

Annotated Study Book for Study Design: HFN_FIGHT

Study Design Version: 6.0

Sponsor: NHLBI

Protocol: HFN_FIGHT

Sponsor Date: November 19, 2012 12:00AM

Generic Drug Name: Liraglutide

Functional Impact of GLP-1 for Heart Failure Treatment (FIGHT)

Generated by Central Designer™

Time and Events Schedule For Study Design: HFN_FIGHT																					
Element	CRF	System		CLINOPS (CLINOPS) [S]	BASELINE (BASE) [S]	DAY 2 (D2) [S]	DAY 7 (D7) [S]	DAY 14 (D14) [S]	DAY 30 (D30) [S]	DAY 60 (D60) [S]	DAY 90 (D90) [S]	DAY 120 (D120) [S]	DAY 150 (D150) [S]	DAY 180 (D180) [S]	DAY 210 (D210) [S]	KITS (KITS) [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 (SYSENR) [S]																		
Visit Start Hours		0	0	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1 System Screening	SYSSCR	1																			
2 System Enrollment	SYSENR		1																		
3 Clinical Operations Review	CLINOPS			1																	
4 RANDOMIZATION AND DEMOGRAPHICS	DEMOG				1																
5 INDEX HOSPITAL DISCHARGE	INDXDC				2																
6 CLINICAL HISTORY	MEDHIST1				3																
7 CLINICAL HISTORY	MEDHIST2				4																
8 Baseline Assessments	BASSESS				5																
9 CHEMISTRY LABS	CHEM				6-DF				5-DF		5-DF				5-DF						
10 HEMATOLOGY LABS	HEMACOAG				7-DF				6-DF		6-DF				6-DF						
11 FASTING LABS	FASTLABS				8-DF				7-DF						7-DF						
12 MEDICATIONS	MEDS				9				8-DF		7-DF				8-DF						
13 INITIAL STUDY DRUG ADMINISTRATION	ISDADMIN				10																
14 EXAMINATION	EXAM				11				2-DF		2-DF				2-DF						
15 ECG	ECG				12																
16 SIX MINUTE WALK TEST	SIXMWT				13-DF				9-DF		8-DF				9-DF						
17 Kansas City Cardiomyopathy Questionnaire	KCCQ				14-DF				11-DF		10-DF				11-DF						
18 BIOLOGICAL SAMPLES	SAMPLES				15-DF				14-DF		13-DF				14-DF						
19 ECHOCARDIOGRAM	ECHO				16-DF										15-DF						
20 ECHO RESULTS PART 1	ECHOLAB1				17-DF										16-DF						
21 ECHO RESULTS PART 2	ECHOLAB2				18-DF										17-DF						
22 VISIT STATUS	VISIT					1	1	1	1	1	1	1	1	1	1						
23 ADHERENCE AND DOSAGE ASSESSMENT	ADHASMT					2-DF	2-DF	2-DF	12-DF	2-DF	11-DF	2-DF	2-DF	12-DF							
24 STUDY DRUG DOSING	DRGDOSE					3-DF	3-DF	3-DF	13-DF	3-DF	12-DF	3-DF	3-DF	13-DF							
25 Events of Interest	EVNTINT					4-DF	4-DF	4-DF	4-DF	4-DF	4-DF	4-DF	4-DF	4-DF							
26 Additional Protocol Assessments	ASSESS								3-DF		3-DF				3-DF						
27 PATIENT GLOBAL ASSESSMENT	GLOBAL								10-DF		9-DF				10-DF						
28 DRUG KIT DISPENSING	DRUGKIT															1-RF					
29 REHOSPITALIZATION	REHOSP																1-RF				
30 EMERGENCY DEPARTMENT VISIT	EDVISIT																	1-RF			
31 SERIOUS ADVERSE EVENTS	SAE																		1-RF		
32 END OF STUDY	EOS																				1
33 DEATH	DEATH																				2-DF
34 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_FIGHT: System Screening (SYSSCR) [frSCI XRS]		
System Screening [frSCI XRS]		
1. *	IXRS ID [IXRS ID]	[IXRSID] A3
Key: [*] = Item is required		

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

HFN_FIGHT: 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_FIGHT: 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 type="radio"/> [INCLNOT] Inclusion not met [N: 1] <input type="radio"/> Age >= 18 years [N: 2] <input type="radio"/> AHFS as defined by the presence of at least 1 symptom (dyspnea, orthopnea, or edema) AND 1 sign (rales on auscultation, peripheral edema, ascites, pulmonary vascular congestion on chest radiography) [N: 3] <input type="radio"/> AHFS is the primary cause of hospitalization [N: 4] <input type="radio"/> Prior clinical diagnosis of HF [N: 5] <input type="radio"/> LVEF <= 40% during the preceding 3 months (if no echo within the preceding 3 months, an LVEF <= 30% during the preceding three years is acceptable) [N: 6] <input type="radio"/> On evidence-based medication for HF (including beta-blocker and ACE-inhibitor/ARB) or previously deemed intolerant [N: 7] <input type="radio"/> Use of at least 40 mg or furosemide (or equivalent) prior to admission for AHFS (a lower dose of a loop diuretic combined with a thiazide will count as an "equivalent") [N: 8] <input type="radio"/> Willingness to provide informed consent [N: 2] <input type="radio"/> [EXCLMET] Exclusion met [N: 1] <input type="radio"/> AHFS due to acute myocarditis or acute MI [N: 2] <input type="radio"/> Ongoing hemodynamically significant arrhythmias contributing to HF decompensation [N: 3] <input type="radio"/> Inotrope, intra-aortic balloon pump (IABP) or other mechanical circulatory support use at the time of consent. Prior use will not exclude a patient. [N: 4] <input type="radio"/> Current or planned left ventricular assist device therapy in next 180 days [N: 5] <input type="radio"/> United Network for Organ Sharing status 1A or 1B [N: 6] <input type="radio"/> BNP < 250 or NT-proBNP < 1,000 (Not required per protocol but if available and too low would be an exclusion; within 48 hours of consent) [N: 7] <input type="radio"/> Hemoglobin (Hgb) < 8.0 g/dl [N: 8] <input type="radio"/> GFR < 20 ml/min/1.73 m2 within 48 hours of consent [N: 9] <input type="radio"/> Systolic blood pressure < 80 mmHg at consent [N: 10] <input type="radio"/> Resting HR > 110 at consent [N: 11] <input type="radio"/> Acute coronary syndrome within 4 weeks as defined by electrocardiographic (ECG) changes and biomarkers of myocardial necrosis (e.g. troponin) in an appropriate clinical setting (chest discomfort or anginal equivalent) [N: 12] <input type="radio"/> PCI, coronary artery bypass grafting or new biventricular pacing within past 4 weeks [N: 13] <input type="radio"/> Primary hypertrophic cardiomyopathy [N: 14] <input type="radio"/> Infiltrative cardiomyopathy [N: 15] <input type="radio"/> Constrictive pericarditis or tamponade [N: 16] <input type="radio"/> Complex congenital heart disease [N: 17] <input type="radio"/> Non-cardiac pulmonary edema [N: 18] <input type="radio"/> More than mild aortic or mitral stenosis [N: 19] <input type="radio"/> Intrinsic (prolapse, rheumatic) valve disease with severe mitral, aortic or tricuspid regurgitation [N: 20] <input type="radio"/> Sepsis, active infection (excluding cystitis) or other comorbidity driving the HF decompensation [N: 21] <input type="radio"/> Acute or chronic severe liver disease as evidenced by any of the following: encephalopathy, variceal bleeding, INR > 1.7 in the absence of anticoagulation treatment [N: 22] <input type="radio"/> Terminal illness (other than HF) with expected survival of less than 1 year [N: 23] <input type="radio"/> Previous adverse reaction to the study drug [N: 24] <input type="radio"/> Receipt of any investigational product in the previous 30 days. [N: 25] <input type="radio"/> Enrollment or planned enrollment in another randomized therapeutic clinical trial in next 6 months. [N: 26] <input type="radio"/> Inability to comply with planned study procedures [N: 27] <input type="radio"/> Pregnancy or breastfeeding mothers [N: 28] <input type="radio"/> Women of reproductive age not on adequate contraception [N: 29] <input type="radio"/> History of acute or chronic pancreatitis [N: 30] <input type="radio"/> History of symptomatic gastroparesis [N: 31] <input type="radio"/> Familial or personal history of medullary thyroid cancer or multiple endocrine neoplasia type-2 (MEN2) [N: 32] <input type="radio"/> Prior weight-loss surgery (i.e., Roux-en-Y gastric bypass) or other gastric surgery associated with increased endogenous GLP-1 production [N: 33] <input type="radio"/> Ongoing treatment with GLP-1 receptor agonists [N: 34] <input type="radio"/> Ongoing treatment with dipeptidyl peptide-IV inhibitors (1 week washout required) [N: 35] <input type="radio"/> Ongoing treatment with thiazolidinedione therapy [N: 36] <input type="radio"/> Oxygen-dependent chronic obstructive pulmonary disease [N: 37] <input type="radio"/> Diabetic patients with history of 2 or more severe hypoglycemia episodes, DKA or hyperglycemic, hyperosmotic nonketotic coma in the preceding 12 months. [N: 39] <input type="radio"/> Diagnosis of Type 1 Diabetes Mellitus [N: 40] <input type="radio"/> If diabetic, inadequate glycemic control with glucose level >300 mg/dL within 24 hours of randomization		
2.2 Was a waiver granted? [Waiver granted?]		[WAIVER] [N: 1] <input type="radio"/> [WAI VRDT] Yes Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2012-2025)		

		[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_FIGHT: 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] (2013-2018) 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] (2013-2018) [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] (2013-2018) [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] (2013-2018) 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] (1912-1995)
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
11.	Update Workflow [Update Workflow]	[UPDTWKF] [N:1] <input type="checkbox"/>
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
	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
UPDTWKF	UPDTWKF_ND	VARCHAR2
UPDTWKF - Yes	UPDTWKF_CIYES_C	NUMBER
	UPDTWKF_CIYES	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_FIGHT: INDEX HOSPITAL DISCHARGE (INDXDC) [frINDXDC]		
Index Hospital Discharge [stINDXDC1]		
1.* ✓	Date of index discharge [Date of index discharge]	[INDXDCDT] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018)
2.*	Location subject was discharged to: [Location subject was discharged to:]	[EXTDSCHG] [N:1] <input type="radio"/> Home [N:2] <input type="radio"/> Other medical facility [N:3] <input type="radio"/> Subject died [N:99] <input type="radio"/> Unknown
Key: [*] = Item is required [✓] = Source verification required		

RDE Analytics: RD_FRINDXDC		
Data Variable RefName	RD Column Name	Column Data Type
INDXDCDT	INDXDCDT	DATE
	INDXDCDT_DTS	VARCHAR2
	INDXDCDT_ND	VARCHAR2
EXTDSCHG	EXTDSCHG_C	NUMBER
	EXTDSCHG	VARCHAR2
	EXTDSCHG_ND	VARCHAR2

HFN_FIGHT: 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] xxxxxxxx. <input type="text"/> % [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"/> [FACTORYYN] 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>
<p>Key: [*] = Item is required [✓] = Source verification required</p>		

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_FIGHT: 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_FIGHT: 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 ECHO performed (If yes, complete ECHO form) [Was ECHO performed (If yes, complete ECHO form)]	[BECHODN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [BECHONDR] 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"/> [BECHONDS] Unknown/other Specify: <input type="text" value="A50"/>

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
BSIXMWTD	BSIXMWTD_C	NUMBER
	BSIXMWTD	VARCHAR2
	BSIXMWTD_ND	VARCHAR2
BSIXMWTD - BSMWNDRS	BSMWNDRS_C	NUMBER
	BSMWNDRS	VARCHAR2
BSIXMWTD - BSMWNDSP	BSMWNDSP	VARCHAR2
BKCCQDN	BKCCQDN_C	NUMBER
	BKCCQDN	VARCHAR2
	BKCCQDN_ND	VARCHAR2
BKCCQDN - BKCCQNDR	BKCCQNDR_C	NUMBER
	BKCCQNDR	VARCHAR2
BKCCQDN - BKCCQNDS	BKCCQNDS	VARCHAR2
BECHODN	BECHODN_C	NUMBER
	BECHODN	VARCHAR2
	BECHODN_ND	VARCHAR2
BECHODN - BECHONDR	BECHONDR_C	NUMBER
	BECHONDR	VARCHAR2
BECHODN - BECHONDS	BECHONDS	VARCHAR2

