

Annotated Study Book for Study Design: HFN_IRON

Study Design Version: 5.0

HFN_IRON

Generated by Central Designer™

Time and Events Schedule For Study Design: HFN_IRON															
Element		System													
Assessment	CRF	System Screening (SYSSCR) [S]	System Enrollment (SYSENR) [S]	CLINOPS (CLINOPS) [S]	SCREENING (SCREEN) [S]	BASELINE (BASELINE) [S]	WEEK 1 (WEEK1) [S]	WEEK 8 (WEEK8) [S]	WEEK 16 (WEEK16) [S]	DRUG KIT (KITS) [S]	REHOSPITALIZATION (REHOSP) [S]	ED VISIT (EDVISIT) [S]	AESAE (AESAE) [S]	END OF STUDY (EOS) [S]	INVESTIGATOR SIGNATURE (INVSIG) [S]
Visit Start Hours		0	0	0	1	2	170	1514	2858	2859	2860	2861	2862	2863	2864
1 System Screening	SYSSCR	1													
2 System Enrollment	SYSENR		1												
3 Clinical Operations Review	CLINOPS			1											
4 RANDOMIZATION AND DEMOGRAPHICS	DEMOG				1										
5 CHEMISTRY LABS	CHEM				2				6-DF						
6 HEMATOLOGY AND IRON LABS	HEMAIRON				3										
7 CLINICAL HISTORY	MEDHIST1					1									
8 CLINICAL HISTORY	MEDHIST2					2									
9 EXAMINATION	EXAM					3		2-DF	2-DF						
10 MEDICATIONS	MEDS					4	2-DF	3-DF	3-DF						
11 EVENTS OF INTEREST	EVNTINT					5	3-DF	4-DF	4-DF						
12 STUDY DRUG ADMINISTRATION	SDADMIN					6									
13 Baseline Assessments	BASSESS					7									
14 BIOLOGICAL SAMPLES	SAMPLES					8-DF			8-DF						
15 SIX MINUTE WALK TEST	SIXMWT					9-DF		6-DF	9-DF						
16 Kansas City Cardiomyopathy Questionnaire	KCCQ					10-DF		7-DF	10-DF						
17 CPET	CPET					11-DF			12-DF						
18 VISIT STATUS	VISIT						1	1	1						
19 STUDY DRUG DOSING	DRGDOSE						4-DF	8-DF	11-DF						
20 Additional Protocol Assessments WK8	ASSESS1							5-DF							
21 Additional Protocol Assessments WK16	ASSESS2								5-DF						
22 HEMATOLOGY LABS	HEMA								7-DF						
23 DRUG KIT DISPENSING	DRUGKIT									1-RF					
24 REHOSPITALIZATION	REHOSP										1-RF				
25 EMERGENCY DEPARTMENT VISIT	EDVISIT											1-RF			
26 Adverse Event/Serious Adverse Event	AESAE												1-RF		
27 END OF STUDY	EOS													1	
28 DEATH	DEATH													2-DF	
29 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_IRON: System Screening (SYSSCR) [frSCRIXRS]		
System Screening [frSCRIXRS]		
1.*	IXRS ID [IXRS ID]	[IXRSID] A3
Key: [*] = Item is required		

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

HFN_IRON: System Enrollment (SYSENK) [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_IRON: 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		
2.	Ineligible Criteria	Waiver granted?	Waiver granted by	Reason for Waiver
Reason for waiver, continued				
Ineligible criteria Entry [rsCLINOPS2]				
2.1	Criteria [Ineligible Criteria]	[CRITTYPE] [N:1] <input type="radio"/> [INCLNOT] Inclusion not met [N:1] <input type="radio"/> IE1 [N:2] <input type="radio"/> IE2 [N:3] <input type="radio"/> IE3 [N:4] <input type="radio"/> IE4 [N:5] <input type="radio"/> IE5 [N:6] <input type="radio"/> IE6 [N:2] <input type="radio"/> [EXCLMET] Exclusion met [N:1] <input type="radio"/> EC1 [N:2] <input type="radio"/> EC2 [N:3] <input type="radio"/> EC3 [N:4] <input type="radio"/> EC4 [N:5] <input type="radio"/> EC5 [N:6] <input type="radio"/> EC6 [N:7] <input type="radio"/> EC7 [N:8] <input type="radio"/> EC8 [N:9] <input type="radio"/> EC9 [N:10] <input type="radio"/> EC10 [N:11] <input type="radio"/> EC11 [N:12] <input type="radio"/> EC12 [N:13] <input type="radio"/> EC13 [N:14] <input type="radio"/> EC14 [N:15] <input type="radio"/> EC15		
2.2	Was a waiver granted? [Waiver granted?]	[WAI VER] [N:1] <input type="radio"/> [WAI VRDT] Yes Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2017) [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_IRON: RANDOMIZATION AND DEMOGRAPHICS (DEMOG) [frDEMOG]	
Consent and Randomization [stDEMOG1]	
1.* Subject Identifier [Subject Identifier]	[SUBJID] A20
2.* Date/Time Informed Consent Signed [Date/Time Informed Consent Signed]	[CONSDTM] Req [v] / Req [v] / Req [v] (2014-2017) 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 checked="" type="radio"/> [BIORPCDT] Yes Date consent obtained Req [v] / Req [v] / Req [v] (2014-2017) [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 checked="" type="radio"/> [GENCONDY] Yes Date consent obtained Req [v] / Req [v] / Req [v] (2014-2017) [N: 0] <input type="radio"/> No [N: 2] <input type="radio"/> Site not participating
5.* Date and Time of Randomization [Date and Time of Randomization]	[RANDDTM] Req [v] / Req [v] / Req [v] (2014-2017) 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 checked="" type="radio"/> No
Demographics [stDEMOG2]	
7.* Date of Birth [Date of Birth]	[DOBDT] Req [v] / Req [v] / Req [v] (1914-1996)
8.* Sex [Sex]	[SEX] [N: 1] <input type="radio"/> Male [N: 2] <input checked="" type="radio"/> Female
9.* Ethnicity [Ethnicity]	[ETHNIC] [N: 1] <input type="radio"/> Hispanic or Latino [N: 2] <input checked="" type="radio"/> Not Hispanic or Latino
10.* Race (check all that apply) [Race]	[cpRACE] [AMERIIND] [N: 1] <input type="checkbox"/> American Indian or Alaskan Native [ASIAN] [N: 1] <input type="checkbox"/> Asian [BLACK] [N: 1] <input type="checkbox"/> Black or African American [NATHWN] [N: 1] <input type="checkbox"/> Native Hawaiian or Other Pacific Islander [WHITE] [N: 1] <input type="checkbox"/> White/Caucasian
Key: [*] = Item is required [v] = Source verification required	

RDE Analytics: RD_FRDEMOG		
Data Variable RefName	RD Column Name	Column Data Type
SUBJID	SUBJID	VARCHAR2
	SUBJID_ND	VARCHAR2
CONSDTM	CONSDTM	DATE

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

HFN_IRON: 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"/> (2014-2017) 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.*	ALT/SGPT [ALT/SGPT]	<p>[ALT] [N: 1] <input type="radio"/> [cpALT] [ALTVAL] xxxxxxx.</p> <p>[ALTUNT] Unit: [N: 5] <input type="radio"/> U/L [N: 6] <input type="radio"/> IU/L [N: 97] <input type="radio"/> Not Done</p>
9.*	AST/SGOT [AST/SGOT]	<p>[AST] [N: 1] <input type="radio"/> [cpAST] [ASTVAL] xxxxxxx.</p> <p>[ASTUNT] Unit: [N: 5] <input type="radio"/> U/L [N: 6] <input type="radio"/> IU/L [N: 97] <input type="radio"/> Not Done</p>
10.*	Alkaline Phosphatase [Alkaline Phosphatase]	<p>[ALKPH] [N: 1] <input type="radio"/> [cpALKPH] [ALKPHVAL] xxxxxxx.</p> <p>[ALKPHUNT] Unit: [N: 5] <input type="radio"/> U/L [N: 6] <input type="radio"/> IU/L [N: 97] <input type="radio"/> Not Done</p>
11.*	Total Bilirubin [Total Bilirubin]	<p>[TBILI] [N: 1] <input type="radio"/> [cpTBILI] [TBILIVAL] xxxxxxx.</p> <p>[TBILIUNT] Unit: [N: 3] <input type="radio"/> mg/dl [N: 4] <input type="radio"/> umol/L [N: 97] <input type="radio"/> Not Done</p>
12.*	Glucose [Glucose]	<p>[GLUC] [N: 1] <input type="radio"/> [cpGLUC] [GLUCVAL] xxxxxxx.</p> <p>[GLUCUNT] [N: 1] <input type="radio"/> mmol/L [N: 3] <input type="radio"/> mg/dl</p> <p>[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</p>

