

Annotated Study Book for Study Design: HF_INDIE

Study Design Version: 5.0

Study Design

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June 23, 2017 2:43PM

Time and Events Schedule For Study Design: HF_INDIE																						
Element	System																					
Assessment	CRF	System Screening (SYSSCR) [S]	System Enrollment (SYSENR) [S]	STATUS (STATUS) [S]	SCREENING (SCREEN) [S/D]	BASELINE (BASE) [S/D]	STUDY VISIT 2 (WEEK 7) [S/D]	STUDY VISIT 3 (WEEK 13) [S/D]	PHONE WEEK 15 (WEEK 15) [S/D]	PHONE VISIT LOG (PHONE) [S/D]	Study Drug Log (DRGLOG) [S/D]	DRUG KITS (KITS) [S/D]	ACCELEROMETER LOG (AXM) [S/D]	NEBULIZER LOG (NEB) [S/D]	DEVICE DEFICIENCY (DEVDEF) [S/D]	REHOSPITALIZATION (REHOSP) [S/D]	ED VISIT (EDVISIT) [S/D]	EVENTS OF INTEREST (EVNTINT) [S/D]	ADVERSE EVENTS (AE) [S/D]	END OF STUDY (EOS) [S/D]	INVESTIGATOR SIGNATURE (INVSIG) [S/D]	DEATH (DEATH) [U/D]
Visit Start Hours		0	0	0	1	2	1178	2186	2522	2523	2524	2525	2526	2527	2528	2529	2530	2531	2532	2533	2534	2535
1 System Screening	SYSSCR	1																				
2 System Enrollment	SYSENR		1																			
3 Clinical Operations Review	CLINOPS			1																		
4 Clinical Operations Review 2	CLINOPS2			2																		
5 Status	STATUS			3																		
6 DEMOGRAPHICS	DEMOG				1																	
7 INCLUSION/EXCLUSION PART 1	ELIG1				2																	
8 INCLUSION/EXCLUSION PART 2	ELIG2				3																	
9 SCREENING VISIT ASSESSMENTS	SCRVISIT				4																	
10 TEST DOSE	TESTDOSE				5-DF																	
11 RANDOMIZATION AND BIOMARKER CONSENT	RAND					1																
12 CLINICAL HISTORY	MEDHIST1					2																
13 CLINICAL HISTORY	MEDHIST2					3																
14 EXAMINATION	EXAM					4	2-DF	2-DF														
15 MEDICATIONS	MEDS					5	3-DF	3-DF														
16 CPET	CPET					6-DF	5-DF	5-DF														
17 ECG	ECG					7-DF																
18 CHEMISTRY LABS	CHEM					8-DF	6-DF	6-DF														
19 CBC	CBC					9-DF	7-DF	7-DF														
20 BIOLOGICAL SAMPLES	SAMPLES					10-DF	8-DF	8-DF														
21 Kansas City Cardiomyopathy Questionnaire	KCCQ					11-DF	9-DF	9-DF														
22 VISIT STATUS	VISIT						1	1	1													
23 Additional Protocol Assessments	ASSESS						4-DF	4-DF														
24 ECHO RESULTS	ECHOLAB						10-DF	10-DF														
25 PATIENT PREFERENCE	PREF							11-DF														
26 WEEK 15 PATIENT RESPONSE	RESPONSE								2													
27 PHONE VISIT LOG	PHONE									1-RF												
28 STUDY DRUG DOSING LOG	DRGDOSE										1											
29 DRUG KIT DISPENSING	DRUGKIT											1-RF										
30 ACCELEROMETER LOG	AXM												1									
31 NEBULIZER LOG	NEB													1								
32 DEVICE DEFICIENCY	DEVDEF														1-RF							
33 REHOSPITALIZATION	REHOSP															1-RF						
34 EMERGENCY DEPARTMENT VISIT	EDVISIT																1-RF					
35 EVENTS OF INTEREST	EVNTINT																	1-RF				
36 Adverse Event	AE																		1-RF			
37 END OF STUDY	EOS																				1	
38 DEATH	DEATH																				2-DF	1
39 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

HF_INDIE: System Screening (SYSSCR) [frSYSSCR2]	
System Screening [frSYSSCR2]	
1. * Subject Initials [Subject Initials]	[SUBJINIT] A3
Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

RDE Analytics: RD_FRSYSSCR2		
Data Variable RefName	RD Column Name	Column Data Type
SUBJINIT	SUBJINIT	VARCHAR2
	SUBJINIT_ND	VARCHAR2

HF_INDIE: System Enrollment (SYSENR) [frENRSYS1]	
System Enrollment [frENRSYS1]	
1. * Subject Identifier [Subject Identifier]	[SUBJID] A20
Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

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

HF_INDIE: Clinical Operations Review (CLINOPS) [frCLINOPS]					
Eligibility criteria [stCLINOPS1]					
1. For Clinops use only		[CLINOPSUSE] [N:1] <input type="checkbox"/> Yes			
2. Per eCRF eligibility review, was subject found to be eligible?		[INCMET] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No			
Ineligible Criteria		Waiver granted?	Waiver granted by	Reason for Waiver	
3.					
Ineligible criteria Entry [rsCLINOPS2]					
3.1 Criteria [Ineligible Criteria]		[CRITYPE] [N:1] <input checked="" type="radio"/> [INCLNOT] Inclusion not met [N:1] <input type="radio"/> IE1 [N:2] <input type="radio"/> IE2 [N:3] <input type="radio"/> IE3 [N:4] <input type="radio"/> IE4 [N:5] <input type="radio"/> IE5 [N:6] <input type="radio"/> IE6 [N:7] <input type="radio"/> IE7 [N:8] <input type="radio"/> IE8 [N:9] <input type="radio"/> IE9 [N:10] <input type="radio"/> IE10 [N:11] <input type="radio"/> IE11 [N:13] <input type="radio"/> IE12 [N:2] <input type="radio"/> [EXCLMET] Exclusion met [N:1] <input type="radio"/> EC1 [N:2] <input type="radio"/> EC2 [N:3] <input type="radio"/> EC3 [N:4] <input type="radio"/> EC4 [N:5] <input type="radio"/> EC5 [N:6] <input type="radio"/> EC6 [N:7] <input type="radio"/> EC7 [N:8] <input type="radio"/> EC8 [N:9] <input type="radio"/> EC9 [N:10] <input type="radio"/> EC10 [N:11] <input type="radio"/> EC11 [N:12] <input type="radio"/> EC12 [N:13] <input type="radio"/> EC13 [N:14] <input type="radio"/> EC14 [N:15] <input type="radio"/> EC15 [N:16] <input type="radio"/> EC16 [N:17] <input type="radio"/> EC17 [N:18] <input type="radio"/> EC18 [N:19] <input type="radio"/> EC19 [N:20] <input type="radio"/> EC20 [N:21] <input type="radio"/> EC21 [N:22] <input type="radio"/> EC22 [N:23] <input type="radio"/> EC23 [N:24] <input type="radio"/> EC24 [N:25] <input type="radio"/> EC25 [N:26] <input type="radio"/> EC26			
3.2 Was a waiver granted? [Waiver granted?]		[WAIWER] [N:1] <input type="radio"/> [WAIVRDT] Yes Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2016-2018) [N:0] <input type="radio"/> No			
3.3 Who granted waiver? [Waiver granted by]		[WHOGRTWV] A200			
3.4 Reason for Waiver Narrative [Reason for Waiver]		[ELIGNRT] A200			
3.5 Reason for Waiver Narrative continued [Reason for waiver, continued]		[ELIGNRT1] A200			
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.					

RDE Analytics: RD_FRCLINOPS		
Data Variable RefName	RD Column Name	Column Data Type
CLINOPSUSE	CLINOPSUSE_ND	VARCHAR2

CLINOPSUSE - Yes	CLINOPSUSE_C1YES_C	NUMBER
	CLINOPSUSE_C1YES	VARCHAR2
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.		

HF_INDIE: Clinical Operations Review 2 (CLINOPS2) [frCLINOPS2]		
Clinical Operations Review 2 [frCLINOPS2]		
1. For Clinops use only	[CLINOPSUSE2] [N:1] <input type="checkbox"/> Yes	
2. <input checked="" type="checkbox"/>	SDV Completed	Comments
SDV Review Entry [rsCLINOPS2_1]		
2.1 SDV Completed [SDV Completed]	[SDV] [N:1] <input type="radio"/> [SDVDT] Yes. Date Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018)	
2.2 Comments [Comments]	[SDVCOMM] A200	
3. <input checked="" type="checkbox"/>	ICD Review Completed	Comments
ICD Review Entry [rsCLINOPS2_2]		
3.1 ICD Review Completed [ICD Review Completed]	[ICD] [N:1] <input type="radio"/> [cpICDDT] Yes [ICDDT] ICD Date Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018) [ICDVERDT] Version Date of ICD Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018)	
3.2 Comments [Comments]	[ICDCOMM] A200	
4. <input checked="" type="checkbox"/>	Logistical Review Completed	Comments
Logistical Review Entry [rsCLINOPS2_3]		
4.1 Logistical Review Completed [Logistical Review Completed]	[LOGISTIC] [N:1] <input type="radio"/> [LOGISDT] Yes. Date Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018)	
4.2 Comments [Comments]	[LOGCOMM] A200	
Key: <input checked="" type="checkbox"/> = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

RDE Analytics: RD_FRCLINOPS2		
Data Variable RefName	RD Column Name	Column Data Type
CLINOPSUSE2	CLINOPSUSE2_ND	VARCHAR2
CLINOPSUSE2 - Yes	CLINOPSUSE2_CIYES_C	NUMBER
	CLINOPSUSE2_CIYES	VARCHAR2
*RD_FRCLINOPS2_RSCLINOPS2_1		
SDV	SDV_C	**NUMBER
	SDV	VARCHAR2
	SDV_ND	VARCHAR2
SDV - SDVDT	SDVDT	DATE
	SDVDT_DTS	VARCHAR2
SDVCOMM	SDVCOMM	VARCHAR2
	SDVCOMM_ND	VARCHAR2
*RD_FRCLINOPS2_RSCLINOPS2_2		
ICD	ICD_C	**NUMBER
	ICD	VARCHAR2
	ICD_ND	VARCHAR2
ICD - ICDDT	ICDDT	DATE
	ICDDT_DTS	VARCHAR2
ICD - ICDVERDT	ICDVERDT	DATE
	ICDVERDT_DTS	VARCHAR2
ICDCOMM	ICDCOMM	VARCHAR2

	ICDCOMM_ND	VARCHAR2
*RD_FRCLINOPS2_RSCLINOPS2_3		
LOGISTIC	LOGISTIC_C	**NUMBER
	LOGISTIC	VARCHAR2
	LOGISTIC_ND	VARCHAR2
LOGISTIC - LOGISDT	LOGISDT	DATE
	LOGISDT_DTS	VARCHAR2
LOGCOMM	LOGCOMM	VARCHAR2
	LOGCOMM_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.		