HFN_FIGHT: CHEMISTRY LABS (CHEM) [frCHEM]	
Chemistry [stCHEM1]	
1.* ✓	Collection Date and Time [Collection Date and Time]
<p>[CHEMLDTM] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018) Req/Unk <input type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock</p>	
2.* ✓	Sodium [Sodium]
<p>[SODIUM] [N: 1] <input type="radio"/> [cpSODIUM] [SODVAL] xxxxxxxx. [SODUNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 2] <input type="radio"/> mEq/L [N: 97] <input type="radio"/> Not Done</p>	
3.* ✓	Potassium [Potassium]
<p>[POTAS] [N: 1] <input type="radio"/> [cpPOTAS] [POTASVAL] xxxxxxxx. [POTASUNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 2] <input type="radio"/> mEq/L [N: 97] <input type="radio"/> Not Done</p>	
4.*	Chloride [Chloride]
<p>[CHLORIDE] [N: 1] <input type="radio"/> [cpCHLORIDE] [CHLORVAL] xxxxxxxx. [CHLORUNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 2] <input type="radio"/> mEq/L [N: 97] <input type="radio"/> Not Done</p>	
5.*	Bicarbonate (total CO ₂) [Bicarbonate]
<p>[CO2] [N: 1] <input type="radio"/> [cpCO2] [CO2VAL] xxxxxxxx. [CO2UNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 2] <input type="radio"/> mEq/L [N: 97] <input type="radio"/> Not Done</p>	
6.* ✓	BUN/Urea [BUN/Urea]
<p>[BUN] [N: 1] <input type="radio"/> [cpBUN] [BUNVAL] xxxxxxxx. [BUNUNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 3] <input type="radio"/> mg/dl [N: 97] <input type="radio"/> Not Done</p>	
7.* ✓	Creatinine [Creatinine]
<p>[CREAT] [N: 1] <input type="radio"/> [cpCREAT] [CREATVAL] xxxxxxxx. [CREATUNT] Unit: [N: 3] <input type="radio"/> mg/dl [N: 4] <input type="radio"/> umol/L [N: 97] <input type="radio"/> Not Done</p>	
8.*	Total calcium [Total calcium]
<p>[CALC] [N: 1] <input type="radio"/> [cpCALC] [CALCVAL] xxxxxxxx. [CALCUNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 2] <input type="radio"/> mEq/L</p>	

		<p>[N: 3] <input type="radio"/> mg/dl</p> <p>[N: 97] <input type="radio"/> Not Done</p>
9.*	Total Protein [Total Protein]	<p>[TPRO]</p> <p>[N: 1] <input type="radio"/> [cpTPRO]</p> <p>[TPROVAL]</p> <p>xxxxxxx.</p> <p>[TPROUNT]</p> <p>Unit:</p> <p>[N: 7] <input type="radio"/> g/dL</p> <p>[N: 8] <input type="radio"/> g/L</p> <p>[N: 97] <input type="radio"/> Not Done</p>
10.*	Albumin [Albumin]	<p>[ALBUMIN]</p> <p>[N: 1] <input type="radio"/> [cpALBUMIN]</p> <p>[ALBVAL]</p> <p>xxxxxxx.</p> <p>[ALBUNT]</p> <p>Unit:</p> <p>[N: 7] <input type="radio"/> g/dL</p> <p>[N: 8] <input type="radio"/> g/L</p> <p>[N: 97] <input type="radio"/> Not Done</p>
11.*	ALT/SGPT [ALT/SGPT]	<p>[ALT]</p> <p>[N: 1] <input type="radio"/> [cpALT]</p> <p>[ALTVAL]</p> <p>xxxxxxx.</p> <p>[ALTUNT]</p> <p>Unit:</p> <p>[N: 5] <input type="radio"/> U/L</p> <p>[N: 6] <input type="radio"/> IU/L</p> <p>[N: 97] <input type="radio"/> Not Done</p>
12.*	AST/SGOT [AST/SGOT]	<p>[AST]</p> <p>[N: 1] <input type="radio"/> [cpAST]</p> <p>[ASTVAL]</p> <p>xxxxxxx.</p> <p>[ASTUNT]</p> <p>Unit:</p> <p>[N: 5] <input type="radio"/> U/L</p> <p>[N: 6] <input type="radio"/> IU/L</p> <p>[N: 97] <input type="radio"/> Not Done</p>
13.*	Alkaline Phosphatase [Alkaline Phosphatase]	<p>[ALKPH]</p> <p>[N: 1] <input type="radio"/> [cpALKPH]</p> <p>[ALKPHVAL]</p> <p>xxxxxxx.</p> <p>[ALKPHUNT]</p> <p>Unit:</p> <p>[N: 5] <input type="radio"/> U/L</p> <p>[N: 6] <input type="radio"/> IU/L</p> <p>[N: 97] <input type="radio"/> Not Done</p>
14.*	Total Bilirubin [Total Bilirubin]	<p>[TBILI]</p> <p>[N: 1] <input type="radio"/> [cpTBILI]</p> <p>[TBILIVAL]</p> <p>xxxxxxx.</p> <p>[TBILIUNT]</p> <p>Unit:</p> <p>[N: 3] <input type="radio"/> mg/dl</p> <p>[N: 4] <input type="radio"/> umol/L</p> <p>[N: 97] <input type="radio"/> Not Done</p>
15.*	Magnesium [Magnesium]	<p>[MAG]</p> <p>[N: 1] <input type="radio"/> [cpMAG]</p> <p>[MAGVAL]</p> <p>xxxxxxx.</p> <p>[MAGUNT]</p> <p>Unit:</p> <p>[N: 1] <input type="radio"/> mmol/L</p> <p>[N: 2] <input type="radio"/> mEq/L</p> <p>[N: 3] <input type="radio"/> mg/dl</p> <p>[N: 97] <input type="radio"/> Not Done</p>
16.*	Glucose [Glucose]	<p>[GLUC]</p> <p>[N: 1] <input type="radio"/> [cpGLUC]</p>

✓		<input type="radio"/> [GLUCVAL] xxxxxxxx. <input type="radio"/> [GLUCUNT] [N:1] <input type="radio"/> mmol/L [N:3] <input type="radio"/> mg/dl <input type="radio"/> [GLUCFAST] Is this a fasting sample? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:97] <input type="radio"/> Not Done
17.*	Uric Acid [Uric Acid]	<input type="radio"/> [URAC] [N:1] <input type="radio"/> [cpURAC] <input type="radio"/> [URACVAL] xxxxxxxx. <input type="radio"/> [URACUNT] Unit: [N:1] <input type="radio"/> mmol/L [N:3] <input type="radio"/> mg/dl [N:4] <input type="radio"/> umol/L [N:97] <input type="radio"/> Not Done
18.*	HbA1c [HbA1c]	<input type="radio"/> [HBA1C] [N:1] <input type="radio"/> [HBA1CVAL] xxxxxxxx. % [N:97] <input type="radio"/> Not Done
19.*	BNP [BNP]	<input type="radio"/> [BNP] [N:1] <input type="radio"/> [cpBNP] <input type="radio"/> [BNPVVAL] xxxxxxxx. <input type="radio"/> [BNPUNT] Unit: [N:17] <input type="radio"/> pg/mL [N:18] <input type="radio"/> ng/L [N:97] <input type="radio"/> Not Done
20.*	NT-proBNP [NT-proBNP]	<input type="radio"/> [NTBNP] [N:1] <input type="radio"/> [cpNTBNP] <input type="radio"/> [NTBNPVVAL] xxxxxxxx. <input type="radio"/> [NTBNPUNT] Unit: [N:17] <input type="radio"/> pg/mL [N:18] <input type="radio"/> ng/L [N:97] <input type="radio"/> 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
CALC	CALC_C	**NUMBER
	CALC	VARCHAR2
	CALC_ND	VARCHAR2
CALC - CALCVAL	CALCVAL	FLOAT
CALC - CALCUNT	CALCUNT_C	NUMBER
	CALCUNT	VARCHAR2
TPRO	TPRO_C	**NUMBER
	TPRO	VARCHAR2
	TPRO_ND	VARCHAR2
TPRO - TPROVAL	TPROVAL	FLOAT
TPRO - TPROUNT	TPROUNT_C	NUMBER
	TPROUNT	VARCHAR2
ALBUMIN	ALBUMIN_C	**NUMBER
	ALBUMIN	VARCHAR2
	ALBUMIN_ND	VARCHAR2
ALBUMIN - ALBVAL	ALBVAL	FLOAT
ALBUMIN - ALBUNT	ALBUNT_C	NUMBER
	ALBUNT	VARCHAR2
ALT	ALT_C	**NUMBER
	ALT	VARCHAR2
	ALT_ND	VARCHAR2
ALT - ALTVAL	ALTVAL	FLOAT
ALT - ALTUNT	ALTUNT_C	NUMBER
	ALTUNT	VARCHAR2
AST	AST_C	**NUMBER
	AST	VARCHAR2
	AST_ND	VARCHAR2
AST - ASTVAL	ASTVAL	FLOAT
AST - ASTUNT	ASTUNT_C	NUMBER
	ASTUNT	VARCHAR2

ALKPH	ALKPH_C	**NUMBER
	ALKPH	VARCHAR2
	ALKPH_ND	VARCHAR2
ALKPH - ALKPHVAL	ALKPHVAL	FLOAT
ALKPH - ALKPHUNT	ALKPHUNT_C	NUMBER
	ALKPHUNT	VARCHAR2
TBILI	TBILI_C	**NUMBER
	TBILI	VARCHAR2
	TBILI_ND	VARCHAR2
TBILI - TBILIVAL	TBILIVAL	FLOAT
TBILI - TBILIUNT	TBILIUNT_C	NUMBER
	TBILIUNT	VARCHAR2
MAG	MAG_C	**NUMBER
	MAG	VARCHAR2
	MAG_ND	VARCHAR2
MAG - MAGVAL	MAGVAL	FLOAT
MAG - MAGUNT	MAGUNT_C	NUMBER
	MAGUNT	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
URAC	URAC_C	**NUMBER
	URAC	VARCHAR2
	URAC_ND	VARCHAR2
URAC - URACVAL	URACVAL	FLOAT
URAC - URACUNT	URACUNT_C	NUMBER
	URACUNT	VARCHAR2
HBA1C	HBA1C_C	**NUMBER
	HBA1C	VARCHAR2
	HBA1C_ND	VARCHAR2
HBA1C - HBA1CVAL	HBA1CVAL	FLOAT
BNP	BNP_C	**NUMBER
	BNP	VARCHAR2
	BNP_ND	VARCHAR2
BNP - BNPVAL	BNPVAL	FLOAT
BNP - BNPUNT	BNPUNT_C	NUMBER
	BNPUNT	VARCHAR2
NTBNP	NTBNP_C	**NUMBER
	NTBNP	VARCHAR2
	NTBNP_ND	VARCHAR2
NTBNP - NTBNPVAL	NTBNPVAL	FLOAT
NTBNP - NTBNPUNT	NTBNPUNT_C	NUMBER
	NTBNPUNT	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_FIGHT: 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"/> (2013-2018) 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_FIGHT: FASTING LABS (FASTLABS) [frFASTLABS]	
Fasting Labs [stFASTLABS1]	
1.* Collection Date and Time [Collection Date and Time]	[FSTLBDTM] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018) Req/Unk <input type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock
2.* Confirm this is a fasting sample [Confirm this is a fasting sample]	[FASTYN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No
3.* Fasting Insulin [Fasting Insulin]	[FASINS] [N: 1] <input type="radio"/> cpFASINS [FINSVAL] xxxxxxxx. [FINSUNT] Unit: [N: 14] <input type="radio"/> uIU/ml, uU/ml OR mIU/L, mIU/L [N: 16] <input type="radio"/> pmol/L [N: 97] <input type="radio"/> Not Done
4.* C-Peptide [C-Peptide]	[CPEPTDE] [N: 1] <input type="radio"/> cpCPEPTDE [CPEPVAL] xxxxxxxx. [CPEPUNT] Unit: [N: 12] <input type="radio"/> ng/mL [N: 13] <input type="radio"/> nmol/L [N: 97] <input type="radio"/> Not Done
5.* Total Cholesterol [Total Cholesterol]	[TCHOL] [N: 1] <input type="radio"/> cpTCHOL [TCHOLVAL] xxxxxxxx. [TCHOLUNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 3] <input type="radio"/> mg/dl [N: 97] <input type="radio"/> Not Done
6.* LDL [LDL]	[LDL] [N: 1] <input type="radio"/> cpLDL [LDLVAL] xxxxxxxx. [LDLUNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 3] <input type="radio"/> mg/dl [N: 97] <input type="radio"/> Not Done
7.* HDL [HDL]	[HDL] [N: 1] <input type="radio"/> cpHDL [HDLVAL] xxxxxxxx. [HDLUNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 3] <input type="radio"/> mg/dl [N: 97] <input type="radio"/> Not Done
8.* Triglycerides [Triglycerides]	[TRIGL] [N: 1] <input type="radio"/> cpTRIGL [TRIGLVAL] xxxxxxxx. [TRIGLUNT] Unit: [N: 1] <input type="radio"/> mmol/L [N: 3] <input type="radio"/> mg/dl [N: 97] <input type="radio"/> Not Done
Key: [*] = Item is required	