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

HFN_IRON: HEMATOLOGY AND IRON LABS (HEMAIRON) [frHEMAIRON]	
Hematology and Iron Labs [stHEMAIRON1]	
1.* Collection Date and Time [Collection Date and Time]	[HEMALDTM] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2017) Req/Unk <input type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock
2.* ✓ Hemoglobin (Hgb) [Hemoglobin]	[HGB] [N: 1] <input type="radio"/> [cpHGB] [HGBVAL] xxxxxxxx. [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] xxxxxxxx. [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] xxxxxxxx. 10 ¹² /L [N: 97] <input type="radio"/> Not Done
5.* RDW [RDW]	[RDW] [N: 1] <input type="radio"/> [RDWVAL] xxxxxxxx. % [N: 97] <input type="radio"/> Not Done
6.* WBC [WBC]	[WBC] [N: 1] <input type="radio"/> [cpWBC] [WBCVAL] xxxxxxxx. [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] xxxxxxxx. [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
8.* ✓ Serum Iron (SI) [Serum Iron (SI)]	[IRON] [N: 1] <input type="radio"/> [cpIRON] [IRONVAL] xxxxxxxx. [IRONUNT] Unit: [N: 19] <input type="radio"/> mcg/dL [N: 4] <input type="radio"/> umol/L [N: 97] <input type="radio"/> Not Done

<p>9.* ✓</p>	<p>Serum Ferritin [Serum Ferritin]</p>	<p>[FERRITIN] [N: 1] <input type="radio"/> [cpFERRITIN] [FERRVAL] xxxxxxxx. [FERRUNT] Unit: [N: 12] <input type="radio"/> ng/mL [N: 16] <input type="radio"/> pmol/L [N: 97] <input type="radio"/> Not Done</p>
<p>10.* ✓</p>	<p>Total Iron Binding Capacity (TIBC) [Total Iron Binding Capacity (TIBC)]</p>	<p>[TIBC] [N: 1] <input type="radio"/> [cpTIBC] [TIBCVAl] xxxxxxxx. [TIBcUNT] Unit: [N: 19] <input type="radio"/> mcg/dL [N: 4] <input type="radio"/> umol/L [N: 97] <input type="radio"/> Not Done</p>
<p>11.* ✓</p>	<p>Transferrin Saturation [Transferrin Saturation]</p>	<p>[TRFRSAT] [N: 1] <input type="radio"/> [TRFRSVAL] xxxxxxxx. % [N: 97] <input type="radio"/> Not Done</p>
<p>Key: [*] = Item is required [✓] = Source verification required</p>		

RDE Analytics: RD_FRHEMAIRON		
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
IRON	IRON_C	**NUMBER
	IRON	VARCHAR2
	IRON_ND	VARCHAR2
IRON - IRONVAL	IRONVAL	FLOAT
IRON - IRONUNT	IRONUNT_C	NUMBER
	IRONUNT	VARCHAR2
FERRITIN	FERRITIN_C	**NUMBER
	FERRITIN	VARCHAR2
	FERRITIN_ND	VARCHAR2
FERRITIN - FERRVAL	FERRVAL	FLOAT
FERRITIN - FERRUNT	FERRUNT_C	NUMBER
	FERRUNT	VARCHAR2
TIBC	TIBC_C	**NUMBER
	TIBC	VARCHAR2
	TIBC_ND	VARCHAR2
TIBC - TIBCVAL	TIBCVAL	FLOAT
TIBC - TIBCUNT	TIBCUNT_C	NUMBER
	TIBCUNT	VARCHAR2
TRFRSAT	TRFRSAT_C	**NUMBER
	TRFRSAT	VARCHAR2
	TRFRSAT_ND	VARCHAR2
TRFRSAT - TRFRSVAL	TRFRSVAL	FLOAT
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_IRON: 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="button" value="v"/> / Req/Unk <input type="button" value="v"/> (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
3.* Number of hospitalizations with primary diagnosis of heart failure within past 12 months (provide best estimate if exact number is unknown): [Number of hospitalizations with primary diagnosis of heart failure within past 12 months]	[NUMHFHSP] N3
4.* Has LV function been assessed (prior to randomization)? <input checked="" type="checkbox"/> [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="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> (1920-2020) [LVEF] Value of last LVEF: [N: 1] <input type="text" value="xxxxxxx."/> % [N: 2] <input type="radio"/> Normal [N: 3] <input type="radio"/> Mild dysfunction [N: 4] <input type="radio"/> Moderate dysfunction [N: 5] <input type="radio"/> Severe dysfunction [N: 0] <input type="radio"/> No
5.* <input checked="" type="checkbox"/> Has the subject had a myocardial infarction (MI)? [Has the subject had a myocardial infarction (MI)]	[MI] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
6.* Has the subject had a left heart catheterization? [Has the subject had a left heart catheterization]	[LTCATH] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
7.* <input checked="" type="checkbox"/> Has the subject had a percutaneous coronary intervention (PCI)? [Has the subject had a percutaneous coronary intervention (PCI)]	[PCIHX] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
8.* <input checked="" type="checkbox"/> Has the subject had a coronary artery bypass graft (CABG)? [Has the subject had a coronary artery bypass graft (CABG)]	[CABGHX] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
9.* <input checked="" type="checkbox"/> Has subject had any other factors contributing to cardiomyopathy? [Has subject had any other factors contributing to cardiomyopathy]	[FACTORYN] [N: 1] <input checked="" type="radio"/> [cpFACTORYN] 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] Valvular

[HCM]

[N: 1] HCM

[MYOOTH]

[N: 1] [MYOPSP]
Other/uncertain
Specify

A100

[N: 0] No

[N: 99] Unknown

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

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
LVASSESS	LVASSESS_C	**NUMBER
	LVASSESS	VARCHAR2
	LVASSESS_ND	VARCHAR2
LVASSESS - LVASSDT	LVASSDT	DATE
	LVASSDT_DTS	VARCHAR2
	LVASSDT_DTR	VARCHAR2
LVASSESS - LVEF	LVEF_C	**NUMBER
	LVEF	VARCHAR2
LVASSESS - LVEFEF	LVEFEF	FLOAT
MI	MI_C	NUMBER
	MI	VARCHAR2
	MI_ND	VARCHAR2
LTCATH	LTCATH_C	NUMBER
	LTCATH	VARCHAR2
	LTCATH_ND	VARCHAR2
PCIHX	PCIHX_C	NUMBER
	PCIHX	VARCHAR2
	PCIHX_ND	VARCHAR2
CABGHX	CABGHX_C	NUMBER
	CABGHX	VARCHAR2
	CABGHX_ND	VARCHAR2
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
<p>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.</p>		

HFN_IRON: CLINICAL HISTORY (MEDHIST2) [frMEDHIST2]		
Clinical History [stMEDHIST2_1]		
1.*	<p>Does subject have moderate to severe valvular heart disease? [Moderate to severe valvular heart disease]</p>	<p>[VALVULAR] [N: 1] <input checked="" type="radio"/> [cpVALVULAR] Yes (check all that apply) [MREGURG] [N: 1] <input type="checkbox"/> Mitral regurgitation [AREGURG] [N: 1] <input type="checkbox"/> Aortic regurgitation [TREGURG] [N: 1] <input type="checkbox"/> Tricuspid regurgitation [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
2.*	<p>Has subject had prior valvular surgery? [Prior valvular surgery]</p>	<p>[PVALSRG] [N: 1] <input checked="" type="radio"/> [cpPVALSRG] Yes (check all that apply) [MITSURG] [N: 1] <input type="checkbox"/> Mitral [AORSURG] [N: 1] <input type="checkbox"/> Aortic [TRISURG] [N: 1] <input type="checkbox"/> Tricuspid [PULSURG] [N: 1] <input type="checkbox"/> Pulmonic [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
3.*	<p>Hypertension [Hypertension]</p>	<p>[HYPRTESN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
4.*	<p>TIA [TIA]</p>	<p>[TIA] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
5.*	<p>Stroke [Stroke]</p>	<p>[STROKE] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
6.*	<p>Arrhythmia [Arrhythmia]</p>	<p>[ARRHYTHM] [N: 1] <input checked="" type="radio"/> [cpARRHYTHM] Yes (check all that apply) [ATRIALFB] [N: 1] <input type="checkbox"/> Atrial fibrillation [SUSVT] [N: 1] <input type="checkbox"/> VT/VF [ARRHUNKO] [N: 1] <input type="checkbox"/> Unknown/Other [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
7.*	<p>Pacemaker/ICD [Pacemaker/ICD]</p>	<p>[PACEICD] [N: 1] <input checked="" 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.*	<p>Peripheral vascular disease</p>	<p>[PVD]</p>