HF_INDIE: Status (STATUS) [frSTATUS]	
Almac Status [stSTATUS1]	
1. * Subject Identifier [Subject Identifier]	[SUBJID] A20
2. * Subject Initials [Subject Initials]	[SUBINIT] A3
3. Subject Status [Subject Status]	[SUBSTAT] [N: 1] <input type="radio"/> Consented and in Active Screening [N: 2] <input type="radio"/> Screen Failure [N: 3] <input type="radio"/> Randomized
4. Date Status Updated [Date Status Updated]	[STATUSDT] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018)
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

RDE Analytics: RD_FRSTATUS		
Data Variable RefName	RD Column Name	Column Data Type
SUBJID	SUBJID	VARCHAR2
	SUBJID_ND	VARCHAR2
SUBINIT	SUBINIT	VARCHAR2
	SUBINIT_ND	VARCHAR2
SUBSTAT	SUBSTAT_C	NUMBER
	SUBSTAT	VARCHAR2
	SUBSTAT_ND	VARCHAR2
STATUSDT	STATUSDT	DATE
	STATUSDT_DTS	VARCHAR2
	STATUSDT_ND	VARCHAR2

HF_INDIE: DEMOGRAPHICS (DEMOG) [frDEMOG]		
Informed Consent and Randomization [stDEMOG1]		
1.* Date/Time Informed Consent Signed [Date/Time Informed Consent Signed]		[CONSDTM] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018) Req/Unk <input type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock
2.* Date of Birth [Date of Birth]		[DOBDT] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (1912-1995)
3.* Sex [Sex]		[SEX] [N: 1] <input type="radio"/> Male [N: 2] <input type="radio"/> Female
4.* Ethnicity [Ethnicity]		[ETHNIC] [N: 1] <input type="radio"/> Hispanic or Latino [N: 2] <input type="radio"/> Not Hispanic or Latino
5.* Race (check all that apply) [Race]		[cpRACE] [AMERIND] [N: 1] <input type="checkbox"/> American Indian or Alaskan Native [ASIAN] [N: 1] <input type="checkbox"/> Asian [BLACK] [N: 1] <input type="checkbox"/> Black or African American [NATHWN] [N: 1] <input type="checkbox"/> Native Hawaiian or Other Pacific Islander [WHITE] [N: 1] <input type="checkbox"/> White/Caucasian
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

RDE Analytics: RD_FRDEMOG		
Data Variable RefName	RD Column Name	Column Data Type
CONSDTM	CONSDTM	DATE
	CONSDTM_DTS	VARCHAR2
	CONSDTM_DTR	VARCHAR2
	CONSDTM_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.		

HF_INDIE: INCLUSION/EXCLUSION PART 1 (ELIG1) [frELIG1]	
Inclusion [stELIGIBLE1A]	
1.* ✓ Subject ≥40 years old?	[SUB40YR] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Not Evaluated
2.* ✓ Symptoms of dyspnea (NYHA Class II-IV) without evidence of a non-cardiac or ischemic explanation for dyspnea?	[SYMDYSP] [N:1] <input checked="" type="radio"/> [NYHACL] Yes [N:2] <input type="radio"/> II [N:3] <input type="radio"/> III [N:4] <input type="radio"/> IV [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Not Evaluated
3.* ✓ EF ≥ 50% as determined on imaging study within 12 months of enrollment with no change in clinical status suggesting potential for deterioration in systolic function?	[EF50] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Not Evaluated
4.* ✓ Has the subject had any of the following:	[HADANY] [N:1] <input checked="" type="radio"/> [cpHADANY] Yes (check all criteria used to determine eligibility): [PREHOSH] [PREHOSHT] Previous hospitalization for HF with radiographic evidence (pulmonary venous hypertension, vascular congestion, interstitial edema, pleural effusion) of pulmonary congestion Date: Req/Unk <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1916-2018) [PCWP15] [N:1] <input type="checkbox"/> [cpPCWP15] Catheterization documented elevated filling pressures at rest (PCWP ≥15) [PCWP15DT] Date: Req/Unk <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1916-2018) [PCWP15VL] Value: xxxxxxxx. [LVEDP18] [N:1] <input type="checkbox"/> [cpLVEDP18] Catheterization documented elevated filling pressures at rest (LVEDP ≥18) [LVED18DT] Date: Req/Unk <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1916-2018) [LVED18VL] Value: xxxxxxxx. [PCWP25] [N:1] <input type="checkbox"/> [cpPCWP25] Catheterization documented elevated filling pressures with exercise (PCWP ≥25) [PCWP25DT] Date: Req/Unk <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1916-2018) [PCWP25VL] Value: xxxxxxxx. [ELVNT] [N:1] <input type="checkbox"/> [cpELVNT] Elevated NT-proBNP (>400 pg/ml) [ELVNTDT] Date: Req/Unk <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1916-2018) [ELVNTVL] Value: xxxxxxxx. [ELVBNP] [N:1] <input type="checkbox"/> [cpELVBNP] Elevated BNP (>200 pg/ml) [ELVBNPDT] Date: Req/Unk <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1916-2018) [ELVBNPVL] Value: xxxxxxxx. [ECHOEV] [N:1] <input type="checkbox"/> [ECHOEVD] Echo evidence of diastolic dysfunction/elevated filling pressures manifest by medial E/e ratio ≥15 and/or left atrial enlargement and chronic treatment with a loop diuretic for signs or symptoms of heart failure Date of Echo: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1916-2018) [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Not Evaluated
5.* ✓ Is heart failure the primary factor limiting activity (i.e., shortness of breath and/or fatigue and/or chest pain):	[PRIMFACT] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Not Evaluated
6.* ✓ Peak VO2 ≤ 75% predicted with peak respiratory exchange ratio of ≥ 1.0 CPET?	[PEAKVO2] [N:1] <input type="radio"/> [cpPEAKVO2] Yes [ACTVO2] Actual Peak VO2 Value: xxxxxxxx.

		<p>[PREDVO2] Predicted Peak VO2 Value: xxxxxxx.</p> <p>[PEAKRESP] Peak respiratory exchange ratio: xxxxxxx.</p> <p>[N:0] <input type="radio"/> No [N:2] <input type="radio"/> Not Evaluated</p>
7.* ✓	No chronic nitrate therapy or is not using intermittent sublingual nitroglycerin (requirement for > 1 SL nitroglycerin per week) within last 7 days?	<p>[NOCHRNT] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Not Evaluated</p>
8.* ✓	Subject is not on daily use of phosphodiesterase 5 inhibitors or soluble guanylyl cyclase activators?	<p>[PHOSP5] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Not Evaluated</p>
9.* ✓	Subject is NOT on PRN use of phosphodiesterase 5 inhibitors?	<p>[PRN] [N:1] <input type="radio"/> Yes (not on PRN) [N:0] <input checked="" type="radio"/> [HOLDPRN] No (on PRN) Willing to hold PRN for the duration of the study? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Not Evaluated</p>
10.* ✓	Is the subject ambulatory (not wheelchair/scooter dependent)?	<p>[AMBULATO] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Not Evaluated</p>
11.* ✓	Does subjects body size allow for the wearing of the accelerometer belt as confirmed by the ability to comfortably fasten the test belt provided for the screening process?	<p>[BODYSIZE] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Not Evaluated</p>
12.* ✓	Subject willing to wear the accelerometer belt for the duration of the trial?	<p>[WILLWEAR] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Not Evaluated</p>
13.* ✓	Did subject meet all Inclusion Criteria?	<p>[METINC] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No (update WEBEZ to Screen Fail patient)</p>

Key: [*] = Item is required [✓] = Source verification required
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RDE Analytics: RD_FRELIG1		
Data Variable RefName	RD Column Name	Column Data Type
SUB40YR	SUB40YR_C	NUMBER
	SUB40YR	VARCHAR2
	SUB40YR_ND	VARCHAR2
SYMDYSP	SYMDYSP_C	**NUMBER
	SYMDYSP	VARCHAR2
	SYMDYSP_ND	VARCHAR2
SYMDYSP - NYHA	NYHA_C	NUMBER
	NYHA	VARCHAR2
EF50	EF50_C	NUMBER
	EF50	VARCHAR2
	EF50_ND	VARCHAR2
HADANY	HADANY_C	**NUMBER
	HADANY	VARCHAR2
	HADANY_ND	VARCHAR2
HADANY - Previous hospitalization for HF with radiographic evidence (pulmonary venous hypertension, vascular congestion, interstitial edema, pleural effusion) of pulmonary congestion	PREHOSHF_PREHOSDT_C	**NUMBER
	PREHOSHF_PREHOSDT	VARCHAR2
HADANY - PREHOSDT	PREHOSDT	DATE
	PREHOSDT_DTS	VARCHAR2
	PREHOSDT_DTR	VARCHAR2
	PCWP15_CPCWP15_C	**NUMBER
HADANY - PCWP15DT	PCWP15_CPCWP15	VARCHAR2
	PCWP15DT	DATE
	PCWP15DT_DTS	VARCHAR2
	PCWP15DT_DTR	VARCHAR2
HADANY - PCWP15VL	PCWP15VL	FLOAT
	LVEDP18_CPLVEDP18_C	**NUMBER
HADANY - Catheterization documented elevated filling pressures at rest (LVEDP ≥18)	LVEDP18_CPLVEDP18	VARCHAR2
	LVED18DT	DATE

