HEART FAILURE NETWORK **EXACT**

PROTOCOL=HFN_EXACT
STUDYBOOK=DATA_FORMS
FORM= SCREENING

NODATA<ZYES>

Screening

Subject ID: EX ___ ___ ___ - ___ ___ ___ (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> ☐ Native Hawaiian or other Pacific Islander NATHWN<XYES> ☐ Asian ASIAN<XYES> ☐ White/Caucasian WHITE<XYES> ☐ Black BLACK<XYES>

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

6 What is the highest level of education the subject has completed (check only one)? EDUCATE<EXEDU>

1=☐1 Less than high school diploma
2=☐2 High school diploma/GED
3=☐3 Some college but no degree
4=☐4 Associate's degree
5=☐5 Bachelor's degree
6=☐6 Master's degree
7=☐7 Doctoral degree
8=☐8 Professional degree (M.D., J.D.)

Enroll panel will contain:
SUBJNO: derived from 'EX'II INVSITE II '-'II PATID
INITIALS V:3
RANDTM<DATETIME>
RANDDT<DATE>
CREALEVL<EXCRLV>
1=creatinine ≤ 2
2=creatinine >2 to 3

7 How many years of post-high school education has the subject completed (check only one)? PSTEDUC<EXPTED>

1=☐1 1-2 2=☐2 3-4 3=☐3 5-6 4=☐4 7-8 5=☐5 > 8 6=☐6 NA

8 What does the subject indicate as the best source of information for him/her about how to manage his/her heart failure (check only one)? INFOSRC<EXINSC>

1=☐1 Healthcare providers (physicians, nurses, pharmacists)
2=☐2 Family and friends
3=☐3 Print (books, magazines, newspapers)
4=☐4 Radio and/or television
5=☐5 The internet

Clinical Assessment—Screening

ASSESSMT(TYPE 3)

Assessment	Not Done	Provide Details
1 Height:	☐	___ ___ ___ . ___ ☐1 in ☐2 cm
2 Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg
3 Current NYHA heart failure classification (check only one):	☐	☐1 I ☐2 II ☐3 III ☐4 IV

SEE ANNOTATION P.5

SUPRESS ALL EXCEPT FOR 4,5,12

Core Lab Assessments

EXATCORE (TYPE 4)PS

SEE ANNOTATION P.32

SUPRESS EXCOREND EXCRND

1= Echocardiography: Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

HEART FAILURE NETWORK **EXACT**

NODATA<XYES>

Screening

Subject ID: EX ___ ___ ___ - ___ ___ ___ (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 Total number of ER visits or urgent clinic visits requiring IV diuretics within prior 12 months: ___ ERCLINIC<I:2>

5 Has LV function been assessed?

☐ 0 No LVASSESS<XYESNO>

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

Value of last LVEF: EF ___ ___ % **OR Check only one:** LVEF<I:2>

☐ 1 Normal LVEFSTAT<HFLVEF>
☐ 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

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

☐ 0 No ISCHEMIC<XYESNO>

☐ 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

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

☐ LM<XYES> ☐ LAD<XYES> ☐ LCX<XYES> ☐ RCA<XYES> ☐ None

☐ PTCI<XYES> Percutaneous coronary intervention *(PCI)* → **Date of most recent:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) PTCIDT

☐ CABG<XYES> Coronary artery bypass graft (CABG) → **Date of most recent:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) CABGDT

7 Does the subject have evidence of non-ischemic cardiomyopathy?

☐ 0 No NONISCH<XYESNO>

☐ 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:100>

HEART FAILURE NETWORK **EXACT**

NODATA<ZYES>

Screening

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

Clinical History (continued)

Does the subject have a documented history of any of the following?

MEDHIST2(TYPE 1)

8 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>

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

10 TIA: TIA<XYESNO> ☐0 No ☐1 Yes

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

12 Arrhythmia: ARRHYTHM <XYESNO>

☐0 No

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

FIBFLUTR<HFFIBF>

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

SUSVTVF<XYES> ☐ Sustained VT or VF

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

PACETYPE<HFCHBR>

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

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

ICDTYPE<HFCHBR>

15 Peripheral vascular disease: PVD<XYESNO> ☐0 No ☐1 Yes

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

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

DIABTYPE<HFDIAB>

18 Gout: GOUT<XYESNO> ☐0 No ☐1 Yes

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

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

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

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

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

24 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

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

HEART FAILURE NETWORK **EXACT**

NODATA<ZYES>

NOTE: NEW LABS HAVE BEEN ADDED TO THIS CODELIST. PLEASE DISPLAY LABS IN THE ORDER OF THE CRF

Screening

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

Labs

LABASSES<HFLAB>

LABS(TYPE 4)PS

LABVALUE<F:9:3>

LABUNIT<HFLABU>

LABND<XYES>

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= ☐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
25= **25** Uric acid:	☐	_____	☐1 mmol/L ☐3 mg/dL ☐4 µmol/L

HEART FAILURE NETWORK **EXACT** FORM= BASELINE

NODATA<ZYES>

Baseline

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

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? ☐0 No ☐1 Yes WAIVER <XYESNO>

☐1 Yes ELIGCRIT<XYESNO>

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

ECG (TYPE 3)

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

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

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 (longest QRS duration excluding paced beat): ___ ___ ___ msec OR ☐ Not done ECGQRSND<XYES> ECGQRS<I:3>

Clinical Assessment

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>	☐	___ ___ (systolic) / ___ ___ (diastolic) mmHg BPSYS <I:3> BPDIA<I:3> Suppress PEREDEMA<HFEDEM>
3	SpO_2: SPONOTDN<XYES>	☐	___ ___ ___ % SPO2<I:3>
4	Height: HTNOTDN<XYES>	☐	___ ___ ___ . ___ ☐1 in ☐2 cm HEIGHT <F:9:3> HTUNITS<XHGTU>
5	Weight: WTNOTDN<XYES>	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg WEIGHT <F:9:3> 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 1+ ☐2 2+ ☐3 3+ ☐4 4+ PEREDEMA<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>	☐	☐0 None ☐1 One pillow (10 cm) ☐2 Two pillows (20 cm) ☐3 Three or more pillows ☐4 Not evaluable ORTHPNEA<HFORTH>

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

HFN_EXACT V.2.1_14Aug2012

HEART FAILURE NETWORK **EXACT**

NODATA<XYES>

Baseline

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

MEDS(TYPE 4)PS

Medications

HFMEDS<HFHFMD>

MEDSCRN<XYESNO>

SUPPRESS
MEDSANS
DISCHND
MEDDSCG
MEDSCONT

		At Screening	At Randomization (MEDRAND<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

HEART FAILURE NETWORK **EXACT**

NODATA<XYES>

Baseline

Subject ID: EX ___ ___

DIURETIC (TYPE 4)PS

Oral Diuretics

DIURANS<HFRESP>

	Medication		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)

HEART FAILURE NETWORK **EXACT**

NODATA<ZYES>

Baseline

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

Core Lab Assessments

EXATCORE (TYPE 4)PS

Test EXSCHDAS<EXSCHD>	Date of Test OR Check if Not Done	Reason Not Done (check only one) EXCRND<HECORE>
2= Biomarkers—blood	EXCOREDT ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Not done → EXCOREND<XYES>	☐ 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/other
3= Ancillary study—blood *(insulin resistance)*	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Not done →	☐ 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 not participating ☐ 99 Unknown/other

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

Kansas City Cardiomyopathy Questionnaire (KCCQ)

The following questions refer to your **heart failure** and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

KCCQ1(TYPE 3)

1 **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** *(shortness of breath or fatigue)* in your ability to do the following activities over the past 2 weeks.

