HEART FAILURE NETWORK **ROSE**

PROTOCOL=HFN_ROSE
STUDYBOOK=DATA_FORMS
FORM= BASELINE

NODATA<ZYES>

Baseline

Subject ID: RS ____ - ____ (site # / subject #) SUBJNO

Subject Initials: ___ ___ ___ INITIALS

Demographics

DEMOG (TYPE 1)

1 Date of birth: ___/___/___ (day/month/year) DOBDT

2 Sex: ☐1 Male ☐2 Female SEX<XGENDR>

3 Ethnicity (check only one): ☐1 Hispanic or Latino ☐2 Not Hispanic or Latino ETHNIC<XETHN>

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

5 Date of consent: ___/___/___ (day/month) CONSNTDT<DATE>

Eligibility

ELIGIBLE (TYPE 1)

Did the subject meet all eligibility criteria?

☐0 No → If No: Inclusion criteria not met: # ____, # ____, # ____ INCL1<I:3> INCL2<I:3> INCL3<I:3>

Exclusion criteria present: # ____, # ____, # ____ EXCL1<I:3> EXCL2<I:3> EXCL3<I:3>

Was a waiver granted for all of the above exceptions?

☐0 No ☐1 Yes WAIVER <XYESNO>

☐1 Yes ELIGCRIT<XYESNO>

Hospitalization

INITHOSP (TYPE 1)

Date and time of initial presentation to acute care facility: ___/___/___ ___:___ (day/month/year hour:min) PRESENDT<DATE> PRESENTM<DATETIME>

7-Day Prior Oral Diuretics

DIURETIC (TYPE 4)PS

	Medication	DIURANS<HFRESP>	Average Total Daily Dose	Units
1=	1 Furosemide	☐0 No ☐1 Yes →	_____	mg
2=	2 Torsemide	☐0 No ☐1 Yes →	_____	mg
3=	3 Bumetanide	☐0 No ☐1 Yes →	_____	mg
4=	4 Metolazone	☐0 No ☐2 Yes, daily ☐3 Yes, PRN →	_____	mg
5=	5 HCTZ	☐0 No ☐2 Yes, daily ☐3 Yes, PRN →	_____	mg

DIUMEDS<HFDIUR>

DIURDOSE<F:9:3>

0=NO
1=YES
2=YES,DAILY
3=YES,PRN

6=CHLOROTHIZIDE (SUPPRESS P. 22 ONLY)

Enroll panel will contain:
SUBJNO: derived from 'RS'II INVSITE II '-'II PATID
INITIALS V:3
RANDTM<DATETIME>
RANDDT<DATE>
HMDIUDOS <I:3>

HEART FAILURE NETWORK **ROSE**

NODATA<ZYES>

Baseline

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Clinical History

MEDHIST1(TYPE 1)

1 Estimated date of initial diagnosis of heart failure: DIAGHFM <ZMONTH> ___ (month) DIAGHFY <I:4> ___ (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>

☐ 0 No

☐ 1 Yes → **If Yes: Date of last LVEF:** LVASSDT ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

LVEF<I:2>

Value of last LVEF: EF ___ ___ % **OR Check only one:** LVEFSTAT<HFLVEF>

☐ 1 Normal
☐ 2 Mild dysfunction
☐ 3 Moderate dysfunction
☐ 4 Severe dysfunction

Method of assessment of LV function *(check only one)*: LVMETH<HFMETH>

☐ 1 Radionuclide ventriculogram
☐ 2 Left ventriculogram
☐ 3 Echocardiogram
☐ 4 MRI
☐ 98 Other

5 Does the subject have a documented history of ischemic heart disease?

ISCHEMIC<XYESNO>

☐ 0 No

☐ 1 Yes → **If Yes: Specify** *(check all that apply)*:

☐ Angina pectoris: ANGINA<XYES>

MI<XYES> ☐ Myocardial infarction *(MI)* → **Date of most recent:** MIDT ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

LTCATH<XYES> ☐ Left heart catheterization before randomization → **Date of most recent:** LTCATHDT ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

LM<XYES>
LAD<XYES>
LCX<XYES>
RCA<XYES>

Vessels with > 70% stenosis *(check all that apply)*: NON<XYES>

☐ LM ☐ LAD ☐ LCX ☐ RCA ☐ None

PTCI<XYES> ☐ Percutaneous transluminal coronary intervention *(PTCI)* → **Date of most recent:** PTCIDT ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (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?

NONISCH<XYESNO>

☐ 0 No

☐ 1 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>

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HEART FAILURE NETWORK **ROSE**

NODATA<ZYES>

Baseline

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Clinical History (continued)

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

7 Valvular heart disease:

☐0 No VALVULAR<XYESNO>

☐1 Yes → If Yes: Specify: ALL BELOW CODE< HFVALV> EXCEPT PRIOR VALVULAR SURGERY

MSTENOS	Mitral stenosis →	Check one:	☐0 None/Trivial	☐1 Mild	☐2 Moderate	☐3 Severe	☐99 Unknown
MREGURG	Mitral regurgitation →	Check one:	☐0 None/Trivial	☐1 Mild	☐2 Moderate	☐3 Severe	☐99 Unknown
ATSTENOS	Aortic stenosis →	Check one:	☐0 None/Trivial	☐1 Mild	☐2 Moderate	☐3 Severe	☐99 Unknown
AREGURG	Aortic regurgitation →	Check one:	☐0 None/Trivial	☐1 Mild	☐2 Moderate	☐3 Severe	☐99 Unknown
TSTENOS	Tricuspid stenosis →	Check one:	☐0 None/Trivial	☐1 Mild	☐2 Moderate	☐3 Severe	☐99 Unknown
TREGURG	Tricuspid regurgitation →	Check one:	☐0 None/Trivial	☐1 Mild	☐2 Moderate	☐3 Severe	☐99 Unknown
	Prior valvular surgery →	Check all that apply:	☐ None	☐ Mitral	☐ Aortic	☐ Tricuspid	☐ Pulmonic

8 Hypertension: HYPRTESN<XYESNO> ☐0 No ☐1 Yes NONSURG,MITSURG, AORSURG, TRISURG, PULSURG All <XYES>

9 TIA: TIA<XYESNO> ☐0 No ☐1 Yes

10 Stroke: STROKE<XYESNO> ☐0 No ☐1 Yes

11 Arrhythmia: ARRHYTHM <XYESNO>

☐0 No

☐1 Yes → If Yes: Specify *(check all that apply)*:

ATRIALFB<XYES> ☐ Atrial fibrillation/flutter → Check one: FIBFLUTR<HFFIBF> ☐1 New onset ☐2 Paroxysmal ☐3 Persistent ☐4 Permanent

SUSVTVF<XYES> ☐ Sustained VT or VF

ARREST<XYES> ☐ Cardiac arrest *(etiology unclear)*

12 Pacemaker without ICD: PACEMAKR<XYESNO> ☐0 No ☐1 Yes → Check one: PACETYPE<HFCHBR> ☐1 Single ☐2 Dual ☐3 Biventricular

13 ICD: ICD<XYESNO> ☐0 No ☐1 Yes → Check one: ☐1 Single ☐2 Dual ☐3 Biventricular

14 Peripheral vascular disease: PVD<XYESNO> ☐0 No ☐1 Yes ICDTYPE<HFCHBR>

15 Chronic obstructive pulmonary disease: ☐0 No ☐1 Yes COPD<XYESNO>

16 Diabetes: DIABETES<XYESNO> ☐0 No ☐1 Yes → Check one: DIABTYPE<HFDIAB> ☐1 Insulin treated ☐2 Non-insulin medically treated ☐3 Diet only

17 Gout: GOUT<XYESNO> ☐0 No ☐1 Yes

18 Hepatic disease: HEPATIC<XYESNO> ☐0 No ☐1 Yes

19 Malignancy *(past 5 years, other than skin)*: ☐0 No ☐1 Yes MALIGNCY<XYESNO>

20 Depression *(treated with prescription medications)*: ☐0 No ☐1 Yes DEPRESS<XYESNO>

21 Chronic alcohol use: ☐0 No ☐1 Yes ALCOHOL<XYESNO>

22 Cigarette smoking *(check only one)*: CIGARETT<HFCIGR> ☐1 Current ☐2 Quit < 6 months ago ☐3 Quit ≥ 6 months ago ☐4 Never

23 Heart transplant status *(check only one)*: TRANSPLT<HFTRAN>

☐1 Ineligible

☐2 No evaluation planned

☐3 Active evaluation

☐4 Currently listed

☐5 Post → Date of transplant: TRANSPDT ___ (day) / ___ (month) / ___ ___ ___ (year)

24 Hyperlipidemia: LIPIDEMA<XYESNO> ☐0 No ☐1 Yes

HEART FAILURE NETWORK **ROSE**

NODATA<ZYES>

Baseline

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

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

ECG (TYPE 1)

1 Date: ___/___/___ (day/month/year) OR ☐ Not done ECGDT ECGNOTDN<XYES>

2 Rate: ___ ___ ___ bpm ECGHRATE<I:3>

3 Rhythm (check only one): ECGRHYTH<HFECGR>
☐1 Sinus bradycardia ☐2 Normal sinus rhythm ☐3 Sinus tachycardia
☐4 Atrial fibrillation/flutter ☐98 Other

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

5 QRS duration: ___ ___ ___ msec OR ☐ Not done ECGQRS<I:3> ECGQRSND<XYES>

Heart Failure Clinical Assessment At Randomization

ASSESSMT(TYPE 3)

