HEART FAILURE NETWORK

RELAX

PROTOCOL=HFN_RELAX
STUDYBOOK=DATA_FORMS
FORM= BASELINE

NODATA<ZYES>

Baseline

SUBJNO

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

Eligibility

ELIGIBLE (TYPE 1)

Did the subject meet all eligibility criteria? ☐ 0 No → If No: Inclusion criteria not met: # ____ , # ____ , # ____ INCL1<I:3> INCL2<I:3> INCL3<I:3>

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

Was a waiver granted for all of the above exceptions? ELIGCRIT<XYESNO> WAIVER <XYESNO>

☐ 0 No
☐ 1 Yes

☐ 1 Yes

Enroll panel will contain:
SUBJNO: derived from 'RX'll INVSITE ll '-'ll PATID
INITIALS V:3
RANDTM<DATETIME>
RANDDT<DATE>
RXAFIB<XYESNO> (Atrial fibrillation subject)

HEART FAILURE NETWORK **RELAX**

NODATA<ZYES>

Baseline

Subject ID: RX ___ ___ ___ - ___ ___ ___ (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 **RELAX**

NODATA<ZYES>

Baseline

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

Clinical History (continued)

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

7 Valvular heart disease:

☐0 No VALVULAR<XYESNO>

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

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

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

9 TIA: TIA<XYESNO> ☐0 No ☐1 Yes

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

11 Arrhythmia: ARRHYTHM <XYESNO>

☐0 No

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

ATRIALFB<XYES> ☐ Atrial fibrillation/flutter → Check one: ☐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)*: ☐1 Current ☐2 Quit < 6 months ago ☐3 Quit ≥ 6 months ago ☐4 Never CIGARETT<HFCIGR>

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 **RELAX**

NODATA<ZYES>

Baseline

Subject ID: RX ___ ___ ___ - ___ ___ ___ (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>

Clinical Assessment

ASSESSMT(TYPE 3)

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> (systolic) / BPDIA<I:3> (diastolic) mmHg
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>	☐	JVP<HFJVP> ☐1 < 8 cm ☐2 8–12 cm ☐3 13–16 cm ☐4 > 16 cm
7 Rales (check only one): RASNOTDN<XYES>	☐	RALES<HFRALE> ☐0 None ☐1 < 1/3 ☐2 1/3–2/3 ☐3 > 2/3
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>	☐	PEREDEMA<HFEDEM> ☐0 None ☐1 Trace ☐2 Moderate ☐3 Severe
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 ☐3 Three or more pillows ☐1 One pillow (10 cm) ☐4 Not evaluable ☐2 Two pillows (20 cm) ORTHPNEA<HFORTH>

HEART FAILURE NETWORK **RELAX**

NODATA<ZYES>

Baseline

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

Labs

LABS(TYPE 4)PS

	Assessment	Not Done	Value	Units
1=	**1** Sodium:	☐	_____	☐1 mmol/L ☐2 mEq/L
2=	**2** Potassium:	☐	_____	☐1 mmol/L ☐2 mEq/L
3=	**3** BUN/Urea:	☐	_____	☐1 mmol/L ☐3 mg/dL
4=	**4** Bicarbonate:	☐	_____	☐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/mm^3 ☐10 /mm^3
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

LABASSES<HFLAB>

LABVALUE<F:9:3>

LABND<XYES>

LABUNIT<HFLABU>

HEART FAILURE NETWORK **RELAX**

NODATA<XYES>

Baseline

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

MEDS(TYPE 4)PS

Medications Medications prior to Randomization

HFMEDS<HFHFMD> MEDRAND<XYESNO> MEDSCONT<XYNUNK>

		* If No: Documented Evidence of Contraindication
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	
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	

Do not hardcode X in database

SUPPRESS
~~MEDSANS~~
DISCHND
MEDDSCG

DIURETIC (TYPE 4)PS

Oral Diuretics

DIUMEDS<HFDIUR> DIURANS<HFRESP>

	Medication		Average Total Daily Dose	Units
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=CHLORTHIZIDE(SUPPRESS)

†Long-acting medications

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

HEART FAILURE NETWORK **RELAX**

NODATA<ZYES>

Baseline

Subject ID: RX ___ ___ ___ - ___ ___ ___ ___ (site # / pt #) Subject Initials: ___

