Annotated Study Book for Study Design: HFN_ATHENA

Study Design Version: 6.0

Sponsor: National Heart, Lung, and Blood Institute

Randomized, double blind, placebo-controlled study of high-dose spironolactone vs. placebo (for patients not receiving MRA at home) or low-dose spironolactone (for patients already receiving low-dose spironolactone) in AHF.

Generated by Central Designer TM

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Time and Events Schedule For Study Design: HFN_ATHENA

	Element		System																	
	Assessment	CRF	System Screening (SYSSCR) [S]	System Enrollment (SYSENR) [S]	Randomization (RAND) [S]	BASELINE (BASE) [S/D]	24 Hours (24H) [S/D]	48 Hours (48H) [S/D]	72 Hours (72H) [S/D]	96 Hours (96H) [S/D]	DISCHARGE (DISCHRGE) [S/D]	DAY 30 (DAY30) [S/D]	DAY 60 (DAY60) [S/D]	HOSPDC (HOSPDC) [S/D]	EF (EF) [S/D]	REHOSPITALIZATION (REHOSP) [S/D]	OUTPATIENT VISITS (OUTPTVIS) [S/D]	SERIOUS ADVERSE EVENTS (SAE) [S/D]	END OF STUDY (EOS) [S/D]	INVESTIGATOR SIGNATURE (INVSIG) [S/D]
	Visit Start Hours		0	0	0	1	25	73	145	241	242	962	2402	2403	2404	2405	2406	2407	2408	2409
1	System Screening	SYSSCR	1																	
2	System Enrollment	SYSENR		1																
3	STRATIFY	STRATIFY			1															
4	RAND	RAND			2-DF															
5	DEMOGRAPHICS	DEMOG			3-DF															
6	CLINICAL HISTORY	MEDHIST1			4-DF															
7	CLINICAL HISTORY	MEDHIST2			5-DF															
8	PRE-HOSPITAL MEDICATIONS	PREMEDS			6-DF															
9	MEDICATIONS	MEDS				1	2-DF	2-DF	2-DF	2-DF										
10	EXAMINATION	EXAM				2	3-DF	3-DF	3-DF	3-DF	2-DF									
11	LABS1	LABS1				3					3-DF									
12	BIOLOGICAL SAMPLES	SAMPLES				4	7-DF	7-DF	7-DF	7-DF										
13	STUDY DRUG ADMINISTRATION	SDADMIN				5	8-DF	8-DF	8-DF											
14	EVENTS OF INTEREST	EVNTINT				6	9-DF	9-DF	9-DF	8-DF	4-DF									
15	Diuretic	DIURETIC				7	10-DF	10-DF	10-DF	9-DF										
16	IN-HOSPITAL ASSESSMENT	ASSESS					1	1	1	1										
17	FLUID INTAKE/OUTPUT	FLUID					4-DF	4-DF	4-DF	4-DF										
18	LABS2	LABS2					5-DF	5-DF	5-DF	5-DF										
19	POTASSIUM AND CREATININE LABS	KCREAT					6-DF	6-DF	6-DF	6-DF										
20	DISCHARGE MEDICATIONS	DCMEDS					11-DF	11-DF	11-DF	10-DF	5-DF									
21	DISCHARGE VISIT	DCVISIT									1									
22	VISIT STATUS	VISIT										1								
23	DAY30 EVENTS OF INTEREST	EVNTINT1										2-DF								
24	DAY 30 MEDICATIONS	DAY30MED										3-DF								
25	VITAL STATUS	VITAL											1							
26	INDEX HOSPITAL DISCHARGE	INHOSPDC												1						
27	EJECTION FRACTION	EF													1					
28	REHOSPITALIZATION	REHOSP														1-RF				
29	OUTPATIENT VISIT	OUTPTVIS															1-RF			
30	SERIOUS ADVERSE EVENTS	SAE																1-RF		
31	DAY 30 PARTICIPATION STATUS	EOS																	1	
32	DEATH	DEATH																	2-DF	
33	Signature Completion	SIGN																		1

Key: [S] = Scheduled Visit [D] = Dynamic Visit [U] = Unscheduled Visit [R] = Repeating Visit
C = Common Form DF = Dynamic Form RF = Repeating Form

HFN_ATHENA: System Screening (SYSSCR) [frSYSSCR1]		
System Screening [frSYSSCR1]		
1.*	Check box to screen subject into InForm system. [Check to screen subject]	**[SCRSUBJ]** *[N:1]* ☐ Screen Subject
2.	System generated initials *[hidden]* [System generated initials]	**[SUBJINIT]** A3
3.*	Sex [Sex]	**[SCRGEND]** *[N:1]* ◯ Male *[N:2]* ◯ Female
4.*	Date of Birth [Date of Birth]	**[SCRDOB]** Req / Req / Req (1912-1993)
Key: [*] = Item is required		

Study Object Descriptions: System Screening

Type	RefName	Description
Form	frSYSSCR1	Inform System Screening form
Item	SCRSUBJ	Inform System Screening Checkbox for screening patient
Item	SUBJINIT	Inform System generated Initals
Item	SCRGEND	
Item	SCRDOB	

HFN_ATHENA: System Enrollment (SYSENR) [frENRSYS2]		
System Enrollment [frENRSYS2]		
1.*	Check the box to enroll the subject into the InForm system. [Check to enroll subject]	**[ENRSUBJ]** *[N:1]* ☐ Enroll Subject
Key: [*] = Item is required		

Study Object Descriptions: System Enrollment

Type	RefName	Description
Form	frENRSYS2	Inform System Enrollment form
Item	ENRSUBJ	Inform System Enroll Subject check box

HFN_ATHENA: STRATIFY (STRATIFY) [frSTRATIFY]		
Stratification Information [stSTRATIFY1]		
1.* ✔	MRA Usage at Baseline [MRA Usage at Baseline]	**[MRASTRAT]** *[N:1]* ◯ Not on MRA on admission *[N:2]* ◯ On low dose MRA on admission

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: STRATIFY		
Type	**RefName**	**Description**
Form	frSTRATIFY	Stratification
Section	stSTRATIFY1	
Item	MRASTRAT	

HFN_ATHENA: RAND (RAND) [frSIRERAND]		
Randomization [stRAND1]		
1.	Patient Number *[read-only]* [Patient Number]	**[RSUBJID]** A200
Randomization Information [stRAND2]		
2.*	Does subject qualify for study? [Does subject qualify for study?]	**[RNDQUAL]** *[N:1]* ◯ Yes *[N:0]* ◯ No
3.	Arm *[read-only]* [Arm]	**[ARM]** A200
4.	Site Randomization date/time *[read-only]* [Site Randomization date/time]	**[SITEDTM]** Req / Req / Req (2011-2020) Req : Req *24-hour clock*
5.	Check this box if a randomization error message appears in Arm question above and the form needs to be resubmitted to populate Arm with randomization information [Re-submit]	**[RESUBMIT]** *[N:1]* ☐ Resubmit
6.	Cohort *[hidden]*	**[COHORT]** N10
STRATA [stRAND3]		
7.	STRATA 1 *[hidden]* [STRATA 1]	**[STRATA1]** A200
8.	STRATA 2 *[hidden]* [STRATA 2]	**[STRATA2]** A200
9.	STRATA 3 *[hidden]* [STRATA 3]	**[STRATA3]** A200
10.	STRATA 4 *[hidden]* [STRATA 4]	**[STRATA4]** A200
Key: [*] = Item is required		

Study Object Descriptions: RAND

Type	RefName	Description
Form	frSIRERAND	SIRE Randomization form
Section	stRAND1	Section 1 - Randomization
Item	RSUBJID	
Section	stRAND2	SECTION 2: Randomization Information
Item	RNDQUAL	
Item	ARM	
Item	SITEDTM	
Item	RESUBMIT	
Item	COHORT	Cohort
Section	stRAND3	SECTION 3: STRATA
Item	STRATA1	
Item	STRATA2	
Item	STRATA3	
Item	STRATA4	

HFN_ATHENA: DEMOGRAPHICS (DEMOG) [frDEMOG]

Informed Consent [stDEMOG1]

1.* ✔	Date/Time Informed Consent Signed [Date/Time Informed Consent Signed]	**[CONSDTM]** Req / Req / Req (2014-2017) Req/Unk : Req/Unk *24-hour clock*
2.* ✔	Did the subject agree to participate in the biorepository substudy [Subject agree to participate in biorepository substudy]	**[BIORPSTY]** *[N:1]* **[BIORPCDT]** Yes Date consent obtained Req / Req / Req (2014-2017) *[N:0]* No *[N:2]* Site not participating
3.* ✔	Did the subject agree to participate in the pharmacogenomics (genetics) substudy [Subject agree to participate in pharmacogenomics substudy]	**[GENETICS]** *[N:1]* **[GENCONDT]** Yes Date consent obtained Req / Req / Req (2014-2017) *[N:0]* No *[N:2]* Site not participating

Demographics [stDEMOG2]

4.*	Date of Birth [Date of Birth]	**[DOBDT]** Req / Req / Req (1912-1993)
5.*	Sex [Sex]	**[SEX]** *[N:1]* Male *[N:2]* Female
6.*	Ethnicity [Ethnicity]	**[ETHNIC]** *[N:1]* Hispanic or Latino *[N:2]* Not Hispanic or Latino
7.*	Race (check all that apply) [Race]	**[cpRACE]** **[AMERIND]** *[N:1]* American Indian or Alaskan Native **[ASIAN]** *[N:1]* Asian **[BLACK]** *[N:1]* Black or African American **[NATHWN]** *[N:1]* Native Hawaiian or Other Pacific Islander **[WHITE]** *[N:1]* White/Caucasian
8.	Subject ID [Subject ID]	**[SUBJID]** A20
9.	Check box to update subjects workflow	**[UPDTWRK]** *[N:1]* Yes

IV Diuretic [stDEMOG3]

10.*	Date/Time admitted with AHF diagnosis [Date/Time admitted with AHF diagnosis]	**[ADMITDTM]** Req / Req / Req (2014-2017) Req/Unk : Req/Unk *24-hour clock*
11.*	Date/Time IV Diuretic Administered [Date/Time IV Diuretic Administered]	**[IVDDTM]** Req / Req / Req (2014-2017) Req/Unk : Req/Unk *24-hour clock*

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Study Object Descriptions: DEMOGRAPHICS

Type	RefName	Description
Form	frDEMOG	
Section	stDEMOG1	
Item	CONSDTM	
Item	BIORPSTY	
Item	BIORPCDT	
Item	GENETICS	
Item	GENCONDT	
Section	stDEMOG2	

Item	DOBDT	
Item	SEX	
Item	ETHNIC	
Item	cpRACE	
Item	AMERIND	
Item	ASIAN	
Item	BLACK	
Item	NATHWN	
Item	WHITE	
Item	SUBJID	
Item	UPDTWRK	
Section	stDEMOG3	
Item	ADMITDTM	
Item	IVDDTM	

HFN_ATHENA: CLINICAL HISTORY (MEDHIST1) [frMEDHIST1]

Clinical History [stMEDHIST1]

1.*	Estimated date of initial diagnosis of heart failure [Estimated date of initial diagnosis of heart failure]	**[DIAGDT]** Req/Unk / Req/Unk (1920-2017)
2.*	Total number of hospitalizations within prior 12 months (provide best estimate if exact number is unknown) [Total number of hospitalizations within prior 12 months]	**[HOSPVAL]** N3
3.*	Number of hospitalizations with primary diagnosis of heart failure within past 12 months (provide best estimate if exact number is unknown): [Number of hospitalizations with primary diagnosis of heart failure within past 12 months]	**[NUMHFHSP]** N3
4.*	Has LV function been assessed within 6 months of Randomization? [Has LV function been assessed]	**[LVASSESS]** *[N:1]* **[cpLVASSESS]** Yes **[LVASSDT]** Date: Req/Unk / Req/Unk / Req/Unk (1920-2020) **[LVEF]** Value of last LVEF: *[N:1]* **[LVEFEF]** xxxxxxxx. % *[N:2]* Normal *[N:3]* Mild dysfunction *[N:4]* Moderate dysfunction *[N:5]* Severe dysfunction *[N:0]* No
5.*	Has the subject had a myocardial infarction (MI)? [Has the subject had a myocardial infarction (MI)]	**[MI]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
6.*	Has the subject had a left heart catheterization? [Has the subject had a left heart catheterization]	**[LTCATH]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
7.*	Has the subject had a percutaneous coronary intervention (PCI)? [Has the subject had a percutaneous coronary intervention (PCI)]	**[PCIHX]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
8.*	Has the subject had a coronary artery bypass graft (CABG)? [Has the subject had a coronary artery bypass graft (CABG)]	**[CABGHX]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
9.*	Has subject had any other factors contributing to cardiomyopathy? [Has subject had any other factors contributing to cardiomyopathy]	**[FACTORYN]** *[N:1]* **[cpFACTORYN]** Yes (check all that apply) **[ALCOHOLC]** *[N:1]* Alcoholic **[CYTOTOX]** *[N:1]* Cytotoxic drug therapy **[FAMILIAL]** *[N:1]* Familial **[HYPERTN]** *[N:1]* Hypertensive **[IDIODIL]** *[N:1]* Idiopathic dilated cardiomyopathy **[IDIORES]** *[N:1]* Idiopathic restrictive cardiomyopathy **[PERIPRT]** *[N:1]* Peripartum **[VALVUL]** *[N:1]* Valvular **[HCM]** *[N:1]* HCM **[MYOOTH]** *[N:1]* **[MYOPSP]** Other/uncertain Specify A100 *[N:0]* No *[N:99]* Unknown