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting): HRNOTDN<XYES>	☐	___ ___ ___ bpm HRATE<I:3>
2 Blood pressure (sitting or resting): BPNOTDN<XYES>	☐	BPSYS <I:3> (systolic) / BPDIA<I:3> (diastolic) mm Hg
3 SpO_2: SPONOTDN<XYES>	☐	___ ___ ___ % SPO2<I:3>
4 Height: HTNOTDN<XYES>	☐	HEIGHT <F:9:3> ☐1 in ☐2 cm HTUNITS<XHGTU>
5 Weight: WTNOTDN<XYES> WTMEASR<RSWGT>	☐	WEIGHT <F:9:3> ___ ___ ___ . ___ ☐1 lb ☐2 kg WTUNITS<XWGTU> Assessed by (check only one): ☐1 Bed scale ☐2 Standing ☐99 Unknown WGTTM<TIME> Suppress pg 4 (See p.8)
6 Jugular venous pressure (check only one): JVPNOTDN<XYES>	☐	☐1 < 8 cm ☐2 8–12 cm ☐3 13–18 cm ☐4 JVP<HFJVP>
7 Rales (check only one): RASNOTDN<XYES>	☐	☐0 None ☐1 < 1/3 ☐2 1/3–2/3 ☐3 > 2/3 RALES<HFRALE>
8 S3 auscultation: AUSNOTDN<XYES>	☐	☐0 No ☐1 Yes AUSCULTN<XYESNO>
9 Hepatomegaly: HEPNOTDN<XYES>	☐	☐0 No ☐1 Yes HEPATOM<XYESNO>
10 Ascites: ASCNOTDN<XYES>	☐	☐0 No ☐1 Yes ASCITES<XYESNO>
11 Peripheral edema (check only one): PEDNOTDN<XYES>	☐	☐0 None ☐1 1+ ☐2 2+ ☐3 3+ ☐4 PERIEDMA<EXEDEM>
12 Current NYHA heart failure classification (check only one): NYNOTDN<XYES>	☐	☐1 I ☐2 II ☐3 III ☐4 IV NYHA<XKCLAS>
13 Orthopnea (check only one): ORTNOTDN<XYES> DYSNOTDN<XYES>	☐	☐0 None ☐1 One pillow (10 cm) ☐2 Two pillows (20 cm) ORTHPNEA<HFORTH> ☐3 Three or more pillows ☐4 Not evaluable DYSPNEA<RSDYSP>
14 Dyspnea (check only one):	☐	☐1 None ☐2 At rest ☐3 With minimal exertion
15 Chest x-ray (check only one): CXRNOTDN<XYES>	☐	☐1 Normal ☐2 Pulmonary vascular congestion present ☐3 Plural effusion present CHSTXRAY<RSCHSX>

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HEART FAILURE NETWORK **ROSE**

NODATA<XYES>

Baseline

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Labs

LABS(TYPE 4)PS

	Assessment	Not Done	Value	Units
1=	**1** Sodium:	☐	_____	☐1 mmol/L ☐2 mEq/L
2=	**2** Potassium:	☐	_____	☐1 mmol/L ☐2 mEq/L
3=	**3** BUN/Urea:	☐	_____	☐1 mmol/L ☐3 mg/dL
4=	**4** Bicarbonate (*total CO_2*):	☐	_____	☐1 mmol/L ☐2 mEq/L
5=	**5** Creatinine:	☐	_____	☐3 mg/dL ☐4 µmol/L
6=	**6** Magnesium:	☐	_____	☐1 mmol/L ☐2 mEq/L ☐3 mg/dL
7=	**7** Glucose:	☐	_____	☐1 mmol/L ☐3 mg/dL
20=	**8** Chloride:	☐	_____	☐1 mmol/L ☐2 mEq/L
21=	**9** Calcium:	☐	_____	☐1 mmol/L ☐2 mEq/L ☐3 mg/dL
8=	**10** Total cholesterol:	☐	_____	☐1 mmol/L ☐3 mg/dL
9=	**11** AST/SGOT:	☐	_____	☐5 U/L ☐6 IU/L
10=	**12** ALT/SGPT:	☐	_____	☐5 U/L ☐6 IU/L
11=	**13** Alkaline phosphatase:	☐	_____	☐5 U/L ☐6 IU/L
12=	**14** Total bilirubin:	☐	_____	☐3 mg/dL ☐4 µmol/L
22=	**15** Total protein:	☐	_____	☐7 g/dL ☐8 g/L
13=	**16** Albumin:	☐	_____	☐7 g/dL ☐8 g/L
15=	**17** WBC:	☐	_____	☐9 10^9/L OR 10^3/mm³ ☐10 /mm³
16=	**18** Lymphocyte %:	☐	_____	☐11 %
14=	**19** Hemoglobin (*Hgb*):	☐	_____	☐7 g/dL ☐8 g/L ☐1 mmol/L
23=	**20** Hematocrit:	☐	_____	☐15 L/L ☐11 %
24=	**21** Platelets:	☐	_____	☐9 10^9/L OR 10^3/mm³ ☐10 /mm³
17=	**22** Red cell distribution (*RDW*):	☐	_____	☐11 %
18=	**23** BNP:	☐	_____	☐12 pg/mL ☐13 ng/L
19=	**24** NT-pro-BNP:	☐	_____	☐12 pg/mL ☐13 ng/L

LABASSES<HFLAB>

LABVALUE<F:9:3>

LABND<XYES>

LABUNIT<HFLABU>

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HEART FAILURE NETWORK **ROSE**

NODATA<XYES>

Baseline

Subject ID: RS ___ ___ ___ - ___ ___ ___ Subject Initials: ___ ___ ___
site # subject #

MEDS(TYPE 4)PS

Medications

	HFMEDS<HFHFMD>	Baseline MEDSANS<XYESNO>
1=	**1** ACE inhibitor	☐0 No ☐1 Yes
2=	**2** Angiotensin receptor blocker	☐0 No ☐1 Yes
3=	**3** Beta blocker	☐0 No ☐1 Yes
4=	**4** Aldosterone antagonist	☐0 No ☐1 Yes
5=	**5** Hydralazine	☐0 No ☐1 Yes
6=	**6** Nitrates *(long-acting)*	☐0 No ☐1 Yes
7=	**7** Aspirin *(if taken daily)*	☐0 No ☐1 Yes
8=	**8** Warfarin	☐0 No ☐1 Yes
9=	**9** Thienopyridine *(ticlopidine, clopidogrel)*	☐0 No ☐1 Yes
10=	**10** Alpha blocker	☐0 No ☐1 Yes
11=	**11** Digoxin	☐0 No ☐1 Yes
12=	**12** Amiodarone	☐0 No ☐1 Yes
13=	**13** Other antiarrhythmic	☐0 No ☐1 Yes
14=	**14** Statin	☐0 No ☐1 Yes
15=	**15** Lipid lowering agent *(other than statin)*	☐0 No ☐1 Yes
16=	**16** Calcium channel blocker	☐0 No ☐1 Yes
17=	**17** Insulin	☐0 No ☐1 Yes
18=	**18** Oral diabetic agent	☐0 No ☐1 Yes
19=	**19** Anti-depressant	☐0 No ☐1 Yes

Delete in this protocol:
~~DISCHND~~
MEDDSCG
MEDSCONT
MEDSCRN
MEDRAND

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HEART FAILURE NETWORK **ROSE**

NODATA<XYES>

Baseline

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Subject Self-report of Symptoms

VAS (TYPE 3)

1 Dyspnea: VAS score: ___ ___ ___ mm DYSPVAS <I:3>

2 Global VAS score: ___ ___ ___ mm GLOBLVAS <I:3>

SUPPRESS
VASTM<TIME>
SEE P. 10

Core Lab Biomarker–Blood Assessments

ROSECORE (TYPE 3)

Test	Date of Test	Not Done	Reason Not Done
Biomarkers—blood	RSCOREDT __ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59) RSCORETM	☐ → RSCOREND<XYES>	RSCRND<RSCORE> ☐1 Died → Fill out Death form ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐7 Subject withdrew consent ☐99 Unknown/other

Core Lab Biomarker–Urine Assessments

RSURICOR (TYPE 3)

Test	Date of Test	Not Done	Reason Not Done (check only one)
Biomarkers—urine	RSURINDT __ __ / __ __ __ / __ __ __ __ (day / month / year) RSURINTM __ __ : __ __ (00:00 to 23:59) RSURLBND<XYES>	☐ →	☐1 Died → Fill o ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐7 Subject withdrew consent ☐99 Unknown/other RSURINRE<RSCORE>

Biorepository and Genetics Substudy

GENETICS (TYPE 1)

1 Did the subject agree to participate in the biorepository substudy?
☐0 No
☐1 Yes BIORPSTY<XYESNO>

2 Did the subject agree to participate in the pharmacogenomics (genetics) substudy? GENETICS<XYESNO>
☐0 No → If No: Check only one: ☐1 Died
☐2 Subject declined consent
☐3 Subject not approached
☐98 Other
GENRSN<RSGNT>

☐1 Yes → If Yes: Date drawn: __ __ / __ __ / __ __ __ __ (day / month / year) GENETCDT<DATE>

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HEART FAILURE NETWORK **ROSE**

Red Rose Baseline

NODATA<XYES>

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Red Rose Substudy

NOREDRS <XYES>

REDSUB (TYPE 3)

☐ Subject not enrolled in Red Rose Substudy → **Stop. Do not complete the remainder of this page.**

