output: **TOTALOUT <I:4>** \_\_\_\_\_ mL **WORSENIG(TYPE 3)**

**Treatment of Worsening or Persistent Heart Failure**

Did the subject meet criteria for worsening or persistent heart failure in the last 24 hours? **WORSENHF<XYESNO>**  
 No  Yes → If Yes: Specify treatment (check all that apply): **ALL <XYES>**  
**MORELOOP**  Additional open label loop diuretic doses  Addition of thiazide or metolazone **THIAZIDE**  
**VASOACTV**  IV vasoactive agent for heart failure treatment  Ultrafiltration **ULTRAFIL**  
**CIRSUPPT**  Mechanical circulatory support  Mechanical ventilation support for heart failure **MECHVENT**

SEE ANNOTATION PAGE 6

Subject ID: DS \_\_\_\_\_ - \_\_\_\_\_  
site # subject #

Subject Initials: \_\_\_\_\_

**Subject Status**

Was assessment performed?

STATUS(TYPE 3)

- No → If No: Reason: <sub>1</sub> Subject discharged <sub>2</sub> Subject withdrew <sub>3</sub> Subject died <sub>99</sub> Other (specify): \_\_\_\_\_
- Yes → If Yes: Assessment date and time: \_\_\_\_/\_\_\_\_/\_\_\_\_ :\_\_\_\_:\_\_\_\_  
day month year 00:00 to 23:59

**Clinical Assessment** from same daily assessment time

Assessment	Not Done	Provide Details
<b>1 Heart rate</b> (sitting or resting):	<input type="checkbox"/>	_____ bpm ASSESSMT(TYPE 3)
<b>2 Blood pressure</b> (sitting or resting):	<input type="checkbox"/>	_____ / _____ mm Hg <small>systolic diastolic</small>
<b>3 SpO<sub>2</sub>:</b>	<input type="checkbox"/>	_____ %
<b>4 Weight:</b>	<input type="checkbox"/>	_____ . _____ <input type="checkbox"/> <sub>1</sub> lb <input type="checkbox"/> <sub>2</sub> kg
<b>5 Jugular venous pressure</b> (check only one):	<input type="checkbox"/>	<input type="checkbox"/> <sub>1</sub> < 8 cm <input type="checkbox"/> <sub>2</sub> 8–12 cm <input type="checkbox"/> <sub>3</sub> 13–16 cm <input type="checkbox"/> <sub>4</sub> > 16 cm
<b>6 Peripheral edema</b> (check only one):	<input type="checkbox"/>	<input type="checkbox"/> <sub>0</sub> None <input type="checkbox"/> <sub>1</sub> Trace <input type="checkbox"/> <sub>2</sub> Moderate <input type="checkbox"/> <sub>3</sub> Severe
<b>7 Orthopnea</b> (check only one):	<input type="checkbox"/>	<input type="checkbox"/> <sub>0</sub> None <input type="checkbox"/> <sub>3</sub> Three or more pillows <input type="checkbox"/> <sub>1</sub> One pillow (10 cm) <input type="checkbox"/> <sub>4</sub> Not evaluable <input type="checkbox"/> <sub>2</sub> Two pillows (20 cm)

**Labs—Chemistry** from same daily assessment time

Assessment	Not Done	Value	Units
<b>1 Sodium</b>	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>2</sub> mEq/L
<b>2 Potassium</b>	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>2</sub> mEq/L
<b>3 BUN/Urea</b>	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>3</sub> mg/dL
<b>4 Bicarbonate</b>	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>2</sub> mEq/L
<b>5 Creatinine</b>	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>3</sub> mg/dL <input type="checkbox"/> <sub>4</sub> μmol/L

**24 Hour Fluid Intake/Output** from same daily assessment time

**1** Total input: \_\_\_\_\_ mL **2** Total output: \_\_\_\_\_ mL FLUID(TYPE 3)

**Treatment of Worsening or Persistent Heart Failure**

Did the subject meet criteria for worsening or persistent heart failure in the last 24 hours?

WORSENI(TYPE 3)

- No  Yes → If Yes: Specify treatment (check all that apply):
- Additional open label loop diuretic doses
  - Addition of thiazide or metolazone
  - IV vasoactive agent for heart failure treatment
  - Ultrafiltration
  - Mechanical circulatory support
  - Mechanical ventilation support for heart failure

SEE ANNOTATION PAGE 6

Subject ID: DS \_\_\_\_\_ - \_\_\_\_\_  
site # subject #

Subject Initials: \_\_\_\_\_

**Subject Status**

Was assessment performed?

STATUS(TYPE 3)

- No → If No: Reason: <sub>1</sub> Subject discharged <sub>2</sub> Subject withdrew <sub>3</sub> Subject died <sub>99</sub> Other (specify): \_\_\_\_\_
- Yes → If Yes: Assessment date and time: \_\_\_\_/\_\_\_\_/\_\_\_\_ :\_\_\_\_:\_\_\_\_  
day month year 00:00 to 23:59

**Clinical Assessment** from same daily assessment time

Assessment	Not Done	Provide Details
<b>1</b> Heart rate (sitting or resting):	<input type="checkbox"/>	_____ bpm ASSESSMT(TYPE 3)
<b>2</b> Blood pressure (sitting or resting):	<input type="checkbox"/>	_____ / _____ mm Hg systolic diastolic
<b>3</b> SpO <sub>2</sub> :	<input type="checkbox"/>	_____ %
<b>4</b> Weight:	<input type="checkbox"/>	_____ . _____ <input type="checkbox"/> <sub>1</sub> lb <input type="checkbox"/> <sub>2</sub> kg
<b>5</b> Jugular venous pressure (check only one):	<input type="checkbox"/>	<input type="checkbox"/> <sub>1</sub> < 8 cm <input type="checkbox"/> <sub>2</sub> 8–12 cm <input type="checkbox"/> <sub>3</sub> 13–16 cm <input type="checkbox"/> <sub>4</sub> > 16 cm
<b>6</b> Peripheral edema (check only one):	<input type="checkbox"/>	<input type="checkbox"/> <sub>0</sub> None <input type="checkbox"/> <sub>1</sub> Trace <input type="checkbox"/> <sub>2</sub> Moderate <input type="checkbox"/> <sub>3</sub> Severe
<b>7</b> Orthopnea (check only one):	<input type="checkbox"/>	<input type="checkbox"/> <sub>0</sub> None <input type="checkbox"/> <sub>3</sub> Three or more pillows <input type="checkbox"/> <sub>1</sub> One pillow (10 cm) <input type="checkbox"/> <sub>4</sub> Not evaluable <input type="checkbox"/> <sub>2</sub> Two pillows (20 cm)