Place an X in one box on each line

<EXKCCA>

Activity	1 Extremely limited	2 Quite a bit limited	3 Moderately limited	4 Slightly limited	5 Not at all limited	6 Limited for other reasons or did not do the activity
Dressing yourself KCCQ1A<I:3>	1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6
Showering/Bathing KCCQ1B<I:3>	☐1	☐2	☐3	☐4	☐5	☐6
Walking 1 block on level ground KCCQ1C<I:3>	☐1	☐2	☐3	☐4	☐5	☐6
Doing yardwork, housework or carrying groceries KCCQ1D<I:3>	☐1	☐2	☐3	☐4	☐5	☐6
Climbing a flight of stairs without stopping KCCQ1E<I:3>	☐1	☐2	☐3	☐4	☐5	☐6
Hurrying or jogging (as if to catch a bus) KCCQ1F<I:3>	☐1	☐2	☐3	☐4	☐5	☐6

2 Compared with 2 weeks ago, have your symptoms of **heart failure** *(shortness of breath, fatigue, or ankle swelling)* changed? My symptoms of heart failure have become... KCCQ2<I:3><EXHFSY>

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6

3 Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning? KCCQ3<I:3><EXSWFT>

Every morning	3 or more times a week, but not every morning	1–2 times a week	Less than once a week	Never over the past 2 weeks
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5

KCCQ4<I:3><EXSWM>

4 Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
☐1 1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

5 Over the past 2 weeks, on average, how many times has **fatigue** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6	7 ☐7

KCCQ5<I:3><EXAVSH>

6 Over the past 2 weeks, how much has your **fatigue** bothered you? It has been... KCCQ6<I:3><EXMUFT>

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
☐1	☐2	☐3	4 ☐4	5 ☐5	6 ☐6

KCCQ7<I:3><EXAVSH>

7 Over the past 2 weeks, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6	7 ☐7

8 Over the past 2 weeks, how much has your **shortness of breath** bothered you? It has been... KCCQ8<I:3><EXMUSH>

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
☐1	☐2	☐3	☐4	5 ☐5	6 ☐6

9 Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

KCCQ9<I:3><EXAVFS>

Every night	3 or more times a week, but not every night	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	5 ☐5

10 **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do or who to call, if your **heart failure** gets worse?

KCCQ10<I:3><EXHFHF>

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
☐1	☐2	☐3	☐4	☐5

11 How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting **worse** *(for example, weighing yourself, eating a low-salt diet etc.)*?

KCCQ11<I:3><EXHFUN>

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
☐1	☐2	☐3	☐4	☐5

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

KCCQ3(TYPE 3)

12 Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

KCCQ12<I:3><EXHFLM>

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
☐1	☐2	☐3	☐4	☐5

13 If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

KCCQ13<I:3><EXHFLF>

Not at all satisfied	**Mostly** dissatisfied	**Somewhat** satisfied	**Mostly** satisfied	**Completely** satisfied
☐1	☐2	☐3	☐4	☐5

14 Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

KCCQ14<I:3><EXHFDC>

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
☐1	☐2	☐3	☐4	☐5

15 How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

Please place an X in one box on each line

<EXHFLS>

Activity	Severely limited	Limited **quite a bit**	Moderately limited	Slightly limited	Did not limit at all	Does not apply or did not do for other reasons
Hobbies, recreational activities KCCQ15A<I:3>	☐1	☐2	☐3	☐4	☐5	☐6
Working or doing household chores KCCQ15B<I:3>	☐1	☐2	☐3	☐4	☐5	☐6
Visiting family or friends out of your home KCCQ15C<I:3>	☐1	☐2	☐3	☐4	☐5	☐6
Intimate relationships with loved ones KCCQ15D<I:3>	☐1	☐2	☐3	☐4	☐5	☐6

6-Minute Walk Test (6MWT)

WALKTEST (TYPE 4)

1 Was walk performed?

☐ 0 No → **Specify reason** *(check only one)*: WALK<XYESNO>
- ☐ 1 Died → **Fill out Death form** WLKND<HFNOWL>
- ☐ 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)*
- ☐ 6 Neurological reasons
- ☐ 99 Unknown/other

☐ 1 Yes → **If Yes: Complete below.**

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

3 Pre- and post-walk data:

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

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>
- ☐ Lightheadedness 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>

Initial Study Drug Administration

ISDADMIN (TYPE 1)

Was study drug initial dose administered? ISTDRUG<XYESNO>

☐ 0 No → If No: Specify reason (check only one): ISDREASN<RXREAS>
- ☐ 1 Subject withdrew consent
- ☐ 2 MD decision
- ☐ 3 Other

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

Dose administered (check only one): ☐ 1 100 mg ☐ 2 300 mg ISTDOSE<EXDOSE>

Metabolic Cart Assessment

METABCRT (TYPE 3)

1 Is subject participating in metabolic cart ancillary study?
- ☐ 0 No MTBCRT<XYESNO>
- ☐ 1 Yes → If Yes: Oxygen consumption (VO_2): _____ OXYCMP<F:9:3>
  Carbon dioxide production (VCO_2): _____ CRBDXP<F:9:3>

2 Method by which gas exchange is measured (check only one): MTBGAS<EXGASX>
- ☐ 1 Hood
- ☐ 2 Mouthpiece

3 Manufacturer of metabolic cart equipment (check only one): MTBEQP<EXEQUP>
- ☐ 1 Medgraphics
- ☐ 2 ParvoMedics
- ☐ 3 SensorMedics
- ☐ 4 Other

• **Record any adverse events and serious adverse events on Adverse Events page**

NODATA<ZYES>

HEART FAILURE NETWORK **EXACT**

FORM= WEEK 1

Week 1 (Visit 1) Phone Call

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

Subject Status

STATUS(TYPE 3)

Was assessment performed?

SUBJSTAT<HFSUBJ>
SEE CODELIST P.14
SUPPRESS 1,4,5

- ☐ 0 No → If No: Reason:
  - ☐ 2 Subject withdrew consent
  - ☐ 3 Subject died
  - ☐ 6 Unable to contact subject
  - ☐ 98 Other (specify): _____ SEE ANNOTATION P.14
- ☐ 1 Yes → If Yes: Assessment date: ___/___/___ (day / month / year)

Study Drug Dosing Changes (stopped, changed, started since previous recorded visit)

SDACHG (TYPE 3)

Was study drug dose adjusted/uptitrated/discontinued?

SDADJUST<XYESNO>

- ☐ 0 No
- ☐ 1 Yes → Record on Study Drug Dose Adjustment Log

- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record all hospitalizations ≥ 24 hours on Hospitalization form**
- **Record all unscheduled clinic or emergency department visits that did not result in a hospitalization on Unscheduled Clinic/Emergency Department Visit form**

FORM=WEEK 4

HEART FAILURE NETWORK **EXACT**

EARLYTRM<XYES>
HIDE UNTIL P.29 WEEK 24

<HFSUBJ>
1=SUBJECT DISCHARGED
2=SUBJECT WITHDREW
3=SUBJECT DIED
4=MISSED VISIT
5=CONTACTED SUBJECT, BUT MISSED VISIT
6=UNABLE TO CONTACT SUBJECT
98=OTHER

NODATA<ZYES>

Week 4 (Visit 2)

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

Subject Status

EVALUTE<XYESNO>

Was assessment performed? ☐0 No → If No: Reason: ☐2 Subject withdrew consent — STATUS(TYPE 3)

SUBJSTAT<HFSUBJ>
SEE CODELIST ABOVE

☐3 Subject died
☐5 Contacted subject, but missed visit
☐6 Unable to contact subject
☐98 Other (specify): _____ STATUSSP<V:50>