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: CLINICAL HISTORY		
Type	**RefName**	**Description**
Form	frMEDHIST1	
Section	stMEDHIST1	
Item	DIAGDT	
Item	HOSPVAL	
Item	NUMHFHSP	
Item	LVASSESS	
Item	cpLVASSESS	
Item	LVASSDT	
Item	LVEF	
Item	LVEFEF	
Item	MI	
Item	LTCATH	
Item	PCIHX	
Item	CABGHX	
Item	FACTORYN	
Item	cpFACTORYN	
Item	ALCOHOLC	
Item	CYTOTOX	
Item	FAMILIAL	
Item	HYPERTN	
Item	IDIODIL	
Item	IDIORES	
Item	PERIPRT	
Item	VALVUL	
Item	HCM	
Item	MYOOTH	
Item	MYOPSP	

HFN_ATHENA: CLINICAL HISTORY (MEDHIST2) [frMEDHIST2]

Clinical History [stMEDHIST2_1]

1.*	Does subject have moderate to severe valvular heart disease? [Moderate to severe valvular heart disease]	**[VALVULAR]** *[N:1]* ◯ **[cpVALVULAR]** Yes (check all that apply) **[MREGURG]** *[N:1]* ☐ Mitral regurgitation **[AREGURG]** *[N:1]* ☐ Aortic regurgitation **[TREGURG]** *[N:1]* ☐ Tricuspid regurgitation *[N:0]* ◯ No *[N:99]* ◯ Unknown
2.*	Has subject had prior valvular surgery? [Prior valvular surgery]	**[PVALSRG]** *[N:1]* ◯ **[cpPVALSRG]** Yes (check all that apply) **[MITSURG]** *[N:1]* ☐ Mitral **[AORSURG]** *[N:1]* ☐ Aortic **[TRISURG]** *[N:1]* ☐ Tricuspid **[PULSURG]** *[N:1]* ☐ Pulmonic *[N:0]* ◯ No *[N:99]* ◯ Unknown
3.*	Hypertension [Hypertension]	**[HYPRTESN]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
4.*	TIA [TIA]	**[TIA]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
5.*	Stroke [Stroke]	**[STROKE]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
6.*	Arrhythmia [Arrhythmia]	**[ARRHYTHM]** *[N:1]* ◯ **[cpARRHYTHM]** Yes (check all that apply) **[ATRIALFB]** *[N:1]* ☐ Atrial fibrillation **[SUSVT]** *[N:1]* ☐ VT/VF **[ARRHUNKO]** *[N:1]* ☐ Unknown/Other *[N:0]* ◯ No *[N:99]* ◯ Unknown
7.*	Pacemaker/ICD [Pacemaker/ICD]	**[PACEICD]** *[N:1]* ◯ **[PACICDTY]** Yes *[N:1]* ◯ Pacemaker (single/dual) *[N:2]* ◯ Biventricular Pacemaker with ICD *[N:3]* ◯ Biventricular Pacemaker without ICD *[N:4]* ◯ ICD only (single/dual) *[N:0]* ◯ No *[N:99]* ◯ Unknown
8.*	Peripheral vascular disease [Peripheral vascular disease]	**[PVD]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
9.*	Chronic obstructive pulmonary disease [Chronic obstructive pulmonary disease]	**[COPD]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
10.*	Diabetes [Diabetes]	**[DIABETES]** *[N:1]* ◯ Yes

		[N:0] No *[N:99]* Unknown
11.*	Hepatic disease [Hepatic disease]	**[HEPATIC]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
12.*	Chronic renal insufficiency [Chronic renal insufficiency]	**[CRINSUF]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
13.*	Depression (treated with prescription medication) [Depression]	**[DEPRESS]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
14.*	Cigarette smoking [Cigarette smoking]	**[SMOKING]** *[N:1]* Current *[N:2]* Quit <6 months ago *[N:3]* Quit >= 6 months ago *[N:4]* Never *[N:99]* Unknown
15.*	Hyperlipidemia [Hyperlipidemia]	**[HYPRLIP]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
16.*	Obstructive sleep apnea [Obstructive sleep apnea]	**[OSA]** *[N:1]* **[OSATX]** Yes Treated: *[N:1]* Yes *[N:0]* No *[N:0]* No *[N:99]* Unknown
Key: [*] = Item is required [✔] = Source verification required		

Study Object Descriptions: CLINICAL HISTORY

Type	RefName	Description
Form	frMEDHIST2	
Section	stMEDHIST2_1	
Item	VALVULAR	
Item	cpVALVULAR	
Item	MREGURG	
Item	AREGURG	
Item	TREGURG	
Item	PVALSRG	
Item	cpPVALSRG	
Item	MITSURG	
Item	AORSURG	
Item	TRISURG	
Item	PULSURG	
Item	HYPRTESN	
Item	TIA	
Item	STROKE	
Item	ARRHYTHM	
Item	cpARRHYTHM	
Item	ATRIALFB	
Item	SUSVT	
Item	ARRHUNKO	
Item	PACEICD	
Item	PACICDTY	
Item	PVD	
Item	COPD	

Item	DIABETES	
Item	HEPATIC	
Item	CRINSUF	
Item	DEPRESS	
Item	SMOKING	
Item	HYPRLIP	
Item	OSA	
Item	OSATX	

HFN_ATHENA: PRE-HOSPITAL MEDICATIONS (PREMEDS) [frPREMEDS]

Medications [stPREMEDS1]

1.* ✔	ACE inhibitor [ACE inhibitor]	**[ACE]** [N:1] ◯ Yes [N:0] ◯ **[ACECONT]** If no: Is there documented evidence of contraindication? [N:1] ◯ Yes [N:0] ◯ No [N:99] ◯ Unknown [N:99] ◯ Unknown
2.* ✔	Angiotensin receptor blocker [Angiotensin receptor blocker]	**[ARB]** [N:1] ◯ Yes [N:0] ◯ **[ARBCONT]** If no: Is there documented evidence of contraindication? [N:1] ◯ Yes [N:0] ◯ No [N:99] ◯ Unknown [N:99] ◯ Unknown
3.*	Beta Blocker [Beta Blocker]	**[BETAB]** [N:1] ◯ Yes [N:0] ◯ **[BETACONT]** If no: Is there documented evidence of contraindication? [N:1] ◯ Yes [N:0] ◯ No [N:99] ◯ Unknown [N:99] ◯ Unknown
4.*	Aldosterone antagonist [Aldosterone antagonist]	**[ALDOS]** [N:1] ◯ Yes [N:0] ◯ No [N:99] ◯ Unknown
5.*	Hydralazine [Hydralazine]	**[HYDR]** [N:1] ◯ Yes [N:0] ◯ No [N:99] ◯ Unknown
6.*	Nitrates (long acting) [Nitrates]	**[NITR]** [N:1] ◯ Yes [N:0] ◯ No [N:99] ◯ Unknown
7.*	Calcium channel blocker [Calcium channel blocker]	**[CCB]** [N:1] ◯ Yes [N:0] ◯ No [N:99] ◯ Unknown
8.*	Antiplatelets [Antiplatelets]	**[ANTIPLT]** [N:1] ◯ **[cpANTIPLT]** Yes (check all that apply) **[ANTIPASP]** [N:1] ☐ Aspirin (taken daily) **[ANTIPTHI]** [N:1] ☐ Thienopyridines (eg: ticlopidine, clopidogrel, prasugrel) **[ANTIPOTH]** [N:1] ☐ Other [N:0] ◯ **[ANTIPTCI]** If no: Is there documented evidence of contraindication? [N:1] ◯ Yes [N:0] ◯ No [N:99] ◯ Unknown [N:99] ◯ Unknown
9.*	Anticoagulants [Anticoagulants]	**[ANTICAG]** [N:1] ◯ **[cpANTICAG]** Yes (check all that apply) **[ANTICWAR]** [N:1] ☐ Warfarin **[ANTICFACX]** [N:1] ☐ Factor Xa Inhibitor **[ANTICDTH]** [N:1] ☐ Direct Thrombin Inhibitor **[ANTICOTH]** [N:1] ☐ Other [N:0] ◯ **[ANTICACI]**

		If no: Is there documented evidence of contraindication? *[N:1]* Yes *[N:0]* No *[N:99]* Unknown *[N:99]* Unknown
10.*	Digoxin [Digoxin]	**[DIGX]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
11.*	Amiodarone [Amiodarone]	**[AMIOD]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
12.*	Statin [Statin]	**[STATIN]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
13.*	Lipid lowering agent (other than statin) [Lipid lowering agent]	**[LLIPID]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
14.*	Ambulatory IV Inotropes [Ambulatory IV Inotropes]	**[IVINOTRP]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
15.* ✔	Metolazone [Metolazone]	**[METAZ]** *[N:1]* **[METODOSE]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* No *[N:99]* Unknown
16.* ✔	HCTZ [HCTZ]	**[HCTZ]** *[N:1]* **[HCTZDOSE]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* No *[N:99]* Unknown
17.* ✔	Furosemide [Furosemide]	**[FURO]** *[N:1]* **[FURODOSE]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* No *[N:99]* Unknown
18.* ✔	Torsemide [Torsemide]	**[TORS]** *[N:1]* **[TORSDOSE]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* No *[N:99]* Unknown
19.* ✔	Bumetanide [Bumetanide]	**[BUME]** *[N:1]* **[BUMDOSE]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* No *[N:99]* Unknown
20.* ✔	Spironolactone (open label) [Spironolactone (open label)]	**[SPIROUSE]** *[N:1]* **[SPIRDOSE]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* No *[N:99]* Unknown
21.* ✔	Eplerenone [Eplerenone]	**[EPLEUSE]** *[N:1]* **[EPLEDOSE]**

		Yes Total Daily Dose: xxxxxxxx. *[N:0]* No *[N:99]* Unknown
22.* ✔	Potassium [Potassium]	**[KUSE]** *[N:1]* **[KDOSE]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* No *[N:99]* Unknown

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: PRE-HOSPITAL MEDICATIONS

Type	RefName	Description
Form	frPREMEDS	
Section	stPREMEDS1	
Item	ACE	
Item	ACECONT	
Item	ARB	
Item	ARBCONT	
Item	BETAB	
Item	BETACONT	
Item	ALDOS	
Item	HYDR	
Item	NITR	
Item	CCB	
Item	ANTIPLT	
Item	cpANTIPLT	
Item	ANTIPASP	
Item	ANTIPTHI	
Item	ANTIPOTH	
Item	ANTIPTCI	
Item	ANTICAG	
Item	cpANTICAG	
Item	ANTICWAR	
Item	ANTICFACX	
Item	ANTICDTH	
Item	ANTICOTH	
Item	ANTICACI	
Item	DIGX	
Item	AMIOD	
Item	STATIN	
Item	LLIPID	
Item	IVINOTRP	
Item	METAZ	
Item	METODOSE	
Item	HCTZ	
Item	HCTZDOSE	
Item	FURO	
Item	FURODOSE	
Item	TORS	
Item	TORSDOSE	
Item	BUME	
Item	BUMDOSE	
Item	SPIROUSE	
Item	SPIRDOSE	

Item	EPLEUSE	
Item	EPLEDOSE	
Item	KUSE	
Item	KDOSE	

HFN_ATHENA: MEDICATIONS (MEDS) [frMEDS]

Medications [stMEDS1]