	[Peripheral vascular disease]	[N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
9.*	Chronic obstructive pulmonary disease [Chronic obstructive pulmonary disease]	[COPD] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
10.*	Diabetes [Diabetes]	[DIABETES] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
11.*	Hepatic disease [Hepatic disease]	[HEPATIC] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
12.*	Chronic renal insufficiency [Chronic renal insufficiency]	[CRINSUF] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
13.*	Depression (treated with prescription medication) [Depression]	[DEPRESS] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
14.*	Cigarette smoking [Cigarette smoking]	[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
15.*	Hyperlipidemia [Hyperlipidemia]	[HYPRLIP] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
16.*	Obstructive sleep apnea [Obstructive sleep apnea]	[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
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 regurgitation	*MREGURG_CIMITRALREGURGITATION_C	NUMBER
	*MREGURG_CIMITRALREGURGITATION	VARCHAR2
VALVULAR - Aortic regurgitation	*AREGURG_CIAORTICREGURGITATION_C	NUMBER
	*AREGURG_CIAORTICREGURGITATION	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	*ATRIALFB_CIATRIALFIBRILLATION_C	NUMBER
	*ATRIALFB_CIATRIALFIBRILLATION	VARCHAR2
ARRHYTHM - VT/VF	SUSVT_CIVTVF_C	NUMBER
	SUSVT_CIVTVF	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
HEPATIC	HEPATIC_C	NUMBER
	HEPATIC	VARCHAR2
	HEPATIC_ND	VARCHAR2
CRINSUF	CRINSUF_C	NUMBER
	CRINSUF	VARCHAR2

	CRINSUF_ND	VARCHAR2
DEPRESS	DEPRESS_C	NUMBER
	DEPRESS	VARCHAR2
	DEPRESS_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_IRON: EXAMINATION (EXAM) [frEXAM1]	
Examination [stEXAM1]	
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.* Height (at Baseline visit only) [Height]	[HEIGHT] [N: 1] <input type="radio"/> [HGTVAL] xxxxxxxx. [HGTUNIT] Unit [N: 1] <input type="radio"/> in [N: 2] <input type="radio"/> cm [N: 97] <input type="radio"/> Not Done
4.* Weight [Weight]	[WEIGHT] [N: 1] <input type="radio"/> [WGTVAL] xxxxxxxx. [WGTUNIT] Unit [N: 1] <input type="radio"/> lb [N: 2] <input type="radio"/> kg [N: 97] <input type="radio"/> Not Done
5.* 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
6.* Peripheral edema [Peripheral edema]	[EDEMA] [N: 1] <input type="radio"/> None [N: 2] <input type="radio"/> Trace [N: 5] <input type="radio"/> Mild (1+) [N: 3] <input type="radio"/> Moderate (2+, 3+) [N: 4] <input type="radio"/> Severe (4+) [N: 97] <input type="radio"/> Not Done
7.* 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
8.* 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	

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
HEIGHT	HEIGHT_C	**NUMBER
	HEIGHT	VARCHAR2
	HEIGHT_ND	VARCHAR2
HEIGHT - HGTVAL	HGTVAL	FLOAT
HEIGHT - HGTUNIT	HGTUNIT_C	NUMBER
	HGTUNIT	VARCHAR2
WEIGHT	WEIGHT_C	**NUMBER
	WEIGHT	VARCHAR2
	WEIGHT_ND	VARCHAR2
WEIGHT - WGTVAL	WGTVAL	FLOAT
WEIGHT - WGTUNIT	WGTUNIT_C	NUMBER
	WGTUNIT	VARCHAR2
JVP	JVP_C	NUMBER
	JVP	VARCHAR2
	JVP_ND	VARCHAR2
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_IRON: MEDICATIONS (MEDS) [frMEDS]	
Medications [stMEDS1]	
1.*	ACE inhibitor [ACE inhibitor]
	<p>[ACE] [N: 1] <input type="radio"/> Yes [N: 0] <input 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 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 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 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 type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
6.*	Nitrates (do not include sublingual nitroglycerin) [Nitrates]
	<p>[NITR] [N: 1] <input type="radio"/> Yes [N: 0] <input 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 type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
8.*	Antiplatelets [Antiplatelets]
	<p>[ANTIPLT] [N: 1] <input type="radio"/> [cpANTIPLTY] Yes (check all that apply) [ANTIPASP] [N: 1] <input type="checkbox"/> Aspirin (taken daily) [ANTIPTHI] [N: 1] <input type="checkbox"/> Thienopyridines (eg: ticlopidine, clopidogrel, prasugrel) [ANTIPOTH] [N: 1] <input type="checkbox"/> Other [N: 0] <input type="radio"/> [ANTIPTCI]</p>

		<p>No If no: Is there documented evidence of contraindication? [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown [N: 99] <input checked="" type="radio"/> Unknown</p>
9.*	<p>Anticoagulants [Anticoagulants]</p>	<p>[ANTICAG] [N: 1] <input checked="" type="radio"/> [cpANTICAGY] 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 checked="" type="radio"/> Yes [N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown [N: 99] <input checked="" type="radio"/> Unknown</p>
10.*	<p>Digoxin [Digoxin]</p>	<p>[DIGX] [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
11.*	<p>Amiodarone [Amiodarone]</p>	<p>[AMIOD] [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
12.*	<p>Statin [Statin]</p>	<p>[STATIN] [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
13.*	<p>Lipid lowering agent (other than statin) [Lipid lowering agent]</p>	<p>[LLIPID] [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
14.*	<p>Ambulatory IV Inotropes [Ambulatory IV Inotropes]</p>	<p>[IVINOTRP] [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
15.*	<p>Metolazone [Metolazone]</p>	<p>[METAZ] [N: 1] <input checked="" type="radio"/> [METZAFRQ] Yes [N: 1] <input checked="" type="radio"/> Chronic (>=1x/week) [N: 2] <input checked="" type="radio"/> PRN (<1x/week) [N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
16.*	<p>HCTZ [HCTZ]</p>	<p>[HCTZ] [N: 1] <input checked="" type="radio"/> [HCCTZFRQ] Yes [N: 1] <input checked="" type="radio"/> Chronic (>=1x/week) [N: 2] <input checked="" type="radio"/> PRN (<1x/week) [N: 0] <input checked="" type="radio"/> No [N: 99] <input checked="" type="radio"/> Unknown</p>
17.*	<p>Furosemide [Furosemide]</p>	<p>[FURO] [N: 1] [FURODOSE]</p>

		<input type="radio"/> Yes Daily Dose: <input type="text" value="xxxxxxx"/> [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
18.*	Torsemide [Torsemide]	[TORS] [N: 1] <input type="radio"/> [TORSDOSE] Yes Daily Dose: <input type="text" value="xxxxxxx"/> [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
19.*	Bumetanide [Bumetanide]	[BUME] [N: 1] <input type="radio"/> [BUMDOSE] Yes Daily Dose: <input type="text" value="xxxxxxx"/> [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
STATIN	STATIN_C	NUMBER
	STATIN	VARCHAR2
	STATIN_ND	VARCHAR2
LLIPID	LLIPID_C	NUMBER
	LLIPID	VARCHAR2
	LLIPID_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

	HCCTZFRO	VARCHAR2
FURO	FURO_C	**NUMBER
	FURO	VARCHAR2
	FURO_ND	VARCHAR2
FURO - FURODOSE	FURODOSE	FLOAT
TORS	TORS_C	**NUMBER
	TORS	VARCHAR2
	TORS_ND	VARCHAR2
TORS - TORSDOSE	TORSDOSE	FLOAT
BUME	BUME_C	**NUMBER
	BUME	VARCHAR2
	BUME_ND	VARCHAR2
BUME - BUMDOSE	BUMDOSE	FLOAT
Key: [*] = The column and/or table name in the actual RDE extract may be different. [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_IRON: EVENTS OF INTEREST (EVNTINT) [frEVNTINT]		
Events of Interest [stEVNTINT1]		
1.* ✓	Did subject experience any of the following anticipated, 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, 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="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2017)
Key: [*] = Item is required [✓] = Source verification required		