RELXCORE (TYPE 4)PS

Core Lab Assessments

Test	Date and Time of Test OR Check if Not Done	Reason Not Done *(check only one)*
CPX *(cardio-pulmonary exercise test) (screening acceptable if done per protocol)*	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Not done → SEE ANNOTATION P.24 SUPPRESS 1=PEAK SILDENAFIL LEVEL ___ ___ : ___ ___ (00:00 to 23:59)	☐ 1 Died → **Fill out Death form** ☐ 2 Too sick to perform ☐ 3 Unwilling to perform test but subjectively able ☐ 4 Due to oversight or technical problem ☐ 99 Unknown
Echocardiography	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Not done → ___ ___ : ___ ___ (00:00 to 23:59)	☐ 1 Died → **Fill out Death form** ☐ 2 Too sick to perform ☐ 3 Unwilling to perform test but subjectively able ☐ 4 Due to oversight or technical problem ☐ 99 Unknown
Cardiac MRI	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Not done → ___ ___ : ___ ___ (00:00 to 23:59)	☐ 1 Died → **Fill out Death form** ☐ 2 Too sick to perform ☐ 3 Unwilling to perform test but subjectively able ☐ 4 Due to oversight or technical problem ☐ 6 Atrial fibrillation subject or implanted device ☐ 99 Unknown
Biomarkers—blood	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Not done → ___ ___ : ___ ___ (00:00 to 23:59)	☐ 1 Died → **Fill out Death form** ☐ 2 Too sick to perform ☐ 3 Unwilling to perform test but subjectively able ☐ 4 Due to oversight or technical problem ☐ 99 Unknown

HEART FAILURE NETWORK **RELAX**

NODATA<ZYES> **Baseline**

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

MLHFQ (TYPE 4)PS

Minnesota Living with Heart Failure Questionnaire®

Instructions: These questions ask how much your heart failure (heart condition) affected your life during the last month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

MLWHF<HFMLWH> MLWHFANS<HFMLHF>

	Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by:	No		Very Little →			Very Much
1=	**1** Causing swelling in your ankles, legs, etc.?	0=0	1= 1	2= 2	3= 3	4=4	5= 5
2=	**2** Making you sit or lie down to rest during the day?	0	1	2	3	4	5
3=	**3** Making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4=	**4** Making your working around the house or yard difficult?	0	1	2	3	4	5
5=	**5** Making your going places away from home difficult?	0	1	2	3	4	5
6=	**6** Making it difficult for you to sleep well at night?	0	1	2	3	4	5
7=	**7** Making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8=	**8** Making your working to earn a living difficult?	0	1	2	3	4	5
9=	**9** Making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10=	**10** Making your sexual activities difficult?	0	1	2	3	4	5
11=	**11** Making you eat less of the foods you like?	0	1	2	3	4	5
12=	**12** Making you short of breath?	0	1	2	3	4	5
13=	**13** Making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14=	**14** Making you stay in a hospital?	0	1	2	3	4	5
15=	**15** Costing you money for medical care?	0	1	2	3	4	5
16=	**16** Giving you side effects from treatments?	0	1	2	3	4	5
17=	**17** Making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18=	**18** Making you feel a loss of self-control in your life?	0	1	2	3	4	5
19=	**19** Making you worry?	0	1	2	3	4	5
20=	**20** Making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21=	**21** Making you feel depressed?	0	1	2	3	4	5

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

☐ 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> ___ ___ ___ / PREBPDIA<I:3> ___ ___ ___ mmHg (systolic / diastolic)
Post-walk	PSTHRATE<I:3> ___ ___ ___ bpm	PSTBPSYS<I:3> ___ ___ ___ / PSTBPDIA<I:3> ___ ___ ___ mmHg (systolic / diastolic)

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

5 Did the subject complete the 6-minute walk?

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

☐ 1 Yes WLKCOMPL<XYESNO>

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

- ☐ None WLKNONE<XYES>
- ☐ Angina WLKANGIN<XYES>
- ☐ 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>

HEART FAILURE NETWORK **RELAX**

NODATA<ZYES>

Baseline

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

Initial Study Drug Administration

ISDADMIN (TYPE 1)

Was study drug initial dose *(20 mg)* administered?

