

Annotated Study Book for Study Design: HFN_NEAT

Study Design Version: 2.0

Protocol: HFN_NEAT

Nitrate's Effect on Activity Tolerance in Diastolic Heart Failure with Preserved Ejection Fraction-NEAT-HFpEF

Generated by Central Designer™

Time and Events Schedule For Study Design: HFN_NEAT															
Element	CRF	System		CLINOPS (CLINOPS) [S]	STUDY VISIT 1 (BASE) [S]	STUDY VISIT 2 (WEEK7) [S]	STUDY VISIT 3 (WEEK13) [S]	PHONE WEEK 15 (WEEK15) [S]	ACCELEROMETER LOG (DEVICE_LOG) [S]	PHONE VISIT LOG (PHONE) [S]	REHOSPITALIZATION (REHOSP) [S]	ED VISIT (EDVISIT) [S]	SERIOUS ADVERSE EVENTS (SAE) [S]	END OF STUDY (EOS) [S]	INVESTIGATOR SIGNATURE (INVSIG) [S]
		System Screening (SYSSCR) [S]	System Enrollment (SYSENRR) [S]												
Visit Start Hours		0	0	0	1	1177	2185	2521	2522	2523	2524	2548	2572	2596	2620
1 System Screening	SYSSCR	1													
2 System Enrollment	SYSENRR		1												
3 Clinical Operations Review	CLINOPS			1											
4 RANDOMIZATION AND DEMOGRAPHICS	DEMOG				1										
5 CLINICAL HISTORY	MEDHIST1				2										
6 CLINICAL HISTORY	MEDHIST2				3										
7 EXAMINATION	EXAM				4	2-DF	2-DF								
8 MEDICATIONS	MEDS				5	3-DF	3-DF								
9 STUDY DRUG ADMINISTRATION	SDADMIN				6	5-DF									
10 ECG	ECG				7										
11 Baseline Assessments	BASSESS				8										
12 CHEMISTRY LABS	CHEM				9-DF										
13 HEMATOLOGY LABS	HEMACOAG				10-DF										
14 BIOLOGICAL SAMPLES	SAMPLES				11-DF	7-DF	6-DF								
15 SIX MINUTE WALK TEST	SIXMWT				12-DF	8-DF	7-DF								
16 Kansas City Cardiomyopathy Questionnaire	KCCQ				13-DF	9-DF	8-DF								
17 MINNESOTA LIVING WITH HEART FAILURE QUESTIONNAIRE	MLHFQ				14-DF	10-DF	9-DF								
18 ECHOCARDIOGRAM	ECHO				15										
19 BASELINE EVENTS OF INTEREST	BLEVNT				16										
20 VISIT STATUS	VISIT					1	1	1							
21 EVENTS OF INTEREST	EVNTINT					4	4	2							
22 Additional Protocol Assessments	ASSESS					6-DF	5-DF								
23 STUDY DRUG DOSING	DRGDOSE					11	10								
24 PATIENT PREFERENCE	PREF						11-DF								
25 ACCELEROMETER LOG	DEVICE								1						
26 PHONE VISIT LOG	PHONE									1-RF					
27 REHOSPITALIZATION	REHOSP										1-RF				
28 EMERGENCY DEPARTMENT VISIT	EDVISIT											1-RF			
29 SERIOUS ADVERSE EVENTS	SAE												1-RF		
30 END OF STUDY	EOS													1	
31 DEATH	DEATH													2-DF	
32 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_NEAT: System Screening (SYSSCR) [frSCRIXRS]		
System Screening [frSCRIXRS]		
1.*	IXRS ID [IXRS ID]	[IXRSID] A3
Key: [*] = Item is required		

RDE Analytics: RD_FRSCRIXRS		
Data Variable RefName	RD Column Name	Column Data Type
IXRSID	IXRSID	VARCHAR2
	IXRSID_ND	VARCHAR2

HFN_NEAT: System Enrollment (SYSENR) [frENRSYS1]		
System Enrollment [frENRSYS1]		
1. *	Subject Identifier [Subject Identifier]	[SUBJID] A20
Key: [*] = Item is required		

RDE Analytics: RD_FRENRSYS1		
Data Variable RefName	RD Column Name	Column Data Type
SUBJID	SUBJID	VARCHAR2
	SUBJID_ND	VARCHAR2

HFN_NEAT: Clinical Operations Review (CLINOPS) [frCLINOPS]				
Eligibility criteria [stCLINOPS1]				
1. Per eCRF eligibility review, was subject found to be eligible? [Per eCRF eligibility review, was subject found to be eligible]		[INCMET] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No		
Ineligible Criteria	Waiver granted?	Waiver granted by	Reason for Waiver	Reason for waiver, continued
2.				
Ineligible criteria Entry [rsCLINOPS2]				
2.1 Criteria [Ineligible Criteria]		[CRITTYPE] [N: 1] <input checked="" type="radio"/> [INCLNOT] Inclusion not met [N: 1] <input type="radio"/> IE1 [N: 2] <input type="radio"/> IE2 [N: 3] <input type="radio"/> IE3 [N: 4] <input type="radio"/> IE4 [N: 5] <input type="radio"/> IE5 [N: 6] <input type="radio"/> IE6 [N: 7] <input type="radio"/> IE7 [N: 8] <input type="radio"/> IE8 [N: 9] <input type="radio"/> IE9 [N: 10] <input type="radio"/> IE10 [N: 11] <input type="radio"/> IE11 [N: 2] <input type="radio"/> [EXCLMET] Exclusion met [N: 1] <input type="radio"/> EC1 [N: 2] <input type="radio"/> EC2 [N: 3] <input type="radio"/> EC3 [N: 4] <input type="radio"/> EC4 [N: 5] <input type="radio"/> EC5 [N: 6] <input type="radio"/> EC6 [N: 7] <input type="radio"/> EC7 [N: 8] <input type="radio"/> EC8 [N: 9] <input type="radio"/> EC9 [N: 10] <input type="radio"/> EC10 [N: 11] <input type="radio"/> EC11 [N: 12] <input type="radio"/> EC12 [N: 13] <input type="radio"/> EC13 [N: 14] <input type="radio"/> EC14 [N: 15] <input type="radio"/> EC15 [N: 16] <input type="radio"/> EC16 [N: 17] <input type="radio"/> EC17 [N: 18] <input type="radio"/> EC18 [N: 19] <input type="radio"/> EC19 [N: 20] <input type="radio"/> EC20 [N: 21] <input type="radio"/> EC21		
2.2 Was a waiver granted? [Waiver granted?]		[WAI VER] [N: 1] <input checked="" type="radio"/> [WAI VRDT] Yes Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2018) [N: 0] <input type="radio"/> No		
2.3 Who granted waiver? [Waiver granted by]		[WHOGRTWV] A200		
2.4 Reason for Waiver Narrative [Reason for Waiver]		[ELIGNRT] A200		
2.5 Reason for Waiver Narrative continued [Reason for waiver, continued]		[ELIGNRT1] A200		

RDE Analytics: RD_FRCLINOPS		
Data Variable RefName	RD Column Name	Column Data Type
INCMET	INCMET_C	NUMBER
	INCMET	VARCHAR2
	INCMET_ND	VARCHAR2
RD_FRCLINOPS_RSCLINOPS2		
CRITTYPE	CRITTYPE_C	**NUMBER
	CRITTYPE	VARCHAR2
	CRITTYPE_ND	VARCHAR2
CRITTYPE - INCLNOT	INCLNOT_C	NUMBER
	INCLNOT	VARCHAR2
CRITTYPE - EXCLMET	EXCLMET_C	NUMBER
	EXCLMET	VARCHAR2
WAIVER	WAIVER_C	**NUMBER
	WAIVER	VARCHAR2
	WAIVER_ND	VARCHAR2
WAIVER - WAIVRDT	WAIVRDT	DATE
	WAIVRDT_DTS	VARCHAR2
WHOGRTWV	WHOGRTWV	VARCHAR2
	WHOGRTWV_ND	VARCHAR2
ELIGNRT	ELIGNRT	VARCHAR2
	ELIGNRT_ND	VARCHAR2
ELIGNRT1	ELIGNRT1	VARCHAR2
	ELIGNRT1_ND	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: RANDOMIZATION AND DEMOGRAPHICS (DEMOG) [frDEMOG]		
Consent and Randomization [stDEMOG1]		
1.*	Subject Identifier [Subject Identifier]	[SUBJID] A20
2.*	Date/Time Informed Consent Signed [Date/Time Informed Consent Signed]	[CONSDTM] Req [v] / Req [v] / Req [v] (2014-2018) Req/Unk [v] : Req/Unk [v] 24-hour clock
3.*	Did the subject agree to participate in the biorepository substudy [Subject agree to participate in biorepository substudy]	[BIORPSTY] [N:1] <input type="radio"/> [BIORPCDT] Yes Date consent obtained Req [v] / Req [v] / Req [v] (2014-2018) [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Site not participating
4.*	Did the subject agree to participate in the pharmacogenomics (genetics) substudy [Subject agree to participate in pharmacogenomics substudy]	[GENETICS] [N:1] <input type="radio"/> [GENCONDT] Yes Date consent obtained Req [v] / Req [v] / Req [v] (2014-2018) [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Site not participating
5.*	Date and Time of Randomization [Date and Time of Randomization]	[RANDDTM] Req [v] / Req [v] / Req [v] (2014-2018) Req [v] : Req [v] 24-hour clock
6.*	Has the subject met all eligibility criteria [Subject met all eligibility criteria]	[ELIGIBLE] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
Demographics [stDEMOG2]		
7.*	Date of Birth [Date of Birth]	[DOBDT] Req [v] / Req [v] / Req [v] (1914-1964)
8.*	Sex [Sex]	[SEX] [N:1] <input type="radio"/> Male [N:2] <input type="radio"/> Female
9.*	Ethnicity [Ethnicity]	[ETHNIC] [N:1] <input type="radio"/> Hispanic or Latino [N:2] <input type="radio"/> Not Hispanic or Latino
10.*	Race (check all that apply) [Race]	[cpRACE] [AMERIND] [N:1] <input type="checkbox"/> American Indian or Alaskan Native [ASIAN] [N:1] <input type="checkbox"/> Asian [BLACK] [N:1] <input type="checkbox"/> Black or African American [NATHWN] [N:1] <input type="checkbox"/> Native Hawaiian or Other Pacific Islander [WHITE] [N:1] <input type="checkbox"/> White/Caucasian
Key: [*] = Item is required [v] = Source verification required		

RDE Analytics: RD_FRDEMOG		
Data Variable RefName	RD Column Name	Column Data Type
SUBJID	SUBJID	VARCHAR2
	SUBJID_ND	VARCHAR2
CONSDTM	CONSDTM	DATE
	CONSDTM_DTS	VARCHAR2
	CONSDTM_DTR	VARCHAR2
	CONSDTM_ND	VARCHAR2
BIORPSTY	BIORPSTY_C	**NUMBER
	BIORPSTY	VARCHAR2
	BIORPSTY_ND	VARCHAR2

BIORPSTY - BIORPCDT	BIORPCDT	DATE
	BIORPCDT_DTS	VARCHAR2
GENETICS	GENETICS_C	**NUMBER
	GENETICS	VARCHAR2
	GENETICS_ND	VARCHAR2
GENETICS - GENCONDT	GENCONDT	DATE
	GENCONDT_DTS	VARCHAR2
RANDDTM	RANDDTM	DATE
	RANDDTM_DTS	VARCHAR2
	RANDDTM_ND	VARCHAR2
ELIGIBLE	ELIGIBLE_C	NUMBER
	ELIGIBLE	VARCHAR2
	ELIGIBLE_ND	VARCHAR2
DOBDT	DOBDT	DATE
	DOBDT_DTS	VARCHAR2
	DOBDT_ND	VARCHAR2
SEX	SEX_C	NUMBER
	SEX	VARCHAR2
	SEX_ND	VARCHAR2
ETHNIC	ETHNIC_C	NUMBER
	ETHNIC	VARCHAR2
	ETHNIC_ND	VARCHAR2
cpRACE	CPRACE_ND	VARCHAR2
cpRACE - American Indian or Alaskan Native	*AMERIND_CIAMERICANINDIANALASKANNATIVE_C	NUMBER
	*AMERIND_CIAMERICANINDIANALASKANNATIVE	VARCHAR2
cpRACE - Asian	ASIAN_CIASIAN_C	NUMBER
	ASIAN_CIASIAN	VARCHAR2
cpRACE - Black or African American	*BLACK_CIBLACKAFRICANAMERICAN_C	NUMBER
	*BLACK_CIBLACKAFRICANAMERICAN	VARCHAR2
cpRACE - Native Hawaiian or Other Pacific Islander	*NATHWN_CINATIVEHAWAIIANOTHPACIFICISLANDER_C	NUMBER
	*NATHWN_CINATIVEHAWAIIANOTHPACIFICISLANDER	VARCHAR2
cpRACE - White/Caucasian	WHITE_CIWHITECAUCASIAN_C	NUMBER
	WHITE_CIWHITECAUCASIAN	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different. [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: 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 <input type="text"/> / Req/Unk <input type="text"/> (1920-2020)
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 <input type="text"/>
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 <input type="text"/>
4.* Number of other cardiovascular hospitalizations within past 12 months (provide best estimate if exact number is unknown): [Number of other cardiovascular hospitalizations within past 12 months]	[NUMCDHSP] N3 <input type="text"/>
5.* Has LV function been assessed (prior to randomization)? [Has LV function been assessed]	[LVASSESS] [N: 1] <input checked="" type="radio"/> [cpLVASSESS] Yes [LVASSDT] If Yes: date of last LVEF (prior to randomization): Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req/Unk <input type="text"/> (1920-2020) [LVEF] Value of last LVEF: [N: 1] <input checked="" type="radio"/> [LVEFEF] <input type="text"/> % xxxxxxx. [N: 2] <input type="radio"/> Normal [N: 3] <input type="radio"/> Mild dysfunction [N: 4] <input type="radio"/> Moderate dysfunction [N: 5] <input type="radio"/> Severe dysfunction [METHLV] Method of assessment of LV function: [N: 1] <input type="radio"/> Radionuclide ventriculogram [N: 2] <input type="radio"/> Left ventriculogram by cardiac catheterization [N: 3] <input type="radio"/> Echocardiogram [N: 4] <input type="radio"/> MRI [N: 98] <input type="radio"/> Other [N: 0] <input type="radio"/> No
6.* Has the subject had a myocardial infarction (MI)? [Has the subject had a myocardial infarction (MI)]	[MI] [N: 1] <input checked="" type="radio"/> [MIYR] Yes [N: 1] <input checked="" type="radio"/> [MIYRVAL] Year of most recent N4 <input type="text"/> [N: 99] <input type="radio"/> Unknown [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
7.* Has the subject had a left heart catheterization? [Has the subject had a left heart catheterization]	[LTCATH] [N: 1] <input checked="" type="radio"/> [cpLTCATH] Yes [LTCATHYR] [N: 1] <input checked="" type="radio"/> [LCYRVAL] Year of most recent N4 <input type="text"/> [N: 99] <input type="radio"/> Unknown [cpVESSELS] Vessels with >50% stenosis (check all that apply): [LM] [N: 1] <input type="checkbox"/> LM [LAC] [N: 1] <input type="checkbox"/> LAD [LCX] [N: 1] <input type="checkbox"/> LCX [RCA] [N: 1] <input type="checkbox"/> RCA [GRAFT] [N: 1] <input type="checkbox"/> Graft [NOVSS] [N: 1] <input type="checkbox"/> None [VESUNK] [N: 1] <input type="checkbox"/> Unknown [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown

<p>8.* ✓</p>	<p>Has the subject had a percutaneous coronary intervention (PCI)? [Has the subject had a percutaneous coronary intervention (PCI)]</p>	<p>[PCIHX] [N: 1] <input type="radio"/> [PCIYR] Yes [N: 1] <input type="radio"/> [PCIIVAL] Year of most recent N4 [N: 99] <input type="radio"/> Unknown [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
<p>9.* ✓</p>	<p>Has the subject had a coronary artery bypass graft (CABG)? [Has the subject had a coronary artery bypass graft (CABG)]</p>	<p>[CABGHX] [N: 1] <input type="radio"/> [CABGYR] Yes [N: 1] <input type="radio"/> [CABGVAL] Year of most recent N4 [N: 99] <input type="radio"/> Unknown [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
<p>10.* ✓</p>	<p>Has subject had any other factors contributing to cardiomyopathy? [Has subject had any other factors contributing to cardiomyopathy]</p>	<p>[FACTORYN] [N: 1] <input type="radio"/> [OpFACTORYN] Yes (check all that apply) [ALCOHOLC] [N: 1] <input type="checkbox"/> Alcoholic [CYTOTOX] [N: 1] <input type="checkbox"/> Cytotoxic drug therapy [FAMILIAL] [N: 1] <input type="checkbox"/> Familial [HYPERTN] [N: 1] <input type="checkbox"/> Hypertensive [IDIODIL] [N: 1] <input type="checkbox"/> Idiopathic dilated cardiomyopathy [IDIORES] [N: 1] <input type="checkbox"/> Idiopathic restrictive cardiomyopathy [PERIPRT] [N: 1] <input type="checkbox"/> Peripartum [VALVUL] [N: 1] <input type="checkbox"/> Valvular [HCM] [N: 1] <input type="checkbox"/> HCM [MYOOTH] [N: 1] <input type="checkbox"/> [MYOPSP] Other/uncertain Specify A100 [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>

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

RDE Analytics: RD_FRMEDHIST1		
Data Variable RefName	RD Column Name	Column Data Type
DIAGDT	DIAGDT_DTS	VARCHAR2
	DIAGDT_DTR	VARCHAR2
	DIAGDT_ND	VARCHAR2
HOSPVAL	HOSPVAL	NUMBER
	HOSPVAL_ND	VARCHAR2
NUMHFHSP	NUMHFHSP	NUMBER
	NUMHFHSP_ND	VARCHAR2
NUMCDHSP	NUMCDHSP	NUMBER
	NUMCDHSP_ND	VARCHAR2
LVASSESS	LVASSESS_C	**NUMBER
	LVASSESS	VARCHAR2
	LVASSESS_ND	VARCHAR2
LVASSESS - LVASSDT	LVASSDT	DATE

	LVASSTDT_DTS	VARCHAR2
	LVASSTDT_DTR	VARCHAR2
LVASSESS - LVEF	LVEF_C	**NUMBER
	LVEF	VARCHAR2
LVASSESS - LVEFEF	LVEFEF	FLOAT
LVASSESS - METHLV	METHLV_C	NUMBER
	METHLV	VARCHAR2
MI	MI_C	**NUMBER
	MI	VARCHAR2
	MI_ND	VARCHAR2
MI - MIYR	MIYR_C	**NUMBER
	MIYR	VARCHAR2
MI - MIYRVAL	MIYRVAL	NUMBER
LTCATH	LTCATH_C	**NUMBER
	LTCATH	VARCHAR2
	LTCATH_ND	VARCHAR2
LTCATH - LTCATHYR	LTCATHYR_C	**NUMBER
	LTCATHYR	VARCHAR2
LTCATH - LCYRVAL	LCYRVAL	NUMBER
LTCATH - LM	LM_CILM_C	NUMBER
	LM_CILM	VARCHAR2
LTCATH - LAD	LAC_CILAD_C	NUMBER
	LAC_CILAD	VARCHAR2
LTCATH - LCX	LCX_CILCX_C	NUMBER
	LCX_CILCX	VARCHAR2
LTCATH - RCA	RCA_CIRCA_C	NUMBER
	RCA_CIRCA	VARCHAR2
LTCATH - Graft	GRAFT_CIGRAFT_C	NUMBER
	GRAFT_CIGRAFT	VARCHAR2
LTCATH - None	NOVSS_CINONE1_C	NUMBER
	NOVSS_CINONE1	VARCHAR2
LTCATH - Unknown	VESUNK_CIUNKNOWN1_C	NUMBER
	VESUNK_CIUNKNOWN1	VARCHAR2
PCIHX	PCIHX_C	**NUMBER
	PCIHX	VARCHAR2
	PCIHX_ND	VARCHAR2
PCIHX - PCIYR	PCIYR_C	**NUMBER
	PCIYR	VARCHAR2
PCIHX - PCIVAL	PCIVAL	NUMBER
CABGHX	CABGHX_C	**NUMBER
	CABGHX	VARCHAR2
	CABGHX_ND	VARCHAR2
CABGHX - CABGYR	CABGYR_C	**NUMBER
	CABGYR	VARCHAR2
CABGHX - CABGVAL	CABGVAL	NUMBER
FACTORYN	FACTORYN_C	**NUMBER
	FACTORYN	VARCHAR2
	FACTORYN_ND	VARCHAR2
FACTORYN - Alcoholic	ALCOHOLC_CIALCOHOLIC_C	NUMBER
	ALCOHOLC_CIALCOHOLIC	VARCHAR2
FACTORYN - Cytotoxic drug therapy	*CYTOTOX_CICYTOTOXICDRUGTHERAPY_C	NUMBER
	*CYTOTOX_CICYTOTOXICDRUGTHERAPY	VARCHAR2
FACTORYN - Familial	FAMILIAL_CIFAMILIAL_C	NUMBER
	FAMILIAL_CIFAMILIAL	VARCHAR2