1.* ✔	ACE inhibitor [ACE inhibitor]	**[ACER]** *[N:1]* Yes *[N:0]* **[ACECONTR]** No If no: Is there documented evidence of contraindication? *[N:1]* Yes *[N:0]* No *[N:99]* Unknown *[N:99]* Unknown
2.* ✔	Angiotensin receptor blocker [Angiotensin receptor blocker]	**[ARBR]** *[N:1]* Yes *[N:0]* **[ARBCONTR]** No If no: Is there documented evidence of contraindication? *[N:1]* Yes *[N:0]* No *[N:99]* Unknown *[N:99]* Unknown
3.*	Beta Blocker [Beta Blocker]	**[BETABR]** *[N:1]* Yes *[N:0]* **[BETACONR]** No If no: Is there documented evidence of contraindication? *[N:1]* Yes *[N:0]* No *[N:99]* Unknown *[N:99]* Unknown
4.*	Aldosterone antagonist [Aldosterone antagonist]	**[ALDOSR]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
5.*	Hydralazine [Hydralazine]	**[HYDRR]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
6.*	Nitrates (long acting) [Nitrates]	**[NITRR]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
7.*	Calcium channel blocker [Calcium channel blocker]	**[CCBR]** *[N:1]* Yes *[N:0]* No *[N:99]* Unknown
8.*	Antiplatelets [Antiplatelets]	**[ANTIPLTR]** *[N:1]* **[cpANTIPLTR]** Yes (check all that apply) **[ANTIPASR]** *[N:1]* Aspirin (taken daily) **[ANTIPTHR]** *[N:1]* Thienopyridines (eg: ticlopidine, clopidogrel, prasugrel) **[ANTIPOTR]** *[N:1]* Other *[N:0]* **[ANTIPTCR]** No If no: Is there documented evidence of contraindication? *[N:1]* Yes *[N:0]* No *[N:99]* Unknown *[N:99]* Unknown
9.*	Anticoagulants [Anticoagulants]	**[ANTICAGR]** *[N:1]* **[cpANTICAGR]** Yes (check all that apply) **[ANTICWRR]** *[N:1]* Warfarin **[ANTICFCR]** *[N:1]* Factor Xa Inhibitor **[ANTICDTR]** *[N:1]* Direct Thrombin Inhibitor

		[ANTICOTR] *[N:1]* ☐ Other *[N:0]* ◯ **[ANTICACR]** No If no: Is there documented evidence of contraindication? *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown *[N:99]* ◯ Unknown
10.*	Digoxin [Digoxin]	**[DIGXR]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
11.*	Amiodarone [Amiodarone]	**[AMIODR]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
12.*	Statin [Statin]	**[STATINR]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
13.*	Lipid lowering agent (other than statin) [Lipid lowering agent]	**[LLIPIDR]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
14.*	Ambulatory IV Inotropes [Ambulatory IV Inotropes]	**[IVINOTRR]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
15.* ✔	Spironolactone (open label) [Spironolactone (open label)]	**[SPIROUSR]** *[N:1]* ◯ **[SPIRDOSR]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* ◯ No *[N:99]* ◯ Unknown
16.* ✔	Eplerenone [Eplerenone]	**[EPLEUSER]** *[N:1]* ◯ **[EPLEDOSR]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* ◯ No *[N:99]* ◯ Unknown
17.* ✔	Potassium [Potassium]	**[KUSER]** *[N:1]* ◯ **[KDOSER]** Yes Total Daily Dose (mEq): xxxxxxxx. *[N:0]* ◯ No *[N:99]* ◯ Unknown

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: MEDICATIONS

Type	RefName	Description
Form	frMEDS	
Section	stMEDS1	
Item	ACER	
Item	ACECONTR	
Item	ARBR	
Item	ARBCONTR	
Item	BETABR	
Item	BETACONR	
Item	ALDOSR	
Item	HYDRR	
Item	NITRR	
Item	CCBR	
Item	ANTIPLTR	
Item	cpANTIPLTR	

Item	ANTIPASR	
Item	ANTIPTHR	
Item	ANTIPOTR	
Item	ANTIPTCR	
Item	ANTICAGR	
Item	cpANTICAGR	
Item	ANTICWRR	
Item	ANTICFCR	
Item	ANTICDTR	
Item	ANTICOTR	
Item	ANTICACR	
Item	DIGXR	
Item	AMIODR	
Item	STATINR	
Item	LLIPIDR	
Item	IVINOTRR	
Item	SPIROUSR	
Item	SPIRDOSR	
Item	EPLEUSER	
Item	EPLEDOSR	
Item	KUSER	
Item	KDOSER	

HFN_ATHENA: EXAMINATION (EXAM) [frEXAM]

EXAMINATION [frEXAM]

1.*	Heart Rate (sitting or resting) [Heart Rate]	**[HRATE]** *[N:1]* **[HRATEVAL]** N3 *[N:97]* Not Done
2.*	Blood Pressure (sitting or resting) [Blood Pressure]	**[BPDONE]** *[N:1]* **[cpBP]** **[BPSYS]** **[BPDIA]** mmHg N3 / N3 *[N:97]* Not Done
3.	Height (at Baseline visit only) [Height]	**[HEIGHT]** *[N:1]* **[HGTVAL]** xxxxxxxx. **[HGTUNITS]** Unit *[N:1]* in *[N:2]* cm *[N:97]* Not Done
4.* ✔	Weight (Secondary Endpoint) [Weight]	**[WEIGHT]** *[N:1]* **[WGTVAL]** xxxxxxxx. **[WGTUNITS]** Unit *[N:1]* lb *[N:2]* kg *[N:97]* Not Done
5.* ✔	JVD (cmH_20) (Secondary Endpoint) [JVD (cmH20)]	**[CCS4]** *[N:1]* <6 *[N:2]* 6 - 9 *[N:3]* 10 - 15 *[N:4]* >15 *[N:97]* Not Done
6.* ✔	Rales (Secondary Endpoint) [Rales]	**[CCS5]** *[N:1]* None *[N:2]* Bases *[N:3]* To <50% *[N:4]* To >50% *[N:97]* Not Done
7.* ✔	Peripheral edema (Secondary Endpoint) [Peripheral edema]	**[CCS6]** *[N:1]* Absent/Trace *[N:2]* Slight *[N:3]* Moderate *[N:4]* Marked *[N:97]* Not Done
8.*	Current NYHA heart failure classification [Current NYHA heart failure classification]	**[NYHA]** *[N:1]* I *[N:2]* II *[N:3]* III *[N:4]* IV *[N:97]* Not Done
9.* ✔	Orthopnea (Secondary Endpoint) [Orthopnea]	**[CCS2]** *[N:1]* None *[N:2]* Seldom *[N:3]* Frequent *[N:4]* Continuous *[N:97]* Not Done
10.* ✔	Fatigue (Secondary Endpoint) [Fatigue]	**[CCS3]** *[N:1]* None *[N:2]* Seldom *[N:3]* Frequent *[N:4]* Continuous *[N:97]* Not Done
11.* ✔	Dyspnea (Secondary Endpoint) [Dyspnea]	**[CCS1]** *[N:1]* None *[N:2]* Seldom *[N:3]* Frequent

		[N:4] Continuous *[N:97]* Not Done
12.* ✔	Dyspnea Relief 7-Point Likert Scale (Secondary Endpoint) [Dyspnea Relief 7-Point Likert Scale]	**[DYSLIKRT]** *[N:1]* Markedly Improved *[N:2]* Moderately Improved *[N:3]* Minimally Improved *[N:4]* No Change *[N:5]* Minimally Worse *[N:6]* Moderately Worse *[N:7]* Markedly Worse *[N:97]* Not Done
13.* ✔	Dyspnea Relief Visual Analog Scale (Secondary Endpoint) [Dyspnea Relief Visual Analog Scale]	**[DYSVISDN]** *[N:1]* **[DYSANAVL]** xxxxxxxx. *[N:97]* Not Done
14.* ✔	In-hospital worsening of HF (defined as worsening HF signs and symptoms requiring additional therapy)? (Secondary Endpoint) [In-hospital worsening of HF]	**[WORSENHF]** *[N:1]* **[cpWORSENHF]** Yes (indicate therapies provided): **[ADDLLOOP]** *[N:1]* Additional loop diuretics **[VASOACTV]** *[N:1]* IV vasoactive agent for HF treatment (please complete Question 15) **[CIRSUPPT]** *[N:1]* Mechanical circulatory support **[THIMETO]** *[N:1]* Addition of thiazide or metolazone **[ULTRAFIL]** *[N:1]* Ultrafiltration **[MECHRESP]** *[N:1]* Mechanical ventilation support for HF **[WHFOTH]** *[N:1]* **[WHFOTHSP]** Other, specify: A100 *[N:0]* No *[N:97]* Not Done
15.	If IV Vasoactive agents for HF treatment were given for worsening heart failure, please indicate medications administered: [IV vasoactive agent for HF treatment]	**[cpVASOACTV]** **[VASINOTP]** *[N:1]* **[cpVASINOTP]** Inotrope **[INODUBUT]** *[N:1]* Dobutamine **[INOMILIR]** *[N:1]* Milrinone **[INOOTHER]** *[N:1]* Other **[VASODILT]** *[N:1]* **[cpVASODILT]** Vasodilators (continuous drip) **[VASDNYGN]** *[N:1]* Nitroglycerin **[VASDNPRU]** *[N:1]* Nitroprusside **[VASDOTH]** *[N:1]* Other **[VASOPRES]** *[N:1]* **[cpVASOPRES]** Vasopressor **[VASOPDOP]** *[N:1]* Dopamine (>3mcg/kg/min) **[VASNOREP]** *[N:1]* Norepinephrine **[VASOPOTH]** *[N:1]* Other

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: EXAMINATION

Type	RefName	Description
Form	frEXAM	

Item	HRATE	
Item	HRATEVAL	
Item	BPDONE	
Item	cpBP	
Item	BPSYS	
Item	BPDIA	
Item	HEIGHT	
Item	HGTVAL	
Item	HGTUNITS	
Item	WEIGHT	
Item	WGTVAL	
Item	WGTUNITS	
Item	CCS4	
Item	CCS5	
Item	CCS6	
Item	NYHA	
Item	CCS2	
Item	CCS3	
Item	CCS1	
Item	DYSLIKRT	
Item	DYSVISDN	
Item	DYSANAVL	
Item	WORSENHF	
Item	cpWORSENHF	
Item	ADDLLOOP	
Item	VASOACTV	
Item	CIRSUPPT	
Item	THIMETO	
Item	ULTRAFIL	
Item	MECHRESP	
Item	WHFOTH	
Item	WHFOTHSP	
Item	cpVASOACTV	
Item	VASINOTP	
Item	cpVASINOTP	
Item	INODUBUT	
Item	INOMILIR	
Item	INOOTHER	
Item	VASODILT	
Item	cpVASODILT	
Item	VASDNYGN	
Item	VASDNPRU	
Item	VASDOTH	
Item	VASOPRES	
Item	cpVASOPRES	
Item	VASOPDOP	
Item	VASNOREP	
Item	VASOPOTH	

HFN_ATHENA: LABS1 (LABS1) [frLABS1]

Labs [stLABS1A]

1.*	Collection Date and Time [Collection Date and Time]	**[LABDTM]** Req / Req / Req (2014-2017) Req/Unk : Req/Unk *24-hour clock*
2.*	Sodium [Sodium]	**[SODIUM]** *[N:1]* **[cpSODIUM]** **[SODVAL]** xxxxxxxx. **[SODUNT]** Unit: *[N:1]* mmol/L *[N:2]* mEq/L *[N:97]* Not Done
3.*	Potassium [Potassium]	**[POTAS]** *[N:1]* **[cpPOTAS]** **[POTASVAL]** xxxxxxxx. **[POTASUNT]** Unit: *[N:1]* mmol/L *[N:2]* mEq/L *[N:97]* Not Done
4.*	Chloride [Chloride]	**[CHLORIDE]** *[N:1]* **[cpCHLORIDE]** **[CHLORVAL]** xxxxxxxx. **[CHLORUNT]** Unit: *[N:1]* mmol/L *[N:2]* mEq/L *[N:97]* Not Done
5.*	Bicarbonate (total CO_2) [Bicarbonate]	**[CO2]** *[N:1]* **[cpCO2]** **[CO2VAL]** xxxxxxxx. **[CO2UNT]** Unit: *[N:1]* mmol/L *[N:2]* mEq/L *[N:97]* Not Done
6.*	BUN/Urea [BUN/Urea]	**[BUN]** *[N:1]* **[cpBUN]** **[BUNVAL]** xxxxxxxx. **[BUNUNT]** Unit: *[N:1]* mmol/L *[N:3]* mg/dl *[N:97]* Not Done
7.*	Creatinine [Creatinine]	**[CREAT]** *[N:1]* **[cpCREAT]** **[CREATVAL]** xxxxxxxx. **[CREATUNT]** Unit: *[N:3]* mg/dl *[N:4]* umol/L *[N:97]* Not Done
8.*	BNP [BNP]	**[BNP]** *[N:1]* **[cpBNP]** **[BNPVAL]** xxxxxxxx. **[BNPUNT]** Unit: *[N:17]* pg/mL *[N:18]* ng/L *[N:97]* Not Done
9.*	NT-proBNP [NT-proBNP]	**[NTBNP]** *[N:1]* **[cpNTBNP]** **[NTBNPVAL]** xxxxxxxx. **[NTBNPUNT]** Unit: *[N:17]* pg/mL *[N:18]* ng/L

		[N:97] ○ Not Done

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: LABS1

Type	RefName	Description
Form	frLABS1	
Section	stLABS1A	
Item	LABDTM	
Item	SODIUM	
Item	cpSODIUM	
Item	SODVAL	
Item	SODUNT	
Item	POTAS	
Item	cpPOTAS	
Item	POTASVAL	
Item	POTASUNT	
Item	CHLORIDE	
Item	cpCHLORIDE	
Item	CHLORVAL	
Item	CHLORUNT	
Item	CO2	
Item	cpCO2	
Item	CO2VAL	
Item	CO2UNT	
Item	BUN	
Item	cpBUN	
Item	BUNVAL	
Item	BUNUNT	
Item	CREAT	
Item	cpCREAT	
Item	CREATVAL	
Item	CREATUNT	
Item	BNP	
Item	cpBNP	
Item	BNPVAL	
Item	BNPUNT	
Item	NTBNP	
Item	cpNTBNP	
Item	NTBNPVAL	
Item	NTBNPUNT	

HFN_ATHENA: BIOLOGICAL SAMPLES (SAMPLES) [frSAMPLES]

Biomarkers [stSAMPLES1]

1.* ✔	Were biomarker samples collected at this visit? (Primary Endpoint) [Were biomarker samples collected at this visit]	**[BIOMRK]** *[N:1]* Yes *[N:0]* **[BIOMNDRS]** No Reason samples were not collected: *[N:1]* Too sick to perform *[N:2]* Unwilling to perform but subjectively able *[N:3]* Due to oversight or technical problem *[N:99]* **[BIOMNDSP]** Other, specify: A200

	Collection Date/Time	Number of Samples Collected	Date sent to lab	Date received	Frozen	Number of Samples Received
2.						