☐ 0 No → **If No: Specify reason** *(check only one)*: ISDREASN<RXREAS>

- ☐ 1 Subject withdrew consent
- ☐ 2 MD decision
- ☐ 3 Other

ISTDRUG<XYESNO>

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

Study Drug Dosing Changes (since safety vitals drawn)

SDACHG (TYPE 3)

Was study drug dose adjusted/discontinued? SDADJUST<XYESNO>

☐ 0 No

☐ 1 Yes → Record on Study Drug Dose Adjustment Log

- **Record study drug dispensing information on Study Drug Accountability Log**
- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record and submit any serious adverse events on the Pfizer Serious Adverse Events Report form**

HEART FAILURE NETWORK **RELAX**

FORM=WEEK1

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

NODATA<ZYES>

Week 1 Phone Call

EARLYTRM<XYES>(Hide until p.23 WEEK24)

*Please insert panel AMEND2 before STATUS

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

Subject Status

Was assessment performed? EVALUTE<XYESNO>

SUBJSTAT<HFSUBJ>
SEE CODELIST ABOVE

STATUS(TYPE 3)

☐0 No → If No: Reason: ☐2 Subject withdrew ☐3 Subject died ☐98 Other (specify): _____ STATUSSP <V:50>

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

EVALDT EVALTM

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

Was study drug dose adjusted/discontinued?

☐0 No

☐1 Yes → Record on Study Drug Dose Adjustment Log

SEE ANNOTATION P.10

SDACHG (TYPE 3)

- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record and submit any serious adverse events on the Pfizer Serious Adverse Events Report form**

AMEND2 is in Database only
Not on CRF

* Data Entry: Is the page being entered under Amendment 2?
NO
YES

AMENDMT2<XYESNO>

*** AMEND2 (TYPE 4)**

This page is included in this document to show CRF Version 1.0_14Aug2008. Clinical Assessment data was collected under that version.

FORM=WEEK1

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

NODATA<ZYES>

Week 1

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

Subject Status

Was assessment performed? EVALUTE<XYESNO>

SUBJSTAT<HFSUBJ>
SEE CODELIST ABOVE

STATUS(TYPE 3)

☐0 No → If No: Reason: ☐2 Subject withdrew ☐3 Subject died ☐98 Other (specify): _____ STATUSSP <V:50>

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

Clinical Assessment

ASSESSMT(TYPE 3)

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	☐	___ bpm
2 Blood pressure (sitting or resting):	☐	___ ___ ___ / ___ ___ ___ mmHg (systolic / diastolic)
3 Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg

SEE ANNOTATION P.4
NOTE: Questions to suppress
SEE BELOW *

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

Was study drug dose adjusted/discontinued?

SDACHG (TYPE 3)

☐0 No

SEE ANNOTATION P.10

☐1 Yes → Record on Study Drug Dose Adjustment Log

- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record and submit any serious adverse events on the Pfizer Serious Adverse Events Report form**

*SUPPRESS
3.SPO2
4.HEIGHT
6.JUGULAR VENOUS PRESSURE
7.RALES
8.S3
9.HEPATOMEGALY
10.ASCITES
11.PERIPHERAL EDEMA
12.CURRENT NYHA
13.ORTHOPNEA

NODATA<ZYES>

HEART FAILURE NETWORK **RELAX** FORM=WEEK3

Week 3

*Please insert panel AMEND2 before STATUS

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

Subject Status

Was assessment performed? SEE ANNOTATION P. 11

STATUS (TYPE 3)

☐0 No → If No: Reason: ☐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)

Clinical Assessment

SEE ANNOTATION P.10

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

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

Was study drug dose adjusted/discontinued? SEE ANNOTATION P. 11

SDACHG (TYPE 3)

☐0 No

☐1 Yes → Record on Study Drug Dose Adjustment Log

Labs

SEE ANNOTATION P.5

SUPPRESS ALL EXCEPT 5=CREATININE

LABS (TYPE 4)PS

Assessment	Not Done	Value	Units
Creatinine	☐	_____	☐3 mg/dL ☐4 µmol/L

- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record and submit any serious adverse events on the Pfizer Serious Adverse Events Report form**

AMEND2 is in Database only
Not on CRF

*** AMEND2 (TYPE 4)**

* Data Entry: Is the page being entered under Amendment 2?
NO
YES

AMENDMT2<XYESNO>

This page is included in this document to show CRF Version 1.0_14Aug2008. Clinical Assessment Data and LABS were not collected under that version.

