HEART FAILURE NETWORK

CARRESS

PROTOCOL=HFN_CARRESS
STUDYBOOK=DATA_FORMS
FORM= BASELINE

NODATA<ZYES>

Baseline

SUBJNO

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

NOTE: Enrollment- see below

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 ☐ Asian ☐ Black ☐ Native Hawaiian or other Pacific Islander ☐ White/Caucasian

AMERIND<XYES> ASIAN<XYES> BLACK<XYES> NATHWN<XYES> WHITE<XYES>

Eligibility

ELIGIBLE (TYPE 1)

Did the subject meet all eligibility criteria? INCL1<I:3> INCL2<I:3> INCL3<I:3>

☐ 0 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> ☐ 0 No ☐ 1 Yes WAIVER <XYESNO>

☐ 1 Yes

PRECREAT (TYPE 2)PS

Pre-Randomization Creatinine

Assessment	Date of Assessment	Location	Value	Units
1 Nadir creatinine *(within 6 weeks prior to randomization)*	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Not done	☐ 1 Inpatient ☐ 2 Outpatient	_____	☐ 3 mg/dL ☐ 4 µmol/L
2 Qualifying creatinine *(most recent)*	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Not done	☐ 1 Inpatient ☐ 2 Outpatient	_____	☐ 3 mg/dL ☐ 4 µmol/L

CREAASST<CRCREA>
1=
CREADT
CREAND<XYES>
CREALOC<CRLOCN>
CREATVAL<F:9:3>
CREAUNIT <HFLABU>
2=

Hospitalization

INITHOSP (TYPE 1)

Date and time of initial presentation to acute care facility: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

PRESENDT<DATE> PRESENTM<DATETIME>

Enroll panel will contain:
SUBJNO: derived from 'CR'll INVSITE ll '-'ll PATID
INITIALS V:3
RANDTM<DATETIME>
RANDDT<DATE>
CARRARM<CRCARM>
1=PHARMACOLOGIC CARE
2=ULTRAFILTRATION

WHITE and YELLOW—Duke Clinical Research Institute • PINK—retain at site

HEART FAILURE NETWORK **CARRESS**

NODATA<ZYES>

Baseline

Subject ID: CR ___ ___ ___ - ___ ___ ___ (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:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) LVASSDT

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

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

Vessels with > 70% stenosis *(check all that apply)*: ☐ LM ☐ LAD ☐ LCX ☐ RCA RCA<XYES>

- PTCI<XYES> ☐ Percutaneous transluminal coronary intervention *(PTCI)* → **Date of most recent:** ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) PTCIDT
- CABG<XYES> ☐ Coronary artery bypass graft (CABG) → **Date of most recent:** ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) CABGDT

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>

HEART FAILURE NETWORK **CARRESS**

NODATA<ZYES>

Baseline

Subject ID: CR ___ ___ ___ - ___ ___ ___ (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

NONSURG,MITSURG, AORSURG, TRISURG, PULSURG All <XYES>

8 Hypertension: HYPRTESN<XYESNO> ☐0 No ☐1 Yes

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: ☐1 New onset ☐2 Paroxysmal ☐3 Persistent ☐4 Permanent FIBFLUTR<HFFIBF>

SUSVTVF<XYES> ☐ Sustained VT or VF

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

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

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: ☐1 Insulin treated ☐2 Non-insulin medically treated ☐3 Diet only DIABTYPE<HFDIAB>

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: ___ (day) / ___ (month) / ___ ___ ___ ___ (year) TRANSPDT

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

HEART FAILURE NETWORK **CARRESS**

NODATA<ZYES>

Baseline

Subject ID: CR ___ ___ ___ - ___ ___ ___ Subject Initials: ___ ___ ___
site # visit#

MEDS(TYPE 4)PS

Pre-Hospitalization Medications

	HFMEDS<HFHFMD>	MEDSANS<XYESNO>	*If No: Documented Evidence of Contraindication MEDSCONT<XYNUNK>
1=	**1** ACE inhibitor	☐0 No* ☐1 Yes	☐0 No ☐1 Yes ☐99 Unknown
2=	**2** Angiotensin receptor blocker	☐0 No* ☐1 Yes	☐0 No ☐1 Yes ☐99 Unknown
3=	**3** Beta blocker	☐0 No* ☐1 Yes	☐0 No ☐1 Yes ☐99 Unknown
4=	**4** Aldosterone antagonist	☐0 No* ☐1 Yes	☐0 No ☐1 Yes ☐99 Unknown
5=	**5** Hydralazine	☐0 No* ☐1 Yes	☐0 No ☐1 Yes ☐99 Unknown
6=	**6** Nitrates *(long-acting)*	☐0 No* ☐1 Yes	☐0 No ☐1 Yes ☐99 Unknown
7=	**7** Aspirin *(if taken daily)*	☐0 No* ☐1 Yes	☐0 No ☐1 Yes ☐99 Unknown
8=	**8** Warfarin	☐0 No* ☐1 Yes	☐0 No ☐1 Yes ☐99 Unknown
9=	**9** Thienopyridine *(ticlopidine, clopidogrel)*	☐0 No ☐1 Yes	SUPPRESS MEDRAND DISCHND MEDDSCG
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** Antidepressant	☐0 No ☐1 Yes	DIURETIC (TYPE 4)PS

Pre-Hospitalization Oral Diuretics

	Medication	DIURANS<HFRESP>	Average Total Daily Dose	Units
	DIUMEDS<HFDIUR>			
1=	**1** Furosemide	☐0 No ☐1 Yes →	DIURDOSE<F:9:3>	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

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

6=CHLOROTHIAZIDE (P. 17 AND 18 ONLY)

WHITE and YELLOW—Duke Clinical Research Institute • PINK—retain at site

HEART FAILURE NETWORK **CARRESS**

NODATA<ZYES>

Baseline

Subject ID: CR ___ ___ ___ - ___ ___ ___ (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 ECGNOTDN<XYES>

ECGDT

ECGHRATE<I:3>

2 Rate: ___ ___ ___ bpm

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

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

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

ECGQRS<I:3>

ASSESSMT(TYPE 3)