**Labs—Chemistry** from same daily assessment time

Assessment	Not Done	Value	Units
<b>1</b> Sodium	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>2</sub> mEq/L LABS(TYPE 4)PS
<b>2</b> Potassium	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>2</sub> mEq/L
<b>3</b> BUN/Urea	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>3</sub> mg/dL
<b>4</b> Bicarbonate	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>2</sub> mEq/L
<b>5</b> Creatinine	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>3</sub> mg/dL <input type="checkbox"/> <sub>4</sub> μmol/L

**24 Hour Fluid Intake/Output** from same daily assessment time

**1** Total input: \_\_\_\_\_ mL **2** Total output: \_\_\_\_\_ mL FLUID(TYPE 3)

**Treatment of Worsening or Persistent Heart Failure**

Did the subject meet criteria for worsening or persistent heart failure in the last 24 hours?

WORSENI(TYPE 3)

- No  Yes → If Yes: Specify treatment (check all that apply):
- Additional open label loop diuretic doses
  - Addition of thiazide or metolazone
  - IV vasoactive agent for heart failure treatment
  - Ultrafiltration
  - Mechanical circulatory support
  - Mechanical ventilation support for heart failure



**Subject Status**

Was assessment performed?

STATUS(TYPE 3)

- No → If No: Reason: <sub>1</sub> Subject discharged <sub>2</sub> Subject withdrew <sub>3</sub> Subject died <sub>99</sub> Other (specify): \_\_\_\_\_
- <sub>1</sub> Yes → If Yes: Assessment date and time: \_\_\_\_/\_\_\_\_/\_\_\_\_ :\_\_\_\_:\_\_\_\_  
day month year 00:00 to 23:59

**Clinical Assessment** from same daily assessment time

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	<input type="checkbox"/>	_____ bpm ASSESSMT(TYPE 3)
2 Blood pressure (sitting or resting):	<input type="checkbox"/>	_____ / _____ mm Hg systolic diastolic
3 SpO <sub>2</sub> :	<input type="checkbox"/>	_____ %
4 Weight:	<input type="checkbox"/>	_____ . _____ <input type="checkbox"/> <sub>1</sub> lb <input type="checkbox"/> <sub>2</sub> kg
5 Jugular venous pressure (check only one):	<input type="checkbox"/>	<input type="checkbox"/> <sub>1</sub> < 8 cm <input type="checkbox"/> <sub>2</sub> 8–12 cm <input type="checkbox"/> <sub>3</sub> 13–16 cm <input type="checkbox"/> <sub>4</sub> > 16 cm
6 Peripheral edema (check only one):	<input type="checkbox"/>	<input type="checkbox"/> <sub>0</sub> None <input type="checkbox"/> <sub>1</sub> Trace <input type="checkbox"/> <sub>2</sub> Moderate <input type="checkbox"/> <sub>3</sub> Severe
7 Orthopnea (check only one):	<input type="checkbox"/>	<input type="checkbox"/> <sub>0</sub> None <input type="checkbox"/> <sub>3</sub> Three or more pillows <input type="checkbox"/> <sub>1</sub> One pillow (10 cm) <input type="checkbox"/> <sub>4</sub> Not evaluable <input type="checkbox"/> <sub>2</sub> Two pillows (20 cm)

**Labs—Chemistry** from same daily assessment time

Assessment	Not Done	Value	Units
1 Sodium	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>2</sub> mEq/L LABS(TYPE 4)PS
2 Potassium	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>2</sub> mEq/L
3 BUN/Urea	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>3</sub> mg/dL
4 Bicarbonate	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>1</sub> mmol/L <input type="checkbox"/> <sub>2</sub> mEq/L
5 Creatinine	<input type="checkbox"/>	_____	<input type="checkbox"/> <sub>3</sub> mg/dL <input type="checkbox"/> <sub>4</sub> μmol/L

**24 Hour Fluid Intake/Output** from same daily assessment time

1 Total input: \_\_\_\_\_ mL      2 Total output: \_\_\_\_\_ mL      FLUID(TYPE 3)

**Treatment of Worsening or Persistent Heart Failure**

Did the subject meet criteria for worsening or persistent heart failure in the last 24 hours?

WORSENI(TYPE 3)

- <sub>0</sub> No <sub>1</sub> Yes → If Yes: Specify treatment (check all that apply):
- Additional open label loop diuretic doses
  - Addition of thiazide or metolazone
  - IV vasoactive agent for heart failure treatment
  - Ultrafiltration
  - Mechanical circulatory support
  - Mechanical ventilation support for heart failure

Subject ID: DS \_\_\_\_\_ - \_\_\_\_\_ Subject Initials: \_\_\_\_\_  
site # subject #

**Subject Status**

Was assessment performed? **SEE ANNOTATION PAGE 6** STATUS(TYPE 3)  
 No → If No: Reason:  Subject discharged  Subject withdrew  Subject died  Other (specify): \_\_\_\_\_  
 Yes → If Yes: Assessment date and time: \_\_\_\_/\_\_\_\_/\_\_\_\_ :\_\_\_\_  
day month year 00:00 to 23:59

**Clinical Assessment**

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	<input type="checkbox"/>	_____ bpm ASSESSMT(TYPE 3) <b>SEE ANNOTATION PAGE 6</b>
2 Blood pressure (sitting or resting):	<input type="checkbox"/>	_____ / _____ mm Hg <small>systolic diastolic</small>
3 SpO <sub>2</sub> :	<input type="checkbox"/>	_____ %
4 Weight:	<input type="checkbox"/>	_____ . _____ <input type="checkbox"/> lb <input type="checkbox"/> kg
5 Jugular venous pressure (check only one):	<input type="checkbox"/>	<input type="checkbox"/> < 8 cm <input type="checkbox"/> 8-12 cm <input type="checkbox"/> 13-16 cm <input type="checkbox"/> > 16 cm
6 Peripheral edema (check only one):	<input type="checkbox"/>	<input type="checkbox"/> None <input type="checkbox"/> Trace <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
7 Orthopnea (check only one):	<input type="checkbox"/>	<input type="checkbox"/> None <input type="checkbox"/> Three or more pillows <input type="checkbox"/> One pillow (10 cm) <input type="checkbox"/> Not evaluable <input type="checkbox"/> Two pillows (20 cm)