EVALDT

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

Study Drug Dosing Changes (stopped, changed, started since previous recorded visit)

Was study drug dose adjusted/discontinued? ☐0 No SEE ANNOTATION P.13 — SDACHG (TYPE 3)

☐1 Yes → Record on Study Drug Dose Adjustment Log any changes lasting 5 or more days

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 SpO_2:	☐	___ ___ ___ %
4 Height:	☐	___ ___ ___ . ___ ☐1 in ☐2 cm
5 Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg
6 Jugular venous pressure (check only one):	☐	☐1 < 8 cm ☐2 8–12 cm ☐3 13–16 cm ☐4 > 16 cm
7 Rales (check only one):	☐	☐0 None ☐1 < 1/3 ☐2 1/3–2/3 ☐3 > 2/3
8 S3 auscultation:	☐	☐0 No ☐1 Yes
9 Hepatomegaly:	☐	☐0 No ☐1 Yes
10 Ascites:	☐	☐0 No ☐1 Yes
11 Peripheral edema (check only one):	☐	☐0 None ☐1 1+ ☐2 2+ ☐3 3+ ☐4 4+
12 Current NYHA heart failure classification (check only one):	☐	☐1 I ☐2 II ☐3 III ☐4 IV
13 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

Patient Global Assessment (Self-report)

PGASSMNT(TYPE 3)

Compared with the beginning of the study, how do you feel that your heart failure condition has changed?

Markedly Better	Moderately Better	Slightly Better	Unchanged	Slightly Worse	Moderately Worse	Markedly Worse
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6	7 ☐7

PGAHFC<EXPGAS>

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 (*total CO_2*):	☐	_____	☐1 mmol/L ☐2 mEq/L
5 Creatinine:	☐	_____	☐3 mg/dL ☐4 µmol/L
6 Magnesium:	☐	_____	☐1 mmol/L ☐2 mEq/L ☐3 mg/dL
7 Glucose:	☐	_____	☐1 mmol/L ☐3 mg/dL
8 Chloride:	☐	_____	☐1 mmol/L ☐2 mEq/L
9 Calcium:	☐	_____	☐1 mmol/L ☐2 mEq/L ☐3 mg/dL
10 Total cholesterol:	☐	_____	☐1 mmol/L ☐3 mg/dL
11 AST/SGOT:	☐	_____	☐5 U/L ☐6 IU/L
12 ALT/SGPT:	☐	_____	☐5 U/L ☐6 IU/L
13 Alkaline phosphatase:	☐	_____	☐5 U/L ☐6 IU/L
14 Total bilirubin:	☐	_____	☐3 mg/dL ☐4 µmol/L
15 Total protein:	☐	_____	☐7 g/dL ☐8 g/L
16 Albumin:	☐	_____	☐7 g/dL ☐8 g/L
17 WBC:	☐	_____	☐9 10^9/L OR 10^3/mm^3 ☐10 /mm^3
18 Lymphocyte %:	☐	_____	☐11 %
19 Hemoglobin (*Hgb*):	☐	_____	☐7 g/dL ☐8 g/L ☐1 mmol/L
20 Hematocrit:	☐	_____	☐15 L/L ☐11 %
21 Platelets:	☐	_____	☐9 10^9/L OR 10^3/mm^3 ☐10 /mm^3
22 Red cell distribution (*RDW*):	☐	_____	☐11 %
23 BNP:	☐	_____	☐12 pg/mL ☐13 ng/L
24 NT-pro-BNP:	☐	_____	☐12 pg/mL ☐13 ng/L

SEE ANNOTATION P4

HEART FAILURE NETWORK **EXACT**

NODATA<XYESNO>

Week 4 (Visit 2)

Subject ID: EX ___ ___ ___ - ___ ___ ___ ___ Subject Initials: ___ ___ ___

site # subject #

MEDS(TYPE 4)PS

Medications

HFMEDS<HFHFMD>	At Week 4 MEDSANS<XYESNO>
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

SUPPRESS
DISCHND
MEDDSCG
MEDSCONT
~~MEDSCRN~~
MEDRAND

DIURETIC (TYPE 4)PS

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

SEE ANNOTATION P.6A

Medication Change for Worsening Heart Failure

MEDCHNG(TYPE 3)

Since Baseline, has subject met criteria for medication change for worsening heart failure *(see criteria below)*?

- Addition of any new drug class for worsening heart failure
- Increase in diuretic dose by ≥ 50% for more than one week
- Increase in beta blocker or renin-angiotensin inhibitor by ≥ 50% for more than one week
- Decrease in beta blocker or renin-angiotensin inhibitor by ≥ 50% for more than one week

☐0 No change to date
☐1 Yes → If Yes: Complete Medication Review form, page 41.

See annotation p.27
Suppress HFMEDCHG

Major Cardiovascular Procedures/Tests/Treatments—Outpatient

MCPT(TYPE 3)

Check No or Yes for procedures/tests/treatments performed as an **outpatient** from Baseline. Please answer all questions.

1 Left heart catheterization: MCPLCATH<XYESNO> ☐0 No ☐1 Yes

2 Right heart catheterization: MCPRCATH<XYESNO> ☐0 No ☐1 Yes

3 PCI: MCPPCI<XYESNO> ☐0 No ☐1 Yes

4 Pacemaker without ICD: MCPNOICD<XYESNO> ☐0 No ☐1 Yes → If Yes:
Check only one: ☐1 Single ☐2 Dual ☐3 Biventricular

5 ICD: MCPICD<XYESNO> MCPPACE<HFCHBR> ☐0 No ☐1 Yes → If Yes:
Check only one: ☐1 Single ☐2 Dual ☐3 Biventricular

6 Dialysis: MCPDIAL<XYESNO> MCPCEICD<HFCHBR> ☐0 No ☐1 Yes

7 Atrial arrhythmia ablation: MCPBLAT<XYESNO> ☐0 No ☐1 Yes

8 CPR: MCPCPR<XYESNO> ☐0 No ☐1 Yes

9 Cardioversion: MCPCARDI<XYESNO> ☐0 No ☐1 Yes

10 Echocardiogram *(not study specified)*: MCPECHO<XYESNO> ☐0 No ☐1 Yes

11 Cardiac stress test: MCPSTRES<XYESNO> ☐0 No ☐1 Yes

- **Record any adverse events and serious adverse events on Adverse Events page**
- **For any procedures/tests/treatments performed when subject was hospitalized, record on Hospitalization page**
- **Record any new study drug dispensing information on Study Drug Accountability Log.**

NODATA<ZYES>

FORM= WEEK 8

Week 8 (Visit 3) Phone Call

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

Subject Status

STATUS(TYPE 3)

Was assessment performed?

☐ 0 No → If No: Reason: ☐ 2 Subject withdrew consent
☐ 3 Subject died
☐ 6 Unable to contact subject
☐ 98 Other (specify): _____

SEE ANNOTATION P.14

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

Study Drug Dosing Changes (stopped, changed, started since previous recorded visit)

SDACHG (TYPE 3)

Was study drug dose adjusted/discontinued?