Heart Failure Clinical Assessment At Randomization

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting): HRNOTDN<XYES>	☐	HRATE<I:3> ___ ___ ___ bpm
2 Blood pressure (sitting or resting): BPNOTDN<XYES>	☐	BPSYS <I:3> BPDIA<I:3> ___ ___ ___ / ___ ___ ___ mmHg (systolic / diastolic)
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>	☐	WEIGHT <F:9:3> ___ ___ ___ . ___ ☐1 lb ☐2 kg WTUNITS<XWGTU>
6 Jugular venous pressure (check only one): JVPNOTDN<XYES>	☐	☐1 < 8 cm ☐2 8–12 cm ☐3 13–16 cm ☐4 > 16 cm 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 Trace ☐2 Moderate ☐3 Severe PEREDEMA<HFEDEM>
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>	☐	☐0 None ☐1 One pillow (10 cm) ☐2 Two pillows (20 cm) ☐3 Three or more pillows ☐4 Not evaluable ORTHPNEA<HFORTH>

Subject Self-report of Symptoms

VAS (TYPE 3)

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

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

HEART FAILURE NETWORK **CARRESS**

NODATA<ZYES>

Baseline

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

Labs

LABASSES<HFLAB> LABVALUE<F:9:3> LABND<XYES> LABUNIT<HFLABU> 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:	☐	_____	☐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
8=	**8** Total cholesterol:	☐	_____	☐1 mmol/L ☐3 mg/dL
9=	**9** AST/SGOT:	☐	_____	☐5 U/L ☐6 IU/L
10=	**10** ALT/SGPT:	☐	_____	☐5 U/L ☐6 IU/L
11=	**11** Alkaline phosphatase:	☐	_____	☐5 U/L ☐6 IU/L
12=	**12** Total bilirubin:	☐	_____	☐3 mg/dL ☐4 µmol/L
13=	**13** Albumin:	☐	_____	☐7 g/dL ☐8 g/L
14=	**14** Hemoglobin *(Hgb)*:	☐	_____	☐7 g/dL ☐8 g/L ☐1 mmol/L
15=	**15** WBC:	☐	_____	☐9 10^9/L OR 10^3/mm³ ☐10 /mm³
16=	**16** Lymphocyte %:	☐	_____	☐11 %
17=	**17** Red cell distribution *(RDW)*:	☐	_____	☐11 %
18=	**18** BNP:	☐	_____	☐12 pg/mL ☐13 ng/L
19=	**19** NT-pro-BNP:	☐	_____	☐12 pg/mL ☐13 ng/L

ULTRALAB(TYPE 4)PS

Labs—Ultrafiltration

ULTRAUNT<HFLABU>

	Assessment	Not Done	Value	Units
1=	**1** Platelets	☐	_____	☐9 10^9/L OR 10^3/mm³ ☐10 /mm³
2=	**2** PT	☐	_____	☐14 secs
3=	**3** aPTT	☐	_____	☐14 secs
4=	**4** INR	☐	_____	☐14 secs

ULTRASST <CRULTR> ULTRAVAL<F:9:3> ULTRAND <XYES>

ADD to HFLABU 14=secs

HEART FAILURE NETWORK **CARRESS**

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

FORM= DAY1

Day 1

EARLYTRM<XYES>(Hide until p.26 DAY60)

Subject ID: CR ___ - ___ ___ ___ (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 and time: ___/___/___ ___:___ (day / month / year / 24 hour time)

EVALDT<DATE>

EVALTM<DATETIME>

STATUSSP<V:50>

All assessments should be done in the morning, post-void, pre-breakfast.

Clinical Assessment

SEE ANNOTATION P.5
SUPPRESS ALL BUT WEIGHT

ASSESSMT (TYPE 3)

Assessment	Not Done	Provide Details
Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg

Labs

LABS (TYPE 4)PS

SEE ANNOTATION P.6
SUPPRESS
6-13
15-19

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	☐	_____	☐1 mmol/L ☐2 mEq/L
5 Creatinine	☐	_____	☐3 mg/dL ☐4 µmol/L
6 Hemoglobin (Hgb):	☐	_____	☐7 g/dL ☐8 g/L ☐1 mmol/L

Labs—Ultrafiltration

ULTRALAB (TYPE 4)PS

SEE ANNOTATION P.6

Assessment	Not Done	Value	Units
1 Platelets	☐	_____	☐9 10^9/L OR 10^3/mm³ ☐10 /mm³
2 PT	☐	_____	☐14 secs
3 aPTT	☐	_____	☐14 secs
4 INR	☐	_____	☐14 secs

CRFLUID(TYPE 3)

Fluid Intake/Output Since randomization

CRIVIN I:5

1 Total IV input: ___ ___ ___ ___ mL

Total oral input: ___ ___ ___ ___ mL

CRORALIN I:5

CRULTOUT I:5

2 Total ultrafiltration output: ___ ___ ___ ___ mL OR ☐ None (0)

Total urine output: ___ ___ ___ ___ mL

CRURINOT I:5

CRFNONE<XYES>

ENDPTASS(TYPE 3)

Endpoint Assessment

Since randomization, did the subject experience:

Dialysis	☐0 No	☐1 Yes
Mechanical circulatory support	☐0 No	☐1 Yes
Mechanical respiratory support	☐0 No	☐1 Yes
Serious adverse event	☐0 No	☐1 Yes → Complete SAE form
Death	☐0 No	☐1 Yes → Complete Death form

CRDIAL<XYESNO>
CRCSUPPT<XYESNO>
CRRESPIR<XYESNO>
CRSAE<XYESNO>
CRDEATH<XYESNO>

We are un-suppressing the following rows in the ASSESSMT panel
row- 1,2,4,5,6 (due to data to be captured at discharge if subject is discharged Day 1)

insert panel 'VAS' (due to data to be captured at discharge if subject is discharged Day 1)
NOTE: WEIGHT and WEIGHT UNIT are already in database

FORM =DAY1

- **ASSESSMT (TYPE 3)**

Clinical Assessment

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	☐	___ ___ ___ bpm
2 Blood pressure (sitting or resting):	☐	___ ___ ___ / ___ ___ ___ mmHg (systolic / diastolic)
4 Jugular venous pressure (check only one):	☐	☐1 < 8 cm ☐2 8-12 cm ☐3 13-16 cm ☐4 > 16 cm
5 Peripheral edema (check only one):	☐	☐0 None ☐1 Trace ☐2 Moderate ☐3 Severe
6 Orthopnea (check only one):	☐	☐0 None ☐1 One pillow (10 cm) ☐2 Two pillows (20 cm) ☐3 Three or more pillows ☐4 Not evaluable

SEE ANNOTATION P.5
SUPPRESS
3-4
7-10
12

Subject Self-report of Symptoms

1 Dyspnea: VAS score: ___ ___ ___ mm See annotation p.5

2 Global VAS score: ___ ___ ___ mm

VAS (TYPE 3)

HEART FAILURE NETWORK **CARRESS**

FORM= DAY2

SEE ANNOTATION P.7

Day 2

Subject ID: CR ___ ___ ___ - ___ ___ ___ (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 and time: ___/___/___ ___:___ (day / month / year / 00:00 to 23:59)

All assessments should be done in the morning, post-void, pre-breakfast.