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

HFN_IRON: STUDY DRUG ADMINISTRATION (SDADMIN) [frSDADMIN]	
Study Drug Administration [stSDADMIN1]	
<p>1.* <input checked="" type="checkbox"/> Was study drug dispensed? [Was study drug dispensed]</p>	<p>[SDRGDISP] [N: 1] <input type="radio"/> [INITDSDT] Yes (go to KITS visit to record each Kit dispensed) Date of Initial Dose: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2017) Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock</p> <p>[N: 0] <input type="radio"/> [INDRGRS] No If No, specify reason: [INDRGRS] [N: 1] <input type="radio"/> Subject withdrew consent [N: 2] <input type="radio"/> MD Decision [N: 98] <input type="radio"/> [INDRGRSP] Other Specify: <input style="width: 100%;" type="text" value="A200"/></p>
<p>Key: [*] = Item is required [✓] = Source verification required</p>	

RDE Analytics: RD_FRSDADMIN		
Data Variable RefName	RD Column Name	Column Data Type
SDRGDISP	SDRGDISP_C	**NUMBER
	SDRGDISP	VARCHAR2
	SDRGDISP_ND	VARCHAR2
SDRGDISP - INITDSDT	INITDSDT	DATE
	INITDSDT_DTS	VARCHAR2
	INITDSDT_DTR	VARCHAR2
SDRGDISP - INDRGRS	INDRGRS_C	NUMBER
	INDRGRS	VARCHAR2
SDRGDISP - INDRGRSP	INDRGRSP	VARCHAR2
<p>Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.</p>		

HFN_IRON: Baseline Assessments (BASSESS) [frBASSESS]	
Additional Baseline Assessments [stBASSESS1]	
1.* Were protocol required biological samples collected (If yes, please complete SAMPLES form) (Secondary Endpoint) [Were protocol required biological samples collected]	<p>[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 test 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: A50</p>
2.* Was 6-Minute Walk performed (If yes, complete SIXMWT form) (Secondary Endpoint) [Was 6-Minute Walk performed]	<p>[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 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"/> [BSMWNDSP] Unknown/other Specify: A50</p>
3.* Was KCCQ completed (If yes, complete KCCQ form) (Secondary Endpoint) [Was KCCQ completed]	<p>[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 test but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 99] <input type="radio"/> [BKCCQNSD] Unknown/other Specify: A50</p>
4.* Was CPET completed (If yes, complete CPET form) (Primary Endpoint) [Was CPET completed]	<p>[BCPETDN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [BCPETNDR] No Reason test was not performed: [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform test but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 99] <input type="radio"/> [BCPETNSD] Unknown/other Specify: A50</p>

Key: [*] = Item is required

RDE Analytics: RD_FRBASSESS		
Data Variable RefName	RD Column Name	Column Data Type
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 - BSMWNDS	BSMWNDS	VARCHAR2
BKCCQDN	BKCCQDN_C	NUMBER
	BKCCQDN	VARCHAR2
	BKCCQDN_ND	VARCHAR2
BKCCQDN - BKCCQDR	BKCCQDR_C	NUMBER
	BKCCQDR	VARCHAR2
BKCCQDN - BKCCQDS	BKCCQDS	VARCHAR2
BCPETDN	BCPETDN_C	NUMBER
	BCPETDN	VARCHAR2
	BCPETDN_ND	VARCHAR2
BCPETDN - BCPETNDR	BCPETNDR_C	NUMBER
	BCPETNDR	VARCHAR2
BCPETDN - BCPETNDS	BCPETNDS	VARCHAR2

HFN_IRON: 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 type="radio"/> Yes [N: 0] <input checked="" type="radio"/> [BIOMNDRS] No Reason samples were not collected: [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform test but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 99] <input type="radio"/> Unknown/Other			
2.	Collection Date/Time	Number of Samples Collected	Date sent to lab	Date received	Frozen	Number of Samples Received
Biomarker Collection Information Entry [rsSAMPLES2]						
2.1* ✓	Collection Date/Time: [Collection Date/Time]		[BIOMKDTM] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2017) Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock			
2.2* ✓	Number of Samples Collected [Number of Samples Collected]		[cpBIOCOLL1] [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]		[BIOMSTDTT] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2017)			
2.4*	Date samples received [Date received]		[BIOMRCDDT] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2017)			
2.5*	Samples received frozen [Frozen]		[BIOMFROZ] [N: 1] <input type="radio"/> Yes [N: 0] <input checked="" 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"/> <input type="checkbox"/> [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"/> <input type="checkbox"/> [BIOMEUSE] Number of usable EDTA samples: <input type="text" value="N2"/>			
Biorepository and Genetics [stSAMPLES3]						
3.* ✓	Were biorepository or genetics samples collected at this visit? [Were biorepository or genetics samples collected at this visit?]		[BIOREP] [N: 1] <input type="radio"/> Yes [N: 0] <input checked="" type="radio"/> [BIORNDRN] 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="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2017) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock
4.2*	Number of Samples Collected [Number of Samples Collected]	[cpBIOCCLL2] [BIORSER] [N: 1] <input type="checkbox"/> [BIORSRNM] Serum cryovials: N2 [BIOREDA] [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 type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2017)
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"/> [BIORNUM] DNA N2 [BIORDUSE] Number of usable DNA samples: N2
Comments [stSAMPLES5]		
5.	Comments [Lab Comments]	[LABCOMM] A200
Key: [*] = Item is required [v] = 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_IRON: SIX MINUTE WALK TEST (SIXMWT) [frSIXMWT]	
Six Minute Walk Test [stSIXMWT1]	
1.* ✓ Date test performed [Date test performed]	[WALKDT] Req ▾ / Req ▾ / Req ▾ (2014-2017)
2.* ✓ Distance walked [Distance walked]	[WLKDIST] [N: 1] <input checked="" type="radio"/> [DISTMET] xxxxxxxx. 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 checked="" 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
4.* ✓ Indicate all symptoms experienced by the subject [Indicate all symptoms experienced by the subject]	[cpSYMPEXP] [SXNONE] [N: 1] <input type="checkbox"/> None [SXANG] [N: 1] <input type="checkbox"/> Angina [SXLGTHD] [N: 1] <input type="checkbox"/> Lightheadedness [SXSYNCOPI] [N: 1] <input type="checkbox"/> Syncope [SXDYSP] [N: 1] <input type="checkbox"/> Dyspnea [SXFATIGI] [N: 1] <input type="checkbox"/> Fatigue [SXCSTPN] [N: 1] <input type="checkbox"/> Chest pain [SXLGJTPN] [N: 1] <input type="checkbox"/> Leg or joint pain [SXINSTBL] [N: 1] <input type="checkbox"/> Instability [SXOTHER] [N: 98] <input type="checkbox"/> [SXOTHSP] Other Specify: A100
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
cpSYMPEXP	CPSYMPEXP_ND	VARCHAR2
cpSYMPEXP - Yes	SXNONE_CIYES_C	NUMBER
	SXNONE_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXANG_CIYES_C	NUMBER
	SXANG_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXLGHTHD_CIYES_C	NUMBER
	SXLGHTHD_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXSYNCOP_CIYES_C	NUMBER
	SXSYNCOP_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXDYSP_CIYES_C	NUMBER
	SXDYSP_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXFATIGE_CIYES_C	NUMBER
	SXFATIGE_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXCSTPN_CIYES_C	NUMBER
	SXCSTPN_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXLGJTPN_CIYES_C	NUMBER
	SXLGJTPN_CIYES	VARCHAR2
cpSYMPEXP - Yes	SXINSTBL_CIYES_C	NUMBER
	SXINSTBL_CIYES	VARCHAR2
cpSYMPEXP - Other	SXOTHER_SXOTHSP_C	**NUMBER
	SXOTHER_SXOTHSP	VARCHAR2
cpSYMPEXP - SXOTHSP	SXOTHSP	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_IRON: 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	KCCQ1A, KCCQ1B, KCCQ1C, KCCQ1D, KCCQ1E, KCCQ1F
		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	KCCQ2
		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	KCCQ3
		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	KCCQ4
		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	KCCQ5, KCCQ7
		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	KCCQ6
		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	KCCQ8
		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	KCCQ9
		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_IRON: CPET (CPET) [frCPET]	
CPET [stCPET1]	
1.* Was CPET data transferred to the core lab? [Was CPET data transferred to the core lab?]	<p>[CPETTX] [N:1] <input type="radio"/> [CPETSUDT] Yes Date submitted Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2017) [N:0] <input type="radio"/> No</p>
2. Date received by core lab [Date received by core lab]	<p>[CPETRCDT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2017)</p>
Key: [*] = Item is required	