RDE Analytics: RD_FRFASTLABS

Data Variable RefName	RD Column Name	Column Data Type
FSTLBDTM	FSTLBDTM	DATE
	FSTLBDTM_DTS	VARCHAR2
	FSTLBDTM_DTR	VARCHAR2
	FSTLBDTM_ND	VARCHAR2
FASTYN	FASTYN_C	NUMBER
	FASTYN	VARCHAR2
	FASTYN_ND	VARCHAR2
FASINS	FASINS_C	**NUMBER
	FASINS	VARCHAR2
	FASINS_ND	VARCHAR2
FASINS - FINSVAL	FINSVAL	FLOAT
FASINS - FINSUNT	FINSUNT_C	NUMBER
	FINSUNT	VARCHAR2
CPEPTDE	CPEPTDE_C	**NUMBER
	CPEPTDE	VARCHAR2
	CPEPTDE_ND	VARCHAR2
CPEPTDE - CPEPVAL	CPEPVAL	FLOAT
CPEPTDE - CPEPUNT	CPEPUNT_C	NUMBER
	CPEPUNT	VARCHAR2
TCHOL	TCHOL_C	**NUMBER
	TCHOL	VARCHAR2
	TCHOL_ND	VARCHAR2
TCHOL - TCHOLVAL	TCHOLVAL	FLOAT
TCHOL - TCHOLUNT	TCHOLUNT_C	NUMBER
	TCHOLUNT	VARCHAR2
LDL	LDL_C	**NUMBER
	LDL	VARCHAR2
	LDL_ND	VARCHAR2
LDL - LDLVAL	LDLVAL	FLOAT
LDL - LDLUNT	LDLUNT_C	NUMBER
	LDLUNT	VARCHAR2
HDL	HDL_C	**NUMBER
	HDL	VARCHAR2
	HDL_ND	VARCHAR2
HDL - HDLVAL	HDLVAL	FLOAT
HDL - HDLUNT	HDLUNT_C	NUMBER
	HDLUNT	VARCHAR2
TRIGL	TRIGL_C	**NUMBER
	TRIGL	VARCHAR2
	TRIGL_ND	VARCHAR2
TRIGL - TRIGLVAL	TRIGLVAL	FLOAT
TRIGL - TRIGLUNT	TRIGLUNT_C	NUMBER
	TRIGLUNT	VARCHAR2

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

HFN_FIGHT: MEDICATIONS (MEDS) [frMEDS]	
Medications [stMEDS1]	
1.* ACE inhibitor [ACE inhibitor]	<p>[ACE] [N:1] <input type="radio"/> Yes [N:0] <input checked="" type="radio"/> [ACECONT] No If no: Is there documented evidence of contraindication? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown [N:99] <input type="radio"/> Unknown</p>
2.* Angiotensin receptor blocker [Angiotensin receptor blocker]	<p>[ARB] [N:1] <input type="radio"/> Yes [N:0] <input checked="" type="radio"/> [ARBCONT] No If no: Is there documented evidence of contraindication? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown [N:99] <input type="radio"/> Unknown</p>
3.* Beta Blocker [Beta Blocker]	<p>[BETAB] [N:1] <input type="radio"/> Yes [N:0] <input checked="" type="radio"/> [BETACONT] No If no: Is there documented evidence of contraindication? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown [N:99] <input type="radio"/> Unknown</p>
4.* Aldosterone antagonist [Aldosterone antagonist]	<p>[ALDOS] [N:1] <input type="radio"/> Yes [N:0] <input checked="" type="radio"/> [ALDOCONT] No If no: Is there documented evidence of contraindication? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown [N:99] <input type="radio"/> Unknown</p>
5.* Hydralazine [Hydralazine]	<p>[HYDR] [N:1] <input type="radio"/> Yes [N:0] <input checked="" type="radio"/> No [N:99] <input type="radio"/> Unknown</p>
6.* Nitrates (long acting) [Nitrates]	<p>[NITR] [N:1] <input type="radio"/> Yes [N:0] <input checked="" type="radio"/> No [N:99] <input type="radio"/> Unknown</p>
7.* Calcium channel blocker [Calcium channel blocker]	<p>[CCB] [N:1] <input type="radio"/> Yes [N:0] <input checked="" type="radio"/> No [N:99] <input type="radio"/> Unknown</p>
8.* Antiplatelets [Antiplatelets]	<p>[ANTIPLT] [N:1] <input checked="" type="radio"/> [cpANTIPLTY] Yes (check all that apply) [ANTIPASP] [N:1] <input type="checkbox"/> Aspirin (taken daily) [ANTIPTH] [N:1] <input type="checkbox"/> Thienopyridines (eg: ticlopidine, clopidogrel, prasugrel) [ANTIPOTH] [N:1] <input type="checkbox"/> Other [N:0] <input checked="" type="radio"/> [ANTIPTCI] No If no: Is there documented evidence of contraindication? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown [N:99] <input type="radio"/> Unknown</p>
9.* Anticoagulants [Anticoagulants]	<p>[ANTICAG] [N:1] <input checked="" type="radio"/> [cpANTICAGY]</p>

		<input type="radio"/> Yes (check all that apply) [ANTICWAR] [N:1] <input type="checkbox"/> Warfarin [ANTICFACX] [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 checked="" type="radio"/> [ANTICACI] No If no: Is there documented evidence of contraindication? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown [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 [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
12.*	Other antiarrhythmic [Other antiarrhythmic]	[OARRH] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
13.*	Statin [Statin]	[STATIN] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
14.*	Lipid lowering agent (other than statin) [Lipid lowering agent]	[LLIPID] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
15.*	Antidepressant [Antidepressant]	[DEPRES] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
16.*	Ambulatory IV Inotropes [Ambulatory IV Inotropes]	[IVINOTRP] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
17.*	Metolazone [Metolazone]	[METAZ] [N:1] <input checked="" 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
18.*	HCTZ [HCTZ]	[HCTZ] [N:1] <input checked="" 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
19.*	Furosemide [Furosemide]	[FURO] [N:1] <input checked="" type="radio"/> [FURODOSE] Yes Daily Dose: xxxxxxxx. [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
20.*	Torsemide	[TORS]

✓	[Torsemide]	[N: 1] <input type="radio"/> [TORSDOSE] Yes Daily Dose: xxxxxxxx. [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
21.* ✓	Bumetanide [Bumetanide]	[BUME] [N: 1] <input type="radio"/> [BUMDOSE] Yes Daily Dose: xxxxxxxx. [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
22.* ✓	Glucose-lowering medications [Glucose-lowering medications]	[GLUCLOW] [N: 1] <input checked="" type="radio"/> [cpGLUCLOW] Yes (check all classes that apply) [BIGUANID] [N: 1] <input type="checkbox"/> Biguanides [SULFONY] [N: 1] <input type="checkbox"/> Sulfonylurea [PPRAMLIN] [N: 1] <input type="checkbox"/> Pramlintide [THIAZOLI] [N: 1] <input type="checkbox"/> Thiazolidinedione [NONSULFS] [N: 1] <input type="checkbox"/> Non-sulfonylurea secretagogues [AGLUIHNB] [N: 1] <input type="checkbox"/> Alpha-glucosidase Inhibitors [INSULIN] [N: 1] <input type="checkbox"/> Insulin [GLP1ANAL] [N: 1] <input type="checkbox"/> GLP-1 Analogues [DPP1VINH] [N: 1] <input type="checkbox"/> DPP-IV Inhibitor [SLGT1HNB] [N: 1] <input type="checkbox"/> SGLT-2 inhibitors [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown

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
ACE - ACECONT	ACECONT_C	NUMBER
	ACECONT	VARCHAR2
ARB	ARB_C	NUMBER
	ARB	VARCHAR2
	ARB_ND	VARCHAR2
ARB - ARBCONT	ARBCONT_C	NUMBER
	ARBCONT	VARCHAR2
BETAB	BETAB_C	NUMBER
	BETAB	VARCHAR2
	BETAB_ND	VARCHAR2
BETAB - BETACONT	BETACONT_C	NUMBER
	BETACONT	VARCHAR2
ALDOS	ALDOS_C	NUMBER
	ALDOS	VARCHAR2
	ALDOS_ND	VARCHAR2
ALDOS - ALDOCONT	ALDOCONT_C	NUMBER
	ALDOCONT	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
ANTIPLT - ANTIPTCI	ANTIPTCI_C	NUMBER
	ANTIPTCI	VARCHAR2
ANTICAG	ANTICAG_C	**NUMBER
	ANTICAG	VARCHAR2
	ANTICAG_ND	VARCHAR2
ANTICAG - Warfarin	ANTICWAR_CIWARFARIN_C	NUMBER
	ANTICWAR_CIWARFARIN	VARCHAR2
ANTICAG - Factor Xa Inhibitor	*ANTICFACX_CIFACTORXAINHIBITOR_C	NUMBER
	*ANTICFACX_CIFACTORXAINHIBITOR	VARCHAR2
ANTICAG - Direct Thrombin Inhibitor	*ANTICDTH_CIDIRECTTHROMBININHIBITOR_C	NUMBER
	*ANTICDTH_CIDIRECTTHROMBININHIBITOR	VARCHAR2
ANTICAG - Other	ANTICOTH_CIOTHER1_C	NUMBER
	ANTICOTH_CIOTHER1	VARCHAR2
ANTICAG - ANTICACI	ANTICACI_C	NUMBER
	ANTICACI	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
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 - HCCTZFRQ	HCCTZFRQ_C	NUMBER
	HCCTZFRQ	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
GLUCLOW	GLUCLOW_C	**NUMBER
	GLUCLOW	VARCHAR2
	GLUCLOW_ND	VARCHAR2
GLUCLOW - Biguanides	BIGUANID_CIBIGUANIDES_C	NUMBER
	BIGUANID_CIBIGUANIDES	VARCHAR2
GLUCLOW - Sulfonylurea	SULFONY_CISULFONYLUREA_C	NUMBER
	SULFONY_CISULFONYLUREA	VARCHAR2
GLUCLOW - Pramlintide	PPRAMLIN_CIPRAMLINTIDE_C	NUMBER
	PPRAMLIN_CIPRAMLINTIDE	VARCHAR2
GLUCLOW - Thiazolidinedione	*THIAZOLI_CITHIAZOLIDINEDIONE_C	NUMBER
	*THIAZOLI_CITHIAZOLIDINEDIONE	VARCHAR2
GLUCLOW - Non-sulfonylurea secretagogues	*NONSULFS_CINONSULFONYLUREASECRETAGOGUES_C	NUMBER
	*NONSULFS_CINONSULFONYLUREASECRETAGOGUES	VARCHAR2
GLUCLOW - Alpha-glucosidase Inhibitors	*AGLUIHNB_CIALPHAGLUCOSIDASEINHIBITORS_C	NUMBER
	*AGLUIHNB_CIALPHAGLUCOSIDASEINHIBITORS	VARCHAR2
GLUCLOW - Insulin	INSULIN_CINSULIN_C	NUMBER
	INSULIN_CINSULIN	VARCHAR2
GLUCLOW - GLP-1 Analogues	GLP1ANAL_CIGLP1ANALOGUES_C	NUMBER
	GLP1ANAL_CIGLP1ANALOGUES	VARCHAR2
GLUCLOW - DPP-IV Inhibitor	DPPIVINH_CIDPPIVINHIBITOR_C	NUMBER
	DPPIVINH_CIDPPIVINHIBITOR	VARCHAR2
GLUCLOW - SGLT-2 inhibitors	*SLGTINHNB_CISGLT2INHIBITORS_C	NUMBER
	*SLGTINHNB_CISGLT2INHIBITORS	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_FIGHT: INITIAL STUDY DRUG ADMINISTRATION (ISDADMIN) [frISDADMIN]	
Initial Study Drug Administration [stISDADMIN1]	
<p>1.* Was study drug initial dose administered ✓ [Was study drug initial dose administered]</p>	<p>[INISDRG] [N: 1] <input checked="" type="radio"/> [INDRGDTM] Yes (record in DRUGKIT form in KITS visit) Date and time administered: Req [v] / Req [v] / Req [v] (2013-2018) Req/Unk [v] : Req/Unk [v] 24-hour clock [INRGAD] Dose Administered: [N: 1] <input checked="" type="radio"/> 0.6 mg [N: 98] <input checked="" type="radio"/> [cpINRGAD] Other Other dose: [INDRGDSE] xxxxxxxx. mg [INDRGDSP] Reason: A200</p> <p>[N: 0] <input checked="" type="radio"/> [cpINDRGRS] No If No, specify reason: [INDRGRS] [N: 1] <input checked="" type="radio"/> Subject withdrew consent [N: 2] <input checked="" type="radio"/> MD Decision [N: 98] <input checked="" type="radio"/> [INDRGRSP] Other Specify: A200</p>
<p>Key: [*] = Item is required [✓] = Source verification required</p>	

RDE Analytics: RD_FRISDADMIN		
Data Variable RefName	RD Column Name	Column Data Type
INISDRG	INISDRG_C	**NUMBER
	INISDRG	VARCHAR2
	INISDRG_ND	VARCHAR2
INISDRG - INDRGDTM	INDRGDTM	DATE
	INDRGDTM_DTS	VARCHAR2
	INDRGDTM_DTR	VARCHAR2
INISDRG - INRGAD	INRGAD_C	NUMBER
	INRGAD	VARCHAR2
INISDRG - INDRGDSE	INDRGDSE	FLOAT
INISDRG - INDRGDSP	INDRGDSP	VARCHAR2
INISDRG - INDRGRS	INDRGRS_C	NUMBER
	INDRGRS	VARCHAR2
INISDRG - INDRGRSP	INDRGRSP	VARCHAR2
<p>Key: [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.</p>		