☐ 0 No

SEE ANNOTATION P.13

☐ 1 Yes → Record on Study Drug Dose Adjustment Log any changes lasting 5 or more days

- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record all hospitalizations ≥ 24 hours on Hospitalization form**
- **Record all unscheduled clinic or emergency department visits that did not result in a hospitalization on Unscheduled Clinic/Emergency Department Visit form**

HEART FAILURE NETWORK **EXACT**

FORM= WEEK 12

NODATA<ZYES>

Week 12 (Visit 4)

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

Subject Status

STATUS(TYPE 3)

Was assessment performed? ☐0 No → If No: Reason:
- ☐2 Subject withdrew consent
- ☐3 Subject died
- ☐5 Contacted subject, but missed visit
- ☐6 Unable to contact subject
- ☐98 Other (specify): _____

SEE ANNOTATION P.14

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

Study Drug Dosing Changes (stopped, changed, started since previous recorded visit)

SDACHG (TYPE 3)

Was study drug dose adjusted/discontinued? ☐0 No

☐1 Yes → Record on Study Drug Dose Adjustment Log any changes lasting 5 or more days

SEE ANNOTATION P.13

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 SpO_2:	☐	___ ___ ___ %
4 Height:	☐	___ ___ . ___ ☐1 in ☐2 cm
5 Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg
6 Jugular venous pressure (check only one):	☐	☐1 < 8 cm ☐2 8–12 cm ☐3 13–16 cm ☐4 > 16 cm
7 Rales (check only one):	☐	☐0 None ☐1 < 1/3 ☐2 1/3–2/3 ☐3 > 2/3
8 S3 auscultation:	☐	☐0 No ☐1 Yes
9 Hepatomegaly:	☐	☐0 No ☐1 Yes
10 Ascites:	☐	☐0 No ☐1 Yes
11 Peripheral edema (check only one):	☐	☐0 None ☐1 1+ ☐2 2+ ☐3 3+ ☐4 4+
12 Current NYHA heart failure classification (check only one):	☐	☐1 I ☐2 II ☐3 III ☐4 IV
13 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

Patient Global Assessment (Self-report)

PGASSMNT(TYPE 3)

Compared with the beginning of the study, how do you feel that your heart failure condition has changed?

Markedly Better	Moderately Better	Slightly Better	Unchanged	Slightly Worse	Moderately Worse	Markedly Worse
☐1	☐2	☐3	☐4	☐5	☐6	☐7

SEE ANNOTATION P.14

NODATA<XYES>

Week 12 (Visit 4)

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

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 *(total CO_2)*:	☐	_____	☐1 mmol/L ☐2 mEq/L
5 Creatinine:	☐	_____	☐3 mg/dL ☐4 µmol/L
6 Magnesium:	☐	_____	☐1 mmol/L ☐2 mEq/L ☐3 mg/dL
7 Glucose:	☐	_____	☐1 mmol/L ☐3 mg/dL
8 Chloride:	☐	_____	☐1 mmol/L ☐2 mEq/L
9 Calcium:	☐	_____	☐1 mmol/L ☐2 mEq/L ☐3 mg/dL
10 Total cholesterol:	☐	_____	☐1 mmol/L ☐3 mg/dL
11 AST/SGOT:	☐	_____	☐5 U/L ☐6 IU/L
12 ALT/SGPT:	☐	_____	☐5 U/L ☐6 IU/L
13 Alkaline phosphatase:	☐	_____	☐5 U/L ☐6 IU/L
14 Total bilirubin:	☐	_____	☐3 mg/dL ☐4 µmol/L
15 Total protein:	☐	_____	☐7 g/dL ☐8 g/L
16 Albumin:	☐	_____	☐7 g/dL ☐8 g/L
17 WBC:	☐	_____	☐9 10^9/L OR 10^3/mm^3 ☐10 /mm^3
18 Lymphocyte %:	☐	_____	☐11 %
19 Hemoglobin *(Hgb)*:	☐	_____	☐7 g/dL ☐8 g/L ☐1 mmol/L
20 Hematocrit:	☐	_____	☐15 L/L ☐11 %
21 Platelets:	☐	_____	☐9 10^9/L OR 10^3/mm^3 ☐10 /mm^3
22 Red cell distribution *(RDW)*:	☐	_____	☐11 %
23 BNP:	☐	_____	☐12 pg/mL ☐13 ng/L
24 NT-pro-BNP:	☐	_____	☐12 pg/mL ☐13 ng/L

SEE ANNOTATION P.4

NODATA<XYES>

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

Medications

MEDS(TYPE 4)PS

	At Week 12
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.16

HEART FAILURE NETWORK **EXACT**

NODATA<XYES> **Week 12 (Visit 4)**

Subject ID: EX _ DIURETIC (TYPE 4)PS _ _ _

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

SEE ANNOTATION P.6A

HEART FAILURE NETWORK **EXACT**

NODATA<XYES>

Week 12 (Visit 4)

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

Core Lab Assessments

Test	Date of Test OR Check if Not Done	Reason Not Done *(check only one)*
Biomarkers—blood	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ Not done →	☐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/other

EXATCORE (TYPE 4)PS

SEE ANNOTATION P.32

ECG

ECG (TYPE 3)

1 **Date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Not done

2 **Rate:** ___ ___ ___ bpm

SEE ANNOTATION P.5

3 **Rhythm** *(check only one)*: ☐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

5 **QRS duration** *(longest QRS duration excluding paced beat)*: ___ ___ ___ msec OR ☐ Not done

Kansas City Cardiomyopathy Questionnaire (KCCQ)

KCCQ1(TYPE 3)

The following questions refer to your **heart failure** and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1 **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** *(shortness of breath or fatigue)* in your ability to do the following activities over the past 2 weeks.

Place an X in one box on each line

SEE ANNOTATION P.8

Activity	Extremely limited	Quite a bit limited	Moderately limited	Slightly limited	Not at all limited	Limited for other reasons or did not do the activity
Dressing yourself	☐1	☐2	☐3	☐4	☐5	☐6
Showering/Bathing	☐1	☐2	☐3	☐4	☐5	☐6
Walking 1 block on level ground	☐1	☐2	☐3	☐4	☐5	☐6
Doing yardwork, housework or carrying groceries	☐1	☐2	☐3	☐4	☐5	☐6
Climbing a flight of stairs without stopping	☐1	☐2	☐3	☐4	☐5	☐6
Hurrying or jogging (as if to catch a bus)	☐1	☐2	☐3	☐4	☐5	☐6

2 Compared with 2 weeks ago, have your symptoms of **heart failure** *(shortness of breath, fatigue, or ankle swelling)* changed? My symptoms of heart failure have become...

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6

3 Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning?

Every morning	3 or more times a week, but not every morning	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5

4 Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
☐1	☐2	☐3	☐4	☐5	☐6

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

SEE ANNOTATION P.9

5 Over the <u>past 2 weeks</u>, on average, how many times has **fatigue** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6	☐7

6 Over the <u>past 2 weeks</u>, how much has your **fatigue** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
☐1	☐2	☐3	☐4	☐5	☐6

7 Over the <u>past 2 weeks</u>, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6	☐7

8 Over the <u>past 2 weeks</u>, how much has your **shortness of breath** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
☐1	☐2	☐3	☐4	☐5	☐6

9 Over the <u>past 2 weeks</u>, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night	3 or more times a week, but not every night	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5

10 **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do or who to call, if your **heart failure** gets worse?

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
☐1	☐2	☐3	☐4	☐5

11 How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting **worse** *(for example, weighing yourself, eating a low-salt diet etc.)*?