NODATA<ZYES>

Week 3 Phone Call

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

Subject Status

Was assessment performed? SEE ANNOTATION P. 11

STATUS (TYPE 3)

☐0 No → If No: Reason: ☐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)

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

Was study drug dose adjusted/discontinued?

SDACHG (TYPE 3)

SEE ANNOTATION P. 10

☐0 No

☐1 Yes → Record on Study Drug Dose Adjustment Log

- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record and submit any serious adverse events on the Pfizer Serious Adverse Events Report form**

*Please insert panel AMEND2 before STATUS

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

This page is a placeholder for subjects under Protocol Amendment 2.

Panels STATUS, ASSESSMT,SDACHG,LABS are available for entry
For subject through Amendment 1
For subjects in Amendment2 enter 'Yes' for NO DATA and 'Yes' to AMENDMT2

* Data Entry: Is the page being entered under Amendment 2?
NO
YES
AMENDMT2<XYESNO>

*** AMEND2 (TYPE 4)**

This page is included in this document to show CRF Version 1.0_14Aug2008. Subject STATUS, Clinical Assessment Data, Study Drug Dosing Changes and LABS were collected under that version.

Week 4

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

Subject Status

SEE ANNOTATION P. 11

STATUS (TYPE 3)

Was assessment performed?

☐0 No → If No: Reason: ☐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)

Clinical Assessment

SEE ANNOTATION P.10

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

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

SEE ANNOTATION P. 11

SDACHG (TYPE 3)

Was study drug dose adjusted/discontinued?

☐0 No

☐1 Yes → Record on Study Drug Dose Adjustment Log

Labs

SEE ANNOTATION P.5

SUPPRESS ALL EXCEPT 5=CREATININE

LABS (TYPE 4)PS

Assessment	Not Done	Value	Units
Creatinine	☐	_____	☐3 mg/dL ☐4 µmol/L

- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record and submit any serious adverse events on the Pfizer Serious Adverse Events Report form**

HEART FAILURE NETWORK **RELAX**

FORM=WEEK8

NODATA<ZYES>

Week 8 Phone Call

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

Subject Status

STATUS(TYPE 3)

Was assessment performed?

☐0 No → If No: Reason: ☐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)

SEE ANNOTATION P. 11

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

SDACHG (TYPE 3)

Was study drug dose adjusted/discontinued?

SEE ANNOTATION P.10

☐0 No

☐1 Yes → Record on Study Drug Dose Adjustment Log

- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record and submit any serious adverse events on the Pfizer Serious Adverse Events Report form**

FORM=WEEK12

NODATA<ZYES>

HEART FAILURE NETWORK **RELAX**

Week 12

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

Subject Status

STATUS(TYPE 3)

Was assessment performed?

SEE ANNOTATION P.11

☐0 No → If No: Reason: ☐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)

Pre CPX Dose

CPXDOSE(TYPE 3)

1 Record date and time of study drug just prior to CPX *(dose noted is closest and prior to the CPX and blood draws)*:

CPXDT ___/___/___ (day/month/year) CPXTM ___:___ (00:00 to 23:59)

2 Dose: PRECPXDS<I:3> _____ mg

Clinical Assessment

ASSESSMT(TYPE 3)

Assessment	Not Done	Provide Details
1 Heart rate *(sitting or resting)*:	☐ SEE ANNOTATION P.11	___ ___ ___ bpm
2 Blood pressure *(sitting or resting)*:	☐	___ ___ ___ / ___ ___ ___ mmHg (systolic / diastolic)
3 Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg

Labs

LABS (TYPE 4)PS

Assessment	Not Done	Value	Units
Creatinine	SEE ANNOTATION P.5 SUPPRESS ALL EXCEPT 5=CREATININE ☐		☐3 mg/dL ☐4 µmol/L

Core Lab Assessments

RELXCORE (TYPE 4)PS

Test	Date and Time of Test OR Check if Not Done	Reason Not Done *(check only one)*
Peak sildenafil level	___/___/___ (day/month/year) OR ☐ Not done → SEE ANNOTATION P.24 SUPPRESS 3=ECHOCARDIOGRAPHY 4=CARDIAC MRI 5=BIOMARKERS-BL00D	☐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
CPX *(cardio-pulmonary exercise test)*	___/___/___ (day/month/year) OR ☐ Not done → ___:___ (00:00 to 23:59)	☐1 Died → Fill out Death form ☐2 Too sick to perform ☐3 Unwilling to perform test but subjectively able ☐4 Due to oversight or technical problem ☐99 Unknown