Worst Symptom

WSYMPTOM (TYPE 1)

Subject's worst reported symptom prompting hospitalization (check only one):

☐1 Dyspnea (difficulty breathing) → **Baseline Dyspnea VAS and Global VAS score documented on CRF page 7.**

☐2 Fatigue

WORST <RSWORS>

☐3 Body swelling

VASUPPLE (TYPE 3)

Baseline Dyspnea VAS Supplemental Additional Information Complete for all subjects

VASOXY<XYNUNK>

VASOXYL<F9:3>

Not Done	Position (Check only one)	
DYSVASND<XYES> ☐ Dyspnea VAS not done	VASPOSIT<RSPOSI> ☐1 < 20° (1=<20 deg) ☐2 20°–59° (2= 20 -59 deg) ☐3 ≥ 60° (3= >=60 deg) ☐4 Ambulatory in room (4= Ambulatory in room) ☐99 Unknown (99= Unknown)	☐0 ☐1 Yes → _____ Liters/min ☐99 Unknown

Baseline Dyspnea — pDSS1 Complete for all subjects

PDSS (TYPE 3)

1 Was pDSS1 performed?

PDSSP<XYESNO>

☐0 No → **If No: Specify reason** *(check only one)*: ☐1 Died ☐2 Too sick to perform ☐3 Due to oversight or technical problem ☐99 Unknown

PDSSREA<RSPDSR>

☐1 Yes

STAGEASC<I:2>

2 Stage A score: _____ *(1–5)* OR ☐ Not done

STAGEAND<XYES>

3 Stage B score: _____ *(6–10)*

STAGEBSC<I:2>

4 Stage C score: _____ *(11–15)*

STAGECSC<I:2>

STAGEDND<XYES>

5 BP: ___ ___ ___ / ___ ___ ___ Stage D score: _____ *(16–20)* OR ☐ Stage D not done → **Reason** *(check only one)*: ☐1 Mechanical limitation ☐2 Unstable standing position ☐3 Oversight ☐4 Refused

STAGESYS<I:3>

STAGEDIA<I:3>

STAGEDSC<I:2>

STAGEREA<RSTREA>

Baseline Fatigue as Worst Symptom

FATNAPP<XYES>

FATIGUE (TYPE 3)

☐ Not applicable *(not subject's Baseline worst symptom)*

Fatigue VAS: _____ *(0–100)* OR ☐ Not done

FATVASND<XYES>

FATVAS<I:3>

Baseline Body Swelling as Worst Symptom

SWELLING (TYPE 3)

BSWELLNA<XYES>

☐ Not applicable *(not subject's Baseline worst symptom)*

Body Swelling VAS: _____ *(0–100)* OR ☐ Not done

BSVASND<XYES>

BSVAS<I:3>

HEART FAILURE NETWORK **ROSE**

<HFSUBJ>
1=SUBJECT DISCHARGED
2=SUBJECT WITHDREW
3=SUBJECT DIED
4=MISSED VISIT
98=OTHER

NODATA<ZYES>

EARLYTRM<XYES>
SUPPRESS

FORM= 24 HOURS

24 Hours

Subject ID: RS___ - ____ ____ (site # / subject #) Subject Initials: ___ ___ ___

Subject Status

Was assessment performed? EVALUTE<XYESNO>

SUBJSTAT<HFSUBJ>
SEE CODELIST ABOVE

STATUS (TYPE 3)

☐0 No → If No: Reason: ☐1 Subject discharged ☐2 Subject withdrew ☐3 Subject died ☐98 Other (specify): _____

☐1 Yes → If Yes: Assessment date: ___/___/____ (day / month / year) EVALDT<DATE>

STATUSSP<V:50>

Clinical Assessment from same daily assessment time

ASSESSMT(TYPE 3)

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	☐	___ ___ ___ bpm SEE ANNOTATION P. 4
2 Blood pressure (sitting or resting):	☐	___ ___ (systolic) / ___ ___ (diastolic) mm Hg
3 SpO_2:	☐	___ ___ ___ %
4 Weight: SUPPRESS 4,7,8,9,10,12, 14,15	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg Assessed by (check only one): ☐1 Bed scale ☐2 Standing ☐99 Unknown Time assessed (24 hour clock): ___:___ (00:00 to 23:59) WGTTM<TIME>
5 Jugular venous pressure (check only one):	☐	☐1 < 8 cm ☐2 8–12 cm ☐3 13–16 cm ☐4 > 16 cm
6 Peripheral edema (check only one):	☐	☐0 None ☐1 1+ ☐2 2+ ☐3 3+ ☐4 4+
7 Orthopnea (check only one):	☐	☐0 None ☐3 Three or more pillows ☐1 One pillow (10 cm) ☐4 Not evaluable ☐2 Two pillows (20 cm)

Labs—Chemistry from same daily assessment time

LABS(TYPE 4)PS

Assessment	Not Done	Value	Units
1 Sodium:	☐	_____	☐1 mmol/L ☐2 mEq/L
2 Potassium:	☐	_____	☐1 mmol/L ☐2 mEq/L
3 BUN/Urea:	☐	_____	☐1 mmol/L ☐3 mg/dL
4 Bicarbonate (total CO_2):	☐ SEE ANNOTATION P. 5	_____	☐1 mmol/L ☐2 mEq/L
5 Creatinine: SUPRESS ALL EXCEPT 1,2,3,4,5,20,21, 11	☐	_____	☐3 mg/dL ☐4 µmol/L
6 Chloride:	☐	_____	☐1 mmol/L ☐2 mEq/L
7 Calcium:	☐	_____	☐1 mmol/L ☐2 mEq/L ☐3 mg/dL
8 Alkaline phosphatase:	☐	_____	☐5 U/L ☐6 IU/L

RSFLUID(TYPE 3)

Fluid Input/Output from same daily assessment time

1 Total IV intake: RSIVIN I:5 ___ ___ ___ ___ mL

Total oral intake: RSORALIN I:5 ___ ___ ___ ___ mL

2 Total urine output: RSUROUT I:5 ___ ___ ___ ___ mL

Total non-urine output: RSNUROUT I:5 ___ ___ ___ ___ mL

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HEART FAILURE NETWORK **ROSE**

NODATA<XYES>

24 Hours

Subject ID: RS ___ ___ ___ ___ (site # / pt #) Subject Initials: ___ ___ ___

MEDS(TYPE 4)PS

Medications

	24 Hours
1 ACE inhibitor	☐0 No ☐1 Yes
2 Angiotensin receptor blocker	☐0 No ☐1 Yes
3 Beta blocker	☐0 No ☐1 Yes
4 Aldosterone antagonist	☐0 No ☐1 Yes
5 Hydralazine	☐0 No ☐1 Yes
6 Nitrates *(long-acting)*	☐0 No ☐1 Yes
7 Aspirin *(if taken daily)*	☐0 No ☐1 Yes
8 Warfarin	☐0 No ☐1 Yes
9 Thienopyridine *(ticlopidine, clopidogrel)*	☐0 No ☐1 Yes
10 Alpha blocker	☐0 No ☐1 Yes
11 Digoxin	☐0 No ☐1 Yes
12 Amiodarone	☐0 No ☐1 Yes
13 Other antiarrhythmic	☐0 No ☐1 Yes
14 Statin	☐0 No ☐1 Yes
15 Lipid lowering agent *(other than statin)*	☐0 No ☐1 Yes
16 Calcium channel blocker	☐0 No ☐1 Yes
17 Insulin	☐0 No ☐1 Yes
18 Oral diabetic agent	☐0 No ☐1 Yes
19 Anti-depressant	☐0 No ☐1 Yes

SEE ANNOTATION P.6

HEART FAILURE NETWORK **ROSE**

NODATA<XYES>

24 Hours

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Subject Self-report of Symptoms

VASTM<TIME>

VAS (TYPE 3)

Time completed *(24 hour clock)*: ___ ___ : ___ ___ (00:00 to 23:59)

1 Dyspnea: VAS score: ___ ___ ___ mm

2 Global VAS score: ___ ___ ___ mm

SEE ANNOTATION P. 7

Core Lab Biomarker–Blood Assessments

ROSECORE (TYPE 3)

Test	Date of Test	Not Done	Reason Not Done (check only one)
Biomarkers—blood	SEE ANNOTATION P. 7 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	☐ →	☐1 Died → Fill out Death form ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐5 Discharged ☐7 Subject withdrew consent ☐99 Unknown/other

Core Lab Biomarker–Urine Assessments

RSURICOR (TYPE 3)

Test	Date of Test	Not Done	Reason Not Done (check only one)
Biomarkers—urine	SEE ANNOTATION P. 7 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	☐ →	☐1 Died → Fill out Death form ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐5 Discharged ☐7 Subject withdrew consent ☐99 Unknown/other

Treatment of Worsening or Persistent Heart Failure

WORSENIG(TYPE 3)

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

WORSENHF<XYESNO>

☐0 No

ALL <XYES>

☐1 Yes → **If Yes: Specify treatment** *(check all that apply)*:

VASOACTV ☐ IV vasoactive agent for heart failure treatment

☐ Ultrafiltration ULTRAFIL

CIRSUPPT ☐ Mechanical circulatory support

☐ Mechanical respiratory suppor MECHRESP

Delete for this protocol: MORELOOP,THIAZIDE,MECHVENT

NODATA<XYES>

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Red Rose Substudy

REDSUB (TYPE 3)

☐ Subject not enrolled in Red Rose Substudy → **Stop. Do not complete the remainder of this page.**