	LVED18DT_DTS	VARCHAR2
	LVED18DT_DTR	VARCHAR2
HADANY - LVED18VL	LVED18VL	FLOAT
HADANY - Catheterization documented elevated filling pressures with exercise (PCWP ≥25)	PCWP25_CPPCWP25_C	**NUMBER
	PCWP25_CPPCWP25	VARCHAR2
HADANY - PCWP25DT	PCWP25DT	DATE
	PCWP25DT_DTS	VARCHAR2
	PCWP25DT_DTR	VARCHAR2
HADANY - PCWP25VL	PCWP25VL	FLOAT
HADANY - Elevated NT-proBNP (>400 pg/ml)	ELVNT_CPELVNT_C	**NUMBER
	ELVNT_CPELVNT	VARCHAR2
HADANY - ELVNTDT	ELVNTDT	DATE
	ELVNTDT_DTS	VARCHAR2
	ELVNTDT_DTR	VARCHAR2
HADANY - ELVNTVL	ELVNTVL	FLOAT
HADANY - Elevated BNP (>200 pg/ml)	ELVBNP_CPELVBNP_C	**NUMBER
	ELVBNP_CPELVBNP	VARCHAR2
HADANY - ELVBNPDT	ELVBNPDT	DATE
	ELVBNPDT_DTS	VARCHAR2
	ELVBNPDT_DTR	VARCHAR2
HADANY - ELVBNPVL	ELVBNPVL	FLOAT
HADANY - Echo evidence of diastolic dysfunction/elevated filling pressures manifest by medial E/e' ratio ≥15 and/or left atrial enlargement and chronic treatment with a loop diuretic for signs or symptoms of heart failure	ECHOEV_ECHOEVDT_C	**NUMBER
	ECHOEV_ECHOEVDT	VARCHAR2
HADANY - ECHOEVDT	ECHOEVDT	DATE
	ECHOEVDT_DTS	VARCHAR2
PRIMFACT	PRIMFACT_C	NUMBER
	PRIMFACT	VARCHAR2
	PRIMFACT_ND	VARCHAR2
PEAKVO2	PEAKVO2_C	**NUMBER
	PEAKVO2	VARCHAR2
	PEAKVO2_ND	VARCHAR2
PEAKVO2 - ACTVO2	ACTVO2	FLOAT
PEAKVO2 - PREDVO2	PREDVO2	FLOAT
PEAKVO2 - PEAKRESP	PEAKRESP	FLOAT
NOCHRNIT	NOCHRNIT_C	NUMBER
	NOCHRNIT	VARCHAR2
	NOCHRNIT_ND	VARCHAR2
PHOSP5	PHOSP5_C	NUMBER
	PHOSP5	VARCHAR2
	PHOSP5_ND	VARCHAR2
PRN	PRN_C	NUMBER
	PRN	VARCHAR2
	PRN_ND	VARCHAR2
PRN - HOLDPRN	HOLDPRN_C	NUMBER
	HOLDPRN	VARCHAR2
AMBULATO	AMBULATO_C	NUMBER
	AMBULATO	VARCHAR2
	AMBULATO_ND	VARCHAR2
BODYSIZE	BODYSIZE_C	NUMBER
	BODYSIZE	VARCHAR2
	BODYSIZE_ND	VARCHAR2
WILLWEAR	WILLWEAR_C	NUMBER
	WILLWEAR	VARCHAR2
	WILLWEAR_ND	VARCHAR2
METINC	METINC_C	NUMBER
	METINC	VARCHAR2
	METINC_ND	VARCHAR2

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

HF_INDIE: INCLUSION/EXCLUSION PART 2 (ELIG2) [frELIG2]	
Exclusion [stELIGIBLE2A]	
1. RETIRED ITEM - Recent (< 1 month) hospitalization for heart failure?	<p>[RECHOSHF]</p> <p>[N:0] <input type="radio"/> [HOSPHFDT]</p> <p>Date of Most Recent: Req [▼] / Req [▼] / Req [▼] (2016-2018)</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
2.* Recent (< 1 month) hospitalization for heart failure?	<p>[HOSPHF]</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
3.* Ongoing requirement for PDE5 inhibitor, organic nitrate, or soluble guanylyl cyclase activators?	<p>[PDES]</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
4.* Hgb <8.0 g/dl within 90 days prior to randomization?	<p>[HGB30DAY]</p> <p>[N:0] <input type="radio"/> [cpHGB30DAY]</p> <p>No</p> <p>[HGBDT]</p> <p>Date: Req [▼] / Req [▼] / Req [▼] (2016-2018)</p> <p>[HGB30VAL]</p> <p>Value: xxxxxxxx.</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
5.* GFR < 20 ml/min/1.73m ² within 90 days prior to randomization?	<p>[GFR30DAY]</p> <p>[N:0] <input type="radio"/> [cpGFR30DAY]</p> <p>No</p> <p>[GFR30DT]</p> <p>Date of Most Recent: Req [▼] / Req [▼] / Req [▼] (2016-2018)</p> <p>[GFR30VAL]</p> <p>Value: xxxxxxxx.</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
6.* Systolic blood pressure < 115 mmHg seated or < 90 mmHg standing just prior to test dose?	<p>[SYSTEST]</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
7.* Resting heart rate >110 just prior to test dose?	<p>[RESTHRT]</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
8.* Previous adverse reaction to study drug which necessitated withdrawal of therapy?	<p>[PREAEDRG]</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
9.* Significant chronic obstructive pulmonary disease thought to contribute to dyspnea?	<p>[SIGPULDS]</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
10.* Ischemia thought to contribute to dyspnea?	<p>[ISCHDYSP]</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
11.* Documentation of previous EF <45%?	<p>[DOCEF45]</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
12.* ACS within 3 months defined by ECG changes and biomarkers of myocardial necrosis (e.g., troponin) in an appropriate clinical setting (chest discomfort or angina equivalent)?	<p>[ACS3MNTH]</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
13.* PCI, coronary artery bypass grafting, or new biventricular pacing within the past 3 months?	<p>[PCI3MNTH]</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
14.* Primary hypertrophic cardiomyopathy?	<p>[PRMHYPCR]</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
15.* Infiltrative cardiomyopathy (amyloid)?	<p>[AMYL0ID]</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>
16.* Constrictive pericarditis or tamponade?	<p>[CONSPERI]</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:2] <input type="radio"/> Not Evaluated</p>

17.* ✓	Active myocarditis?	[ACTMYO] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes [N:2] <input type="radio"/> Not Evaluated
18.* ✓	Complex congenital heart disease?	[CMXHRTDS] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes [N:2] <input type="radio"/> Not Evaluated
19.* ✓	Active collagen vascular disease?	[ACTCOLLA] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes [N:2] <input type="radio"/> Not Evaluated
20.* ✓	More than mild aortic or mitral stenosis?	[MORAORT] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes [N:2] <input type="radio"/> Not Evaluated
21.* ✓	Intrinsic (prolapse, rheumatic) valve disease with moderate to severe or severe mitral, tricuspid, or aortic regurgitation?	[INTRINSIC] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes [N:2] <input type="radio"/> Not Evaluated
22.* ✓	Acute or chronic severe liver disease as evidenced by any of the following: encephalopathy, variceal bleeding, INR > 1.7 in the absence of anticoagulation treatment?	[ACTLIVR] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes [N:2] <input type="radio"/> Not Evaluated
23.* ✓	Terminal illness (other than HF) with expected survival of <1 year	[TERMLLN] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes [N:2] <input type="radio"/> Not Evaluated
24.* ✓	Swim or do water aerobics regularly (> 1x per week)?	[SWIM] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes [N:2] <input type="radio"/> Not Evaluated
25.* ✓	Enrolled or planning to enroll in another therapeutic clinical trial in the next 3 months?	[ENRLOTH] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes [N:2] <input type="radio"/> Not Evaluated
26.* ✓	Unable to comply with planned study procedures?	[UNCOMPLY] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes [N:2] <input type="radio"/> Not Evaluated
27.* ✓	Pregnant or breastfeeding?	[PREGBRST] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes [N:2] <input type="radio"/> Not Evaluated
28.* ✓	Did subject meet any Exclusion Criteria?	[EXCCRT] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes (update WEBEZ to Screen Fail patient) [N:2] <input type="radio"/> Not Evaluated
29.* ✓	Did patient withdraw consent prior to Randomization?	[PTWDRW] [N:0] <input type="radio"/> No [N:1] <input type="radio"/> [RESNOSP] Yes Specify: A200 [N:2] <input type="radio"/> Not Evaluated

Key: [*] - Item is required [✓] - Source verification required
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

RDE Analytics: RD_FRELI G2		
Data Variable RefName	RD Column Name	Column Data Type
RECHOSHF	RECHOSHF_C	**NUMBER
	RECHOSHF	VARCHAR2
	RECHOSHF_ND	VARCHAR2
RECHOSHF - HOSPHFDT	HOSPHFDT	DATE
	HOSPHFDT_DTS	VARCHAR2
HOSPHF	HOSPHF_C	NUMBER
	HOSPHF	VARCHAR2
	HOSPHF_ND	VARCHAR2
PDE5	PDE5_C	NUMBER
	PDE5	VARCHAR2
	PDE5_ND	VARCHAR2
HGB30DAY	HGB30DAY_C	**NUMBER

	HGB30DAY	VARCHAR2
	HGB30DAY_ND	VARCHAR2
HGB30DAY - HGBDT	HGBDT	DATE
	HGBDT_DTS	VARCHAR2
HGB30DAY - HGB30VAL	HGB30VAL	FLOAT
GFR30DAY	GFR30DAY_C	**NUMBER
	GFR30DAY	VARCHAR2
	GFR30DAY_ND	VARCHAR2
GFR30DAY - GFR30DT	GFR30DT	DATE
	GFR30DT_DTS	VARCHAR2
GFR30DAY - GFR30VAL	GFR30VAL	FLOAT
SYSTEST	SYSTEST_C	NUMBER
	SYSTEST	VARCHAR2
	SYSTEST_ND	VARCHAR2
RETHRT	RETHRT_C	NUMBER
	RETHRT	VARCHAR2
	RETHRT_ND	VARCHAR2
PREAEDRG	PREAEDRG_C	NUMBER
	PREAEDRG	VARCHAR2
	PREAEDRG_ND	VARCHAR2
SIGPULDS	SIGPULDS_C	NUMBER
	SIGPULDS	VARCHAR2
	SIGPULDS_ND	VARCHAR2
ISCHDYSP	ISCHDYSP_C	NUMBER
	ISCHDYSP	VARCHAR2
	ISCHDYSP_ND	VARCHAR2
DOCEF45	DOCEF45_C	NUMBER
	DOCEF45	VARCHAR2
	DOCEF45_ND	VARCHAR2
ACS3MNTH	ACS3MNTH_C	NUMBER
	ACS3MNTH	VARCHAR2
	ACS3MNTH_ND	VARCHAR2
PCI3MNTH	PCI3MNTH_C	NUMBER
	PCI3MNTH	VARCHAR2
	PCI3MNTH_ND	VARCHAR2
PRMHYPCR	PRMHYPCR_C	NUMBER
	PRMHYPCR	VARCHAR2
	PRMHYPCR_ND	VARCHAR2
AMYLOID	AMYLOID_C	NUMBER
	AMYLOID	VARCHAR2
	AMYLOID_ND	VARCHAR2
CONSPERI	CONSPERI_C	NUMBER
	CONSPERI	VARCHAR2
	CONSPERI_ND	VARCHAR2
ACTMYO	ACTMYO_C	NUMBER
	ACTMYO	VARCHAR2
	ACTMYO_ND	VARCHAR2
CMXHRTDS	CMXHRTDS_C	NUMBER
	CMXHRTDS	VARCHAR2
	CMXHRTDS_ND	VARCHAR2
ACTCOLLA	ACTCOLLA_C	NUMBER
	ACTCOLLA	VARCHAR2
	ACTCOLLA_ND	VARCHAR2
MORAORT	MORAORT_C	NUMBER
	MORAORT	VARCHAR2
	MORAORT_ND	VARCHAR2
INTRINSIC	INTRINSIC_C	NUMBER
	INTRINSIC	VARCHAR2
	INTRINSIC_ND	VARCHAR2
ACTLIVR	ACTLIVR_C	NUMBER
	ACTLIVR	VARCHAR2
	ACTLIVR_ND	VARCHAR2
TERMILLN	TERMILLN_C	NUMBER
	TERMILLN	VARCHAR2
	TERMILLN_ND	VARCHAR2
SWIM	SWIM_C	NUMBER