HFN_FIGHT: EXAMINATION (EXAM) [frEXAM]	
EXAMINATION [frEXAM]	
1.* Heart Rate (sitting or resting) [Heart Rate]	[HRATE] [N: 1] <input type="radio"/> [HRATEVAL] N3 [N: 97] <input type="radio"/> Not Done
2.* Blood Pressure (sitting or resting) [Blood Pressure]	[BPDONE] [N: 1] <input type="radio"/> [cpBP] [BPSYS] [BPDIA] mmHg N3 / N3 [N: 97] <input type="radio"/> Not Done
3.* SpO2 [SpO2]	[SPO2] [N: 1] <input type="radio"/> [SPO2VAL] xxxxxxxx. % ^[b] [N: 97] <input type="radio"/> Not Done
4.* Height (at Baseline visit only) [Height]	[HEIGHT] [N: 1] <input type="radio"/> [HGTVAL] xxxxxxxx. in ^[b] cm [N: 97] <input type="radio"/> Not Done
5.* Weight [Weight]	[WEIGHT] [N: 1] <input type="radio"/> [WGTVAL] xxxxxxxx. lbs ^[b] kg [N: 97] <input type="radio"/> Not Done
6.* JVP [JVP]	[JVP] [N: 1] <input type="radio"/> Not elevated/not distended [N: 2] <input type="radio"/> Elevated/distended [N: 97] <input type="radio"/> Not Done
7.* Rales [Rales]	[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
8.* S3 auscultation [S3 auscultation]	[S3AUS] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 97] <input type="radio"/> Not Done
9.* Hepatomegaly [Hepatomegaly]	[HEPATO] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 97] <input type="radio"/> Not Done
10.* Ascites [Ascites]	[ASCITES] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 97] <input type="radio"/> Not Done
11.* Peripheral edema [Peripheral edema]	[EDEMA] [N: 1] <input type="radio"/> None [N: 2] <input type="radio"/> Trace (1+) [N: 3] <input type="radio"/> Moderate (2+, 3+) [N: 4] <input type="radio"/> Severe (4+) [N: 97] <input type="radio"/> Not Done
12.* Current NYHA heart failure classification [Current NYHA heart failure classification]	[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 [N: 97] <input type="radio"/> Not Done
13.* Orthopnea [Orthopnea]	[ORTHOP] [N: 1] <input type="radio"/> None [N: 2] <input type="radio"/> One pillow (10cm) [N: 3] <input type="radio"/> Two pillows (20cm) [N: 4] <input type="radio"/> Three or more pillows [N: 97] <input type="radio"/> Not Done

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

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
	HGTVAL_N	FLOAT
	HGTVAL_U	VARCHAR2
	HGTVAL_NU	VARCHAR2
WEIGHT	WEIGHT_C	**NUMBER
	WEIGHT	VARCHAR2
	WEIGHT_ND	VARCHAR2
WEIGHT - WGTVAL	WGTVAL	FLOAT
	WGTVAL_N	FLOAT
	WGTVAL_U	VARCHAR2
	WGTVAL_NU	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_FIGHT: ECG (ECG) [frECG]	
ECG [stECG1]	
1.* Date of ECG closest (prior) to Randomization [Date of ECG closest (prior) to Randomization]	<p>[ECG] [N: 1] <input type="radio"/> [ECGDT] Req [v] / Req [v] / Req [v] (2013-2018) [N: 97] <input type="radio"/> Not Done</p>
2.* Heart Rate [Heart Rate]	<p>[ECGRATE] [N: 1] <input type="radio"/> [ECGHRVAL] N3 bpm [N: 97] <input type="radio"/> Not Done</p>
3.* ECG Rhythm [ECG Rhythm]	<p>[ECGRHYTH] [N: 1] <input type="radio"/> Sinus rhythm [N: 2] <input type="radio"/> Atrial fibrillation [N: 3] <input type="radio"/> Atrial flutter [N: 4] <input type="radio"/> [PACERHYT] Paced Underlying rhythm [N: 1] <input type="radio"/> Sinus [N: 2] <input type="radio"/> Atrial fibrillation [N: 3] <input type="radio"/> Atrial flutter [N: 98] <input type="radio"/> [PACEDSP] Other, specify: A50 [N: 99] <input type="radio"/> Unknown [N: 98] <input type="radio"/> Other [N: 97] <input type="radio"/> Not Done</p>
4.* QRS duration [QRS duration]	<p>[ECGQRS] [N: 1] <input type="radio"/> [cpECGQRS] [ECGQRSVL] xxxxxxx. msec [ECGQRSTY] QRS complex for this measurement: [N: 1] <input type="radio"/> Intrinsic rhythm [N: 2] <input type="radio"/> Only ventricular paced QRS complexes present [N: 99] <input type="radio"/> Unknown [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_FIGHT: SIX MINUTE WALK TEST (SIXMWT) [frSIXMWT]		
Six Minute Walk Test [stSIXMWT1]		
1.* ✓	Date test performed [Date test performed]	[WALKDT] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018)
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 [N: 99] <input type="radio"/> Unknown

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

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

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

HFN_FIGHT: 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_FIGHT: 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
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"/> (2013-2018) Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock
2.2*	Number of Samples Collected [Number of Samples Collected]				
					[cpBIOCCL1] [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]				
					[BIOMSTD1] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2013-2018)
2.4*	Date samples received [Date received]				
					[BIOMRCD1] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2013-2018)
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 type="radio"/> [BIORNRN] 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"/> (2013-2018) Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock
4.2*	Number of Samples Collected [Number of Samples Collected]				
					[cpBIOCCL2] [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"/> (2013-2018)
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_FIGHT: ECHOCARDIOGRAM (ECHO) [frECHO]	
ECHOCARDIOGRAM [frECHO]	
TO BE COMPLETED BY STUDY SITE:	
<p>1.* <input checked="" type="checkbox"/> Was ECHO performed at this visit [Was ECHO performed at this visit]</p>	<p>[ECHO] [N: 1] <input type="radio"/> [cpECHO] Yes [ECHODT] Date ECHO performed Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2013-2018) [ECSMTDT] Date ECHO submitted Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2013-2018) [ECHOHR] Heart Rate [N: 1] <input type="radio"/> [ECHOHRVL] <input type="text" value="N3"/> [N: 97] <input type="radio"/> Not Done [ECHOBP] Blood Pressure [N: 1] <input type="radio"/> [cpECHOBP] [ECHOSYS] [ECHODIA] mmHg <input type="text" value="N3"/> / <input type="text" value="N3"/> [N: 97] <input type="radio"/> Not Done [ECHORHY] Rhythm [N: 1] <input type="radio"/> NSR [N: 2] <input type="radio"/> A Fib [N: 98] <input type="radio"/> [ECHORHSP] Other, specify <input type="text" value="A50"/> [N: 0] <input type="radio"/> [ECNDRSN] No Reason not done: [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</p>
<p>Key: [*] = Item is required [✓] = Source verification required</p>	

RDE Analytics: RD_FRECHO		
Data Variable RefName	RD Column Name	Column Data Type
ECHO	ECHO_C	**NUMBER
	ECHO	VARCHAR2
	ECHO_ND	VARCHAR2
ECHO - ECHODT	ECHODT	DATE
	ECHODT_DTS	VARCHAR2
ECHO - ECSMTDT	ECSMTDT	DATE
	ECSMTDT_DTS	VARCHAR2
ECHO - ECHOHR	ECHOHR_C	**NUMBER
	ECHOHR	VARCHAR2
ECHO - ECHOHRVL	ECHOHRVL	NUMBER
ECHO - ECHOBP	ECHOBP_C	**NUMBER
	ECHOBP	VARCHAR2
ECHO - ECHOSYS	ECHOSYS	NUMBER
ECHO - ECHODIA	ECHODIA	NUMBER
ECHO - ECHORHY	ECHORHY_C	NUMBER
	ECHORHY	VARCHAR2
ECHO - ECHORHSP	ECHORHSP	VARCHAR2
ECHO - ECNDRSN	ECNDRSN_C	NUMBER
	ECNDRSN	VARCHAR2
<p>Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.</p>		

HFN_FIGHT: ECHO RESULTS PART 1 (ECHOLAB1) [frECHOLAB1]	
TO BE COMPLETED BY ECHO CORE LAB: [stECHOLAB1_1]	
1.* Echo Date [Echo Date]	[CECHODT] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018)
2. Quality of LV Volumes [Quality of LV Volumes]	[LVQUAL] [N:1] <input type="radio"/> Excellent (publication quality) [N:2] <input type="radio"/> Good (biplane vol) [N:3] <input type="radio"/> Adequate (single plane vol) [N:4] <input type="radio"/> Poor (vis EF only) [N:5] <input type="radio"/> Inadequate (no LV data)
3. Quality of Doppler diastolic function [Quality of Doppler diastolic function]	[DOPPOQUAL] [N:1] <input type="radio"/> Excellent (publication quality) [N:2] <input type="radio"/> Good (MVI and DTIs) [N:3] <input type="radio"/> Adequate (MVI only) [N:4] <input type="radio"/> Poor/Inadequate [N:5] <input type="radio"/> Not performed [N:6] <input type="radio"/> Not applicable (MVR, rhythm etc.)
4. Quality of MR Assessment [Quality of MR Assessment]	[MRQUAL] [N:1] <input type="radio"/> Excellent (publication quality) [N:2] <input type="radio"/> Good (PISA and CF) [N:3] <input type="radio"/> Adequate (either PISA or CF) [N:4] <input type="radio"/> Poor/Inadequate [N:5] <input type="radio"/> Not performed [N:6] <input type="radio"/> Not applicable (Less than grade 2 MR)
5. 2D PLAX: IVS systolic dimension [2D PLAX: IVS systolic dimension]	[IVSDD] [N:1] <input type="radio"/> [IVSD] xxxxxxxx. <input type="text"/> cm [N:2] <input type="radio"/> [IVVSD] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent
6. 2D PLAX: PW systolic dimension [2D PLAX: PW systolic dimension]	[PWSDD] [N:1] <input type="radio"/> [PWSD] xxxxxxxx. <input type="text"/> cm [N:2] <input type="radio"/> [VPWSD] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent
7. 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
8. 2D PLAX: LV systolic dimension [2D PLAX: LV systolic dimension]	[LVSD] [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
9. EF by 2D PLAX [EF by 2D PLAX]	[EFPLAXD] [N:1] <input type="radio"/> [EFPLAX] xxxxxxxx. <input type="text"/> % [N:2] <input type="radio"/> [VEFPLAX] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent
10. MR Vena contracta PLAX [MR Vena contracta PLAX]	[MRPLAXD] [N:1] <input type="radio"/> [MRPLAX] xxxxxxxx. <input type="text"/> cm [N:2] <input type="radio"/> [VMRPLAX] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent

		[N: 3] <input type="radio"/> Not clinically indicated
11. LVOT Diameter [LVOT Diameter]	<p>[LVOTD]</p> <p>[N: 1] <input type="radio"/> [LVOT] xxxxxxxx. <input type="text"/> cm</p> <p>[N: 2] <input type="radio"/> [VLVOT] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>	
12. MV Inflow: E velocity at leaf tip [MV Inflow: E velocity at leaf tip]	<p>[EVELOCD]</p> <p>[N: 1] <input type="radio"/> [EVELOC] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VEVELOC] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>	
13. MV Inflow: A velocity at leaf tip [MV Inflow: A velocity at leaf tip]	<p>[AVELOCD]</p> <p>[N: 1] <input type="radio"/> [AVELOC] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VAVELOC] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent [N: 3] <input type="radio"/> Not clinically indicated</p>	
14. MV Inflow: Decel time at leaf tip [MV Inflow: Decel time at leaf tip]	<p>[DECELTMD]</p> <p>[N: 1] <input type="radio"/> [DECELTM] xxxxxxxx. <input type="text"/> ms</p> <p>[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>	
15. Pul Vein: Systolic Forward [Pul Vein: Systolic Forward]	<p>[SYSFWRDD]</p> <p>[N: 1] <input type="radio"/> [SYSFWRD] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VSYSFWRD] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>	
16. Pul Vein: Diastolic Forward [Pul Vein: Diastolic Forward]	<p>[DYSFWRDD]</p> <p>[N: 1] <input type="radio"/> [DYSFWRD] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VDYSFWRD] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>	
17. LVOT Velocity [LVOT Velocity]	<p>[LVOVELCD]</p> <p>[N: 1] <input type="radio"/> [LVOVELC] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VLVOVELC] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>	
18. LVOT: TVI [LVOT: TVI]	<p>[TVID]</p> <p>[N: 1] <input type="radio"/> [TVI] xxxxxxxx. <input type="text"/> cm</p> <p>[N: 2] <input type="radio"/> [VTVI] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>	
19. LVET [LVET]	<p>[LVETD]</p> <p>[N: 1] <input type="radio"/> [LVET] xxxxxxxx. <input type="text"/> msec</p> <p>[N: 2] <input type="radio"/> [VLVET] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>	
20. AR Severity Grade [AR Severity Grade]	<p>[ARSEVGRD]</p> <p>[ctSeverityGrade] <input type="text"/></p>	
21. MV C-W Diastolic Flow: Mean Gradient		