SEE ANNOTATION P.7A

24 Hours Dyspnea VAS and Global VAS scores are documented on CRF page 10.

24 Hours Dyspnea VAS Supplemental Additional Informatio

VASUPPLE (TYPE 3)

Not Done	Position (Check only one)	Oxygen (Check only one)
☐ Dyspnea VAS not done	SEE ANNOTATION P. 7A ☐1 < 20° ☐2 20°–59° ☐3 ≥ 60° ☐4 Ambulatory in room ☐99 Unknown	☐0 No ☐1 Yes → _____ Liters/min ☐99 Unknown

24 Hours Dyspnea — pDSS1 Complete for all subjects

PDSS (TYPE 3)

1 Was pDSS1 performed?

☐0 No → **If No: Specify reason** *(check only one)*: ☐1 Died ☐3 Due to oversight or technical problem ☐2 Too sick to perform ☐99 Unknown

☐1 Yes

2 Stage A score: _____ *(1–5)* OR ☐ Not done

SEE ANNOTATION P. 7A

3 Stage B score: _____ *(6–10)*

4 Stage C score: _____ *(11–15)*

5 BP: ___ ___ / ___ ___ (systolic / diastolic) Stage D score: _____ *(16–20)* OR ☐ Stage D not done → **Reason** *(check only one)*:

☐1 Mechanical limitation ☐2 Unstable standing position ☐3 Oversight ☐4 Refused

24 Hours Fatigue as Worst Symptom

FATIGUE (TYPE 3)

☐ Not applicable *(not subject's Baseline worst symptom)*

Fatigue VAS: _____ *(0–100)* OR ☐ Not done

SEE ANNOTATION P. 7A

24 Hours Body Swelling as Worst Symptom

SWELLING (TYPE 3)

☐ Not applicable *(not subject's Baseline worst symptom)*

Body Swelling VAS: _____ *(0–100)* OR ☐ Not done

SEE ANNOTATION P. 7A

HEART FAILURE NETWORK **ROSE**

NODATA<ZYES>

48 Hours

FORM= 48 HOURS

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Subject Status

STATUS (TYPE 3)

Was assessment performed?

☐0 No → If No: Reason: ☐1 Subject discharged ☐2 Subject withdrew ☐3 Subject died ☐98 Other (specify): _____

☐1 Yes → If Yes: Assessment date: ___ ___/___ ___ ___ ___ (day / month / year)

SEE ANNOTATION P. 8

Clinical Assessment from same daily assessment time

ASSESSMT(TYPE 3)

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	☐	___ ___ ___ bpm
2 Blood pressure (sitting or resting):	☐	___ ___ (systolic) / ___ ___ (diastolic) mm Hg
3 SpO_2:	☐	___ ___ ___ %
4 Weight: SEE ANNOTATION P. 8	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg Assessed by (check only one): ☐1 Bed scale ☐2 Standing ☐99 Unknown Time assessed (24 hour clock): ___ ___ : ___ ___ (00:00 to 23:59)
5 Jugular venous pressure (check only one):	☐	☐1 < 8 cm ☐2 8–12 cm ☐3 13–16 cm ☐4 > 16 cm
6 Peripheral edema (check only one):	☐	☐0 None ☐1 1+ ☐2 2+ ☐3 3+ ☐4 4+
7 Orthopnea (check only one):	☐	☐0 None ☐3 Three or more pillows ☐1 One pillow (10 cm) ☐4 Not evaluable ☐2 Two pillows (20 cm)

Labs—Chemistry from same daily assessment time

LABS(TYPE 4)PS

Assessment	Not Done	Value	Units
1 Sodium:	☐	_____	☐1 mmol/L ☐2 mEq/L
2 Potassium:	☐	_____	☐1 mmol/L ☐2 mEq/L
3 BUN/Urea:	☐	_____	☐1 mmol/L ☐3 mg/dL
4 Bicarbonate (total CO_2):	☐	_____	☐1 mmol/L ☐2 mEq/L
5 Creatinine:	☐	_____	☐3 mg/dL ☐4 µmol/L
6 Chloride:	☐	_____	☐1 mmol/L ☐2 mEq/L
7 Calcium:	☐	_____	☐1 mmol/L ☐2 mEq/L ☐3 mg/dL
8 Alkaline phosphatase:	☐	_____	☐5 U/L ☐6 IU/L

SEE ANNOTATION P. 8

Fluid Input/Output from same daily assessment time

RSFLUID(TYPE 3)

1 Total IV intake: ___ ___ ___ ___ mL

Total oral intake: ___ ___ ___ ___ mL

SEE ANNOTATION P. 8

2 Total urine output: ___ ___ ___ ___ mL

Total non-urine output: ___ ___ ___ ___ mL

Medications

	48 Hours
1 ACE inhibitor	☐0 No ☐1 Yes
2 Angiotensin receptor blocker	☐0 No ☐1 Yes
3 Beta blocker	☐0 No ☐1 Yes
4 Aldosterone antagonist	☐0 No ☐1 Yes
5 Hydralazine	☐0 No ☐1 Yes
6 Nitrates *(long-acting)*	☐0 No ☐1 Yes
7 Aspirin *(if taken daily)*	☐0 No ☐1 Yes
8 Warfarin	☐0 No ☐1 Yes
9 Thienopyridine *(ticlopidine, clopidogrel)*	☐0 No ☐1 Yes
10 Alpha blocker	☐0 No ☐1 Yes
11 Digoxin	☐0 No ☐1 Yes
12 Amiodarone	☐0 No ☐1 Yes
13 Other antiarrhythmic	☐0 No ☐1 Yes
14 Statin	☐0 No ☐1 Yes
15 Lipid lowering agent *(other than statin)*	☐0 No ☐1 Yes
16 Calcium channel blocker	☐0 No ☐1 Yes
17 Insulin	☐0 No ☐1 Yes
18 Oral diabetic agent	☐0 No ☐1 Yes
19 Anti-depressant	☐0 No ☐1 Yes

SEE ANNOTATION P.6

Subject Self-report of Symptoms

VAS (TYPE 3)

Time completed *(24 hour clock)*: ___ ___ : ___ ___ (00:00 to 23:59)

1 Dyspnea: VAS score: ___ ___ ___ mm

2 Global VAS score: ___ ___ ___ mm

SEE ANNOTATION P. 10

Core Lab Biomarker–Blood Assessments

ROSECORE (TYPE 3)

Test	Date of Test	Not Done	Reason Not Done (check only one)
Biomarkers—blood	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SEE ANNOTATION P. 10 ___ ___ : ___ ___ (00:00 to 23:59)	☐ →	☐1 Died → **Fill out Death form** ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐5 Discharged ☐7 Subject withdrew consent ☐99 Unknown/other

Core Lab Biomarker–Urine Assessments

RSURICOR (TYPE 3)

Test	Date of Test	Not Done	Reason Not Done (check only one)
Biomarkers—urine	SEE ANNOTATION P. 10 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	☐ →	☐1 Died → **Fill out Death form** ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐5 Discharged ☐7 Subject withdrew consent ☐99 Unknown/other

Treatment of Worsening or Persistent Heart Failure

WORSENIG(TYPE 3)

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

☐0 No

SEE ANNOTATION P. 10

☐1 Yes → **If Yes: Specify treatment** *(check all that apply)*:

- ☐ IV vasoactive agent for heart failure treatment
- ☐ Ultrafiltration
- ☐ Mechanical circulatory support
- ☐ Mechanical respiratory support

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Red Rose Substudy

REDSUB (TYPE 3)

☐ Subject not enrolled in Red Rose Substudy → **Stop. Do not complete the remainder of this page.**

SAME AS P. 7A

48 Hours Dyspnea VAS and Global VAS scores are documented on CRF page 13.

48 Hours Dyspnea VAS Supplemental Additional Informatio

VASUPPLE (TYPE 3)

Not Done	Position (Check only one)	Oxygen (Check only one)
☐ Dyspnea VAS not done	SAME AS P. 7A ☐1 < 20° ☐2 20°-59° ☐3 ≥ 60° ☐4 Ambulatory in room ☐99 Unknown	☐0 No ☐1 Yes → _____ Liters/min ☐99 Unknown

48 Hours Dyspnea — pDSS1 Complete for all subjects

PDSS (TYPE 3)

1 Was pDSS1 performed?

☐0 No → **If No: Specify reason** *(check only one)*: ☐1 Died ☐3 Due to oversight or technical problem ☐2 Too sick to perform ☐99 Unknown

☐1 Yes

2 Stage A score: _____ *(1-5)* OR ☐ Not done

SAME AS P. 7A

3 Stage B score: _____ *(6-10)*

4 Stage C score: _____ *(11-15)*

5 BP: ___ ___ / ___ ___ (systolic / diastolic) Stage D score: _____ *(16-20)* OR ☐ Stage D not done → **Reason** *(check only one)*:

☐1 Mechanical limitation ☐2 Unstable standing position ☐3 Oversight ☐4 Refused

48 Hours Fatigue as Worst Symptom

FATIGUE (TYPE 3)

☐ Not applicable *(not subject's Baseline worst symptom)*

SAME AS P. 7A

Fatigue VAS: _____ *(0-100)* OR ☐ Not done

48 Hours Body Swelling as Worst Symptom

SWELLING (TYPE 3)

☐ Not applicable *(not subject's Baseline worst symptom)*

SAME AS P. 7A

Body Swelling VAS: _____ *(0-100)* OR ☐ Not done

HEART FAILURE NETWORK **ROSE**

NODATA<ZYES>

72 Hours

FORM= 72 HOURS

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Subject Status

STATUS (TYPE 3)

Was assessment performed?