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
☐1	☐2	☐3	☐4	☐5

NODATA<ZYES>

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

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

KCCQ3(TYPE 3)

12 Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
☐1	☐2	☐3	☐4	☐5

SEE ANNOTATION P.10

13 If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	**Mostly** dissatisfied	**Somewhat** satisfied	**Mostly** satisfied	**Completely** satisfied
☐1	☐2	☐3	☐4	☐5

14 Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
☐1	☐2	☐3	☐4	☐5

15 How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

Please place an X in one box on each line

Activity	Severely limited	Limited **quite a bit**	Moderately limited	Slightly limited	Did not limit at all	Does not apply or did not do for other reasons
Hobbies, recreational activities	☐1	☐2	☐3	☐4	☐5	☐6
Working or doing household chores	☐1	☐2	☐3	☐4	☐5	☐6
Visiting family or friends out of your home	☐1	☐2	☐3	☐4	☐5	☐6
Intimate relationships with loved ones	☐1	☐2	☐3	☐4	☐5	☐6

6-Minute Walk Test (6MWT)

WALKTEST (TYPE 4)

SEE ANNOTATION P.11

1 Was walk performed?

☐ 0 No → **Specify reason** *(check only one)*:
- ☐ 1 Died → **Fill out Death form**
- ☐ 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)*
- ☐ 6 Neurological reasons
- ☐ 99 Unknown/other

☐ 1 Yes → **If Yes: Complete below.**

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

3 Pre- and post-walk data:

	Heart Rate	Blood Pressure
Pre-walk	___ ___ ___ bpm	___ ___ ___ / ___ ___ ___ mmHg (systolic / diastolic)
Post-walk	___ ___ ___ bpm	___ ___ ___ / ___ ___ ___ mmHg (systolic / diastolic)

4 Distance walked: _____ meters

5 Did the subject complete the 6-minute walk?

☐ 0 No → **If No: Duration of walk:** ___ / ___ (minutes / seconds)

☐ 1 Yes

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

- ☐ None
- ☐ Angina
- ☐ Lightheadedness
- ☐ Syncope
- ☐ Dyspnea
- ☐ Fatigue
- ☐ Chest pain
- ☐ Leg or joint pain
- ☐ Instability
- ☐ Other *(specify)*: _____

Medication Change for Worsening Heart Failure

MEDCHNG(TYPE 3)

Since the last in-clinic study visit, has subject met criteria for medication change for worsening heart failure *(see criteria below)*?

- Addition of any new drug class for worsening heart failure
- Increase in diuretic dose by ≥ 50% for more than one week
- Increase in beta blocker or renin-angiotensin inhibitor by ≥ 50% for more than one week
- Decrease in beta blocker or renin-angiotensin inhibitor by ≥ 50% for more than one week

☐0 No change to date

MDCHANGE<XYESNO>

☐1 Yes → If Yes: Is this the first time the subject met criteria for medication change for worsening heart failure?

HFMEDCHG<XYESNO>

☐0 No → If No: No further documentation of medication change is required

☐1 Yes → If Yes: Record details of the medication change on the Medication Review form, page 41.

Major Cardiovascular Procedures/Tests/Treatments—Outpatient

MCPT(TYPE 3)

Check No or Yes for procedures/tests/treatments performed as an **outpatient** since the last in-clinic study visit. Please answer all questions.

1	Left heart catheterization:	☐0 No	☐1 Yes
2	Right heart catheterization:	☐0 No	☐1 Yes
3	PCI:	☐0 No	☐1 Yes
4	Pacemaker without ICD:	☐0 No	☐1 Yes → If Yes: Check only one: ☐1 Single ☐2 Dual ☐3 Biventricular
5	ICD:	☐0 No	☐1 Yes → If Yes: Check only one: ☐1 Single ☐2 Dual ☐3 Biventricular
6	Dialysis:	☐0 No	☐1 Yes
7	Atrial arrhythmia ablation:	☐0 No	☐1 Yes
8	CPR:	☐0 No	☐1 Yes
9	Cardioversion:	☐0 No	☐1 Yes
10	Echocardiogram *(not study specified)*:	☐0 No	☐1 Yes
11	Cardiac stress test:	☐0 No	☐1 Yes

SEE ANNOTATION P.17

- **Record any adverse events and serious adverse events on Adverse Events page**
- **For any procedures/tests/treatments performed when subject was hospitalized, record on Hospitalization page**
- **Record any new study drug dispensing information on Study Drug Accountability Log.**

HEART FAILURE NETWORK **EXACT**

Week 18 (Visit 5) Phone Call

NODATA<ZYES>

FORM= WEEK 18

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

Subject Status

STATUS(TYPE 3)

Was assessment performed?

☐ 0 No → If No: Reason:
- ☐ 2 Subject withdrew consent
- ☐ 3 Subject died
- ☐ 6 Unable to contact subject
- ☐ 98 Other (specify): _____

SEE ANNOTATION P.14

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

Study Drug Dosing Changes (stopped, changed, started since previous recorded visit)

SDACHG (TYPE 3)

Was study drug dose adjusted/discontinued?

SEE ANNOTATION P.13

☐ 0 No

☐ 1 Yes → Record on Study Drug Dose Adjustment Log any changes lasting 5 or more days

- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record all hospitalizations ≥ 24 hours on Hospitalization form**
- **Record all unscheduled clinic or emergency department visits that did not result in a hospitalization on Unscheduled Clinic/Emergency Department Visit form**

HEART FAILURE NETWORK **EXACT**

NODATA<ZYES>

FORM= WEEK 24

EARLYTRM<XYES>

Week 24 (Visit 6) (Early Termination)

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

☐ Check if Early Termination visit

STATUS(TYPE 3)

Subject Status

Was assessment performed? SEE ANNOTATION P.14

☐0 No → **If No: Reason:** ☐2 Subject withdrew consent ☐3 Subject died ☐5 Contacted subject, but missed visit ☐6 Unable to contact subject ☐98 Other *(specify)*: _____

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

Study Drug Dosing Changes (stopped, changed, started since previous recorded visit)

SDACHG (TYPE 3)

Was study drug dose adjusted/discontinued?

☐0 No SEE ANNOTATION P.13

☐1 Yes → Record on Study Drug Dose Adjustment Log any changes lasting 5 or more days

Clinical Assessment

ASSESSMT(TYPE 3)

Assessment	Not Done	Provide Details
1 Heart rate *(sitting or resting)*: SEE ANNOTATION P.15	☐	___ ___ ___ bpm
2 Blood pressure *(sitting or resting)*:	☐	___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg
3 SpO_2:	☐	___ ___ ___ %
4 Height:	☐	___ ___ ___ . ___ ☐1 in ☐2 cm
5 Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg
6 Jugular venous pressure *(check only one)*:	☐	☐1 < 8 cm ☐2 8–12 cm ☐3 13–16 cm ☐4 > 16 cm
7 Rales *(check only one)*:	☐	☐0 None ☐1 < 1/3 ☐2 1/3–2/3 ☐3 > 2/3
8 S3 auscultation:	☐	☐0 No ☐1 Yes
9 Hepatomegaly:	☐	☐0 No ☐1 Yes
10 Ascites:	☐	☐0 No ☐1 Yes
11 Peripheral edema *(check only one)*:	☐	☐0 None ☐1 1+ ☐2 2+ ☐3 3+ ☐4 4+
12 Current NYHA heart failure classification *(check only one)*:	☐	☐1 I ☐2 II ☐3 III ☐4 IV
13 Orthopnea *(check only one)*:	☐	☐0 None ☐1 One pillow *(10 cm)* ☐2 Two pillows *(20 cm)* ☐3 Three or more pillows ☐4 Not evaluable

Patient Global Assessment (Self-report)

PGASSMNT(TYPE 3)

Compared with the beginning of the study, how do you feel that your heart failure condition has changed?