RDE Analytics: RD_FRCPET		
Data Variable RefName	RD Column Name	Column Data Type
CPETTX	CPETTX_C	**NUMBER
	CPETTX	VARCHAR2
	CPETTX_ND	VARCHAR2
CPETTX - CPETSUDT	CPETSUDT	DATE
	CPETSUDT_DTS	VARCHAR2
	CPETSUDT_DTR	VARCHAR2
CPETRCDT	CPETRCDT	DATE
	CPETRCDT_DTS	VARCHAR2
	CPETRCDT_DTR	VARCHAR2
	CPETRCDT_ND	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_IRON: VISIT STATUS (VISIT) [fr-VISIT]

Visit Status [stVISIT1]

<p>1.* ✓ Was the visit performed [Visit performed]</p>	<p>[STATUS] [N: 1] <input type="radio"/> [ASSESSDT] Yes Visit date: Req [▼] / Req [▼] / Req [▼] (2014-2017) [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"/> [ASENDSP] 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 - ASENDSP	ASENDSP	VARCHAR2

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

HFN_IRON: 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/Unk <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2017)	
2.2*	Dose [Dose]	[SDRGDOSE] [N: 1] <input type="radio"/> 150 mg BID [N: 2] <input type="radio"/> 150 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 or Discontinuation [Primary Reason for Dose Change]	[CHGREAS] [N: 1] <input type="radio"/> [AERXSP] Adverse reaction, specify: A128 [DRGSAE] 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 - AERXSP	AERXSP	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_IRON: Additional Protocol Assessments WK8 (ASSESS1) [frASSESS1]	
Additional Protocol Assessments [stASSESS1]	
1.* Was 6-Minute Walk performed (If yes, complete SIXMWT form)?(Secondary Endpoint) [Was 6-Minute Walk performed]	<p>[SIXMWT1] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [SMWNRS1] 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"/> [SMWNDSP1] Unknown/other Specify: A50</p>
2.* Was KCCQ completed (If yes, complete KCCQ form)?(Secondary Endpoint) [Was KCCQ completed]	<p>[KCCQDN1] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [KCCQNRS1] 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"/> [KCCQNSP1] Unknown/other Specify: A50</p>
3.* 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>[NEWSAE1] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
4.* Has the subject been hospitalized since the last visit (If yes, complete REHOSP form)? [Has the subject been hospitalized since the last visit]	<p>[REHOSP1] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
5.* Has the subject had any emergency department visits since the last visit (If yes, complete EDVIS form)? [Has the subject had any emergency department visits since the last visit]	<p>[EDVIST1] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown</p>
Key: [*] = Item is required	

RDE Analytics: RD_FRASSESS1		
Data Variable RefName	RD Column Name	Column Data Type
SIXMWT1	SIXMWT1_C	NUMBER
	SIXMWT1	VARCHAR2
	SIXMWT1_ND	VARCHAR2
SIXMWT1 - SMWNRS1	SMWNRS1_C	NUMBER
	SMWNRS1	VARCHAR2
SIXMWT1 - SMWNDSP1	SMWNDSP1	VARCHAR2
KCCQDN1	KCCQDN1_C	NUMBER
	KCCQDN1	VARCHAR2
	KCCQDN1_ND	VARCHAR2
KCCQDN1 - KCCQNRS1	KCCQNRS1_C	NUMBER
	KCCQNRS1	VARCHAR2
KCCQDN1 - KCCQNSP1	KCCQNSP1	VARCHAR2

NEWSAE1	NEWSAE1_C	NUMBER
	NEWSAE1	VARCHAR2
	NEWSAE1_ND	VARCHAR2
REHOSP1	REHOSP1_C	NUMBER
	REHOSP1	VARCHAR2
	REHOSP1_ND	VARCHAR2
EDVIST1	EDVIST1_C	NUMBER
	EDVIST1	VARCHAR2
	EDVIST1_ND	VARCHAR2

HFN_IRON: Additional Protocol Assessments WK16 (ASSESS2) [frASSESS2]	
Additional Protocol Assessments [stASSESS2]	
1.* Were local labs performed (If yes, please complete lab forms)? [Were local labs performed]	<p>[LABSDNE] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [LABNDRN] 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>
2.* Were protocol required biological samples collected (If yes, please complete SAMPLES form)?(Secondary Endpoint) [Were protocol required biological samples collected]	<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>
3.* Was 6-Minute Walk performed (If yes, complete SIXMWT form)?(Secondary Endpoint) [Was 6-Minute Walk performed]	<p>[SIXMWT2] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [SMWDRS] 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"/> [SMWNDSP] Unknown/other Specify: <input type="text" value="A50"/></p>
4.* Was KCCQ completed (If yes, complete KCCQ form)?(Secondary Endpoint) [Was KCCQ completed]	<p>[KCCQDN2] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [KCCQDRS] No [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform test but subjectively able [N: 3] <input type="radio"/> Not done due to oversight or technical problem [N: 99] <input type="radio"/> [KCCQNDSP] Unknown/other Specify: <input type="text" value="A50"/></p>
5.* Was CPET completed (If yes, complete CPET form)(Primary Endpoint) [Was CPET completed]	<p>[CPETDN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [CPETNDR] 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"/> [CPETNDS] Unknown/other Specify: <input type="text" value="A50"/></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>[NEWSAE2] [N: 1] <input type="radio"/> Yes</p>

		[N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
7.*	Has the subject been hospitalized since the last visit (If yes, complete REHOSP form)? [Has the subject been hospitalized since the last visit]	[REHOSP2] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
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]	[EDVIST2] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
Key: [*] = Item is required		

RDE Analytics: RD_FRASSESS2		
Data Variable RefName	RD Column Name	Column Data Type
LABSDNE	LABSDNE_C	NUMBER
	LABSDNE	VARCHAR2
	LABSDNE_ND	VARCHAR2
LABSDNE - LABNDRN	LABNDRN_C	NUMBER
	LABNDRN	VARCHAR2
LABSDNE - LABNDSP	LABNDSP	VARCHAR2
BIOSAMP	BIOSAMP_C	NUMBER
	BIOSAMP	VARCHAR2
	BIOSAMP_ND	VARCHAR2
BIOSAMP - BIONDRSN	BIONDRSN_C	NUMBER
	BIONDRSN	VARCHAR2
BIOSAMP - BIONDSP	BIONDSP	VARCHAR2
SIXMWT2	SIXMWT2_C	NUMBER
	SIXMWT2	VARCHAR2
	SIXMWT2_ND	VARCHAR2
SIXMWT2 - SMWNDRS	SMWNDRS_C	NUMBER
	SMWNDRS	VARCHAR2
SIXMWT2 - SMWNSP	SMWNSP	VARCHAR2
KCCQDN2	KCCQDN2_C	NUMBER
	KCCQDN2	VARCHAR2
	KCCQDN2_ND	VARCHAR2
KCCQDN2 - KCCQNDRS	KCCQNDRS_C	NUMBER
	KCCQNDRS	VARCHAR2
KCCQDN2 - KCCQNSP	KCCQNSP	VARCHAR2
CPETDN	CPETDN_C	NUMBER
	CPETDN	VARCHAR2
	CPETDN_ND	VARCHAR2
CPETDN - CPETNDR	CPETNDR_C	NUMBER
CPETDN - CPETNDR	CPETNDR	VARCHAR2
CPETDN - CPETNDS	CPETNDS	VARCHAR2
NEWSAE2	NEWSAE2_C	NUMBER
	NEWSAE2	VARCHAR2
	NEWSAE2_ND	VARCHAR2
REHOSP2	REHOSP2_C	NUMBER
	REHOSP2	VARCHAR2

	REHOSP2_ND	VARCHAR2
EDVIST2	EDVIST2_C	NUMBER
	EDVIST2	VARCHAR2
	EDVIST2_ND	VARCHAR2

HFN_IRON: HEMATOLOGY AND IRON LABS (HEMA) [frHEMA]	
Copy of Hematology and Iron Labs [stHEMA1]	
1.* Collection Date and Time [Collection Date and Time]	[HEMADTM] Req [v] / Req [v] / Req [v] (2014-2017) Req/Unk [v] : Req/Unk [v] 24-hour clock
2.* Hemoglobin (Hgb) [Hemoglobin]	[HGB1] [N: 1] [cpHGB1] [HGBVAL1] xxxxxxxx. [HGBUNT1] Unit: [N: 7] [v] g/dL [N: 8] [v] g/L [N: 1] [v] mmol/L [N: 97] [v] Not Done
3.* Hematocrit [Hematocrit]	[HCT1] [N: 1] [cpHCT1] [HCTVAL1] xxxxxxxx. [HCTUNT1] Unit: [N: 15] [v] L/L [N: 11] [v] % [N: 97] [v] Not Done
4.* RBC [RBC]	[RBC1] [N: 1] [RBCVAL1] xxxxxxxx. 10 ¹² /L [N: 97] [v] Not Done
5.* RDW [RDW]	[RDW1] [N: 1] [RDWVAL1] xxxxxxxx. % [N: 97] [v] Not Done
6.* WBC [WBC]	[WBC1] [N: 1] [cpWBC1] [WBCVAL1] xxxxxxxx. [WBCUNT1] Unit: [N: 9] [v] 10 ⁹ /L or 10 ³ /mm ³ [N: 10] [v] /mm ³ [N: 97] [v] Not Done
7.* Platelet Count [Platelet Count]	[PLATLET1] [N: 1] [cpPLATLET1] [PLATVAL1] xxxxxxxx. [PLATUNT1] Unit: [N: 9] [v] 10 ⁹ /L or 10 ³ /mm ³ [N: 10] [v] /mm ³ [N: 97] [v] Not Done
Key: [*] = Item is required [v] = Source verification required	