☐0 No → If No: Reason: ☐1 Subject discharged ☐2 Subject withdrew ☐3 Subject died ☐98 Other (specify): _____

☐1 Yes → If Yes: Assessment Date: ___ ___ ___ (day / month / year)

SEE ANNOTATION P. 8

Clinical Assessment from same daily assessment time

ASSESSMT(TYPE 3)

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	☐	___ ___ ___ bpm
2 Blood pressure (sitting or resting):	☐	___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mm Hg
3 SpO_2:	☐	___ ___ ___ %
4 Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg Assessed by (check only one): ☐1 Bed scale ☐2 Standing ☐99 Unknown Time assessed (24 hour clock): ___ ___ : ___ ___ (00:00 to 23:59)
5 Jugular venous pressure (check only one):	☐	☐1 < 8 cm ☐2 8–12 cm ☐3 13–16 cm ☐4 > 16 cm
6 Peripheral edema (check only one):	☐	☐0 None ☐1 1+ ☐2 2+ ☐3 3+ ☐4 4+
7 Orthopnea (check only one):	☐	☐0 None ☐3 Three or more pillows ☐1 One pillow (10 cm) ☐4 Not evaluable ☐2 Two pillows (20 cm)

SEE ANNOTATION P. 8

Labs—Chemistry from same daily assessment time

LABS(TYPE 4)PS

Assessment	Not Done	Value	Units
1 Sodium:	☐	_____	☐1 mmol/L ☐2 mEq/L
2 Potassium:	☐	_____	☐1 mmol/L ☐2 mEq/L
3 BUN/Urea:	☐	_____	☐1 mmol/L ☐3 mg/dL
4 Bicarbonate (total CO_2):	☐	_____	☐1 mmol/L ☐2 mEq/L
5 Creatinine:	☐	_____	☐3 mg/dL ☐4 µmol/L
6 Chloride:	☐	_____	☐1 mmol/L ☐2 mEq/L
7 Calcium:	☐	_____	☐1 mmol/L ☐2 mEq/L ☐3 mg/dL
8 Alkaline phosphatase:	☐	_____	☐5 U/L ☐6 IU/L

SEE ANNOTATION P. 8

RSFLUID(TYPE 3)

Fluid Input/Output from same daily assessment time

1 Total IV intake: ___ ___ ___ ___ mL

Total oral intake: ___ ___ ___ ___ mL

2 Total urine output: ___ ___ ___ ___ mL

Total non-urine output: ___ ___ ___ ___ mL

SEE ANNOTATION P. 8

NODATA<XYES>

72 Hours

Subject ID: RS ___ ___ ___ ___ site # ___ ___ ___ ___ Subject Initials: ___ ___ ___

MEDS(TYPE 4)PS

Medications

	72 Hours
1 ACE inhibitor	☐0 No ☐1 Yes
2 Angiotensin receptor blocker	☐0 No ☐1 Yes
3 Beta blocker	☐0 No ☐1 Yes
4 Aldosterone antagonist	☐0 No ☐1 Yes
5 Hydralazine	☐0 No ☐1 Yes
6 Nitrates *(long-acting)*	☐0 No ☐1 Yes
7 Aspirin *(if taken daily)*	☐0 No ☐1 Yes
8 Warfarin	☐0 No ☐1 Yes
9 Thienopyridine *(ticlopidine, clopidogrel)*	☐0 No ☐1 Yes
10 Alpha blocker	☐0 No ☐1 Yes
11 Digoxin	☐0 No ☐1 Yes
12 Amiodarone	☐0 No ☐1 Yes
13 Other antiarrhythmic	☐0 No ☐1 Yes
14 Statin	☐0 No ☐1 Yes
15 Lipid lowering agent *(other than statin)*	☐0 No ☐1 Yes
16 Calcium channel blocker	☐0 No ☐1 Yes
17 Insulin	☐0 No ☐1 Yes
18 Oral diabetic agent	☐0 No ☐1 Yes
19 Anti-depressant	☐0 No ☐1 Yes

SEE ANNOTATION P. 6

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Subject Self-report of Symptoms

Time completed *(24 hour clock)*: ___ ___ : ___ ___ (00:00 to 23:59)

VAS (TYPE 3)

1 Dyspnea: VAS score: ___ ___ ___ mm

2 Global VAS score: ___ ___ ___ mm

SEE ANNOTATION P. 10

Core Lab Biomarker–Blood Assessments

Test	Date of Test	Not Done	Reason Not Done *(check only one)*
Biomarkers—blood	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SEE ANNOTATION P. 10 ___ ___ : ___ ___ (00:00 to 23:59)	☐ →	☐1 Died → **Fill out Death form** ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐5 Discharged ☐7 Subject withdrew consent ☐99 Unknown/other

ROSECORE (TYPE 3)

Core Lab Biomarker–Urine Assessments

Test	Date of Test	Not Done	Reason Not Done *(check only one)*
Biomarkers—urine	SEE ANNOTATION P. 10 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	☐ →	☐1 Died → **Fill out Death form** ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐5 Discharged ☐7 Subject withdrew consent ☐99 Unknown/other

RSURICOR (TYPE 3)

Treatment of Worsening or Persistent Heart Failure

WORSENIG(TYPE 3)

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

SEE ANNOTATION P. 10

☐0 No

☐1 Yes → **If Yes: Specify treatment** *(check all that apply)*:

- ☐ IV vasoactive agent for heart failure treatment
- ☐ Ultrafiltration
- ☐ Mechanical circulatory support
- ☐ Mechanical respiratory support

HEART FAILURE NETWORK **ROSE**

NODATA<XYES>

Red Rose 72 Hours

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Red Rose Substudy

REDSUB (TYPE 3)

☐ Subject not enrolled in Red Rose Substudy → **Stop. Do not complete the remainder of this page.**

SAME AS P. 7A

72 Hours Dyspnea VAS and Global VAS scores are documented on CRF page 16.

72 Hours Dyspnea VAS Supplemental Additional Informatio

VASUPPLE (TYPE 3)

Not Done	Position (Check only one)	Oxygen (Check only one)
☐ Dyspnea VAS not done	☐1 < 20° ☐2 20°-59° ☐3 ≥ 60° ☐4 Ambulatory in room ☐99 Unknown	☐0 No ☐1 Yes → _____ Liters/min ☐99 Unknown

SAME AS P. 7A

72 Hours Dyspnea — pDSS1 Complete for all subjects

PDSS (TYPE 3)

1 Was pDSS1 performed?

☐0 No → **If No: Specify reason** *(check only one)*: ☐1 Died ☐2 Too sick to perform ☐3 Due to oversight or technical problem ☐99 Unknown

☐1 Yes

2 Stage A score: _____ *(1-5)* OR ☐ Not done

3 Stage B score: _____ *(6-10)*

SAME AS P. 7A

4 Stage C score: _____ *(11-15)*

5 BP: ___ ___ / ___ ___ (systolic / diastolic) Stage D score: _____ *(16-20)* OR ☐ Stage D not done → **Reason** *(check only one)*: ☐1 Mechanical limitation ☐2 Unstable standing position ☐3 Oversight ☐4 Refused

72 Hours pDSS2

PDSS2 (TYPE 3)

STAGEESC<I:2>

Stage E score: _____ *(21-25)* OR ☐ Not done

STAGEEND<XYES>

72 Hours Fatigue as Worst Symptom

FATIGUE (TYPE 3)

☐ Not applicable *(not subject's Baseline worst symptom)*

Fatigue VAS: _____ *(0-100)* OR ☐ Not done

SAME AS P. 7A

72 Hours Body Swelling as Worst Symptom

SWELLING (TYPE 3)

☐ Not applicable *(not subject's Baseline worst symptom)*

Body Swelling VAS: _____ *(0-100)* OR ☐ Not done

SAME AS P. 7A

HFN_ROSE V.3.1_15Aug2012

HEART FAILURE NETWORK **ROSE**

NODATA<XYES>

Red Rose 72 Hours

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Red Rose 6-Minute Walk Test (6MWT)

WALKTEST (TYPE 4)

☐ Subject not enrolled in Red Rose Substudy → **Stop. Do not complete the remainder of this page** NORSWLK<XYES>

1 Was walk performed? WALK<XYESNO>

WLKND<HFNOWL>

☐$_0$ No → **Specify reason** *(check only one)*: ☐$_1$ Died → **Fill out Death form**

WLKND<HFNOWL>
See addition below

☐$_2$ Too sick to perform
☐$_3$ Unwilling to perform test but subjectively able
☐$_4$ Not done due to oversight
☐$_5$ Cannot walk for technical reasons *(e.g., amputee, orthopedic)*
☐ Neurological reasons

*HFNOWL
Add: 7=Did not reach Stage E

7 Did not reach Stage E

☐$_{99}$ Unknown/other

☐$_1$ Yes → **If Yes: Complete below.** WALKDT

2 Date of assessment: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)

3 Pre- and post-walk data:

	Heart Rate	Blood Pressure
Pre-walk	PREHRATE<I:3> ___ bpm	PREBPSYS<I:3> / PREBPDIA<I:3> ___ / ___ mmHg (systolic / diastolic)
Post-walk	PSTHRATE<I:3> ___ bpm	PSTBPSYS<I:3> / PSTBPDIA<I:3> ___ / ___ mmHg (systolic / diastolic)