HEART FAILURE NETWORK **RELAX**

NODATA<ZYES>

Week 12

Subject ID: RX ____ - ____ site # subject # 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	SUPPRESS: MEDRAND DISCHND MEDDSCG MEDSCONT	☐0 No ☐1 Yes
4=	**4** Aldosterone antagonist		☐0 No ☐1 Yes
5=	**5** Hydralazine		☐0 No ☐1 Yes
6=	**6** Nitrates *(long-acting)* ***(contraindicated unless off study drug)***		☐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 ***(contraindicated unless off study drug)***		☐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

Oral Diuretics

SEE ANNOTATION P.6

DIURETIC(TYPE 4)PS

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

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

Minnesota Living with Heart Failure Questionnaire®

Instructions: These questions ask how much your heart failure (heart condition) affected your life during the last month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

SEE ANNOTATION P.8

MLHFQ (TYPE 4)PS

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by:	No	Very Little →				Very Much
1 Causing swelling in your ankles, legs, etc.?	0	1	2	3	4	5
2 Making you sit or lie down to rest during the day?	0	1	2	3	4	5
3 Making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4 Making your working around the house or yard difficult?	0	1	2	3	4	5
5 Making your going places away from home difficult?	0	1	2	3	4	5
6 Making it difficult for you to sleep well at night?	0	1	2	3	4	5
7 Making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8 Making your working to earn a living difficult?	0	1	2	3	4	5
9 Making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10 Making your sexual activities difficult?	0	1	2	3	4	5
11 Making you eat less of the foods you like?	0	1	2	3	4	5
12 Making you short of breath?	0	1	2	3	4	5
13 Making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14 Making you stay in a hospital?	0	1	2	3	4	5
15 Costing you money for medical care?	0	1	2	3	4	5
16 Giving you side effects from treatments?	0	1	2	3	4	5
17 Making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18 Making you feel a loss of self-control in your life?	0	1	2	3	4	5
19 Making you worry?	0	1	2	3	4	5
20 Making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21 Making you feel depressed?	0	1	2	3	4	5

6-Minute Walk Test (6MWT)

WALKTEST (TYPE 4)

1 **Was walk performed?**

SEE ANNOTATION P.9

☐ 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

☐ 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)*: _____

Study Drug Escalation

ESCALATN (TYPE 3)

Was study drug escalated dose *(60 mg)* administered?

☐ 0 No → **If No: Specify reason** *(check only one)*: ☐ 1 Subject withdrew consent

SDESCAL<XYESNO>

☐ 2 MD decision

☐ 3 Other *(specify)*: ESCALREA<RXREAS> _____

ESCALSP<V:100>

☐ 1 Yes → **Record on Study Drug Dose Adjustment Log**

Study Drug Dosing Changes (after safety vitals)

SDACHG (TYPE 3)

Was study drug dose adjusted/discontinued? SEE ANNOTATION P.10

☐ 0 No

☐ 1 Yes → **Record on Study Drug Dose Adjustment Log**

- **Record study drug dispensing information on Study Drug Accountability Log**
- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record and submit any serious adverse events on the Pfizer Serious Adverse Events Report form**

HEART FAILURE NETWORK **RELAX** FORM=WEEK13

NODATA<ZYES> **Week 13 Phone Call**

*Please insert panel AMEND2 before STATUS

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

Subject Status

STATUS(TYPE 3)

Was assessment performed?

SEE ANNOTATION P.11

☐ 0 No → If No: Reason: ☐ 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)

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

SDACHG (TYPE 3)

Was study drug dose adjusted/discontinued?

SEE ANNOTATION P.10

☐ 0 No

☐ 1 Yes → Record on Study Drug Dose Adjustment Log

- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record and submit any serious adverse events on the Pfizer Serious Adverse Events Report form**

AMEND2 is in Database only
Not on CRF

* Data Entry: Is the page being entered under Amendment 2?
NO
YES
AMENDMT2<XYESNO>

*** AMEND2 (TYPE 4)**

This page is included in this document to show CRF Version 1.0_14Aug2008. Clinical Assessment Data was collected under that version.