Biomarker Collection Information Entry [rsSAMPLES2]

2.1* ✔	Collection Date/Time: [Collection Date/Time]	**[BIOMKDTM]** Req / Req / Req (2014-2017) Req/Unk : Req/Unk *24-hour clock*
2.2* ✔	Number of Samples Collected [Number of Samples Collected]	**[cpBIOCOLL1]** **[BIOMSER]** *[N:1]* **[BIOMSRNM]** Serum cryovials: N2 **[BIOMEDTA]** *[N:1]* **[BIOMEDNM]** EDTA cryovials: N2
2.3	Date sent to core lab [Date sent to lab]	**[BIOMSTDT]** Req / Req / Req (2014-2017)
2.4	Date samples received [Date received]	**[BIOMRCDT]** Req / Req / Req (2014-2017)
2.5	Samples received frozen [Frozen]	**[BIOMFROZ]** *[N:1]* Yes *[N:0]* No
2.6	Number of Samples Received [Number of Samples Received]	**[cpSAMPREC1]** **[BIOMSRCD]** *[N:1]* **[BIOMSNUM]** Serum cryovials: N2 **[BIOMSUSE]** Number of usable serum samples: N2 **[BIOMERCD]** *[N:1]* **[BIOMENUM]** EDTA cryovials: N2 **[BIOMEUSE]** Number of usable EDTA samples: N2

Biorepository and Genetics [stSAMPLES3]

3.* ✔	Were biorepository or genetics samples collected at this visit? [Were biorepository or genetics samples collected at this visit]	**[BIOREP]** *[N:1]* Yes *[N:0]* **[BIORNDRN]** No Reason samples were not collected: *[N:1]* Subject did not provide consent *[N:2]* Subject withdrew consent *[N:3]* Too sick to perform *[N:4]* Unwilling to perform test but subjectively able *[N:5]* Due to oversight or technical problem *[N:99]* **[BIORNDSP]** Other, specify A200

	Collection Date/Time	Number of Samples Collected	Date sent to lab	Date received	Frozen	Number of Samples Received
4.						

Biorepository and Genetics Collection Information Entry [rsSAMPLES4]

	Collection Date/Time:	**[BIORPDTM]**

4.1* ✔	[Collection Date/Time]	Req / Req / Req (2014-2017) Req/Unk : Req/Unk *24-hour clock*
4.2* ✔	Number of Samples Collected [Number of Samples Collected]	**[cpBIOCOLL2]** **[BIORSER]** *[N:1]* **[BIORSRNM]** Serum cryovials: N2 **[BIOREDTA]** *[N:1]* **[BIOREDNM]** EDTA cryovials: N2 **[BIORDNA]** *[N:1]* **[BIORDNUM]** DNA N2
4.3	Date sent to core lab [Date sent to lab]	**[BIORSTDT]** Req / Req / Req (2014-2017)
4.4	Date samples received [Date received]	**[BIORRCDT]** Req / Req / Req (2014-2017)
4.5	Samples received frozen [Frozen]	**[BIORFROZ]** *[N:1]* Yes *[N:0]* No
4.6	Number of Samples Received (Record the number of cryoviles) [Number of Samples Received]	**[cpSAMPREC2]** **[BIORSRCD]** *[N:1]* **[BIORSNUM]** Serum cryovials: N2 **[BIORSUSE]** Number of usable serum samples: N2 **[BIORERCD]** *[N:1]* **[BIORENUM]** EDTA cryovials: N2 **[BIOREUSE]** Number of usable EDTA samples: N2 **[BIORDRCD]** *[N:1]* **[BIORNUM]** DNA N2 **[BIORDUSE]** Number of usable DNA samples: N2

Comments [stSAMPLES5]

5.	Comments [Lab Comments]	**[LABCOMM]** A200

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: BIOLOGICAL SAMPLES

Type	RefName	Description
Form	frSAMPLES	
Section	stSAMPLES1	
Item	BIOMRK	
Item	BIOMNDRS	
Item	BIOMNDSP	
Section	rsSAMPLES2	
Item	BIOMKDTM	
Item	cpBIOCOLL1	
Item	BIOMSER	
Item	BIOMSRNM	
Item	BIOMEDTA	
Item	BIOMEDNM	
Item	BIOMSTDT	
Item	BIOMRCDT	
Item	BIOMFROZ	
Item	cpSAMPREC1	
Item	BIOMSRCD	
Item	BIOMSNUM	

Item	BIOMSUSE	
Item	BIOMERCD	
Item	BIOMENUM	
Item	BIOMEUSE	
Section	stSAMPLES3	
Item	BIOREP	
Item	BIORNDRN	
Item	BIORNDSP	
Section	rsSAMPLES4	
Item	BIORPDTM	
Item	cpBIOCOLL2	
Item	BIORSER	
Item	BIORSRNM	
Item	BIOREDTA	
Item	BIOREDNM	
Item	BIORDNA	
Item	BIORDNUM	
Item	BIORSTDT	
Item	BIORRCDT	
Item	BIORFROZ	
Item	cpSAMPREC2	
Item	BIORSRCD	
Item	BIORSNUM	
Item	BIORSUSE	
Item	BIORERCD	
Item	BIORENUM	
Item	BIOREUSE	
Item	BIORDRCD	
Item	BIORNUM	
Item	BIORDUSE	
Section	stSAMPLES5	
Item	LABCOMM	

HFN_ATHENA: STUDY DRUG ADMINISTRATION (SDADMIN) [frSDADMIN]

Study Drug Administration [stSDADMIN1]

1.* ✔ Was study drug administered?
[Was study drug administered?]

[DGADMIN]

[N:1] ○ **[cpDGADMIN]**
Yes

[DRGDTM]
Yes
Date and time administered:
Req / Req / Req (2014-2017)
Req : Req *24-hour clock*

[DSTIMING]
Dose was administered:

[N:1] ○ At time of assessment

[N:2] ○ **[DELAYDRS]**
Delayed
Reason delayed:

[N:1] ○ Hyperkalemia
[N:2] ○ Worsening Renal Function
[N:3] ○ Adverse Reaction (not an SAE)
[N:4] ○ SAE (complete SAE form)
[N:5] ○ Subject Refused
[N:6] ○ **[MDDLAYSP]**
Physician Decision
Specify:
A200

[N:98] ○ **[DELAYDSP]**
Other, specify:
A100

[DOSEADM]
Dose Administered:

[N:1] ○ Full (4 pills)
[N:2] ○ **[RDCEREAS]**
Half (4 pills)
Reason half dose administered:

[N:1] ○ Hyperkalemia
[N:2] ○ Worsening Renal Function
[N:3] ○ Adverse Reaction (not an SAE)
[N:4] ○ SAE (complete SAE form)
[N:6] ○ **[MDRDCESP]**
Physician Decision
Specify:
A200

[N:98] ○ **[RDCRSSP]**
Other, specify:
A200

[N:3] ○ **[LTFOUR]**
<4 pills
Specify:
A100

[N:0] ○ **[NOADRSN]**
No
Reason study drug was not administered:

[N:1] ○ Hyperkalemia
[N:2] ○ Worsening Renal Function
[N:3] ○ Adverse Reaction (not an SAE)
[N:4] ○ SAE (complete SAE form)
[N:5] ○ Subject Refused
[N:6] ○ **[MDNODSSP]**
Physician Decision
Specify:
A200

[N:98] ○ **[NOADMSP]**
Other, specify:

			A100

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: STUDY DRUG ADMINISTRATION		
Type	**RefName**	**Description**
Form	frSDADMIN	
Section	stSDADMIN1	
Item	DGADMIN	
Item	cpDGADMIN	
Item	DRGDTM	
Item	DSTIMING	
Item	DELAYDRS	
Item	MDDLAYSP	
Item	DELAYDSP	
Item	DOSEADM	
Item	RDCEREAS	
Item	MDRDCESP	
Item	RDCRSSP	
Item	LTFOUR	
Item	NOADRSN	
Item	MDNODSSP	
Item	NOADMSP	

HFN_ATHENA: EVENTS OF INTEREST (EVNTINT) [frEVNTINT]

Events of Interest [stEVNTINT1]

1.* ✔	Did subject experience any of the following anticipated disease-related events since the last assessment? Arrhythmias Sudden cardiac death Acute coronary syndrome Cerebrovascular event Venous thromboembolism Lightheadedness, presyncope or syncope Acute kidney injury as defined by KDOQI guidelines In hospital worsening of HF Hyperkalemia (K^+ >5.5 - 5.9 mmol/L) Hyperkalemia (K^+ >6.0 mmol/L) [Did subject experience any of the following anticipated, serious, disease-related events since the last visit:]	**[EVNTINT]** *[N:1]* ◯ Yes (click on Add Entry button) *[N:0]* ◯ No

	Anticipated, disease-related event:	Onset Date
2.		

Anticipated Disease Related Events Entry [rsEVNTINT2]

2.1* ✔	Anticipated, disease-related event: [Anticipated, disease-related event:]	**[EVNTTYPE]** *[N:1]* ◯ Arrhythmias *[N:2]* ◯ Sudden cardiac death *[N:3]* ◯ Acute coronary syndrome *[N:4]* ◯ Cerebrovascular event *[N:5]* ◯ Venous thromboembolism *[N:6]* ◯ Lightheadedness, presyncope or syncope *[N:7]* ◯ Acute kidney injury as defined by KDOQI guidelines *[N:8]* ◯ In hospital worsening of HF *[N:9]* ◯ Hyperkalemia (K^+ >5.5 - 5.9 mmol/L) *[N:10]* ◯ Hyperkalemia (K^+ >6.0 mmol/L)
2.2* ✔	Onset Date [Onset Date]	**[EVNTDT]** Req/Unk / Req/Unk / Req (2014-2017)

Clinical Event Assessment [stEVNTINT3]

3.* ✔	Has the subject experienced any SAEs since the last assessment? [Has the subject experienced any SAEs since the last assessment]	**[SAEYN]** *[N:1]* ◯ Yes (complete the SAE form) *[N:0]* ◯ No

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: EVENTS OF INTEREST

Type	RefName	Description
Form	frEVNTINT	
Section	stEVNTINT1	
Item	EVNTINT	
Section	rsEVNTINT2	
Item	EVNTTYPE	
Item	EVNTDT	
Section	stEVNTINT3	
Item	SAEYN	

HFN_ATHENA: Diuretic (DIURETIC) [frDIURETIC]

Diuretics [stDIURETIC1]

1.* ✔	Were diuretics administered since the last assessment? [Were diuretics administered since the last assessment]	**[DIURAMNI]** *[N:1]* ◯ Yes (please complete Add Entry section for each diuretic administered) *[N:0]* ◯ No

	Diuretic	Route	Dose
2.			