	SWIM	VARCHAR2
	SWIM_ND	VARCHAR2
ENRLOTH	ENRLOTH_C	NUMBER
	ENRLOTH	VARCHAR2
	ENRLOTH_ND	VARCHAR2
UNCOMPLY	UNCOMPLY_C	NUMBER
	UNCOMPLY	VARCHAR2
	UNCOMPLY_ND	VARCHAR2
PREGBRST	PREGBRST_C	NUMBER
	PREGBRST	VARCHAR2
	PREGBRST_ND	VARCHAR2
EXCCRIT	EXCCRIT_C	NUMBER
	EXCCRIT	VARCHAR2
	EXCCRIT_ND	VARCHAR2
PTWTDRAW	PTWTDRAW_C	NUMBER
	PTWTDRAW	VARCHAR2
	PTWTDRAW_ND	VARCHAR2
PTWTDRAW - RESNOSPF	RESNOSPF	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HF_INDIE: SCREENING VISIT ASSESSMENTS (SCRVISIT) [frSCRVISIT]		
Screening/Baseline Visit Assessments [stSCRVISIT1]		
1.* ✓	CPET Performed?	[CPETSCR] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No
2.* ✓	Baseline CBC Collected?	[BASECBC] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No
3.* ✓	Baseline Complete Chemistry Panel Collected?	[BASECHEM] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No
4.* ✓	Baseline Biomarkers Collected?	[BASEBIO] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No
5.* ✓	Baseline ECG Performed?	[BASEECG] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No
6.* ✓	Baseline KCCO Performed?	[BASEKCCO] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No
7.* ✓	Test Dose Administered?	[BASETSDS] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> [TSTDOSNO] No [N: 1] <input type="radio"/> Subject withdrew consent [N: 2] <input type="radio"/> MD Decision [N: 3] <input type="radio"/> Failed BP criteria [N: 4] <input type="radio"/> Failed other eligibility criteria [N: 98] <input type="radio"/> [TSTDOSSP] Other Specify: A100
8.* ✓	Has the subject experienced any adverse events or events of interest since informed consent (If yes, complete AE or EVTINT form)?	[BASEAEI] [N: 1] <input type="radio"/> [RELTCPET] Yes Related to CPET? [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
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

RDE Analytics: RD_FRSCRVISIT		
Data Variable RefName	RD Column Name	Column Data Type
CPETSCR	CPETSCR_C	NUMBER
	CPETSCR	VARCHAR2
	CPETSCR_ND	VARCHAR2
BASECBC	BASECBC_C	NUMBER
	BASECBC	VARCHAR2
	BASECBC_ND	VARCHAR2
BASECHEM	BASECHEM_C	NUMBER
	BASECHEM	VARCHAR2
	BASECHEM_ND	VARCHAR2
BASEBIO	BASEBIO_C	NUMBER
	BASEBIO	VARCHAR2
	BASEBIO_ND	VARCHAR2
BASEECG	BASEECG_C	NUMBER
	BASEECG	VARCHAR2
	BASEECG_ND	VARCHAR2
BASEKCCO	BASEKCCO_C	NUMBER
	BASEKCCO	VARCHAR2
	BASEKCCO_ND	VARCHAR2
BASETSDS	BASETSDS_C	NUMBER
	BASETSDS	VARCHAR2
	BASETSDS_ND	VARCHAR2
BASETSDS - TSTDOSNO	TSTDOSNO_C	NUMBER
	TSTDOSNO	VARCHAR2
BASETSDS - TSTDOSSP	TSTDOSSP	VARCHAR2
BASEAEI	BASEAEI_C	**NUMBER
	BASEAEI	VARCHAR2
	BASEAEI_ND	VARCHAR2

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

HF_INDIE: TEST DOSE (TESTDOSE) [frTESTDOSE]	
Pre Dose BP Assesment [stTESTDOSE1]	
1.* ✓ Seated BP	<p>[PRESEAT] [N: 1] <input type="radio"/> [cpPRESEAT] Time: [PRESETM] Req <input type="checkbox"/> : Req <input type="checkbox"/> 24-hour clock [PRESEVAL] Value: [N: 1] <input type="radio"/> [cpPRESEBP] [PRESESYS] [PRESEDIA] N3 <input type="text"/> / N3 <input type="text"/> mmHg [N: 97] <input type="radio"/> Not Done [N: 97] <input type="radio"/> Not Done</p>
2.* ✓ Standing BP	<p>[PRESTAND] [N: 1] <input type="radio"/> [cpPRESTAND] Time: [PRESTTM] Req <input type="checkbox"/> : Req <input type="checkbox"/> 24-hour clock [PRESTVAL] Value: [N: 1] <input type="radio"/> [cpPRESTVAL] [PRESTSYS] [PRESTDIA] N3 <input type="text"/> / N3 <input type="text"/> mmHg [N: 97] <input type="radio"/> Not Done [N: 97] <input type="radio"/> Not Done</p>
3.* ✓ Resting Heart Rate	<p>[PREHRTRT] [N: 1] <input type="radio"/> [cpPREHRTRT] Time: [PREHRTM] Req <input type="checkbox"/> : Req <input type="checkbox"/> 24-hour clock [PREHRVAL] Value: [N: 1] <input type="radio"/> [PREHRTL] N3 <input type="text"/> bpm(b) [N: 97] <input type="radio"/> Not Done [N: 97] <input type="radio"/> Not Done</p>
Test Dose [stTESTDOSE2]	
4.* ✓ Test Dose Nebulizer Serial Number [Test Dose Nebulizer #]	[TDNEBSN] A20
5.* ✓ Test Dose Start Date/Time	[INDRGDTM] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018) Req <input type="checkbox"/> : Req <input type="checkbox"/> 24-hour clock
6.* ✓ Test Dose Stop Date/Time	[INDRSDTM] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018) Req <input type="checkbox"/> : Req <input type="checkbox"/> 24-hour clock
7.* ✓ Was Complete Dose Administered?	<p>[INISDRG] [N: 1] <input type="radio"/> [TESTOLR] Yes Was test dose tolerated by subject? [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 0] <input type="radio"/> [INDGRS] No If No, specify reason: [N: 1] <input type="radio"/> Subject withdrew consent [N: 2] <input type="radio"/> MD Decision [N: 98] <input type="radio"/> [INDGRSP] Other Specify: A200</p>
8.* ✓ Did the subject experience any adverse events or events of interest related to the test dose? (If yes, complete AE or EVTINT form)?	[NEWSAE2] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No
Post Dose BP Assesments [stTESTDOSE3]	
9.* ✓ Seated BP Reading # 1	<p>[SEATBP1] [N: 1] <input type="radio"/> [cpSEATBP1] Time: [SEBP1TM] Req <input type="checkbox"/> : Req <input type="checkbox"/> 24-hour clock [SEBP1VAL] [N: 1] <input type="radio"/> [cpSEBP1VAL] Value: [SEAT1SYS] [SEAT1DIA] N3 <input type="text"/> / N3 <input type="text"/> mmHg [N: 97] <input type="radio"/> Not Done [N: 97] <input type="radio"/> Not Done</p>
10.* Seated BP Reading # 2	[SEATBP2] [N: 1] <input type="radio"/> [cpSEATBP2]