FORM=WEEK13

NODATA<ZYES>

Week 13

*Please insert panel AMEND2 before STATUS

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

Subject Status

STATUS(TYPE 3)

Was assessment performed?

SEE ANNOTATION P.11

☐0 No → If No: Reason: ☐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)

Clinical Assessment

ASSESSMT(TYPE 3)

Assessment	Not Done	Provide Details
1 Heart rate (sitting or resting):	☐	___ ___ ___ bpm
2 Blood pressure (sitting or resting):	☐	___ ___ ___ / ___ ___ ___ mmHg (systolic / diastolic)
3 Weight:	☐	___ ___ ___ . ___ ☐1 lb ☐2 kg

SEE ANNOTATION P.11

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

SDACHG (TYPE 3)

Was study drug dose adjusted/discontinued?

SEE ANNOTATION P.10

☐0 No

☐1 Yes → Record on Study Drug Dose Adjustment Log

- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record and submit any serious adverse events on the Pfizer Serious Adverse Events Report form**

HEART FAILURE NETWORK **RELAX**

FORM=WEEK16

NODATA<ZYES>

Week 16 Phone Call

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

Subject Status

STATUS(TYPE 3)

SEE ANNOTATION P.11

Was assessment performed?

☐ 0 No → If No: Reason: ☐ 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)

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

SDACHG (TYPE 3)

SEE ANNOTATION P.10

Was study drug dose adjusted/discontinued?

☐ 0 No

☐ 1 Yes → Record on Study Drug Dose Adjustment Log

- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record and submit any serious adverse events on the Pfizer Serious Adverse Events Report form**

HEART FAILURE NETWORK **RELAX**

FORM=WEEK20

NODATA<ZYES>

Week 20 Phone Call

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

Subject Status

STATUS(TYPE 3)

SEE ANNOTATION P.11

Was assessment performed?

☐ 0 No → If No: Reason: ☐ 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)

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

SDACHG (TYPE 3)

SEE ANNOTATION P.10

Was study drug dose adjusted/discontinued?

☐ 0 No

☐ 1 Yes → Record on Study Drug Dose Adjustment Log

- **Record any adverse events and serious adverse events on Adverse Events page**
- **Record and submit any serious adverse events on the Pfizer Serious Adverse Events Report form**

HEART FAILURE NETWORK **RELAX**

FORM=WEEK24

NODATA<ZYES>

Week 24 (Early Termination)

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

☐ Check if Early Termination visit EARLYTRM<XYES>

STATUS(TYPE 3)

Subject Status

Was assessment performed?

SEE ANNOTATION P.11

☐0 No → If No: Reason: ☐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)

Pre CPX Dose

CPXDOSE(TYPE 3)

1 Record date and time of study drug just prior to CPX *(dose noted is closest and prior to the CPX and blood draws)*:

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

SEE ANNOTATION P.15

2 Dose: _____ mg

Clinical Assessment

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

ASSESSMT(TYPE 3)

SEE ANNOTATION P.11

Labs

Assessment	Not Done	Value	Units
Creatinine	☐	_____	☐3 mg/dL ☐4 µmol/L

SEE ANNOTATION P.15

LABS(TYPE 4)PS

Core Lab Assessments

Test	Date and Time of Test OR Check if Not Done	Reason Not Done (check only one)
RXSCHDAS<RXSCHD> **Peak sildenafil level** 1=	RXCOREDT ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year) OR ☐ Not done → RXCORETM ___ ___ : ___ ___ (00:00 to 23:59)	RXCRND<HFCORE> ☐ 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
CPX *(cardio-pulmonary exercise test)* 2=	___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year) OR ☐ Not done → ___ ___ : ___ ___ (00:00 to 23:59)	☐ 1 Died → **Fill out Death form** ☐ 2 Too sick to perform ☐ 3 Unwilling to perform test but subjectively able ☐ 4 Due to oversight or technical problem ☐ 99 Unknown
Echocardiography 3=	___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year) OR ☐ Not done → ___ ___ : ___ ___ (00:00 to 23:59)	☐ 1 Died → **Fill out Death form** ☐ 2 Too sick to perform ☐ 3 Unwilling to perform test but subjectively able ☐ 4 Due to oversight or technical problem ☐ 99 Unknown
Cardiac MRI 4=	___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year) OR ☐ Not done → ___ ___ : ___ ___ (00:00 to 23:59)	☐ 1 Died → **Fill out Death form** ☐ 2 Too sick to perform ☐ 3 Unwilling to perform test but subjectively able ☐ 4 Due to oversight or technical problem ☐ 6 Atrial fibrillation subject or implanted device ☐ 99 Unknown
Biomarkers—blood 5=	___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year) OR ☐ Not done → ___ ___ : ___ ___ (00:00 to 23:59)	☐ 1 Died → **Fill out Death form** ☐ 2 Too sick to perform ☐ 3 Unwilling to perform test but subjectively able ☐ 4 Due to oversight or technical problem ☐ 99 Unknown