Diuretic Log Entry [rsDIURETIC2]

2.1* ✔	Diuretic Administered: [Diuretic]	**[DIURETIC]** *[N:1]* ◯ Furosemide *[N:2]* ◯ Torsemide *[N:3]* ◯ Bumetanide *[N:4]* ◯ Metolazone *[N:5]* ◯ HCTZ *[N:6]* ◯ Chlorothiazide
2.2* ✔	Route: [Route]	**[DIURTE]** *[N:1]* ◯ IV bolus *[N:2]* ◯ IV continuous *[N:3]* ◯ **[PODTM]** PO Date and Time Oral Dose Administered: Req / Req / Req (2014-2017) Req : Req *24-hour clock*
2.3* ✔	Total Daily Dose [Dose]	**[DIURDOSE]** *[N:1]* ◯ **[DIURDSVL]** xxxxxxxx. mg *[N:99]* ◯ Unknown

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: Diuretic

Type	RefName	Description
Form	frDIURETIC	
Section	stDIURETIC1	
Item	DIURAMNI	
Section	rsDIURETIC2	
Item	DIURETIC	
Item	DIURTE	
Item	PODTM	
Item	DIURDOSE	
Item	DIURDSVL	

HFN_ATHENA: IN-HOSPITAL ASSESSMENT (ASSESS) [frASSESS]

In-Hospital Assessment [stASSESS1]

1.* ✔	Was the assessment performed? [Was the assessment performed?]	**[ASSESS]** *[N:1]* ◯ **[cpASSESYES]** Yes **[ASSMTDTM]** Assessment date and time: Req / Req / Req (2014-2017) Req : Req *24-hour clock* **[DCVISYN]** Was subject discharged at this visit? *[N:1]* ◯ Yes (complete Index Hospital Discharge Form) *[N:0]* ◯ No *[N:0]* ◯ **[AMTNDRES]** No Reason assessment was not performed: *[N:1]* ◯ Subject no longer participating in study (died, permanently withdrew consent, etc). *[N:2]* ◯ Subject discharged prior to assessment (complete Index Hospital Discharge Form) *[N:98]* ◯ **[ASMTNDSP]** Other, specify A100

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: IN-HOSPITAL ASSESSMENT

Type	RefName	Description
Form	frASSESS	
Section	stASSESS1	
Item	ASSESS	
Item	cpASSESYES	
Item	ASSMTDTM	
Item	DCVISYN	
Item	AMTNDRES	
Item	ASMTNDSP	

HFN_ATHENA: FLUID INTAKE/OUTPUT (FLUID) [frFLUID]		
Fluid Intake/Output [stFLUID1]		
1.* ✔	Total IV Intake [Total IV Intake]	**[IVIN]** *[N:1]* **[IVINVAL]** xxxxxxxx. mL *[N:97]* Not Done
2.* ✔	Total Oral Intake [Total Oral Intake]	**[ORALIN]** *[N:1]* **[ORLINVAL]** xxxxxxxx. mL *[N:97]* Not Done
3.* ✔	Total Urine Output (Secondary Endpoint) [Total Urine Output]	**[UROUT]** *[N:1]* **[UROUTVAL]** xxxxxxxx. mL *[N:97]* Not Done
4.* ✔	Total Non-Urine Output [Total Non-Urine Output]	**[NONUOUT]** *[N:1]* **[NONUOTVL]** xxxxxxxx. mL *[N:97]* Not Done
Key: [*] = Item is required [✔] = Source verification required		

Study Object Descriptions: FLUID INTAKE/OUTPUT

Type	RefName	Description
Form	frFLUID	
Section	stFLUID1	
Item	IVIN	
Item	IVINVAL	
Item	ORALIN	
Item	ORLINVAL	
Item	UROUT	
Item	UROUTVAL	
Item	NONUOUT	
Item	NONUOTVL	

HFN_ATHENA: LABS2 (LABS2) [frLABS2]		
Labs [stLABS2A]		
1.*	Collection Date and Time [Collection Date and Time]	**[LABDTM2]** Req / Req / Req (2014-2017) Req/Unk : Req/Unk *24-hour clock*
2.*	Sodium [Sodium]	**[SODIUM2]** *[N:1]* **[cpSODIUM2]** **[SODVAL2]** xxxxxxxx. **[SODUNT2]** Unit: *[N:1]* mmol/L *[N:2]* mEq/L *[N:97]* Not Done
3.*	Chloride [Chloride]	**[CHLORID2]** *[N:1]* **[cpCHLORID2]** **[CHLORVA2]** xxxxxxxx. **[CHLORUN2]** Unit: *[N:1]* mmol/L *[N:2]* mEq/L *[N:97]* Not Done
4.*	Bicarbonate (total CO_2) [Bicarbonate]	**[CO22]** *[N:1]* **[cpCO22]** **[CO2VAL2]** xxxxxxxx. **[CO2UNT2]** Unit: *[N:1]* mmol/L *[N:2]* mEq/L *[N:97]* Not Done
5.*	BUN/Urea [BUN/Urea]	**[BUN2]** *[N:1]* **[cpBUN2]** **[BUNVAL2]** xxxxxxxx. **[BUNUNT2]** Unit: *[N:1]* mmol/L *[N:3]* mg/dl *[N:97]* Not Done
Key: [*] = Item is required [✔] = Source verification required		

Study Object Descriptions: LABS2

Type	RefName	Description
Form	frLABS2	
Section	stLABS2A	
Item	LABDTM2	
Item	SODIUM2	
Item	cpSODIUM2	
Item	SODVAL2	
Item	SODUNT2	
Item	CHLORID2	
Item	cpCHLORID2	
Item	CHLORVA2	
Item	CHLORUN2	
Item	CO22	
Item	cpCO22	
Item	CO2VAL2	
Item	CO2UNT2	
Item	BUN2	
Item	cpBUN2	
Item	BUNVAL2	
Item	BUNUNT2	

HFN_ATHENA: POTASSIUM AND CREATININE LABS (KCREAT) [frKCREAT]

Potassium and Creatinine Labs [stKCREAT1]

1.*	Collection Date and Time [Collection Date and Time]	**[KCRDTM]** Req / Req / Req (2014-2017) Req/Unk : Req/Unk *24-hour clock*

Potassium Labs [stKCREAT2]

2.*	Potassium [Potassium]	**[POTAS3]** *[N:1]* **[CPPOTAS3]** **[POTASVL3]** xxxxxxxx. **[POTASUT3]** Unit: *[N:1]* mmol/L *[N:2]* mEq/L *[N:97]* Not Done
3.* ✔	Were any repeat results obtained? [Were any repeat results obtained?]	**[KRPTYN3]** *[N:1]* Yes (click on Add Entry button) *[N:0]* No

	Potassium Re-test Date and Time	Result	Unit:
4.			

Additional Potassium Labs Entry [rsKCREAT3]

4.1* ✔	Potassium Re-test Date and Time [Potassium Re-test Date and Time]	**[KRPT3DTM]** Req / Req / Req (2014-2017) Req : Req *24-hour clock*
4.2* ✔	Result [Result]	**[KRPTRLT3]** xxxxxxxx.
4.3* ✔	Unit: [Unit:]	**[KRPTUNT3]** *[N:1]* mmol/L *[N:2]* mEq/L

Creatinine Labs [stKCREAT4]

5.*	Creatinine [Creatinine]	**[CREAT3]** *[N:1]* **[CPCREAT3]** **[CREATVL3]** xxxxxxxx. **[CREATUT3]** Unit: *[N:3]* mg/dl *[N:4]* umol/L *[N:97]* Not Done
6.* ✔	Were any repeat results obtained? [Were any repeat results obtained?]	**[CRRPTYN3]** *[N:1]* Yes (click on Add Entry button) *[N:0]* No

	Creatinine Re-test Date and Time	Result	Unit
7.			

Additional Creatinine Labs Entry [rsKCREAT5]

7.1* ✔	Creatinine Re-test Date and Time [Creatinine Re-test Date and Time]	**[CRPT3DTM]** Req / Req / Req (2014-2017) Req : Req *24-hour clock*
7.2* ✔	Result [Result]	**[CRPTRLT3]** xxxxxxxx.
7.3* ✔	Unit: [Unit]	**[CRPTUNT3]** *[N:3]* mg/dl *[N:4]* umol/L

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: POTASSIUM AND CREATININE LABS

Type	RefName	Description
Form	frKCREAT	
Section	stKCREAT1	
Item	KCRDTM	
Section	stKCREAT2	
Item	POTAS3	
Item	CPPOTAS3	

Item	POTASVL3	
Item	POTASUT3	
Item	KRPTYN3	
Section	rsKCREAT3	
Item	KRPT3DTM	
Item	KRPTRLT3	
Item	KRPTUNT3	
Section	stKCREAT4	
Item	CREAT3	
Item	CPCREAT3	
Item	CREATVL3	
Item	CREATUT3	
Item	CRRPTYN3	
Section	rsKCREAT5	
Item	CRPT3DTM	
Item	CRPTRLT3	
Item	CRPTUNT3	

HFN_ATHENA: DISCHARGE MEDICATIONS (DCMEDS) [frDCMEDS]

Medications [stDCMEDS1]

1.* ✔	ACE inhibitor [ACE inhibitor]	**[ACED]** *[N:1]* ◯ Yes *[N:0]* ◯ **[ACECONTD]** No If no: Is there documented evidence of contraindication? *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown *[N:99]* ◯ Unknown
2.* ✔	Angiotensin receptor blocker [Angiotensin receptor blocker]	**[ARBD]** *[N:1]* ◯ Yes *[N:0]* ◯ **[ARBCONTD]** No If no: Is there documented evidence of contraindication? *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown *[N:99]* ◯ Unknown
3.*	Beta Blocker [Beta Blocker]	**[BETABD]** *[N:1]* ◯ Yes *[N:0]* ◯ **[BETACOND]** No If no: Is there documented evidence of contraindication? *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown *[N:99]* ◯ Unknown
4.*	Aldosterone antagonist [Aldosterone antagonist]	**[ALDOSD]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
5.*	Hydralazine [Hydralazine]	**[HYDRD]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
6.*	Nitrates (long acting) [Nitrates]	**[NITRD]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
7.*	Calcium channel blocker [Calcium channel blocker]	**[CCBD]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
8.*	Antiplatelets [Antiplatelets]	**[ANTIPLTD]** *[N:1]* ◯ **[cpANTIPLTD]** Yes (check all that apply) **[ANTIPASD]** *[N:1]* ☐ Aspirin (taken daily) **[ANTIPTHD]** *[N:1]* ☐ Thienopyridines (eg: ticlopidine, clopidogrel, prasugrel) **[ANTIPOTD]** *[N:1]* ☐ Other *[N:0]* ◯ **[ANTIPTCD]** No If no: Is there documented evidence of contraindication? *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown *[N:99]* ◯ Unknown
9.*	Anticoagulants [Anticoagulants]	**[ANTICAGD]** *[N:1]* ◯ **[cpANTICAGD]** Yes (check all that apply) **[ANTICWAD]** *[N:1]* ☐ Warfarin **[ANTICFAD]** *[N:1]* ☐ Factor Xa Inhibitor **[ANTICDTD]** *[N:1]* ☐ Direct Thrombin Inhibitor

		[ANTICOTD] *[N:1]* ☐ Other *[N:0]* ◯ **[ANTICACD]** No If no: Is there documented evidence of contraindication? *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown *[N:99]* ◯ Unknown
10.*	Digoxin [Digoxin]	**[DIGXD]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
11.*	Amiodarone [Amiodarone]	**[AMIODD]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
12.*	Statin [Statin]	**[STATIND]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
13.*	Lipid lowering agent (other than statin) [Lipid lowering agent]	**[LLIPIDD]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
14.*	Ambulatory IV Inotropes [Ambulatory IV Inotropes]	**[IVINOTRD]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
15.* ✔	Metolazone [Metolazone]	**[METAZD]** *[N:1]* ◯ **[METODOSD]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* ◯ No *[N:99]* ◯ Unknown
16.* ✔	HCTZ [HCTZ]	**[HCTZD]** *[N:1]* ◯ **[HCTZDOSD]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* ◯ No *[N:99]* ◯ Unknown
17.* ✔	Furosemide [Furosemide]	**[FUROD]** *[N:1]* ◯ **[FURODOSD]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* ◯ No *[N:99]* ◯ Unknown
18.* ✔	Torsemide [Torsemide]	**[TORSD]** *[N:1]* ◯ **[TORSDOSD]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* ◯ No *[N:99]* ◯ Unknown
19.* ✔	Bumetanide [Bumetanide]	**[BUMED]** *[N:1]* ◯ **[BUMDOSED]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* ◯ No *[N:99]* ◯ Unknown
20.* ✔	Spironolactone (open label) [Spironolactone (open label)]	**[SPIROUSD]** *[N:1]* ◯ **[SPIRDOSD]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* ◯ No *[N:99]* ◯ Unknown
21.* ✔	Eplerenone [Eplerenone]	**[EPLEUSED]** *[N:1]* ◯ **[EPLEDOSD]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* ◯ No *[N:99]* ◯ Unknown

22.* ✔	Potassium [Potassium]	**[KUSED]** *[N:1]* **[KDOSED]** Yes Total Daily Dose (mEq): xxxxxxxx. *[N:0]* No *[N:99]* Unknown