Clinical Assessment

ASSESSMT (TYPE 3)

Assessment	Not Done	Provide Details
Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg

Labs

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	☐	_____	☐1 mmol/L ☐2 mEq/L
5 Creatinine	☐	_____	☐3 mg/dL ☐4 µmol/L
6 Hemoglobin *(Hgb)*:	☐	_____	☐7 g/dL ☐8 g/L ☐1 mmol/L

Labs—Ultrafiltration

ULTRALAB (TYPE 4)PS

Assessment	Not Done	Value	Units
1 Platelets	☐	_____	☐9 10^9/L OR 10^3/mm^3 ☐10 /mm^3
2 PT	☐	_____	☐14 secs
3 aPTT	☐	_____	☐14 secs
4 INR	☐	_____	☐14 secs

CRFLUID (TYPE 3)

Fluid Intake/Output from same daily assessment time on previous day

1 Total IV input: ___ ___ ___ ___ mL

Total oral input: ___ ___ ___ ___ mL

2 Total ultrafiltration output: ___ ___ ___ ___ mL OR ☐ None (0)

Total urine output: ___ ___ ___ ___ mL

ENDPTASS (TYPE 3)

Endpoint Assessment

Since prior day assessment, did the subject experience:

Dialysis	☐0 No	☐1 Yes
Mechanical circulatory support	☐0 No	☐1 Yes
Mechanical respiratory support	☐0 No	☐1 Yes
Serious adverse event	☐0 No	☐1 Yes → Complete SAE form
Death	☐0 No	☐1 Yes → Complete Death form

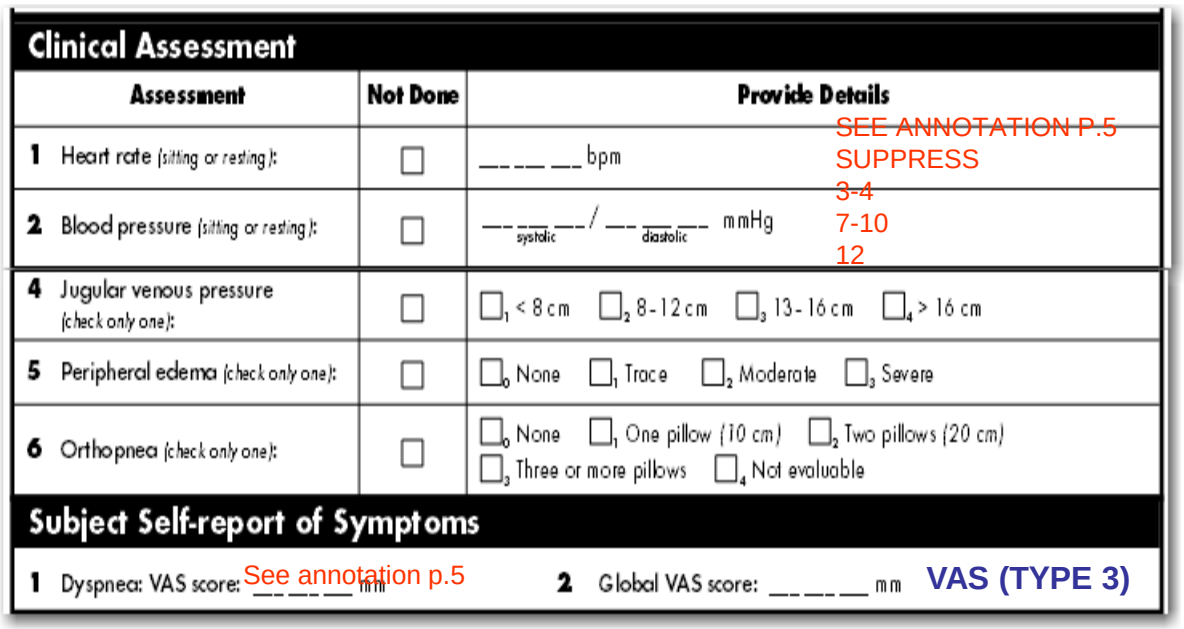
We are un-suppressing the following rows in the ASSESSMT panel
row- 1,2,4,5,6 (due to data to be captured at discharge if subject is discharged Day 2)

insert panel 'VAS' (due to data to be captured at discharge if subject is discharged Day 2)

NOTE: WEIGHT and WEIGHT UNIT are already in database

FORM =DAY2

- **ASSESSMT (TYPE 3)**



Clinical Assessment

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	☐	___ ___ bpm
2 Blood pressure (sitting or resting):	☐	___ ___ / ___ ___ mmHg (systolic / diastolic)
4 Jugular venous pressure (check only one):	☐	☐1 < 8 cm ☐2 8-12 cm ☐3 13-16 cm ☐4 > 16 cm
5 Peripheral edema (check only one):	☐	☐0 None ☐1 Trace ☐2 Moderate ☐3 Severe
6 Orthopnea (check only one):	☐	☐0 None ☐1 One pillow (10 cm) ☐2 Two pillows (20 cm) ☐3 Three or more pillows ☐4 Not evaluable

Subject Self-report of Symptoms

1 Dyspnea: VAS score: ___ ___ ___ mm

2 Global VAS score: ___ ___ ___ mm

SEE ANNOTATION P.5
SUPPRESS
3-4
7-10
12

See annotation p.5

VAS (TYPE 3)

HEART FAILURE NETWORK **CARRESS**

FORM= DAY3

SEE ANNOTATION P.7

Day 3

Subject ID: CR ___ ___ ___ - ___ ___ ___ (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 and time: ___/___/___ ___:___ (day / month / year / 00:00 to 23:59)

All assessments should be done in the morning, post-void, pre-breakfast.