<p>[MV C-W Diastolic Flow: Mean Gradient]</p>	<p>[MEANGRDD] [N: 1] <input type="radio"/> [MEANGRD] xxxxxxxx. mmHg [N: 2] <input type="radio"/> [VMEANGRD] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent [N: 3] <input type="radio"/> Not clinically indicated</p>
<p>22. MV C-W Diastolic Flow: Pressure half-time [MV C-W Diastolic Flow: Pressure half-time]</p>	<p>[PRESHLFD] [N: 1] <input type="radio"/> [PRESHLRF] xxxxxxxx. ms [N: 2] <input type="radio"/> [VPRESHLRF] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent [N: 3] <input type="radio"/> Not clinically indicated</p>
<p>23. Peak TR velocity [Peak TR velocity]</p>	<p>[PKTRVELD] [N: 1] <input type="radio"/> [PEAKVELC] xxxxxxxx. 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>
<p>24. 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>	<p>[RAPRESSD] [N: 1] <input type="radio"/> [RAPRESS] xxxxxxxx. mmHg [N: 97] <input type="radio"/> Not Done</p>
<p>25. TR Severity Grade [TR Severity Grade]</p>	<p>[TRSEVGRD] [ctSeverityGrade] <input type="button" value="v"/></p>
<p>Key: [*] = Item is required</p>	

Codelist Values and Tables: ECHO RESULTS PART 1					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
ctSeverityGrade	Integer	0 = 0	0	ci0	ARSEVGRD, TRSEVGRD
		1 = Trivial	1	ci1Trivial	
		2 = 1	2	ci2equal1	
		3 = 2	3	ci3equal2	
		4 = 3	4	ci4equal3	
		5 = 4	5	ci5equal4	
		6 = Indeterminate	6	ci6Indeterminate	

RDE Analytics: RD_FRECHOLAB1		
Data Variable RefName	RD Column Name	Column Data Type
CECHODT	CECHODT	DATE
	CECHODT_DTS	VARCHAR2
	CECHODT_ND	VARCHAR2
LVQUAL	LVQUAL_C	NUMBER
	LVQUAL	VARCHAR2
	LVQUAL_ND	VARCHAR2
DOPQUAL	DOPQUAL_C	NUMBER
	DOPQUAL	VARCHAR2
	DOPQUAL_ND	VARCHAR2
MRQUAL	MRQUAL_C	NUMBER
	MRQUAL	VARCHAR2
	MRQUAL_ND	VARCHAR2
IVSDD	IVSDD_C	**NUMBER
	IVSDD	VARCHAR2
	IVSDD_ND	VARCHAR2
IVSDD - IVSD	IVSD	FLOAT
IVSDD - VIVSD	VIVSD_C	NUMBER

	VIVSD	VARCHAR2
PWSDD	PWSDD_C	**NUMBER
	PWSDD	VARCHAR2
	PWSDD_ND	VARCHAR2
PWSDD - PWSDD	PWSDD	FLOAT
PWSDD - VPWSDD	VPWSDD_C	NUMBER
	VPWSDD	VARCHAR2
LVDDD	LVDDD_C	**NUMBER
	LVDDD	VARCHAR2
	LVDDD_ND	VARCHAR2
LVDDD - LVDDD	LVDDD	FLOAT
LVDDD - VLDDD	VLDDD_C	NUMBER
	VLDDD	VARCHAR2
LVSSD	LVSSD_C	**NUMBER
	LVSSD	VARCHAR2
	LVSSD_ND	VARCHAR2
LVSSD - LVSSD	LVSSD	FLOAT
LVSSD - VLSSD	VLSSD_C	NUMBER
	VLSSD	VARCHAR2
EFPLAXD	EFPLAXD_C	**NUMBER
	EFPLAXD	VARCHAR2
	EFPLAXD_ND	VARCHAR2
EFPLAXD - EFPLAXD	EFPLAXD	FLOAT
EFPLAXD - VEFPLAXD	VEFPLAXD_C	NUMBER
	VEFPLAXD	VARCHAR2
MRPLAXD	MRPLAXD_C	**NUMBER
	MRPLAXD	VARCHAR2
	MRPLAXD_ND	VARCHAR2
MRPLAXD - MRPLAXD	MRPLAXD	FLOAT
MRPLAXD - VMRPLAXD	VMRPLAXD_C	NUMBER
	VMRPLAXD	VARCHAR2
LVOTD	LVOTD_C	**NUMBER
	LVOTD	VARCHAR2
	LVOTD_ND	VARCHAR2
LVOTD - LVOTD	LVOTD	FLOAT
LVOTD - VLVOTD	VLVOTD_C	NUMBER
	VLVOTD	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

	VDECELM	VARCHAR2
SYSFWRDD	SYSFWRDD_C	**NUMBER
	SYSFWRDD	VARCHAR2
	SYSFWRDD_ND	VARCHAR2
SYSFWRDD - SYSFWRD	SYSFWRD	FLOAT
SYSFWRDD - VSYSFWRD	VSYSFWRD_C	NUMBER
	VSYSFWRD	VARCHAR2
DYSFWRDD	DYSFWRDD_C	**NUMBER
	DYSFWRDD	VARCHAR2
	DYSFWRDD_ND	VARCHAR2
DYSFWRDD - DYSFWRD	DYSFWRD	FLOAT
DYSFWRDD - VDYSFWRD	VDYSFWRD_C	NUMBER
	VDYSFWRD	VARCHAR2
LVOVELCD	LVOVELCD_C	**NUMBER
	LVOVELCD	VARCHAR2
	LVOVELCD_ND	VARCHAR2
LVOVELCD - LVOVELC	LVOVELC	FLOAT
LVOVELCD - VLVOVELC	VLVOVELC_C	NUMBER
	VLVOVELC	VARCHAR2
TVID	TVID_C	**NUMBER
	TVID	VARCHAR2
	TVID_ND	VARCHAR2
TVID - TVI	TVI	FLOAT
TVID - VTVI	VTVI_C	NUMBER
	VTVI	VARCHAR2
LVETD	LVETD_C	**NUMBER
	LVETD	VARCHAR2
	LVETD_ND	VARCHAR2
LVETD - LVET	LVET	FLOAT
LVETD - VLVET	VLVET_C	NUMBER
	VLVET	VARCHAR2
ARSEVGRD	ARSEVGRD_C	NUMBER
	ARSEVGRD	VARCHAR2
	ARSEVGRD_ND	VARCHAR2
MEANGRDD	MEANGRDD_C	**NUMBER
	MEANGRDD	VARCHAR2
	MEANGRDD_ND	VARCHAR2
MEANGRDD - MEANGRD	MEANGRD	FLOAT
MEANGRDD - VMEANGRD	VMEANGRD_C	NUMBER
	VMEANGRD	VARCHAR2
PRESHLFD	PRESHLFD_C	**NUMBER
	PRESHLFD	VARCHAR2
	PRESHLFD_ND	VARCHAR2
PRESHLFD - PRESRLF	PRESRLF	FLOAT
PRESHLFD - VPRESRLF	VPRESRLF_C	NUMBER
	VPRESRLF	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
TRSEVGRD	TRSEVGRD_C	NUMBER
	TRSEVGRD	VARCHAR2
	TRSEVGRD_ND	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_FIGHT: ECHO RESULTS PART 2 (ECHOLAB2) [frECHOLAB2]	
TO BE COMPLETED BY ECHO CORE LAB: [stECHOLAB2_1]	
1. Peak MR Velocity [Peak MR Velocity]	<p>[PKMRVELD] [N: 1] <input type="radio"/> [PEAKVEL] xxxxxxxx. <input type="text"/> cm/sec</p> <p>[N: 2] <input type="radio"/> [VPPEAKMR] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent [N: 3] <input type="radio"/> Not clinically indicated</p>
2. MR TVI [MR TVI]	<p>[MRTVID] [N: 1] <input type="radio"/> [MRTVI] xxxxxxxx. <input type="text"/> cm</p> <p>[N: 2] <input type="radio"/> [MVRTVI] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent [N: 3] <input type="radio"/> Not clinically indicated</p>
3. PISA Radius [PISA Radius]	<p>[PISARADD] [N: 1] <input type="radio"/> [PISARAD] xxxxxxxx. <input type="text"/> cm</p> <p>[N: 2] <input type="radio"/> [VPI SARAD] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent [N: 3] <input type="radio"/> Not clinically indicated</p>
4. PISA: Alias vel [PISA: Alias vel]	<p>[PISAVELD] [N: 1] <input type="radio"/> [PISAVEL] xxxxxxxx. <input type="text"/> cm</p> <p>[N: 2] <input type="radio"/> [VPI SAVEL] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent [N: 3] <input type="radio"/> Not clinically indicated</p>
5. PISA: ERO [PISA: ERO]	<p>[PISAEROD] [N: 1] <input type="radio"/> [PISAERO] xxxxxxxx. <input type="text"/> cm²</p> <p>[N: 97] <input type="radio"/> Not Done</p>
6. PISA: Reg Vol [PISA: Reg Vol]	<p>[PISAVOLD] [N: 1] <input type="radio"/> [PISAVOL] xxxxxxxx. <input type="text"/> ml</p> <p>[N: 97] <input type="radio"/> Not Done</p>
7. PISA MR Grade [PISA MR Grade]	<p>[PISAGRD] [ctMRGrade] <input type="text"/></p>
8. ERO MR Severity Scale [ERO MR Severity Scale]	<p>[EROMRSEV] [ctMRSeverityScale] <input type="text"/></p>
9. Multiple Jets [Multiple Jets]	<p>[MULTJETS] [N: 1] <input type="checkbox"/> Yes</p>
10. LA Area [LA Area]	<p>[LAAREAD] [N: 1] <input type="radio"/> [LAAREA] xxxxxxxx. <input type="text"/> cm²</p> <p>[N: 2] <input type="radio"/> [VLAAREA] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent [N: 3] <input type="radio"/> Not clinically indicated</p>
11. MR Jet [MR Jet]	<p>[MRJETD] [N: 1] <input type="radio"/> [MRJET] xxxxxxxx. <input type="text"/> cm²</p> <p>[N: 2] <input type="radio"/> [VMRJET] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent [N: 3] <input type="radio"/> Not clinically indicated</p>
12. MR Vena contracta Apical [MR Vena contracta Apical]	<p>[MRCONTD] [N: 1] <input type="text"/> [MRCONT]</p>

		<input type="radio"/> xxxxxxxx. _____ cm [N:2] <input type="radio"/> [VMRCONT] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent [N:3] <input type="radio"/> Not clinically indicated
13.	Overall MR Severity Grade [Overall MR Severity Grade]	[OVRALGRD] [ctSeverityGrade] ▾
14.	DTI Medial Annulus e [DTI Medial Annulus e]	[DTIMEDED] [N:1] <input type="radio"/> [DTIMEDE] xxxxxxxx. _____ 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
15.	DTI Medial Annulus s [DTI Medial Annulus s]	[DTIMEDSD] [N:1] <input type="radio"/> [DTIMEDS] xxxxxxxx. _____ m/sec [N:2] <input type="radio"/> [VDTIMEDS] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent
16.	DTI Lateral Annulus e [DTI Lateral Annulus e]	[DTILATED] [N:1] <input type="radio"/> [DTILATE] xxxxxxxx. _____ 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
17.	DTI Lateral Annulus s [DTI Lateral Annulus s]	[DTILATSD] [N:1] <input type="radio"/> [DTILATS] xxxxxxxx. _____ m/sec [N:2] <input type="radio"/> [VDTILATS] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent
18.	DTI Tricuspid Lateral Annulus e [DTI Tricuspid Lateral Annulus e]	[DTITRIED] [N:1] <input type="radio"/> [DTITRIE] xxxxxxxx. _____ m/sec [N:2] <input type="radio"/> [VDTITRIE] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent
19.	DTI Tricuspid Lateral Annulus s [DTI Tricuspid Lateral Annulus s]	[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
20.	Apical LV LAX Length Diastole [Apical LV LAX Length Diastole]	[APLVDIAD] [N:1] <input type="radio"/> [APLV DIA] xxxxxxxx. _____ cm [N:2] <input type="radio"/> [VAPLV DIA] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent
21.	Apical LV LAX Length Systole [Apical LV LAX Length Systole]	[APLVSYSD] [N:1] <input type="radio"/> [APLVSY S] xxxxxxxx. _____ cm [N:2] <input type="radio"/> [VAPLVSY S] Missing - indicate view quality: [N:1] <input type="radio"/> Poor Views [N:2] <input type="radio"/> Views Absent
22.	Biplane: LVED 4ch/2ch Volume [Biplane: LVED 4ch/2ch Volume]	[LVEDCHD] [N:1] <input type="radio"/> [LVEDCH] xxxxxxxx. _____ ml [N:2] <input type="radio"/> [VLVEDVOL]

		Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
23.	Biplane: LVES 4ch/2ch Volume [Biplane: LVES 4ch/2ch Volume]	[LVECHCHD] [N: 1] <input type="radio"/> [LVECHCH] xxxxxxxx. <input type="text"/> ml [N: 2] <input type="radio"/> [VLVESCH] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
24.	Bp Simp 4/2ch EF [Bp Simp 4/2ch EF]	[BPSIMPED] [N: 1] <input type="radio"/> [BPSIMPEF] xxxxxxxx. <input type="text"/> % [N: 97] <input type="radio"/> Not Done
25.	Single Plane: LVED 4ch Volume [Single Plane: LVED 4ch Volume]	[LVEDVOLD] [N: 1] <input type="radio"/> [LVEDVOL] xxxxxxxx. <input type="text"/> ml [N: 2] <input type="radio"/> [VLVEDVL4] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
26.	Single Plane: LVES 4ch Volume [Single Plane: LVES 4ch Volume]	[LVESVOLD] [N: 1] <input type="radio"/> [LVESVOL] xxxxxxxx. <input type="text"/> ml [N: 2] <input type="radio"/> [VLVESVOL] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
27.	EF by Single Plane Vol [EF by Single Plane Vol]	[EFSINGD] [N: 1] <input type="radio"/> [EFSINGLE] xxxxxxxx. <input type="text"/> % [N: 97] <input type="radio"/> Not Done
28.	Visual EF [Visual EF]	[VISLEFD] [N: 1] <input type="radio"/> [VISUALEF] xxxxxxxx. <input type="text"/> % [N: 2] <input type="radio"/> [VVISUEF] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
29.	LA 4c Area [LA 4c Area]	[LACAREAD] [N: 1] <input type="radio"/> [LACAREA] xxxxxxxx. <input type="text"/> cm ² [N: 2] <input type="radio"/> [VLACAREA] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
30.	LA 4c Length [LA 4c Length]	[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
31.	LA 2ch Area [LA 2ch Area]	[LACHARD] [N: 1] <input type="radio"/> [LACHAREA] xxxxxxxx. <input type="text"/> cm ² [N: 2] <input type="radio"/> [VLACHARE] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
32.	LA 2c Length [LA 2c Length]	[LALEND] [N: 1] <input type="radio"/> [LALEN] xxxxxxxx. <input type="text"/> cm [N: 2] <input type="radio"/> [VLALEN] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
33.	RV Function	

	[RV Function]		[RVFUNC] [ctRVFunction]
34.	Wall Motion [Wall Motion]		[WALLMOTN] [ctWallMotion]
35.	Hepatic Vein Flow Residuals [Hepatic Vein Flow Residuals]		[HEPVEN] [ctHepaticVeinFlowResiduals]
36.	Additional Comments [Additional Comments]		[ECHOCOM] A200

Codelist Values and Tables: ECHO RESULTS PART 2					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
ctMRGrade	Integer	0 = 0/Trivial	0	ci0Trivial	PISAGRD
		1 = Mild	1	ci1Mild	
		2 = Moderate	2	ci2Moderate	
		3 = Severe	3	ci3Severe	
		4 = Indeterminate	4	ci4Indeterminate	
ctMRSeverityScale	Integer	0 = < 0.20 cm2 (Mild MR)	0	ciMildMR	EROMRSEV
		1 = 0.20-0.29 cm2 (Moderate MR)	1	ciModerateMR	
		2 = 0.30-0.40 cm2 (Moderately Severe MR)	2	ciModeratelySevereMR	
		3 = > 0.40 cm2 (Severe MR)	3	ciSevereMR	
ctSeverityGrade	Integer	0 = 0	0	ci0	OVRALGRD
		1 = Trivial	1	ci1Trivial	
		2 = 1	2	ci2equal1	
		3 = 2	3	ci3equal2	
		4 = 3	4	ci4equal3	
		5 = 4	5	ci5equal4	
ctRVFunction	Integer	0 = Normal	0	ci0Normal	RVFUNC
		1 = Mild Dysfx	1	ci1MildDysfx	
		2 = Moderate Dysfx	2	ci2ModerateDysfx	
		3 = Severe Dysfx	3	ci3SevereDysfx	
		4 = Indeterminate	4	ci4Indeterminate	
ctWallMotion	Integer	0 = Normal	0	ci0Normal	WALLMOTN
		1 = Global hypo	1	ci1GlobalHypo	
		2 = RWMA	2	ci2RWMA	
		3 = Abnormal septal motion	3	ci3AbdominalSeptalMotion	
ctHepaticVeinFlowResiduals	Integer	0 = No	0	ci0No	HEPVEN
		1 = Yes (inspiration only)	1	ci1Yes	
		2 = Yes (all respiration)	2	ci2Yes	
		3 = Indeterminate	3	ci3Indeterminate	
		4 = Not available	4	ci4NotAvailable	

RDE Analytics: RD_FRECHOLAB2		
Data Variable RefName	RD Column Name	Column Data Type
PKMRVELD	PKMRVELD_C	**NUMBER
	PKMRVELD	VARCHAR2
	PKMRVELD_ND	VARCHAR2
PKMRVELD - PEAKVEL	PEAKVEL	FLOAT
PKMRVELD - VPEAKMR	VPEAKMR_C	NUMBER
	VPEAKMR	VARCHAR2
MRTVID	MRTVID_C	**NUMBER

	MRTVID	VARCHAR2
	MRTVID_ND	VARCHAR2
MRTVID - MRTVI	MRTVI	FLOAT
MRTVID - MVRTVI	MVRTVI_C	NUMBER
	MVRTVI	VARCHAR2
PISARADD	PISARADD_C	**NUMBER
	PISARADD	VARCHAR2
	PISARADD_ND	VARCHAR2
PISARADD - PISARAD	PISARAD	FLOAT
PISARADD - VPISARAD	VPISARAD_C	NUMBER
	VPISARAD	VARCHAR2
PISAVELD	PISAVELD_C	**NUMBER
	PISAVELD	VARCHAR2
	PISAVELD_ND	VARCHAR2
PISAVELD - PISAVEL	PISAVEL	FLOAT
PISAVELD - VPISAVEL	VPISAVEL_C	NUMBER
	VPISAVEL	VARCHAR2
PISAEROD	PISAEROD_C	**NUMBER
	PISAEROD	VARCHAR2
	PISAEROD_ND	VARCHAR2
PISAEROD - PISAERO	PISAERO	FLOAT
PISAVOLD	PISAVOLD_C	**NUMBER
	PISAVOLD	VARCHAR2
	PISAVOLD_ND	VARCHAR2
PISAVOLD - PISAVOL	PISAVOL	FLOAT
PISAGRD	PISAGRD_C	NUMBER
	PISAGRD	VARCHAR2
	PISAGRD_ND	VARCHAR2
EROMRSEV	EROMRSEV_C	NUMBER
	EROMRSEV	VARCHAR2
	EROMRSEV_ND	VARCHAR2
MULTJETS	MULTJETS_ND	VARCHAR2
MULTJETS - Yes	MULTJETS_CIYES_C	NUMBER
	MULTJETS_CIYES	VARCHAR2
LAAREAD	LAAREAD_C	**NUMBER
	LAAREAD	VARCHAR2
	LAAREAD_ND	VARCHAR2
LAAREAD - LAAREA	LAAREA	FLOAT
LAAREAD - VLAAREA	VLAAREA_C	NUMBER
	VLAAREA	VARCHAR2
MRJTD	MRJTD_C	**NUMBER
	MRJTD	VARCHAR2
	MRJTD_ND	VARCHAR2
MRJTD - MRJET	MRJET	FLOAT
MRJTD - VMRJET	VMRJET_C	NUMBER
	VMRJET	VARCHAR2
MRCONTD	MRCONTD_C	**NUMBER
	MRCONTD	VARCHAR2
	MRCONTD_ND	VARCHAR2
MRCONTD - MRCONT	MRCONT	FLOAT
MRCONTD - VMRCONT	VMRCONT_C	NUMBER
	VMRCONT	VARCHAR2
OVRALGRD	OVRALGRD_C	NUMBER
	OVRALGRD	VARCHAR2

	OVRALGRD_ND	VARCHAR2
DTIMEDED	DTIMEDED_C	**NUMBER
	DTIMEDED	VARCHAR2
	DTIMEDED_ND	VARCHAR2
DTIMEDED - DTIMEDE	DTIMEDE	FLOAT
DTIMEDED - VDTIMEDE	VDTIMEDE_C	NUMBER
	VDTIMEDE	VARCHAR2
DTIMEDSD	DTIMEDSD_C	**NUMBER
	DTIMEDSD	VARCHAR2
	DTIMEDSD_ND	VARCHAR2
DTIMEDSD - DTIMEDS	DTIMEDS	FLOAT
DTIMEDSD - VDTIMEDS	VDTIMEDS_C	NUMBER
	VDTIMEDS	VARCHAR2
DTILATED	DTILATED_C	**NUMBER
	DTILATED	VARCHAR2
	DTILATED_ND	VARCHAR2
DTILATED - DTILATE	DTILATE	FLOAT
DTILATED - VDTILATE	VDTILATE_C	NUMBER
	VDTILATE	VARCHAR2
DTILATSD	DTILATSD_C	**NUMBER
	DTILATSD	VARCHAR2
	DTILATSD_ND	VARCHAR2
DTILATSD - DTILATS	DTILATS	FLOAT
DTILATSD - VDTILATS	VDTILATS_C	NUMBER
	VDTILATS	VARCHAR2
DTITRIED	DTITRIED_C	**NUMBER
	DTITRIED	VARCHAR2
	DTITRIED_ND	VARCHAR2
DTITRIED - DTITRIE	DTITRIE	FLOAT
DTITRIED - VDTITRIE	VDTITRIE_C	NUMBER
	VDTITRIE	VARCHAR2
DTITRISD	DTITRISD_C	**NUMBER
	DTITRISD	VARCHAR2
	DTITRISD_ND	VARCHAR2
DTITRISD - DTITRIS	DTITRIS	FLOAT
DTITRISD - VDTITRIS	VDTITRIS_C	NUMBER
	VDTITRIS	VARCHAR2
APLVDIAD	APLVDIAD_C	**NUMBER
	APLVDIAD	VARCHAR2
	APLVDIAD_ND	VARCHAR2
APLVDIAD - APLVDIA	APLVDIA	FLOAT
APLVDIAD - VAPLVDIA	VAPLVDIA_C	NUMBER
	VAPLVDIA	VARCHAR2
APLVSYS	APLVSYS_C	**NUMBER
	APLVSYS	VARCHAR2
	APLVSYS_ND	VARCHAR2
APLVSYS - APLVSYS	APLVSYS	FLOAT
APLVSYS - VAPLVSYS	VAPLVSYS_C	NUMBER
	VAPLVSYS	VARCHAR2
LVEDCHD	LVEDCHD_C	**NUMBER
	LVEDCHD	VARCHAR2
	LVEDCHD_ND	VARCHAR2
LVEDCHD - LVEDCH	LVEDCH	FLOAT
LVEDCHD - VLVEDVOL	VLVEDVOL_C	NUMBER

	VLVEDVOL	VARCHAR2
LVECHCHD	LVECHCHD_C	**NUMBER
	LVECHCHD	VARCHAR2
	LVECHCHD_ND	VARCHAR2
LVECHCHD - LVECHCH	LVECHCH	FLOAT
LVECHCHD - VLVESCH	VLVESCH_C	NUMBER
	VLVESCH	VARCHAR2
BPSIMPED	BPSIMPED_C	**NUMBER
	BPSIMPED	VARCHAR2
	BPSIMPED_ND	VARCHAR2
BPSIMPED - BPSIMPEF	BPSIMPEF	FLOAT
LVEDVOLD	LVEDVOLD_C	**NUMBER
	LVEDVOLD	VARCHAR2
	LVEDVOLD_ND	VARCHAR2
LVEDVOLD - LVEDVOL	LVEDVOL	FLOAT
LVEDVOLD - VLVEDVL4	VLVEDVL4_C	NUMBER
	VLVEDVL4	VARCHAR2
LVESVOLD	LVESVOLD_C	**NUMBER
	LVESVOLD	VARCHAR2
	LVESVOLD_ND	VARCHAR2
LVESVOLD - LVESVOL	LVESVOL	FLOAT
LVESVOLD - VLVESVOL	VLVESVOL_C	NUMBER
	VLVESVOL	VARCHAR2
EFSINGD	EFSINGD_C	**NUMBER
	EFSINGD	VARCHAR2
	EFSINGD_ND	VARCHAR2
EFSINGD - EFSINGLE	EFSINGLE	FLOAT
VISLEFD	VISLEFD_C	**NUMBER
	VISLEFD	VARCHAR2
	VISLEFD_ND	VARCHAR2
VISLEFD - VISUALEF	VISUALEF	FLOAT
VISLEFD - VVISUEF	VVISUEF_C	NUMBER
	VVISUEF	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
RVFUNC	RVFUNC_C	NUMBER
	RVFUNC	VARCHAR2
	RVFUNC_ND	VARCHAR2
WALLMOTN	WALLMOTN_C	NUMBER
	WALLMOTN	VARCHAR2
	WALLMOTN_ND	VARCHAR2
HEPVEN	HEPVEN_C	NUMBER
	HEPVEN	VARCHAR2
	HEPVEN_ND	VARCHAR2
ECHOCOM	ECHOCOM	VARCHAR2
	ECHOCOM_ND	VARCHAR2
Key: [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_FIGHT: VISIT STATUS (VISIT) [frVISIT]

Visit Status [stVISIT1]