✓		<input type="radio"/> Time: [SEBP2TM] Req [▼] : Req [▼] 24-hour clock [SEBP2VAL] [N:1] <input type="radio"/> [cpSEBP2VAL] Value: [SEAT2SYS] [SEAT2DIA] N3 / N3 mmHg <input type="radio"/> [N:97] Not Done <input type="radio"/> [N:97] Not Done
11. ✓	Seated BP Reading #3	[SEATBP3] [N:1] <input type="radio"/> [cpSEATBP3] Time: [SEBP3TM] Req [▼] : Req [▼] 24-hour clock [SEBP3VAL] [N:1] <input type="radio"/> [cpSEBP3VAL] Value: [SEAT3SYS] [SEAT3DIA] N3 / N3 mmHg <input type="radio"/> [N:97] Not Done <input type="radio"/> [N:97] Not Done
12. ✓	Seated BP Reading #4	[SEATBP4] [N:1] <input type="radio"/> [cpSEATBP4] Time: [SEBP4TM] Req [▼] : Req [▼] 24-hour clock [SEBP4VAL] [N:1] <input type="radio"/> [cpSEBP4VAL] Value: [SEAT4SYS] [SEAT4DIA] N3 / N3 mmHg <input type="radio"/> [N:97] Not Done <input type="radio"/> [N:97] Not Done
13. ✓	Standing BP Reading #1	[STANBP1] [N:1] <input type="radio"/> [cpSTANBP1] Time: [STAN1TM] Req [▼] : Req [▼] 24-hour clock [STBP1VAL] [N:1] <input type="radio"/> [cpSTBP1VAL] Value: [STAN1SYS] [STAN1DIA] N3 / N3 mmHg <input type="radio"/> [N:97] Not Done <input type="radio"/> [N:97] Not Done
14. ✓	Standing BP Reading #2	[STANBP2] [N:1] <input type="radio"/> [cpSTANBP2] Time: [STAN2TM] Req [▼] : Req [▼] 24-hour clock [STBP2VAL] [N:1] <input type="radio"/> [cpSTBP2VAL] Value: [STAN2SYS] [STAN2DIA] N3 / N3 mmHg <input type="radio"/> [N:97] Not Done <input type="radio"/> [N:97] Not Done
15. ✓	Standing BP Reading #3	[STANBP3] [N:1] <input type="radio"/> [cpSTANBP3] Time: [STAN3TM] Req [▼] : Req [▼] 24-hour clock [STBP3VAL] [N:1] <input type="radio"/> [cpSTBP3VAL] Value: [STAN3SYS] [STAN3DIA] N3 / N3 mmHg <input type="radio"/> [N:97] Not Done <input type="radio"/> [N:97] Not Done
16. ✓	Standing BP Reading #4	[STANBP4] [N:1] <input type="radio"/> [cpSTANBP4] Time: [STAN4TM] Req [▼] : Req [▼] 24-hour clock [STBP4VAL] [N:1] <input type="radio"/> [cpSTBP4VAL] Value: [STAN4SYS] [STAN4DIA] N3 / N3 mmHg <input type="radio"/> [N:97] Not Done <input type="radio"/> [N:97] Not Done
Patient Eligibility Verification [s1TESTDOSE4]		
17. ✓	Investigator has confirmed subject is eligible to be Randomized	[PI CONFIR]

✓ [N: 1] Yes
[N: 0] No

Key: [*] = Item is required [✓] = Source verification required [b] = Base Unit
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

RDE Analytics: RD_FRTESTDOSE		
Data Variable RefName	RD Column Name	Column Data Type
PRESEAT	PRESEAT_C	**NUMBER
	PRESEAT	VARCHAR2
	PRESEAT_ND	VARCHAR2
PRESEAT - PRESETM	PRESETM	DATE
	PRESETM_TMS	VARCHAR2
PRESEAT - PRESEVAL	PRESEVAL_C	**NUMBER
	PRESEVAL	VARCHAR2
PRESEAT - PRESESYS	PRESESYS	NUMBER
PRESEAT - PRESEDIA	PRESEDIA	NUMBER
PRESTAND	PRESTAND_C	**NUMBER
	PRESTAND	VARCHAR2
	PRESTAND_ND	VARCHAR2
PRESTAND - PRESTM	PRESTM	DATE
	PRESTM_TMS	VARCHAR2
PRESTAND - PRESTVAL	PRESTVAL_C	**NUMBER
	PRESTVAL	VARCHAR2
PRESTAND - PRESTSYS	PRESTSYS	NUMBER
PRESTAND - PRESTDIA	PRESTDIA	NUMBER
PREHRTRT	PREHRTRT_C	**NUMBER
	PREHRTRT	VARCHAR2
	PREHRTRT_ND	VARCHAR2
PREHRTRT - PREHRTM	PREHRTM	DATE
	PREHRTM_TMS	VARCHAR2
PREHRTRT - PREHRVAL	PREHRVAL_C	**NUMBER
	PREHRVAL	VARCHAR2
PREHRTRT - PREHRTL	PREHRTL	NUMBER
	PREHRTL_U	VARCHAR2
TDNEBSN	TDNEBSN	VARCHAR2
	TDNEBSN_ND	VARCHAR2
INDRGDTM	INDRGDTM	DATE
	INDRGDTM_DTS	VARCHAR2
	INDRGDTM_ND	VARCHAR2
INDRSDTM	INDRSDTM	DATE
	INDRSDTM_DTS	VARCHAR2
	INDRSDTM_ND	VARCHAR2
INISDRG	INISDRG_C	**NUMBER
	INISDRG	VARCHAR2
	INISDRG_ND	VARCHAR2
INISDRG - TESTTOLR	TESTTOLR_C	NUMBER
	TESTTOLR	VARCHAR2
INISDRG - INDRGRS	INDRGRS_C	NUMBER
	INDRGRS	VARCHAR2
INISDRG - INDRGRSP	INDRGRSP	VARCHAR2
NEWSAE2	NEWSAE2_C	NUMBER
	NEWSAE2	VARCHAR2
	NEWSAE2_ND	VARCHAR2
SEATBP1	SEATBP1_C	**NUMBER
	SEATBP1	VARCHAR2
	SEATBP1_ND	VARCHAR2
SEATBP1 - SEBP1TM	SEBP1TM	DATE
	SEBP1TM_TMS	VARCHAR2
SEATBP1 - SEBP1VAL	SEBP1VAL_C	**NUMBER
	SEBP1VAL	VARCHAR2
SEATBP1 - SEAT1SYS	SEAT1SYS	NUMBER
SEATBP1 - SEAT1DIA	SEAT1DIA	NUMBER
SEATBP2	SEATBP2_C	**NUMBER
	SEATBP2	VARCHAR2
	SEATBP2_ND	VARCHAR2
SEATBP2 - SEBP2TM	SEBP2TM	DATE

	SEBP2TM_TMS	VARCHAR2
SEATBP2 - SEBP2VAL	SEBP2VAL_C	**NUMBER
	SEBP2VAL	VARCHAR2
SEATBP2 - SEAT2SYS	SEAT2SYS	NUMBER
SEATBP2 - SEAT2DIA	SEAT2DIA	NUMBER
SEATBP3	SEATBP3_C	**NUMBER
	SEATBP3	VARCHAR2
	SEATBP3_ND	VARCHAR2
SEATBP3 - SEBP3TM	SEBP3TM	DATE
	SEBP3TM_TMS	VARCHAR2
SEATBP3 - SEBP3VAL	SEBP3VAL_C	**NUMBER
	SEBP3VAL	VARCHAR2
SEATBP3 - SEAT3SYS	SEAT3SYS	NUMBER
SEATBP3 - SEAT3DIA	SEAT3DIA	NUMBER
SEATBP4	SEATBP4_C	**NUMBER
	SEATBP4	VARCHAR2
	SEATBP4_ND	VARCHAR2
SEATBP4 - SEBP4TM	SEBP4TM	DATE
	SEBP4TM_TMS	VARCHAR2
SEATBP4 - SEBP4VAL	SEBP4VAL_C	**NUMBER
	SEBP4VAL	VARCHAR2
SEATBP4 - SEAT4SYS	SEAT4SYS	NUMBER
SEATBP4 - SEAT4DIA	SEAT4DIA	NUMBER
STANDBP1	STANDBP1_C	**NUMBER
	STANDBP1	VARCHAR2
	STANDBP1_ND	VARCHAR2
STANDBP1 - STAN1TM	STAN1TM	DATE
	STAN1TM_TMS	VARCHAR2
STANDBP1 - STBP1VAL	STBP1VAL_C	**NUMBER
	STBP1VAL	VARCHAR2
STANDBP1 - STAN1SYS	STAN1SYS	NUMBER
STANDBP1 - STAN1DIA	STAN1DIA	NUMBER
STANDBP2	STANDBP2_C	**NUMBER
	STANDBP2	VARCHAR2
	STANDBP2_ND	VARCHAR2
STANDBP2 - STAN2TM	STAN2TM	DATE
	STAN2TM_TMS	VARCHAR2
STANDBP2 - STBP2VAL	STBP2VAL_C	**NUMBER
	STBP2VAL	VARCHAR2
STANDBP2 - STAN2SYS	STAN2SYS	NUMBER
STANDBP2 - STAN2DIA	STAN2DIA	NUMBER
STANDBP3	STANDBP3_C	**NUMBER
	STANDBP3	VARCHAR2
	STANDBP3_ND	VARCHAR2
STANDBP3 - STAN3TM	STAN3TM	DATE
	STAN3TM_TMS	VARCHAR2
STANDBP3 - STBP3VAL	STBP3VAL_C	**NUMBER
	STBP3VAL	VARCHAR2
STANDBP3 - STAN3SYS	STAN3SYS	NUMBER
STANDBP3 - STAN3DIA	STAN3DIA	NUMBER
STANDBP4	STANDBP4_C	**NUMBER
	STANDBP4	VARCHAR2
	STANDBP4_ND	VARCHAR2
STANDBP4 - STAN4TM	STAN4TM	DATE
	STAN4TM_TMS	VARCHAR2
STANDBP4 - STBP4VAL	STBP4VAL_C	**NUMBER
	STBP4VAL	VARCHAR2
STANDBP4 - STAN4SYS	STAN4SYS	NUMBER
STANDBP4 - STAN4DIA	STAN4DIA	NUMBER
PICONFIR	PICONFIR_C	NUMBER
	PICONFIR	VARCHAR2
	PICONFIR_ND	VARCHAR2

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

HF_INDIE: RANDOMIZATION AND BIOMARKER CONSENT (RAND) [frRAND]		
Randomization and Biomarker Consent [stRAND1]		
1.* ✓	Date and Time of Randomization [Date and Time of Randomization]	[RANDDTM] Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2016-2018) Req <input checked="" type="checkbox"/> : Req <input checked="" type="checkbox"/> 24-hour clock
2.* ✓	Did the subject agree to participate in the biorepository substudy [Subject agree to participate in biorepository substudy]	[BIORPSTY] [N:1] <input type="radio"/> [BIORPCDT] Yes Date consent obtained Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2016-2018) [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Site not participating
3.* ✓	Did the subject agree to participate in the pharmacogenomics (genetics) substudy [Subject agree to participate in pharmacogenomics substudy]	[GENETICS] [N:1] <input type="radio"/> [GENCONDT] Yes Date consent obtained Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2016-2018) [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Site not participating
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