Clinical Assessment

ASSESSMT (TYPE 3)

Assessment	Not Done	Provide Details
Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg

Labs

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	☐	_____	☐1 mmol/L ☐2 mEq/L
5 Creatinine	☐	_____	☐3 mg/dL ☐4 µmol/L
6 Hemoglobin (Hgb):	☐	_____	☐7 g/dL ☐8 g/L ☐1 mmol/L

Labs—Ultrafiltration

ULTRALAB (TYPE 4)PS

Assessment	Not Done	Value	Units
1 Platelets	☐	_____	☐9 10^9/L OR 10^3/mm^3 ☐10 /mm^3
2 PT	☐	_____	☐14 secs
3 aPTT	☐	_____	☐14 secs
4 INR	☐	_____	☐14 secs

Fluid Intake/Output from same daily assessment time on previous day

CRFLUID (TYPE 3)

1 Total IV input: ___ ___ ___ ___ mL

Total oral input: ___ ___ ___ ___ mL

2 Total ultrafiltration output: ___ ___ ___ ___ mL OR ☐ None (0)

Total urine output: ___ ___ ___ ___ mL

Endpoint Assessment

ENDPTASS (TYPE 3)

Since prior day assessment, did the subject experience:		
Dialysis	☐0 No	☐1 Yes
Mechanical circulatory support	☐0 No	☐1 Yes
Mechanical respiratory support	☐0 No	☐1 Yes
Serious adverse event	☐0 No	☐1 Yes → Complete SAE form
Death	☐0 No	☐1 Yes → Complete Death form

We are un-suppressing the following rows in the ASSESSMT panel
row- 1,2,4,5,6 (due to data to be captured at discharge if subject is discharged Day 3)

insert panel 'VAS' (due to data to be captured at discharge if subject is discharged Day 3)

NOTE: WEIGHT and WEIGHT UNIT are already in database

FORM =DAY3

ASSESSMT (TYPE 3)

Clinical Assessment

Assessment	Not Done	Provide Details
1 Heart rate *(sitting or resting)*:	☐	___ ___ ___ bpm
2 Blood pressure *(sitting or resting)*:	☐	___ ___ (systolic) / ___ ___ (diastolic) mmHg
4 Jugular venous pressure *(check only one)*:	☐	☐1 < 8 cm ☐2 8-12 cm ☐3 13-16 cm ☐4 > 16 cm
5 Peripheral edema *(check only one)*:	☐	☐0 None ☐1 Trace ☐2 Moderate ☐3 Severe
6 Orthopnea *(check only one)*:	☐	☐0 None ☐1 One pillow (10 cm) ☐2 Two pillows (20 cm) ☐3 Three or more pillows ☐4 Not evaluable

SEE ANNOTATION P.5
~~SUPPRESS~~
3-4
7-10
12

Subject Self-report of Symptoms

1 Dyspnea: VAS score: ___ ___ ___ mm SEE ANNOTATION P.5 2 Global VAS score: ___ ___ ___ mm

VAS (TYPE 3)

HEART FAILURE NETWORK **CARRESS**

FORM= DAY4

Day 4

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

Subject Status

SEE ANNOTATION P.7

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 and time: ___/___/___ ___:___ (day / month / year / 00:00 to 23:59)

All assessments should be done in the morning, post-void, pre-breakfast

Clinical Assessment

ASSESSMT (TYPE 3)

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	☐	___ ___ ___ bpm
2 Blood pressure (sitting or resting):	☐	___ ___ (systolic) / ___ ___ (diastolic) mmHg
3 Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg
4 Jugular venous pressure (check only one):	☐	☐1 < 8 cm ☐2 8–12 cm ☐3 13–16 cm ☐4 > 16 cm
5 Peripheral edema (check only one):	☐	☐0 None ☐1 Trace ☐2 Moderate ☐3 Severe
6 Orthopnea (check only one):	☐	☐0 None ☐1 One pillow (10 cm) ☐2 Two pillows (20 cm) ☐3 Three or more pillows ☐4 Not evaluable

SEE ANNOTATION P.5
SUPPRESS
3-4
7-10
12

Subject Self-report of Symptoms

SEE ANNOTATION P.5

VAS (TYPE 3)

1 Dyspnea: VAS score: ___ ___ ___ mm 2 Global VAS score: ___ ___ ___ mm

Labs

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	☐	_____	☐1 mmol/L ☐2 mEq/L
5 Creatinine	☐	_____	☐3 mg/dL ☐4 µmol/L
6 Hemoglobin (Hgb):	☐	_____	☐7 g/dL ☐8 g/L ☐1 mmol/L

SEE ANNOTATION P.7

Labs—Ultrafiltration

ULTRALAB (TYPE 4)PS

Assessment	Not Done	Value	Units
1 Platelets	☐	_____	☐9 10^9/L OR 10^3/mm^3 ☐10 /mm^3
2 PT	☐	_____	☐14 secs
3 aPTT	☐	_____	☐14 secs
4 INR	☐	_____	☐14 secs

SEE ANNOTATION P.6

HEART FAILURE NETWORK **CARRESS**

Day 4

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

Fluid Intake/Output from same daily assessment time on previous day

SEE ANNOTATION P.7

1 Total IV input: ___ ___ ___ ___ mL

Total oral input: ___ ___ ___ ___ mL

2 Total ultrafiltration output: ___ ___ ___ ___ mL OR ☐ None (0)

Total urine output: ___ ___ ___ ___ mL

CRFLUID (TYPE 3)

Endpoint Assessment

SEE ANNOTATION P.7

ENDPTASS (TYPE 3)

Since prior day assessment, did the subject experience:

Dialysis	☐ 0 No	☐ 1 Yes
Mechanical circulatory support	☐ 0 No	☐ 1 Yes
Mechanical respiratory support	☐ 0 No	☐ 1 Yes
Serious adverse event	☐ 0 No	☐ 1 Yes → Complete SAE form
Death	☐ 0 No	☐ 1 Yes → Complete Death form

HEART FAILURE NETWORK **CARRESS**

FORM= DAY5

Day 5

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

Subject Status

SEE ANNOTATION P.7

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 and time: ___/___/___ ___:___ (day / month / year / 00:00 to 23:59)

All assessments should be done in the morning, post-void, pre-breakfast

Clinical Assessment

ASSESSMT (TYPE 3)

Assessment	Not Done	SEE ANNOTATION P.7 Provide Details
Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg

Fluid Intake/Output from same daily assessment time on previous day

SEE ANNOTATION P.7

CRFLUID (TYPE 3)

1 Total IV input: ___ ___ ___ ___ mL

2 Total ultrafiltration output: ___ ___ ___ ___ mL OR ☐ None (0)

Total oral input: ___ ___ ___ ___ mL

Total urine output: ___ ___ ___ ___ mL

Endpoint Assessment

ENDPTASS(TYPE 3)

SEE ANNOTATION P.7

Since prior day assessment, did the subject experience:

Dialysis	☐0 No	☐1 Yes
Mechanical circulatory support	☐0 No	☐1 Yes
Mechanical respiratory support	☐0 No	☐1 Yes
Serious adverse event	☐0 No	☐1 Yes → Complete SAE form
Death	☐0 No	☐1 Yes → Complete Death form