FACTORYN - Hypertensive	HYPERTN_CIHYPERTENSIVE_C	NUMBER
	HYPERTN_CIHYPERTENSIVE	VARCHAR2
FACTORYN - Idiopathic dilated cardiomyopathy	*IDIODIL_CIIDIOPATHICDILATEDCARDIOMYOPATHY_C	NUMBER
	*IDIODIL_CIIDIOPATHICDILATEDCARDIOMYOPATHY	VARCHAR2
FACTORYN - Idiopathic restrictive cardiomyopathy	*IDIORES_CIIDIOPATHICRESTRICTIVECARDIOMYOPATHY_C	NUMBER
	*IDIORES_CIIDIOPATHICRESTRICTIVECARDIOMYOPATHY	VARCHAR2
FACTORYN - Peripartum	PERIPRT_CIPERIPARTUM_C	NUMBER
	PERIPRT_CIPERIPARTUM	VARCHAR2
FACTORYN - Valvular	VALVUL_CIVALVULAR_C	NUMBER
	VALVUL_CIVALVULAR	VARCHAR2
FACTORYN - HCM	HCM_CIHCM_C	NUMBER
	HCM_CIHCM	VARCHAR2
FACTORYN - Other/uncertain	MYOOTH_MYOPSP_C	**NUMBER
	MYOOTH_MYOPSP	VARCHAR2
FACTORYN - MYOPSP	MYOPSP	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different. [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: CLINICAL HISTORY (MEDHIST2) [frMEDHIST2]	
Clinical History [stMEDHIST2_1]	
1.* Does subject have moderate to severe valvular heart disease? [Moderate to severe valvular heart disease]	<p>[VALVULAR] [N: 1] <input checked="" type="radio"/> [cpVALVULAR] Yes (check all that apply)</p> <p>[MSTENOS] [N: 1] <input type="checkbox"/> Mitral stenosis</p> <p>[MREGURG] [N: 1] <input type="checkbox"/> Mitral regurgitation</p> <p>[ATSTENOS] [N: 1] <input type="checkbox"/> Aortic stenosis</p> <p>[AREGURG] [N: 1] <input type="checkbox"/> Aortic regurgitation</p> <p>[TSTENOS] [N: 1] <input type="checkbox"/> Tricuspid stenosis</p> <p>[TREGURG] [N: 1] <input type="checkbox"/> Tricuspid regurgitation</p> <p>[N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
2.* Has subject had prior valvular surgery? [Prior valvular surgery]	<p>[PVALSRG] [N: 1] <input checked="" type="radio"/> [cpPVALSRG] Yes (check all that apply)</p> <p>[MITSURG] [N: 1] <input type="checkbox"/> Mitral</p> <p>[AORSURG] [N: 1] <input type="checkbox"/> Aortic</p> <p>[TRISURG] [N: 1] <input type="checkbox"/> Tricuspid</p> <p>[PULSURG] [N: 1] <input type="checkbox"/> Pulmonic</p> <p>[N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
3.* Hypertension [Hypertension]	<p>[HYPRTESN] [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
4.* TIA [TIA]	<p>[TIA] [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
5.* Stroke [Stroke]	<p>[STROKE] [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
6.* Arrhythmia [Arrhythmia]	<p>[ARRHYTHM] [N: 1] <input checked="" type="radio"/> [cpARRHYTHM] Yes (check all that apply)</p> <p>[ATRIALFB] [N: 1] <input type="checkbox"/> [ATRIALTY] Atrial fibrillation (check one) [N: 1] <input checked="" type="radio"/> New onset [N: 2] <input checked="" type="radio"/> Paroxysmal [N: 3] <input checked="" type="radio"/> Chronic (Persistent/Permanent) [N: 99] <input checked="" type="radio"/> Unknown/Other</p> <p>[FLUTTER] [N: 1] <input type="checkbox"/> Atrial Flutter</p> <p>[SUSVT] [N: 1] <input type="checkbox"/> Sustained VT</p> <p>[VF] [N: 1] <input type="checkbox"/> VF</p> <p>[ARREST] [N: 1] <input type="checkbox"/> Cardiac arrest (etiology unclear)</p> <p>[ARRHUNKO] [N: 1] <input type="checkbox"/> Unknown/Other</p> <p>[N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
Pacemaker/ICD	[PACEICD]

7.*	[Pacemaker/ICD]	<p>[N: 1] <input type="radio"/> [PACICDTY] Yes [N: 1] <input type="radio"/> Pacemaker (single/dual) [N: 2] <input type="radio"/> Biventricular Pacemaker with ICD [N: 3] <input type="radio"/> Biventricular Pacemaker without ICD [N: 4] <input type="radio"/> ICD only (single/dual) [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
8.*	Peripheral vascular disease [Peripheral vascular disease]	<p>[PVD] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
9.*	Chronic obstructive pulmonary disease [Chronic obstructive pulmonary disease]	<p>[COPD] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
10.*	Diabetes [Diabetes]	<p>[DIABETES] [N: 1] <input type="radio"/> [DIABTYPE] Yes [N: 1] <input type="radio"/> Type I [N: 2] <input type="radio"/> Type II [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
11.*	Gout [Gout]	<p>[GOUT] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
12.*	Hepatic disease [Hepatic disease]	<p>[HEPATIC] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
13.*	Chronic renal insufficiency [Chronic renal insufficiency]	<p>[CRINSUF] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
14.*	Malignancy (past 5 years other than skin) [Malignancy]	<p>[MALIG] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
15.*	Depression (treated with prescription medication) [Depression]	<p>[DEPRESS] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
16.*	Chronic alcohol use [Chronic alcohol use]	<p>[ALCOHOL] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
17.*	Cigarette smoking [Cigarette smoking]	<p>[SMOKING] [N: 1] <input type="radio"/> Current [N: 2] <input type="radio"/> Quit < 6 months ago [N: 3] <input type="radio"/> Quit >= 6 months ago [N: 4] <input type="radio"/> Never [N: 99] <input type="radio"/> Unknown</p>
18.*	Hyperlipidemia [Hyperlipidemia]	<p>[HYPRLIP] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
19.*	Obstructive sleep apnea [Obstructive sleep apnea]	<p>[OSA] [N: 1] <input type="radio"/> [OSATX] Yes Treated: [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>

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

RDE Analytics: RD_FRMEDHIST2		
Data Variable RefName	RD Column Name	Column Data Type
VALVULAR	VALVULAR_C	**NUMBER
	VALVULAR	VARCHAR2
	VALVULAR_ND	VARCHAR2
VALVULAR - Mitral stenosis	MSTENOS_CIMITRALSTENOSIS_C	NUMBER
	MSTENOS_CIMITRALSTENOSIS	VARCHAR2
VALVULAR - Mitral regurgitation	*MREGURG_CIMITRALREGURGITATION_C	NUMBER
	*MREGURG_CIMITRALREGURGITATION	VARCHAR2
VALVULAR - Aortic stenosis	ATSTENOS_CIAORTICSTENOSIS_C	NUMBER
	ATSTENOS_CIAORTICSTENOSIS	VARCHAR2
VALVULAR - Aortic regurgitation	*AREGURG_CIAORTICREGURGITATION_C	NUMBER
	*AREGURG_CIAORTICREGURGITATION	VARCHAR2
VALVULAR - Tricuspid stenosis	*TSTENOS_CITRICUSPIDSTENOSIS_C	NUMBER
	*TSTENOS_CITRICUSPIDSTENOSIS	VARCHAR2
VALVULAR - Tricuspid regurgitation	*TREGURG_CITRICUSPIDREGURGITATION_C	NUMBER
	*TREGURG_CITRICUSPIDREGURGITATION	VARCHAR2
PVALSRG	PVALSRG_C	**NUMBER
	PVALSRG	VARCHAR2
	PVALSRG_ND	VARCHAR2
PVALSRG - Mitral	MITSURG_CIMITRAL_C	NUMBER
	MITSURG_CIMITRAL	VARCHAR2
PVALSRG - Aortic	AORSURG_CIAORTIC_C	NUMBER
	AORSURG_CIAORTIC	VARCHAR2
PVALSRG - Tricuspid	TRISURG_CITRICUSPID_C	NUMBER
	TRISURG_CITRICUSPID	VARCHAR2
PVALSRG - Pulmonic	PULSURG_CIPULMONIC_C	NUMBER
	PULSURG_CIPULMONIC	VARCHAR2
HYPRTESN	HYPRTESN_C	NUMBER
	HYPRTESN	VARCHAR2
	HYPRTESN_ND	VARCHAR2
TIA	TIA_C	NUMBER
	TIA	VARCHAR2
	TIA_ND	VARCHAR2
STROKE	STROKE_C	NUMBER
	STROKE	VARCHAR2
	STROKE_ND	VARCHAR2
ARRHYTHM	ARRHYTHM_C	**NUMBER
	ARRHYTHM	VARCHAR2
	ARRHYTHM_ND	VARCHAR2
ARRHYTHM - Atrial fibrillation (check one)	ATRIALFB_ATRIALTY_C	**NUMBER
	ATRIALFB_ATRIALTY	VARCHAR2
ARRHYTHM - ATRIALTY	ATRIALTY_C	NUMBER
	ATRIALTY	VARCHAR2
ARRHYTHM - Atrial Flutter	FLUTTER_CIATRIALFLUTTER_C	NUMBER
	FLUTTER_CIATRIALFLUTTER	VARCHAR2
ARRHYTHM - Sustained VT	SUSVT_CISUSTAINEDVT_C	NUMBER
	SUSVT_CISUSTAINEDVT	VARCHAR2
ARRHYTHM - VF	VF_CIVF_C	NUMBER
	VF_CIVF	VARCHAR2
ARRHYTHM - Cardiac arrest (etiology unclear)	*ARREST_CICARDIACARRESTETIOLOGYUNCLEAR_C	NUMBER
	*ARREST_CICARDIACARRESTETIOLOGYUNCLEAR	VARCHAR2

ARRHYTHM - Unknown/Other	*ARRHUNKO_CIUNKNOWNOTHERCHKALL_C	NUMBER
	*ARRHUNKO_CIUNKNOWNOTHERCHKALL	VARCHAR2
PACEICD	PACEICD_C	**NUMBER
	PACEICD	VARCHAR2
	PACEICD_ND	VARCHAR2
PACEICD - PACICDTY	PACICDTY_C	NUMBER
	PACICDTY	VARCHAR2
PVD	PVD_C	NUMBER
	PVD	VARCHAR2
	PVD_ND	VARCHAR2
COPD	COPD_C	NUMBER
	COPD	VARCHAR2
	COPD_ND	VARCHAR2
DIABETES	DIABETES_C	**NUMBER
	DIABETES	VARCHAR2
	DIABETES_ND	VARCHAR2
DIABETES - DIABTYPE	DIABTYPE_C	NUMBER
	DIABTYPE	VARCHAR2
GOUT	GOUT_C	NUMBER
	GOUT	VARCHAR2
	GOUT_ND	VARCHAR2
HEPATIC	HEPATIC_C	NUMBER
	HEPATIC	VARCHAR2
	HEPATIC_ND	VARCHAR2
CRINSUF	CRINSUF_C	NUMBER
	CRINSUF	VARCHAR2
	CRINSUF_ND	VARCHAR2
MALIG	MALIG_C	NUMBER
	MALIG	VARCHAR2
	MALIG_ND	VARCHAR2
DEPRESS	DEPRESS_C	NUMBER
	DEPRESS	VARCHAR2
	DEPRESS_ND	VARCHAR2
ALCOHOL	ALCOHOL_C	NUMBER
	ALCOHOL	VARCHAR2
	ALCOHOL_ND	VARCHAR2
SMOKING	SMOKING_C	NUMBER
	SMOKING	VARCHAR2
	SMOKING_ND	VARCHAR2
HYPRLIP	HYPRLIP_C	NUMBER
	HYPRLIP	VARCHAR2
	HYPRLIP_ND	VARCHAR2
OSA	OSA_C	**NUMBER
	OSA	VARCHAR2
	OSA_ND	VARCHAR2
OSA - OSATX	OSATX_C	NUMBER
	OSATX	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different. [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: EXAMINATION (EXAM) [frEXAM]	
Examination [stEXAM1]	
1.* Heart Rate (sitting or resting) [Heart Rate]	<p>[HRATE] [N: 1] <input type="radio"/> [HRATEVAL] N3 [N: 97] <input type="radio"/> Not Done</p>
2.* Blood Pressure (sitting or resting) [Blood Pressure]	<p>[BPDONE] [N: 1] <input type="radio"/> [cpBP] [BPSYS] [BPDIA] mmHg N3 / N3 [N: 97] <input type="radio"/> Not Done</p>
3.* SpO2 [SpO2]	<p>[SPO2] [N: 1] <input type="radio"/> [SPO2VAL] xxxxxxxx. %^[b] [N: 97] <input type="radio"/> Not Done</p>
4.* Height (at Baseline visit only) [Height]	<p>[HEIGHT] [N: 1] <input type="radio"/> [HGTVAL] xxxxxxxx. [HGTUNIT] Unit [N: 1] <input type="radio"/> in [N: 2] <input type="radio"/> cm [N: 97] <input type="radio"/> Not Done</p>
5.* Weight [Weight]	<p>[WEIGHT] [N: 1] <input type="radio"/> [WGTVAL] xxxxxxxx. [WGTUNIT] Unit [N: 1] <input type="radio"/> lb [N: 2] <input type="radio"/> kg [N: 97] <input type="radio"/> Not Done</p>
6.* JVP [JVP]	<p>[JVP] [N: 1] <input type="radio"/> Not elevated/not distended [N: 2] <input type="radio"/> Elevated/distended [N: 97] <input type="radio"/> Not Done</p>
7.* Rales [Rales]	<p>[RALES] [N: 1] <input type="radio"/> None [N: 2] <input type="radio"/> < 1/3 [N: 3] <input type="radio"/> 1/3 - 2/3 [N: 4] <input type="radio"/> > 2/3 [N: 97] <input type="radio"/> Not Done</p>
8.* S3 auscultation [S3 auscultation]	<p>[S3AUS] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 97] <input type="radio"/> Not Done</p>
9.* Hepatomegaly [Hepatomegaly]	<p>[HEPATO] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 97] <input type="radio"/> Not Done</p>
10.* Ascites/Abdominal Distention [Ascites/Abdominal Distention]	<p>[ASCITES] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 97] <input type="radio"/> Not Done</p>
11.* Peripheral edema [Peripheral edema]	<p>[EDEMA] [N: 1] <input type="radio"/> None [N: 2] <input type="radio"/> Trace [N: 5] <input type="radio"/> Mild (1+) [N: 3] <input type="radio"/> Moderate (2+ , 3+) [N: 4] <input type="radio"/> Severe (4+) [N: 97] <input type="radio"/> Not Done</p>
12.* Current NYHA heart failure classification [Current NYHA heart failure classification]	<p>[NYHA] [N: 1] <input type="radio"/> I [N: 2] <input type="radio"/> II [N: 3] <input type="radio"/> III [N: 4] <input type="radio"/> IV</p>

13.*	Orthopnea [Orthopnea]	<p>[N: 97] <input type="radio"/> Not Done</p> <p>[ORTHOP]</p> <p>[N: 1] <input type="radio"/> None</p> <p>[N: 2] <input type="radio"/> One pillow (10cm)</p> <p>[N: 3] <input type="radio"/> Two pillows (20cm)</p> <p>[N: 4] <input type="radio"/> Three or more pillows</p> <p>[N: 97] <input type="radio"/> Not Done</p>
<p>Key: [*] = Item is required [✓] = Source verification required [b] = Base Unit</p>		

RDE Analytics: RD_FREXAM		
Data Variable RefName	RD Column Name	Column Data Type
HRATE	HRATE_C	**NUMBER
	HRATE	VARCHAR2
	HRATE_ND	VARCHAR2
HRATE - HRATEVAL	HRATEVAL	NUMBER
BPDONE	BPDONE_C	**NUMBER
	BPDONE	VARCHAR2
	BPDONE_ND	VARCHAR2
BPDONE - BPSYS	BPSYS	NUMBER
BPDONE - BPDIA	BPDIA	NUMBER
SPO2	SPO2_C	**NUMBER
	SPO2	VARCHAR2
	SPO2_ND	VARCHAR2
SPO2 - SPO2VAL	SPO2VAL	FLOAT
	SPO2VAL_U	VARCHAR2
HEIGHT	HEIGHT_C	**NUMBER
	HEIGHT	VARCHAR2
	HEIGHT_ND	VARCHAR2
HEIGHT - HGTVAL	HGTVAL	FLOAT
HEIGHT - HGTUNIT	HGTUNIT_C	NUMBER
	HGTUNIT	VARCHAR2
WEIGHT	WEIGHT_C	**NUMBER
	WEIGHT	VARCHAR2
	WEIGHT_ND	VARCHAR2
WEIGHT - WGTVAL	WGTVAL	FLOAT
WEIGHT - WGTUNIT	WGTUNIT_C	NUMBER
	WGTUNIT	VARCHAR2
JVP	JVP_C	NUMBER
	JVP	VARCHAR2
	JVP_ND	VARCHAR2
RALES	RALES_C	NUMBER
	RALES	VARCHAR2
	RALES_ND	VARCHAR2
S3AUS	S3AUS_C	NUMBER
	S3AUS	VARCHAR2
	S3AUS_ND	VARCHAR2
HEPATO	HEPATO_C	NUMBER
	HEPATO	VARCHAR2
	HEPATO_ND	VARCHAR2
ASCITES	ASCITES_C	NUMBER
	ASCITES	VARCHAR2
	ASCITES_ND	VARCHAR2
EDEMA	EDEMA_C	NUMBER
	EDEMA	VARCHAR2

	EDEMA_ND	VARCHAR2
NYHA	NYHA_C	NUMBER
	NYHA	VARCHAR2
	NYHA_ND	VARCHAR2
ORTHOP	ORTHOP_C	NUMBER
	ORTHOP	VARCHAR2
	ORTHOP_ND	VARCHAR2

Key: [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.

HFN_NEAT: MEDICATIONS (MEDS) [frMEDS]	
Medications [stMEDS1]	
1.* ✓ ACE inhibitor [ACE inhibitor]	[ACE] [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
2.* ✓ Angiotensin receptor blocker [Angiotensin receptor blocker]	[ARB] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
3.* ✓ Beta Blocker [Beta Blocker]	[BETAB] [N: 1] <input checked="" type="radio"/> [BBCARV] Yes Taking Carvedilol? [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
4.* ✓ Aldosterone antagonist [Aldosterone antagonist]	[ALDOS] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
5.* ✓ Hydralazine [Hydralazine]	[HYDR] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
6.* ✓ Nitrates (do not include sublingual nitroglycerin) [Nitrates]	[NITR] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
7.* Calcium channel blocker [Calcium channel blocker]	[CCB] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
8.* Antiplatelets [Antiplatelets]	[ANTIPLT] [N: 1] <input checked="" type="radio"/> [cpANTIPLTY] Yes (check all that apply) [ANTIPASP] [N: 1] <input type="checkbox"/> Aspirin (taken daily) [ANTIPTHI] [N: 1] <input type="checkbox"/> Thienopyridines (eg: ticlopidine, clopidogrel, prasugrel) [ANTIPOTH] [N: 1] <input type="checkbox"/> Other [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
9.* Anticoagulants [Anticoagulants]	[ANTICAG] [N: 1] <input checked="" type="radio"/> [cpANTICAGY] Yes (check all that apply) [ANTICWAR] [N: 1] <input type="checkbox"/> Warfarin [ANTICFCX] [N: 1] <input type="checkbox"/> Factor Xa Inhibitor [ANTICDTH] [N: 1] <input type="checkbox"/> Direct Thrombin Inhibitor [ANTICOTH] [N: 1] <input type="checkbox"/> Other [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
10.* Digoxin [Digoxin]	[DIGX] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
11.* Amiodarone [Amiodarone]	[AMIOD] [N: 1] <input type="radio"/> Yes

		<p>[N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
12.*	Other antiarrhythmic [Other antiarrhythmic]	<p>[OARRH] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
13.*	Statin [Statin]	<p>[STATIN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
14.*	Lipid lowering agent (other than statin) [Lipid lowering agent]	<p>[LLIPID] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
15.*	Insulin [Insulin]	<p>[INSULIN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
16.*	Oral diabetic agent [Oral diabetic agent]	<p>[ODIAGT] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
17.*	Antidepressant [Antidepressant]	<p>[DEPRES] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
18.*	Ambulatory IV Inotropes [Ambulatory IV Inotropes]	<p>[IVINOTRP] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
19.*	Metolazone [Metolazone]	<p>[METAZ] [N: 1] <input type="radio"/> [METZAFRQ] Yes [N: 1] <input type="radio"/> Chronic (>=1x/week) [N: 2] <input type="radio"/> PRN (<1x/week) [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
20.*	HCTZ [HCTZ]	<p>[HCTZ] [N: 1] <input type="radio"/> [HCCTZFRQ] Yes [N: 1] <input type="radio"/> Chronic (>=1x/week) [N: 2] <input type="radio"/> PRN (<1x/week) [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
21.*	Furosemide [Furosemide]	<p>[FURO] [N: 1] <input type="radio"/> [FURODOSE] Yes Daily Dose: xxxxxxxx. [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
22.*	Torsemide [Torsemide]	<p>[TORS] [N: 1] <input type="radio"/> [TORSDOSE] Yes Daily Dose: xxxxxxxx. [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
23.*	Bumetanide [Bumetanide]	<p>[BUME] [N: 1] <input type="radio"/> [BUMDOSE] Yes Daily Dose: xxxxxxxx. [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>

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

RDE Analytics: RD_FRMEDS		
Data Variable RefName	RD Column Name	Column Data Type
ACE	ACE_C	NUMBER
	ACE	VARCHAR2
	ACE_ND	VARCHAR2
ARB	ARB_C	NUMBER
	ARB	VARCHAR2
	ARB_ND	VARCHAR2
BETAB	BETAB_C	**NUMBER
	BETAB	VARCHAR2
	BETAB_ND	VARCHAR2
BETAB - BBCARV	BBCARV_C	NUMBER
	BBCARV	VARCHAR2
ALDOS	ALDOS_C	NUMBER
	ALDOS	VARCHAR2
	ALDOS_ND	VARCHAR2
HYDR	HYDR_C	NUMBER
	HYDR	VARCHAR2
	HYDR_ND	VARCHAR2
NITR	NITR_C	NUMBER
	NITR	VARCHAR2
	NITR_ND	VARCHAR2
CCB	CCB_C	NUMBER
	CCB	VARCHAR2
	CCB_ND	VARCHAR2
ANTIPLT	ANTIPLT_C	**NUMBER
	ANTIPLT	VARCHAR2
	ANTIPLT_ND	VARCHAR2
ANTIPLT - Aspirin (taken daily)	*ANTIPASP_CIASPIRINTAKENDAILY_C	NUMBER
	*ANTIPASP_CIASPIRINTAKENDAILY	VARCHAR2
ANTIPLT - Thienopyridines (eg: ticlopidine, clopidogrel, prasugrel)	*ANTIPTHI_CITHIENOPYRIDINES_C	NUMBER
	*ANTIPTHI_CITHIENOPYRIDINES	VARCHAR2
ANTIPLT - Other	ANTIPOTH_CIOTHER1_C	NUMBER
	ANTIPOTH_CIOTHER1	VARCHAR2
ANTICAG	ANTICAG_C	**NUMBER
	ANTICAG	VARCHAR2
	ANTICAG_ND	VARCHAR2
ANTICAG - Warfarin	ANTICWAR_CIWARFARIN_C	NUMBER
	ANTICWAR_CIWARFARIN	VARCHAR2
ANTICAG - Factor Xa Inhibitor	*ANTICFCX_CIFACTORXAINHIBITOR_C	NUMBER
	*ANTICFCX_CIFACTORXAINHIBITOR	VARCHAR2
ANTICAG - Direct Thrombin Inhibitor	*ANTICDTH_CIDIRECTTHROMBININHIBITOR_C	NUMBER
	*ANTICDTH_CIDIRECTTHROMBININHIBITOR	VARCHAR2
ANTICAG - Other	ANTICOTH_CIOTHER1_C	NUMBER
	ANTICOTH_CIOTHER1	VARCHAR2
DIGX	DIGX_C	NUMBER
	DIGX	VARCHAR2
	DIGX_ND	VARCHAR2
AMIOD	AMIOD_C	NUMBER
	AMIOD	VARCHAR2
	AMIOD_ND	VARCHAR2
OARRH	OARRH_C	NUMBER