RDE Analytics: RD_FRRAND		
Data Variable RefName	RD Column Name	Column Data Type
RANDDTM	RANDDTM	DATE
	RANDDTM_DTS	VARCHAR2
	RANDDTM_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
Key: [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HF_INDIE: 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="checkbox"/> / Req/Unk <input type="checkbox"/> (1920-2018)
2.* ✓	Total number of hospitalizations within prior 12 months (provide best estimate if exact number is unknown) [Total number of hospitalizations within prior 12 months]	[HOSPVAL] N3 <input type="text"/>
3.* ✓	Number of hospitalizations with primary diagnosis of heart failure within past 12 months (provide best estimate if exact number is unknown): [Number of hospitalizations with primary diagnosis of heart failure within past 12 months]	[NUMHFHSP] N3 <input type="text"/>
4.* ✓	Has LV function been assessed within 12 months of Randomization? [Has LV function been assessed]	[LVASSESS] [N: 1] <input type="radio"/> Yes [LVASSED] Date: Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> (2014-2018) [LVEF] Value of last LVEF: [N: 1] <input type="radio"/> [LVEFEF] 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.* ✓	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.* ✓	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.* ✓	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.* ✓	Has subject had any other factors contributing to cardiomyopathy? [Has subject had any other factors contributing to cardiomyopathy]	[FACTORYN] [N: 1] <input type="radio"/> Yes (check all that apply) [ALCOHOLC] [N: 1] <input type="checkbox"/> Alcoholic [CYTOTOX] [N: 1] <input type="checkbox"/> Cytotoxic drug therapy [FAMILIAL] [N: 1] <input type="checkbox"/> Familial [HYPERTN] [N: 1] <input type="checkbox"/> Hypertensive [IDIODIL] [N: 1] <input type="checkbox"/> Idiopathic dilated cardiomyopathy [IDIORES] [N: 1] <input type="checkbox"/> Idiopathic restrictive cardiomyopathy [PERIPRT] [N: 1] <input type="checkbox"/> Peripartum [VALVUL] [N: 1] <input type="checkbox"/> Valvular [HCM] [N: 1] <input type="checkbox"/> HCM [MYOOTH] [N: 1] <input type="checkbox"/> [MYOPSP] Other/uncertain Specify A100 <input type="text"/> [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown

Key: [*] = Item is required [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

RDE Analytics: RD_FRMEDHIST1		
Data Variable RefName	RD Column Name	Column Data Type
DIAGDT	DIAGDT_DTS	VARCHAR2
	DIAGDT_DTR	VARCHAR2
	DIAGDT_ND	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
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.		

HF_INDIE: CLINICAL HISTORY (MEDHIST2) [frMEDHIST2]	
Clinical History [stMEDHIST2_1]	
1.* ✓ Does subject have moderate to severe valvular heart disease? [Moderate to severe valvular heart disease]	[VALVULAR] [N: 1] <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
2.* ✓ Has subject had prior valvular surgery? [Prior valvular surgery]	[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
3.* ✓ Hypertension [Hypertension]	[HYPRTESN] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
4.* ✓ TIA [TIA]	[TIA] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
5.* ✓ Stroke [Stroke]	[STROKE] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
6.* ✓ Arrhythmia [Arrhythmia]	[ARRHYTHM] [N: 1] <input checked="" type="radio"/> [cpARRHYTHM] Yes (check all that apply) [ATRIFB] [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
7.* ✓ Pacemaker/ICD [Pacemaker/ICD]	[PACEICD] [N: 1] <input checked="" type="radio"/> [PACICDVTY] 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
8.* ✓ Peripheral vascular disease [Peripheral vascular disease]	[PVD] [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] Yes

✓			<input type="radio"/> [N:0] No <input type="radio"/> [N:99] 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 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.			

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_CIUNKKNOWNOTHER1_C	NUMBER
	ARRHUNKO_CIUNKKNOWNOTHER1	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.		

HF_INDIE: EXAMINATION (EXAM) [frEXAM]	
Examination [stEXAM1]	
1.* Date of Exam [Date of Exam]	[EXDN] [N: 1] <input type="radio"/> [EXDT] Req <input type="text" value=""/> / Req <input type="text" value=""/> / Req <input type="text" value=""/> (2016-2018) [N: 97] <input type="radio"/> Not Done
2.* Heart Rate (sitting or resting) [Heart Rate]	[HRATE] [N: 1] <input type="radio"/> [HRATEVAL] N3 <input type="text" value=""/> [N: 97] <input type="radio"/> Not Done
3.* Blood Pressure (sitting or resting) [Blood Pressure]	[BPDONE] [N: 1] <input type="radio"/> [cpBPP] [BPSYS] N3 <input type="text" value=""/> / [BPDIA] mmHg N3 <input type="text" value=""/> [N: 97] <input type="radio"/> Not Done
4.* SpO2 [SpO2]	[SPO2] [N: 1] <input type="radio"/> [SPO2VAL] xxxxxxxx. <input type="text" value=""/> % ^[b] [N: 97] <input type="radio"/> Not Done
5.* Height (at Baseline visit only) [Height]	[HEIGHT] [N: 1] <input type="radio"/> [HGTVAL] xxxxxxxx. <input type="text" value=""/> [HGTUNIT] Unit [N: 1] <input type="radio"/> in [N: 2] <input type="radio"/> cm [N: 97] <input type="radio"/> Not Done
6.* Weight [Weight]	[WEIGHT] [N: 1] <input type="radio"/> [WGTVAL] xxxxxxxx. <input type="text" value=""/> [WGTUNIT] Unit [N: 1] <input type="radio"/> lb [N: 2] <input type="radio"/> kg [N: 97] <input type="radio"/> Not Done
7.* 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
8.* Rales [Rales]	[RALES] [N: 1] <input type="radio"/> None [N: 2] <input type="radio"/> < 1/3 [N: 3] <input type="radio"/> 1/3 - 2/3 [N: 4] <input type="radio"/> > 2/3 [N: 97] <input type="radio"/> Not Done
9.* S3 auscultation [S3 auscultation]	[S3AUS] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 97] <input type="radio"/> Not Done
10.* Hepatomegaly [Hepatomegaly]	[HEPATO] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 97] <input type="radio"/> Not Done
11.* Ascites/Abdominal Distention [Ascites/Abdominal Distention]	[ASCITES] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 97] <input type="radio"/> Not Done
12.* 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
13.* 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
14.* Orthopnea [Orthopnea]	[ORTHOP] [N: 1] <input type="radio"/> None [N: 2] <input type="radio"/> One pillow (10cm) [N: 3] <input type="radio"/> Two pillows (20cm) [N: 4] <input type="radio"/> Three or more pillows [N: 97] <input type="radio"/> Not Done

Key: [*] = Item is required [✓] = Source verification required [b] = Base Unit
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

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

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

HF_INDIE: MEDICATIONS (MEDS) [frMEDS]	
Medications [stMEDS1]	
1.* ✓ ACE inhibitor [ACE inhibitor]	[ACE] [N:1] <input checked="" 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
2.* ✓ Angiotensin receptor blocker [Angiotensin receptor blocker]	[ARB] [N:1] <input checked="" 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
3.* ✓ Beta Blocker [Beta Blocker]	[BETAB] [N:1] <input checked="" 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
4.* ✓ Aldosterone antagonist [Aldosterone antagonist]	[ALDOS] [N:1] <input checked="" type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
5.* ✓ Hydralazine [Hydralazine]	[HYDR] [N:1] <input checked="" type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
6.* ✓ Nitrates (long acting) [Nitrates]	[NITR] [N:1] <input checked="" type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
7.* ✓ Nitrates (short acting)	[NITRSHRT] [N:1] <input checked="" type="radio"/> [NITRFREQ] Yes Frequency: [N:1] <input checked="" type="radio"/> < /= 1 week [N:2] <input type="radio"/> > 1week [N:99] <input type="radio"/> Unknown [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
8.* ✓ PDE5 Inhibitors [PDE5 Inhibitors]	[PDES1] [N:1] <input checked="" type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
9.* ✓ Soluble Guanylyl Cyclase Activators [Soluble Guanylyl Cyclase Activators]	[SGCA] [N:1] <input checked="" type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
10.* ✓ Calcium channel blocker [Calcium channel blocker]	[CCB] [N:1] <input checked="" type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
11.* ✓ Antiplatelets [Antiplatelets]	[ANTIPLT] [N:1] <input checked="" type="radio"/> [cpANTIPLTY] Yes (check all that apply) [ANTIPLTY] [N:1] <input type="checkbox"/> Aspirin (taken daily) [ANTIPLTY] [N:1] <input type="checkbox"/> Thienopyridines (eg: ticlopidine, clopidogrel, prasugrel) [ANTIPLTY] [N:1] <input type="checkbox"/> Other [N:0] <input checked="" type="radio"/> [ANTIPTCI] No If no: Is there documented evidence of contraindication? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown [N:99] <input type="radio"/> Unknown
12.* ✓ Anticoagulants [Anticoagulants]	[ANTICAG] [N:1] <input checked="" type="radio"/> [cpANTICAGY] Yes (check all that apply) [ANTICWAR]

		<p>[N: 1] <input type="checkbox"/> Warfarin</p> <p>[ANTICFCX] [N: 1] <input type="checkbox"/> Factor Xa Inhibitor</p> <p>[ANTICDTH] [N: 1] <input type="checkbox"/> Direct Thrombin Inhibitor</p> <p>[ANTICOTH] [N: 1] <input type="checkbox"/> Other</p> <p>[N: 0] <input type="radio"/> [ANTICACI]</p> <p>If no: Is there documented evidence of contraindication?</p> <p>[N: 1] <input type="radio"/> Yes</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
13. ✓	Digoxin [Digoxin]	<p>[DIGX] [N: 1] <input type="radio"/> Yes</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
14. ✓	Amlodarone [Amlodarone]	<p>[AMIOD] [N: 1] <input type="radio"/> Yes</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
15. ✓	Statin [Statin]	<p>[STATIN] [N: 1] <input type="radio"/> Yes</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
16. ✓	Lipid lowering agent (other than statin) [Lipid lowering agent]	<p>[LLIPID] [N: 1] <input type="radio"/> Yes</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
17. ✓	Ambulatory IV Inotropes [Ambulatory IV Inotropes]	<p>[IVINOTRP] [N: 1] <input type="radio"/> Yes</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
18. ✓	Sacubitril/Valsartan (Entresto) [Sacubitril/Valsartan]	<p>[ENTRESTO] [N: 1] <input type="radio"/> Yes</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
19. ✓	Ivabradine (Corlanor) [Ivabradine]	<p>[IVABRAD] [N: 1] <input type="radio"/> Yes</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
20. ✓	Metolazone [Metolazone]	<p>[METAZ] [N: 1] <input type="radio"/> [METODOSE]</p> <p>Yes Total Daily Dose (mg): xxxxxxx.</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
21. ✓	HCTZ [HCTZ]	<p>[HCTZ] [N: 1] <input type="radio"/> [HCTZDOSE]</p> <p>Yes Total Daily Dose (mg): xxxxxxx.</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
22. ✓	Furosemide [Furosemide]	<p>[FURO] [N: 1] <input type="radio"/> [FURODOSE]</p> <p>Yes Total Daily Dose (mg): xxxxxxx.</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
23. ✓	Torsemide [Torsemide]	<p>[TORS] [N: 1] <input type="radio"/> [TORSDOSE]</p> <p>Yes Total Daily Dose (mg): xxxxxxx.</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
24. ✓	Bumetanide [Bumetanide]	<p>[BUME] [N: 1] <input type="radio"/> [BUMDOSE]</p> <p>Yes Total Daily Dose (mg): xxxxxxx.</p> <p>[N: 0] <input type="radio"/> No</p> <p>[N: 99] <input type="radio"/> Unknown</p>
25. ✓	Chlorothiazide [Chlorothiazide]	<p>[CHLORTH] [N: 1] <input type="radio"/> [CHLORDSE]</p> <p>Yes Total Daily Dose (mg):</p>