HEART FAILURE NETWORK **CARRESS**

FORM= DAY6

Day 6

SEE ANNOTATION P.12

Subject ID: CR ___ ___ ___ - ___ ___ ___ (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 and time:** ___/___/___ ___:___ (day / month / year / 00:00 to 23:59)

All assessments should be done in the morning, post-void, pre-breakfast

Clinical Assessment

ASSESSMT (TYPE 3)

Assessment	Not Done	Provide Details
Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg

Fluid Intake/Output from same daily assessment time on previous day

CRFLUID (TYPE 3)

1 Total IV input: ___ ___ ___ ___ mL

Total oral input: ___ ___ ___ ___ mL

2 Total ultrafiltration output: ___ ___ ___ ___ mL OR ☐ None (0)

Total urine output: ___ ___ ___ ___ mL

Endpoint Assessment

ENDPTASS(TYPE 3)

Since prior day assessment, did the subject experience:

Dialysis	☐0 No	☐1 Yes
Mechanical circulatory support	☐0 No	☐1 Yes
Mechanical respiratory support	☐0 No	☐1 Yes
Serious adverse event	☐0 No	☐1 Yes → Complete SAE form
Death	☐0 No	☐1 Yes → Complete Death form

HEART FAILURE NETWORK **CARRESS**

Day 7 (or Discharge Day 5 or 6)

FORM= DAY7

SEE ANNOTATION P.10

Subject ID: CR ___ ___ ___ - ___ ___ ___ (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 and time: ___/___/___ ___:___ (day / month / year / 00:00 to 23:59)

All assessments should be done in the morning, post-void, pre-breakfast

Clinical Assessment

ASSESSMT (TYPE 3)

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	☐	___ ___ ___ bpm
2 Blood pressure (sitting or resting):	☐	___ ___ (systolic) / ___ ___ (diastolic) mmHg
3 Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg
4 Jugular venous pressure (check only one):	☐	☐1 < 8 cm ☐2 8–12 cm ☐3 13–16 cm ☐4 > 16 cm
5 Peripheral edema (check only one):	☐	☐0 None ☐1 Trace ☐2 Moderate ☐3 Severe
6 Orthopnea (check only one):	☐	☐0 None ☐1 One pillow (10 cm) ☐2 Two pillows (20 cm) ☐3 Three or more pillows ☐4 Not evaluable

Subject Self-report of Symptoms

VAS (TYPE 3)

1 Dyspnea: VAS score: ___ ___ ___ mm

2 Global VAS score: ___ ___ ___ mm

Labs

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	☐	_____	☐1 mmol/L ☐2 mEq/L
5 Creatinine	☐	_____	☐3 mg/dL ☐4 µmol/L
6 Hemoglobin (Hgb):	☐	_____	☐7 g/dL ☐8 g/L ☐1 mmol/L

Labs—Ultrafiltration

ULTRALAB (TYPE 4)PS

Assessment	Not Done	Value	Units
1 Platelets	☐	_____	☐9 10^9/L OR 10^3/mm^3 ☐10 /mm^3
2 PT	☐	_____	☐14 secs
3 aPTT	☐	_____	☐14 secs
4 INR	☐	_____	☐14 secs

HEART FAILURE NETWORK **CARRESS**

Day 7 (or Discharge Day 5 or 6)

SEE ANNOTATION P.11

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

Fluid Intake/Output from same daily assessment time on previous day

1 Total IV input: ___ ___ ___ ___ mL

Total oral input: ___ ___ ___ ___ mL

2 Total ultrafiltration output: ___ ___ ___ ___ mL OR ☐ None (0)

Total urine output: ___ ___ ___ ___ mL

CRFLUID (TYPE 3)

Endpoint Assessment

ENDPTASS(TYPE 3)

Since prior day assessment, did the subject experience:			
	Dialysis	☐ 0 No	☐ 1 Yes
	Mechanical circulatory support	☐ 0 No	☐ 1 Yes
	Mechanical respiratory support	☐ 0 No	☐ 1 Yes
	Serious adverse event	☐ 0 No	☐ 1 Yes → Complete SAE form
	Death	☐ 0 No	☐ 1 Yes → Complete Death form

HEART FAILURE NETWORK **CARRESS**

Index Hospitalization Medications

FORM=INDEXHOSP NODATA<ZYES>

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

Medications

MEDS(TYPE 4)RS

HFMEDS<HFHFMD>

SUPPRESS
MEDSANS
MEDSCONT

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

Diuretics timeframe
CRTIMEPT<CRTIME>
1=At Randomization
2=Randomization to Day 1
3=Day 1 to Day 2
4=Day 2 to Day 3
5=Day 3 to Day 4
6=Day 4 to Day 5
7=Day 5 to Day 6
8=Day 6 to Day 7
9=Discharge

HEART FAILURE NETWORK

CARRESS

Index Hospitalization/Medications

NODATA<ZYES>

Subject ID: CR ___ ___ ___ - ___ ___ ___ (site #) Subject Initials: ___ ___ ___

CRNADIUR<XYES>

CRDAYDIU (TYPE 4)PS

CRDIUR<XYESNO>
CRBOLUS<XYES>
CRIV<XYES>
CRPO<XYES>
CRDAILY<HFDIUR>
See annotation p.4
CRBOLVAL<F:9:3>
CRIVVAL<F:9:3>
CRPOVAL<F:9:3>

Diuretic

Medication	At Randomization (prior 24 hours)	Randomization to Day 1*	Day 1* to Day 2* OR ☐ NA	Day 2* to Day 3* OR ☐ NA	Day 3* to Day 4* OR ☐ NA
1 Furosemide	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg
2 Torsemide	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg
3 Bumetanide	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg
4 Metolazone	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg
5 HCTZ	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg
6 Chlorothiazide (Diuril)	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → ____ mg ☐ IV cont → ____ mg ☐ PO → ____ mg

*Daily assessment time: Morning, post void, pre-breakfast

HEART FAILURE NETWORK **CARRESS**

Index Hospitalization/Medications

SEE ANNOTATION P.17

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

CRDAYDIU (TYPE 4)PS

Diuretic

Medication	Day 4* to Day 5* OR ☐ NA	Day 5* to Day 6* OR ☐ NA	Day 6* to Day 7* OR ☐ NA	Discharge OR ☐ NA (Prescribed Dose)
1 Furosemide	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg
2 Torsemide	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg
3 Bumetanide	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg
4 Metolazone	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg
5 HCTZ	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg
6 Chlorothiazide (Diuril)	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg	☐0 No ☐1 Yes → Route: Daily dose: ☐ IV bolus → _____ mg ☐ IV cont → _____ mg ☐ PO → _____ mg

*Daily assessment time: Morning, post void, pre-breakfast

HEART FAILURE NETWORK **CARRESS**

Index Hospitalization Medications

NODATA<ZYES>

Subject ID: CR ___ ___ ___ - ___ ___ ___ ___ Subject Initials: ___

site # subject #

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 Check 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	☐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	☐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 **CARRESS**

Index Hospitalization Treatment

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

Stepped Pharmacologic Care (SPC)

SPC(TYPE 1)

Were IV diuretics started at any time point from randomization to Day 7 *(discharge)*?