Medications

SEE ANNOTATION P.16

MEDS(TYPE 4) PS

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)* ***(contraindicated unless off study drug)***	☐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 ***(contraindicated unless off study drug)***	☐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

SEE ANNOTATION P.6

DIURETICS (TYPE 4)PS

	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 ☐1 Yes, daily ☐2 Yes, PRN →	_____	mg
5	HCTZ	☐0 No ☐1 Yes, daily ☐2 Yes, PRN →	_____	mg

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

Minnesota Living with Heart Failure Questionnaire®

Instructions: These questions ask how much your heart failure (heart condition) affected your life during the last month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

SEE ANNOTATION P.8

MLHFQ (TYPE 4)PS

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by:	No	Very Little →				Very Much
1 Causing swelling in your ankles, legs, etc.?	0	1	2	3	4	5
2 Making you sit or lie down to rest during the day?	0	1	2	3	4	5
3 Making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4 Making your working around the house or yard difficult?	0	1	2	3	4	5
5 Making your going places away from home difficult?	0	1	2	3	4	5
6 Making it difficult for you to sleep well at night?	0	1	2	3	4	5
7 Making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8 Making your working to earn a living difficult?	0	1	2	3	4	5
9 Making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10 Making your sexual activities difficult?	0	1	2	3	4	5
11 Making you eat less of the foods you like?	0	1	2	3	4	5
12 Making you short of breath?	0	1	2	3	4	5
13 Making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14 Making you stay in a hospital?	0	1	2	3	4	5
15 Costing you money for medical care?	0	1	2	3	4	5
16 Giving you side effects from treatments?	0	1	2	3	4	5
17 Making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18 Making you feel a loss of self-control in your life?	0	1	2	3	4	5
19 Making you worry?	0	1	2	3	4	5
20 Making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21 Making you feel depressed?	0	1	2	3	4	5

6-Minute Walk Test (6MWT)

SEE ANNOTATION P.9

WALKTEST (TYPE 4)

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

☐ 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)*: _____

HEART FAILURE NETWORK **RELAX**

NODATA<ZYES>

FORM=TERMINATION

End of Study

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

Study Termination/Completion

RXTERM (TYPE 1)

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

☐ 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)*: RXSTPREA<RXSTPR>

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

4 Was study drug unblinded?

☐ 0 No RXUNBLND<XYESNO>

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

Endpoint/Safety Review

SAFETY (TYPE 1)

1 How many adverse events did subject have?

_____ → Record all on Adverse Events form SAENUMB<I:3>

2 How many hospitalizations did subject have?

_____ → Record all hospitalizations ≥ 24 hours on Hospitalization form REHOSNUM<I:3>

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

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NODATA<ZYES>

HEART FAILURE NETWORK **RELAX**

This is a repeating page

Study Drug Accountability Log
Baseline through Week 24

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

DRUGLOG (TYPE 4)R

Record of Study Drug

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

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

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

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HEART FAILURE NETWORK **RELAX**

This is a repeating page

NODATA<ZYES>

Study Drug Dose Adjustment Log

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

Study Drug Dose Adjustment or Discontinuation

Was study drug dose changed *(stopped, changed, started)* since initial Baseline dose?