	OARRH	VARCHAR2
	OARRH_ND	VARCHAR2
STATIN	STATIN_C	NUMBER
	STATIN	VARCHAR2
	STATIN_ND	VARCHAR2
LLIPID	LLIPID_C	NUMBER
	LLIPID	VARCHAR2
	LLIPID_ND	VARCHAR2
INSULIN	INSULIN_C	NUMBER
	INSULIN	VARCHAR2
	INSULIN_ND	VARCHAR2
ODIAGT	ODIAGT_C	NUMBER
	ODIAGT	VARCHAR2
	ODIAGT_ND	VARCHAR2
DEPRES	DEPRES_C	NUMBER
	DEPRES	VARCHAR2
	DEPRES_ND	VARCHAR2
IVINOTRP	IVINOTRP_C	NUMBER
	IVINOTRP	VARCHAR2
	IVINOTRP_ND	VARCHAR2
METAZ	METAZ_C	**NUMBER
	METAZ	VARCHAR2
	METAZ_ND	VARCHAR2
METAZ - METZAFRO	METZAFRO_C	NUMBER
	METZAFRO	VARCHAR2
HCTZ	HCTZ_C	**NUMBER
	HCTZ	VARCHAR2
	HCTZ_ND	VARCHAR2
HCTZ - HCCTZFRO	HCCTZFRO_C	NUMBER
	HCCTZFRO	VARCHAR2
FURO	FURO_C	**NUMBER
	FURO	VARCHAR2
	FURO_ND	VARCHAR2
FURO - FURODOSE	FURODOSE	FLOAT
TORS	TORS_C	**NUMBER
	TORS	VARCHAR2
	TORS_ND	VARCHAR2
TORS - TORSDOSE	TORSDOSE	FLOAT
BUME	BUME_C	**NUMBER
	BUME	VARCHAR2
	BUME_ND	VARCHAR2
BUME - BUMDOSE	BUMDOSE	FLOAT
Key: [*] = The column and/or table name in the actual RDE extract may be different. [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: STUDY DRUG ADMINISTRATION (SDADMIN) [frSDADMIN]	
Study Drug Administration [stSDADMIN1]	
1.* <input checked="" type="checkbox"/> Was study drug dispensed? [Was study drug dispensed]	[SDRGDISP] [N: 1] <input type="radio"/> [SDRGDDT] Yes (click Add Entry to record each Kit dispensed) Date dispensed: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2018) Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock [N: 0] <input type="radio"/> [cpINDRGRS] No If No, specify reason: [INDRGRS] [N: 1] <input type="radio"/> Subject withdrew consent [N: 2] <input type="radio"/> MD Decision [N: 98] <input type="radio"/> [INDRGRSP] Other Specify: <input type="text" value="A200"/>
Kit Number	
Study Drug Kit Details Entry [stSDADMIN2]	
2.1* <input checked="" type="checkbox"/> Kit number [Kit Number]	[KITNUM] <input type="text" value="N5"/>
Key: [*] = Item is required [✓] = Source verification required	

RDE Analytics: RD_FRSDADMIN		
Data Variable RefName	RD Column Name	Column Data Type
SDRGDISP	SDRGDISP_C	**NUMBER
	SDRGDISP	VARCHAR2
	SDRGDISP_ND	VARCHAR2
SDRGDISP - SDRGDDT	SDRGDDT	DATE
	SDRGDDT_DTS	VARCHAR2
	SDRGDDT_DTR	VARCHAR2
SDRGDISP - INDRGRS	INDRGRS_C	NUMBER
	INDRGRS	VARCHAR2
SDRGDISP - INDRGRSP	INDRGRSP	VARCHAR2
RD_FRSDADMIN_STSDADMIN2		
KITNUM	KITNUM	NUMBER
	KITNUM_ND	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: ECG (ECG) [frECG]	
ECG [stECG1]	
1.* Date of ECG closest (prior) to Randomization [Date of ECG closest (prior) to Randomization]	<p>[ECG]</p> <p>[N: 1] <input type="radio"/> [ECGDT] Req [v] / Req [v] / Req [v] (2014-2018)</p> <p>[N: 97] <input type="radio"/> Not Done</p>
2.* Heart Rate [Heart Rate]	<p>[ECGRATE]</p> <p>[N: 1] <input type="radio"/> [ECGHRVAL] N3 bpm</p> <p>[N: 97] <input type="radio"/> Not Done</p>
3.* ECG Rhythm [ECG Rhythm]	<p>[ECGRHYTH]</p> <p>[N: 1] <input type="radio"/> Sinus rhythm</p> <p>[N: 2] <input type="radio"/> Atrial fibrillation</p> <p>[N: 3] <input type="radio"/> Atrial flutter</p> <p>[N: 4] <input type="radio"/> [PACERHYT] Paced Underlying rhythm</p> <p>[N: 1] <input type="radio"/> Sinus</p> <p>[N: 2] <input type="radio"/> Atrial fibrillation</p> <p>[N: 3] <input type="radio"/> Atrial flutter</p> <p>[N: 98] <input type="radio"/> [PACEDSP] Other, specify: A50</p> <p>[N: 99] <input type="radio"/> Unknown</p> <p>[N: 98] <input type="radio"/> Other</p> <p>[N: 97] <input type="radio"/> Not Done</p>
4.* QRS duration [QRS duration]	<p>[ECGQRS]</p> <p>[N: 1] <input type="radio"/> [cpECGQRS] [ECGQRSVL] xxxxxxx. msec</p> <p>[ECGQRSTY] QRS complex for this measurement:</p> <p>[N: 1] <input type="radio"/> Intrinsic rhythm</p> <p>[N: 2] <input type="radio"/> Only ventricular paced QRS complexes present</p> <p>[N: 99] <input type="radio"/> Unknown</p> <p>[N: 97] <input type="radio"/> Not Done</p>

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

RDE Analytics: RD_FRECG		
Data Variable RefName	RD Column Name	Column Data Type
ECG	ECG_C	**NUMBER
	ECG	VARCHAR2
	ECG_ND	VARCHAR2
ECG - ECGDT	ECGDT	DATE
	ECGDT_DTS	VARCHAR2
ECGRATE	ECGRATE_C	**NUMBER
	ECGRATE	VARCHAR2
	ECGRATE_ND	VARCHAR2
ECGRATE - ECGHRVAL	ECGHRVAL	NUMBER
ECGRHYTH	ECGRHYTH_C	NUMBER
	ECGRHYTH	VARCHAR2
	ECGRHYTH_ND	VARCHAR2
ECGRHYTH - PACERHYT	PACERHYT_C	NUMBER
	PACERHYT	VARCHAR2
ECGRHYTH - PACEDSP	PACEDSP	VARCHAR2
ECGQRS	ECGQRS_C	**NUMBER
	ECGQRS	VARCHAR2
	ECGQRS_ND	VARCHAR2
ECGQRS - ECGQRSVL	ECGQRSVL	FLOAT
ECGQRS - ECGQRSTY	ECGQRSTY_C	NUMBER
	ECGQRSTY	VARCHAR2

Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.

HFN_NEAT: Baseline Assessments (BASSESS) [frBASSESS]	
Additional Baseline Assessments [stBASSESS1]	
1.* Were local labs performed (If yes, please complete lab forms) [Were local labs performed (If yes, please complete lab forms)]	[BLABSDNE] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [BLABNDRN] No Reason test was not performed: [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 99] <input type="radio"/> [BLABNDSP] Unknown/other Specify: <input type="text" value="A50"/>
2.* Were protocol required biological samples collected (If yes, please complete SAMPLES form) [Were protocol required biological samples collected (If yes, please complete SAMPLES form)]	[BBIOSAMP] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [BBIONDRN] No Reason test was not performed: [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 99] <input type="radio"/> [BBIONDSP] Unknown/other Specify: <input type="text" value="A50"/>
3.* Was 6-Minute Walk performed (If yes, complete SIXMWT form) [Was 6-Minute Walk performed (If yes, complete SIXMWT form)]	[BSIXMWTD] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [BSMWNDRS] No Reason test was not performed: [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 4] <input type="radio"/> Cannot walk for mechanical reasons (e.g., amputee, orthopedic) [N: 5] <input type="radio"/> Neurological reasons [N: 99] <input type="radio"/> [BSMWNDSP] Unknown/other Specify: <input type="text" value="A50"/>
4.* Was KCCQ completed (If yes, complete KCCQ form) [Was KCCQ completed (If yes, complete KCCQ form)]	[BKCCQDN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [BKCCQNDR] No Reason test was not performed: [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 99] <input type="radio"/> [BKCCQNDS] Unknown/other Specify: <input type="text" value="A50"/>
5.* Was MLHFQ completed (If yes, complete MLHFQ form) [Was MLHFQ completed (If yes, complete MLHFQ form)]	[BMLHFQDN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [BMLHQNDR] No Reason test was not performed: [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 99] <input type="radio"/> [BMLHQNDS] Unknown/other Specify: <input type="text" value="A50"/>
6.* ECHO Submission Date: [ECHO Submission Date:]	[ECHOSBMT] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2018)

Key: [*] = Item is required

RDE Analytics: RD_FRBASSESS

Data Variable RefName	RD Column Name	Column Data Type
BLABSDNE	BLABSDNE_C	NUMBER
	BLABSDNE	VARCHAR2
	BLABSDNE_ND	VARCHAR2
BLABSDNE - BLABNDRN	BLABNDRN_C	NUMBER
	BLABNDRN	VARCHAR2
BLABSDNE - BLABNDSP	BLABNDSP	VARCHAR2
BBIOSAMP	BBIOSAMP_C	NUMBER
	BBIOSAMP	VARCHAR2
	BBIOSAMP_ND	VARCHAR2
BBIOSAMP - BBIONDRN	BBIONDRN_C	NUMBER
	BBIONDRN	VARCHAR2
BBIOSAMP - BBIONDSP	BBIONDSP	VARCHAR2
BSIXMWT	BSIXMWT_C	NUMBER
	BSIXMWT	VARCHAR2
	BSIXMWT_ND	VARCHAR2
BSIXMWT - BSMWNDRS	BSMWNDRS_C	NUMBER
	BSMWNDRS	VARCHAR2
BSIXMWT - BSMWNSP	BSMWNSP	VARCHAR2
BKCCQDN	BKCCQDN_C	NUMBER
	BKCCQDN	VARCHAR2
	BKCCQDN_ND	VARCHAR2
BKCCQDN - BKCCQDR	BKCCQDR_C	NUMBER
	BKCCQDR	VARCHAR2
BKCCQDN - BKCCQNS	BKCCQNS	VARCHAR2
BMLHFQDN	BMLHFQDN_C	NUMBER
	BMLHFQDN	VARCHAR2
	BMLHFQDN_ND	VARCHAR2
BMLHFQDN - BMLHONDR	BMLHONDR_C	NUMBER
	BMLHONDR	VARCHAR2
BMLHFQDN - BMLHQNS	BMLHQNS	VARCHAR2
ECHOSBMT	ECHOSBMT	DATE
	ECHOSBMT_DTS	VARCHAR2
	ECHOSBMT_ND	VARCHAR2

HFN_NEAT: CHEMISTRY LABS (CHEM) [frCHEM]	
Chemistry [stCHEM1]	
1.* Collection Date and Time [Collection Date and Time]	[CHEMLDTM] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2018) Req/Unk <input type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock
2.* Sodium [Sodium]	[SODIUM] [N: 1] <input type="radio"/> [cpSODIUM] [SODVAL] xxxxxxx. [SODUNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 2] <input type="radio"/> mEq/L [N: 97] <input type="radio"/> Not Done
3.* Potassium [Potassium]	[POTAS] [N: 1] <input type="radio"/> [cpPOTAS] [POTASVAL] xxxxxxx. [POTASUNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 2] <input type="radio"/> mEq/L [N: 97] <input type="radio"/> Not Done
4.* Chloride [Chloride]	[CHLORIDE] [N: 1] <input type="radio"/> [cpCHLORIDE] [CHLORVAL] xxxxxxx. [CHLORUNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 2] <input type="radio"/> mEq/L [N: 97] <input type="radio"/> Not Done
5.* Bicarbonate (total CO ₂) [Bicarbonate]	[CO2] [N: 1] <input type="radio"/> [cpCO2] [CO2VAL] xxxxxxx. [CO2UNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 2] <input type="radio"/> mEq/L [N: 97] <input type="radio"/> Not Done
6.* BUN/Urea [BUN/Urea]	[BUN] [N: 1] <input type="radio"/> [cpBUN] [BUNVAL] xxxxxxx. [BUNUNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 3] <input type="radio"/> mg/dl [N: 97] <input type="radio"/> Not Done
7.* Creatinine [Creatinine]	[CREAT] [N: 1] <input type="radio"/> [cpCREAT] [CREATVAL] xxxxxxx. [CREATUNT] Unit: [N: 3] <input type="radio"/> mg/dl [N: 4] <input type="radio"/> umol/L [N: 97] <input type="radio"/> Not Done
8.* Glucose [Glucose]	[GLUC] [N: 1] <input type="radio"/> [cpGLUC] [GLUCVAL] xxxxxxx. [GLUCUNT] [N: 1] <input type="radio"/> mmol/L [N: 3] <input type="radio"/> mg/dl [GLUCFAST]

Is this a fasting sample?
 [N:1] Yes
 [N:0] No
 [N:97] Not Done

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

RDE Analytics: RD_FRCHEM		
Data Variable RefName	RD Column Name	Column Data Type
CHEMLDTM	CHEMLDTM	DATE
	CHEMLDTM_DTS	VARCHAR2
	CHEMLDTM_DTR	VARCHAR2
	CHEMLDTM_ND	VARCHAR2
SODIUM	SODIUM_C	**NUMBER
	SODIUM	VARCHAR2
	SODIUM_ND	VARCHAR2
SODIUM - SODVAL	SODVAL	FLOAT
SODIUM - SODUNT	SODUNT_C	NUMBER
	SODUNT	VARCHAR2
POTAS	POTAS_C	**NUMBER
	POTAS	VARCHAR2
	POTAS_ND	VARCHAR2
POTAS - POTASVAL	POTASVAL	FLOAT
POTAS - POTASUNT	POTASUNT_C	NUMBER
	POTASUNT	VARCHAR2
CHLORIDE	CHLORIDE_C	**NUMBER
	CHLORIDE	VARCHAR2
	CHLORIDE_ND	VARCHAR2
CHLORIDE - CHLORVAL	CHLORVAL	FLOAT
CHLORIDE - CHLORUNT	CHLORUNT_C	NUMBER
	CHLORUNT	VARCHAR2
CO2	CO2_C	**NUMBER
	CO2	VARCHAR2
	CO2_ND	VARCHAR2
CO2 - CO2VAL	CO2VAL	FLOAT
CO2 - CO2UNT	CO2UNT_C	NUMBER
	CO2UNT	VARCHAR2
BUN	BUN_C	**NUMBER
	BUN	VARCHAR2
	BUN_ND	VARCHAR2
BUN - BUNVAL	BUNVAL	FLOAT
BUN - BUNUNT	BUNUNT_C	NUMBER
	BUNUNT	VARCHAR2
CREAT	CREAT_C	**NUMBER
	CREAT	VARCHAR2
	CREAT_ND	VARCHAR2
CREAT - CREATVAL	CREATVAL	FLOAT
CREAT - CREATUNT	CREATUNT_C	NUMBER
	CREATUNT	VARCHAR2
GLUC	GLUC_C	**NUMBER
	GLUC	VARCHAR2
	GLUC_ND	VARCHAR2
GLUC - GLUCVAL	GLUCVAL	FLOAT
GLUC - GLUCUNT	GLUCUNT_C	NUMBER
	GLUCUNT	VARCHAR2

GLUC - GLUCFAST	GLUCFAST_C	NUMBER
	GLUCFAST	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: HEMATOLOGY LABS (HEMACOAG) [frHEMACOAG]	
Hematology [stHEMACOAG1]	
1.* Collection Date and Time [Collection Date and Time]	[HEMALDTM] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2018) Req/Unk <input type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock
2.* Hemoglobin (Hgb) [Hemoglobin]	[HGB] [N: 7] <input type="radio"/> [cpHGB] [HGBVAL] xxxxxxx. [HGBUNT] Unit: [N: 7] <input type="radio"/> g/dL [N: 8] <input type="radio"/> g/L [N: 1] <input type="radio"/> mmol/L [N: 97] <input type="radio"/> Not Done
3.* Hematocrit [Hematocrit]	[HCT] [N: 1] <input type="radio"/> [cpHCT] [HCTVAL] xxxxxxx. [HCTUNT] Unit: [N: 15] <input type="radio"/> L/L [N: 11] <input type="radio"/> % [N: 97] <input type="radio"/> Not Done
4.* RBC [RBC]	[RBC] [N: 1] <input type="radio"/> [RBCVAL] xxxxxxx. 10 ¹² /L [N: 97] <input type="radio"/> Not Done
5.* RDW [RDW]	[RDW] [N: 1] <input type="radio"/> [RDWVAL] xxxxxxx. % [N: 97] <input type="radio"/> Not Done
6.* WBC [WBC]	[WBC] [N: 1] <input type="radio"/> [cpWBC] [WBCVAL] xxxxxxx. [WBCUNT] Unit: [N: 9] <input type="radio"/> 10 ⁹ /L or 10 ³ /mm ³ [N: 10] <input type="radio"/> /mm ³ [N: 97] <input type="radio"/> Not Done
7.* Platelet Count [Platelet Count]	[PLATLET] [N: 1] <input type="radio"/> [cpPLATLET] [PLATVAL] xxxxxxx. [PLATUNT] Unit: [N: 9] <input type="radio"/> 10 ⁹ /L or 10 ³ /mm ³ [N: 10] <input type="radio"/> /mm ³ [N: 97] <input type="radio"/> Not Done

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

RDE Analytics: RD_FRHEMACOAG		
Data Variable RefName	RD Column Name	Column Data Type
HEMALDTM	HEMALDTM	DATE
	HEMALDTM_DTS	VARCHAR2
	HEMALDTM_DTR	VARCHAR2
	HEMALDTM_ND	VARCHAR2
HGB	HGB_C	**NUMBER
	HGB	VARCHAR2
	HGB_ND	VARCHAR2
HGB - HGBVAL	HGBVAL	FLOAT
HGB - HGBUNT	HGBUNT_C	NUMBER

	HGBUNT	VARCHAR2
HCT	HCT_C	**NUMBER
	HCT	VARCHAR2
	HCT_ND	VARCHAR2
HCT - HCTVAL	HCTVAL	FLOAT
HCT - HCTUNT	HCTUNT_C	NUMBER
	HCTUNT	VARCHAR2
RBC	RBC_C	**NUMBER
	RBC	VARCHAR2
	RBC_ND	VARCHAR2
RBC - RBCVAL	RBCVAL	FLOAT
RDW	RDW_C	**NUMBER
	RDW	VARCHAR2
	RDW_ND	VARCHAR2
RDW - RDWVAL	RDWVAL	FLOAT
WBC	WBC_C	**NUMBER
	WBC	VARCHAR2
	WBC_ND	VARCHAR2
WBC - WBCVAL	WBCVAL	FLOAT
WBC - WBCUNT	WBCUNT_C	NUMBER
	WBCUNT	VARCHAR2
PLATLET	PLATLET_C	**NUMBER
	PLATLET	VARCHAR2
	PLATLET_ND	VARCHAR2
PLATLET - PLATVAL	PLATVAL	FLOAT
PLATLET - PLATUNT	PLATUNT_C	NUMBER
	PLATUNT	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: BIOLOGICAL SAMPLES (SAMPLES) [frSAMPLES]						
Biomarkers [stSAMPLES1]						
1.*	Were biomarker samples collected at this visit? [Were biomarker samples collected at this visit]	[BIOMRK] [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input type="radio"/> [BIOMNDRS] No Reason samples were not collected: [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform test but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 99] <input type="radio"/> Unknown/Other				
2.	Collection Date/Time	Number of Samples Collected	Date sent to lab	Date received	Frozen	Number of Samples Received
Biomarker Collection Information Entry [rsSAMPLES2]						
2.1*	Collection Date/Time: [Collection Date/Time]	[BIOMKDTM] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2018) Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock				
2.2*	Number of Samples Collected [Number of Samples Collected]	[cpBIOCCLL1] [BIOMSER] [N: 1] <input type="checkbox"/> [BIOMSRNM] Serum cryovials: <input type="text" value="N2"/> [BIOMEDTA] [N: 1] <input type="checkbox"/> [BIOMEDNM] EDTA cryovials: <input type="text" value="N2"/>				
2.3*	Date sent to core lab [Date sent to lab]	[BIOMSTDT] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2018)				
2.4*	Date samples received [Date received]	[BIOMRCDT] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2018)				
2.5*	Samples received frozen [Frozen]	[BIOMFROZ] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No				
2.6*	Number of Samples Received [Number of Samples Received]	[cpSAMPREC1] [BIOMSRCD] [N: 1] <input type="checkbox"/> [BIOMSNUM] Serum cryovials: <input type="text" value="N2"/> [BIOMSUSE] Number of usable serum samples: <input type="text" value="N2"/> [BIOMERCD] [N: 1] <input type="checkbox"/> [BIOMENUM] EDTA cryovials: <input type="text" value="N2"/> [BIOMEUSE] Number of usable EDTA samples: <input type="text" value="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] <input type="radio"/> Yes [N: 0] <input checked="" type="radio"/> [BIORDRN] No Reason samples were not collected: [N: 4] <input type="radio"/> Subject did not provide consent [N: 5] <input type="radio"/> Subject withdrew consent [N: 6] <input type="radio"/> Site not participating [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform test but subjectively able [N: 3] <input type="radio"/> Due to oversight or technical problem [N: 99] <input type="radio"/> Unknown/Other				
4.	Collection Date/Time	Number of Samples Collected	Date received	Frozen	Number of Samples Received	
Biorepository and Genetics Collection Information Entry [rsSAMPLES4]						
4.1*	Collection Date/Time: [Collection Date/Time]	[BIORPDTM] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2018) Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock				
4.2*	Number of Samples Collected [Number of Samples Collected]	[cpBIOCCLL2] [BIORSER] [N: 1] <input type="checkbox"/> [BIORSRNM]				

		Serum cryovials: N2 [BIOREDTA] [N: 1] <input type="checkbox"/> [BIOREDNM] EDTA cryovials: N2 [BIORDNA] [N: 1] <input type="checkbox"/> [BIORDNUM] DNA N2
4.3*	Date samples received [Date received]	[BIORRCDT] Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2014-2018)
4.4*	Samples received frozen [Frozen]	[BIORFROZ] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No
4.5*	Number of Samples Received [Number of Samples Received]	[cpSAMPREC2] [BIORSRCD] [N: 1] <input type="checkbox"/> [BIORSNUM] Serum cryovials: N2 [BIORSUSE] Number of usable serum samples: N2 [BIORERCD] [N: 1] <input type="checkbox"/> [BIORENUM] EDTA cryovials: N2 [BIOREUSE] Number of usable EDTA samples: N2 [BIORDRCD] [N: 1] <input type="checkbox"/> [BIORDNUM] DNA N2 [BIORDUSE] Number of usable DNA samples: N2
Comments [stSAMPLES5]		
5.	Comments [Lab Comments]	[LABCOMM] A200