☐0 No → **If No: Reason** *(check only one)*: ☐1 Subject randomized to ultrafiltration arm — SPCREASN<CRSPCR>
IVDIURET<XYESNO>
☐2 Subject withdrew consent
☐3 MD decision
☐4 Subject died → **Complete Death form**
☐98 Other *(specify)*: _____ SPCOTHSP< V:100>

☐1 Yes → **If Yes: Check only one:** ☐1 Subject randomized to stepped pharmacologic care arm — SPCRANAR<CRARM>
☐2 Subject crossed over to stepped pharmacologic care arm

Date IV diuretics started *(after randomization)*: ___/___/___ (day/month/year) SPSTRTDT

Date and time IV diuretics stopped: SPSTOPDT<DATE> ___:___ (00:00 to 23:59) SPSTOPTM<DATETIME>

Why was the SPC algorithm stopped? *(check all that apply)*:

☐ Achieved optimal volume status — SPCOPTML<XYES>
☐ Significant blood pressure drop/clinical instability — SPCBPDWN<XYES>
☐ Evidence of intravascular volume depletion — SPCVOL<XYES>
☐ Increased creatinine — SPCREAUP<XYES>
☐ Vascular access failure — SPCAFAIL<XYES>
☐ MD decision — SPCMDDEC<XYES>
☐ Subject withdrew consent — SPCWTHDR<XYES>
☐ Subject died → **Complete Death form** — SPCDIED<XYES>
☐ Other *(specify)*: _____ SPCOTHER<XYES> STPOTHSP<V:100>

Were each of the indicated steps of the SPC algorithm followed as described in the protocol?

ALGORITH<XYESNO> ☐0 No → **Reason:** _____ NALGOREA<V:100>
☐1 Yes

Ultrafiltration

ULTRA(TYPE 1)

Was ultrafiltration started at any time point from randomization to Day 7 (discharge)?

☐0 No → **If No: Specify reason** *(check only one)*: ☐1 Subject randomized to pharmacological care arm — NOULTRA<CRUFND>
STRTULTR<XYESNO>
☐2 Subject withdrew consent
☐3 MD decision
☐4 Subject died → **Complete Death form**
☐98 Other *(specify)*: _____ OTHULTSP <V :100>

☐1 Yes → **If Yes: Specify reason** *(check only one)*: ☐1 Subject randomized to ultrafiltration arm — YESULTRA<CRUFDN>
☐2 Subject crossed over to ultrafiltration arm

How many circuits were used: ___ ___ CIRCUITS <I:3>

HEART FAILURE NETWORK **CARRESS**

Index Hospitalization/Ultrafiltration

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

ULOGNUMB<I:3>

ULTRALOG (TYPE 4)R

Ultrafiltration Log

☐ No Ultrafiltration performed NOULTLOG<XYES>

Record new entry each time ultrafiltration was stopped for more than an hour: ALL<XYES>

Date and Time Started	Rate (cc/hour)	IV Access	Date and Time Stopped	Reason Stopped/Changed (check all that apply)
___/___/___ (day/month/year) ___:___ (00:00 to 23:59) ULSTRTDT<DATE> ULSTRTTM<DATETIME>	___ ___ ___ ULTRATE<I:3>	**Withdraw** (check only one): ☐1 Central WITHDRAW<CRIVAC> OR Peripheral: ☐2 ELC single ☐3 ELC double ☐4 Large bore IV catheter **Return** (check only one): ☐1 Central RETRN<CRIVAC> OR Peripheral: ☐2 ELC single ☐3 ELC double ☐4 Large bore IV catheter	___/___/___ (day/month/year) ___:___ (00:00 to 23:59) ULSTOPDT<DATE> ULSTOPTM<DATETIME>	☐ Achieved optimal volume status OPTVOL ☐ Significant blood pressure drop/clinical instability BPDROP ☐ Evidence of intravascular volume depletion DEPLETE ☐ Increased creatinine INCREATN ☐ Filter clogged CLOGGED ☐ Vascular access failure ACCFAIL ☐ MD decision MDECISN ☐ Subject withdrew consent SWCONSNT ☐ Subject died → **Complete Death form** LOGDEATH ☐ Other LOGOTH
___/___/___ (day/month/year) ___:___ (00:00 to 23:59)	___ ___ ___	**Withdraw** (check only one): ☐1 Central OR Peripheral: ☐2 ELC single ☐3 ELC double ☐4 Large bore IV catheter **Return** (check only one): ☐1 Central OR Peripheral: ☐2 ELC single ☐3 ELC double ☐4 Large bore IV catheter	___/___/___ (day/month/year) ___:___ (00:00 to 23:59)	☐ Achieved optimal volume status ☐ Significant blood pressure drop/clinical instability ☐ Evidence of intravascular volume depletion ☐ Increased creatinine ☐ Filter clogged ☐ Vascular access failure ☐ MD decision ☐ Subject withdrew consent ☐ Subject died → **Complete Death form** ☐ Other
___/___/___ (day/month/year) ___:___ (00:00 to 23:59)	___ ___ ___	**Withdraw** (check only one): ☐1 Central OR Peripheral: ☐2 ELC single ☐3 ELC double ☐4 Large bore IV catheter **Return** (check only one): ☐1 Central OR Peripheral: ☐2 ELC single ☐3 ELC double ☐4 Large bore IV catheter	___/___/___ (day/month/year) ___:___ (00:00 to 23:59)	☐ Achieved optimal volume status ☐ Significant blood pressure drop/clinical instability ☐ Evidence of intravascular volume depletion ☐ Increased creatinine ☐ Filter clogged ☐ Vascular access failure ☐ MD decision ☐ Subject withdrew consent ☐ Subject died → **Complete Death form** ☐ Other