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: DISCHARGE MEDICATIONS

Type	RefName	Description
Form	frDCMEDS	
Section	stDCMEDS1	
Item	ACED	
Item	ACECONTD	
Item	ARBD	
Item	ARBCONTD	
Item	BETABD	
Item	BETACOND	
Item	ALDOSD	
Item	HYDRD	
Item	NITRD	
Item	CCBD	
Item	ANTIPLTD	
Item	cpANTIPLTD	
Item	ANTIPASD	
Item	ANTIPTHD	
Item	ANTIPOTD	
Item	ANTIPTCD	
Item	ANTICAGD	
Item	cpANTICAGD	
Item	ANTICWAD	
Item	ANTICFAD	
Item	ANTICDTD	
Item	ANTICOTD	
Item	ANTICACD	
Item	DIGXD	
Item	AMIODD	
Item	STATIND	
Item	LLIPIDD	
Item	IVINOTRD	
Item	METAZD	
Item	METODOSD	
Item	HCTZD	
Item	HCTZDOSD	
Item	FUROD	
Item	FURODOSD	
Item	TORSD	
Item	TORSDOSD	
Item	BUMED	
Item	BUMDOSED	
Item	SPIROUSD	
Item	SPIRDOSD	
Item	EPLEUSED	
Item	EPLEDOSD	
Item	KUSED	
Item	KDOSED	

HFN_ATHENA: DISCHARGE VISIT (DCVISIT) [frDCVISIT]		
Discharge Visit [stDISCHARGE1]		
1.* ✔	Was Discharge Assessment Performed (post 96 hours and prior to Day 30)? [Was Discharge Assessment Performed]	**[DCVISDN]** *[N:1]* **[DCVISDT]** Yes Visit date: Req / Req / Req (2014-2017) *[N:0]* No

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: DISCHARGE VISIT

Type	RefName	Description
Form	frDCVISIT	
Section	stDISCHARGE1	
Item	DCVISDN	
Item	DCVISDT	

HFN_ATHENA: VISIT STATUS (VISIT) [frVISIT]

Visit Status [stVISIT1]

1.* ✔	Was the visit performed [Visit performed]	**[STATUS]** *[N:1]* **[ASSESSDT]** Yes Visit date: Req / Req / Req (2014-2017) *[N:0]* **[VISNDRES]** No Reason visit was not performed: *[N:1]* Missed visit *[N:2]* Suspected LTFU *[N:3]* Subject no longer participating in study (died, permanently withdrew consent, etc). *[N:98]* **[ASESNDSP]** Other, specify A100

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: VISIT STATUS

Type	RefName	Description
Form	frVISIT	
Section	stVISIT1	
Item	STATUS	
Item	ASSESSDT	
Item	VISNDRES	
Item	ASESNDSP	

HFN_ATHENA: DAY30 EVENTS OF INTEREST (EVNTINT1) [frEVNTINT1]

Events of Interest [stEVNTINT1A]

1.* ✔	Did subject experience any of the following anticipated disease-related events since the last assessment? Arrhythmias Sudden cardiac death Acute coronary syndrome Cerebrovascular event Venous thromboembolism Lightheadedness, presyncope or syncope Acute kidney injury as defined by KDOQI guidelines Worsening of HF Hyperkalemia (K^+ >5.5 - 5.9 mmol/L) Hyperkalemia (K^+ >6.0 mmol/L) [Did subject experience any of the following anticipated, serious, disease-related events since the last visit:]	**[EVNTINT1]** *[N:1]* ◯ Yes (click on Add Entry button) *[N:0]* ◯ No

	Anticipated, disease-related event:	Onset Date
2.		

Anticipated Disease Related Events Entry [rsEVNTINT1B]

2.1* ✔	Anticipated, disease-related event: [Anticipated, disease-related event:]	**[EVNTTYP1]** *[N:1]* ◯ Arrhythmias *[N:2]* ◯ Sudden cardiac death *[N:3]* ◯ Acute coronary syndrome *[N:4]* ◯ Cerebrovascular event *[N:5]* ◯ Venous thromboembolism *[N:6]* ◯ Lightheadedness, presyncope or syncope *[N:7]* ◯ Acute kidney injury as defined by KDOQI guidelines *[N:8]* ◯ Worsening of HF *[N:9]* ◯ Hyperkalemia (K^+ >5.5 - 5.9 mmol/L) *[N:10]* ◯ Hyperkalemia (K^+ >6.0 mmol/L)
2.2* ✔	Onset Date [Onset Date]	**[EVNTDT1]** Req/Unk / Req/Unk / Req (2014-2017)

Clinical Event Assessment [stEVNTINT1C]

3.* ✔	Has the subject experienced any SAEs since the last assessment? [Has the subject experienced any SAEs since the last assessment]	**[SAEYN1]** *[N:1]* ◯ Yes (complete the SAE form) *[N:0]* ◯ No
4.* ✔	Has the subject had any hospitalizations since index hospitalization discharge? [Has the subject had any hospitalizations since index hospitalization discharge]	**[HOSPYN]** *[N:1]* ◯ Yes (complete the REHOSP form) *[N:0]* ◯ No *[N:96]* ◯ Not Applicable (subject still hospitalized)
5.* ✔	Has the subject experienced outpatient worsening heart failure since the index hospitalization discharge? [Has the subject experienced outpatient worsening heart failure since the index hospitalization discharge]	**[D30WRSHF]** *[N:1]* ◯ Yes (complete REHOSP or OUTPTVIS form as applicable) *[N:0]* ◯ No *[N:96]* ◯ Not Applicable (subject still hospitalized)

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: DAY30 EVENTS OF INTEREST

Type	RefName	Description
Form	frEVNTINT1	
Section	stEVNTINT1A	
Item	EVNTINT1	
Section	rsEVNTINT1B	
Item	EVNTTYP1	
Item	EVNTDT1	
Section	stEVNTINT1C	
Item	SAEYN1	
Item	HOSPYN	
Item	D30WRSHF	

HFN_ATHENA: DAY 30 MEDICATIONS (DAY30MED) [frDAY30MED]

Medications [stDAY30MED1]

1.* ✔	ACE inhibitor [ACE inhibitor]	**[ACE1]** *[N:1]* ◯ Yes *[N:0]* ◯ **[DCECONT1]** No If no: Is there documented evidence of contraindication? *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown *[N:99]* ◯ Unknown
2.* ✔	Angiotensin receptor blocker [Angiotensin receptor blocker]	**[ARB1]** *[N:1]* ◯ Yes *[N:0]* ◯ **[ARBCONT1]** No If no: Is there documented evidence of contraindication? *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown *[N:99]* ◯ Unknown
3.*	Beta Blocker [Beta Blocker]	**[BETAB1]** *[N:1]* ◯ Yes *[N:0]* ◯ **[BETACON1]** No If no: Is there documented evidence of contraindication? *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown *[N:99]* ◯ Unknown
4.*	Aldosterone antagonist [Aldosterone antagonist]	**[ALDOS1]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
5.*	Hydralazine [Hydralazine]	**[HYDR1]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
6.*	Nitrates (long acting) [Nitrates]	**[NITR1]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
7.*	Calcium channel blocker [Calcium channel blocker]	**[CCB1]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
8.*	Antiplatelets [Antiplatelets]	**[ANTIPLT1]** *[N:1]* ◯ **[cpANTIPLTY1]** Yes (check all that apply) **[ANTIPAS1]** *[N:1]* ☐ Aspirin (taken daily) **[ANTIPTH1]** *[N:1]* ☐ Thienopyridines (eg: ticlopidine, clopidogrel, prasugrel) **[ANTIPOT1]** Other *[N:1]* ☐ Other *[N:0]* ◯ **[ANTIPTC1]** No If no: Is there documented evidence of contraindication? *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown *[N:99]* ◯ Unknown
9.*	Anticoagulants [Anticoagulants]	**[ANTICAG1]** *[N:1]* ◯ **[cpANTICAG1]** Yes (check all that apply) **[ANTICWA1]** *[N:1]* ☐ Warfarin **[ANTICFA1]** *[N:1]* ☐ Factor Xa Inhibitor **[ANTICDT1]**

		[N:1] Direct Thrombin Inhibitor **[ANTICOT1]** [N:1] Other [N:0] **[ANTICAC1]** No If no: Is there documented evidence of contraindication? [N:1] Yes [N:0] No [N:99] Unknown [N:99] Unknown
10.*	Digoxin [Digoxin]	**[DIGX1]** [N:1] Yes [N:0] No [N:99] Unknown
11.*	Amiodarone [Amiodarone]	**[AMIOD1]** [N:1] Yes [N:0] No [N:99] Unknown
12.*	Statin [Statin]	**[STATIN1]** [N:1] Yes [N:0] No [N:99] Unknown
13.*	Lipid lowering agent (other than statin) [Lipid lowering agent]	**[LLIPID1]** [N:1] Yes [N:0] No [N:99] Unknown
14.*	Ambulatory IV Inotropes [Ambulatory IV Inotropes]	**[IVINOTR1]** [N:1] Yes [N:0] No [N:99] Unknown
15.* ✔	Metolazone [Metolazone]	**[METAZ1]** [N:1] **[METODOS1]** Yes Total Daily Dose: xxxxxxxx. [N:0] No [N:99] Unknown
16.* ✔	HCTZ [HCTZ]	**[HCTZ1]** [N:1] **[HCTZDOS1]** Yes Total Daily Dose: xxxxxxxx. [N:0] No [N:99] Unknown
17.* ✔	Furosemide [Furosemide]	**[FURO1]** [N:1] **[FURODOS1]** Yes Total Daily Dose: xxxxxxxx. [N:0] No [N:99] Unknown
18.* ✔	Torsemide [Torsemide]	**[TORS1]** [N:1] **[TORSDOS1]** Yes Total Daily Dose: xxxxxxxx. [N:0] No [N:99] Unknown
19.* ✔	Bumetanide [Bumetanide]	**[BUME1]** [N:1] **[BUMDOSE1]** Yes Total Daily Dose: xxxxxxxx. [N:0] No [N:99] Unknown
20.* ✔	Spironolactone (open label) [Spironolactone (open label)]	**[SPIROUS1]** [N:1] **[SPIRDOS1]** Yes Total Daily Dose:

		xxxxxxxx. *[N:0]* No *[N:99]* Unknown
21.* ✔	Eplerenone [Eplerenone]	**[EPLEUSE1]** *[N:1]* **[EPLEDOS1]** Yes Total Daily Dose: xxxxxxxx. *[N:0]* No *[N:99]* Unknown
22.* ✔	Potassium [Potassium]	**[KUSE1]** *[N:1]* **[KDOSE1]** Yes Total Daily Dose (mEq): xxxxxxxx. *[N:0]* No *[N:99]* Unknown
Key: [*] = Item is required [✔] = Source verification required		

Study Object Descriptions: DAY 30 MEDICATIONS

Type	RefName	Description
Form	frDAY30MED	
Section	stDAY30MED1	
Item	ACE1	
Item	DCECONT1	
Item	ARB1	
Item	ARBCONT1	
Item	BETAB1	
Item	BETACON1	
Item	ALDOS1	
Item	HYDR1	
Item	NITR1	
Item	CCB1	
Item	ANTIPLT1	
Item	cpANTIPLTY1	
Item	ANTIPAS1	
Item	ANTIPTH1	
Item	ANTIPOT1	
Item	ANTIPTC1	
Item	ANTICAG1	
Item	cpANTICAG1	
Item	ANTICWA1	
Item	ANTICFA1	
Item	ANTICDT1	
Item	ANTICOT1	
Item	ANTICAC1	
Item	DIGX1	
Item	AMIOD1	
Item	STATIN1	
Item	LLIPID1	
Item	IVINOTR1	
Item	METAZ1	
Item	METODOS1	
Item	HCTZ1	
Item	HCTZDOS1	
Item	FURO1	
Item	FURODOS1	
Item	TORS1	
Item	TORSDOS1	

Item	BUME1	
Item	BUMDOSE1	
Item	SPIROUS1	
Item	SPIRDOS1	
Item	EPLEUSE1	
Item	EPLEDOS1	
Item	KUSE1	
Item	KDOSE1	

HFN_ATHENA: VITAL STATUS (VITAL) [frVITAL]		
Day 60 Status [stVITAL1]		
1.* ✔	Status at Day 60 Follow-Up: [Status at Day 60 Follow-Up:]	**[D60VST]** *[N:1]* ○ **[D60CNTDT]** Alive Date of Contact: Req / Req / Req (2014-2017) *[N:2]* ○ **[D60DTHDT]** Dead Date of Death: Req / Req / Req (2014-2017) *[N:3]* ○ Unknown/Unable to Contact
Key: [*] = Item is required [✔] = Source verification required		

Study Object Descriptions: VITAL STATUS		
Type	**RefName**	**Description**
Form	frVITAL	
Section	stVITAL1	
Item	D60VST	
Item	D60CNTDT	
Item	D60DTHDT	

HFN_ATHENA: INDEX HOSPITAL DISCHARGE (INHOSPDC) [frINHOSPDC]

Index Hospitalization Discharge [stINHOSPDC]

1.* ✔	Was subject discharged alive? [Was subject discharged alive?]	**[DCALIVE]** *[N:1]* **[DCDT]** Yes Discharge Date: Req / Req / Req (2014-2017) *[N:0]* No (If No, complete DEATH form)

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: INDEX HOSPITAL DISCHARGE

Type	RefName	Description
Form	frINHOSPDC	
Section	stINHOSPDC	
Item	DCALIVE	
Item	DCDT	

HFN_ATHENA: EJECTION FRACTION (EF) [frEF]		
Ejection Fraction [stEF1]		
1.* ✔	Date of EF Measurement [Date of EF Measurement]	**[EFDT]** Req / Req / Req (2014-2017)
2.* ✔	Value [Value]	**[EFVAL1]** *[N:1]* **[EFVALUE]** xxxxxxxx. % *[N:2]* Normal *[N:3]* Mild dysfunction *[N:4]* Moderate dysfunction *[N:5]* Severe dysfunction
Key: [*] = Item is required [✔] = Source verification required		

Study Object Descriptions: EJECTION FRACTION

Type	RefName	Description
Form	frEF	
Section	stEF1	
Item	EFDT	
Item	EFVAL1	
Item	EFVALUE	

HFN_ATHENA: REHOSPITALIZATION (REHOSP) - Repeating Form [frREHOSP]

#	Admission Date	Unplanned?	Discharge Date	Primary reason for admission	Contributing causes	Clinical manifestations	Biomarker or radiographic evidence	Pharmacologic or mechanical interventions	Heart Cath?	Revascularization	Pacemaker/ICD	Heart Transplant	LVAD
1													

Hospitalization Information [stREHOSP1]

1.* ✔ Admission Date
[Admission Date]

[ADMITDT]
Req/Unk / Req/Unk / Req (2014-2017)

2.* ✔ Was this an unplanned hospitalization?
[Unplanned?]