RDE Analytics: RD_FRHEMA		
Data Variable RefName	RD Column Name	Column Data Type
HEMADTM	HEMADTM	DATE
	HEMADTM_DTS	VARCHAR2
	HEMADTM_DTR	VARCHAR2

	HEMADTM_ND	VARCHAR2
HGB1	HGB1_C	**NUMBER
	HGB1	VARCHAR2
	HGB1_ND	VARCHAR2
HGB1 - HGBVAL1	HGBVAL1	FLOAT
HGB1 - HGBUNT1	HGBUNT1_C	NUMBER
	HGBUNT1	VARCHAR2
HCT1	HCT1_C	**NUMBER
	HCT1	VARCHAR2
	HCT1_ND	VARCHAR2
HCT1 - HCTVAL1	HCTVAL1	FLOAT
HCT1 - HCTUNT1	HCTUNT1_C	NUMBER
	HCTUNT1	VARCHAR2
RBC1	RBC1_C	**NUMBER
	RBC1	VARCHAR2
	RBC1_ND	VARCHAR2
RBC1 - RBCVAL1	RBCVAL1	FLOAT
RDW1	RDW1_C	**NUMBER
	RDW1	VARCHAR2
	RDW1_ND	VARCHAR2
RDW1 - RDWVAL1	RDWVAL1	FLOAT
WBC1	WBC1_C	**NUMBER
	WBC1	VARCHAR2
	WBC1_ND	VARCHAR2
WBC1 - WBCVAL1	WBCVAL1	FLOAT
WBC1 - WBCUNT1	WBCUNT1_C	NUMBER
	WBCUNT1	VARCHAR2
PLATLET1	PLATLET1_C	**NUMBER
	PLATLET1	VARCHAR2
	PLATLET1_ND	VARCHAR2
PLATLET1 - PLATVAL1	PLATVAL1	FLOAT
PLATLET1 - PLATUNT1	PLATUNT1_C	NUMBER
	PLATUNT1	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_IRON: 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="text"/> / Req <input type="text"/> / Req <input type="text"/> (2014-2017)	
2.* ✓	Kit number [Kit number]	[KITNUM] <input type="text" value="N5"/>	
3.* ✓	Reason dispensed: [Reason dispensed:]	[DISPREAS] [N: 1] <input type="radio"/> Initial [N: 3] <input type="radio"/> Week 8 [N: 2] <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_IRON: REHOSPITALIZATION (REHOSP) - Repeating Form [frREHOSP]									
#	Admission Date	Unplanned?	Discharge Date	Primary reason for admission	Clinical manifestations	Biomarker or radiographic evidence	Pharmacologic or mechanical interventions	Heart Transplant	LVAD
Hospitalization Information [stREHOSP1]									
1.*	Admission Date [Admission Date]				[ADMITDT] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2017)				
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"/> [REDCHGD] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2017) [N:2] <input type="radio"/> Remains hospitalized [N:3] <input type="radio"/> Subject died while hospitalized (complete DEATH form and SAE form as applicable)				
4.*	Primary reason for admission [Primary reason for admission]				[HOSPRS] [N:1] <input type="radio"/> Heart failure [N:2] <input type="radio"/> Acute coronary syndrome [N:3] <input type="radio"/> Cerebral Vascular Accident (CVA)/stroke [N:4] <input type="radio"/> Atrial arrhythmia [N:5] <input type="radio"/> Ventricular arrhythmia [N:6] <input type="radio"/> Sudden death with resuscitation [N:7] <input checked="" type="radio"/> [PRMCRDSP] Other cardiovascular Specify: A100 [N:8] <input type="radio"/> [PRMNCSP] Other non-cardiovascular Specify: A100				
5.*	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 [HFNOCSDYS] [N:1] <input type="checkbox"/> Paroxysmal nocturnal dyspnea [HFEDEMA] [N:1] <input type="checkbox"/> Edema [HFRALES] [N:1] <input type="checkbox"/> Pulmonary rales [HFJVD] [N:1] <input type="checkbox"/> Jugular venous distension [HFGALLOP] [N:1] <input type="checkbox"/> S3 Gallop [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 [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) [HFOTHR] [N:1] <input type="checkbox"/> [HFOTHRSP] Other, specify A100 [HFUNK] [N:1] <input type="checkbox"/> Unknown [N:0] <input checked="" type="radio"/> None				

6.*	<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) [HFIMGING] [N:1] <input type="checkbox"/> Documented worsening pulmonary congestion or pulmonary edema on chest X-ray or other generally recognized imaging pattern. [BIOOTH] [N:1] <input type="checkbox"/> [BIOOTHSP] Other, specify A100 [BIOUNK] [N:1] <input type="checkbox"/> Unknown [N:0] <input checked="" type="radio"/> None</p>
7.*	<p>Indicate any additional or increased pharmacologic or mechanical interventions directed at the treatment of heart failure during this hospitalization (check all that apply) [Pharmacologic or mechanical interventions]</p>	<p>[PHARMINT] [N:1] <input checked="" type="radio"/> [cpPHARMINT] [INITHRPY] [N:1] <input type="checkbox"/> Initiation of intravenous diuretic, inotropic, or vasodilator therapy [ORLTHPY] [N:1] <input type="checkbox"/> Significant addition or increase in oral heart failure therapy [UPTITRTE] [N:1] <input type="checkbox"/> Up-titration of intravenous therapy, if already on therapy [MECHSURG] [N:1] <input type="checkbox"/> Initiation of mechanical or surgical intervention to improve cardiac function), or the use of ultrafiltration, hemofiltration, or dialysis that is specifically directed at treatment of heart failure. [OTHINTVN] [N:1] <input type="checkbox"/> [INTVNSP] Other, specify A100 [INTVUNK] [N:1] <input type="checkbox"/> Unknown [N:0] <input checked="" type="radio"/> None</p>
8.*	<p>Heart Transplant [Heart Transplant]</p>	<p>[PROHTRAN] [N:1] <input checked="" type="radio"/> [PRHTRDDT] Yes Date of Transplant: Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (2014-2017) [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown</p>
9.*	<p>LVAD [LVAD]</p>	<p>[LVAD] [N:1] <input checked="" type="radio"/> [LVADDT] Yes Date of Implant: Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (2014-2017) [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown</p>

Key: [*] = Item is required [✓] = 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_C	NUMBER
ELECTAD	ELECTAD	VARCHAR2
	ELECTAD_ND	VARCHAR2
	INREHOSP_C	**NUMBER