<p>1.* <input checked="" type="checkbox"/> Was the visit performed [Visit performed]</p>	<p>[STATUS] [N: 1] <input type="radio"/> [ASSESSDT] Yes Visit date: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2013-2018)</p> <p>[N: 0] <input type="radio"/> [VISNDRES] No Reason visit was not performed: [N: 1] <input type="radio"/> Missed visit [N: 2] <input type="radio"/> Suspected LTFU [N: 3] <input type="radio"/> Subject no longer participating in study (died, permanently withdrew consent, etc). [N: 98] <input type="radio"/> [ASESNDSP] Other, specify 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 - ASSESSDT	ASSESSDT	DATE
	ASSESSDT_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_FIGHT: ADHERENCE AND DOSAGE ASSESSMENT (ADHASMT) [frADHASMT]

Study Drug Adherence [stADHASMT1]

1. *	Has the subject missed any prescribed doses since the last visit [Has the subject missed any prescribed doses since the last visit]	[MISSDOS] [N: 1] <input type="radio"/> [NUMMISS] Yes Approximate number of doses missed: <input type="text" value="N3"/> [N: 0] <input type="radio"/> No
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Key: [*] = Item is required

RDE Analytics: RD_FRADHASMT

Data Variable RefName	RD Column Name	Column Data Type
MISSDOS	MISSDOS_C	**NUMBER
	MISSDOS	VARCHAR2
	MISSDOS_ND	VARCHAR2
MISSDOS - NUMMISS	NUMMISS	NUMBER

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

HFN_FIGHT: STUDY DRUG DOSING (DRGDOSE) [frDRGDOSE]		
Study Drug Changes [stDRGDOSE1]		
If any kits were dispensed, please record on the DRUGKIT form in the KITS visit		
1.* ✓	Did study drug dose change since the last visit [Did study drug dose change since the last visit]	[DOSCHG] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No
2.	Date of Dose Change	Dose Primary Reason for Dose Change
Dose Changes Entry [rsDRGDOSE2]		
2.1* ✓	Date of Dose Change [Date of Dose Change]	[SDCHGDT] Req <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018)
2.2* ✓	Dose [Dose]	[SDRGDOSE] [N: 1] <input type="radio"/> 0.6 mg OD [N: 2] <input type="radio"/> 1.2 mg OD [N: 3] <input type="radio"/> 1.8 mg OD [N: 98] <input type="radio"/> [DRGDOSSP] Other Specify A30 [N: 4] <input type="radio"/> Temporary discontinuation [N: 5] <input type="radio"/> Permanent discontinuation
2.3* ✓	Primary Reason for Dose Change [Primary Reason for Dose Change]	[CHGREAS] [N: 1] <input type="radio"/> Protocol specified up-titration [N: 2] <input type="radio"/> [DRGSAE] Adverse reaction Is this a Serious Adverse event? [N: 1] <input type="radio"/> [DRGSAENO] Yes SAE Number (from SAE form) A4 [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown [N: 98] <input type="radio"/> [CHGRSSP] Other, specify: A100
Key: [*] = Item is required [✓] = Source verification required		

RDE Analytics: RD_FRDRGDOSE		
Data Variable RefName	RD Column Name	Column Data Type
DOSCHG	DOSCHG_C	NUMBER
	DOSCHG	VARCHAR2
	DOSCHG_ND	VARCHAR2
RD_FRDRGDOSE_RSDRGDOSE2		
SDCHGDT	SDCHGDT	DATE
	SDCHGDT_DTS	VARCHAR2
	SDCHGDT_DTR	VARCHAR2
	SDCHGDT_ND	VARCHAR2
SDRGDOSE	SDRGDOSE_C	NUMBER
	SDRGDOSE	VARCHAR2
	SDRGDOSE_ND	VARCHAR2
SDRGDOSE - DRGDOSSP	DRGDOSSP	VARCHAR2
CHGREAS	CHGREAS_C	NUMBER
	CHGREAS	VARCHAR2
	CHGREAS_ND	VARCHAR2
CHGREAS - DRGSAE	DRGSAE_C	**NUMBER
	DRGSAE	VARCHAR2
CHGREAS - DRGSAENO	DRGSAENO	VARCHAR2
CHGREAS - CHGRSSP	CHGRSSP	VARCHAR2
Key: [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_FIGHT: 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 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
Anticipated, disease-related event:		Onset Date
2.		
Anticipated Disease Related Events Entry [rsEVNTINT2]		
2.1* ✓	Anticipated, disease-related event: [Anticipated, disease-related event:]	[EVNTTYPE] [N: 1] <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="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018)
Hypoglycemic Events [stEVNTINT3]		
3.* ✓	Has the subject had severe hypoglycemia since the last visit? [Has the subject had severe hypoglycemia since the last visit?]	[SVRHYPHO] [N: 1] <input type="radio"/> Yes (click on Add Entry button) [N: 0] <input type="radio"/> No
Date of severe hypoglycemic event		SAE Criteria Met?
4.		
Hypoglycemic Event Details Entry [rsEVNTINT4]		
4.1* ✓	Date of severe hypoglycemic event [Date of severe hypoglycemic event]	[SVRHYPDT] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018)
4.2* ✓	Did event meet SAE criteria as defined by the protocol? [SAE Criteria Met?]	[HYPOSAE] [N: 1] <input type="radio"/> Yes (complete SAE form) [N: 0] <input type="radio"/> No
Hyperglycemia [stEVNTINT5]		
5.* ✓	Has the subject experienced hyperglycemia (>350 mg/dL) since the last clinic visit? [Has the subject experienced hyperglycemia (>350 mg/dL) since the last clinic visit?]	[HYPERGLY] [N: 1] <input type="radio"/> Yes (click on Add Entry button) [N: 0] <input type="radio"/> No
Hyperglycemia date		
6.		
Hyperglycemia Details Entry [rsEVNTINT6]		
6.1* ✓	Hyperglycemia date [Hyperglycemia date]	[HYPERDT] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018)
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
SVRHYPHO	SVRHYPHO_C	NUMBER
	SVRHYPHO	VARCHAR2
	SVRHYPHO_ND	VARCHAR2
HYPERGLY	HYPERGLY_C	NUMBER
	HYPERGLY	VARCHAR2
	HYPERGLY_ND	VARCHAR2

RD_FREVNTINT_RSEVNTINT2		
EVNTTYPE	EVNTTYPE_C	NUMBER
	EVNTTYPE	VARCHAR2
	EVNTTYPE_ND	VARCHAR2
EVNTDT	EVNTDT	DATE
	EVNTDT_DTS	VARCHAR2
	EVNTDT_DTR	VARCHAR2
	EVNTDT_ND	VARCHAR2
RD_FREVNTINT_RSEVNTINT4		
SVRHYPDT	SVRHYPDT	DATE
	SVRHYPDT_DTS	VARCHAR2
	SVRHYPDT_DTR	VARCHAR2
	SVRHYPDT_ND	VARCHAR2
HYPOSAE	HYPOSAE_C	NUMBER
	HYPOSAE	VARCHAR2
	HYPOSAE_ND	VARCHAR2
RD_FREVNTINT_RSEVNTINT6		
HYPERDT	HYPERDT	DATE
	HYPERDT_DTS	VARCHAR2
	HYPERDT_DTR	VARCHAR2
	HYPERDT_ND	VARCHAR2

HFN_FIGHT: Additional Protocol Assessments (ASSESS) [frASSESS]	
Additional Protocol Assessments [stASSESS1]	
<p>1.* Were local labs performed (If yes, please complete lab forms)? [Were local labs performed]</p>	<p>[LABSDONE] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [LABNDRSN] 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 type="radio"/> [LABNDSP] Unknown/other Specify: <input type="text" value="A50"/></p>
<p>2.* 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 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 type="radio"/> [BIONDSP] Unknown/other Specify: <input type="text" value="A50"/></p>
<p>3.* Was 6-Minute Walk performed (If yes, complete SIXMWT form)? [Was 6-Minute Walk performed]</p>	<p>[SIXMWTD] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [SMWNDRS] 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 type="radio"/> [SMWNDSNP] Unknown/other Specify: <input type="text" value="A50"/></p>
<p>4.* Was Patient Global Assessment Completed (If yes, complete GLOBAL form)? [Was Patient Global Assessment Completed]</p>	<p>[GLOBALDN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [GLOBNDRS] 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 type="radio"/> [GLOBNDSP] Unknown/other Specify: <input type="text" value="A50"/></p>
<p>5.* Was KCCQ completed (If yes, complete KCCQ form)? [Was KCCQ completed]</p>	<p>[KCCQDN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [KCCQNDRS] 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 type="radio"/> [KCCQNDSP] Unknown/other Specify: <input type="text" value="A50"/></p>
<p>6.* 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 type="radio"/> Unknown</p>
<p>7.* 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 type="radio"/> Unknown</p>

8. *	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?]	[EDVIST] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
9. *	Has subject had a positive pregnancy test since the last visit? [Has subject had a positive pregnancy test since the last visit?]	[POSPREG] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 96] <input type="radio"/> Not Applicable

Key: [*] = Item is required

RDE Analytics: RD_FRASSESS		
Data Variable RefName	RD Column Name	Column Data Type
LABSDONE	LABSDONE_C	NUMBER
	LABSDONE	VARCHAR2
	LABSDONE_ND	VARCHAR2
LABSDONE - LABNDRSN	LABNDRSN_C	NUMBER
	LABNDRSN	VARCHAR2
LABSDONE - LABNDSP	LABNDSP	VARCHAR2
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 - SMWNDSP	SMWNDSP	VARCHAR2
GLOBALDN	GLOBALDN_C	NUMBER
	GLOBALDN	VARCHAR2
	GLOBALDN_ND	VARCHAR2
GLOBALDN - GLOBNDRS	GLOBNDRS_C	NUMBER
	GLOBNDRS	VARCHAR2
GLOBALDN - GLOBNDSP	GLOBNDSP	VARCHAR2
KCCQDN	KCCQDN_C	NUMBER
	KCCQDN	VARCHAR2
	KCCQDN_ND	VARCHAR2
KCCQDN - KCCQNDRS	KCCQNDRS_C	NUMBER
	KCCQNDRS	VARCHAR2
KCCQDN - KCCQNDSP	KCCQNDSP	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_FIGHT: PATIENT GLOBAL ASSESSMENT (GLOBAL) [frGLOBAL]	
Patient Global Assessment [stGLOBAL1]	
1. *	Patient global assessment score (since the last visit) [Patient global assessment score]
	[GLOBALSC] [N: 1] <input type="radio"/> 1 Markedly better [N: 2] <input type="radio"/> 2 Moderately better [N: 3] <input type="radio"/> 3 Slightly better [N: 4] <input type="radio"/> 4 Unchanged [N: 5] <input type="radio"/> 5 Slightly worse [N: 6] <input type="radio"/> 6 Moderately worse [N: 7] <input type="radio"/> 7 Markedly worse
Key: [*] = Item is required	

RDE Analytics: RD_FRGLOBAL		
Data Variable RefName	RD Column Name	Column Data Type
GLOBALSC	GLOBALSC_C	NUMBER
	GLOBALSC	VARCHAR2
	GLOBALSC_ND	VARCHAR2

HFN_FIGHT: DRUG KIT DISPENSING (DRUGKIT) - Repeating Form [frDRUGKIT]			
#	Date kit dispensed	Kit number	Reason dispensed:
1			
Drug Kit dispensed [stDRUGKIT1]			
1.* ✓	Date kit dispensed [Date kit dispensed]	[DISPDT] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018)	
2.* ✓	Kit number [Kit number]	[KITNUM] N5	
3.* ✓	Reason dispensed: [Reason dispensed:]	[DISPREAS] [N: 1] <input type="radio"/> Initial [N: 2] <input type="radio"/> Day 30 resupply [N: 3] <input type="radio"/> Day 90 resupply [N: 4] <input type="radio"/> [DISPUNSC] Unscheduled [N: 1] <input type="radio"/> Lost kit [N: 2] <input type="radio"/> Damaged kit [N: 3] <input type="radio"/> Subject ran out of drug prior to scheduled visit [N: 4] <input type="radio"/> Mis-use by subject [N: 98] <input type="radio"/> Other	
Key: [*] = Item is required [✓] = Source verification required			

RDE Analytics: RD_FRDRUGKIT			
Data Variable	RefName	RD Column Name	Column Data Type
DISPDT		DISPDT	DATE
		DISPDT_DTS	VARCHAR2
		DISPDT_ND	VARCHAR2
KITNUM		KITNUM	NUMBER
		KITNUM_ND	VARCHAR2
DISPREAS		DISPREAS_C	NUMBER
		DISPREAS	VARCHAR2
		DISPREAS_ND	VARCHAR2
DISPREAS - DISPUNSC		DISPUNSC_C	NUMBER
		DISPUNSC	VARCHAR2

HFN_FIGHT: 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	Narrative	Additional Narrative	Trigger Number	Elective?	Event classification	
1																			
Hospitalization Information [stREHOSP1]																			
1.*	Admission Date [Admission Date]						[ADMITDT] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018)												
2.*	Was this an unplanned hospitalization? [Unplanned?]						[ELECTAD] [N:1] <input checked="" type="radio"/> Yes [N:0] <input type="radio"/> No												
3.*	Discharge Date [Discharge Date]						[INREHOSP] [N:1] <input checked="" type="radio"/> [REDCHGDT] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018) [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 checked="" 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 checked="" type="radio"/> [PRMCRDSP] Other cardiovascular Specify: A100 [N:8] <input checked="" type="radio"/> [PRMNCSP] Other non-cardiovascular Specify: A100												
5.*	Contributing causes (check all that apply) [Contributing causes]						[cpCONCAUS] [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 checked="" type="radio"/> [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]												