DRUGCHGS(TYPE 4)R

☐0 No

ANYDRCHG<XYESNO>

☐1 Yes → If Yes: Record changes below

CHGNUMB<I:3> **Date of Change**	CHANGES<RXCHG> **New Dose** *(check only one)*
1 CHGDT ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐1 Permanent discontinuation ☐2 Temporary discontinuation ☐3 20 mg TID ☐4 60 mg TID ☐5 Other *(specify total daily dose)*: _____ mg CHGOTH<F:9:3>
2 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐1 Permanent discontinuation ☐2 Temporary discontinuation ☐3 20 mg TID ☐4 60 mg TID ☐5 Other *(specify total daily dose)*: _____ mg
3 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐1 Permanent discontinuation ☐2 Temporary discontinuation ☐3 20 mg TID ☐4 60 mg TID ☐5 Other *(specify total daily dose)*: _____ mg
4 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐1 Permanent discontinuation ☐2 Temporary discontinuation ☐3 20 mg TID ☐4 60 mg TID ☐5 Other *(specify total daily dose)*: _____ mg
5 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐1 Permanent discontinuation ☐2 Temporary discontinuation ☐3 20 mg TID ☐4 60 mg TID ☐5 Other *(specify total daily dose)*: _____ mg
6 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐1 Permanent discontinuation ☐2 Temporary discontinuation ☐3 20 mg TID ☐4 60 mg TID ☐5 Other *(specify total daily dose)*: _____ mg
7 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐1 Permanent discontinuation ☐2 Temporary discontinuation ☐3 20 mg TID ☐4 60 mg TID ☐5 Other *(specify total daily dose)*: _____ mg
8 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐1 Permanent discontinuation ☐2 Temporary discontinuation ☐3 20 mg TID ☐4 60 mg TID ☐5 Other *(specify total daily dose)*: _____ mg
9 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐1 Permanent discontinuation ☐2 Temporary discontinuation ☐3 20 mg TID ☐4 60 mg TID ☐5 Other *(specify total daily dose)*: _____ mg
10 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐1 Permanent discontinuation ☐2 Temporary discontinuation ☐3 20 mg TID ☐4 60 mg TID ☐5 Other *(specify total daily dose)*: _____ mg
11 ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐1 Permanent discontinuation ☐2 Temporary discontinuation ☐3 20 mg TID ☐4 60 mg TID ☐5 Other *(specify total daily dose)*: _____ mg

HEART FAILURE NETWORK **RELAX**

NODATA<ZYES>

FORM= REHOSPITALIZATION

Hospitalization

THIS IS A REPEATING PAGE

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

Hospitalization ≥ 24 Hours

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
- ☐ Ventricular arrhythmia REATRIAL 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 **RELAX**

Unscheduled Clinic OR Emergency Department Visit

FORM= UNSCHEDULED

THIS IS A REPEATING PAGE

Subject ID: RX ___ ___ ___ - ___ ___ ___ (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 → If 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>

DEATHPAG (TYPE 1)

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

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.

SEE ANNOTATION P.28

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

HEART FAILURE NETWORK **RELAX**

FORM=SAE

THIS IS A REPEATING PAGE

NODATA<ZYES>

Adverse Events

Subject ID: RX ___ ___ ___ - ___ ___ ___ (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 only one)	Was this Event Serious?	Was this Event Unexpected per Product Labeling?
1	☐0 No → Name of event: _____ ☐1 Yes → HFN Code #: ____	___/___/___ day/month/year ___:___ 00:00 to 23:59	___/___/___ day/month/year ___:___ 00:00 to 23:59 OR ☐1 Ongoing	☐0 No ☐1 Yes	☐1 Resolved ☐2 Resolved with sequelae ☐3 Unresolved ☐4 Death	☐1 Mild ☐2 Moderate ☐3 Severe ☐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 possibility	☐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	☐1 Mild ☐2 Moderate ☐3 Severe	☐0 None ☐1 Interrupted ☐2 Discontinued	☐1 Not a reasonable possibility	☐0 No ☐1 Yes*	☐0 No ☐1 Yes

AETERM <V:100>

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

HFNCODE<I:3> See attached for 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>

AEONSTDT
AEONSTTM
EVENT<XYESNO>
AEENDDT
AEENDTM
AECONT<XYES>
AEOUTCM <HFOUTC>
AEINTENS <XINTNS>
AEACTION <HFACTN>
AERELAT <HFRELA>
AEHOSP <XYESNO>
AESERIUS <XYESNO>
AEUNEXPT <XYESNO>

**AESERIUS 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.

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

SIGNATUR (TYPE 4)

SEE ANNOTATION P. 28

*** Record all Serious Adverse Events on Pfizer Averse Event Form and fax to DCRI Safety Surveillance (FAX: 1-866-668-7138)**

HFN_RELAX V.2.2_16Jul2009

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

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

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'