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

RDE Analytics: RD_FRSAMPLES		
Data Variable RefName	RD Column Name	Column Data Type
BIOMRK	BIOMRK_C	NUMBER
	BIOMRK	VARCHAR2
	BIOMRK_ND	VARCHAR2
BIOMRK - BIOMNDRS	BIOMNDRS_C	NUMBER
	BIOMNDRS	VARCHAR2
BIOREP	BIOREP_C	NUMBER
	BIOREP	VARCHAR2
	BIOREP_ND	VARCHAR2
BIOREP - BIORNDRN	BIORNDRN_C	NUMBER
	BIORNDRN	VARCHAR2
LABCOMM	LABCOMM	VARCHAR2
	LABCOMM_ND	VARCHAR2
RD_FRSAMPLES_RSSAMPLES2		
BIOMKDTM	BIOMKDTM	DATE
	BIOMKDTM_DTS	VARCHAR2
	BIOMKDTM_DTR	VARCHAR2
	BIOMKDTM_ND	VARCHAR2
cpBIOCOLL1	CPBIOCOLL1_ND	VARCHAR2
cpBIOCOLL1 - Serum	BIOMSER_BIOMSRNM_C	**NUMBER
	BIOMSER_BIOMSRNM	VARCHAR2

cpBIOCOLL1 - BIOMSRNM	BIOMSRNM	NUMBER
cpBIOCOLL1 - EDTA	BIOMEDTA_BIOMEDNM_C	**NUMBER
	BIOMEDTA_BIOMEDNM	VARCHAR2
cpBIOCOLL1 - BIOMEDNM	BIOMEDNM	NUMBER
BIOMSTDT	BIOMSTDT	DATE
	BIOMSTDT_DTS	VARCHAR2
	BIOMSTDT_ND	VARCHAR2
BIOMRCDT	BIOMRCDT	DATE
	BIOMRCDT_DTS	VARCHAR2
	BIOMRCDT_ND	VARCHAR2
BIOMFROZ	BIOMFROZ_C	NUMBER
	BIOMFROZ	VARCHAR2
	BIOMFROZ_ND	VARCHAR2
cpSAMPREC1	CPSAMPREC1_ND	VARCHAR2
cpSAMPREC1 - Serum	BIOMSRCD_BIOMSNUM_C	**NUMBER
	BIOMSRCD_BIOMSNUM	VARCHAR2
cpSAMPREC1 - BIOMSNUM	BIOMSNUM	NUMBER
cpSAMPREC1 - BIOMSUSE	BIOMSUSE	NUMBER
cpSAMPREC1 - EDTA	BIOMERCD_BIOMENUM_C	**NUMBER
	BIOMERCD_BIOMENUM	VARCHAR2
cpSAMPREC1 - BIOMENUM	BIOMENUM	NUMBER
cpSAMPREC1 - BIOMEUSE	BIOMEUSE	NUMBER
RD_FRSAMPLES_RSSAMPLES4		
BIORPDTM	BIORPDTM	DATE
	BIORPDTM_DTS	VARCHAR2
	BIORPDTM_DTR	VARCHAR2
	BIORPDTM_ND	VARCHAR2
cpBIOCOLL2	CPBIOCOLL2_ND	VARCHAR2
cpBIOCOLL2 - Serum	BIORSER_BIORSRNM_C	**NUMBER
	BIORSER_BIORSRNM	VARCHAR2
cpBIOCOLL2 - BIORSRNM	BIORSRNM	NUMBER
cpBIOCOLL2 - EDTA	BIOREDTA_BIOREDNM_C	**NUMBER
	BIOREDTA_BIOREDNM	VARCHAR2
cpBIOCOLL2 - BIOREDNM	BIOREDNM	NUMBER
cpBIOCOLL2 - DNA	BIORDNA_BIORDNUM_C	**NUMBER
	BIORDNA_BIORDNUM	VARCHAR2
cpBIOCOLL2 - BIORDNUM	BIORDNUM	NUMBER
BIORRCDT	BIORRCDT	DATE
	BIORRCDT_DTS	VARCHAR2
	BIORRCDT_ND	VARCHAR2
BIORFROZ	BIORFROZ_C	NUMBER
	BIORFROZ	VARCHAR2
	BIORFROZ_ND	VARCHAR2
cpSAMPREC2	CPSAMPREC2_ND	VARCHAR2
cpSAMPREC2 - Serum	BIORSRCD_BIORSNUM_C	**NUMBER
	BIORSRCD_BIORSNUM	VARCHAR2
cpSAMPREC2 - BIORSNUM	BIORSNUM	NUMBER
cpSAMPREC2 - BIORSUSE	BIORSUSE	NUMBER
cpSAMPREC2 - EDTA	BIORERCD_BIORENUM_C	**NUMBER
	BIORERCD_BIORENUM	VARCHAR2
cpSAMPREC2 - BIORENUM	BIORENUM	NUMBER
cpSAMPREC2 - BIOREUSE	BIOREUSE	NUMBER
cpSAMPREC2 - DNA	BIORDRCD_BIORNUM_C	**NUMBER
	BIORDRCD_BIORNUM	VARCHAR2

cpSAMPREC2 - BIORNUM	BIORNUM	NUMBER
cpSAMPREC2 - BIORDUSE	BIORDUSE	NUMBER
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: SIX MINUTE WALK TEST (SIXMWT) [frSIXMWT]	
Six Minute Walk Test [stSIXMWT1]	
1.* Date test performed [Date test performed]	[WALKDT] Req [v] / Req [v] / Req [v] (2014-2018)
2.* Distance walked [Distance walked]	[WLKDIST] [N: 1] <input type="radio"/> [DISTMET] xxxxxxx. meters [N: 99] <input type="radio"/> Unknown
3.* Did subject complete the 6-minute walk? [Did subject complete the 6-minute walk]	[WLKCOMP] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [WLKDUR] No [N: 1] <input type="radio"/> [cpWLKDUR] If No: What was the duration of the walk test (min:sec): [WLKDURM] [WLKDURS] N2 : N2 [N: 99] <input type="radio"/> Unknown
4.* Pre-walk heart Rate [Pre-walk heart Rate]	[PRHRDN] [N: 1] <input type="radio"/> [PRWLKHR] N3 [N: 97] <input type="radio"/> Not Done
5.* Pre-walk blood pressure [Pre-walk blood pressure]	[PRWBPDNE] [N: 1] <input type="radio"/> [cpPRWBP] [PRWBPSYS] [PRWBPIA] mmHg N3 / N3 [N: 97] <input type="radio"/> Not Done
6.* Post-walk heart Rate [Post-walk heart Rate]	[PSTHRDN] [N: 1] <input type="radio"/> [PSTWLKHR] N3 [N: 97] <input type="radio"/> Not Done
7.* Post-walk blood pressure [Post-walk blood pressure]	[PSWBPDNE] [N: 1] <input type="radio"/> [cpPSWBP] [PSWBPSYS] [PSWBPIA] mmHg N3 / N3 [N: 97] <input type="radio"/> Not Done
8.* Indicate all symptoms experienced by the subject [Indicate all symptoms experienced by the subject]	[cpSYMPEXP] [SXNONE] [N: 1] <input type="checkbox"/> None [SXANG] [N: 1] <input type="checkbox"/> Angina [SXLGHTHD] [N: 1] <input type="checkbox"/> Lightheadedness [SXSYNCOPI] [N: 1] <input type="checkbox"/> Syncope [SXDYSP] [N: 1] <input type="checkbox"/> Dyspnea [SXFATIGE] [N: 1] <input type="checkbox"/> Fatigue [SXCSTPN] [N: 1] <input type="checkbox"/> Chest pain [SXLGJTPN] [N: 1] <input type="checkbox"/> Leg or joint pain [SXINSTBL] [N: 1] <input type="checkbox"/> Instability [SXOTHER] [N: 98] <input type="checkbox"/> [SXOTHSP] Other Specify: A100
9.* Pre-Walk Borg Dyspnea Score [Pre-Walk Borg Dyspnea Score]	[PREBDYS] [ctDyspneaScore] [v]
10.* Post-Walk Borg Dyspnea Score [Post-Walk Borg Dyspnea Score]	[PSTBDYS] [ctDyspneaScore] [v]

11.* ✓	Pre-Walk Rating of Perceived Exertion [Pre-Walk Rating of Perceived Exertion]	[PRERPE] [ctRatingPerceivedExertion] ▼
12.* ✓	Post-Walk Rating of Perceived Exertion [Post-Walk Rating of Perceived Exertion]	[PSTRPE] [ctRatingPerceivedExertion] ▼
Key: [*] = Item is required [✓] = Source verification required		

Codelist Values and Tables: SIX MINUTE WALK TEST					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
ctDyspneaScore	Integer	0	1	ci0	PREBDYS, PSTBDYS
		0.5	2	ci0point5	
		1	3	ci1	
		2	4	ci2	
		3	5	ci3	
		4	6	ci4	
		5	7	ci5	
		6	8	ci6	
		7	9	ci7	
		8	10	ci8	
		9	11	ci9	
		10	12	ci10	
		Not Done	97	ciNotDone	
ctRatingPerceivedExertion	Integer	6	1	ciPerceivedExertion6	PRERPE, PSTRPE
		7	2	ciPerceivedExertion7	
		8	3	ciPerceivedExertion8	
		9	4	ciPerceivedExertion9	
		10	5	ciPerceivedExertion10	
		11	6	ciPerceivedExertion11	
		12	7	ciPerceivedExertion12	
		13	8	ciPerceivedExertion13	
		14	9	ciPerceivedExertion14	
		15	10	ciPerceivedExertion15	
		16	11	ciPerceivedExertion16	
		17	12	ciPerceivedExertion17	
		18	13	ciPerceivedExertion18	
		19	14	ciPerceivedExertion19	
		20	15	ciPerceivedExertion20	
		Not Done	97	ciNotDone	

RDE Analytics: RD_FRSI XMWT		
Data Variable RefName	RD Column Name	Column Data Type
WALKDT	WALKDT	DATE
	WALKDT_DTS	VARCHAR2
	WALKDT_ND	VARCHAR2
WLKDIST	WLKDIST_C	**NUMBER
	WLKDIST	VARCHAR2
	WLKDIST_ND	VARCHAR2
WLKDIST - DISTMET	DISTMET	FLOAT
WLKCOMP	WLKCOMP_C	NUMBER
	WLKCOMP	VARCHAR2
	WLKCOMP_ND	VARCHAR2
WLKCOMP - WLKDUR	WLKDUR_C	**NUMBER
	WLKDUR	VARCHAR2
WLKCOMP - WLKDURM	WLKDURM	NUMBER
WLKCOMP - WLKDURS	WLKDURS	NUMBER

PRHRDN	PRHRDN_C	**NUMBER
	PRHRDN	VARCHAR2
	PRHRDN_ND	VARCHAR2
PRHRDN - PRWLKHR	PRWLKHR	NUMBER
PRWBPDNE	PRWBPDNE_C	**NUMBER
	PRWBPDNE	VARCHAR2
	PRWBPDNE_ND	VARCHAR2
PRWBPDNE - PRWBPSYS	PRWBPSYS	NUMBER
PRWBPDNE - PRWBPDIA	PRWBPDIA	NUMBER
PSTHRDN	PSTHRDN_C	**NUMBER
	PSTHRDN	VARCHAR2
	PSTHRDN_ND	VARCHAR2
PSTHRDN - PSTWLKHR	PSTWLKHR	NUMBER
PSWBPDNE	PSWBPDNE_C	**NUMBER
	PSWBPDNE	VARCHAR2
	PSWBPDNE_ND	VARCHAR2
PSWBPDNE - PSWBPSYS	PSWBPSYS	NUMBER
PSWBPDNE - PSWBPDIA	PSWBPDIA	NUMBER
cpSYMPEXP	CPSYMPEXP_ND	VARCHAR2
cpSYMPEXP - Yes	SXNONE_CIYES_C	NUMBER
	SXNONE_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXANG_CIYES_C	NUMBER
	SXANG_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXLGHTHD_CIYES_C	NUMBER
	SXLGHTHD_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXSYNCOP_CIYES_C	NUMBER
	SXSYNCOP_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXDYSP_CIYES_C	NUMBER
	SXDYSP_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXFATIGE_CIYES_C	NUMBER
	SXFATIGE_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXCSTPN_CIYES_C	NUMBER
	SXCSTPN_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXLGJTPN_CIYES_C	NUMBER
	SXLGJTPN_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXINSTBL_CIYES_C	NUMBER
	SXINSTBL_CIYES	VARCHAR2
cpSYMPEXP - Other	SXOTHER_SXOTHSP_C	**NUMBER
	SXOTHER_SXOTHSP	VARCHAR2
cpSYMPEXP - SXOTHSP	SXOTHSP	VARCHAR2
PREBDYS	PREBDYS_C	NUMBER
	PREBDYS	VARCHAR2
	PREBDYS_ND	VARCHAR2
PSTBDYS	PSTBDYS_C	NUMBER
	PSTBDYS	VARCHAR2
	PSTBDYS_ND	VARCHAR2
PRERPE	PRERPE_C	NUMBER
	PRERPE	VARCHAR2
	PRERPE_ND	VARCHAR2
PSTRPE	PSTRPE_C	NUMBER
	PSTRPE	VARCHAR2
	PSTRPE_ND	VARCHAR2
Key: [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: KANSAS CITY CARDIOMYOPATHY QUESTIONNAIRE (KCCQ) [frKCCQ]		
Please indicate how much you are limited by heart failure (shortness of breath or fatigue) in your ability to do the following activities over the past 2 weeks: [stKCCQ1]		
1.* ✓	Dressing yourself [Dressing yourself]	[KCCQ1A] [ctLimited1] ▼
2.* ✓	Showering/Bathing [Showering/Bathing]	[KCCQ1B] [ctLimited1] ▼
3.* ✓	Walking 1 block on level ground [Walking 1 block on level ground]	[KCCQ1C] [ctLimited1] ▼
4.* ✓	Doing yardwork, housework or carrying groceries [Doing yardwork, housework or carrying groceries]	[KCCQ1D] [ctLimited1] ▼
5.* ✓	Climbing a flight of stairs without stopping [Climbing a flight of stairs without stopping]	[KCCQ1E] [ctLimited1] ▼
6.* ✓	Hurrying or jogging (as if to catch a bus) [Hurrying or jogging]	[KCCQ1F] [ctLimited1] ▼
7.* ✓	Compared to 2 weeks ago, have your symptoms of heart failure (shortness of breath, fatigue, or ankle swelling) changed? My symptoms of heart failure have become [Compared to 2 weeks ago, have your symptoms of heart failure changed? My symptoms of heart failure have become]	[KCCQ2] [ctSymptomsHaveBecome] ▼
8.* ✓	Over the past 2 few weeks, how many times did you have swelling in your feet, ankles or legs when you woke up in the morning? [Over the past 2 few weeks, how many times did you have swelling in your feet, ankles or legs when you woke up in the morning?]	[KCCQ3] [ctTimesSwelling] ▼
9.* ✓	Over the past 2 weeks, how much has the swelling in your feet, ankles or legs bothered you. It has been? [Over the past 2 weeks, how much has the swelling in your feet, ankles or legs bothered you. It has been?]	[KCCQ4] [ctMuchBothered] ▼
10.* ✓	Over the past 2 weeks, on average, how many times has fatigue limited your ability to do what you wanted? [Over the past 2 weeks, on average, how many times has fatigue limited your ability to do what you wanted?]	[KCCQ5] [ctTimesLimited] ▼
11.* ✓	Over the past 2 weeks, how much has fatigue bothered you? It has been [Over the past 2 weeks, how much has fatigue bothered you? It has been]	[KCCQ6] [ctMuchBothered1] ▼
12.* ✓	Over the past 2 weeks, on average, how many times has shortness of breath limited your ability to do what you wanted? [Over the past 2 weeks, on average, how many times has shortness of breath limited your ability to do what you wanted?]	[KCCQ7] [ctTimesLimited] ▼
13.* ✓	Over the past 2 weeks, how much has your shortness of breath bothered you? It has been [Over the past 2 weeks, how much has your shortness of breath bothered you? It has been]	[KCCQ8] [ctMuchBothered2] ▼
14.* ✓	Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of shortness of breath? [Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of shortness of breath?]	[KCCQ9] [ctTimesSleepUpright] ▼
15.* ✓	Heart failure symptoms can worsen for a number of reasons. How sure are you that you know what to do or who to call, if your heart failure gets worse? [Heart failure symptoms can worsen for a number of reasons. How sure are you that you know what to do or who to call, if your heart failure gets worse?]	[KCCQ10] [ctHowSure] ▼
16.* ✓	How well do you understand what things you are able to do to keep your heart failure symptoms from getting worse (for example, weighing yourself, eating a low-salt diet etc.)? [How well do you understand what things you are able to do to keep your heart failure symptoms from getting worse (for example, weighing yourself, eating a low-salt diet etc.)?]	[KCCQ11] [ctHowWellUnderstand] ▼
17.* ✓	Over the past 2 weeks, how much has your heart failure limited your enjoyment of life? [Over the past 2 weeks, how much has your heart failure limited your enjoyment of life?]	[KCCQ12] [ctLimited2] ▼
18.* ✓	If you had to spend the rest of your life with your heart failure the way it is right now, how would you feel about this? [If you had to spend the rest of your life with your heart failure the way it is right now, how would you feel about this?]	[KCCQ13] [ctSatisfaction] ▼
19.* ✓	Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of heart failure? [Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of heart failure?]	[KCCQ14] [ctHowOften] ▼
How much does your heart failure affect your lifestyle? Please indicate how your heart failure may have limited your participation in the following activities over the past 2 weeks. [stKCCQ2]		
20.* ✓	Hobbies, recreational activities [Hobbies, recreational activities]	[KCCQ15A] [ctLimited3] ▼
21.* ✓	Working or doing household chores [Working or doing household chores]	[KCCQ15B] [ctLimited3] ▼
22.* ✓	Visiting family or friends out of your home [Visiting family or friends out of your home]	[KCCQ15C] [ctLimited3] ▼
23.* ✓	Intimate relationships with loved ones [Intimate relationships with loved ones]	[KCCQ15D] [ctLimited3] ▼
Key: [*] = Item is required [✓] = Source verification required		

Codelist Values and Tables: KANSAS CITY CARDIOMYOPATHY QUESTIONNAIRE

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
ctLimited1	Integer	1 Extremely limited	1	ciExtremelyLimited	KCC01A, KCC01B, KCC01C, KCC01D, KCC01E, KCC01F
		2 Quite a bit limited	2	ciQuiteBitLimited	
		3 Moderately limited	3	ciModeratelyLimited	
		4 Slightly limited	4	ciSlightlyLimited	
		5 Not at all limited	5	ciNotAllLimited	
		6 Limited for other reasons or did not do the activity	6	ciLimitedOtherReasons	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctSymptomsHaveBecome	Integer	1 Much worse	1	ciMuchWorse	KCC02
		2 Slightly worse	2	ciSlightlyWorse2	
		3 Not changed	3	ciNotChanged	
		4 Slightly better	4	ciSlightlyBetter4	
		5 Much better	5	ciMuchBetter	
		6 I have had no symptoms over the last 2 weeks	6	ciNoSymptomsLast2Weeks	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctTimesSwelling	Integer	1 Every morning	1	ciEveryMorning	KCC03
		2 3 or more times a week, but not every morning	2	ci3MoreTimesPerWeek2	
		3 1-2 times a week	3	ci1to2TimesPerWeek3	
		4 Less than once a week	4	ciLessThanOnceWeek4	
		5 Never over the past 2 weeks	5	ciNeverOverPast2Weeks5	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctMuchBothered	Integer	1 Extremely bothersome	1	ciExtremely	KCC04
		2 Quite a bit bothersome	2	ciQuiteBit2	
		3 Moderately bothersome	3	ciModerately	
		4 Slightly bothersome	4	ciSlightly	
		5 Not at all bothersome	5	ciNotAtAll4	
		6 I have had no swelling	6	ciNone6	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctTimesLimited	Integer	1 All of the time	1	ciAllTime	KCC05, KCC07
		2 Several times per day	2	ciSeveralTimesPerDay	
		3 At least once a day	3	ciAtLeastOnceDay	
		4 3 or more times per week but not every day	4	ci3MoreTimesPerWeek4	
		5 1-2 times a week	5	ci1to2TimesPerWeek5	
		6 Less than once a week	6	ciLessThanOnceWeek6	
		7 Never over the past 2 weeks	7	ciNeverOverPast2Weeks	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctMuchBothered1	Integer	1 Extremely bothersome	1	ciExtremely	KCC06
		2 Quite a bit bothersome	2	ciQuiteBit2	
		3 Moderately bothersome	3	ciModerately	
		4 Slightly bothersome	4	ciSlightly	
		5 Not at all bothersome	5	ciNotAtAll4	
		6 I have had no fatigue	6	ciNoFatigue	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctMuchBothered2	Integer	1 Extremely bothersome	1	ciExtremely	KCC08
		2 Quite a bit bothersome	2	ciQuiteBit2	
		3 Moderately bothersome	3	ciModerately	
		4 Slightly bothersome	4	ciSlightly	
		5 Not at all bothersome	5	ciNotAtAll4	
		6 I have had no shortness of breath	6	ciNoShortnessBreath	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctTimesSleepUpright	Integer	1 Every night	1	ciEveryNight	KCC09
		2 3 or more times a week, but not every night	2	ci3xWeekNotEveryNight	
		3 1-2 times a week	3	ci1to2TimesPerWeek3	
		4 Less than once a week	4	ciLessThanOnceWeek4	

		5 Never over the past 2 weeks	5	ciNeverOverPast2Weeks5	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctHowSure	Integer	1 Not at all sure	1	ciNotAtAllSure	KCCQ10
		2 Not very sure	2	ciNotVerySure	
		3 Somewhat sure	3	ciSomewhatSure	
		4 Mostly sure	4	ciMostlySure	
		5 Completely sure	5	ciCompletelySure	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctHowWellUnderstand	Integer	1 Do not understand at all	1	ciDoNotUnderstandAtAll	KCCQ11
		2 Do not understand very well	2	ciDoNotUnderstandVeryWell	
		3 Somewhat understand	3	ciSomewhatUnderstand	
		4 Mostly understand	4	ciMostlyUnderstand	
		5 Completely understand	5	ciCompletelyUnderstand	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctLimited2	Integer	1 It has extremely limited my enjoyment of life	1	ciExtremelyLimited1	KCCQ12
		2 It has limited my enjoyment of life quite a bit	2	ciQuiteBitLimited2	
		3 It has moderately limited my enjoyment of life	3	ciModeratelyLimited3	
		4 It has slightly limited my enjoyment of life	4	ciSlightlyLimited4	
		5 It has not limited my enjoyment of life at all	5	ciNotAllLimited5	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctSatisfaction	Integer	1 Not at all satisfied	1	ciNotAtAllSatisfied	KCCQ13
		2 Mostly dissatisfied	2	ciMostlyDissatisfied	
		3 Somewhat satisfied	3	ciSomewhatSatisfied	
		4 Mostly satisfied	4	ciMostlySatisfied	
		5 Completely satisfied	5	ciCompletelySatisfied	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctHowOften	Integer	1 I felt that way all of the time	1	ciAllTheTime	KCCQ14
		2 I felt that way most of the time	2	ciMostTime	
		3 I occasionally felt that way	3	ciOccasionally2	
		4 I rarely felt that way	4	ciRarely	
		5 I never felt that way	5	ciNever5	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctLimited3	Integer	1 Severely limited	1	ciSeverelyLimited	KCCQ15A, KCCQ15B, KCCQ15C, KCCQ15D
		2 Limited quite a bit	2	ciLimitedQuiteBit	
		3 Moderately limited	3	ciModeratelyLimited2	
		4 Slightly limited	4	ciSlightlyLimited3	
		5 Did not limit at all	5	ciDidNotLimitAtAll	
		6 Does not apply or did not do for other reasons	6	ciDoesNotApply	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	