4 Distance walked: _____ meters WLKDIST<I:3>

5 Did the subject complete the 6-minute walk?

☐$_0$ No → **If No: Duration of walk:** ___ (minutes) / ___ ___ (seconds) WLKMIN<I:3> WLKSEC<I:3>

☐$_1$ Yes WLKCOMPL<XYESNO>

6 Did the subject experience any of the following symptoms *(check all that apply)*:

☐ None WLKNONE<XYES>
☐ Angina WLKANGIN<XYES>
☐ Lightheaded WLKLGTHD<XYES>
☐ Syncope WLKSYNCP<XYES>
☐ Dyspnea WLKDYSPN<XYES>
☐ Fatigue WLKFATIG<XYES>
☐ Chest pain WLKCHTPN<XYES>
☐ Leg or joint pain WLKLEGPN<XYES>
☐ Instability WLKINSTA<XYES>
☐ Other *(specify)*: _____ WLKOTH<XYES> WLKOTHSP<V:100>

HEART FAILURE NETWORK **ROSE**

Cumulative Urinary Sodium Excretion Core Lab

NODATA<XYES>

FORM= UNAVCORE

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

UNaV Collection for Core Lab

Scheduled	Date and Time of Collection	Not Done	Reason Not Done (check only one)
1= 24 Hours	RSUNAVDT UNAVSCHD<RSSCHD> ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) RSUNAVTM ___ ___ : ___ ___ (00:00 to 23:59) UNAVOLM<F:9:3> See item in 4th box	RSUNAVND<XYES> ☐ →	RSUNACOR (TYPE 4)PS ☐1 Died → **Fill out Death form** ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐5 Discharged ☐7 Subject withdrew consent ☐99 Unknown/other UNAVREA<RSUNAV> NOTE: 96= Not Applicable Is part of codelist-see 4th box
2= 48 Hours	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	☐ →	☐1 Died → **Fill out Death form** ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐5 Discharged ☐7 Subject withdrew consent ☐99 Unknown/other
3= 72 Hours	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	☐ →	☐1 Died → **Fill out Death form** ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐5 Discharged ☐7 Subject withdrew consent ☐99 Unknown/other

Additional UNaV Collection for Core Lab If ≥ 6 hour delay between Randomization and infusion start

4= 72 Hours to end of infusion *(when applicable)*	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) *Volume collected: ___ ___ ___ ___ mL	☐ →	☐96 **Not applicable** *(study drug started within 6 hours of Randomization)* ☐1 Died → **Fill out Death form** ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐5 Discharged ☐7 Subject withdrew consent ☐99 Unknown/other

* Volume collected = The **actual** amount of urine collected during the interval from 72 hours post-Randomization to end of study drug infusion.

HEART FAILURE NETWORK **ROSE**

NODATA<XYES>

Day 7 (or Day of Discharge on Day 4, 5, 6)

FORM= DAY 7

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Subject Status

STATUS (TYPE 3)

Was assessment performed?

☐0 No → If No: Reason: ☐1 Subject discharged ☐2 Subject withdrew ☐3 Subject died ☐98 Other (specify): _____

☐1 Yes → If Yes: Assessment date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

SEE ANNOTATION P. 8

Clinical Assessment from same daily assessment time

ASSESSMT(TYPE 3)

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	☐	___ ___ ___ bpm
2 Blood pressure (sitting or resting):	☐	___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mm Hg
3 SpO_2:	☐	___ ___ ___ %
4 Weight: SEE ANNOTATION P. 8	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg Assessed by (check only one): ☐1 Bed scale ☐2 Standing ☐99 Unknown Time assessed (24 hour clock): ___ ___ : ___ ___ (00:00 to 23:59)
5 Jugular venous pressure (check only one):	☐	☐1 < 8 cm ☐2 8–12 cm ☐3 13–16 cm ☐4 > 16 cm
6 Peripheral edema (check only one):	☐	☐0 None ☐1 1+ ☐2 2+ ☐3 3+ ☐4 4+
7 Orthopnea (check only one):	☐	☐0 None ☐3 Three or more pillows ☐1 One pillow (10 cm) ☐4 Not evaluable ☐2 Two pillows (20 cm)

Labs—Chemistry from same daily assessment time

LABS(TYPE 4)PS

Assessment	Not Done	Value	Units
1 Sodium:	☐	_____	☐1 mmol/L ☐2 mEq/L
2 Potassium:	☐	_____	☐1 mmol/L ☐2 mEq/L
3 BUN/Urea:	☐	_____	☐1 mmol/L ☐3 mg/dL
4 Bicarbonate (total CO_2):	☐	_____	☐1 mmol/L ☐2 mEq/L
5 Creatinine:	☐	_____	☐3 mg/dL ☐4 µmol/L
6 Chloride:	☐	_____	☐1 mmol/L ☐2 mEq/L
7 Calcium: SEE ANNOTATION P. 8	☐	_____	☐1 mmol/L ☐2 mEq/L ☐3 mg/dL
8 Alkaline phosphatase:	☐	_____	☐5 U/L ☐6 IU/L

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HEART FAILURE NETWORK **ROSE**

NODATA<XYES>

Day 7 (or Day of Discharge on Day 4, 5, 6)

Subject ID: RS ___ ___ ___ ___ (site # / subj #) Subject Initials: ___ ___ ___

MEDS(TYPE 4)PS

Medications

	Day 7 (or Day of Discharge on Day 4, 5, 6)
1 ACE inhibitor	☐0 No ☐1 Yes
2 Angiotensin receptor blocker	☐0 No ☐1 Yes
3 Beta blocker	☐0 No ☐1 Yes
4 Aldosterone antagonist	☐0 No ☐1 Yes
5 Hydralazine	☐0 No ☐1 Yes
6 Nitrates *(long-acting)*	☐0 No ☐1 Yes
7 Aspirin *(if taken daily)*	☐0 No ☐1 Yes
8 Warfarin	☐0 No ☐1 Yes
9 Thienopyridine *(ticlopidine, clopidogrel)*	☐0 No ☐1 Yes
10 Alpha blocker	☐0 No ☐1 Yes
11 Digoxin	☐0 No ☐1 Yes
12 Amiodarone	☐0 No ☐1 Yes
13 Other antiarrhythmic	☐0 No ☐1 Yes
14 Statin	☐0 No ☐1 Yes
15 Lipid lowering agent *(other than statin)*	☐0 No ☐1 Yes
16 Calcium channel blocker	☐0 No ☐1 Yes
17 Insulin	☐0 No ☐1 Yes
18 Oral diabetic agent	☐0 No ☐1 Yes
19 Anti-depressant	☐0 No ☐1 Yes

SEE ANNOTATION P. 6

HEART FAILURE NETWORK **ROSE**

NODATA<XYES>

Day 7
(or Day of Discharge on Day 4, 5, 6)

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Core Lab Biomarker–Blood Assessments

Test	Date of Test	Not Done	Reason Not Done (check only one)
Biomarkers—blood	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) SEE ANNOTATION P. 7 ___ ___ : ___ ___ (00:00 to 23:59)	☐ →	ROSECORE (TYPE 3) ☐1 Died → Fill out Death form ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐5 Discharged ☐7 Subject withdrew consent ☐99 Unknown/other

Core Lab Biomarker–Urine Assessments

Test	Date of Test	Not Done	Reason Not Done (check only one)
Biomarkers—urine	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) SEE ANNOTATION P. 7 ___ ___ : ___ ___ (00:00 to 23:59)	☐ →	RSURICOR (TYPE 3) ☐1 Died → Fill out Death form ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐5 Discharged ☐7 Subject withdrew consent ☐99 Unknown/other

HEART FAILURE NETWORK **ROSE**

NODATA<ZYES>

FORM=INDEX HOSPITALIZATIO

Index Hospitalization

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Study Drug Administration

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

☐0 No → If No: Reason *(check only one)*: ☐1 Subject refused
☐2 Physician decision
☐3 Death → **Complete Death form**
SDREASON<HFDRUG>
See addition below
☐4 Access complications
☐98 Other *(specify)*: _____ SDREASP <V:50>

☐1 Yes → If Yes: Complete all questions and Study Drug Administration Log, page 21.

2 Was study drug unblinded? UNBLIND<XYESNO>

☐0 No
☐1 Yes → If Yes: Date unblinded: ___/___/___ (day / month / year) UNBLNDDT
Reason: _____ UNBLDSP <V:100>

3 Within the first 72 hours did the subject receive open label nesiritide or dopamine? OPNLABL<XYESNO>

☐0 No
☐1 Yes → If Yes: **Complete Intravenous Vasoactive Infusions form, page 23**

*HFDRUG
Add: 4=Access complications

HEART FAILURE NETWORK **ROSE**

NODATA<ZYES>

This is a repeating page

Index Hospitalization

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Study Drug Administration Log

Record study drug infusion start and stop dates and times. Record new entry for each time infusion stops for more than 3 hours and then is restarted.