		<input type="text" value="xxxxxxx"/> [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
26.* ✓	Chlorthalidone [Chlorthalidone]	[THALID] [N: 1] <input type="radio"/> [THALIDOSE] Yes Total Daily Dose (mg): <input type="text" value="xxxxxxx"/> [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
27.* ✓	Spirolactone [Spirolactone]	[SPIROUSE] [N: 1] <input type="radio"/> [SPIRDOSE] Yes Total Daily Dose (mg): <input type="text" value="xxxxxxx"/> [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
28.* ✓	Eplerenone [Eplerenone]	[EPLEUSE] [N: 1] <input type="radio"/> [EPLEDOSE] Yes Total Daily Dose (mg): <input type="text" value="xxxxxxx"/> [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
29.* ✓	Potassium [Potassium]	[KUSE] [N: 1] <input type="radio"/> [KDOSE] Yes Total Daily Dose (mEq): <input type="text" value="xxxxxxx"/> [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
30.* ✓	Magnesium [Magnesium]	[MAGUSE] [N: 1] <input type="radio"/> [MAGDOSE] Yes Total Daily Dose (mg): <input type="text" value="xxxxxxx"/> [N: 0] <input type="radio"/> No [N: 99] <input type="radio"/> Unknown
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

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
HYDR	HYDR_C	NUMBER
	HYDR	VARCHAR2
	HYDR_ND	VARCHAR2
NITR	NITR_C	NUMBER
	NITR	VARCHAR2
	NITR_ND	VARCHAR2
NITRSHRT	NITRSHRT_C	**NUMBER
	NITRSHRT	VARCHAR2
	NITRSHRT_ND	VARCHAR2
NITRSHRT - NITRFREQ	NITRFREQ_C	NUMBER
	NITRFREQ	VARCHAR2
PDE5I	PDE5I_C	NUMBER
	PDE5I	VARCHAR2

	PDE5I_ND	VARCHAR2
SGCA	SGCA_C	NUMBER
	SGCA	VARCHAR2
	SGCA_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	*ANTICFCX_CIFACTORXAINHIBITOR_C	NUMBER
	*ANTICFCX_CIFACTORXAINHIBITOR	VARCHAR2
ANTICAG - Direct Thrombin Inhibitor	*ANTICDTH_CIDIRECTTHROMBININHIBITOR_C	NUMBER
	*ANTICDTH_CIDIRECTTHROMBININHIBITOR	VARCHAR2
ANTICAG - Other	ANTICOOTH_CIOTHER1_C	NUMBER
	ANTICOOTH_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
ENTRESTO	ENTRESTO_C	NUMBER
	ENTRESTO	VARCHAR2
	ENTRESTO_ND	VARCHAR2
IVABRAD	IVABRAD_C	NUMBER
	IVABRAD	VARCHAR2
	IVABRAD_ND	VARCHAR2
METAZ	METAZ_C	**NUMBER
	METAZ	VARCHAR2
	METAZ_ND	VARCHAR2
METAZ - METODOSE	METODOSE	FLOAT
HCTZ	HCTZ_C	**NUMBER
	HCTZ	VARCHAR2
	HCTZ_ND	VARCHAR2
HCTZ - HCTZDOSE	HCTZDOSE	FLOAT
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
CHLORTH	CHLORTH_C	**NUMBER
	CHLORTH	VARCHAR2
	CHLORTH_ND	VARCHAR2
CHLORTH - CHLORDSE	CHLORDSE	FLOAT
THALID	THALID_C	**NUMBER
	THALID	VARCHAR2
	THALID_ND	VARCHAR2
THALID - THALIDOSE	THALIDOSE	FLOAT
SPIROUSE	SPIROUSE_C	**NUMBER
	SPIROUSE	VARCHAR2
	SPIROUSE_ND	VARCHAR2
SPIROUSE - SPIRDOSE	SPIRDOSE	FLOAT
EPLAUSE	EPLAUSE_C	**NUMBER
	EPLAUSE	VARCHAR2
	EPLAUSE_ND	VARCHAR2
EPLAUSE - EPLEDOSE	EPLEDOSE	FLOAT
KUSE	KUSE_C	**NUMBER
	KUSE	VARCHAR2
	KUSE_ND	VARCHAR2
KUSE - KDOSE	KDOSE	FLOAT
MAGUSE	MAGUSE_C	**NUMBER
	MAGUSE	VARCHAR2
	MAGUSE_ND	VARCHAR2
MAGUSE - MAGDOSE	MAGDOSE	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.		

HF_INDIE: CPET (CPET) [frCPET]	
CPET (Site Entry) [stCPET1]	
1.* Was pre-CPET dose given? <input checked="" type="checkbox"/>	<p>[CPETDOSG] [N: 96] <input type="radio"/> Not applicable (Screening) [N: 1] <input checked="" type="radio"/> [cpCPETDT] Yes [CPETDDTM] Date/Time of Most Recent Study Drug Dose Started: Req [v] / Req [v] / Req [v] (2016-2018) Req [v] : Req [v] 24-hour clock [CPESPOTM] Date/Time Study Drug Dose Ended: Req [v] / Req [v] / Req [v] (2016-2018) Req [v] : Req [v] 24-hour clock [N: 0] <input checked="" type="radio"/> [CPETDNOR] No Reason not given: A100</p>
2.* CPX Weight (at time of CPET) <input checked="" type="checkbox"/>	<p>[CPXWEGND] [N: 1] <input checked="" type="radio"/> [CPXWGT] xxxxxxxx. kg^[b] [N: 97] <input type="radio"/> Not Done/Unavailable</p>
3.* Exercise Modality <input checked="" type="checkbox"/>	<p>[EXERCISE] [N: 1] <input type="radio"/> Treadmill [N: 2] <input checked="" type="radio"/> Cycle</p>
4.* Metabolic Cart Type <input checked="" type="checkbox"/>	<p>[METACART] [N: 1] <input type="radio"/> Medgraphics/Breeze [N: 2] <input type="radio"/> Parvomedics [N: 3] <input type="radio"/> VMAX [N: 98] <input checked="" type="radio"/> [METACRTS] Other, specify: A100</p>
5.* FEV1 <input checked="" type="checkbox"/>	<p>[FEV1ND] [N: 1] <input checked="" type="radio"/> [FEV1] xxxxxxxx. L/min [N: 97] <input type="radio"/> Not Done/Unavailable</p>
6.* CPX Test Start Date/Time <input checked="" type="checkbox"/>	<p>[CPXTSDTM] Req [v] / Req [v] / Req [v] (2016-2018) Req [v] : Req [v] 24-hour clock</p>
CPET (Core Lab Entry) [stCPET2]	
7. CPX Receipt Date/Time	<p>[CPXRCDTM] Req [v] / Req [v] / Req [v] (2016-2018) Req [v] : Req [v] 24-hour clock</p>
8. CPX Analysis Date/Time	<p>[CPXANDTM] Req [v] / Req [v] / Req [v] (2016-2018) Req [v] : Req [v] 24-hour clock</p>
9. Resting VO2	<p>[RSTVO2ND] [N: 1] <input type="radio"/> [RSTVO2] xxxxxxxx. ml/min [N: 97] <input type="radio"/> Not Done/Unavailable</p>
10. Resting VO2 (weight-adjusted)	<p>[RSTVO2WT] xxxxxxxx. ml/kg/min</p>
11. Resting RER	<p>[RSTRERND] [N: 1] <input type="radio"/> [RSTRER] xxxxxxxx. [N: 97] <input type="radio"/> Not Done/Unavailable</p>
12. Resting RR	<p>[RSTRRRND] [N: 1] <input type="radio"/> [RSTRRR] xxxxxxxx. [N: 97] <input type="radio"/> Not Done/Unavailable</p>
13. Resting VE	<p>[RESTVEND] [N: 1] <input type="radio"/> [RESTVE] xxxxxxxx. L [N: 97] <input type="radio"/> Not Done/Unavailable</p>
14. Resting Heart Rate	<p>[RSTHRTND] [N: 1] <input type="radio"/> [RSTHTR] N3 bpm^[b] [N: 97] <input type="radio"/> Not Done/Unavailable</p>
15. Resting O2 Saturation	<p>[RESTO2ND] [N: 1] <input type="radio"/> [RESTO2] xxxxxxxx. %^[b] [N: 97] <input type="radio"/> Not Done/Unavailable</p>
16. Resting Blood Pressure	<p>[RESTBPND] [N: 1] <input type="radio"/> [cpRESTBP] [RESTSYS] [RESTDIA]</p>