	INREHOSP	VARCHAR2
	INREHOSP_ND	VARCHAR2
INREHOSP - REDCHGDT	REDCHGDT	DATE
	REDCHGDT_DTS	VARCHAR2
	REDCHGDT_DTR	VARCHAR2
HOSPRS	HOSPRS_C	NUMBER
	HOSPRS	VARCHAR2
	HOSPRS_ND	VARCHAR2
HOSPRS - PRMCRDSP	PRMCRDSP	VARCHAR2
HOSPRS - PRMNCSP	PRMNCSP	VARCHAR2
MANIFEST	MANIFEST_C	**NUMBER
	MANIFEST	VARCHAR2
	MANIFEST_ND	VARCHAR2
MANIFEST - Dyspnea	HFDYSP_CIDYSPNEA_C	NUMBER
	HFDYSP_CIDYSPNEA	VARCHAR2
MANIFEST - Orthopnea	HFORTHOC_IORTHOPNEA1_C	NUMBER
	HFORTHOC_IORTHOPNEA1	VARCHAR2
MANIFEST - Paroxysmal nocturnal dyspnea	*HFNOCDYS_CIPAROXYSMALNOCTURNALDYSYSPNEA1_C	NUMBER
	*HFNOCDYS_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_CIUNKNOWN1_C	NUMBER
	HFUNK_CIUNKNOWN1	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_CIIINCREASEDNATRIURETICPEPTIDE	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_CIINITIATIONOFTHERAPY_C	NUMBER
	*INITHRPY_CIINITIATIONOFTHERAPY	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_CIUPTITRATIONINTRAVENOUS THERAPY_C	NUMBER
	*UPTITRTE_CIUPTITRATIONINTRAVENOUS THERAPY	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_CIINITIATIONMECHSURGICALINTERVENTION_C	NUMBER
	*MECHSURG_CIINITIATIONMECHSURGICALINTERVENTION	VARCHAR2
PHARMINT - Other	OTHINTVN_INTVNSP_C	**NUMBER
	OTHINTVN_INTVNSP	VARCHAR2
PHARMINT - INTVNSP	INTVNSP	VARCHAR2
PHARMINT - Unknown	INTVUNK_CIUNKNOWN1_C	NUMBER
	INTVUNK_CIUNKNOWN1	VARCHAR2
PROHTRAN	PROHTRAN_C	**NUMBER
	PROHTRAN	VARCHAR2
	PROHTRAN_ND	VARCHAR2
PROHTRAN - PRHTRDDT	PRHTRDDT	DATE
	PRHTRDDT_DTS	VARCHAR2
	PRHTRDDT_DTR	VARCHAR2
LVAD	LVAD_C	**NUMBER
	LVAD	VARCHAR2
	LVAD_ND	VARCHAR2
LVAD - LVADDT	LVADDT	DATE
	LVADDT_DTS	VARCHAR2
	LVADDT_DTR	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different. [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFN_IRON: EMERGENCY DEPARTMENT VISIT (EDVISIT) - Repeating Form [frEDVISIT]		
#	Encounter Date	Primary reason for emergency department visit
1		
ED Visit Information [stEDVISIT1]		
1.* ✓	Encounter Date [Encounter Date]	[UNSCHDT] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2017)
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_IRON: Adverse Event/Serious Adverse Event (AESAE) - Repeating Form [frAESAE]																			
#	AE #	AE	Onset Date/Time	Severity	Relationship to Study Drug	Outcome	Stop Date	Action Taken	AE diminish/abate	AE reappear	Alternate Causes of SAE	Serious	AE Summary	Relevant Labs	Relevant Laboratory and Diagnostic Tests Details	On concomitant medications	Con Med Details	SAE verify	Evaluation date/time
1																			
Adverse Event/Serious Adverse Event [stAESAE1]																			
1.*	✓	AE Number (non-enterable field) <i>[read-only]</i> [AE #]										[AENUM] A4							
2.*	✓	AE Term [AE]										[AETERM] A100							
3.*	✓	AE Onset Date and Time [Onset Date/Time]										[AESTDTM] Req/Unk ▾ / Req ▾ / Req ▾ (2014-2017) Req/Unk ▾ : Req/Unk ▾ 24-hour clock							
4.*	✓	AE Severity [Severity]										[SEVERITY] [N: 1] <input type="radio"/> Mild [N: 2] <input type="radio"/> Moderate [N: 3] <input type="radio"/> Severe							
5.*	✓	Relationship of AE with Study Drug [Relationship to Study Drug]										[AEREL] [N: 1] <input type="radio"/> Not related [N: 2] <input type="radio"/> [UNLIKREL] Unlikely Related Rationale A100 [N: 3] <input type="radio"/> [PRRATREL] Possibly Related Rationale A100 [N: 4] <input type="radio"/> [RRATREL] Related Rationale A100							
6.*	✓	AE Outcome [Outcome]										[AEOUT] [N: 1] <input type="radio"/> Resolved [N: 2] <input type="radio"/> Resolving [N: 3] <input type="radio"/> Not resolved [N: 4] <input type="radio"/> Resolved with sequelae [N: 5] <input type="radio"/> Fatal [N: 99] <input type="radio"/> Unknown							
7.*	✓	AE Stop Date and Time [Stop Date]										[AEONGO] [N: 1] <input type="radio"/> [AESPDTM] Req/Unk ▾ / Req/Unk ▾ / Req/Unk ▾ (2014-2017) Req/Unk ▾ : Req/Unk ▾ 24-hour clock [N: 2] <input type="radio"/> Ongoing							
8.*	✓	Action Taken Regarding Study Drug [Action Taken]										[AEACN] [N: 1] <input type="radio"/> Dose not changed [N: 2] <input type="radio"/> Dose reduced [N: 3] <input type="radio"/> Dose increased [N: 4] <input type="radio"/> [INTDTAE] Drug Interrupted If study drug was interrupted, is this adverse event the primary reason for study drug interruption? [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 5] <input type="radio"/> [DCDTAE] Drug discontinued If study drug was discontinued, is this adverse event the primary reason for study drug discontinuation? [N: 1] <input type="radio"/> Yes							

		<p>[N: 0] <input checked="" type="radio"/> No [N: 96] <input type="radio"/> Not Applicable [N: 99] <input type="radio"/> Unknown [N: 96] <input type="radio"/> Not Applicable</p>
9.* <input checked="" type="checkbox"/>	If study drug was discontinued, interrupted, or reduced (dechallenged), did AE diminish/abate? [AE diminish/abate]	<p>[AEDIMTD] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 96] <input type="radio"/> Not Applicable</p>
10.* <input checked="" type="checkbox"/>	If study drug was restarted (Rechallenge), did AE recur? [AE reappear]	<p>[AERAPR] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 96] <input type="radio"/> Not Applicable</p>
11.* <input checked="" type="checkbox"/>	Possible alternate causes of the SAE (check all that apply) [Alternate Causes of SAE]	<p>[cpALTC AUS] [PRIMDIS] [N: 1] <input type="checkbox"/> Primary disease under study</p> <p>[INTERILL] [N: 1] <input type="checkbox"/> [I INLSPEC] Concomitant illness Specify: A200</p> <p>[CONCOM] [N: 1] <input type="checkbox"/> [CONSPEC] Concomitant medication Specify: A100</p> <p>[OKNWN] [N: 1] <input type="checkbox"/> [OTHSPEC] Other known or suspected cause Specify: A200</p> <p>[ALTNONE] [N: 1] <input type="checkbox"/> None (Only applicable if study drug related and considered only cause of AE)</p>
12.* <input checked="" type="checkbox"/>	Was this event serious? (If Yes, check all that apply) [Serious]	<p>[AESERYN] [N: 1] <input checked="" type="radio"/> [cpSERICRIT] Yes</p> <p>[SAEDEATH] [N: 1] <input type="checkbox"/> Death</p> <p>[SAELIFE] [N: 1] <input type="checkbox"/> Life-Threatening</p> <p>[SAEHOSP] [N: 1] <input type="checkbox"/> Hospitalization required or prolongation of existing hospitalization</p> <p>[SAEDIS] [N: 1] <input type="checkbox"/> Persistent or significant disability/incapacity</p> <p>[SAEANO] [N: 1] <input type="checkbox"/> Congenital anomaly or birth defect</p> <p>[SAEIMPNT] [N: 1] <input type="checkbox"/> Important medical event</p> <p>[N: 0] <input type="radio"/> No</p>
Adverse Event Summary		
13.		
AE Summary Entry [rsAESAE2]		
13.1 <input checked="" type="checkbox"/>	Provide a summary, in chronological order, of the clinical course of this AE from onset through resolution. 1. Presenting signs and symptoms; 2. Treatments and response to treatments 3. Subjects status at time of report and/or final outcome, as applicable [Adverse Event Summary]	<p>[SAENAR] A200</p>
Relevant Laboratory and Diagnostic Tests [stAESAE3]		

14. ✓	Were there any relevant laboratory or diagnostic tests for this AE? [Relevant Labs]				[SAELABYN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No	
15.	Date	Test	Result	Unit	Normal Range or Value	
Relevant Laboratory and Diagnostic Tests Details Entry [rsAESAE4]						
15.1 * ✓	Date and time [Date]				[DRAWDTM] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2017) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock	
15.2 * ✓	Test [Test]				[TESTNAM] A200	
15.3 * ✓	Result [Result]				[TESTRST] A200	
15.4 * ✓	Unit (applicable for labs only) [Unit]				[TESTUNT] A200	
15.5 * ✓	Normal range or value [Normal Range or Value]				[NRANGE] A200	
Concomitant Medications [stAESAE5]						
16. ✓	Was the subject on any relevant concomitant medications within 30 days prior to onset of this AE? If yes, list all concomitant medications: [On concomitant medications]				[SAECMYN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No	
17.	Med Name	Med Start Date	Med Stop Date	Medication Total Daily Dose	Medication Unit	Medication Indication
Con Med Details Entry [rsAESAE6]						
17.1 * ✓	Medication Name [Med Name]				[SAECMED] A50	
17.2 * ✓	Relevant Medication Start Date [Med Start Date]				[CONSTRDT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> (1914-2017) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock	
17.3 * ✓	Relevant Medication Stop Date [Med Stop Date]				[CONSTP] [N: 1] <input type="radio"/> [CONSTPDT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> (1914-2017) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock [N: 2] <input type="radio"/> Ongoing	
17.4 * ✓	Medication Total Daily Dose [Medication Total Daily Dose]				[CONDOSE] xxxxxxxx.	
17.5 * ✓	Unit [Medication Unit]				[CONUNIT] [N: 1] <input type="radio"/> mg [N: 2] <input type="radio"/> g [N: 3] <input type="radio"/> mL [N: 4] <input type="radio"/> cc [N: 98] <input type="radio"/> [CONOUNIT] Other unit specify: A20	