**Labs—Chemistry**

Assessment	Not Done	Value	Units
1 Sodium	<input type="checkbox"/>	_____	<input type="checkbox"/> mmol/L <input type="checkbox"/> mEq/L <b>SEE ANNOTATION PAGE 6</b>
2 Potassium	<input type="checkbox"/>	_____	<input type="checkbox"/> mmol/L <input type="checkbox"/> mEq/L
3 BUN/Urea	<input type="checkbox"/>	_____	<input type="checkbox"/> mmol/L <input type="checkbox"/> mg/dL
4 Bicarbonate	<input type="checkbox"/>	_____	<input type="checkbox"/> mmol/L <input type="checkbox"/> mEq/L
5 Creatinine	<input type="checkbox"/>	_____	<input type="checkbox"/> mg/dL <input type="checkbox"/> μmol/L

**Study Drug Administration**

**1** Was study drug administered? **STDRUG<XYESNO>** **SDADMIN (TYPE 1)**

- No → If No: Reason (check only one): <sub>1</sub> Subject refused  
**SDREASON<HFDRUG>** <sub>2</sub> Physician decision  
<sub>3</sub> Death → Complete Death form **SDREASP <V:50>**  
<sub>98</sub> Other (specify): \_\_\_\_\_

Yes → If Yes: Complete questions 2-4 below.

**2** Study drug start date and time: **SDSTRTDT<DATE>** **SDSTRTTM<DATETIME>**  
day / month / year 00:00 to 23:59

**3** Was study drug strategy changed prior to 72 hours?

No, same dose infusion continued for 72 hours **SDSTRATG<XYESNO>**

Yes → If Yes: Reason changed (check only one):

- <sub>1</sub> Increased dose by 50% at 48 hours **SDCHANGE<DSCHGE>**  
<sub>2</sub> Switched to oral furosemide in preparation for discharge  
<sub>3</sub> Due to over-diuresis requiring intervention  
<sub>4</sub> Subject withdrew consent  
<sub>5</sub> Death → Complete Death form **SDDISCSP<V:50>**  
<sub>6</sub> Discontinued for other reason (specify): \_\_\_\_\_

**4** Study drug stop date and time: **SDSTOPDT<DATE>** **SDSTOPTM<DATETIME>**  
day / month / year 00:00 to 23:59

Subject ID: DS \_\_\_\_\_ - \_\_\_\_\_ Subject Initials: \_\_\_\_\_  
site # subject #

Subject Self Report of Symptoms				
	Date and Time	Not Done	SUBJSYMP (TYPE 4)PS	
			Dyspnea VAS	Global VAS
1=	<b>Baseline</b> <small>SELFREPT&lt;DSSELF&gt;      SELFDTM&lt;DATETIME&gt;</small> SELFDT<DATE>      SELFND<XYES> <small>day / month / year      00:00 to 23:59</small>	<input type="checkbox"/>	VASDYSPN<I:3> _____ mm	VASGLOBL<I:3> _____ mm
2=	<b>6 Hour</b> <small>day / month / year      00:00 to 23:59</small>	<input type="checkbox"/>	_____ mm	_____ mm
3=	<b>12 Hour</b> <small>day / month / year      00:00 to 23:59</small>	<input type="checkbox"/>	_____ mm	_____ mm
4=	<b>24 Hour</b> <small>day / month / year      00:00 to 23:59</small>	<input type="checkbox"/>	_____ mm	_____ mm
5=	<b>48 Hour</b> <small>day / month / year      00:00 to 23:59</small>	<input type="checkbox"/>	_____ mm	_____ mm
6=	<b>72 Hour</b> <small>day / month / year      00:00 to 23:59</small>	<input type="checkbox"/>	_____ mm	_____ mm
7=	<b>96 Hour</b> <small>day / month / year      00:00 to 23:59</small>	<input type="checkbox"/>	_____ mm	_____ mm



Core Lab Assessments				
Scheduled	Test	Date of Test	Not Done	Reason Not Done <i>(check only one)</i>
1= Baseline	Biomarkers— blood	____/____/____ <i>day month</i> COREND<XYES> CORED <HFCORE> Add to list 5=DISCHARGE		<div style="background-color: yellow; padding: 2px;">COREASND&lt;HFCORE&gt;</div> <input type="checkbox"/> 1 Died → Fill out Death form <input type="checkbox"/> 2 Too sick to perform <input type="checkbox"/> 3 Unwilling to perform test but subjectively able <input type="checkbox"/> 4 Due to oversight or technical problem <input type="checkbox"/> 99 Unknown
2= 72 Hours	Biomarkers— blood	____/____/____ <i>day month year</i>	<input type="checkbox"/> →	<input type="checkbox"/> 1 Died → Fill out Death form <input type="checkbox"/> 2 Too sick to perform <input type="checkbox"/> 3 Unwilling to perform test but subjectively able <input type="checkbox"/> 4 Due to oversight or technical problem <input type="checkbox"/> 99 Unknown
3= Day 7/Discharge	Biomarkers— blood	____/____/____ <i>day month year</i>	<input type="checkbox"/> →	<input type="checkbox"/> 1 Died → Fill out Death form <input type="checkbox"/> 2 Too sick to perform <input type="checkbox"/> 3 Unwilling to perform test but subjectively able <input type="checkbox"/> 4 Due to oversight or technical problem <input type="checkbox"/> 99 Unknown

4= DAY 60 (HIDE ON P.13)

Subject ID: DS \_\_\_\_\_ - \_\_\_\_\_ Subject Initials: \_\_\_\_\_  
site # subject #