STDRGLOG (TYPE 4)R

	Start Date and Time	Infusion Rate (cc/hour)	Stop Date and Time	Primary Reason for Stopping (check only one) SDAREA<RSSDRE>
1	SDALOGNM<I:3> SDASRTDT<DATE> ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) SDASRTTM<DATETIME>	_____ cc/hr SDARATE<F:9:3>	SDASTPDT<DATE> ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) SDASTPTM<DATETIME>	☐1 Completed per protocol ☐2 Significant hypotension ☐3 Significant tachycardia ☐4 MD decision ☐5 Equipment access problem ☐6 Withdrew consent ☐7 Death ☐98 Other
2	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	_____ cc/hr	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	☐1 Completed per protocol ☐2 Significant hypotension ☐3 Significant tachycardia ☐4 MD decision ☐5 Equipment access problem ☐6 Withdrew consent ☐7 Death ☐98 Other
3	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	_____ cc/hr	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	☐1 Completed per protocol ☐2 Significant hypotension ☐3 Significant tachycardia ☐4 MD decision ☐5 Equipment access problem ☐6 Withdrew consent ☐7 Death ☐98 Other

HEART FAILURE NETWORK **ROSE**

NODATA<ZYES>

Optimal Diuretic Dose

Subject ID: RS ___ ___ ___ - ___ ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Optimal Diuretic Dose

OPTDOSE (TYPE 1)

OPTDIUST<XYESNO>

1 Was subject started on optimal diuretic dose per protocol?

OPNEVER<RSOPNO>

☐0 No → Check only one: OPTDIU<RSOPDI>

☐1 Diuretics never started → Check **primary** reason: ☐1 Withdrew ☐3 Patient improvement *(diuretics not required)* ☐2 Died ☐4 Patient condition worsening ☐98 Other

☐2 Alternative dose prescribed → Date and time started: ___ ___ (day) ALTERTM ___ ___ : ___ ___ (00:00 to 23:59)

Check **primary** reason: ☐1 Hypotension ☐4 Physician decision ☐2 Over diuresis ☐5 SAE ☐3 Accidental/technical problem

OPALTREA<RSALT>

OPTDIUTM

☐1 Yes → Date and time started: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

OPTDOSE 2 (TYPE 4) PS

2= **2** Was IV diuretic dose changed between Randomization and 24 Hours?

☐0 No OPTDIUCH<XYESNO>

☐1 Yes → Check all that apply: ALL<XYES>

OPTDEC<XYES> ☐ Decreased → Check all that apply:

WRENAL DCOVDIU

☐ Significant hypotens DCHYPO ☐ Worsening renal failure DCFAIL ☐ Over diuresis

DCSUCCES ☐ MD decision due to treatment success ☐ MD decision due to treatment failure DCOTHDIU<XYES

OPTINC<XYES> ☐ Increased → Check a INPWHF ☐ Persistent or worsening heart failure ☐ Other INCROTH<XYES>

☐ Stopped → Check all that apply:

STWRENAL STDCHG

OPTSTOP<XYES> ☐ Significant hyp STHYPO ☐ Worsening renal failure ☐ P…charge

STSUCCES ☐ MD decision due to treatment … STACCESS …ss problem ☐ Death STDEATH

STFAIL ☐ MD decision due to treatment failure ☐ Withdrew consent ☐ Other STOTHDIU

3= **3** Was IV diuretic dose changed between 24 Hours and 48 Hours?

☐0 No

☐1 Yes → Check all that apply:

OPTIMEPT<RSOPTM>
2= RANDOMIZATION TO 24 HOURS
3= 24 HOURS TO 48 HOURS
4= 48 HOURS TO 72 HOURS

☐ Decreased → Check all that apply:

☐ Significant hypotension ☐ Over diuresis

☐ MD decision due to treatment success ☐ MD decision due to treatment failure ☐ Other

☐ Increased → Check all that apply: ☐ Persistent or worsening heart failure ☐ Other

☐ Stopped → Check all that apply:

☐ Significant hypotension	☐ Worsening renal failure	☐ Preparing for discharge
☐ MD decision due to treatment success	☐ Access problem	☐ Death
☐ MD decision due to treatment failure	☐ Withdrew consent	☐ Other

4= **4** Was IV diuretic dose changed between 48 Hours and 72 Hours?

☐0 No

☐1 Yes → Check all that apply:

☐ Decreased → Check all that apply:

☐ Significant hypotension ☐ Over diuresis

☐ MD decision due to treatment success ☐ MD decision due to treatment failure ☐ Other

☐ Increased → Check all that apply: ☐ Persistent or worsening heart failure ☐ Other

☐ Stopped → Check all that apply:

☐ Significant hypotension	☐ Worsening renal failure	☐ Preparing for discharge
☐ MD decision due to treatment success	☐ Access problem	☐ Death
☐ MD decision due to treatment failure	☐ Withdrew consent	☐ Other

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Diuretics timeframe
RSTIMEPT<RSTIME>
1=At Randomization
2=Randomization to 24 HRS
3=24 to 48 HRS
4=48 to 72 HRS
5=Discharge

HEART FAILURE NETWORK **ROSE**

Index Hospitalization/Medications

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

NODATA<ZYES>

RSNADIUR<XYES> RSDAYDIU (TYPE 4)PS

Diuretic

SDAILY<HFDIUR>

RSDIUR<XYESNO>
RSBOLUS<XYES>
RSIV<XYES>
RSPO<XYES>

RSBOLVAL<F:9:3>
RSIVVAL<F:9:3>
RSPOVAL<F:9:3>

Medication	At Randomization (prior 24 hrs)	Randomization to 24 Hrs	24 to 48 Hrs OR ☐ NA	48 to 72 Hrs OR ☐ NA	Discharge OR ☐ NA (prescribed dose)
1 Furosemide	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg
2 Torsemide	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg
3 Bumetanide	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg
4 Metolazone	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg
5 HCTZ	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg
6 Chlorothiazide (Diuril)	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐$_0$ No ☐$_1$ Yes → Route: Total daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg

HEART FAILURE NETWORK **ROSE**

Index Hospitalization Medications

NODATA<ZYES>

Subject ID: RS ___ ___ ___ - ___ ___ ___ ___ (site # / subject #) Subject Initials: ___

VASOINFU(TYPE 2)PS

Intravenous Vasoactive Infusions

	VASODRUG<HFVASO>	VASOANS<XYESNO>	Start Date and Time (VASTARDT<DATE>, VASTARTM<DATETIME>)	Permanent Stop Date and Time OR ☑ if Ongoing at Discharge (VASTOPDT<DATE>, VASTOPTM<DATETIME>, VASOCONT<XYES>)
1=	1 Dobutamine	☐0 No ☐1 Yes →	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) ☐1 Ongoing at Discharge
2=	2 Dopamine *(open label)*	☐0 No ☐1 Yes →	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) ☐1 Ongoing at Discharge
3=	3 Milrinone	☐0 No ☐1 Yes →	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) ☐1 Ongoing at Discharge
4=	4 Nitroglycerin	☐0 No ☐1 Yes →	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) ☐1 Ongoing at Discharge
5=	5 Nitroprusside	☐0 No ☐1 Yes →	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) ☐1 Ongoing at Discharge
6=	6 Nesiritide *(open label)*	☐0 No ☐1 Yes →	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) ☐1 Ongoing at Discharge
7=	7 Other inotrope/ vasopressor	☐0 No ☐1 Yes →	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) ☐1 Ongoing at Discharge

HEART FAILURE NETWORK **ROSE**

Index Hospitalization Discharge

NODATA<ZYES>

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Hospital Discharge

DISCHARG (TYPE 1)

1 Was the subject discharged alive? DCALIVE <XYESNO>

☐0 No → If No: Complete Death form

☐1 Yes → If Yes: Date of discharge: ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year) DISCHDT

Discharge to *(check only one)*: DCHGLOC<HFDCHG>

- ☐1 Home
- ☐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>	☐0 No	☐1 Yes
Right heart catheterization: PRORCATH<XYESNO>	☐0 No	☐1 Yes
PCI: PROPCI<XYESNO>	☐0 No	☐1 Yes
Coronary artery bypass graft *(CABG)*: PROCABG<XYESNO>	☐0 No	☐1 Yes
Pacemaker without ICD: PRONOICD<XYESNO>	☐0 No	☐1 Yes → If Yes:
Check only one: ☐1 Single ☐2 Dual ☐3 Biventricular PROCPACE<HFCHBR>		
ICD: PROCICD<XYESNO>	☐0 No	☐1 Yes → If Yes:
Check only one: ☐1 Single ☐2 Dual ☐3 Biventricular PROCEICD<HFCHBR>		
Intra-aortic balloon pump placement: PROIABP<XYESNO>	☐0 No	☐1 Yes
Ultrafiltration: PROULTRA<XYESNO>	☐0 No	☐1 Yes
Dialysis: PRODIAL<XYESNO>	☐0 No	☐1 Yes
Atrial arrhythmia ablation: PROBLAT<XYESNO>	☐0 No	☐1 Yes
CPR: PROCPR<XYESNO>	☐0 No	☐1 Yes
Cardioversion: PROCARDI<XYESNO>	☐0 No	☐1 Yes
LVAD placement: PROLVAD<XYESNO>	☐0 No	☐1 Yes → If Yes:
Date: ___ ___ (day) / ___ ___ (month) / ___ ___ ___ ___ (year) PRLVADDT		
Heart transplant: PROHTRAN<XYESNO>	☐0 No	☐1 Yes → If Yes:
Date: ___ ___ (day) / ___ ___ (month) / ___ ___ ___ ___ (year) PRHTRDDT		
Thoracentesis PROTHO<XYESNO>	☐0 No	☐1 Yes
Paracentesis PROPAR<XYESNO>	☐0 No	☐1 Yes

Record all SAEs on Serious Adverse Event form.

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HEART FAILURE NETWORK **ROSE**

NODATA<ZYES>

FORM=TERMINATION

Day 60
Study Completion/End of Study

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Study Termination/Completion

RSTERM (TYPE 1)

Did the subject complete the study *(through Day 60)*?