Markedly Better	Moderately Better	Slightly Better	Unchanged	Slightly Worse	Moderately Worse	Markedly Worse
☐1	☐2	☐3	☐4	☐5	☐6	☐7

SEE ANNOTATION P.14

HEART FAILURE NETWORK **EXACT**

NODATA<XYES>

Week 24 (Visit 6) (Early Termination)

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

Labs

LABS(TYPE 4)PS

SEE ANNOTATION P.4

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 Magnesium:	☐	_____	☐1 mmol/L ☐2 mEq/L ☐3 mg/dL
7 Glucose:	☐	_____	☐1 mmol/L ☐3 mg/dL
8 Chloride:	☐	_____	☐1 mmol/L ☐2 mEq/L
9 Calcium:	☐	_____	☐1 mmol/L ☐2 mEq/L ☐3 mg/dL
10 Total cholesterol:	☐	_____	☐1 mmol/L ☐3 mg/dL
11 AST/SGOT:	☐	_____	☐5 U/L ☐6 IU/L
12 ALT/SGPT:	☐	_____	☐5 U/L ☐6 IU/L
13 Alkaline phosphatase:	☐	_____	☐5 U/L ☐6 IU/L
14 Total bilirubin:	☐	_____	☐3 mg/dL ☐4 µmol/L
15 Total protein:	☐	_____	☐7 g/dL ☐8 g/L
16 Albumin:	☐	_____	☐7 g/dL ☐8 g/L
17 WBC:	☐	_____	☐9 10^9/L OR 10^3/mm^3 ☐10 /mm^3
18 Lymphocyte %:	☐	_____	☐11 %
19 Hemoglobin *(Hgb)*:	☐	_____	☐7 g/dL ☐8 g/L ☐1 mmol/L
20 Hematocrit:	☐	_____	☐15 L/L ☐11 %
21 Platelets:	☐	_____	☐9 10^9/L OR 10^3/mm^3 ☐10 /mm^3
22 Red cell distribution *(RDW)*:	☐	_____	☐11 %
23 BNP:	☐	_____	☐12 pg/mL ☐13 ng/L
24 NT-pro-BNP:	☐	_____	☐12 pg/mL ☐13 ng/L

HEART FAILURE NETWORK **EXACT**

NODATA<XYES>

Week 24 (Visit 6) (Early Termination)

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

MEDS(TYPE 4)PS

Medications

SEE ANNOTATION P.16	At Week 24
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

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

SEE ANNOTATION P.6A

HEART FAILURE NETWORK **EXACT**

NODATA<XYES>

Week 24 (Visit 6) (Early Termination)

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

EXATCORE (TYPE 4)PS

Core Lab Assessments

Test	Date of Test OR Check if Not Done	Reason Not Done (check only one)
EXSCHDAS<EXSCHD> Echocardiography 1=	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Not done → EXCOREDT EXCOREND<XYES>	☐ 1 Died → Fill out Death form ☐ 2 Too sick to perform EXCRND<HFCORE> ☐ 3 Unwilling to perform test but subjectively able ☐ 4 Due to oversight or technical problem ☐ 99 Unknown/other
Biomarkers—blood 2=	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Not done →	☐ 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/other
Ancillary study—blood *(insulin resistance)* 3=	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Not done →	☐ 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 not participating ☐ 99 Unknown/other

ECG

ECG (TYPE 3)

1 **Date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Not done SEE ANNOTATION P.5

2 **Rate:** ___ ___ ___ bpm

3 **Rhythm** *(check only one)*: ☐ 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

5 **QRS duration** *(longest QRS duration excluding paced beat)*: ___ ___ ___ msec OR ☐ Not done

Metabolic Cart Assessment

METABCRT (TYPE 3)

1 **Is subject participating in metabolic cart ancillary study?**

☐ 0 No

☐ 1 Yes → **If Yes: Oxygen consumption** (VO_2): _____

Carbon dioxide production (VCO_2): _____

2 **Method by which gas exchange is measured** *(check only one)*:

☐ 1 Hood

☐ 2 Mouthpiece

SEE ANNOTATION P.12

3 **Manufacturer of metabolic cart equipment** *(check only one)*:

☐ 1 Medgraphics

☐ 2 ParvoMedics

☐ 3 SensorMedics

☐ 4 Other

Kansas City Cardiomyopathy Questionnaire (KCCQ)

KCCQ1(TYPE 3)

The following questions refer to your **heart failure** and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1 **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** *(shortness of breath or fatigue)* in your ability to do the following activities over the past 2 weeks.

Place an X in one box on each line

SEE ANNOTATION P.8

Activity	Extremely limited	Quite a bit limited	Moderately limited	Slightly limited	Not at all limited	Limited for other reasons or did not do the activity
Dressing yourself	☐1	☐2	☐3	☐4	☐5	☐6
Showering/Bathing	☐1	☐2	☐3	☐4	☐5	☐6
Walking 1 block on level ground	☐1	☐2	☐3	☐4	☐5	☐6
Doing yardwork, housework or carrying groceries	☐1	☐2	☐3	☐4	☐5	☐6
Climbing a flight of stairs without stopping	☐1	☐2	☐3	☐4	☐5	☐6
Hurrying or jogging (as if to catch a bus)	☐1	☐2	☐3	☐4	☐5	☐6

2 Compared with 2 weeks ago, have your symptoms of **heart failure** *(shortness of breath, fatigue, or ankle swelling)* changed? My symptoms of heart failure have become...

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6

3 Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning?

Every morning	3 or more times a week, but not every morning	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5

4 Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
☐1	☐2	☐3	☐4	☐5	☐6

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

SEE ANNOTATION P.9

5 Over the past 2 weeks, on average, how many times has **fatigue** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6	☐7

6 Over the past 2 weeks, how much has your **fatigue** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
☐1	☐2	☐3	☐4	☐5	☐6

7 Over the past 2 weeks, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6	☐7

8 Over the past 2 weeks, how much has your **shortness of breath** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
☐1	☐2	☐3	☐4	☐5	☐6

9 Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night	3 or more times a week, but not every night	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5

10 **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do or who to call, if your **heart failure** gets worse?

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
☐1	☐2	☐3	☐4	☐5

11 How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting **worse** *(for example, weighing yourself, eating a low-salt diet etc.)*?

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
☐1	☐2	☐3	☐4	☐5

NODATA<ZYES>

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

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

KCCQ3(TYPE 3)

12 Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

SEE ANNOTATION P.10

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
☐1	☐2	☐3	☐4	☐5

13 If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	**Mostly** dissatisfied	**Somewhat** satisfied	**Mostly** satisfied	**Completely** satisfied
☐1	☐2	☐3	☐4	☐5

14 Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
☐1	☐2	☐3	☐4	☐5

15 How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

Please place an X in one box on each line

Activity	Severely limited	Limited **quite a bit**	Moderately limited	Slightly limited	Did not limit at all	Does not apply or did not do for other reasons
Hobbies, recreational activities	☐1	☐2	☐3	☐4	☐5	☐6
Working or doing household chores	☐1	☐2	☐3	☐4	☐5	☐6
Visiting family or friends out of your home	☐1	☐2	☐3	☐4	☐5	☐6
Intimate relationships with loved ones	☐1	☐2	☐3	☐4	☐5	☐6

6-Minute Walk Test (6MWT)

WALKTEST (TYPE 4)

1 Was walk performed?

☐ 0 No → **Specify reason** *(check only one)*: ☐ 1 Died → **Fill out Death form**

SEE ANNOTATION P.11

☐ 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)*
☐ 6 Neurological reasons
☐ 99 Unknown/other

☐ 1 Yes → **If Yes: Complete below.**

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

3 Pre- and post-walk data:

	Heart Rate	Blood Pressure
Pre-walk	___ ___ ___ bpm	___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg
Post-walk	___ ___ ___ bpm	___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

4 Distance walked: _____ meters

5 Did the subject complete the 6-minute walk?

☐ 0 No → **If No: Duration of walk:** _____ (minutes) / ___ ___ (seconds)

☐ 1 Yes

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

☐ None
☐ Angina
☐ Lightheadedness
☐ Syncope
☐ Dyspnea
☐ Fatigue
☐ Chest pain
☐ Leg or joint pain
☐ Instability
☐ Other *(specify)*: _____

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

Medication Change for Worsening Heart Failure

MEDCHNG(TYPE 3)

Since the last in-clinic study visit, has subject met criteria for medication change for worsening heart failure *(see criteria below)*?