Medications		
	At Randomization MEDRAND<XYESNO>	At Discharge OR <input type="checkbox"/> NA DISCHND<XYES> MEDDSCG<XYESNO>
1= <b>1</b> ACE inhibitor	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
2= <b>2</b> Angiotensin receptor blocker	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
3= <b>3</b> Beta blocker	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
4= <b>4</b> Aldosterone antagonist	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
5= <b>5</b> Hydralazine	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
6= <b>6</b> Nitrates (long-acting)	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
7= <b>7</b> Aspirin (if taken daily)	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
8= <b>8</b> Warfarin	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
9= <b>9</b> Thienopyridine (ticlopidine, clopidogrel)	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
10= <b>10</b> Alpha blocker	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
11= <b>11</b> Digoxin	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
12= <b>12</b> Amiodarone	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
13= <b>13</b> Other antiarrhythmic	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
14= <b>14</b> Statin	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
15= <b>15</b> Lipid lowering agent (other than statin)	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
16= <b>16</b> Calcium channel blocker	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
17= <b>17</b> Insulin	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
18= <b>18</b> Oral diabetic agent	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
19= <b>19</b> Anti-depressant	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes

Diuretics timeframe

TIMEPT<DSTIME>

1=At Randomization

2=Randomization to 24 Hrs

3=24 to 48 Hrs

4=48 to 72 Hrs

5=72 to 96 Hrs

6=Discharge

Set up database so that each time frame is represented by a pagerep (ex: At randomization= pagerep .1, Randomization to 24Hrs=-2

# Index Hospitalization/Medications

NODATA<YES>

Subject Initials:

Subject ID: DS

Subject #

NADIURET<XYES>

## Diuretic

Medication	At Randomization (prior 24 hours)	Randomization to 24 Hrs	24 to 48 Hrs OR NA	48 to 72 Hrs OR NA
<b>1 Furosemide</b> <i>(if open label)</i>  <b>DIUDAILY&lt;HFDIUR&gt;</b> See annotation p.1	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg
<b>2 Torsemide</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg
<b>3 Bumetanide</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg
<b>4 Metolazone</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg
<b>5 HCTZ</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg
<b>6 Chlorothiazide (Diuril)</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg

# Index Hospitalization/Medications

Subject ID: DS \_\_\_\_\_ site # \_\_\_\_\_ subject # \_\_\_\_\_ Subject Initials: \_\_\_\_\_

## DAILYDIU (TYPE 4)PS

See annotation p.15



Diuretic (continued)	72 to 96 Hrs OR NA	Discharge OR NA (prescribed dose)
<b>1 Furosemide</b>  <b>DIUDAILY&lt;HFDIUR&gt;</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg
<b>2 Torsemide</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg
<b>3 Bumetanide</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg
<b>4 Metolazone</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg
<b>5 HCTZ</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg
<b>6 Chlorothiazide (Diuril)</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg	<input type="checkbox"/> No <input type="checkbox"/> Yes → Route: Daily dose: <input type="checkbox"/> IV bolus → _____ mg <input type="checkbox"/> IV cont → _____ mg <input type="checkbox"/> PO → _____ mg



**Intravenous Vasoactive Infusions**

	VASODRUG<HFVASO>	VASOANS<XYESNO>	Start Date and Time VASTARDT<DATE> day / month / year VASTARTM<DATETIME> 00:00 to 23:59	Permanent Stop Date and Time OR Check if Ongoing at Discharge VASTOPDT<DATE> day / month / year VASTOPTM<DATETIME> 00:00 to 23:59 VASOCONT<XYES> <input type="checkbox"/> Ongoing at Discharge
1=	<b>1</b> Dobutamine	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes →	day / month / year 00:00 to 23:59	day / month / year 00:00 to 23:59 <input type="checkbox"/> <sub>1</sub> Ongoing at Discharge
2=	<b>2</b> Dopamine	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes →	day / month / year 00:00 to 23:59	day / month / year 00:00 to 23:59 <input type="checkbox"/> <sub>1</sub> Ongoing at Discharge
3=	<b>3</b> Milrinone	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes →	day / month / year 00:00 to 23:59	day / month / year 00:00 to 23:59 <input type="checkbox"/> <sub>1</sub> Ongoing at Discharge
4=	<b>4</b> Nitroglycerin	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes →	day / month / year 00:00 to 23:59	day / month / year 00:00 to 23:59 <input type="checkbox"/> <sub>1</sub> Ongoing at Discharge
5=	<b>5</b> Nitroprusside	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes →	day / month / year 00:00 to 23:59	day / month / year 00:00 to 23:59 <input type="checkbox"/> <sub>1</sub> Ongoing at Discharge
6=	<b>6</b> Nesiritide	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes →	day / month / year 00:00 to 23:59	day / month / year 00:00 to 23:59 <input type="checkbox"/> <sub>1</sub> Ongoing at Discharge
7=	<b>7</b> Other inotrope/ vasopressor	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes →	day / month / year 00:00 to 23:59	day / month / year 00:00 to 23:59 <input type="checkbox"/> <sub>1</sub> Ongoing at Discharge

Subject ID: DS \_\_\_\_\_ - \_\_\_\_\_ Subject Initials: \_\_\_\_\_  
site # subject #

**Hospital Discharge**

**1** Was the subject discharged alive? **DCALIVE <XYESNO>** **DISCHARG (TYPE 1)**

No → If No: Complete Death form  
 Yes → If Yes: Date of discharge: \_\_\_/\_\_\_/\_\_\_  
day month year

Discharge to (check only one):  
 1 Home **DCHGLOC<HFDCHG>**  
 2 Assisted living  
 3 Skilled nursing facility  
 4 Acute care hospital  
 5 Rehabilitation center  
 98 Other

**PROCEDUR (TYPE 4)**

**2** Major procedures/tests/treatments (check No or Yes for procedures/tests/treatments performed during this hospitalization):

Left heart catheterization: **PROLCATH<XYESNO>**  No  Yes  
 Right heart catheterization: **PRORCATH<XYESNO>**  No  Yes  
 PCI: **PROPCI<XYESNO>**  No  Yes  
 Coronary artery bypass graft (CABG): **PROCABG<XYESNO>**  No  Yes  
 Pacemaker without ICD: **PRONOICD<XYESNO>**  No  Yes → If Yes:  
 Check only one:  1 Single  2 Dual  3 Biventricular **PROCPACE<HFCHBR>**  
 ICD: **PROICD<XYESNO>**  No  Yes → If Yes:  
 Check only one:  1 Single  2 Dual  3 Biventricular **PROCEICD<HFCHBR>**  
 Intra-aortic balloon pump placement: **PROIABP<XYESNO>**  No  Yes  
 Ultrafiltration: **PROULTRA<XYESNO>**  No  Yes  
 Dialysis: **PRODIAL<XYESNO>**  No  Yes  
 Atrial arrhythmia ablation: **PROBLAT<XYESNO>**  No  Yes  
 CPR: **PROCPR<XYESNO>**  No  Yes  
 Cardioversion: **PROCARDI<XYESNO>**  No  Yes  
 LVAD placement: **PRLVAD<XYESNO>**  No  Yes → If Yes:  
 Date: \_\_\_/\_\_\_/\_\_\_  
day month year **PRLVADDT**  
 Heart transplant: **PROHTRAN<XYESNO>**  No  Yes → If Yes:  
 Date: \_\_\_/\_\_\_/\_\_\_  
day month year **PRHTRDDT**