17.6* ✓	Indication [Medication Indication]	[MEDIND] A200
Investigator Verification [stAESAE7]		
18. ✓	I verify that this SAE report form accurately displays the results of the examination, tests, evaluations and treatments noted within. [SAE verify]	[PIVER] [N: 1] <input type="checkbox"/> Yes
19. ✓	Evaluation date and time (electronic verification non-enterable system generated) [read-only] [Evaluation date/time]	[PIDATE] 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_FRAESAE		
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
SEVERITY	SEVERITY_C	NUMBER
	SEVERITY	VARCHAR2
	SEVERITY_ND	VARCHAR2
AEREL	AEREL_C	NUMBER
	AEREL	VARCHAR2
	AEREL_ND	VARCHAR2
AEREL - UNLIKREL	UNLIKREL	VARCHAR2
AEREL - PRRATREL	PRRATREL	VARCHAR2
AEREL - RRATREL	RRATREL	VARCHAR2
AEOUT	AEOUT_C	NUMBER
	AEOUT	VARCHAR2
	AEOUT_ND	VARCHAR2
AEONGO	AEONGO_C	** NUMBER
	AEONGO	VARCHAR2
	AEONGO_ND	VARCHAR2
AEONGO - AESPDTM	AESPDTM	DATE
	AESPDTM_DTS	VARCHAR2
	AESPDTM_DTR	VARCHAR2
AEACN	AEACN_C	NUMBER
	AEACN	VARCHAR2
	AEACN_ND	VARCHAR2
AEACN - INTDTAE	INTDTAE_C	NUMBER
	INTDTAE	VARCHAR2
AEACN - DCDTAE	DCDTAE_C	NUMBER
	DCDTAE	VARCHAR2
AEDIMTD	AEDIMTD_C	NUMBER

	AEDIMTD	VARCHAR2
	AEDIMTD_ND	VARCHAR2
AERAPR	AERAPR_C	NUMBER
	AERAPR	VARCHAR2
	AERAPR_ND	VARCHAR2
cpALTCaus	CPALTCaus_ND	VARCHAR2
cpALTCaus - Primary disease under study	*PRIMDIS_CIPRIMARYDISEASEUNDERSTUDY_C	NUMBER
	*PRIMDIS_CIPRIMARYDISEASEUNDERSTUDY	VARCHAR2
cpALTCaus - Concomitant illness	INTERILL_INILSPEC_C	**NUMBER
	INTERILL_INILSPEC	VARCHAR2
cpALTCaus - INILSPEC	INILSPEC	VARCHAR2
cpALTCaus - Concomitant medication	CONCOM_CONSPEC_C	**NUMBER
	CONCOM_CONSPEC	VARCHAR2
cpALTCaus - CONSPEC	CONSPEC	VARCHAR2
cpALTCaus - Other	OKNWN_OTHSPEC_C	**NUMBER
	OKNWN_OTHSPEC	VARCHAR2
cpALTCaus - OTHSPEC	OTHSPEC	VARCHAR2
cpALTCaus - None (Only applicable if study drug related and considered only cause of AE)	ALTNONE_CISAECAUSENONE_C	NUMBER
	ALTNONE_CISAECAUSENONE	VARCHAR2
AESERYN	AESERYN_C	**NUMBER
	AESERYN	VARCHAR2
	AESERYN_ND	VARCHAR2
AESERYN - Death	SAEDEATH_CIDEATH1_C	NUMBER
	SAEDEATH_CIDEATH1	VARCHAR2
AESERYN - Life-Threatening	SAELIFE_CILIFETHREATENING_C	NUMBER
	SAELIFE_CILIFETHREATENING	VARCHAR2
AESERYN - Hospitalization required or prolongation of existing hospitalization	*SAEHOSP_CIREQUIREINPATIENTHOSP_C	NUMBER
	*SAEHOSP_CIREQUIREINPATIENTHOSP	VARCHAR2
AESERYN - Persistent or significant disability/incapacity	*SAEDIS_CIPERSISTENTSIGNIFICANTDISABILITY_C	NUMBER
	*SAEDIS_CIPERSISTENTSIGNIFICANTDISABILITY	VARCHAR2
AESERYN - Congenital anomaly or birth defect	*SAEANO_CICONGENITALANOMALYBIRTHDEFECT_C	NUMBER
	*SAEANO_CICONGENITALANOMALYBIRTHDEFECT	VARCHAR2
AESERYN - Important medical event	*SAEIMPNT_CIIMPORTANTMEDICALEVENT_C	NUMBER
	*SAEIMPNT_CIIMPORTANTMEDICALEVENT	VARCHAR2
SAELABYN	SAELABYN_C	NUMBER
	SAELABYN	VARCHAR2
	SAELABYN_ND	VARCHAR2
SAECMYN	SAECMYN_C	NUMBER
	SAECMYN	VARCHAR2
	SAECMYN_ND	VARCHAR2
PIVER	PIVER_ND	VARCHAR2
PIVER - Yes	PIVER_CIYES_C	NUMBER
	PIVER_CIYES	VARCHAR2
PIDATE	PIDATE	DATE
	PIDATE_DTS	VARCHAR2
	PIDATE_ND	VARCHAR2
RD_FRAESAE_RSAESAE2		
SAENAR	SAENAR	VARCHAR2

	SAENAR_ND	VARCHAR2
RD_FRAESAE_RSAESAE4		
DRAWDTM	DRAWDTM	DATE
	DRAWDTM_DTS	VARCHAR2
	DRAWDTM_DTR	VARCHAR2
	DRAWDTM_ND	VARCHAR2
TESTNAM	TESTNAM	VARCHAR2
	TESTNAM_ND	VARCHAR2
TESTRST	TESTRST	VARCHAR2
	TESTRST_ND	VARCHAR2
TESTUNT	TESTUNT	VARCHAR2
	TESTUNT_ND	VARCHAR2
NRANGE	NRANGE	VARCHAR2
	NRANGE_ND	VARCHAR2
RD_FRAESAE_RSAESAE6		
SAECMED	SAECMED	VARCHAR2
	SAECMED_ND	VARCHAR2
CONSTRDT	CONSTRDT	DATE
	CONSTRDT_DTS	VARCHAR2
	CONSTRDT_DTR	VARCHAR2
	CONSTRDT_ND	VARCHAR2
CONSTP	CONSTP_C	**NUMBER
	CONSTP	VARCHAR2
	CONSTP_ND	VARCHAR2
CONSTP - CONSTPDT	CONSTPDT	DATE
	CONSTPDT_DTS	VARCHAR2
	CONSTPDT_DTR	VARCHAR2
CONDOSE	CONDOSE	FLOAT
	CONDOSE_ND	VARCHAR2
CONUNIT	CONUNIT_C	NUMBER
	CONUNIT	VARCHAR2
	CONUNIT_ND	VARCHAR2
CONUNIT - CONUNIT	CONUNIT	VARCHAR2
MEDIND	MEDIND	VARCHAR2
	MEDIND_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_IRON: END OF STUDY (EOS) [frEOS]	
End of Study Participation [stEOS1]	
1.* <input checked="" type="checkbox"/> Date of last contact [Date of last contact]	[LSTCONDT] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2014-2017)
2.* <input checked="" type="checkbox"/> 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_IRON: DEATH (DEATH) [frDEATH]	
Death [stDEATH1]	
1.* ✓ Location of Death [Location of Death]	[DEATHLOC] [N: 1] <input type="radio"/> Inpatient/ER [N: 2] <input type="radio"/> Outpatient
2.* ✓ Date of Death [Date of Death]	[DEATHDT] Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2017)
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_IRON: 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_CIYES_C	NUMBER
	PISIGN_CIYES	VARCHAR2