[ELECTAD]
[N:1] Yes
[N:0] No

3.* ✔ Discharge Date
[Discharge Date]

[INREHOSP]
[N:1] **[REDCHGDT]**
Req/Unk / Req/Unk / Req (2014-2017)
[N:2] Remains hospitalized
[N:3] Subject died while hospitalized

4.* ✔ Primary reason for admission
[Primary reason for admission]

[HOSPRS]
[N:1] Heart failure
[N:2] Acute coronary syndrome
[N:3] Cerebral Vascular Accident (CVA)/stroke
[N:4] Atrial arrhythmia
[N:5] Ventricular arrhythmia
[N:6] Sudden death with resuscitation
[N:7] **[PRMCRDSP]**
Other cardiovascular Specify: A100
[N:8] **[PRMNCSP]**
Other non-cardiovascular Specify: A100

5. Contributing causes (check all that apply)
[Contributing causes]

[cpCONTCAUS]
[CONHF]
[N:1] Heart failure
[CONACS]
[N:1] Acute coronary syndrome
[CONCVA]
[N:1] Cerebral Vascular Accident (CVA)/stroke
[CONARRH]
[N:1] Atrial arrhythmia
[CONVENTA]
[N:1] Ventricular arrhythmia
[RENFAIL]
[N:1] Renal Failure
[CONSDTH]
[N:1] Sudden death with resuscitation
[CONOTHC]
[N:1] Other cardiovascular
[CONOTHNC]
[N:1] Other non-cardiovascular

6.* ✔ Indicate any clinical manifestations of heart failure that occurred during this hospitalization (check all that apply)
[Clinical manifestations]

[MANIFEST]
[N:1] **[cpMANIFEST]**
[HFDYSP]
[N:1] Dyspnea
[HFORTHO]
[N:1] Orthopnea
[HFNOCDYS]
[N:1] Paroxysmal nocturnal dyspnea
[HFEDEMA]
[N:1] Edema
[HFRALES]
[N:1] Pulmonary rales
[HFJVD]
[N:1] Jugular venous distension
[HFGALLOP]
[N:1] S3 Gallop
[HFHYPO]
[N:1] Hypotension or cardiogenic shock not occurring in the context of an acute myocardial infarction or as the consequence of an arrhythmia
[HFEVDNCE]
[N:1] Other clinical evidence of new or worsening heart failure (eg. weight gain, or confinement to bed predominantly due to heart failure symptoms)
[HFOTHR]
[N:1] **[HFOTHRSP]**

		Other, specify A100 **[HFUNK]** *[N:1]* Unknown *[N:0]* None
7.* ✔	Indicate any Biomarker or radiographic evidence consistent with heart failure during this hospitalization (check all that apply) [Biomarker or radiographic evidence]	**[RADIOEV]** *[N:1]* **[cpRADIOEV]** **[INCBNP]** *[N:1]* Documented increased or increasing levels of a natriuretic peptide (BNP or NTproBNP) **[HFIMGING]** *[N:1]* Documented worsening pulmonary congestion or pulmonary edema on chest X-ray or other generally recognized imaging pattern. **[BIOOTH]** *[N:1]* **[BIOOTHSP]** Other, specify A100 **[BIOUNK]** *[N:1]* Unknown *[N:0]* None
8.* ✔	Indicate any additional or increased pharmacologic or mechanical interventions directed at the treatment of heart failure during this hospitalization (check all that apply) [Pharmacologic or mechanical interventions]	**[PHARMINT]** *[N:1]* **[cpPHARMINT]** **[INITHRPY]** *[N:1]* Initiation of intravenous diuretic, inotropic, or vasodilator therapy **[ORLTHPY]** *[N:1]* Significant addition or increase in oral heart failure therapy **[UPTITRTE]** *[N:1]* Up-titration of intravenous therapy, if already on therapy **[MECHSURG]** *[N:1]* Initiation of mechanical or surgical intervention to improve cardiac function), or the use of ultrafiltration, hemofiltration, or dialysis that is specifically directed at treatment of heart failure. **[OTHINTVN]** *[N:1]* **[INTVNSP]** Other, specify A100 **[INTVUNK]** *[N:1]* Unknown *[N:0]* None
9.*	Was a heart catheterization performed? [Heart Cath?]	**[PROCATH]** *[N:1]* **[cpPROCATH]** Yes **[LCATH]** *[N:1]* Left **[RCATH]** *[N:1]* Right *[N:0]* No *[N:99]* Unknown
10.*	Revascularization [Revascularization]	**[REVASC]** *[N:1]* **[cpREVASC]** Yes **[CABG]** *[N:1]* CABG **[PCI]** *[N:1]* PCI *[N:0]* No *[N:99]* Unknown
11.*	Pacemaker/ICD [Pacemaker/ICD]	**[HOSPICD]** *[N:1]* **[PACTYPE]** Yes *[N:1]* Pacemaker (single/dual) *[N:2]* Biventricular Pacemaker with ICD *[N:3]* Biventricular Pacemaker without ICD *[N:4]* ICD only (single/dual) *[N:0]* No *[N:99]* Unknown
12.*	Heart Transplant [Heart Transplant]	**[PROHTRAN]** *[N:1]* **[PRHTRDDT]** Yes Date of Transplant: Req/Unk / Req/Unk / Req (2014-2017) *[N:0]* No *[N:99]* Unknown
13.*	LVAD [LVAD]	**[LVAD]** *[N:1]* **[LVADDT]** Yes Date of Implant: Req/Unk / Req/Unk / Req (2014-2017) *[N:0]* No *[N:99]* Unknown

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: REHOSPITALIZATION		
Type	**RefName**	**Description**
Form	frREHOSP	
Section	stREHOSP1	
Item	ADMITDT	
Item	ELECTAD	
Item	INREHOSP	
Item	REDCHGDT	
Item	HOSPRS	
Item	PRMCRDSP	
Item	PRMNCSP	
Item	cpCONTCAUS	
Item	CONHF	
Item	CONACS	
Item	CONCVA	
Item	CONARRH	
Item	CONVENTA	
Item	RENFAIL	
Item	CONSDTH	
Item	CONOTHC	
Item	CONOTHNC	
Item	MANIFEST	
Item	cpMANIFEST	
Item	HFDYSP	
Item	HFORTHO	
Item	HFNOCDYS	
Item	HFEDEMA	
Item	HFRALES	
Item	HFJVD	
Item	HFGALLOP	
Item	HFHYPO	
Item	HFEVDNCE	
Item	HFOTHR	
Item	HFOTHRSP	
Item	HFUNK	
Item	RADIOEV	
Item	cpRADIOEV	
Item	INCBNP	
Item	HFIMGING	
Item	BIOOTH	
Item	BIOOTHSP	
Item	BIOUNK	
Item	PHARMINT	
Item	cpPHARMINT	
Item	INITHRPY	
Item	ORLTHPY	
Item	UPTITRTE	
Item	MECHSURG	
Item	OTHINTVN	
Item	INTVNSP	
Item	INTVUNK	
Item	PROCATH	
Item	cpPROCATH	

Item	LCATH	
Item	RCATH	
Item	REVASC	
Item	cpREVASC	
Item	CABG	
Item	PCI	
Item	HOSPICD	
Item	PACTYPE	
Item	PROHTRAN	
Item	PRHTRDDT	
Item	LVAD	
Item	LVADDT	

HFN_ATHENA: OUTPATIENT VISIT (OUTPTVIS) - Repeating Form [frOUTPTVIS]

#	Encounter Date:	Visit Type:	Primary reason for visit:
1			

Outpatient Visit Information [stOPTVISIT1]

1.* ✔	Encounter Date: [Encounter Date:]	**[UNSCHDT]** Req / Req / Req (2013-2026)
2.* ✔	Visit Type: [Visit Type:]	**[OTPTYPE]** *[N:1]* Unscheduled Clinic *[N:2]* Emergency Department (non-admission) *[N:3]* Observational Unit (short stay)
3.* ✔	Primary reason for visit: [Primary reason for visit:]	**[UNSCREAS]** *[N:1]* **[cpHARTFAIL]** Heart failure **[DECOMP]** Signs or symptoms indicating decompensated heart failure *[N:1]* Yes *[N:0]* No **[EDIVTX]** Did subject receive IV treatment for heart failure? *[N:1]* Yes *[N:0]* No *[N:2]* Other cardiovascular *[N:3]* Other non-cardiovascular

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: OUTPATIENT VISIT

Type	RefName	Description
Form	frOUTPTVIS	
Section	stOPTVISIT1	
Item	UNSCHDT	
Item	OTPTYPE	
Item	UNSCREAS	
Item	cpHARTFAIL	
Item	DECOMP	
Item	EDIVTX	

HFN_ATHENA: SERIOUS ADVERSE EVENTS (SAE) - Repeating Form [frSAE]

#	SAE #	SAE Term	SAE Onset Date/Time	Severity	Relationship	Outcome	SAE Stop Date/Time	Action Taken	SAE Diminish/Abate	SAE reappear	Possible alternate causes	Serious Criteria	Unexpected?	SAE Summary	Relevant Labs	Relevant Laboratory and Diagnostic Tests Details	On concomitant medications	Con Med Details	SAE verify	Evaluation date/time	MedDRA Preferred Term	AE expected	Assessment of relationship	Medical Monitor Rationale for Assessment	Medical Monitor Reviewed	Evaluation Date/Time
1																										

Serious Adverse Events [stSAE1]

If this is an anticipated disease related event, please do not complete this form. Instead, please complete the EVNTINT form.

1.* ✔ SAE Number (non-enterable field) *[read-only]*
[SAE #]

[AENUM]
A4

2.* ✔ Event Term
[SAE Term]

[AETERM]
A100

3.* ✔ SAE Onset Date/Time
[SAE Onset Date/Time]

[AESTDTM]
Req / Req/Unk / Req (2014-2017)
Req/Unk : Req/Unk *24-hour clock*

4.* ✔ SAE Severity
[Severity]

[SEVERITY]
[N:1] Mild
[N:2] Moderate
[N:3] Severe

5.* ✔ What is the relationship to study drug?
[Relationship]

[AEREL]
[N:1] Not related
[N:2] Unlikely related
[N:3] **[PRRATREL]**
Possibly Related
Rationale for positive relationship:
A100
[N:4] **[RRATREL]**
Related
Rationale for positive relationship:
A100

6.* ✔ Outcome
[Outcome]

[AEOUT]
[N:1] Resolved
[N:2] Resolved with sequelae
[N:3] Unresolved
[N:4] Death (complete DEATH form)
[N:99] Unknown

7.* ✔ SAE Stop Date/Time
[SAE Stop Date/Time]

[AEONGO]
[N:1] **[AESPDTM]**
Req/Unk / Req/Unk / Req/Unk (2014-2017)
Req/Unk : Req/Unk *24-hour clock*
[N:2] Ongoing

8.* ✔ Action Taken Regarding Study Drug
[Action Taken]

[AEACN]
[N:1] Dose not changed
[N:2] Dose reduced
[N:3] Dose increased
[N:4] **[INTDTAE]**
Drug Interrupted
If study drug was interrupted, is this adverse event the primary reason for study drug interruption?
[N:1] Yes
[N:0] No
[N:5] **[DCDTAE]**
Drug discontinued
If study drug was discontinued, is this adverse event the primary reason for study drug discontinuation?
[N:1] Yes
[N:0] No
[N:96] Not Applicable
[N:99] Unknown
[N:96] Not Applicable

9.* ✔ If study drug was discontinued, interrupted, or reduced (dechallenged), did SAE diminish/abate?
[SAE Diminish/Abate]

[AEDIMTD]
[N:1] Yes
[N:0] No
[N:96] Not Applicable

10.* If study drug was restarted (Rechallenge), did SAE recur?
[SAE reappear]

[AERAPR]
[N:1] Yes

✔		[N:0] No [N:96] Not Applicable
11.* ✔	Possible alternate causes of the SAE (check all that apply) [Possible alternate causes]	**[cpALTCAUS]** **[PRIMDIS]** [N:1] Primary disease under study **[INTERILL]** [N:1] **[INILSPEC]** Concomitant illness Specify: A200 **[CONCOM]** [N:1] **[CONSPEC]** Concomitant medication Specify: A100 **[OKNWN]** [N:1] **[OTHSPEC]** Other known or suspected cause Specify: A200 **[ALTNONE]** [N:1] None (Only applicable if study drug related and considered only cause of AE)
12.* ✔	Serious Criteria [Serious Criteria]	**[cpSERICRIT]** Check all that apply: **[SAEDEATH]** [N:1] Death **[SAELIFE]** [N:1] Life-Threatening **[SAEHOSP]** [N:1] Require inpatient hospitalization or prolongation of existing hospitalization **[SAEDIS]** [N:1] Persistent or significant disability/incapacity **[SAEANO]** [N:1] Congenital anomaly or birth defect **[SAEIMPNT]** [N:1] Important medical event
13.* ✔	Was this event unexpected per product labeling? [Unexpected?]	**[SAEUNEX]** [N:1] Yes [N:0] No

	SAE Summary
14.	