**Record all SAEs on Serious Adverse Event form.**

Subject ID: DS \_\_\_\_\_ site # \_\_\_\_\_ subject # \_\_\_\_\_ Subject Initials: \_\_\_\_\_

Check if early termination visit See annotation p.6

STATUS(TYPE 3)

Subject Status

Was assessment performed?

No → If No: Reason:  Subject withdrew  Subject died  98 Other (specify): \_\_\_\_\_

Yes → If Yes: Assessment date and time: \_\_\_\_/\_\_\_\_/\_\_\_\_ : \_\_\_\_:\_\_\_\_

ASSESSMT(TYPE 3)

Clinical Assessment

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	<input type="checkbox"/>	SEE ANNOTATION PAGE 4 bpm
2 Blood pressure (sitting or resting):	<input type="checkbox"/>	SUPPRESS ____/____ mm Hg systolic diastolic
3 SpO <sub>2</sub> :	<input type="checkbox"/>	4.HEIGHT 7.RALES ____ %
4 Weight:	<input type="checkbox"/>	8.S3 ____ . ____ <input type="checkbox"/> lb <input type="checkbox"/> kg
5 Jugular venous pressure (check only one):	<input type="checkbox"/>	9.HEPATOMEGALY 10.ASCITES <input type="checkbox"/> < 8 cm <input type="checkbox"/> 8-12 cm <input type="checkbox"/> 13-16 cm <input type="checkbox"/> > 16 cm
6 Peripheral edema (check only one):	<input type="checkbox"/>	<input type="checkbox"/> None <input type="checkbox"/> Trace <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
7 Current NYHA heart failure classification (check only one):	<input type="checkbox"/>	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV
8 Orthopnea (check only one):	<input type="checkbox"/>	<input type="checkbox"/> None <input type="checkbox"/> One pillow (10 cm) <input type="checkbox"/> Two pillows (20 cm) <input type="checkbox"/> Three or more pillows <input type="checkbox"/> Not evaluable

LABS(TYPE 4)PS

Labs—Chemistry

Assessment	Not Done	Value	Units
1 Sodium	<input type="checkbox"/>	SEE ANNOTATION PAGE 6	<input type="checkbox"/> mmol/L <input type="checkbox"/> mEq/L
2 Potassium	<input type="checkbox"/>	_____	<input type="checkbox"/> mmol/L <input type="checkbox"/> mEq/L
3 BUN/Urea	<input type="checkbox"/>	_____	<input type="checkbox"/> mmol/L <input type="checkbox"/> mg/dL
4 Bicarbonate	<input type="checkbox"/>	_____	<input type="checkbox"/> mmol/L <input type="checkbox"/> mEq/L
5 Creatinine	<input type="checkbox"/>	_____	<input type="checkbox"/> mg/dL <input type="checkbox"/> μmol/L

DOSECORE(TYPE 4)PS

Core Lab Assessments

Test	Date of Test	Not Done	Reason Not Done (check only one)
SCHDASSE<DSSCHD> (HIDE 1-3) 4=DAY60 Biomarkers—blood	____/____/____ day month year	<input type="checkbox"/> →	<input type="checkbox"/> 1 Died → Fill out Death form <input type="checkbox"/> 2 Too sick to perform <input type="checkbox"/> 3 Unwilling to perform test but subjectively able <input type="checkbox"/> 4 Due to oversight or technical problem <input type="checkbox"/> 99 Unknown

Subject ID: DS \_\_\_\_\_ site # \_\_\_\_\_ subject # \_\_\_\_\_ Subject Initials: \_\_\_\_\_

MEDS(TYPE 4)PS

**Medications**

1=	1 ACE inhibitor HF MEDS<HFHFMD>	MEDSANS	<input type="checkbox"/> No	<input type="checkbox"/> Yes
2=	2 Angiotensin receptor blocker	<XYESNO>	<input type="checkbox"/> No	<input type="checkbox"/> Yes
3=	3 Beta blocker	SUPPRESS:	<input type="checkbox"/> No	<input type="checkbox"/> Yes
4=	4 Aldosterone antagonist	MEDRAND DISCHND	<input type="checkbox"/> No	<input type="checkbox"/> Yes
5=	5 Hydralazine	MEDDSCG MEDSCONT	<input type="checkbox"/> No	<input type="checkbox"/> Yes
6=	6 Nitrates (long-acting)		<input type="checkbox"/> No	<input type="checkbox"/> Yes
7=	7 Aspirin (if taken daily)		<input type="checkbox"/> No	<input type="checkbox"/> Yes
8=	8 Warfarin		<input type="checkbox"/> No	<input type="checkbox"/> Yes
9=	9 Thienopyridine (ticlopidine, clopidogrel)		<input type="checkbox"/> No	<input type="checkbox"/> Yes
10=	10 Alpha blocker		<input type="checkbox"/> No	<input type="checkbox"/> Yes
11=	11 Digoxin		<input type="checkbox"/> No	<input type="checkbox"/> Yes
12=	12 Amiodarone		<input type="checkbox"/> No	<input type="checkbox"/> Yes
13=	13 Other antiarrhythmic		<input type="checkbox"/> No	<input type="checkbox"/> Yes
14=	14 Statin		<input type="checkbox"/> No	<input type="checkbox"/> Yes
15=	15 Lipid lowering agent (other than statin)		<input type="checkbox"/> No	<input type="checkbox"/> Yes
16=	16 Calcium channel blocker		<input type="checkbox"/> No	<input type="checkbox"/> Yes
17=	17 Insulin		<input type="checkbox"/> No	<input type="checkbox"/> Yes
18=	18 Oral diabetic agent		<input type="checkbox"/> No	<input type="checkbox"/> Yes
19=	19 Antidepressant		<input type="checkbox"/> No	<input type="checkbox"/> Yes