RDE Analytics: RD_FRKCCQ		
Data Variable RefName	RD Column Name	Column Data Type
KCCQ1A	KCCQ1A_C	NUMBER
	KCCQ1A	VARCHAR2
	KCCQ1A_ND	VARCHAR2
KCCQ1B	KCCQ1B_C	NUMBER
	KCCQ1B	VARCHAR2
	KCCQ1B_ND	VARCHAR2
KCCQ1C	KCCQ1C_C	NUMBER
	KCCQ1C	VARCHAR2
	KCCQ1C_ND	VARCHAR2
KCCQ1D	KCCQ1D_C	NUMBER
	KCCQ1D	VARCHAR2
	KCCQ1D_ND	VARCHAR2

KCCQ1E	KCCQ1E_C	NUMBER
	KCCQ1E	VARCHAR2
	KCCQ1E_ND	VARCHAR2
KCCQ1F	KCCQ1F_C	NUMBER
	KCCQ1F	VARCHAR2
	KCCQ1F_ND	VARCHAR2
KCCQ2	KCCQ2_C	NUMBER
	KCCQ2	VARCHAR2
	KCCQ2_ND	VARCHAR2
KCCQ3	KCCQ3_C	NUMBER
	KCCQ3	VARCHAR2
	KCCQ3_ND	VARCHAR2
KCCQ4	KCCQ4_C	NUMBER
	KCCQ4	VARCHAR2
	KCCQ4_ND	VARCHAR2
KCCQ5	KCCQ5_C	NUMBER
	KCCQ5	VARCHAR2
	KCCQ5_ND	VARCHAR2
KCCQ6	KCCQ6_C	NUMBER
	KCCQ6	VARCHAR2
	KCCQ6_ND	VARCHAR2
KCCQ7	KCCQ7_C	NUMBER
	KCCQ7	VARCHAR2
	KCCQ7_ND	VARCHAR2
KCCQ8	KCCQ8_C	NUMBER
	KCCQ8	VARCHAR2
	KCCQ8_ND	VARCHAR2
KCCQ9	KCCQ9_C	NUMBER
	KCCQ9	VARCHAR2
	KCCQ9_ND	VARCHAR2
KCCQ10	KCCQ10_C	NUMBER
	KCCQ10	VARCHAR2
	KCCQ10_ND	VARCHAR2
KCCQ11	KCCQ11_C	NUMBER
	KCCQ11	VARCHAR2
	KCCQ11_ND	VARCHAR2
KCCQ12	KCCQ12_C	NUMBER
	KCCQ12	VARCHAR2
	KCCQ12_ND	VARCHAR2
KCCQ13	KCCQ13_C	NUMBER
	KCCQ13	VARCHAR2
	KCCQ13_ND	VARCHAR2
KCCQ14	KCCQ14_C	NUMBER
	KCCQ14	VARCHAR2
	KCCQ14_ND	VARCHAR2
KCCQ15A	KCCQ15A_C	NUMBER
	KCCQ15A	VARCHAR2
	KCCQ15A_ND	VARCHAR2
KCCQ15B	KCCQ15B_C	NUMBER
	KCCQ15B	VARCHAR2
	KCCQ15B_ND	VARCHAR2
KCCQ15C	KCCQ15C_C	NUMBER
	KCCQ15C	VARCHAR2
	KCCQ15C_ND	VARCHAR2

KCCQ15D	KCCQ15D_C	NUMBER
	KCCQ15D	VARCHAR2
	KCCQ15D_ND	VARCHAR2

HFN_NEAT: MINNESOTA LIVING WITH HEART FAILURE QUESTIONNAIRE (MLHFQ) [frMLHFQ]		
Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by: [stMLHFQ1]		
1.* ✓	Causing swelling in your ankles, legs, etc.? [Causing swelling in your ankles, legs, etc.]	[MLHFQ1] [ctMLHFQRate] ▼
2.* ✓	Making you sit or lie down to rest during the day? [Making you sit or lie down to rest during the day]	[MLHFQ2] [ctMLHFQRate] ▼
3.* ✓	Making your walking about or climbing stairs difficult? [Making your walking about or climbing stairs difficult]	[MLHFQ3] [ctMLHFQRate] ▼
4.* ✓	Making your working around the house or yard difficult? [Making your working around the house or yard difficult]	[MLHFQ4] [ctMLHFQRate] ▼
5.* ✓	Making your going places away from home difficult? [Making your going places away from home difficult]	[MLHFQ5] [ctMLHFQRate] ▼
6.* ✓	Making it difficult for you to sleep well at night? [Making it difficult for you to sleep well at night]	[MLHFQ6] [ctMLHFQRate] ▼
7.* ✓	Making your relating to or doing things with your friends or family difficult? [Making your relating to or doing things with your friends or family difficult]	[MLHFQ7] [ctMLHFQRate] ▼
8.* ✓	Making your working to earn a living difficult? [Making your working to earn a living difficult]	[MLHFQ8] [ctMLHFQRate] ▼
9.* ✓	Making your recreational pastimes, sports or hobbies difficult? [Making your recreational pastimes, sports or hobbies difficult]	[MLHFQ9] [ctMLHFQRate] ▼
10.* ✓	Making your sexual activities difficult? [Making your sexual activities difficult]	[MLHFQ10] [ctMLHFQRate] ▼
11.* ✓	Making you eat less of the foods you like? [Making you eat less of the foods you like]	[MLHFQ11] [ctMLHFQRate] ▼
12.* ✓	Making you short of breath? [Making you short of breath]	[MLHFQ12] [ctMLHFQRate] ▼
13.* ✓	Making you tired, fatigued, or low on energy? [Making you tired, fatigued, or low on energy]	[MLHFQ13] [ctMLHFQRate] ▼
14.* ✓	Making you stay in a hospital? [Making you stay in a hospital]	[MLHFQ14] [ctMLHFQRate] ▼
15.* ✓	Costing you money for medical care? [Costing you money for medical care]	[MLHFQ15] [ctMLHFQRate] ▼
16.* ✓	Giving you side effects from treatments? [Giving you side effects from treatments]	[MLHFQ16] [ctMLHFQRate] ▼
17.* ✓	Making you feel you are a burden to your family or friends? [Making you feel you are a burden to your family or friends]	[MLHFQ17] [ctMLHFQRate] ▼
18.* ✓	Making you feel a loss of self-control in your life? [Making you feel a loss of self-control in your life]	[MLHFQ18] [ctMLHFQRate] ▼
19.* ✓	Making you worry? [Making you worry]	[MLHFQ19] [ctMLHFQRate] ▼
20.* ✓	Making it difficult for you to concentrate or remember things? [Making it difficult for you to concentrate or remember things]	[MLHFQ20] [ctMLHFQRate] ▼
21.* ✓	Making you feel depressed? [Making you feel depressed]	[MLHFQ21] [ctMLHFQRate] ▼
Key: [*] = Item is required [✓] = Source verification required		

Codelist Values and Tables: MINNESOTA LIVING WITH HEART FAILURE QUESTIONNAIRE					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
ctMLHFQRate	Integer	0	0	ciMLHFQRate0	MLHFQ1, MLHFQ2, MLHFQ3,
		1	1	ciMLHFQRate1	MLHFQ4, MLHFQ5, MLHFQ6,
		2	2	ciMLHFQRate2	MLHFQ7, MLHFQ8, MLHFQ9,
		3	3	ciMLHFQRate3	MLHFQ10, MLHFQ11,

		4	4	ciMLHFQRate4	MLHFQ12, MLHFQ13, MLHFQ14,
		5	5	ciMLHFQRate5	MLHFQ15, MLHFQ16, MLHFQ17,
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	MLHFQ18, MLHFQ19, MLHFQ20, MLHFQ21

RDE Analytics: RD_FRMLHFQ		
Data Variable RefName	RD Column Name	Column Data Type
MLHFQ1	MLHFQ1_C	NUMBER
	MLHFQ1	VARCHAR2
	MLHFQ1_ND	VARCHAR2
MLHFQ2	MLHFQ2_C	NUMBER
	MLHFQ2	VARCHAR2
	MLHFQ2_ND	VARCHAR2
MLHFQ3	MLHFQ3_C	NUMBER
	MLHFQ3	VARCHAR2
	MLHFQ3_ND	VARCHAR2
MLHFQ4	MLHFQ4_C	NUMBER
	MLHFQ4	VARCHAR2
	MLHFQ4_ND	VARCHAR2
MLHFQ5	MLHFQ5_C	NUMBER
	MLHFQ5	VARCHAR2
	MLHFQ5_ND	VARCHAR2
MLHFQ6	MLHFQ6_C	NUMBER
	MLHFQ6	VARCHAR2
	MLHFQ6_ND	VARCHAR2
MLHFQ7	MLHFQ7_C	NUMBER
	MLHFQ7	VARCHAR2
	MLHFQ7_ND	VARCHAR2
MLHFQ8	MLHFQ8_C	NUMBER
	MLHFQ8	VARCHAR2
	MLHFQ8_ND	VARCHAR2
MLHFQ9	MLHFQ9_C	NUMBER
	MLHFQ9	VARCHAR2
	MLHFQ9_ND	VARCHAR2
MLHFQ10	MLHFQ10_C	NUMBER
	MLHFQ10	VARCHAR2
	MLHFQ10_ND	VARCHAR2
MLHFQ11	MLHFQ11_C	NUMBER
	MLHFQ11	VARCHAR2
	MLHFQ11_ND	VARCHAR2
MLHFQ12	MLHFQ12_C	NUMBER
	MLHFQ12	VARCHAR2
	MLHFQ12_ND	VARCHAR2
MLHFQ13	MLHFQ13_C	NUMBER
	MLHFQ13	VARCHAR2
	MLHFQ13_ND	VARCHAR2
MLHFQ14	MLHFQ14_C	NUMBER
	MLHFQ14	VARCHAR2
	MLHFQ14_ND	VARCHAR2
MLHFQ15	MLHFQ15_C	NUMBER
	MLHFQ15	VARCHAR2
	MLHFQ15_ND	VARCHAR2

MLHFQ16	MLHFQ16_C	NUMBER
	MLHFQ16	VARCHAR2
	MLHFQ16_ND	VARCHAR2
MLHFQ17	MLHFQ17_C	NUMBER
	MLHFQ17	VARCHAR2
	MLHFQ17_ND	VARCHAR2
MLHFQ18	MLHFQ18_C	NUMBER
	MLHFQ18	VARCHAR2
	MLHFQ18_ND	VARCHAR2
MLHFQ19	MLHFQ19_C	NUMBER
	MLHFQ19	VARCHAR2
	MLHFQ19_ND	VARCHAR2
MLHFQ20	MLHFQ20_C	NUMBER
	MLHFQ20	VARCHAR2
	MLHFQ20_ND	VARCHAR2
MLHFQ21	MLHFQ21_C	NUMBER
	MLHFQ21	VARCHAR2
	MLHFQ21_ND	VARCHAR2

HFN_NEAT: ECHOCARDIOGRAM (ECHO) [frECHO]	
ECHOCARDIOGRAM [stECHO1]	
1.* ✓ Date ECHO performed [Date ECHO performed]	[ECHODT] Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2014-2018)
2.* ✓ Heart Rate [Heart Rate]	[ECHOHR] [N: 1] <input type="radio"/> [ECHOHRVL] N3 <input type="text"/> [N: 97] <input type="radio"/> Not Done
3.* ✓ Blood Pressure [Blood Pressure]	[ECHOBP] [N: 1] <input type="radio"/> [cpECHOBP] [ECHOSYS] [ECHODIA] N3 <input type="text"/> / N3 <input type="text"/> mmHg [N: 97] <input type="radio"/> Not Done
4.* ✓ Rhythm [Rhythm]	[ECHORHY] [N: 1] <input type="radio"/> NSR [N: 2] <input type="radio"/> A Fib [N: 98] <input type="radio"/> [ECHORHSP] Other, specify A50 <input type="text"/>
5.* ✓ 2D PLAX: LV diastolic dimension [2D PLAX: LV diastolic dimension]	[LVDDD] [N: 1] <input type="radio"/> [LVDD] xxxxxxxx. <input type="text"/> cm [N: 2] <input type="radio"/> [VLVDD] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
6.* ✓ 2D PLAX: LV systolic dimension [2D PLAX: LV systolic dimension]	[LVSDD] [N: 1] <input type="radio"/> [LVSD] xxxxxxxx. <input type="text"/> cm [N: 2] <input type="radio"/> [VLVSD] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
7.* ✓ 2D PLAX: IVS (intraventricular septum) diastolic thickness [2D PLAX: IVS diastolic dimension]	[IVDDD] [N: 1] <input type="radio"/> [IVDD] xxxxxxxx. <input type="text"/> cm [N: 2] <input type="radio"/> [IVVDD] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
8.* ✓ 2D PLAX: PW (posterior wall) diastolic thickness [2D PLAX: PW diastolic dimension]	[PWDDD] [N: 1] <input type="radio"/> [PWDD] xxxxxxxx. <input type="text"/> cm [N: 2] <input type="radio"/> [VPWDD] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
9.* ✓ 2D PLAX: LVOT (left ventricular outflow track) diameter [2D PLAX: LVOT diameter]	[LVOTD] [N: 1] <input type="radio"/> [LVOT] xxxxxxxx. <input type="text"/> cm [N: 2] <input type="radio"/> [VLVOT] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
10.* ✓ MV Inflow: E velocity at leaf tip [MV Inflow: E velocity at leaf tip]	[EVELOCD] [N: 1] <input type="radio"/> [EVELOC] xxxxxxxx. <input type="text"/> m/sec [N: 2] <input type="radio"/> [VEVELOC] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
11.* ✓ MV Inflow: A velocity at leaf tip [MV Inflow: A velocity at leaf tip]	[AVELOCD] [N: 1] <input type="radio"/> [AVELOC] xxxxxxxx. <input type="text"/> m/sec [N: 2] <input type="radio"/> [VAVELOC] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views

		<p>[N:2] <input type="radio"/> Views Absent [N:3] <input type="radio"/> Atrial Fibrillation</p>
12.* ✓	MV Inflow: Decel time at leaf tip [MV Inflow: Decel time at leaf tip]	<p>[DECELTMD] [N:1] <input type="radio"/> [DECELTM] xxxxxxxx. <input type="text"/> ms [N:2] <input type="radio"/> [VDECELTM] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent</p>
13.* ✓	DTI (Doppler tissue imaging) medial annulus é velocity [DTI Medial Annulus e]	<p>[DTIMEDED] [N:1] <input type="radio"/> [DTIMEDE] xxxxxxxx. <input type="text"/> m/sec [N:2] <input type="radio"/> [VDTIMEDE] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent</p>
14.* ✓	DTI (Doppler tissue imaging) lateral annulus é velocity [DTI Lateral Annulus e]	<p>[DTILATED] [N:1] <input type="radio"/> [DTILATE] xxxxxxxx. <input type="text"/> m/sec [N:2] <input type="radio"/> [VDTILATE] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent</p>
15.* ✓	LA Left atrium (4 chamber view) area [LA 4c Area]	<p>[LACAREAD] [N:1] <input type="radio"/> [LACAREA] xxxxxxxx. <input type="text"/> cm2 [N:2] <input type="radio"/> [VLACAREA] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent</p>
16.* ✓	LA Left atrium (4 chamber view) length [LA 4c Length]	<p>[LACLEND] [N:1] <input type="radio"/> [LACLEN] xxxxxxxx. <input type="text"/> cm [N:2] <input type="radio"/> [VLACLEN] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent</p>
17.* ✓	LA Left atrium (2 chamber view) area [LA 2ch Area]	<p>[LACHARD] [N:1] <input type="radio"/> [LACHAREA] xxxxxxxx. <input type="text"/> cm2 [N:2] <input type="radio"/> [VLACHARE] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent</p>
18.* ✓	LA Left atrium (2 chamber view) length [LA 2c Length]	<p>[LALEND] [N:1] <input type="radio"/> [LALLEN] xxxxxxxx. <input type="text"/> cm [N:2] <input type="radio"/> [VLALLEN] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent</p>
19.* ✓	Peak Tricuspid Regurgitation (TR) velocity [Peak TR velocity]	<p>[PKTRVELD] [N:1] <input type="radio"/> [PEAKVELC] xxxxxxxx. <input type="text"/> m/sec [N:2] <input type="radio"/> [VPEAKTR] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent</p>
20.* ✓	RA Pressure (est) - If no IVC is recorded 10 mmHg will be used for RA Pressure [RA Pressure (est) - If no IVC is recorded 10 mmHg will be used for RA Pressure]	<p>[RAPRESSD] [N:1] <input type="radio"/> [RAPRESS] xxxxxxxx. <input type="text"/> mmHg [N:97] <input type="radio"/> Not Done</p>
21.* ✓	M-mode Tricuspid Annular Systolic Excursion (TAPSE) [mMode Tricuspid Annular Systolic Excursion (TAPSE)]	<p>[TAPSED] [N:1] <input type="radio"/> [TAPSE] xxxxxxxx. <input type="text"/> mm [N:2] <input type="radio"/> [TAPSEQ] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views</p>

22.* <input checked="" type="checkbox"/> DTI Tricuspid Lateral Annulus s [DTI Tricuspid Lateral Annulus s]	[N:2] <input type="radio"/> Views Absent [DTITRISD] [N:1] <input type="radio"/> [DTITRIS] xxxxxxxx. m/sec [N:2] <input type="radio"/> [VDTITRIS] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent
23.* <input checked="" type="checkbox"/> M-mode Inferior vena cava dimension -Expiration (max) [m mode Inferior vena cava dimension -Expiration (max)]	[I1VCDED] [N:1] <input type="radio"/> [I1VCDE] xxxxxxxx. cm [N:2] <input type="radio"/> [I1VCDEQ] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent
24.* <input checked="" type="checkbox"/> M-mode Inferior vena cava dimension -with snif (minimum) [m mode Inferior vena cava dimension -with snif (minimum)]	[I1VCDSD] [N:1] <input type="radio"/> [I1VCDS] xxxxxxxx. cm [N:2] <input type="radio"/> [I1VCDSQ] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent
25.* <input checked="" type="checkbox"/> Pulsed wave Doppler LVOT TVI (avg of >=3) [Pulsed wave Doppler LVOT TVI (avg of >=3)]	[PWDLVOTD] [N:1] <input type="radio"/> [PWDLVOT] xxxxxxxx. cm [N:2] <input type="radio"/> [PWDLVOTO] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent
26.* <input checked="" type="checkbox"/> Final conclusion Ejection Fraction [Final conclusion Ejection Fraction]	[FEJFCTND] [N:1] <input type="radio"/> [FEJFCTNV] xxxxxxxx. % [N:97] <input type="radio"/> Not Done
27.* <input checked="" type="checkbox"/> Method [Method]	[ECHOMETH] [N:1] <input type="radio"/> Visual estimate [N:2] <input type="radio"/> Biplane Simpsons [N:3] <input type="radio"/> 2D formula (modified Quinonies) [N:98] <input type="radio"/> [ECHOMTHS] Other, specify: A50

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

RDE Analytics: RD_FRECHO		
Data Variable RefName	RD Column Name	Column Data Type
ECHODT	ECHODT	DATE
	ECHODT_DTS	VARCHAR2
	ECHODT_ND	VARCHAR2
ECHOHR	ECHOHR_C	**NUMBER
	ECHOHR	VARCHAR2
	ECHOHR_ND	VARCHAR2
ECHOHR - ECHOHRVL	ECHOHRVL	NUMBER
ECHOBP	ECHOBP_C	**NUMBER
	ECHOBP	VARCHAR2
	ECHOBP_ND	VARCHAR2
ECHOBP - ECHOSYS	ECHOSYS	NUMBER
ECHOBP - ECHODIA	ECHODIA	NUMBER
ECHORHY	ECHORHY_C	NUMBER
	ECHORHY	VARCHAR2
	ECHORHY_ND	VARCHAR2
ECHORHY - ECHORHSP	ECHORHSP	VARCHAR2
LVDDD	LVDDD_C	**NUMBER
	LVDDD	VARCHAR2

	LVDDD_ND	VARCHAR2
LVDDD - LVDD	LVDD	FLOAT
LVDDD - VLVD	VLVDD_C	NUMBER
	VLVDD	VARCHAR2
LVSD	LVSD_C	**NUMBER
	LVSD	VARCHAR2
	LVSD_ND	VARCHAR2
LVSD - LVSD	LVSD	FLOAT
LVSD - VLVD	VLVSD_C	NUMBER
	VLVSD	VARCHAR2
IVDD	IVDD_C	**NUMBER
	IVDD	VARCHAR2
	IVDD_ND	VARCHAR2
IVDD - IVDD	IVDD	FLOAT
IVDD - VIVD	VIVDD_C	NUMBER
	VIVDD	VARCHAR2
PWDD	PWDD_C	**NUMBER
	PWDD	VARCHAR2
	PWDD_ND	VARCHAR2
PWDD - PWDD	PWDD	FLOAT
PWDD - VPWDD	VPWDD_C	NUMBER
	VPWDD	VARCHAR2
LVOT	LVOT_C	**NUMBER
	LVOT	VARCHAR2
	LVOT_ND	VARCHAR2
LVOT - LVOT	LVOT	FLOAT
LVOT - VLVOT	VLVOT_C	NUMBER
	VLVOT	VARCHAR2
EVELOCD	EVELOCD_C	**NUMBER
	EVELOCD	VARCHAR2
	EVELOCD_ND	VARCHAR2
EVELOCD - EVELOCD	EVELOCD	FLOAT
EVELOCD - VEVELOCD	VEVELOCD_C	NUMBER
	VEVELOCD	VARCHAR2
AVELOCD	AVELOCD_C	**NUMBER
	AVELOCD	VARCHAR2
	AVELOCD_ND	VARCHAR2
AVELOCD - AVELOCD	AVELOCD	FLOAT
AVELOCD - VAVELOCD	VAVELOCD_C	NUMBER
	VAVELOCD	VARCHAR2
DECELTMD	DECELTMD_C	**NUMBER
	DECELTMD	VARCHAR2
	DECELTMD_ND	VARCHAR2
DECELTMD - DECELTMD	DECELTMD	FLOAT
DECELTMD - VDECELTMD	VDECELTMD_C	NUMBER
	VDECELTMD	VARCHAR2
DTIMEDED	DTIMEDED_C	**NUMBER
	DTIMEDED	VARCHAR2
	DTIMEDED_ND	VARCHAR2
DTIMEDED - DTIMEDED	DTIMEDED	FLOAT
DTIMEDED - VDTIMEDED	VDTIMEDED_C	NUMBER
	VDTIMEDED	VARCHAR2
DTILATED	DTILATED_C	**NUMBER
	DTILATED	VARCHAR2