HFN_CARRESS_V.2.2_04Aug2011

HEART FAILURE NETWORK **CARRESS**

Index Hospitalization
Core Lab and Hemodynamics

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

CRCORE (TYPE 4)PS

Core Lab Assessments

Scheduled	Test	Date of Test	Not Done	Reason Not Done (check only one)
CRSCHDAS<CRSCHD>		CRCOREDT		CRCOREAS<HFCORE>
1= Baseline	Biomarkers—blood	___/___/___ (day/month/year)	☐ →	☐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 ☐99 Unknown CRCOREND<XYES>
2= Day 4	Biomarkers—blood	___/___/___ (day/month/year)	☐ →	☐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 ☐99 Unknown
3= Day 7/Discharge 4=DAY 60 (HIDE P.22)	Biomarkers—blood	___/___/___ (day/month/year)	☐ →	☐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 ☐99 Unknown

Hemodynamics

HEMODYN(TYPE 2)PS

Does subject have a pulmonary artery catheter? ☐0 No ☐1 Yes → If Yes: Complete below:

PACASST<CRPAC>

ANYCATH<XYESNO>

	Date and Time	Not Done	PCWP	CVP
	PACDT<DATE>	PACND<XYES>	PCWPVAL<I:3>	CVPVAL<I:3>
1= 1 Pre-randomization (most recent)	___/___/___ PACTM<DATETIME> ___:___ (day/month/year 00:00 to 23:59)	☐	_____ mmHg	_____ mmHg
2= 2 Post randomization (closest prior to Day 4)	___/___/___ ___:___ (day/month/year 00:00 to 23:59)	☐	_____ mmHg	_____ mmHg

HEART FAILURE NETWORK **CARRESS**

Index Hospitalization Urinary—Core Lab

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

Urinary Biomarker Ancillary Study

Was the subject randomized after IRB approval of Amendment 3?

☐ 0 No URINBIO<XYESNO>

☐ 1 Yes → If Yes: Complete all assessments below:

CRURIBIO (TYPE 1)

CRURICOR (TYPE 2)PS

Core Lab Urinary Assessments

Scheduled	Test	Date of Test	Not Done	Reason Not Done (check only one)
CRURSCH<CRURSC> 1= Baseline	Biomarkers—urine	CRURINDT ___/___/_____ (day/month/year)	☐ →	☐ 1 Died → Fill out Death form ☐ 3 Unwilling to perform test but subjectively able ☐ 4 Due to oversight or technical problem ☐ 99 Unknown CRURINRE<HFCORE>
2= Day 1	Biomarkers—urine	CRURLBND<XYES> ___/___/_____ (day/month/year)	☐ →	☐ 1 Died → Fill out Death form ☐ 3 Unwilling to perform test but subjectively able ☐ 4 Due to oversight or technical problem ☐ 5 Discharged ☐ 99 Unknown
3= Day 4	Biomarkers—urine	___/___/_____ (day/month/year)	☐ →	☐ 1 Died → Fill out Death form ☐ 3 Unwilling to perform test but subjectively able ☐ 4 Due to oversight or technical problem ☐ 5 Discharged ☐ 99 Unknown

HEART FAILURE NETWORK **CARRESS**

Index Hospitalization Discharge

NODATA<ZYES>

Subject ID: CR ___ ___ ___ - ___ ___ ___ (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)*: ☐1 Home ☐2 Assisted living ☐3 Skilled nursing facility ☐4 Acute care hospital ☐5 Rehabilitation center ☐98 Other DCHGLOC<HFDCHG>

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		

Record all SAEs on Serious Adverse Events form

HEART FAILURE NETWORK **CARRESS**

FORM= DAY30

Day 30

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

Subject Status

STATUS(TYPE 3)

Was assessment performed?

☐0 No → If No: Reason: ☐2 Subject withdrew ☐3 Subject died ☐4 Missed visit
☐98 Other (specify): _____

SEE ANNOTATION P.7
<HFSUBJ>SUPPRESS '1'

☐1 Yes → If Yes: Assessment date and time: ___/___/___ ___:___ (day / month / year / 00:00 to 23:59)

Clinical Assessment

ASSESSMT(TYPE 3

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	☐	___ ___ ___ bpm SEE ANNOTATION P.10
2 Blood pressure (sitting or resting):	☐	___ (systolic) / ___ (diastolic) mmHg
3 Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg
4 Jugular venous pressure (check only one):	☐	☐1 < 8 cm ☐2 8–12 cm ☐3 13–16 cm ☐4 > 16 cm
5 Peripheral edema (check only one):	☐	☐0 None ☐1 Trace ☐2 Moderate ☐3 Severe
6 Orthopnea (check only one):	☐	☐0 None ☐1 One pillow (10 cm) ☐2 Two pillows (20 cm) ☐3 Three or more pillows ☐4 Not evaluable

Labs

LABS (TYPE4) PS

Assessment	Not Done	Value	Units
1 Sodium	☐	_____	☐1 mmol/L ☐2 mEq/L SEE ANNOTATION P.7
2 Potassium	☐	_____	☐1 mmol/L ☐2 mEq/L
3 BUN/Urea	☐	_____	☐1 mmol/L ☐3 mg/dL
4 Bicarbonate	☐	_____	☐1 mmol/L ☐2 mEq/L
5 Creatinine	☐	_____	☐3 mg/dL ☐4 µmol/L
6 Hemoglobin (Hgb):	☐	_____	☐7 g/dL ☐8 g/L ☐1 mmol/L

Endpoint/Safety Review Reminder

- Record all SAEs on Serious Adverse Events form
- Record all re-hospitalizations ≥ 24 hours on Re-Hospitalization form
- Record all unscheduled clinic or emergency department visits that did not result in re-hospitalization on Unscheduled Clinic/Emergency Department Visits form

HEART FAILURE NETWORK **CARRESS**

NODATA<ZYES> **Day 30**

Medications

Subject ID: CR ___ ___ ___ - ___ ___ ___ (site # / visit#) Subject Initials: ___ ___ ___

MEDS(TYPE 4)PS

Medications

1=	**1** ACE inhibitor HFMEDS<HFHFMD>	MEDSANS<XYESNO>	☐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	SUPPRESS MEDSCONT MEDRAND DISCHND MEDDSCG	☐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** Antidepressant		☐0 No ☐1 Yes

DIURETIC (TYPE 4)PS

Oral Diuretics

Medication	See annotation p.4	Average Total Daily Dose	Units
1 Furosemide	☐0 No ☐1 Yes →	_____	mg
2 Torsemide	☐0 No ☐1 Yes →	_____	mg
3 Bumetanide	☐0 No ☐1 Yes →	_____	mg
4 Metolazone	☐0 No ☐2 Yes, daily ☐3 Yes, PRN →	_____	mg
5 HCTZ	☐0 No ☐2 Yes, daily ☐3 Yes, PRN →	_____	mg

HEART FAILURE NETWORK **CARRESS**

FORM= DAY60

Day 60 (or Early Termination)

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

☐ Check if early termination visit SEE ANNOTATION P.24 STATUS (TYPE 3)

Subject Status

Was assessment performed?