**Oral Diuretics**

Medication	SEE ANNOTATION P.1	Average Total Daily Dose	Units
1 Furoseamide	<input type="checkbox"/> No <input type="checkbox"/> Yes →	DIURETIC(TYPE 4)PS	mg
2 Torsemide	<input type="checkbox"/> No <input type="checkbox"/> Yes →	_____	mg
3 Bumetanide	<input type="checkbox"/> No <input type="checkbox"/> Yes →	_____	mg
4 Metolazone	<input type="checkbox"/> No <input type="checkbox"/> Yes, daily <input type="checkbox"/> Yes, PRN →	_____	mg
5 HCTZ	<input type="checkbox"/> No <input type="checkbox"/> Yes, daily <input type="checkbox"/> Yes, PRN →	_____	mg



Subject ID: DS \_\_\_\_\_ - \_\_\_\_\_ Subject Initials: \_\_\_\_\_  
site # subject #

**Study Termination/Completion**

**1** Did the subject complete the study (including follow-up protocol)? **TERMDT** **TERM (TYPE 1)**

No → If No: Date of termination/last contact: \_\_\_\_/\_\_\_\_/\_\_\_\_  
day month year

Reason for termination (check only one):

**COMPLETE <XYESNO>**

Subject lost to follow-up

**TERMREAS<HFTERM>**

Adverse event

Subject withdrew consent

Subject died → Complete Death form (termination date above should be date of death)

98 Other (specify): \_\_\_\_\_ **TERMSP <V:100>**

Yes

**2** Was study drug unblinded? **UNBLIND<XYESNO>**

No

Yes → If Yes: Date unblinded: \_\_\_\_/\_\_\_\_/\_\_\_\_ **UNBLNDDT**

**UNBLDSP <V:100>**

Reason unblinded: \_\_\_\_\_

**Endpoint/Safety Review**

**1** How many serious adverse events did subject have? **SAENUMB<I:3>** **SAFETY (TYPE 1)**

\_\_\_\_\_ → Record all on Serious Adverse Events form

**2** How many re-hospitalizations (excluding index hospitalization) did subject have? **REHOSNUM<I:3>**

\_\_\_\_\_ → Record all re-hospitalization ≥ 24 hours on Re-Hospitalization form

**3** How many unscheduled clinic/emergency department visits did subject have? **ERNUMB<I:3>**

\_\_\_\_\_ → Record all on Unscheduled Clinic/Emergency Department Visits form

**Investigator's Signature**

I have reviewed and found all the case report form data pertaining to this subject to be complete and accurate. **SIGNATUR (TYPE 4)**

Principal Investigator: \_\_\_\_\_ **INVSIG <XYES>**  
Signature of Investigator

Date: \_\_\_\_\_ **INVSIGDT**  
day month year

THIS IS A REPEATING PAGE

Subject ID: DS site # - subject # Subject Initials: \_\_\_\_\_

Hospitalization ≥ 24 Hours (Non-protocol)

1 Admission date: REHOSPDT REHOSPTL (TYPE 4)

2 Discharge date: REDCHGDT OR Remains hospitalized INREHOSP<XYES>

3 Primary reason for hospitalization (check only one): PRIMCAUS<HFPRIM>

- 1 Heart failure 2 Angina 3 MI 4 Atrial arrhythmia 5 Ventricular arrhythmia 6 Chest pain 7 Sudden death with resuscitation 8 Cerebral vascular accident (CVA)/stroke 9 Peripheral vascular disease 10 Syncope 11 Hypotension 28 Elective cardiac procedure 29 Other cardiovascular 31 Renal failure 32 Worsening renal function 33 Hyperkalemia 34 Infection 48 Elective non-cardiac procedure 49 Other non-cardiovascular

4 Contributing causes (check all that apply): ALL <XYES>

- Heart failure REHTFAIL REANGINA MI REMI Atrial arrhythmia REATRIAL REARRHY Chest pain RECTPAIN Sudden death with resuscitation RESUSCIT RECVA Cerebral vascular accident (CVA)/stroke Peripheral vascular disease REPVD Syncope RESYNCO Hypotension REHYPOTN Elective cardiac procedure RECARDPR Other cardiovascular REOTCARD Renal failure RERENAL Worsening renal function REWORSE Hyperkalemia REKALEMA Infection REINFECT Elective non-cardiac procedure BENON REOTNON

5 Major procedures/tests/treatments (check No or Yes for procedures/tests/treatments performed during this hospitalization): PROCEDUR (TYPE 4)

- Left heart catheterization: SEE ANNOTATION P.18 0 No 1 Yes
Right heart catheterization: 0 No 1 Yes
PCI: 0 No 1 Yes
Coronary artery bypass graft (CABG): 0 No 1 Yes
Pacemaker without ICD: 0 No 1 Yes -> If Yes:
Check only one: 1 Single 2 Dual 3 Biventricular
ICD: 0 No 1 Yes -> If Yes:
Check only one: 1 Single 2 Dual 3 Biventricular
Intra-aortic balloon pump placement: 0 No 1 Yes
Ultrafiltration: 0 No 1 Yes
Dialysis: 0 No 1 Yes
Atrial arrhythmia ablation: 0 No 1 Yes
CPR: 0 No 1 Yes
Cardioversion: 0 No 1 Yes
LVAD placement: 0 No 1 Yes -> If Yes:
Date: day / month / year
Heart transplant: 0 No 1 Yes -> If Yes:
Date: day / month / year

**THIS IS A REPEATING PAGE**

Subject ID: DS \_\_\_\_\_ - \_\_\_\_\_  
site # subject # Subject Initials: \_\_\_\_\_

**Unscheduled Clinic or Emergency Department (ED) Visit < 24 Hours**

- 1** Visit date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
day month year UNSCHEDT UNSCHEDL (TYPE 4)
- 2** Visit type: <sub>1</sub> Unscheduled clinic <sub>2</sub> Emergency department <sub>3</sub> Observational unit (*short stay*) VISTYPE<HFTYPE>
- 3** Was this visit related to heart failure? HFVISIT<XYESNO>  
<sub>0</sub> No  
<sub>1</sub> Yes → Were there signs or symptoms indicating decompensated heart failure: <sub>0</sub> No <sub>1</sub> Yes  
 Did subject receive IV treatment for heart failure: <sub>0</sub> No <sub>1</sub> Yes DECOMPHF<XYESNO>  
 IVFORHF<XYESNO>