SAE Summary Entry [rsSAE2]

14.1 ✔	Provide a summary, in chronological order, of the clinical course of this SAE from onset through resolution. 1. Presenting signs and symptoms; 2. Treatments and response to treatments 3. Subjects status at time of report and/or final outcome, as applicable [SAE Summary]	**[SAENAR]** A200

Relevant Laboratory and Diagnostic Tests [stSAE3]

15. ✔	Were there any relevant laboratory or diagnostic tests for this SAE? [Relevant Labs]	**[SAELABYN]** [N:1] Yes [N:0] No

	Date	Test	Result	Unit	Normal Range or Value
16.					

Relevant Laboratory and Diagnostic Tests Details Entry [rsSAE4]

16.1* ✔	Date and time [Date]	**[DRAWDTM]** Req/Unk / Req/Unk / Req (2014-2017) Req/Unk : Req/Unk *24-hour clock*
16.2* ✔	Test [Test]	**[TESTNAM]** A200
16.3* ✔	Result [Result]	**[TESTRST]** A200

16.4* ✔	Unit (applicable for labs only) [Unit]	**[TESTUNT]** A200
16.5* ✔	Normal range or value [Normal Range or Value]	**[NRANGE]** A200

Concomitant Medications [stSAE5]

17. ✔	Was the subject on any relevant concomitant medications within 30 days prior to onset of this SAE? If yes, list all concomitant medications: [On concomitant medications]	**[SAECMYN]** *[N:1]* ◯ Yes *[N:0]* ◯ No

	Med Name	Med Start Date	Med Stop Date	Medication Total Daily Dose	Medication Unit	Medication Indication
18.						

Con Med Details Entry [rsSAE6]

18.1* ✔	Medication Name [Med Name]	**[SAECMED]** A50
18.2* ✔	Relevant Medication Start Date [Med Start Date]	**[CONSTRDT]** Req/Unk / Req/Unk / Req/Unk (1914-2017) Req/Unk : Req/Unk *24-hour clock*
18.3* ✔	Relevant Medication Stop Date [Med Stop Date]	**[CONSTP]** *[N:1]* ◯ **[CONSTPDT]** Req/Unk / Req/Unk / Req/Unk (1914-2017); Req/Unk : Req/Unk *24-hour clock* *[N:2]* ◯ Ongoing
18.4* ✔	Medication Total Daily Dose [Medication Total Daily Dose]	**[CONDOSE]** xxxxxxxx.
18.5* ✔	Unit [Medication Unit]	**[CONUNIT]** *[N:1]* ◯ mg *[N:2]* ◯ g *[N:3]* ◯ mL *[N:4]* ◯ cc *[N:98]* ◯ **[CONOUNIT]** Other unit specify: A20
18.6* ✔	Indication [Medication Indication]	**[MEDIND]** A200

Investigator Verification [stSAE7]

19. ✔	I verify that this SAE report form accurately displays the results of the examination, tests, evaluations and treatments noted within. [SAE verify]	**[PICONFRM]** *[N:1]* ☐ Yes
20. ✔	Evaluation date and time (electronic verification non-enterable system generated) *[read-only]* [Evaluation date/time]	**[PICONDT]** Req / Req / Req (2014-2017) Req : Req *24-hour clock*

Medical Monitor Review [stSAE8]

21.	MedDRA Preferred Term [MedDRA Preferred Term]	**[MMMEDDRA]** A100
22.	Was adverse event expected or unexpected according to the product labeling or package insert? [AE expected]	**[MMEXPECT]** *[N:1]* ◯ Expected *[N:2]* ◯ Unexpected
23.	Medical Monitor assessment of relationship of SAE to study drug [Assessment of relationship]	**[MMSCYCAU]** *[N:1]* ◯ Not related *[N:2]* ◯ Unlikely related *[N:3]* ◯ Possibly related *[N:4]* ◯ Related

	Rationale for Assessment
24.	

Medical Monitor Rationale for Assessment Entry [rsSAE9]

24.1	Medical Monitor Rationale for Assessment [Rationale for Assessment]	**[ASRATION]** A200
Medical Monitor Electronic Verification [stSAE10]		
25.	I confirm that I have reviewed the causes and expectedness of this case, and that all my data is complete and accurate to the best of my knowledge. [Medical Monitor Reviewed]	**[SAEMMSIG]** *[N:1]* Yes *[N:0]* No
26.	Evaluation Date and Time (Electronic Verification non-enterable system generated) [Evaluation Date/Time]	**[MMSIGDTC]** Req / Req / Req (2014-2017) Req : Req *24-hour clock*

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: SERIOUS ADVERSE EVENTS

Type	RefName	Description
Form	frSAE	
Section	stSAE1	
Item	AENUM	
Item	AETERM	
Item	AESTDTM	
Item	SEVERITY	
Item	AEREL	
Item	PRRATREL	
Item	RRATREL	
Item	AEOUT	
Item	AEONGO	
Item	AESPDTM	
Item	AEACN	
Item	INTDTAE	
Item	DCDTAE	
Item	AEDIMTD	
Item	AERAPR	
Item	cpALTCAUS	
Item	PRIMDIS	
Item	INTERILL	
Item	INILSPEC	
Item	CONCOM	
Item	CONSPEC	
Item	OKNWN	
Item	OTHSPEC	
Item	ALTNONE	
Item	cpSERICRIT	
Item	SAEDEATH	
Item	SAELIFE	
Item	SAEHOSP	
Item	SAEDIS	
Item	SAEANO	
Item	SAEIMPNT	
Item	SAEUNEX	
Section	rsSAE2	
Item	SAENAR	
Section	stSAE3	
Item	SAELABYN	
Section	rsSAE4	
Item	DRAWDTM	
Item	TESTNAM	

Item	TESTRST	
Item	TESTUNT	
Item	NRANGE	
Section	stSAE5	
Item	SAECMYN	
Section	rsSAE6	
Item	SAECMED	
Item	CONSTRDT	
Item	CONSTP	
Item	CONSTPDT	
Item	CONDOSE	
Item	CONUNIT	
Item	CONOUNIT	
Item	MEDIND	
Section	stSAE7	
Item	PICONFRM	
Item	PICONDT	
Section	stSAE8	
Item	MMMEDDRA	
Item	MMEXPECT	
Item	MMSCYCAU	
Section	rsSAE9	
Item	ASRATION	
Section	stSAE10	
Item	SAEMMSIG	
Item	MMSIGDTC	

HFN_ATHENA: DAY 30 PARTICIPATION STATUS (EOS) [frEOS]		
Day 30 Participation Status [stEOS1]		
1.* ✔	Date of last contact [Date of last contact]	**[LSTCONDT]** Req / Req / Req (2014-2017)
2.* ✔	Status at time of last contact [Status at time of last contact]	**[CMPLTD]** *[N:1]* Died, please complete DEATH form *[N:2]* Completed protocol *[N:3]* Subject lost to follow-up *[N:4]* Subject withdrew consent for study participation *[N:5]* Subject withdrawn from the study by site investigator
3.	Discharge Date (where HOSPDC does not exist) [Discharge Date (where HOSPDC does not exist)]	**[PST96HDC]** *[N:1]* **[PST96HDT]** Yes Discharge Date: Req / Req / Req (2014-2017) *[N:2]* No, remains hospitalized *[N:3]* No, subject died while hospitalized
Key: [*] = Item is required [✔] = Source verification required		

Study Object Descriptions: DAY 30 PARTICIPATION STATUS		
Type	**RefName**	**Description**
Form	frEOS	
Section	stEOS1	
Item	LSTCONDT	
Item	CMPLTD	
Item	PST96HDC	
Item	PST96HDT	

HFN_ATHENA: DEATH (DEATH) [frDEATH]

Please record any applicable SAEs on the SAE form

Death [stDEATH1]

1.* ✔	Location of Death [Location of Death]	**[DEATHLOC]** *[N:1]* ○ Inpatient/ER *[N:2]* ○ Outpatient
2.* ✔	Date of Death [Date of Death]	**[DEATHDT]** Req / Req/Unk / Req (2014-2017)
3.* ✔	Cause of Death [Cause of Death]	**[DTHCAUSE]** *[N:1]* ○ **[DTHCARD]** Cardiovascular *[N:1]* ○ Myocardial infarction *[N:2]* ○ Heart failure/Pump failure/Cardiogenic Shock *[N:3]* ○ **[SDNDTHW]** Sudden Death *[N:1]* ○ Witnessed *[N:2]* ○ Not Witnessed *[N:4]* ○ Stroke *[N:5]* ○ **[DTHCVPR]** CV Procedure *[N:1]* ○ CABG *[N:2]* ○ PCI/Stenting *[N:3]* ○ Valvular *[N:98]* ○ Other CV Procedure *[N:6]* ○ Pulmonary Embolism *[N:98]* ○ **[DTHCRDSP]** Other CV, specify: A100 *[N:2]* ○ **[NCRDSP]** Non-Cardiovascular A100 *[N:99]* ○ Unknown

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: DEATH

Type	RefName	Description
Form	frDEATH	
Section	stDEATH1	
Item	DEATHLOC	
Item	DEATHDT	
Item	DTHCAUSE	
Item	DTHCARD	
Item	SDNDTHW	
Item	DTHCVPR	
Item	DTHCRDSP	
Item	NCRDSP	

HFN_ATHENA: Signature Completion (SIGN) [frSIGN]		
Casebook Ready for Signature [stSIGN]		
1.*	Casebook Ready for Signature [Casebook Ready for Signature]	**[PISIGN]** *[N:1]* ☐ Yes

Key: [*] = Item is required

Study Object Descriptions: Signature Completion		
Type	**RefName**	**Description**
Form	frSIGN	
Section	stSIGN	
Item	PISIGN	

InForm Special Properties For Study Design: HFN_ATHENA			
InForm Special Property	**Property Type**	**Data Object RefName**	**Data Object Path RefName**
Screening	Visit	evSYSSCR	evSYSSCR
Enrollment	Visit	evSYSENR	evSYSENR
Screening	Form	frSYSSCR1	evSYSSCR.frSYSSCR1
Enrollment	Form	frENRSYS2	evSYSENR.frENRSYS2
Patient Identification	Form	frDEMOG	evRAND.frDEMOG
Study Completion	Form	Unassigned	Unassigned
Reg Docs	Form	Unassigned	Unassigned
Visit Report	Form	Unassigned	Unassigned
Initials (Screening)	Item	SUBJINIT	evSYSSCR.frSYSSCR1.SUBJINIT
DOB (Screening)	Item	SCRDOB	evSYSSCR.frSYSSCR1.SCRDOB
Screening date (Screening)	Item	Unassigned	Unassigned
Patient No. (Enrollment)	Item	SUBJID	evRAND.frDEMOG.stDEMOG2.SUBJID
Initials (Patient Identification)	Item	Unassigned	Unassigned
Completion status (Study Completion)	Item	Unassigned	Unassigned
Drop out reason (Study Completion)	Item	Unassigned	Unassigned
DOV (Date of Visit)	Item	Unassigned	Unassigned
Randomization field (Randomization)	Item	Unassigned	Unassigned

Unit Conversions For Study Design: HFN_ATHENA
No unit conversion data.