☐0 No → If No: Reason: ☐2 Subject withdrew ☐3 Subject died ☐4 Missed visit ☐98 Other (specify): _____

☐1 Yes → If Yes: Assessment date and time: ___/___/___ ___:___ (day / month / year / 00:00 to 23:59) ASSESSMT (TYPE 3)

Clinical Assessment

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	☐	___ ___ ___ bpm SEE ANNOTATION P.5 SUPPRESS 3-4 7-10
2 Blood pressure (sitting or resting):	☐	___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg
3 Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg
4 Jugular venous pressure (check only one):	☐	☐1 < 8 cm ☐2 8–12 cm ☐3 13–16 cm ☐4 > 16 cm
5 Peripheral edema (check only one):	☐	☐0 None ☐1 Trace ☐2 Moderate ☐3 Severe
6 Current NYHA heart failure classification (check only one):	☐	☐1 I ☐2 II ☐3 III ☐4 IV
7 Orthopnea (check only one):	☐	☐0 None ☐1 One pillow (10 cm) ☐2 Two pillows (20 cm) ☐3 Three or more pillows ☐4 Not evaluable

Labs

Assessment	Not Done	Value	Units
1 Sodium SEE ANNOTATION P.7	☐	_____	☐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	☐	_____	☐1 mmol/L ☐2 mEq/L
5 Creatinine	☐	_____	☐3 mg/dL ☐4 µmol/L
6 Hemoglobin (Hgb):	☐	_____	☐7 g/dL ☐8 g/L ☐9 mmol/L

LABS (TYPE 4)PS

CRCORE (TYPE 4)PS

Core Lab Assessments

Test	Date of Test	Not Done	Reason Not Done (check only one)
Biomarkers–blood	SEE ANNOTATION P.22 ___ ___ / ___ ___ / ___ ___ ___ (day / month / year)	☐ →	☐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 ☐99 Unknown

CRSCHDAS<CRSCHD>
HIDE 1-3
4= DAY 60

WHITE and YELLOW–Duke Clinical Research Institute • PINK–retain at site

HEART FAILURE NETWORK **CARRESS**

Day 60 (or Early Termination)

See annotation p.25

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

MEDS(TYPE 4)PS

Medications

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	Antidepressant	☐0 No ☐1 Yes

Oral Diuretics

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

DIURETIC(TYPE 4)PS

HEART FAILURE NETWORK **CARRESS**

NODATA<ZYES>

End of Study

FORM=TERMINATION

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

Study Termination/Completion

Did the subject complete the study *(including follow-up protocol)*?

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

TERM (TYPE 1)

Reason for termination *(check only one)*:

COMPLETE <XYESNO>

☐ 1 Subject lost to follow-up

TERMREAS<HFTERM>

☐ 2 Adverse event

☐ 3 Subject withdrew consent

☐ 4 Subject died → **Complete Death form** *(termination date above should be the date of death)*

☐ 98 Other *(specify)*: _____ TERMSP <V:100>

☐ 1 Yes

SUPPRESS

UNBLIND, UNBLINDDT, UNBLDSP

SAFETY (TYPE 3)

Endpoint/Safety Review

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?

_____ → Record all re-hospitalization ≥ 24 hours on Re-Hospitalization form REHOSNUM<I:3>

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

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

HEART FAILURE NETWORK **CARRESS**

NODATA<ZYES>

Re-Hospitalization

FORM= REHOSPITALIZATION

THIS IS A REPEATING PAGE

Subject ID: CR ___ ___ ___ - ___ ___ ___ (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) 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
- ☐ 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 RENON
- ☐ Other non-cardiovascular REOTNON

PROCEDUR (TYPE 4)

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

Left heart catheterization: SEE ANNOTATION P.23	☐ 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)		

NODATA<ZYES>

HEART FAILURE NETWORK **CARRESS**

FORM=UNSCHEDULED

Unscheduled Clinic OR Emergency Department Visit

THIS IS A REPEATING PAGE

Subject ID: CR ___ ___ ___ - ___ ___ ___ (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>

Death

DEATHLOC<HFLOCA>

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

DEATHPAG (TYPE 1)

2 **Date of death:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) DEATHDT

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.

Principal Investigator: SEE ANNOTATION P.28 _____ (Signature of Investigator) Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

HFN_CARRESS_V2.0_04 JUN 2009

NODATA<ZYES>

HEART FAILURE NETWORK **CARRESS**

FORM=SAE

Serious Adverse Events

THIS IS A REPEATING PAGE

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

Serious Adverse Events

ADVERSE (TYPE 4) R

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

AENUMBER<I:3>

#	Is This Event on the HFnet Event List? EVENT<XYESNO>	Onset Date and Time AEONSTDT<DATE> AEONSTTM<DATETIME>	End Date and Time OR ☐ if Ongoing AEENDDT<DATE> AEENDTM<DATETIME>	Was Subject Hospitalized? AEHOSP <XYESNO>	Outcome (check only one) AEOUTCM <HFOUTC>	Maximum Intensity (check only one) AEINTENS <XINTNS>	Action Taken with Study Drug/ Treatment (check only one) AEACTION <HFACTN>	Related to Study Drug/ Treatment (check only one) AERELAT <HFRELA>	Was this Event Unexpected Per Product Labeling? AEUNEXPT <XYESNO>
1	☐0 No → Name of event: AETERM <V:100> ☐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	___/___/___ day month year	☐0 No	☐1 Resolved ☐2 Resolved with	☐1 Mild	☐0 None ☐1 Interrupted ☐2 Discontinued ☐3 Dosage changed	☐1 Not a reasonable possibility ☐2 Reasonable possibility*	☐0 No ☐1 Yes*

AETERM <V:100> (DERIVED) All MEDRA coding from this field

HFNCODE<I:3> See attached Codelist for batchloading into TYPE 0 panel

MEDRA:
MEDRTEXT<V:100>
MEDRCODE<V:8>
WORKFLOW<V:5>
CODETM<DATETIME>
CODER<V:20>
MATCHES<V:4>
CONFLVL<V:2>

DERIVED ITEMS:
PTNAME <V:100>
PTCODE<V:8>
SOCNAME<V:100>
SOCCODE <V:8>

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. 28

SIGNATUR (TYPE 4)

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

*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=	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

- <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=	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

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'