Subject ID: DS \_\_\_\_\_ - \_\_\_\_\_ Subject Initials: \_\_\_\_\_  
site # subject #

**Death**

**DEATHLOC<HFLOCA>**

**1** Location of death (check only one): <sub>1</sub> Inpatient/ER <sub>2</sub> Outpatient

**DEATHPAG (TYPE 1)**

**2** Date of death: \_\_\_\_/\_\_\_\_/\_\_\_\_ **DEATHDT**  
day month year

**3** Cause of death (check only one):

**DEATHCAU<HFDEAT>**

- <sub>1</sub> Heart failure/pump failure
- <sub>2</sub> Sudden death
- <sub>3</sub> Myocardial infarction
- <sub>4</sub> Cardiac procedure
- <sub>5</sub> Other cardiac
- <sub>6</sub> Cerebral vascular accident (CVA)/stroke
- <sub>7</sub> Renal
- <sub>8</sub> Other non-cardiac
- <sub>9</sub> Unknown

**Investigator's Signature**

**SIGNATUR (TYPE 4)**

I have reviewed and found all the case report form data pertaining to this subject to be complete and accurate.

**SEE ANNOTATION P.21**

Principal Investigator: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
Signature of Investigator day month year



THIS IS A REPEATING PAGE

Subject ID: DS

site # \_\_\_\_\_ subject # \_\_\_\_\_

Subject Initials: \_\_\_\_\_

**Serious Adverse Events**

Did the subject have any serious adverse event(s)? <input type="checkbox"/> No <input type="checkbox"/> Yes → If Yes: Provide details below: <b>ANYAE&lt;XYESNO&gt;</b>		<b>ADVERSE (TYPE 4) R</b>							
#	Is This Event on the HFnet Event List? <b>EVENT&lt;XYESNO&gt;</b>	Onset Date and Time <b>AEONSTDTM&lt;DATE&gt;</b> <b>AEONSTTM&lt;DATE&gt;</b>	End Date and Time OR <input checked="" type="checkbox"/> if Ongoing <b>AEENDDT&lt;DATE&gt;</b>	Was Subject Hospitalized? <b>AEHOSP&lt;XYESNO&gt;</b>	Outcome (check only one) <b>AEOUTCM&lt;HIFOUTC&gt;</b>	Maximum Intensity (check only one) <b>AEINTENS&lt;XINTNS&gt;</b>	Action Taken with Study Drug/Treatment (check only one) <b>AEACTION&lt;HIFACTN&gt;</b>	Related to Study Drug/Treatment (check only one)	Was this Event Unexpected Per Product Labeling? <b>AEUNEXPT&lt;XYESNO&gt;</b>
1	No → Name of event: _____ Yes → HFN Code #: _____ <b>AETERM &lt;V:100&gt;</b>	_____/_____/_____ <b>AEODTXT</b> <b>&lt;V:100&gt;</b> <b>(DERIVED)</b> <b>ALL MEDRA</b>	_____/_____/_____ <b>AEENDDT&lt;DATE&gt;</b> <b>OR</b> <input type="checkbox"/> Ongoing	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> 1 Resolved <input type="checkbox"/> 2 Resolved with sequelae <input type="checkbox"/> 3 Unresolved <input type="checkbox"/> 4 Death	<input type="checkbox"/> 1 Mild <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Severe	<input type="checkbox"/> 1 Interrupted <input type="checkbox"/> 2 Discontinued <input type="checkbox"/> 3 Dosage changed	<input type="checkbox"/> 1 Not a reasonable possibility <input type="checkbox"/> 2 Reasonable possibility*	<input type="checkbox"/> 0 No <input type="checkbox"/> 1 Yes*
2	No → Name of event: _____ Yes → HFN Code #: _____ <b>HFNCODE&lt;I:3&gt;</b> <b>See attached for Code list for batch loading into TYPE 0 panel</b>	_____/_____/_____ <b>coding from this field</b>	_____/_____/_____ <b>AEONCT&lt;XYES&gt;</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> 1 Resolved <input type="checkbox"/> 2 Resolved with sequelae <input type="checkbox"/> 3 Unresolved <input type="checkbox"/> 4 Death	<input type="checkbox"/> 1 Mild <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Severe	<input type="checkbox"/> 0 None <input type="checkbox"/> 1 Interrupted <input type="checkbox"/> 2 Discontinued <input type="checkbox"/> 3 Dosage changed	<input type="checkbox"/> 1 Not a reasonable possibility <input type="checkbox"/> 2 Reasonable possibility*	<input type="checkbox"/> 0 No <input type="checkbox"/> 1 Yes*
3	No → Name of event: _____ Yes → HFN Code #: _____ <b>MEDRA: MEDRTEXT&lt;V:100&gt;</b> <b>MEDRCODE&lt;V:8&gt;</b> <b>WORKFLOW&lt;V:5&gt;</b> <b>CODETM&lt;DATE&gt;</b> <b>CODER&lt;V:20&gt;</b> <b>MATCHES&lt;V:4&gt;</b> <b>CONFLVL&lt;V:2&gt;</b>	_____/_____/_____ <b>DERIVED ITEMS:</b> <b>PTNAME&lt;V:100&gt;</b> <b>PTCODE&lt;V:8&gt;</b> <b>SOCNAME&lt;V:100&gt;</b> <b>SOCODE&lt;V:8&gt;</b>	_____/_____/_____ <b>AEONCT&lt;XYES&gt;</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> 1 Resolved <input type="checkbox"/> 2 Resolved with sequelae <input type="checkbox"/> 3 Unresolved <input type="checkbox"/> 4 Death	<input type="checkbox"/> 1 Mild <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Severe	<input type="checkbox"/> 0 None <input type="checkbox"/> 1 Interrupted <input type="checkbox"/> 2 Discontinued <input type="checkbox"/> 3 Dosage changed	<input type="checkbox"/> 1 Not a reasonable possibility <input type="checkbox"/> 2 Reasonable possibility*	<input type="checkbox"/> 0 No <input type="checkbox"/> 1 Yes*
4	No → Name of event: _____ Yes → HFN Code #: _____	_____/_____/_____ <b>AEONCT&lt;XYES&gt;</b>	_____/_____/_____ <b>AEONCT&lt;XYES&gt;</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> 1 Resolved <input type="checkbox"/> 2 Resolved with sequelae <input type="checkbox"/> 3 Unresolved <input type="checkbox"/> 4 Death	<input type="checkbox"/> 1 Mild <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Severe	<input type="checkbox"/> 0 None <input type="checkbox"/> 1 Interrupted <input type="checkbox"/> 2 Discontinued <input type="checkbox"/> 3 Dosage changed	<input type="checkbox"/> 1 Not a reasonable possibility <input type="checkbox"/> 2 Reasonable possibility*	<input type="checkbox"/> 0 No <input type="checkbox"/> 1 Yes*