	DTILATED_ND	VARCHAR2
DTILATED - DTILATE	DTILATE	FLOAT
DTILATED - VDTILATE	VDTILATE_C	NUMBER
	VDTILATE	VARCHAR2
LACAREAD	LACAREAD_C	**NUMBER
	LACAREAD	VARCHAR2
	LACAREAD_ND	VARCHAR2
LACAREAD - LACAREA	LACAREA	FLOAT
LACAREAD - VLACAREA	VLACAREA_C	NUMBER
	VLACAREA	VARCHAR2
LACLEND	LACLEND_C	**NUMBER
	LACLEND	VARCHAR2
	LACLEND_ND	VARCHAR2
LACLEND - LACLEN	LACLEN	FLOAT
LACLEND - VLACLEN	VLACLEN_C	NUMBER
	VLACLEN	VARCHAR2
LACHARD	LACHARD_C	**NUMBER
	LACHARD	VARCHAR2
	LACHARD_ND	VARCHAR2
LACHARD - LACHAREA	LACHAREA	FLOAT
LACHARD - VLACHARE	VLACHARE_C	NUMBER
	VLACHARE	VARCHAR2
LALEND	LALEND_C	**NUMBER
	LALEND	VARCHAR2
	LALEND_ND	VARCHAR2
LALEND - LALEN	LALEN	FLOAT
LALEND - VLALEN	VLALEN_C	NUMBER
	VLALEN	VARCHAR2
PKTRVELD	PKTRVELD_C	**NUMBER
	PKTRVELD	VARCHAR2
	PKTRVELD_ND	VARCHAR2
PKTRVELD - PEAKVELC	PEAKVELC	FLOAT
PKTRVELD - VPEAKTR	VPEAKTR_C	NUMBER
	VPEAKTR	VARCHAR2
RAPRESSD	RAPRESSD_C	**NUMBER
	RAPRESSD	VARCHAR2
	RAPRESSD_ND	VARCHAR2
RAPRESSD - RAPRESS	RAPRESS	FLOAT
TAPSED	TAPSED_C	**NUMBER
	TAPSED	VARCHAR2
	TAPSED_ND	VARCHAR2
TAPSED - TAPSE	TAPSE	FLOAT
TAPSED - TAPSEQ	TAPSEQ_C	NUMBER
	TAPSEQ	VARCHAR2
DTITRISD	DTITRISD_C	**NUMBER
	DTITRISD	VARCHAR2
	DTITRISD_ND	VARCHAR2
DTITRISD - DTITRIS	DTITRIS	FLOAT
DTITRISD - VDTITRIS	VDTITRIS_C	NUMBER
	VDTITRIS	VARCHAR2
IVCDED	IVCDED_C	**NUMBER
	IVCDED	VARCHAR2
	IVCDED_ND	VARCHAR2
IVCDED - IVCDE	IVCDE	FLOAT

IVCDED - IVCDEQ	IVCDEQ_C	NUMBER
	IVCDEQ	VARCHAR2
IVCSDS	IVCSDS_C	**NUMBER
	IVCSDS	VARCHAR2
	IVCSDS_ND	VARCHAR2
IVCSDS - IVCDS	IVCDS	FLOAT
IVCSDS - IVCDSQ	IVCDSQ_C	NUMBER
	IVCDSQ	VARCHAR2
PWDLVOTD	PWDLVOTD_C	**NUMBER
	PWDLVOTD	VARCHAR2
	PWDLVOTD_ND	VARCHAR2
PWDLVOTD - PWDLVOT	PWDLVOT	FLOAT
PWDLVOTD - PWDLVOTQ	PWDLVOTQ_C	NUMBER
	PWDLVOTQ	VARCHAR2
FEJFCTND	FEJFCTND_C	**NUMBER
	FEJFCTND	VARCHAR2
	FEJFCTND_ND	VARCHAR2
FEJFCTND - FEJFCTNV	FEJFCTNV	FLOAT
ECHOMETH	ECHOMETH_C	NUMBER
	ECHOMETH	VARCHAR2
	ECHOMETH_ND	VARCHAR2
ECHOMETH - ECHOMTHS	ECHOMTHS	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: BASELINE EVENTS OF INTEREST (BLEVNT) [frBLEVNT]					
Events of Interest [stBLEVNT1]					
1.* ✓ Did subject experience any of the following anticipated, serious, disease-related events since signing consent? Arrhythmias Sudden cardiac death Acute coronary syndrome Worsening heart failure Cerebrovascular event Venous thromboembolism Lightheadedness, presyncope or syncope Worsening renal function [Did subject experience any of the following anticipated, serious, disease-related events since signing consent?]	[BLEVNT] [N:1] <input type="radio"/> Yes (click on Add Entry button) [N:0] <input type="radio"/> No				
2.	<table border="1"> <thead> <tr> <th>Anticipated, disease-related event:</th> <th>Onset Date</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> </tr> </tbody> </table>	Anticipated, disease-related event:	Onset Date		
Anticipated, disease-related event:	Onset Date				
Anticipated Disease Related Events Entry [rsBLEVNT2]					
2.1* ✓ Anticipated, disease-related event: [Anticipated, disease-related event:]	[BEVNTTPE] [N:1] <input type="radio"/> Arrhythmias [N:2] <input type="radio"/> Sudden cardiac death [N:3] <input type="radio"/> Acute coronary syndrome [N:4] <input type="radio"/> Worsening heart failure [N:5] <input type="radio"/> Cerebrovascular event [N:6] <input type="radio"/> Venous thromboembolism [N:7] <input type="radio"/> Lightheadedness, presyncope or syncope [N:8] <input type="radio"/> Worsening renal function				
2.2* ✓ Onset Date [Onset Date]	[BLEVNTDT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2018)				
Key: [*] = Item is required [✓] = Source verification required					

RDE Analytics: RD_FRBLEVNT		
Data Variable RefName	RD Column Name	Column Data Type
BLEVNT	BLEVNT_C	NUMBER
	BLEVNT	VARCHAR2
	BLEVNT_ND	VARCHAR2
RD_FRBLEVNT_RSBLEVNT2		
BEVNTTPE	BEVNTTPE_C	NUMBER
	BEVNTTPE	VARCHAR2
	BEVNTTPE_ND	VARCHAR2
BLEVNTDT	BLEVNTDT	DATE
	BLEVNTDT_DTS	VARCHAR2
	BLEVNTDT_DTR	VARCHAR2
	BLEVNTDT_ND	VARCHAR2

HFN_NEAT: VISIT STATUS (VISIT) [frVISIT]

Visit Status [stVISIT1]

1.* ✓	Was the visit performed [Visit performed]	<p>[STATUS]</p> <p>[N: 1] <input type="radio"/> [ASSESSDT]</p> <p>Yes</p> <p>Visit date:</p> <p>Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2018)</p> <p>[N: 0] <input type="radio"/> [VISNDRES]</p> <p>No</p> <p>Reason visit was not performed:</p> <p>[N: 1] <input type="radio"/> Missed visit</p> <p>[N: 2] <input type="radio"/> Suspected LTFU</p> <p>[N: 3] <input type="radio"/> Subject no longer participating in study (died, permanently withdrew consent, etc).</p> <p>[N: 98] <input type="radio"/> [ASESNDSP]</p> <p>Other, specify</p> <p>A100</p>
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Key: [*] = Item is required [✓] = Source verification required

RDE Analytics: RD_FRVISIT

Data Variable RefName	RD Column Name	Column Data Type
STATUS	STATUS_C	**NUMBER
	STATUS	VARCHAR2
	STATUS_ND	VARCHAR2
STATUS - ASSESDT	ASSESDT	DATE
	ASSESDT_DTS	VARCHAR2
STATUS - VISNDRES	VISNDRES_C	NUMBER
	VISNDRES	VARCHAR2
STATUS - ASESNDSP	ASESNDSP	VARCHAR2

Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.

HFN_NEAT: EVENTS OF INTEREST (EVNTINT) [frEVNTINT]		
Events of Interest [stEVNTINT1]		
1.* ✓	Did subject experience any of the following anticipated, serious, disease-related events since the last in-person visit? Arrhythmias Sudden cardiac death Acute coronary syndrome Worsening heart failure Cerebrovascular event Venous thromboembolism Lightheadedness, presyncope or syncope Worsening renal function [Did subject experience any of the following anticipated, serious, disease-related events since the last visit:]	[EVNTINT] [N: 1] <input type="radio"/> Yes (click on Add Entry button) [N: 0] <input type="radio"/> No
2.	Anticipated, disease-related event:	Onset Date
Anticipated Disease Related Events Entry [rsEVNTINT2]		
2.1* ✓	Anticipated, disease-related event: [Anticipated, disease-related event:]	[EVNTTYPE] [N: 1] <input type="radio"/> Arrhythmias [N: 2] <input type="radio"/> Sudden cardiac death [N: 3] <input type="radio"/> Acute coronary syndrome [N: 4] <input type="radio"/> Worsening heart failure [N: 5] <input type="radio"/> Cerebrovascular event [N: 6] <input type="radio"/> Venous thromboembolism [N: 7] <input type="radio"/> Lightheadedness, presyncope or syncope [N: 8] <input type="radio"/> Worsening renal function
2.2* ✓	Onset Date [Onset Date]	[EVNTDT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2018)
Key: [*] = Item is required [✓] = Source verification required		

RDE Analytics: RD_FREVTINT		
Data Variable RefName	RD Column Name	Column Data Type
EVNTINT	EVNTINT_C	NUMBER
	EVNTINT	VARCHAR2
	EVNTINT_ND	VARCHAR2
RD_FREVTINT_RSEVTINT2		
EVNTTYPE	EVNTTYPE_C	NUMBER
	EVNTTYPE	VARCHAR2
	EVNTTYPE_ND	VARCHAR2
EVNTDT	EVNTDT	DATE
	EVNTDT_DTS	VARCHAR2
	EVNTDT_DTR	VARCHAR2
	EVNTDT_ND	VARCHAR2

HFN_NEAT: Additional Protocol Assessments (ASSESS) [frASSESS]	
Additional Protocol Assessments [stASSESS1]	
<p>1.* Were protocol required biological samples collected (If yes, please complete SAMPLES form)? [Were protocol required biological samples collected]</p>	<p>[BIOSAMP] [N: 1] <input type="radio"/> Yes [N: 0] <input checked="" type="radio"/> [BIONDRSN] No [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform test but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 99] <input checked="" type="radio"/> [BIONDSP] Unknown/other Specify: A50</p>
<p>2.* Was 6-Minute Walk performed (If yes, complete SIXMWT form)? [Was 6-Minute Walk performed]</p>	<p>[SIXMWTDT] [N: 1] <input type="radio"/> Yes [N: 0] <input checked="" type="radio"/> [SMWDRS] No Reason test was not performed: [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform test but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 4] <input type="radio"/> Cannot walk for mechanical reasons (e.g., amputee, orthopedic) [N: 5] <input type="radio"/> Neurological reasons [N: 99] <input checked="" type="radio"/> [SMWDRSP] Unknown/other Specify: A50</p>
<p>3.* Was KCCQ completed (If yes, complete KCCQ form)? [Was KCCQ completed]</p>	<p>[KCCQDN] [N: 1] <input type="radio"/> Yes [N: 0] <input checked="" type="radio"/> [KCCQDRS] No [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform test but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 99] <input checked="" type="radio"/> [KCCQDRSP] Unknown/other Specify: A50</p>
<p>4.* Was MLHFQ completed (If yes, complete MLHFQ form) [Was MLHFQ completed]</p>	<p>[MLHFQDN] [N: 1] <input type="radio"/> Yes [N: 0] <input checked="" type="radio"/> [MLHQDR] No Reason test was not performed: [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform test but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 99] <input checked="" type="radio"/> [MLHQDRS] Unknown/other Specify: A50</p>
<p>5.* Has the subject experienced an SAE since the last visit (If yes, complete SAE form)? [Has the subject experienced an SAE since the last visit]</p>	<p>[NEWSAE] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
<p>6.* Has the subject been hospitalized since the last visit (If yes, complete REHOSP form)? [Has the subject been hospitalized since the last visit]</p>	<p>[REHOSP] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
<p>7.* Has the subject had any emergency department visits since the last visit (If yes, complete EDVIS form)? [Has the subject had any emergency department visits since the last visit]</p>	<p>[EDVIST] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
<p>8.* Has subject had a positive pregnancy test since the last visit? [Has subject had a positive pregnancy test since the last visit?]</p>	<p>[POSPREG] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 96] <input checked="" type="radio"/> Not Applicable</p>
<p>Key: [*] = Item is required</p>	

RDE Analytics: RD_FRASSESS		
Data Variable RefName	RD Column Name	Column Data Type
BIOSAMP	BIOSAMP_C	NUMBER
	BIOSAMP	VARCHAR2
	BIOSAMP_ND	VARCHAR2
BIOSAMP - BIONDRSN	BIONDRSN_C	NUMBER
	BIONDRSN	VARCHAR2
BIOSAMP - BIONDSP	BIONDSP	VARCHAR2
SIXMWTD	SIXMWTD_C	NUMBER
	SIXMWTD	VARCHAR2
	SIXMWTD_ND	VARCHAR2
SIXMWTD - SMWNDRS	SMWNDRS_C	NUMBER
	SMWNDRS	VARCHAR2
SIXMWTD - SMWNDS	SMWNDS	VARCHAR2
KCCQDN	KCCQDN_C	NUMBER
	KCCQDN	VARCHAR2
	KCCQDN_ND	VARCHAR2
KCCQDN - KCCQNDRS	KCCQNDRS_C	NUMBER
	KCCQNDRS	VARCHAR2
KCCQDN - KCCQNDSP	KCCQNDSP	VARCHAR2
MLHFQDN	MLHFQDN_C	NUMBER
	MLHFQDN	VARCHAR2
	MLHFQDN_ND	VARCHAR2
MLHFQDN - MLHQNDR	MLHQNDR_C	NUMBER
	MLHQNDR	VARCHAR2
MLHFQDN - MLHQNDS	MLHQNDS	VARCHAR2
NEWSAE	NEWSAE_C	NUMBER
	NEWSAE	VARCHAR2
	NEWSAE_ND	VARCHAR2
REHOSP	REHOSP_C	NUMBER
	REHOSP	VARCHAR2
	REHOSP_ND	VARCHAR2
EDVIST	EDVIST_C	NUMBER
	EDVIST	VARCHAR2
	EDVIST_ND	VARCHAR2
POSPREG	POSPREG_C	NUMBER
	POSPREG	VARCHAR2
	POSPREG_ND	VARCHAR2

HFN_NEAT: STUDY DRUG DOSING (DRGDOSE) [frDRGDOSE]		
30mg Dose [stDRGDOSE1]		
1.* ✓ Did subject start 30mg dose? [Did subject start 30mg dose?]	<p>[DOSE30YN] [N: 1] <input checked="" type="radio"/> [D30STDT] Yes Date Started: Req/Unk <input type="text"/> / <input type="text"/> / <input type="text"/> (2014-2018)</p> <p>[N: 0] <input type="radio"/> No</p>	
2. ✓ Did subject maintain 30 mg dose per protocol? [Did subject maintain 30 mg dose per protocol?]	<p>[D30MNT] [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input type="radio"/> [cpD30MNTNO] No</p> <p>[D30SPDT] Stop Date: Req/Unk <input type="text"/> / <input type="text"/> / <input type="text"/> (2014-2018)</p> <p>[cpD30RSN] Reason (check all that apply): [D30HEAD] [N: 1] <input type="checkbox"/> Headache [D30DIZZ] [N: 1] <input type="checkbox"/> Dizziness/lightheadedness [D30HYPO] [N: 1] <input type="checkbox"/> Asymptomatic hypotension (Systolic BP < 90) [D30EVNT] [N: 1] <input type="checkbox"/> Event of Interest (complete EVNTINT form) [D30SAE] [N: 1] <input type="checkbox"/> [D30SAEN] SAE SAE Number: <input type="text" value="A3"/> [D30OTH] [N: 1] <input type="checkbox"/> [D30RSSP] Other, specify: <input type="text" value="A100"/> [N: 96] <input type="radio"/> Not Applicable</p>	
60mg Dose [stDRGDOSE2]		
3.* ✓ Did subject start 60mg dose? [Did subject start 60mg dose?]	<p>[DOSE60YN] [N: 1] <input checked="" type="radio"/> [cpDOSE60Y] Yes [D60STDT] Date Started: Req/Unk <input type="text"/> / <input type="text"/> / <input type="text"/> (2014-2018)</p> <p>[D60MNT] Did subject maintain 60 mg dose per protocol? [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input type="radio"/> No (complete Add Entry Section) [N: 0] <input type="radio"/> No</p>	
4.	Date of Dose Change	New Dose
Reason for decrease/discontinuation (check all that apply):		
60mg Dose Change Details Entry [rsDRGDOSE3]		
4.1* ✓ Date of Dose Change [Date of Dose Change]	<p>[D60DCDT] Req/Unk <input type="text"/> / <input type="text"/> / <input type="text"/> (2014-2018)</p>	
4.2* ✓ New Dose [New Dose]	<p>[D60NDSE] [N: 1] <input checked="" type="radio"/> 30mg [N: 2] <input type="radio"/> 0mg</p>	
4.3* ✓ Reason for decrease/discontinuation (check all that apply): [Reason for decrease/discontinuation (check all that apply):]	<p>[cpD60RSN] [D60HEAD] [N: 1] <input type="checkbox"/> Headache [D60DIZZ] [N: 1] <input type="checkbox"/> Dizziness/lightheadedness [D60HYPO] [N: 1] <input type="checkbox"/> Asymptomatic hypotension (Systolic BP < 90) [D60EVNT] [N: 1] <input type="checkbox"/> Event of Interest (complete EVNTINT form) [D60SAE] [N: 1] <input type="checkbox"/> [D60SAEN] SAE</p>	

		SAE Number: <input type="text" value="A3"/> [D600TH] [N: 1] <input type="checkbox"/> [D60RSSP] Other, specify: <input type="text" value="A100"/>
120mg Dose [stDRGDOSE4]		
5. *	Did subject start 120mg dose? [Did subject start 120mg dose?]	[DS120YN] [N: 1] <input checked="" type="radio"/> [cpDS120Y] Yes [D120STD1] Date Started: Req/Unk <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2018) [D120MNT] Did subject maintain 120 mg dose per protocol? [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No (complete Add Entry Section) [N: 0] <input checked="" type="radio"/> No
6.	Date of Dose Change	New Dose
Reason for decrease/discontinuation (check all that apply):		
120mg Dose Change Details Entry [rsDRGDOSE5]		
6.1 *	Date of Dose Change [Date of Dose Change]	[D120DCDT] Req/Unk <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2018)
6.2 *	New Dose [New Dose]	[D120NDSE] [N: 1] <input checked="" type="radio"/> 60mg [N: 2] <input type="radio"/> 30mg [N: 3] <input type="radio"/> 0mg
6.3 *	Reason for decrease/discontinuation (check all that apply): [Reason for decrease/discontinuation (check all that apply):]	[cpD120RSN] [D120HEAD] [N: 1] <input type="checkbox"/> Headache [D120DIZZ] [N: 1] <input type="checkbox"/> Dizziness/lightheadedness [D120HYPO] [N: 1] <input type="checkbox"/> Asymptomatic hypotension (Systolic BP < 90) [D120EVNT] [N: 1] <input type="checkbox"/> Event of Interest (complete EVNTINT form) [D120SAE] [N: 1] <input type="checkbox"/> [D120SAEN] SAE SAE Number: <input type="text" value="A3"/> [D120OTH] [N: 1] <input type="checkbox"/> [D120RSSP] Other, specify: <input type="text" value="A100"/>
Key: [*] = Item is required [✓] = Source verification required		

RDE Analytics: RD_FRDRGDOSE		
Data Variable RefName	RD Column Name	Column Data Type
DOSE30YN	DOSE30YN_C	**NUMBER
	DOSE30YN	VARCHAR2
	DOSE30YN_ND	VARCHAR2
DOSE30YN - D30STD1	D30STD1	DATE
	D30STD1_DTS	VARCHAR2
	D30STD1_DTR	VARCHAR2
D30MNT	D30MNT_C	NUMBER
	D30MNT	VARCHAR2
	D30MNT_ND	VARCHAR2
D30MNT - D30SPDT	D30SPDT	DATE
	D30SPDT_DTS	VARCHAR2
	D30SPDT_DTR	VARCHAR2

D30MNT - Headache	D30HEAD_CIHEADACHE_C	NUMBER
	D30HEAD_CIHEADACHE	VARCHAR2
D30MNT - Dizziness/lightheadedness	*D30DIZZ_CIDIZZINESSLIGHTHEADEDNESS_C	NUMBER
	*D30DIZZ_CIDIZZINESSLIGHTHEADEDNESS	VARCHAR2
D30MNT - Asymptomatic hypotension (Systolic BP < 90)	*D30HYPO_CIASYMPOMATICHPOTENSION_C	NUMBER
	*D30HYPO_CIASYMPOMATICHPOTENSION	VARCHAR2
D30MNT - Event of Interest (complete EVNTINT form)	D30EVNT_CIEVENTINTEREST_C	NUMBER
	D30EVNT_CIEVENTINTEREST	VARCHAR2
D30MNT - SAE	D30SAE_D30SAEN_C	**NUMBER
	D30SAE_D30SAEN	VARCHAR2
D30MNT - D30SAEN	D30SAEN	VARCHAR2
D30MNT - Other	D30OTH_D30RSSP_C	**NUMBER
	D30OTH_D30RSSP	VARCHAR2
D30MNT - D30RSSP	D30RSSP	VARCHAR2
DOSE60YN	DOSE60YN_C	**NUMBER
	DOSE60YN	VARCHAR2
	DOSE60YN_ND	VARCHAR2
DOSE60YN - D60STDT	D60STDT	DATE
	D60STDT_DTS	VARCHAR2
	D60STDT_DTR	VARCHAR2
DOSE60YN - D60MNT	D60MNT_C	NUMBER
	D60MNT	VARCHAR2
DS120YN	DS120YN_C	**NUMBER
	DS120YN	VARCHAR2
	DS120YN_ND	VARCHAR2
DS120YN - D120STDT	D120STDT	DATE
	D120STDT_DTS	VARCHAR2
	D120STDT_DTR	VARCHAR2
DS120YN - D120MNT	D120MNT_C	NUMBER
	D120MNT	VARCHAR2
RD_FRDRGDOSE_RSDRGDOSE3		
D60DCDT	D60DCDT	DATE
	D60DCDT_DTS	VARCHAR2
	D60DCDT_DTR	VARCHAR2
	D60DCDT_ND	VARCHAR2
D60NDSE	D60NDSE_C	NUMBER
	D60NDSE	VARCHAR2
	D60NDSE_ND	VARCHAR2
cpD60RSN	CPD60RSN_ND	VARCHAR2
cpD60RSN - Headache	D60HEAD_CIHEADACHE_C	NUMBER
	D60HEAD_CIHEADACHE	VARCHAR2
cpD60RSN - Dizziness/lightheadedness	*D60DIZZ_CIDIZZINESSLIGHTHEADEDNESS_C	NUMBER
	*D60DIZZ_CIDIZZINESSLIGHTHEADEDNESS	VARCHAR2
cpD60RSN - Asymptomatic hypotension (Systolic BP < 90)	*D60HYPO_CIASYMPOMATICHPOTENSION_C	NUMBER
	*D60HYPO_CIASYMPOMATICHPOTENSION	VARCHAR2
cpD60RSN - Event of Interest (complete EVNTINT form)	D60EVNT_CIEVENTINTEREST_C	NUMBER
	D60EVNT_CIEVENTINTEREST	VARCHAR2
cpD60RSN - SAE	D60SAE_D60SAEN_C	**NUMBER
	D60SAE_D60SAEN	VARCHAR2
cpD60RSN - D60SAEN	D60SAEN	VARCHAR2
cpD60RSN - Other	D60OTH_D60RSSP_C	**NUMBER
	D60OTH_D60RSSP	VARCHAR2
cpD60RSN - D60RSSP	D60RSSP	VARCHAR2
RD_FRDRGDOSE_RSDRGDOSE5		