		<p>[N: 1] <input type="checkbox"/> S3 Gallop</p> <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>
<p>7.* ✓</p>	<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>
<p>8.* ✓</p>	<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] [INITHRPV] [N: 1] <input type="checkbox"/> Initiation of intravenous diuretic, inotropic, or vasodilator therapy</p> <p>[ORLTHPV] [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>[MEHSURG] [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>
<p>9.*</p>	<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 checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
<p>10.*</p>	<p>Revascularization Performed [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 checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
<p>11.*</p>	<p>Pacemaker/ICD Implanted [Pacemaker/ICD]</p>	<p>[HOSPIDC] [N: 1] <input checked="" type="radio"/> [PACTYPE] Yes [N: 1] <input checked="" type="radio"/> Pacemaker (single/dual) [N: 2] <input checked="" type="radio"/> Biventricular Pacemaker with ICD</p>

		<p>[N: 3] <input type="radio"/> Biventricular Pacemaker without ICD</p> <p>[N: 4] <input type="radio"/> ICD only (single/dual)</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
12.*	Heart Transplant Performed [Heart Transplant]	<p>[PROHTRAN]</p> <p>[N: 1] <input type="radio"/> [PRHTRDDT]</p> <p>Yes</p> <p>Date of Transplant:</p> <p>Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2013-2018)</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
13.*	LVAD Implanted [LVAD]	<p>[LVAD]</p> <p>[N: 1] <input type="radio"/> [LVADDT]</p> <p>Yes</p> <p>Date of Implant:</p> <p>Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2013-2018)</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
Please provide a description of the symptoms, treatment, tests/procedures, and outcome of the rehospitalizaion [stREHOSP2]		
14.*	Narrative [Narrative]	<p>[HSPNARR]</p> <p>A200</p>
Additional narrative		
15.		
Additional Narrative Entry [rsREHOSP3]		
15.1*	Additional narrative [Additional narrative]	<p>[ADHSPNAR]</p> <p>A200</p>
Adjudication [stREHOSP4]		
16.	Trigger Number <i>[read-only]</i> [Trigger Number]	<p>[HOSPTRIG]</p> <p>A100</p>
17.	Was this an elective hospitalization? [Elective?]	<p>[ADJELECT]</p> <p>[N: 1] <input type="radio"/> Yes</p> <p>[N: 0] <input type="radio"/> No</p>
18.	Event classification [Event classification]	<p>[CECCCLASS]</p> <p>[N: 1] <input type="radio"/> Hospitalization due to heart failure</p> <p>[N: 3] <input type="radio"/> Acute Coronary Syndrome/Myocardial Infarction</p> <p>[N: 4] <input type="radio"/> Other cardiovascular</p> <p>[N: 5] <input type="radio"/> Non-Cardiovascular</p>
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
	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
cpCONCAUS - Atrial arrhythmia	*CONARRH_CIATRIALARRHYTHMIA1_C	NUMBER
	*CONARRH_CIATRIALARRHYTHMIA1	VARCHAR2
cpCONCAUS - Ventricular arrhythmia	*CONVENTA_CIVENTRICULARARRHYTHMIA1_C	NUMBER
	*CONVENTA_CIVENTRICULARARRHYTHMIA1	VARCHAR2
cpCONCAUS - Renal Failure	RENFAIL_CIRENALFAILURE_C	NUMBER
	RENFAIL_CIRENALFAILURE	VARCHAR2
cpCONCAUS - Sudden death with resuscitation	*CONSDTH_CISUDDENDEATHRESUSCITATION1_C	NUMBER
	*CONSDTH_CISUDDENDEATHRESUSCITATION1	VARCHAR2
cpCONCAUS - Other cardiovascular	*CONOTHC_CIOTHERCARDIOVASCULAR1_C	NUMBER
	*CONOTHC_CIOTHERCARDIOVASCULAR1	VARCHAR2
cpCONCAUS - Other non-cardiovascular	*CONOTHNC_CIOTHERNONCARDIOVASCULAR1_C	NUMBER
	*CONOTHNC_CIOTHERNONCARDIOVASCULAR1	VARCHAR2
MANIFEST	MANIFEST_C	**NUMBER
	MANIFEST	VARCHAR2
	MANIFEST_ND	VARCHAR2
MANIFEST - Dyspnea	HFDYSP_CIDYSPNEA_C	NUMBER
	HFDYSP_CIDYSPNEA	VARCHAR2
MANIFEST - Orthopnea	HFORTHO_CIORTHOPNEA1_C	NUMBER
	HFORTHO_CIORTHOPNEA1	VARCHAR2
MANIFEST - Paroxysmal nocturnal dyspnea	*HFNOCODYS_CIPAROXYSMALNOCTURNALDYSYSPNEA1_C	NUMBER
	*HFNOCODYS_CIPAROXYSMALNOCTURNALDYSYSPNEA1	VARCHAR2
MANIFEST - Edema	HFEDEMA_CIEDEMA_C	NUMBER
	HFEDEMA_CIEDEMA	VARCHAR2
MANIFEST - Pulmonary rales	HFRALES_CIPULMONARYRALES_C	NUMBER
	HFRALES_CIPULMONARYRALES	VARCHAR2
MANIFEST - Jugular venous distension	*HFJVD_CIJUGULARVENOUSDISTENSION_C	NUMBER
	*HFJVD_CIJUGULARVENOUSDISTENSION	VARCHAR2
MANIFEST - S3 Gallop	HFGALLOP_CIS3GALLOP_C	NUMBER
	HFGALLOP_CIS3GALLOP	VARCHAR2
MANIFEST - Hypotension or cardiogenic shock not occurring in the context of an acute myocardial infarction or as the consequence of an arrhythmia	*HFHYPO_CIHYPOTENSIONCARDIOGENICSHOCK_C	NUMBER
	*HFHYPO_CIHYPOTENSIONCARDIOGENICSHOCK	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_CIOTHCLINICALEVIDENCE_C	NUMBER
	*HFEVDNCE_CIOTHCLINICALEVIDENCE	VARCHAR2
MANIFEST - Other	HFOTHR_HFOTHRSP_C	**NUMBER
	HFOTHR_HFOTHRSP	VARCHAR2
MANIFEST - HFOTHRSP	HFOTHRSP	VARCHAR2
MANIFEST - Unknown	HFUNK_CIUKNOWN1_C	NUMBER
	HFUNK_CIUKNOWN1	VARCHAR2
RADIOEV	RADIOEV_C	**NUMBER
	RADIOEV	VARCHAR2
	RADIOEV_ND	VARCHAR2
RADIOEV - Documented increased or increasing levels of a natriuretic peptide (BNP or NTproBNP)	*INCBNP_CIIINCREASEDNATRIURETICPEPTIDE_C	NUMBER

	* INCBNP_CIINCREASEDNATRIURETICPEPTIDE	VARCHAR2
RADIOEV - Documented worsening pulmonary congestion or pulmonary edema on chest X-ray or other generally recognized imaging pattern.	* HFIMGING_CIDOCWORSENINGPULMONARYCONGESTION_C	NUMBER
	* HFIMGING_CIDOCWORSENINGPULMONARYCONGESTION	VARCHAR2
RADIOEV - Other	BIOOTH_BIOOTHSP_C	**NUMBER
	BIOOTH_BIOOTHSP	VARCHAR2
RADIOEV - BIOOTHSP	BIOOTHSP	VARCHAR2
RADIOEV - Unknown	BIOUNK_CIUNKNOWN1_C	NUMBER
	BIOUNK_CIUNKNOWN1	VARCHAR2
PHARMINT	PHARMINT_C	**NUMBER
	PHARMINT	VARCHAR2
	PHARMINT_ND	VARCHAR2
PHARMINT - Initiation of intravenous diuretic, inotropic, or vasodilator therapy	* INITHRPY_CIIINITIATIONOFTHERAPY_C	NUMBER
	* INITHRPY_CIIINITIATIONOFTHERAPY	VARCHAR2
PHARMINT - Significant addition or increase in oral heart failure therapy	* ORLTHPY_CIORALHEARTFAILURETHERAPY_C	NUMBER
	* ORLTHPY_CIORALHEARTFAILURETHERAPY	VARCHAR2
PHARMINT - Up-titration of intravenous therapy, if already on therapy	* UPTITRTE_CIUPTITRATIONINTRAVENOUSTHERAPY_C	NUMBER
	* UPTITRTE_CIUPTITRATIONINTRAVENOUSTHERAPY	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_CIIINITIATIONMECHSURGICALINTERVENTION_C	NUMBER
	* MECHSURG_CIIINITIATIONMECHSURGICALINTERVENTION	VARCHAR2
PHARMINT - Other	OTHINTVN_INTVNSP_C	**NUMBER
	OTHINTVN_INTVNSP	VARCHAR2
PHARMINT - INTVNSP	INTVNSP	VARCHAR2
PHARMINT - Unknown	INTVUNK_CIUNKNOWN1_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
HSPNARR	HSPNARR	VARCHAR2
	HSPNARR_ND	VARCHAR2
HOSPTRIG	HOSPTRIG	VARCHAR2
	HOSPTRIG_ND	VARCHAR2
ADJELECT	ADJELECT_C	NUMBER
	ADJELECT	VARCHAR2
	ADJELECT_ND	VARCHAR2
CECCCLASS	CECCCLASS_C	NUMBER
	CECCCLASS	VARCHAR2
	CECCCLASS_ND	VARCHAR2
RD_FRREHOSP_RSREHOSP3		
ADHSPNAR	ADHSPNAR	VARCHAR2
	ADHSPNAR_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_FIGHT: 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"/> (2013-2018)
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_FIGHT: 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 [v] / Req/Unk [v] / Req [v] (2013-2018) 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] (2013-2018) 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 type="radio"/> Not Applicable</p>
<p>8.* ✓</p>	<p>Serious Criteria [Serious Criteria]</p>	<p>[cpSERICRIT] [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.* ✓</p>	<p>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 type="radio"/> [RRRATREL] Related Rationale for positive relationship: A100</p>
<p>10.* ✓</p>	<p>Possible alternate causes of the SAE (check all that apply) [Alternate Causes of SAE]</p>	<p>[cpALTCNAUS] [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 [ALTCILL] [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.* ✓</p>	<p>Was this event unexpected per product labeling? [Unexpected?]</p>	<p>[SAEUNEX] [N: 1] <input checked="" type="radio"/> Yes (If Yes, and Possibly Related or Related complete the following sections). [N: 0] <input type="radio"/> No</p>
<p>Narrative</p>		
<p>12.</p>		
<p>SAE NARRATIVES Entry [rsSAE2]</p>		
<p>12.1*</p>	<p>Provide a summary in chronological order of the clinical course of this SAE from onset through resolution. 1. Presenting signs and symptoms; 2. Treatments and response to treatment(s); 3. Subjects status at time of report and/or final outcome, as applicable.</p>	<p>[PICAUSE]</p>

[Narrative]		A200			
Relevant Labs/Tests [stSAE3]					
13.* Were there any relevant Labs/tests drawn for this SAE? [Relevant Labs?]		[SAELABYN] [N:1] <input checked="" type="radio"/> Yes [N:0] <input type="radio"/> No			
Test Date		Lab/Test		Test Result	
14.					
Relevant Labs/Tests Entry [rsSAE4]					
14.1* Test Date [Test Date]		[TESTDT] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018)			
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 checked="" type="radio"/> Yes [N:0] <input type="radio"/> No			
Concomitant Medication		Start Date		Stop Date	
16.					
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="checkbox"/> / Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> (2000-2018) Req/Unk <input type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock			
16.3* Stop Date [Stop Date]		[MEDCONT] [N:1] <input checked="" type="radio"/> [MEDSPDTM] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> (2013-2018) Req/Unk <input type="checkbox"/> : Req/Unk <input type="checkbox"/> 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]		[PICONFIRM] [N:1] <input type="checkbox"/> Yes			
18. Evaluation Date and Time (Electronic Verification non-enterable system generated) [read-only] [PI Verification Date/Time]		[PICONDIT] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018) 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]	[MMSYCAU] [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) <i>[read-only]</i> [Medical Monitor Verification Date/Time]	[MMSGDTM] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2013-2018) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
Key: [*] = Item is required [✓] = 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	ALTCCILL_ALTCCISP_C	**NUMBER
	ALTCCILL_ALTCCISP	VARCHAR2
cpALTCAUS - ALTCCISP	ALTCCISP	VARCHAR2
cpALTCAUS - Concomitant medication	ALTCMED_ALTCMESP_C	**NUMBER
	ALTCMED_ALTCMESP	VARCHAR2
cpALTCAUS - ALTCMESP	ALTCMESP	VARCHAR2
cpALTCAUS - Other	ALTCOTH_ALTCSPP_C	**NUMBER
	ALTCOTH_ALTCSPP	VARCHAR2
cpALTCAUS - ALTCSPP	ALTCSPP	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_CIYES	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_CIYES_C	NUMBER
	SAEMMSIG_CIYES	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_FIGHT: 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"/> (2013-2018)
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 <input type="text" value="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_FIGHT: 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 <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2013-2018)	
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_FIGHT: 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