☐ 0 No → If No: Date of termination/last contact: ___/___/___ (day/month/year) RSTERMDT

Reason for termination *(check only one)*:

RSCOMPLE <XYESNO>

- ☐ 1 Subject lost to follow-up
- ☐ 2 Adverse event
- ☐ 3 Subject withdrew consent
- ☐ 4 Subject died → **Complete Death form** *(termination date above should be date of death)*
- ☐ 98 Other *(specify)*: _____

RSTERMRE<HFTERM>

RSTERMSP <V:100>

☐ 1 Yes → If Yes: Date of Day 60 phone call: ___/___/___ (day/month/year) RS6DTDT

Endpoint/Safety Review

SAFETY (TYPE 1)

1 How many serious adverse events did subject have? SAENUMB<I:3>
_____ → 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?
_____ → Record all on Unscheduled Clinic/Emergency Department Visits form ERNUMB<I:3>

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.

Principal Investigator: _____ INVSIG <XYES> _____ Date: ___/___/___ INVSIGDT
Signature of Investigator (day/month/year)

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HEART FAILURE NETWORK **ROSE**

FORM= REHOSPITALIZATON

THIS IS A REPEATING PAGE

NODATA<ZYES>

Re-Hospitalization

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Hospitalization ≥ 24 Hours (Non-protocol)

REHOSPTL (TYPE 4)

1 Admission date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) REHOSPDT

2 Discharge date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Remains hospitalized REDCHGDT 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
- ☐ Angina REANGINA
- ☐ MI REMI
- ☐ Atrial arrhythmia REATRIAL
- ☐ Ventricular arrhythmia REARRHY
- ☐ Chest pain RECTPAIN
- ☐ Sudden death with resuscitation RESUSCIT
- ☐ Cerebral vascular accident *(CVA)*/stroke RECVA
- ☐ Peripheral vascular disease REPVD
- ☐ Syncope RESYNCOP
- ☐ Hypotension REHYPOTN
- ☐ Elective cardiac procedure RECARDPR
- ☐ Other cardiovascular REOTCARD
- ☐ Renal failure RERENAL
- ☐ Worsening renal function REWORSE
- ☐ Hyperkalemia REKALEMA
- ☐ Infection REINFECT
- ☐ Elective non-cardiac procedure
- ☐ Other non-cardiovascular RENON REOTNON

PROCEDUR (TYPE 4)

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

Left heart catheterization:	☐ 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: SEE ANNOTATION P.24	☐ 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)		
Thoracentesis	☐ 0 No	☐ 1 Yes
Paracentesis	☐ 0 No	☐ 1 Yes

HEART FAILURE NETWORK **ROSE**

NODATA<ZYES>

FORM= UNSCHEDULED

THIS IS A REPEATING PAGE

Unscheduled Clinic OR Emergency Department Visit

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

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

UNSCHEDL (TYPE 4)

1 Visit date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) UNSCHEDT

2 Visit type: ☐1 Unscheduled clinic ☐2 Emergency department ☐3 Observational unit *(short stay)* VISTYPE<HFTYPE>

3 Was this visit related to heart failure? HFVISIT<XYESNO>

☐0 No

☐1 Yes → Were there signs or symptoms indicating decompensated heart failure: ☐0 No ☐1 Yes DECOMPHF<XYESNO>

Did subject receive IV treatment for heart failure: ☐0 No ☐1 Yes IVFORHF<XYESNO>

HEART FAILURE NETWORK **ROSE**

NODATA<ZYES>

FORM=DEATH FORM

Death

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

Death

DEATHLOC<HFLOCA>

DEATHPAG (TYPE 1)

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

2 **Date and time of death:** ___ ___ / ___ ___ ___ / DEATHDT ___ ___ : ___ ___ DEATHTM
(day / month / year / 00:00 to 23:59)

3 **Cause of death** *(check only one)*: DEATHCAU<HFDEAT>

- ☐1 Heart failure/pump failure
- ☐2 Sudden death
- ☐3 Myocardial infarction
- ☐4 Cardiac procedure
- ☐5 Other cardiac
- ☐6 Cerebral vascular accident *(CVA)*/stroke
- ☐7 Renal
- ☐8 Other non-cardiac
- ☐9 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.25

Principal Investigator: _____ (Signature of investigator) Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Submit HFN EE form to DCRI for any death

HFN_ROSE V.3.1_15Aug2012

HEART FAILURE NETWORK **ROSE**

FORM=SAE

NODATA<ZYES>

Serious Adverse Events

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

THIS IS A REPEATING PAGE

Serious Adverse Events

Did the subject have any serious adverse event(s)? ☐0 No ☐1 Yes → If Yes: Provide details below:

ADVERSE (TYPE 4) R

#	Is this Event on the HFnet Event List?	Onset Date and Time	End Date and Time OR ☑ if Ongoing	Was Subject Hospitalized?	Outcome (check only one)	Maximum Intensity (check only one)	Action Taken with Study Drug/ Treatment (check only one)	Related to Study Drug/ Treatment (check only one)	Was this Event Unexpected Per Product Labeling?
1	☐0 No → Name of event: ☐1 Yes → HFN Code #: ___	___/___/___ day month year ___:___ 00:00 to 23:59	___/___/___ day month year ___:___ 00:00 to 23:59 OR ☐1 Ongoing	☐0 No ☐1 Yes	☐1 Resolved ☐2 Resolved with sequelae ☐3 Unresolved ☐4 Death	☐1 Mild ☐2 Moderate ☐3 Severe	☐0 None ☐1 Interrupted ☐2 Discontinued ☐3 Dosage changed	☐1 Not a reasonable possibility ☐2 Reasonable possibility*	☐0 No ☐1 Yes*
2	☐0 No → Name of event: ☐1 Yes → HFN Code #: ___	___/___/___ day month year ___:___ 00:00 to 23:59	___/___/___ day month year ___:___ 00:00 to 23:59 OR ☐1 Ongoing	☐0 No ☐1 Yes	☐1 Resolved ☐2 Resolved with sequelae ☐3 Unresolved ☐4 Death	☐1 Mild ☐2 Moderate ☐3 Severe	☐0 None ☐1 Interrupted ☐2 Discontinued ☐3 Dosage changed	☐1 Not a reasonable possibility ☐2 Reasonable possibility*	☐0 No ☐1 Yes*
3	☐0 No → Name of event: ☐1 Yes → HFN Code #: ___	___/___/___ day month year ___:___ 00:00 to 23:59	___/___/___ day month year ___:___ 00:00 to 23:59 OR ☐1 Ongoing	☐0 No ☐1 Yes	☐1 Resolved ☐2 Resolved with sequelae ☐3 Unresolved ☐4 Death	☐1 Mild ☐2 Moderate ☐3 Severe	☐0 None ☐1 Interrupted ☐2 Discontinued ☐3 Dosage changed	☐1 Not a reasonable possibility ☐2 Reasonable possibility*	☐0 No ☐1 Yes*
4	☐0 No → Name of event: ☐1 Yes → HFN Code #: ___	___/___/___ day month year ___:___ 00:00 to 23:59	___/___/___ day month year ___:___ 00:00 to 23:59 OR ☐1 Ongoing	☐0 No ☐1 Yes	☐1 Resolved ☐2 Resolved with sequelae ☐3 Unresolved ☐4 Death	☐1 Mild ☐2 Moderate ☐3 Severe	☐0 None ☐1 Interrupted ☐2 Discontinued ☐3 Dosage changed	☐1 Not a reasonable possibility ☐2 Reasonable possibility*	☐0 No ☐1 Yes*

AENUMBER<I:3>

EVENT<XYESNO>

AETERM <V:100>

AEONSTDT <DATE>

AEONSTTM <DATETIME>

AEENDDT<DATE>

AEENDTM<DATETIME>

ANYAE<XYESNO>

AEOUTCM <HFOUTC>

AEINTENS <XINTNS>

AEACTION <HFACTN>

AERELAT <HFRELAT>

AEUNEXPT <XYESNO>

HFNCODE<I:3>

See attached for Codelist for batchloading Into TYPE 0 panel

AECODTXT <V:100>

(DERIVED) All MEDRA coding from this field

AECONT<XYES>

AEHOSP <XYESNO>

Coding is performed in the CLINPLUS system PROJ_HFN/CODING_AE table

LLTERM
LLTCODE
PTERM
PTCODE
HLTERM
HLTCODE
HLGTERM
HLGTCOD
SOCTERM
SOCCODE

Conversion procedures on AETERM and HFNCODE to update all coding items

Investigator's Signature

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

SEE ANNOTATION P. 25

SIGNATUR (TYPE 4)

Principal Investigator: _____ Date: ___/___/___
Signature of Investigator (day / month / year)

***If event results in death, or if a reasonable possibility of related to study drug *and* is unexpected, complete HFN EE form and submit to DCRI Safety Surveillance.**

HEART FAILURE NETWORK **ROSE**

NODATA<ZYES>

6 Month Follow-up

FORM=6 MONTH FOLLOW UP

Subject ID: RS ___ ___ ___ - ___ ___ ___ (site # / subject #) Subject Initials: ___ ___ ___

6 Month Status

FU6MSTA<RSFUP>

FU6MON (TYPE 1)

Status of subject at 6 month follow-up:

☐ 1 Alive → **Date of last contact:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

FULSTCDT<DATE>

☐ 2 Dead → **Date of death:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

☐ 99 Unknown/unable to contact

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.25

Principal Investigator: _____ (Signature of Investigator) **Date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

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

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=	Bradyarrhythmia
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

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

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=	Dizzziness
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