D120DCDT	D120DCDT	DATE
	D120DCDT_DTS	VARCHAR2
	D120DCDT_DTR	VARCHAR2
	D120DCDT_ND	VARCHAR2
D120NDSE	D120NDSE_C	NUMBER
	D120NDSE	VARCHAR2
	D120NDSE_ND	VARCHAR2
cpD120RSN	CPD120RSN_ND	VARCHAR2
cpD120RSN - Headache	D120HEAD_CIHEADACHE_C	NUMBER
	D120HEAD_CIHEADACHE	VARCHAR2
cpD120RSN - Dizziness/lightheadedness	*D120DIZZ_CIDIZZINESSLIGHTHEADEDNESS_C	NUMBER
	*D120DIZZ_CIDIZZINESSLIGHTHEADEDNESS	VARCHAR2
cpD120RSN - Asymptomatic hypotension (Systolic BP < 90)	*D120HYPO_CIASYPTOMATICHPOTENSION_C	NUMBER
	*D120HYPO_CIASYPTOMATICHPOTENSION	VARCHAR2
cpD120RSN - Event of Interest (complete EVNTINT form)	D120EVNT_CIEVENTINTEREST_C	NUMBER
	D120EVNT_CIEVENTINTEREST	VARCHAR2
cpD120RSN - SAE	D120SAE_D120SAEN_C	**NUMBER
	D120SAE_D120SAEN	VARCHAR2
cpD120RSN - D120SAEN	D120SAEN	VARCHAR2
cpD120RSN - Other	D120OTH_D120RSSP_C	**NUMBER
	D120OTH_D120RSSP	VARCHAR2
cpD120RSN - D120RSSP	D120RSSP	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different. [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: PATIENT PREFERENCE (PREF) [frPREF]	
Patient Preference [stPREF1]	
1. *	Patient response to question during which study phase did you feel better? [Patient response to question during which study phase did you feel better]
	[PTPREF] [N: 1] <input type="radio"/> Phase 1 [N: 2] <input type="radio"/> Phase 2 [N: 3] <input type="radio"/> No Preference [N: 97] <input type="radio"/> Not Done
Key: [*] = Item is required	

RDE Analytics: RD_FRPREF		
Data Variable RefName	RD Column Name	Column Data Type
PTPREF	PTPREF_C	NUMBER
	PTPREF	VARCHAR2
	PTPREF_ND	VARCHAR2

HFN_NEAT: ACCELEROMETER LOG (DEVICE) [frDEVICE]					
Accelerometer [stDEVICE1]					
1.* ✓	Was accelerometer dispensed? [Was accelerometer dispensed]	[ACCDISP] [N: 1] <input type="radio"/> Yes (click Add Entry to record each Accelerometer dispensed) [N: 0] <input type="radio"/> [ACCNDRSN] No If No, specify reason: [N: 1] <input type="radio"/> Subject withdrew consent [N: 98] <input type="radio"/> [ACCNDSP] Other Specify: A200			
2.	Accelerometer Serial Number	Accelerometer Dispense Date	Replaced	Accelerometer Returned	Received by Core Lab
Accelerometer Details Entry [rsDEVICE2]					
2.1* ✓	Accelerometer Serial Number [Accelerometer Serial Number]	[ACCSN] A20			
2.2* ✓	Accelerometer Dispense Date [Accelerometer Dispense Date]	[ACCDSDT] Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2018)			
2.3* ✓	Was this an unscheduled/replacement device? [Replaced]	[ACCRPLC] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No			
2.4* ✓	Was Accelerometer Returned? [Accelerometer Returned]	[ACCRT] [N: 1] <input type="radio"/> [cpACDT] Yes [ACCRTDT] Date Returned: Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2018) [ACSDDTDT] Date Sent to Core Lab: Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2018) [N: 0] <input type="radio"/> No			
2.5 ✓	Received by Core Lab? [Received by Core Lab]	[ACCCDT] [N: 1] <input type="radio"/> [ACCRCDT] Yes Date Received: Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2018) [N: 0] <input type="radio"/> No			
2.6	Comments [Lab Comments]	[ACCCOMM] A200			
Key: [*] = Item is required [✓] = Source verification required					

RDE Analytics: RD_FRDEVICE		
Data Variable RefName	RD Column Name	Column Data Type
ACCDISP	ACCDISP_C	NUMBER
	ACCDISP	VARCHAR2
	ACCDISP_ND	VARCHAR2
ACCDISP - ACCNDRSN	ACCNDRSN_C	NUMBER
	ACCNDRSN	VARCHAR2
ACCDISP - ACCNDSP	ACCNDSP	VARCHAR2
RD_FRDEVICE_RSDEVICE2		
ACCSN	ACCSN	VARCHAR2
	ACCSN_ND	VARCHAR2
ACCDSDT	ACCDSDT	DATE
	ACCDSDT_DTS	VARCHAR2
	ACCDSDT_ND	VARCHAR2
ACCRPLC	ACCRPLC_C	NUMBER
	ACCRPLC	VARCHAR2

	ACCRPLC_ND	VARCHAR2
ACCRT	ACCRT_C	**NUMBER
	ACCRT	VARCHAR2
	ACCRT_ND	VARCHAR2
ACCRT - ACCRTDT	ACCRTDT	DATE
	ACCRTDT_DTS	VARCHAR2
	ACCRTDT_DTR	VARCHAR2
ACCRT - ACSDDTDT	ACSDDTDT	DATE
	ACSDDTDT_DTS	VARCHAR2
	ACSDDTDT_DTR	VARCHAR2
ACCCDT	ACCCDT_C	**NUMBER
	ACCCDT	VARCHAR2
	ACCCDT_ND	VARCHAR2
ACCCDT - ACCRCDT	ACCRCDT	DATE
	ACCRCDT_DTS	VARCHAR2
	ACCRCDT_DTR	VARCHAR2
ACCCOMM	ACCCOMM	VARCHAR2
	ACCCOMM_ND	VARCHAR2

Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.

HFN_NEAT: PHONE VISIT LOG (PHONE) - Repeating Form [frPHONE]	
#	Phone Visit Performed
1	Phone Visit Date
Phone Visit [stPHONE1]	
1.* ✓	Phone Visit Performed [Phone Visit Performed]
	[PHONEVT] [N: 1] <input type="radio"/> Week 2 Telephone Visit [N: 2] <input type="radio"/> Week 3 Telephone Visit [N: 3] <input type="radio"/> Week 4 Telephone Visit [N: 4] <input type="radio"/> Week 5 Telephone Visit [N: 5] <input type="radio"/> Week 6 Telephone Visit [N: 6] <input type="radio"/> Week 8 Telephone Visit [N: 7] <input type="radio"/> Week 9 Telephone Visit [N: 8] <input type="radio"/> Week 10 Telephone Visit [N: 9] <input type="radio"/> Week 11 Telephone Visit [N: 10] <input type="radio"/> Week 12 Telephone Visit
2.* ✓	Phone Visit Date [Phone Visit Date]
	[PHONDT] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2018)
Key: [*] = Item is required [✓] = Source verification required	

RDE Analytics: RD_FRPHONE		
Data Variable RefName	RD Column Name	Column Data Type
PHONEVT	PHONEVT_C	NUMBER
	PHONEVT	VARCHAR2
	PHONEVT_ND	VARCHAR2
PHONDT	PHONDT	DATE
	PHONDT_DTS	VARCHAR2
	PHONDT_ND	VARCHAR2

HFN_NEAT: 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
Hospitalization Information [stREHOSP1]													
1.*	Admission Date [Admission Date]												
						[ADMITDT] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2018)							
2.*	Was this an unplanned hospitalization? [Unplanned?]												
						[ELECTAD] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No							
3.*	Discharge Date [Discharge Date]												
						[INREHOSP] [N:1] <input type="radio"/> [REDCHGDT] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2018) [N:2] <input type="radio"/> Remains hospitalized [N:3] <input type="radio"/> Subject died while hospitalized							
4.*	Primary reason for admission [Primary reason for admission]												
						[HOSPRS] [N:1] <input type="radio"/> Heart failure [N:2] <input type="radio"/> Acute coronary syndrome [N:3] <input type="radio"/> Cerebral Vascular Accident (CVA)/stroke [N:4] <input type="radio"/> Atrial arrhythmia [N:5] <input type="radio"/> Ventricular arrhythmia [N:6] <input type="radio"/> Sudden death with resuscitation [N:7] <input type="radio"/> [PRMCRDSP] Other cardiovascular Specify: A100 [N:8] <input type="radio"/> [PRMNCSP] Other non-cardiovascular Specify: A100							
5.	Contributing causes (check all that apply) [Contributing causes]												
						[cpCONTC AUS] [CONHF] [N:1] <input type="checkbox"/> Heart failure [CONACS] [N:1] <input type="checkbox"/> Acute coronary syndrome [CONCVA] [N:1] <input type="checkbox"/> Cerebral Vascular Accident (CVA)/stroke [CONARRH] [N:1] <input type="checkbox"/> Atrial arrhythmia [CONVENTA] [N:1] <input type="checkbox"/> Ventricular arrhythmia [RENFALL] [N:1] <input type="checkbox"/> Renal Failure [CONSDTH] [N:1] <input type="checkbox"/> Sudden death with resuscitation [CONOTHC] [N:1] <input type="checkbox"/> Other cardiovascular [CONOTHNC] [N:1] <input type="checkbox"/> 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] <input type="checkbox"/> [cpMANIFEST] [HFDYSP] [N:1] <input type="checkbox"/> Dyspnea [HFORTHO] [N:1] <input type="checkbox"/> Orthopnea [HFNOCDYS] [N:1] <input type="checkbox"/> Paroxysmal nocturnal dyspnea [HFEDEMA] [N:1] <input type="checkbox"/> Edema [HFRALES] [N:1] <input type="checkbox"/> Pulmonary rales [HFJVD] [N:1] <input type="checkbox"/> Jugular venous distension [HFGALLOP] [N:1] <input type="checkbox"/> S3 Gallop							

		<p>[HFHYPO] [N: 1] <input type="checkbox"/> Hypotension or cardiogenic shock not occurring in the context of an acute myocardial infarction or as the consequence of an arrhythmia</p> <p>[HFEVDNCE] [N: 1] <input type="checkbox"/> Other clinical evidence of new or worsening heart failure (eg. weight gain, or confinement to bed predominantly due to heart failure symptoms)</p> <p>[HFOTHR] [N: 1] <input type="checkbox"/> [HFOTHRSP] Other, specify A100</p> <p>[HFUNK] [N: 1] <input type="checkbox"/> Unknown [N: 0] <input checked="" type="radio"/> None</p>
7.*	<p>Indicate any Biomarker or radiographic evidence consistent with heart failure during this hospitalization (check all that apply) [Biomarker or radiographic evidence]</p>	<p>[RADIOEV] [N: 1] <input checked="" type="radio"/> [cpRADIOEV] [INCBNP] [N: 1] <input type="checkbox"/> Documented increased or increasing levels of a natriuretic peptide (BNP or NTproBNP)</p> <p>[HFIMGING] [N: 1] <input type="checkbox"/> Documented worsening pulmonary congestion or pulmonary edema on chest X-ray or other generally recognized imaging pattern.</p> <p>[BIOOTH] [N: 1] <input type="checkbox"/> [BIOOTHSP] Other, specify A100</p> <p>[BIOUNK] [N: 1] <input type="checkbox"/> Unknown [N: 0] <input checked="" type="radio"/> None</p>
8.*	<p>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]</p>	<p>[PHARMINT] [N: 1] <input checked="" type="radio"/> [cpPHARMINT] [INITHRPY] [N: 1] <input type="checkbox"/> Initiation of intravenous diuretic, inotropic, or vasodilator therapy</p> <p>[ORLTHPY] [N: 1] <input type="checkbox"/> Significant addition or increase in oral heart failure therapy</p> <p>[UPTITRTE] [N: 1] <input type="checkbox"/> Up-titration of intravenous therapy, if already on therapy</p> <p>[MECHSURG] [N: 1] <input type="checkbox"/> 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.</p> <p>[OTHINTVN] [N: 1] <input type="checkbox"/> [INTVNSP] Other, specify A100</p> <p>[INTVUNK] [N: 1] <input type="checkbox"/> Unknown [N: 0] <input checked="" type="radio"/> None</p>
9.*	<p>Was a heart catheterization performed? [Heart Cath?]</p>	<p>[PROCATH] [N: 1] <input checked="" type="radio"/> [cpPROCATH] Yes [LCATH] [N: 1] <input type="checkbox"/> Left [RCATH] [N: 1] <input type="checkbox"/> Right [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
10.*	<p>Revascularization [Revascularization]</p>	<p>[REVASC] [N: 1] <input checked="" type="radio"/> [cpREVASC] Yes [CABG] [N: 1] <input type="checkbox"/> CABG [PCI] [N: 1] <input type="checkbox"/> PCI [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
11.*	<p>Pacemaker/ICD [Pacemaker/ICD]</p>	<p>[HOSPICD] [N: 1] <input checked="" type="radio"/> [PACTYPE] Yes [N: 1] <input type="radio"/> Pacemaker (single/dual) [N: 2] <input type="radio"/> Biventricular Pacemaker with ICD [N: 3] <input type="radio"/> Biventricular Pacemaker without ICD [N: 4] <input type="radio"/> ICD only (single/dual)</p>

		<input type="radio"/> No <input type="radio"/> Unknown
12.*	Heart Transplant [Heart Transplant]	[PROHTRAN] [N:1] <input type="radio"/> [PRHTRDDT] Yes Date of Transplant: Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2018) <input type="radio"/> No <input type="radio"/> Unknown
13.*	LVAD [LVAD]	[LVAD] [N:1] <input type="radio"/> [LVADDT] Yes Date of Implant: Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2018) <input type="radio"/> No <input type="radio"/> Unknown
Key: [*] = Item is required [v] = Source verification required		

RDE Analytics: RD_FRREHOSP		
Data Variable RefName	RD Column Name	Column Data Type
ADMITDT	ADMITDT	DATE
	ADMITDT_DTS	VARCHAR2
	ADMITDT_DTR	VARCHAR2
	ADMITDT_ND	VARCHAR2
ELECTAD	ELECTAD_C	NUMBER
	ELECTAD	VARCHAR2
	ELECTAD_ND	VARCHAR2
INREHOSP	INREHOSP_C	**NUMBER
	INREHOSP	VARCHAR2
	INREHOSP_ND	VARCHAR2
INREHOSP - REDCHGDT	REDCHGDT	DATE
	REDCHGDT_DTS	VARCHAR2
	REDCHGDT_DTR	VARCHAR2
HOSPRS	HOSPRS_C	NUMBER
	HOSPRS	VARCHAR2
	HOSPRS_ND	VARCHAR2
HOSPRS - PRMCRDSP	PRMCRDSP	VARCHAR2
HOSPRS - PRMNCSP	PRMNCSP	VARCHAR2
cpCONCAUS	CPCONCAUS_ND	VARCHAR2
cpCONCAUS - Heart failure	CONHF_CIHEARTFAILURE_C	NUMBER
	CONHF_CIHEARTFAILURE	VARCHAR2
cpCONCAUS - Acute coronary syndrome	*CONACS_CIACUTECORONARYSYNDROME1_C	NUMBER
	*CONACS_CIACUTECORONARYSYNDROME1	VARCHAR2
cpCONCAUS - Cerebral Vascular Accident (CVA)/stroke	*CONCVA_CICEREBRALVASCULARACCIDENT1_C	NUMBER
	*CONCVA_CICEREBRALVASCULARACCIDENT1	VARCHAR2
	*CONARRH_CIATRIALARRHYTHMIA1_C	NUMBER
cpCONCAUS - Atrial arrhythmia	*CONARRH_CIATRIALARRHYTHMIA1	VARCHAR2
	*CONVENTA_CIVENTRICULARARRHYTHMIA1_C	NUMBER
cpCONCAUS - Ventricular arrhythmia	*CONVENTA_CIVENTRICULARARRHYTHMIA1	VARCHAR2
	RENFAIL_CIRENALFAILURE_C	NUMBER
cpCONCAUS - Renal Failure	RENFAIL_CIRENALFAILURE	VARCHAR2
	*CONSDTH_CISUDDENDEATHRESUSCITATION1_C	NUMBER
cpCONCAUS - Sudden death with resuscitation	*CONSDTH_CISUDDENDEATHRESUSCITATION1	VARCHAR2
	*CONOTH_CIOTHERCARDIOVASCULAR1_C	NUMBER
cpCONCAUS - Other cardiovascular	*CONOTH_CIOTHERCARDIOVASCULAR1	VARCHAR2
	*CONOTHNC_CIOTHERNONCARDIOVASCULAR1_C	NUMBER
cpCONCAUS - Other non-cardiovascular		

	*CONOTHNC_C IOTHERNONCARDIOVASCULAR1	VARCHAR2
MANIFEST	MANIFEST_C	**NUMBER
	MANIFEST	VARCHAR2
	MANIFEST_ND	VARCHAR2
MANIFEST - Dyspnea	HFDYSP_CIDYSPNEA_C	NUMBER
	HFDYSP_CIDYSPNEA	VARCHAR2
MANIFEST - Orthopnea	HFORTHO_C IORTHOPNEA1_C	NUMBER
	HFORTHO_C IORTHOPNEA1	VARCHAR2
MANIFEST - Paroxysmal nocturnal dyspnea	*HFNOCDYS_C IPAROXYSMALNOCTURNALDYPNEA1_C	NUMBER
	*HFNOCDYS_C IPAROXYSMALNOCTURNALDYPNEA1	VARCHAR2
MANIFEST - Edema	HFEDEMA_C IEDEMA_C	NUMBER
	HFEDEMA_C IEDEMA	VARCHAR2
MANIFEST - Pulmonary rales	HFRALES_C IPULMONARYRALES_C	NUMBER
	HFRALES_C IPULMONARYRALES	VARCHAR2
MANIFEST - Jugular venous distension	*HFJVD_C IJUGULARVENOUSDISTENSION_C	NUMBER
	*HFJVD_C IJUGULARVENOUSDISTENSION	VARCHAR2
MANIFEST - S3 Gallop	HFGALLOP_C IS3GALLOP_C	NUMBER
	HFGALLOP_C IS3GALLOP	VARCHAR2
MANIFEST - Hypotension or cardiogenic shock not occurring in the context of an acute myocardial infarction or as the consequence of an arrhythmia	*HFHYPO_C IHYPOTENSIONCARDIOGENICSHOCK_C	NUMBER
	*HFHYPO_C IHYPOTENSIONCARDIOGENICSHOCK	VARCHAR2
MANIFEST - Other clinical evidence of new or worsening heart failure (eg. weight gain, or confinement to bed predominantly due to heart failure symptoms)	*HFEVDNCE_C IOTHCLINICALEVIDENCE_C	NUMBER
	*HFEVDNCE_C IOTHCLINICALEVIDENCE	VARCHAR2
MANIFEST - Other	HFOTHR_HFOTHRSP_C	**NUMBER
	HFOTHR_HFOTHRSP	VARCHAR2
MANIFEST - HFOTHRSP	HFOTHRSP	VARCHAR2
MANIFEST - Unknown	HFUNK_C IUNKNOWN1_C	NUMBER
	HFUNK_C IUNKNOWN1	VARCHAR2
RADIOEV	RADIOEV_C	**NUMBER
	RADIOEV	VARCHAR2
	RADIOEV_ND	VARCHAR2
RADIOEV - Documented increased or increasing levels of a natriuretic peptide (BNP or NTproBNP)	*INCBNP_C IINCREASEDNATRIURETICPEPTIDE_C	NUMBER
	*INCBNP_C IINCREASEDNATRIURETICPEPTIDE	VARCHAR2
RADIOEV - Documented worsening pulmonary congestion or pulmonary edema on chest X-ray or other generally recognized imaging pattern.	*HFIMGING_C IDOCWORSENINGPULMONARYCONGESTION_C	NUMBER
	*HFIMGING_C IDOCWORSENINGPULMONARYCONGESTION	VARCHAR2
RADIOEV - Other	BIOOTH_BIOOTHSP_C	**NUMBER
	BIOOTH_BIOOTHSP	VARCHAR2
RADIOEV - BIOOTHSP	BIOOTHSP	VARCHAR2
RADIOEV - Unknown	BIOUNK_C IUNKNOWN1_C	NUMBER
	BIOUNK_C IUNKNOWN1	VARCHAR2
PHARMINT	PHARMINT_C	**NUMBER
	PHARMINT	VARCHAR2
	PHARMINT_ND	VARCHAR2
PHARMINT - Initiation of intravenous diuretic, inotropic, or vasodilator therapy	*INITHRPY_C IINITIATIONOFTHERAPY_C	NUMBER
	*INITHRPY_C IINITIATIONOFTHERAPY	VARCHAR2
PHARMINT - Significant addition or increase in oral heart failure therapy	*ORLTHPY_C IORALHEARTFAILURETHERAPY_C	NUMBER
	*ORLTHPY_C IORALHEARTFAILURETHERAPY	VARCHAR2
PHARMINT - Up-titration of intravenous therapy, if already on therapy	*UPTITRTE_C IUPTITRATIONINTRAVENOUSTHERAPY_C	NUMBER
	*UPTITRTE_C IUPTITRATIONINTRAVENOUSTHERAPY	VARCHAR2
PHARMINT - 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.	*MECHSURG_C IINITIATIONMECHSURGICALINTERVENTION_C	NUMBER
	*MECHSURG_C IINITIATIONMECHSURGICALINTERVENTION	VARCHAR2
PHARMINT - Other	OTHINTVN_INTVNSP_C	**NUMBER
	OTHINTVN_INTVNSP	VARCHAR2
PHARMINT - INTVNSP	INTVNSP	VARCHAR2
PHARMINT - Unknown	INTVUNK_C IUNKNOWN1_C	NUMBER