**Investigator's Signature**

I have reviewed and found all the case report form data pertaining to this subject to be complete and **SEE ANNOTATION P. 21**

Principal Investigator: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Signature of investigator

**SIGNATUR (TYPE 4)**

\* If a reasonable possibility of related to study drug/treatment and unexpected, complete and submit MedWatch form to FDA and send copy to DCC.



If HFNCODE is null and AETERM is not null  
 Derive AETERM in AECODTXT  
 Else HFCODE is not null and AETERM is null  
 Decode HFCODE to label and derive in AECODTXT  
 If AETERM is not null and HFCODE is not null do not run derivation

**HFLIST**  
**TYPE 0 panel**

1=	Heart Failure
2=	Acute decompensated heart failure
3=	Cardiac failure chronic
4=	Peripheral edema
5=	Pulmonary edema
6=	Right ventricular failure
7=	Angina Pectoris
8=	Acute Coronary Syndrome
9=	ST segment elevation myocardial infarction
10=	Non ST segment elevation myocardial infarction
11=	Unstable angina
12=	Chest pain
13=	Arrhythmias
14=	Atrial fibrillation
15=	Atrial flutter
16=	Atrial tachycardia
17=	Atrioventricular block second degree
18=	Bradycardia
19=	Bradycardia
20=	Bundle branch block
21=	Bundle branch block left
22=	Bundle branch block right
23=	Complete heart block
24=	Mitral regurgitation

If HFNCODE is null and AETERM is not null  
 Derive AETERM in AECODTXT  
 Else HFCODE is not null and AETERM is null  
 Decode HFCODE to label and derive in AECODTXT  
 If AETERM is not null and HFCODE is not null do not run derivation

• <HFLIST>cont

25=	Paroxysmal arrhythmia
26=	Aortic Regurgitation
27=	Sinoatrial block
28=	Sinus bradycardia
29=	Sinus tachycardia
30=	Supraventricular tachycardia
31=	Tachycardia
32=	Cardiac tamponade
33=	Torsades de pointes
34=	Ventricular arrhythmia
35=	Ventricular fibrillation
36=	Ventricular tachycardia
37=	Cardiac arrest
38=	Hyperkalemia
39=	Hypokalemia
40=	Hyponatremia
41=	Renal failure
42=	Renal failure acute
43=	Renal failure chronic
44=	Renal failure aggravated
45=	Pleural effusion
46=	Pulmonary Embolism
47=	Pneumonia
48=	Respiratory failure

If HFNCODE is null and AETERM is not null  
 Derive AETERM in AECODTXT  
 Else HFCODE is not null and AETERM is null  
 Decode HFCODE to label and derive in AECODTXT  
 If AETERM is not null and HFCODE is not null do not run derivation

• <HFLIST>cont

49=	Acute Respiratory failure
50=	Hypertension
51=	Hypotension
52=	Deep vein thrombosis
53=	Aortic Dissection
54=	Disorder peripheral vascular
55=	Peripheral ischemia
56=	Stroke
57=	TIA
58=	Syncope
59=	Headache
60=	Visual Disturbance
61=	Presyncope
62=	Dizziness
63=	Surgical wound infection
64=	Mediastinitis
65=	Sepsis
66=	Endocarditis
67=	Cellulitis
68=	Anticoagulation level above therapeutic
69=	Upper gastrointestinal hemorrhage
70=	Lower gastrointestinal hemorrhage
71=	Priapism
72=	Hearing loss
73=	Tinnitus

## AE derivation for AECONTXT

- PTCODE
- PTCODE = MEDRA.L\_LOW\_LEVEL\_TERM\_DATA.PT\_CODE where
- this.MEDRCODE = MEDRA.L\_LOW\_LEVEL\_TERM\_DATA.LLT\_CODE
  
- PTNAME
- PTNAME = MEDRA.L\_MD\_HIERARCHY\_DATA.PT\_NAME where
- this.MEDRCODE = MEDRA.L\_LOW\_LEVEL\_TERM\_DATA.LLT\_CODE and
- MEDRA.L\_LOW\_LEVEL\_TERM\_DATA.PT\_CODE =
- MEDRA.L\_MD\_HIERARCHY\_DATA.PT\_CODE and
- MEDRA.L\_MD\_HIERARCHY\_DATA.PRIMARY\_SOC\_FG = 'Y'
  
- SOCCODE
- SOCCODE = MEDRA.L\_MD\_HIERARCHY\_DATA.SOC\_CODE where
- this.MEDRCODE = MEDRA.L\_LOW\_LEVEL\_TERM\_DATA.LLT\_CODE and
- MEDRA.L\_LOW\_LEVEL\_TERM\_DATA.PT\_CODE =
- MEDRA.L\_MD\_HIERARCHY\_DATA.PT\_CODE and
- MEDRA.L\_MD\_HIERARCHY\_DATA.PRIMARY\_SOC\_FG = 'Y'
  
- SOCNAME
- SOCNAME = MEDRA.L\_MD\_HIERARCHY\_DATA.SOC\_NAME where
- this.MEDRCODE = MEDRA.L\_LOW\_LEVEL\_TERM\_DATA.LLT\_CODE and
- MEDRA.L\_LOW\_LEVEL\_TERM\_DATA.PT\_CODE =
- MEDRA.L\_MD\_HIERARCHY\_DATA.PT\_CODE and
- MEDRA.L\_MD\_HIERARCHY\_DATA.PRIMARY\_SOC\_FG = 'Y'