- Addition of any new drug class for worsening heart failure
- Increase in diuretic dose by ≥ 50% for more than one week
- Increase in beta blocker or renin-angiotensin inhibitor by ≥ 50% for more than one week
- Decrease in beta blocker or renin-angiotensin inhibitor by ≥ 50% for more than one week

SEE ANNOTATION P.27

☐0 No change to date → If No change: Complete Medication Review form as part of final documentation, page 41.

☐1 Yes → If Yes: Is this the first time the subject met criteria for medication change for worsening heart failure?

- ☐0 No → If No: No further documentation of medication change is required
- ☐1 Yes → If Yes: Record details of the medication change on the Medication Review form, page 41

Major Cardiovascular Procedures/Tests/Treatments—Outpatient

MCPT(TYPE 3)

Check No or Yes for procedures/tests/treatments performed as an **outpatient** since the last in-clinic study visit. Please answer all questions.

1	Left heart catheterization:	☐0 No	☐1 Yes
2	Right heart catheterization:	☐0 No	☐1 Yes
3	PCI:	☐0 No	☐1 Yes
4	Pacemaker without ICD:	☐0 No	☐1 Yes → If Yes: Check only one: ☐1 Single ☐2 Dual ☐3 Biventricular
5	ICD:	☐0 No	☐1 Yes → If Yes: Check only one: ☐1 Single ☐2 Dual ☐3 Biventricular
6	Dialysis:	☐0 No	☐1 Yes
7	Atrial arrhythmia ablation:	☐0 No	☐1 Yes
8	CPR:	☐0 No	☐1 Yes
9	Cardioversion:	☐0 No	☐1 Yes
10	Echocardiogram *(not study specified)*:	☐0 No	☐1 Yes
11	Cardiac stress test:	☐0 No	☐1 Yes

SEE ANNOTATION P.17

- **Record any adverse events and serious adverse events on Adverse Events page**
- **For any procedures/tests/treatments performed when subject was hospitalized, record on Hospitalization page**
- **Record any new study drug dispensing information on Study Drug Accountability Log.**

HEART FAILURE NETWORK **EXACT**

NODATA<ZYES>

FORM=TERMINATION

End of Study

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

Study Termination/Completion

RXTERM (TYPE 1)

1 Did the subject complete the study *(through Week 24 visit)*?

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

Reason for termination *(check only one)*:

RXCOMPLE <XYESNO>

RXTERMRE<HFTERM>

- ☐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)*: _____ RXTERMSP <V:100>

☐1 Yes

2 Last known date the subject took study drug: ___/___/___ (day/month/year) RXSTPDT

3 Was study drug permanently discontinued prior to study termination?

☐0 No RXPERMST<XYESNO>

☐1 Yes → If Yes: Primary reason for discontinuation *(check only one)*: EXSTPREA<EXSTPR>

- ☐1 Acute coronary syndrome
- ☐2 AV block
- ☐3 Life threatening arrhythmia
- ☐4 Other adverse event
- ☐5 Subject withdrew consent
- ☐6 MD decision
- ☐7 Subject needed allopurinol for gout
- ☐98 Other

Suppress RXSTPREA<RXSTPR>

4 Was study drug unblinded? RXUNBLND<XYESNO>

☐0 No

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

5 Was uric acid measured during study treatment? EXACDMSR<XYESNO>

☐0 No

☐1 Yes → If Yes: Were results revealed to study personnel? ☐0 No ☐1 Yes EXACDRLT<XYESNO>

Endpoint/Safety Review

SAFETY (TYPE 1)

1 How many adverse events did subject have? SAENUMB<I:3>

_____ → Record all on Adverse Events form

2 How many hospitalizations did subject have? REHOSNUM<I:3>

_____ → Record all hospitalizations ≥ 24 hours on 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> _____ (Signature of Investigator) Date: ___/___/___ (day/month/year) INVSIGDT

HEART FAILURE NETWORK **EXACT**

NODATA<ZYES>

This is a repeating page

Study Drug Accountability Log
Baseline through Week 24

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

DRUGLOG (TYPE 4)R

Record of Study Drug

	Bottle Number	Start Date (Date first dose taken)	Number of Pills Dispensed	Stop Date (Date last dose taken)	Number of Pills Returned	Number of Pills Lost*
	KITROWNO<I:3>					
1	KITNUMBR<I:5>	DRGSTRDT __ __ / __ __ __ / __ __ __ __ (day / month / year)	DISPENSE<I:3>	DRGSTPDT __ __ / __ __ __ / __ __ __ __ (day / month / year)	RETURNED<I:3>	LOSTPILL<I:3>
2						
3						
4						

* Best estimate of number of pills not taken but not returned for any reason.

HEART FAILURE NETWORK **EXACT**

This is a repeating page

NODATA<ZYES>

Study Drug Dose Adjustment Log

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

Study Drug Dose Adjustment or Discontinuation

Was study drug dose changed *(stopped, changed, started)* **for 5 or more consecutive days since Randomization?**

☐ 0 No

☐ 1 Yes → **If Yes: Record below:**

ANYDRCHG<XYESNO>

DRUGCHGS(TYPE 4)R

CHGNUMB<I:3> **Date of Change**	**New Dose** *(check only one)*
1 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) CHGDT	☐ 1 100 mg daily ☐ 2 300 mg daily ☐ 3 600 mg daily ☐ 4 Temporary discontinuation ☐ 5 Permanent discontinuation ☐ 6 Other *(specify total daily dose)*: _____ mg CHGDOSE<EXCHG> Suppress CHANGES<RXCHG> CHGOTH<F:9;3>
2 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐ 1 100 mg daily ☐ 2 300 mg daily ☐ 3 600 mg daily ☐ 4 Temporary discontinuation ☐ 5 Permanent discontinuation ☐ 6 Other *(specify total daily dose)*: _____ mg
3 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐ 1 100 mg daily ☐ 2 300 mg daily ☐ 3 600 mg daily ☐ 4 Temporary discontinuation ☐ 5 Permanent discontinuation ☐ 6 Other *(specify total daily dose)*: _____ mg
4 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐ 1 100 mg daily ☐ 2 300 mg daily ☐ 3 600 mg daily ☐ 4 Temporary discontinuation ☐ 5 Permanent discontinuation ☐ 6 Other *(specify total daily dose)*: _____ mg
5 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐ 1 100 mg daily ☐ 2 300 mg daily ☐ 3 600 mg daily ☐ 4 Temporary discontinuation ☐ 5 Permanent discontinuation ☐ 6 Other *(specify total daily dose)*: _____ mg
6 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐ 1 100 mg daily ☐ 2 300 mg daily ☐ 3 600 mg daily ☐ 4 Temporary discontinuation ☐ 5 Permanent discontinuation ☐ 6 Other *(specify total daily dose)*: _____ mg

Medication Review

MEDRVW(TYPE 1)

1 Since randomization, did the subject take any new drug class for worsening heart failure?

☐ 0 No MEDWRSHF<XYESNO>

☐ 1 Yes → If Yes: Check all that apply:

ALL<YES>

- ☐ ACE inhibitor MEDACE
- ☐ Angiotensin receptor blocker MEDANGIO
- ☐ Beta blocker MEDBBLKR
- ☐ Aldosterone antagonist MEDALDOS
- ☐ Hydralazine MEDHYDRA
- ☐ Nitrates MEDNITRA
- ☐ Digoxin MEDDIGOX
- ☐ Loop diuretic MEDLOOPD

2 Since randomization, did the subject have an increase in diuretic dose by 50% or more for more than one week *(≥ 1.5 x baseline dose)*? MEDINCRD<XYESNO>

☐ 0 No

☐ 1 Yes

3 Since randomization, did the subject have an increase in beta blocker or renin-angiotensin system inhibitor dose by 50% or more for more than one week *(≥ 1.5 x baseline dose)*? MEDINCRS<XYESNO>

☐ 0 No

☐ 1 Yes → If Yes: Check all that apply:

- ☐ Beta blocker MEDBETAB<XYES>
- ☐ Renin-angiotensin system inhibitor MEDRASI<XYES>

4 Since randomization, did the subject have a decrease in beta blocker or renin-angiotensin system inhibitor dose by 50% or more for more than one week *(≤ 0.5 x baseline dose)*? MEDDCRSE<XYESNO>

☐ 0 No

☐ 1 Yes → If Yes: Check all that apply:

- ☐ Beta blocker MEDBETBL<XYES>
- ☐ Renin-angiotensin system inhibitor MEDRENIN<XYES>

NODATA<ZYES>

HEART FAILURE NETWORK **EXACT**

FORM= REHOSPITALIZATION

Hospitalization

THIS IS A REPEATING PAGE

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

Hospitalization ≥ 24 Hours

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:	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		

NODATA<ZYES>

HEART FAILURE NETWORK **EXACT**

FORM= UNSCHEDULED

Unscheduled Clinic OR Emergency Department Visit

THIS IS A REPEATING PAGE

Subject ID: EX ___ ___ ___ - ___ ___ ___ (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 Primary reason for unscheduled clinic, emergency department or observational unit visit *(check only one)*:

☐1 Heart failure → **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 IVFORHF<XYESNO>

☐2 Other cardiovascular

☐3 Non-cardiovascular

UNSCVREA<EXUNRE>

SUPPRESS HFVISIT

HEART FAILURE NETWORK **EXACT**

NODATA<ZYES>

Death

FORM=DEATHFORM

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

Death

DEATHLOC<HFLOCA>

DEATHPAG (TYPE 1)

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

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

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

DEATHCAU<HFDEAT>

- ☐ 1 Heart failure/pump failure
- ☐ 3 Myocardial infarction
- ☐ 4 Cardiac procedure
- ☐ 5 Other cardiac
- ☐ 6 Cerebral vascular accident *(CVA)*/stroke)
- ☐ 7 Renal
- ☐ 8 Other non-cardiac
- ☐ 9 Unknown
- ☐ 10 Arrhythmia

SUPPRESS:
2
ADD 10

4 **How would you classify this death?**

DEATHCLS<EXDCLS>

- ☐ 1 Sudden
- ☐ 2 Non-sudden

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.38

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

All deaths should be reported on Expedited Event form.
Fax to DCRI Safety Surveillance at 1-866-668-7138.

HEART FAILURE NETWORK **EXACT**

FORM=SAE

NODATA<ZYES>

Adverse Events

THIS IS A REPEATING PAGE

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

Adverse Events

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

ANYAE<XYESNO>

ADVERSE (TYPE 4) R

AENUMBER<I:3>

#	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 on	Was this Event	Was this Event Unexpected r Product abeling?
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 ☐4 Life-threatening	☐0 None ☐1 Interrupted ☐2 Discontinued ☐3 Dosage changed	☐1 Not a reasonable possibility ☐2 Reasonable possibility	☐0 No ☐1 Yes*	☐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 ☐4 Life-threatening	☐0 None ☐1 Interrupted ☐2 Discontinued ☐3 Dosage change	☐1 Not a reasonable possibility ☐2 Reasonable	☐0 No ☐1 Yes*	☐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 ☐4 Life-threatening	☐0 None ☐1 Interrupted ☐2 ☐3	☐1 Not a reasonable	☐0 No ☐1 Yes*	☐0 No ☐1 Yes*

AEONSTDT
AEONSTTM
AEENDDT
AEOUTCM <HFOUTC>
AEINTENS <XINTNS>
AEACTION <HFACTN>
AESERIOU <XYESNO>
AERELAT <HFRELA>
AEUNEXPT <XYESNO>
EVENT<XYESNO>
AETERM <V:100>
AECODTXT <V:100> (DERIVED) All MEDRA coding from this field
AEENDTM
AEHOSP <XYESNO>
AECONT<XYES>
HFNCODE<I:3>
See attached for Codelist for batchloading Into TYPE 0 panel

Coding is performed in the CLINPLUS system
PROJ_HFN/CODING_AE table
LLTERM
LLTCODE
PTERM
PTCODE
HLTERM
HLTCODE
HLGTERM
HLGTCOD
SOCTERM
SOCCODE

**AESERIOU programmed as AESERIOUS

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.

SIGNATUR (TYPE 4)

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

Signature of Investigator

SEE ANNOTATION P. 38

*If an adverse event results in death or if an SAE is assessed as related to study drug, complete an Expedited Event (EE) form and fax. Fax to DCRI Safety Surveillance at 1-866-668-7138.

HEART FAILURE NETWORK **EXACT**

NODATA<ZYES>

Week 26 (Follow-up Safety Phone Call)

FORM= WEEK 26

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

Follow-up Safety Phone Call

FOLLOWUP (TYPE 1)

1 Did a follow up safety phone call occur? FLWUPCAL<XYESNO>

- ☐ 0 No → If No: Reason:
  - ☐ 2 Subject withdrew consent
  - ☐ 3 Subject died
  - ☐ 6 Unable to contact subject

  FLWUPREA<HFSUBJ>
- ☐ 1 Yes → If Yes: Fill out below and provide date of call: FLWUPDT ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

2 To whom did you talk *(check only one)*? FLWUPTLK<EXTALK>

- ☐ 1 Subject
- ☐ 2 Spouse/significant other
- ☐ 3 Relative
- ☐ 4 Other

3 Is subject still alive? FLWUPALV<XYESNO>

- ☐ 0 No
- ☐ 1 Yes

4 From the date the subject stopped taking study drug did the subject have any adverse events? FLWUPAES<XYESNO>

- ☐ 0 No
- ☐ 1 Yes

5 From the date the subject stopped taking study drug to this phone call, was the subject hospitalized? FLWUPHOS<XYESNO>

- ☐ 0 No
- ☐ 1 Yes

6 From the date the subject stopped taking study drug to this phone call, did the subject have any unscheduled clinic or emergency department visit(s)? FLWUPER<XYESNO>

- ☐ 0 No
- ☐ 1 Yes

7 From the date the subject stopped taking study drug to this phone call, did the subject experience any of the following symptoms *(check all that apply)*?

- ☐ None FSCNONE<XYES>
- ☐ Angina FSCANGIN<XYES>
- ☐ Lightheadedness FSCLGTHD<XYES>
- ☐ Syncope FSCSYNCP<XYES>
- ☐ Dyspnea FSCDYSPN<XYES>
- ☐ Fatigue FSCFATIG<XYES>
- ☐ Chest pain FSCCHTPN<XYES>
- ☐ Leg or joint pain FSCLEGPN<XYES>
- ☐ Instability FSCINST<XYES>
- ☐ Weight gain FSCWTGN<XYES>
- ☐ Edema FSCEDEMA<XYES>
- ☐ Other *(specify)*: FSCOTH<XYES> FSCOTHSP<V:100> _____

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)

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

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

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