	INTVUNK_CIUNKNOWN1	VARCHAR2
PROCATH	PROCATH_C	**NUMBER
	PROCATH	VARCHAR2
	PROCATH_ND	VARCHAR2
PROCATH - Left	LCATH_CILEFT_C	NUMBER
	LCATH_CILEFT	VARCHAR2
PROCATH - Right	RCATH_CIRIGHT_C	NUMBER
	RCATH_CIRIGHT	VARCHAR2
REVASC	REVASC_C	**NUMBER
	REVASC	VARCHAR2
	REVASC_ND	VARCHAR2
REVASC - CABG	CABG_CICABG_C	NUMBER
	CABG_CICABG	VARCHAR2
REVASC - PCI	PCI_CIPCI_C	NUMBER
	PCI_CIPCI	VARCHAR2
HOSPICD	HOSPICD_C	**NUMBER
	HOSPICD	VARCHAR2
	HOSPICD_ND	VARCHAR2
HOSPICD - PACTYPE	PACTYPE_C	NUMBER
	PACTYPE	VARCHAR2
PROHTRAN	PROHTRAN_C	**NUMBER
	PROHTRAN	VARCHAR2
	PROHTRAN_ND	VARCHAR2
PROHTRAN - PRHTRDDT	PRHTRDDT	DATE
	PRHTRDDT_DTS	VARCHAR2
	PRHTRDDT_DTR	VARCHAR2
LVAD	LVAD_C	**NUMBER
	LVAD	VARCHAR2
	LVAD_ND	VARCHAR2
LVAD - LVADDT	LVADDT	DATE
	LVADDT_DTS	VARCHAR2
	LVADDT_DTR	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different. [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: EMERGENCY DEPARTMENT VISIT (EDVISIT) - Repeating Form [frEDVISIT]		
#	Encounter Date	Primary reason for emergency department visit
1		
ED Visit Information [stEDVISIT1]		
1.*	Encounter Date [Encounter Date]	[UNSCHDT] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2018)
2.*	Primary reason for emergency department visit [Primary reason for emergency department visit]	[UNSCREAS] [N: 1] <input type="radio"/> [cpUNSCREAS] Heart failure [DECOMP] Signs or symptoms indicating decompensated heart failure [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [EDIVTX] Did subject receive IV treatment for heart failure? [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 2] <input type="radio"/> Other cardiovascular [N: 3] <input type="radio"/> Other non-cardiovascular
Key: [*] = Item is required [✓] = Source verification required		

RDE Analytics: RD_FREDVISIT		
Data Variable RefName	RD Column Name	Column Data Type
UNSCHDT	UNSCHDT	DATE
	UNSCHDT_DTS	VARCHAR2
	UNSCHDT_DTR	VARCHAR2
	UNSCHDT_ND	VARCHAR2
UNSCREAS	UNSCREAS_C	**NUMBER
	UNSCREAS	VARCHAR2
	UNSCREAS_ND	VARCHAR2
UNSCREAS - DECOMP	DECOMP_C	NUMBER
	DECOMP	VARCHAR2
UNSCREAS - EDIVTX	EDIVTX_C	NUMBER
	EDIVTX	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: SERIOUS ADVERSE EVENTS (SAE) - Repeating Form [frSAE]																							
#	SAE Number	SAE Onset Date	Stop Date	Outcome	Severity	Action Taken	Serious Criteria	Relationship to Study Drug	Alternate Causes of SAE	Unexpected?	SAE NARRATIVES	Relevant Labs?	Relevant Labs/Tests	Relevant Concomitant Medications?	Relevant Concomitant Medications	PI Verification	PI Verification Date/Time	MedDRA Preferred Term	Medical Monitor Expectededness	Medical Monitor Relationship Assessment	Medical Monitor Rationale	Medical Monitor Verification	Medical Monitor Verification 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 Number]										[AENUM] A4												
2.*	Serious Event Term ✓ [SAE]										[AETERM] A200												
3.*	SAE Onset Date/Time ✓ [Onset Date]										[AESTDTM] Req/Unk [v] / Req [v] / Req [v] (2014-2018) Req/Unk [v] : Req/Unk [v] 24-hour clock												
4.*	SAE Stop Date/Time ✓ [Stop Date]										[AESTOP] [N:1] <input type="radio"/> [AESPDTM] Req/Unk [v] / Req/Unk [v] / Req/Unk [v] (2014-2018) Req/Unk [v] : Req/Unk [v] 24-hour clock [N:2] <input type="radio"/> Ongoing												
5.*	Outcome [Outcome]										[AEOUT] [N:1] <input type="radio"/> Resolved [N:2] <input type="radio"/> Resolved with sequelae [N:3] <input type="radio"/> Unresolved [N:4] <input type="radio"/> Death (complete DEATH form) [N:99] <input type="radio"/> Unknown												
6.*	Severity [Severity]										[SEVERITY] [N:1] <input type="radio"/> Mild [N:2] <input type="radio"/> Moderate [N:3] <input type="radio"/> Severe												
7.*	Action Taken Regarding Study Drug ✓ [Action Taken]										[AEACN] [N:1] <input type="radio"/> None [N:2] <input type="radio"/> [cpAEACN1] Drug interrupted [INTDABT] Did the SAE diminish/abate after the study drug was interrupted? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [INTREAP] Did the SAE reappear after study drug was re-introduced? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:96] <input type="radio"/> Not Applicable [N:3] <input type="radio"/> [cpAEACN2] Drug discontinued [DCTDABT] Did the SAE diminish/abate after the study drug was discontinued? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [DCTPRIM] Is the SAE the primary reason for study drug permanent discontinuation? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:4] <input type="radio"/> [cpAEACN3] Dosage Decreased [DECABT] Did the SAE diminish/abate after the study drug was reduced? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [DECREAP] Did the SAE reappear after study drug was re-introduced? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:96] <input type="radio"/> Not Applicable												

		<p>[N: 5] <input type="radio"/> Dosage Increased [N: 99] <input type="radio"/> Unknown [N: 96] <input checked="" type="radio"/> Not Applicable</p>
<p>8.* <input checked="" type="checkbox"/> Serious Criteria [Serious Criteria]</p>		<p>[cpSERICRIT] Check all that apply: [SAEDEATH] [N: 1] <input type="checkbox"/> Death (Complete Death form) [SAELIFE] [N: 1] <input type="checkbox"/> Life-Threatening [SAEPRO] [N: 1] <input type="checkbox"/> Require inpatient hospitalization or prolongation of existing hospitalization [SAEDIS] [N: 1] <input type="checkbox"/> Persistent or significant disability/incapacity [SAENOM] [N: 1] <input type="checkbox"/> Congenital anomaly or birth defect [SAEIMPNT] [N: 1] <input type="checkbox"/> Important medical event</p>
<p>9.* <input checked="" type="checkbox"/> What is the relationship to study drug? [Relationship to Study Drug]</p>		<p>[AEREL] [N: 1] <input type="radio"/> Not related [N: 2] <input type="radio"/> Unlikely related [N: 3] <input checked="" type="radio"/> [PRRATREL] Possibly related Rationale for positive relationship: A100 [N: 4] <input checked="" type="radio"/> [RRRATREL] Related Rationale for positive relationship: A100</p>
<p>10.* <input checked="" type="checkbox"/> Possible alternate causes of the SAE (check all that apply) [Alternate Causes of SAE]</p>		<p>[cpALTC AUS] [ALTCNON] [N: 1] <input type="checkbox"/> None (only applicable if relationship is possibly related or related) [ALTCDIS] [N: 1] <input type="checkbox"/> [ALTDISSP] Primary disease under study Specify: A200 [ALTCPRO] [N: 1] <input type="checkbox"/> [ALTCPSP] Study procedure Specify: A200 [ALTCCELL] [N: 1] <input type="checkbox"/> [ALTCCISP] Concomitant illness Specify: A200 [ALTCMED] [N: 1] <input type="checkbox"/> [ALTCMESP] Concomitant medication Specify: A200 [ALTCOTH] [N: 1] <input type="checkbox"/> [ALTCSSP] Other cause Specify: A200</p>
<p>11.* <input checked="" type="checkbox"/> Was this event unexpected per product labeling? [Unexpected?]</p>		<p>[SAEUNEX] [N: 1] <input type="radio"/> Yes (If Yes, and Possibly Related or Related complete the following sections). [N: 0] <input checked="" type="radio"/> No</p>
Narrative		
<p>12.</p>		
<p>SAE NARRATIVES Entry [rsSAE2]</p>		
<p>Provide a summary in chronological order of the clinical course of this SAE from onset through resolution. 1. Presenting signs and</p>	<p>[PICAUSE] _____</p>	

12.1*	symptoms; 2. Treatments and response to treatment(s); 3. Subjects status at time of report and/or final outcome, as applicable. [Narrative]		A200		
Relevant Labs/Tests [stSAE3]					
13.*	Were there any relevant Labs/tests drawn for this SAE? [Relevant Labs?]		[SAELABYN] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No		
14.	Test Date	Lab/Test	Test Result	Unit	Normal Range
Relevant Labs/Tests Entry [rsSAE4]					
14.1*	Test Date [Test Date]		[TESTDT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2018)		
14.2*	Relevant lab/diagnostic test [Lab/Test]		[TESTNAME] A200		
14.3*	Test Result [Test Result]		[TESTRST] A200		
14.4*	Test Result unit [Unit]		[TESTRSTU] A200		
14.5*	Test Result normal range [Normal Range]		[NRANGE] A200		
Relevant Concomitant Medications [stSAE5]					
15.*	Were there relevant Concomitant Medications for this SAE? [Relevant Concomitant Medications?]		[CMINFYN] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No		
16.	Concomitant Medication	Start Date	Stop Date	Dose	Unit Frequency
Relevant Concomitant Medications Entry [rsSAE6]					
16.1*	Concomitant Medication Name [Concomitant Medication]		[CMINFID] A20		
16.2*	Start Date [Start Date]		[MEDSTDT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> (2000-2018) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock		
16.3*	Stop Date [Stop Date]		[MEDCONT] [N:1] <input type="radio"/> [MEDSPDTM] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> (2014-2018) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock [N:2] <input type="radio"/> Ongoing		
16.4*	Dose [Dose]		[MEDDOSE] xxxxxxxx.		
16.5*	Unit [Unit]		[MEDUNIT] A20		
16.6*	Frequency [Frequency]		[MEDFREQ] A20		
Primary Investigator SAE Electronic Verification [stSAE7]					
17.*	I verify that this SAE report form accurately displays the results of the examination, tests, evaluations and treatments noted within. [PI Verification]		[PICONFRM] [N:1] <input type="checkbox"/> Yes		
18.	Evaluation Date and Time (Electronic Verification non-enterable system generated) [read-only] [PI Verification Date/Time]		[PICONDT] Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2018)		

		Req <input type="checkbox"/> : Req <input type="checkbox"/> 24-hour clock
Medical Monitor Review [stSAE8]		
19.	MedDRA Preferred Term [MedDRA Preferred Term]	[AEMEDDRA] A100
20.	Was adverse event expected or unexpected according to the Investigator Brochure? [Medical Monitor Expectededness]	[MMEXPECT] [N: 1] <input type="radio"/> Expected [N: 2] <input type="radio"/> Unexpected
21.	Medical Monitor assessment of relationship of SAE to study drug [Medical Monitor Relationship Assessment]	[MMSCYCAU] [N: 1] <input type="radio"/> Not related [N: 2] <input type="radio"/> Unlikely related [N: 3] <input type="radio"/> Possibly related [N: 4] <input type="radio"/> Related
22.	Medical Monitor Rationale for Assessment [Medical Monitor Rationale]	[ASRATION] A200
Medical Monitor Electronic Verification [stSAE9]		
23.	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 Verification]	[SAEMMSIG] [N: 1] <input type="checkbox"/> Yes
24.	Evaluation Date and Time (Electronic Verification non-enterable system generated) [read-only] [Medical Monitor Verification Date/Time]	[MMSIGDTM] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2018) Req <input type="checkbox"/> : Req <input type="checkbox"/> 24-hour clock
Key: [*] = Item is required [<input checked="" type="checkbox"/>] = Source verification required		

RDE Analytics: RD_FRSAE		
Data Variable RefName	RD Column Name	Column Data Type
AENUM	AENUM	VARCHAR2
	AENUM_ND	VARCHAR2
AETERM	AETERM	VARCHAR2
	AETERM_ND	VARCHAR2
AESTDTM	AESTDTM	DATE
	AESTDTM_DTS	VARCHAR2
	AESTDTM_DTR	VARCHAR2
	AESTDTM_ND	VARCHAR2
AESTOP	AESTOP_C	**NUMBER
	AESTOP	VARCHAR2
	AESTOP_ND	VARCHAR2
AESTOP - AESPDTM	AESPDTM	DATE
	AESPDTM_DTS	VARCHAR2
	AESPDTM_DTR	VARCHAR2
AEOUT	AEOUT_C	NUMBER
	AEOUT	VARCHAR2
	AEOUT_ND	VARCHAR2
SEVERITY	SEVERITY_C	NUMBER
	SEVERITY	VARCHAR2
	SEVERITY_ND	VARCHAR2
AEACN	AEACN_C	NUMBER
	AEACN	VARCHAR2
	AEACN_ND	VARCHAR2
AEACN - INTDABT	INTDABT_C	NUMBER
	INTDABT	VARCHAR2
AEACN - INTREAP	INTREAP_C	NUMBER
	INTREAP	VARCHAR2
AEACN - DCTDABT	DCTDABT_C	NUMBER

	DCTDABT	VARCHAR2
AEACN - DCTPRIM	DCTPRIM_C	NUMBER
	DCTPRIM	VARCHAR2
AEACN - DECABT	DECABT_C	NUMBER
	DECABT	VARCHAR2
AEACN - DECREAP	DECREAP_C	NUMBER
	DECREAP	VARCHAR2
cpSERICRIT	CPSERICRIT_ND	VARCHAR2
cpSERICRIT - Death (Complete Death form)	SAEDEATH_CIDEATH1_C	NUMBER
	SAEDEATH_CIDEATH1	VARCHAR2
cpSERICRIT - Life-Threatening	SAELIFE_CILIFETHREATENING_C	NUMBER
	SAELIFE_CILIFETHREATENING	VARCHAR2
cpSERICRIT - Require inpatient hospitalization or prolongation of existing hospitalization	*SAEPRO_CIREQUIREINPATIENTHOSP_C	NUMBER
	*SAEPRO_CIREQUIREINPATIENTHOSP	VARCHAR2
cpSERICRIT - Persistent or significant disability/incapacity	*SAEDIS_CIPERSISTENTSIGNIFICANTDISABILITY_C	NUMBER
	*SAEDIS_CIPERSISTENTSIGNIFICANTDISABILITY	VARCHAR2
cpSERICRIT - Congenital anomaly or birth defect	*SAENOM_CICONGENITALANOMALYBIRTHDEFECT_C	NUMBER
	*SAENOM_CICONGENITALANOMALYBIRTHDEFECT	VARCHAR2
cpSERICRIT - Important medical event	*SAEIMPNT_CIIMPORTANTMEDICALEVENT_C	NUMBER
	*SAEIMPNT_CIIMPORTANTMEDICALEVENT	VARCHAR2
AEREL	AEREL_C	NUMBER
	AEREL	VARCHAR2
	AEREL_ND	VARCHAR2
AEREL - PRRATREL	PRRATREL	VARCHAR2
AEREL - RRATREL	RRATREL	VARCHAR2
cpALTCAUS	CPALTCAUS_ND	VARCHAR2
cpALTCAUS - None (only applicable if relationship is possibly related or related)	ALTCNON_CISAECAUSENONE_C	NUMBER
	ALTCNON_CISAECAUSENONE	VARCHAR2
cpALTCAUS - Primary disease under study	ALTCDIS_ALTDISSP_C	**NUMBER
	ALTCDIS_ALTDISSP	VARCHAR2
cpALTCAUS - ALTDISSP	ALTDISSP	VARCHAR2
cpALTCAUS - Study procedure	ALTCPRO_ALTCPSP_C	**NUMBER
	ALTCPRO_ALTCPSP	VARCHAR2
cpALTCAUS - ALTCPSP	ALTCPSP	VARCHAR2
cpALTCAUS - Concomitant illness	ALTCCELL_ALTCCISP_C	**NUMBER
	ALTCCELL_ALTCCISP	VARCHAR2
cpALTCAUS - ALTCCISP	ALTCCISP	VARCHAR2
cpALTCAUS - Concomitant medication	ALTCMED_ALTCMESP_C	**NUMBER
	ALTCMED_ALTCMESP	VARCHAR2
cpALTCAUS - ALTCMESP	ALTCMESP	VARCHAR2
cpALTCAUS - Other	ALTCOTH_ALTCSSP_C	**NUMBER
	ALTCOTH_ALTCSSP	VARCHAR2
cpALTCAUS - ALTCSSP	ALTCSSP	VARCHAR2
SAEUNEX	SAEUNEX_C	NUMBER
	SAEUNEX	VARCHAR2
	SAEUNEX_ND	VARCHAR2
SAELABYN	SAELABYN_C	NUMBER
	SAELABYN	VARCHAR2
	SAELABYN_ND	VARCHAR2
CMINFYN	CMINFYN_C	NUMBER
	CMINFYN	VARCHAR2
	CMINFYN_ND	VARCHAR2
PICONFRM	PICONFRM_ND	VARCHAR2
PICONFRM - Yes	PICONFRM_CIYES_C	NUMBER

	PICONFRM_C IYES	VARCHAR2
PICONDT	PICONDT	DATE
	PICONDT_DTS	VARCHAR2
	PICONDT_ND	VARCHAR2
AEMEDDRA	AEMEDDRA	VARCHAR2
	AEMEDDRA_ND	VARCHAR2
MMEXPECT	MMEXPECT_C	NUMBER
	MMEXPECT	VARCHAR2
	MMEXPECT_ND	VARCHAR2
MMSYCAU	MMSYCAU_C	NUMBER
	MMSYCAU	VARCHAR2
	MMSYCAU_ND	VARCHAR2
ASRATION	ASRATION	VARCHAR2
	ASRATION_ND	VARCHAR2
SAEMMSIG	SAEMMSIG_ND	VARCHAR2
SAEMMSIG - Yes	SAEMMSIG_C IYES_C	NUMBER
	SAEMMSIG_C IYES	VARCHAR2
MMSIGDTM	MMSIGDTM	DATE
	MMSIGDTM_DTS	VARCHAR2
	MMSIGDTM_ND	VARCHAR2
RD_FRSAE_RSSAE2		
PICAUSE	PICAUSE	VARCHAR2
	PICAUSE_ND	VARCHAR2
RD_FRSAE_RSSAE4		
TESTDT	TESTDT	DATE
	TESTDT_DTS	VARCHAR2
	TESTDT_DTR	VARCHAR2
	TESTDT_ND	VARCHAR2
TESTNAME	TESTNAME	VARCHAR2
	TESTNAME_ND	VARCHAR2
TESTRST	TESTRST	VARCHAR2
	TESTRST_ND	VARCHAR2
TESTRSTU	TESTRSTU	VARCHAR2
	TESTRSTU_ND	VARCHAR2
NRANGE	NRANGE	VARCHAR2
	NRANGE_ND	VARCHAR2
RD_FRSAE_RSSAE6		
CMINFID	CMINFID	VARCHAR2
	CMINFID_ND	VARCHAR2
MEDSTD	MEDSTD	DATE
	MEDSTD_DTS	VARCHAR2
	MEDSTD_DTR	VARCHAR2
	MEDSTD_ND	VARCHAR2
MEDCONT	MEDCONT_C	**NUMBER
	MEDCONT	VARCHAR2
	MEDCONT_ND	VARCHAR2
MEDCONT - MEDSPDTM	MEDSPDTM	DATE
	MEDSPDTM_DTS	VARCHAR2
	MEDSPDTM_DTR	VARCHAR2
MEDDOSE	MEDDOSE	FLOAT
	MEDDOSE_ND	VARCHAR2
MEDUNIT	MEDUNIT	VARCHAR2
	MEDUNIT_ND	VARCHAR2
MEDFREQ	MEDFREQ	VARCHAR2

	MEDFREQ_ND	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different. [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: END OF STUDY (EOS) [frEOS]		
End of Study Participation [stEOS1]		
1.* ✓	Date of last contact [Date of last contact]	[LSTCONDT] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2018)
2.* ✓	Status at time of last contact [Status at time of last contact]	[CMPLTD] [N: 1] <input type="radio"/> Died, please complete DEATH form [N: 2] <input type="radio"/> Completed protocol [N: 3] <input type="radio"/> Subject lost to follow-up [N: 4] <input type="radio"/> Subject withdrew consent for study participation [N: 5] <input type="radio"/> Subject withdrawn from the study by site investigator [N: 98] <input type="radio"/> [CMPTOSP] Other, specify A100
Key: [*] = Item is required [✓] = Source verification required		

RDE Analytics: RD_FREOS		
Data Variable RefName	RD Column Name	Column Data Type
LSTCONDT	LSTCONDT	DATE
	LSTCONDT_DTS	VARCHAR2
	LSTCONDT_ND	VARCHAR2
CMPLTD	CMPLTD_C	NUMBER
	CMPLTD	VARCHAR2
	CMPLTD_ND	VARCHAR2
CMPLTD - CMPTOSP	CMPTOSP	VARCHAR2

HFN_NEAT: DEATH (DEATH) [frDEATH]	
Death [stDEATH1]	
1.* ✓ Location of Death [Location of Death]	[DEATHLOC] [N:1] <input type="radio"/> Inpatient/ER [N:2] <input type="radio"/> Outpatient
2.* ✓ Date of Death [Date of Death]	[DEATHDT] Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2018)
3.* ✓ Cause of Death [Cause of Death]	[DTHCAUSE] [N:1] <input type="radio"/> [DTHCARD] Cardiovascular [N:1] <input type="radio"/> Myocardial infarction [N:2] <input type="radio"/> Heart failure/Pump failure/Cardiogenic Shock [N:3] <input type="radio"/> [SDNDTHW] Sudden Death [N:1] <input type="radio"/> Witnessed [N:2] <input type="radio"/> Not Witnessed [N:4] <input type="radio"/> Stroke [N:5] <input type="radio"/> [DTHCVPR] CV Procedure [N:1] <input type="radio"/> CABG [N:2] <input type="radio"/> PCI/Stenting [N:3] <input type="radio"/> Valvular [N:98] <input type="radio"/> Other CV Procedure [N:6] <input type="radio"/> Pulmonary Embolism [N:98] <input type="radio"/> [DTHCRDSP] Other CV, specify: <input type="text" value="A100"/> [N:2] <input type="radio"/> Non-Cardiovascular [N:99] <input type="radio"/> Unknown
Key: [*] = Item is required [✓] = Source verification required	

RDE Analytics: RD_FRDEATH		
Data Variable RefName	RD Column Name	Column Data Type
DEATHLOC	DEATHLOC_C	NUMBER
	DEATHLOC	VARCHAR2
	DEATHLOC_ND	VARCHAR2
DEATHDT	DEATHDT	DATE
	DEATHDT_DTS	VARCHAR2
	DEATHDT_DTR	VARCHAR2
	DEATHDT_ND	VARCHAR2
DTHCAUSE	DTHCAUSE_C	**NUMBER
	DTHCAUSE	VARCHAR2
	DTHCAUSE_ND	VARCHAR2
DTHCAUSE - DTHCARD	DTHCARD_C	NUMBER
	DTHCARD	VARCHAR2
DTHCAUSE - SDNDTHW	SDNDTHW_C	NUMBER
	SDNDTHW	VARCHAR2
DTHCAUSE - DTHCVPR	DTHCVPR_C	NUMBER
	DTHCVPR	VARCHAR2
DTHCAUSE - DTHCRDSP	DTHCRDSP	VARCHAR2
Key: [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_NEAT: Signature Completion (SIGN) [frSIGN]	
Casebook Ready for Signature [stSIGN]	
1. *	Casebook Ready for Signature [Casebook Ready for Signature]
	[PISIGN] [N:1] <input type="checkbox"/> Yes
Key: [*] = Item is required	

RDE Analytics: RD_FRSIGN		
Data Variable RefName	RD Column Name	Column Data Type
PISIGN	PISIGN_ND	VARCHAR2
PISIGN - Yes	PISIGN_C1YES_C	NUMBER
	PISIGN_C1YES	VARCHAR2