		<input type="text" value="N3"/> / <input type="text" value="N3"/> mmHg [N: 97] <input type="radio"/> Not Done/Unavailable
17. Resting Borg Dyspnea	[RESTBORG] [ctBorgDyspnea] <input checked="" type="checkbox"/>	
18. Peak VO2	[PKVO2AND] [N: 1] <input type="radio"/> [PEKVO2A] <input type="text" value="xxxxxxx."/> ml/min [N: 97] <input type="radio"/> Not Done/Unavailable	
19. Peak VO2 (weight-adjusted)	[PKVO2BND] [N: 1] <input type="radio"/> [PEKVO2B] <input type="text" value="xxxxxxx."/> (ml/kg/min) [N: 97] <input type="radio"/> Not Done/Unavailable	
20. Peak RER	[PEKRERND] [N: 1] <input type="radio"/> [PEAKRER] <input type="text" value="xxxxxxx."/> [N: 97] <input type="radio"/> Not Done/Unavailable	
21. Peak RR	[PEAKRRND] [N: 1] <input type="radio"/> [PEAKRR] <input type="text" value="xxxxxxx."/> [N: 97] <input type="radio"/> Not Done/Unavailable	
22. Peak VE	[PEAKVEND] [N: 1] <input type="radio"/> [PEAKVE] <input type="text" value="xxxxxxx."/> L [N: 97] <input type="radio"/> Not Done/Unavailable	
23. Peak Heart Rate	[PEKHRTND] [N: 1] <input type="radio"/> [PEAKHRTR] <input type="text" value="N3"/> bpm ^[b] [N: 97] <input type="radio"/> Not Done/Unavailable	
24. Peak O2 Saturation	[PEAKO2ND] [N: 1] <input type="radio"/> [PEAKO2] <input type="text" value="xxxxxxx."/> % ^[b] [N: 97] <input type="radio"/> Not Done/Unavailable	
25. Peak Blood Pressure	[PEAKBPND] [N: 1] <input type="radio"/> [cpPEAKBP] [PEAKSYS] [PEAKDIA] <input type="text" value="N3"/> / <input type="text" value="N3"/> mmHg [N: 97] <input type="radio"/> Not Done/Unavailable	
26. Peak Borg Dyspnea	[PEAKBORG] [ctBorgDyspnea] <input checked="" type="checkbox"/>	
27. CPX Duration (minutes: seconds)	[CPXDURND] [N: 1] <input type="radio"/> [cpCPXDUR] (minutes: seconds) [CPXDURMN] [CPXDURSC] <input type="text" value="N2"/> : <input type="text" value="N2"/> [N: 97] <input type="radio"/> Not Done/Unavailable	
28. Reason CPX Stopped	[CPXRSNST] <input type="text" value="A100"/>	
29. Peak Power	[PEKPWRND] [N: 1] <input type="radio"/> [PEAKPWR] <input type="text" value="N3"/> watts [N: 97] <input type="radio"/> Not Done/Unavailable	
30. VO2 at AT	[VO2ATND] [N: 1] <input type="radio"/> [VO2AT] <input type="text" value="xxxxxxx."/> ml/min [N: 97] <input type="radio"/> Not Done/Unavailable	
31. VO2 at AT (weight-adjusted)	[VO2ATWT] <input type="text" value="xxxxxxx."/> ml/kg/min	
32. Ventilatory Efficiency (Ve/VCO2 Slope)	[VEVCO2ND] [N: 1] <input type="radio"/> [VEVCO2] <input type="text" value="xxxxxxx."/> [N: 97] <input type="radio"/> Not Done/Unavailable	
33. Ventilatory Efficiency R ² (Ve/VCO2 R ²)	[VCO2RND] [N: 1] <input type="radio"/> [VEVCO2R2] <input type="text" value="xxxxxxx."/> [N: 97] <input type="radio"/> Not Done/Unavailable	
34. Aerobic Efficiency (VO2/Work)	[VO2WRKND] [N: 1] <input type="radio"/> [VO2WRK] <input type="text" value="xxxxxxx."/> mL/joule [N: 97] <input type="radio"/> Not Done/Unavailable	
35. Aerobic Efficiency R ² (VO2/Work R ²)	[VO2WKRND] [N: 1] <input type="radio"/> [VO2WKR2] <input type="text" value="xxxxxxx."/> [N: 97] <input type="radio"/> Not Done/Unavailable	
36. % Predicted	[PREDCND] [N: 1] <input type="radio"/> [PRECPRED] <input type="text" value="xxxxxxx."/> % ^[b]	

[N: 97] Not Done/Unavailable

Key: [✓] = Source verification required [b] = Base Unit
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: CPET					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
ctBorgDyspnea	Integer	0	1	ci0	RESTBORG, PEAKBORG
		0.5	2	ci05	
		1	3	ci1	
		2	4	ci2	
		3	5	ci3	
		4	6	ci4	
		5	7	ci5	
		6	8	ci6	
		7	9	ci7	
		8	10	ci8	
		9	11	ci9	
		10	12	ci10	
		Not Done/Unavailable	97	ciNotDoneUnava	

RDE Analytics: RD_FRCPET		
Data Variable RefName	RD Column Name	Column Data Type
CPETDOSG	CPETDOSG_C	NUMBER
	CPETDOSG	VARCHAR2
	CPETDOSG_ND	VARCHAR2
CPETDOSG - CPETDDTM	CPETDDTM	DATE
	CPETDDTM_DTS	VARCHAR2
CPETDOSG - CPESPTM	CPESPTM	DATE
	CPESPTM_DTS	VARCHAR2
CPETDOSG - CPETDNOR	CPETDNOR	VARCHAR2
CPXWEGND	CPXWEGND_C	**NUMBER
	CPXWEGND	VARCHAR2
	CPXWEGND_ND	VARCHAR2
CPXWEGND - CPXWGT	CPXWGT	FLOAT
	CPXWGT_U	VARCHAR2
EXERCISE	EXERCISE_C	NUMBER
	EXERCISE	VARCHAR2
	EXERCISE_ND	VARCHAR2
METACART	METACART_C	NUMBER
	METACART	VARCHAR2
	METACART_ND	VARCHAR2
METACART - METACRTS	METACRTS	VARCHAR2
FEV1ND	FEV1ND_C	**NUMBER
	FEV1ND	VARCHAR2
	FEV1ND_ND	VARCHAR2
FEV1ND - FEV1	FEV1	FLOAT
CPXTSDTM	CPXTSDTM	DATE
	CPXTSDTM_DTS	VARCHAR2
	CPXTSDTM_ND	VARCHAR2
CPXRCDTM	CPXRCDTM	DATE
	CPXRCDTM_DTS	VARCHAR2
	CPXRCDTM_ND	VARCHAR2
CPXANDTM	CPXANDTM	DATE
	CPXANDTM_DTS	VARCHAR2
	CPXANDTM_ND	VARCHAR2
RSTVO2ND	RSTVO2ND_C	**NUMBER
	RSTVO2ND	VARCHAR2
	RSTVO2ND_ND	VARCHAR2
RSTVO2ND - RESTVO2	RESTVO2	FLOAT
RSTVO2WT	RSTVO2WT	FLOAT
	RSTVO2WT_ND	VARCHAR2
RSTRERND	RSTRERND_C	**NUMBER
	RSTRERND	VARCHAR2
	RSTRERND_ND	VARCHAR2
RSTRERND - RESTRER	RESTRER	FLOAT
RESTRERND	RESTRERND_C	**NUMBER

	RESTRND	VARCHAR2
	RESTRND_ND	VARCHAR2
RESTRND - RESTR	RESTR	FLOAT
RETVEND	RETVEND_C	**NUMBER
	RETVEND	VARCHAR2
	RETVEND_ND	VARCHAR2
RETVEND - RESTVE	RESTVE	FLOAT
RSTHRTND	RSTHRTND_C	**NUMBER
	RSTHRTND	VARCHAR2
	RSTHRTND_ND	VARCHAR2
RSTHRTND - RSTHRTR	RSTHRTR	NUMBER
	RSTHRTR_U	VARCHAR2
RESTO2ND	RESTO2ND_C	**NUMBER
	RESTO2ND	VARCHAR2
	RESTO2ND_ND	VARCHAR2
RESTO2ND - RESTO2	RESTO2	FLOAT
	RESTO2_U	VARCHAR2
RETBPNND	RETBPNND_C	**NUMBER
	RETBPNND	VARCHAR2
	RETBPNND_ND	VARCHAR2
RETBPNND - RESTSYS	RESTSYS	NUMBER
RETBPNND - RESTDIA	RESTDIA	NUMBER
RETBORG	RETBORG_C	NUMBER
	RETBORG	VARCHAR2
	RETBORG_ND	VARCHAR2
PKVO2AND	PKVO2AND_C	**NUMBER
	PKVO2AND	VARCHAR2
	PKVO2AND_ND	VARCHAR2
PKVO2AND - PEKVO2A	PEKVO2A	FLOAT
PKVO2BND	PKVO2BND_C	**NUMBER
	PKVO2BND	VARCHAR2
	PKVO2BND_ND	VARCHAR2
PKVO2BND - PEKVO2B	PEKVO2B	FLOAT
PEKRERND	PEKRERND_C	**NUMBER
	PEKRERND	VARCHAR2
	PEKRERND_ND	VARCHAR2
PEKRERND - PEAKRER	PEAKRER	FLOAT
PEAKRRND	PEAKRRND_C	**NUMBER
	PEAKRRND	VARCHAR2
	PEAKRRND_ND	VARCHAR2
PEAKRRND - PEAKRR	PEAKRR	FLOAT
PEAKVEND	PEAKVEND_C	**NUMBER
	PEAKVEND	VARCHAR2
	PEAKVEND_ND	VARCHAR2
PEAKVEND - PEAKVE	PEAKVE	FLOAT
PEKHRTND	PEKHRTND_C	**NUMBER
	PEKHRTND	VARCHAR2
	PEKHRTND_ND	VARCHAR2
PEKHRTND - PEAKHRTR	PEAKHRTR	NUMBER
	PEAKHRTR_U	VARCHAR2
PEAKO2ND	PEAKO2ND_C	**NUMBER
	PEAKO2ND	VARCHAR2
	PEAKO2ND_ND	VARCHAR2
PEAKO2ND - PEAKO2	PEAKO2	FLOAT
	PEAKO2_U	VARCHAR2
PEAKBPND	PEAKBPND_C	**NUMBER
	PEAKBPND	VARCHAR2
	PEAKBPND_ND	VARCHAR2
PEAKBPND - PEAKSYS	PEAKSYS	NUMBER
PEAKBPND - PEAKDIA	PEAKDIA	NUMBER
PEAKBORG	PEAKBORG_C	NUMBER
	PEAKBORG	VARCHAR2
	PEAKBORG_ND	VARCHAR2
CPXDURND	CPXDURND_C	**NUMBER
	CPXDURND	VARCHAR2
	CPXDURND_ND	VARCHAR2

CPXDURND - CPXDURMN	CPXDURMN	NUMBER
CPXDURND - CPXDURSC	CPXDURSC	NUMBER
CPXRSNST	CPXRSNST	VARCHAR2
	CPXRSNST_ND	VARCHAR2
PEKPWRND	PEKPWRND_C	**NUMBER
	PEKPWRND	VARCHAR2
	PEKPWRND_ND	VARCHAR2
PEKPWRND - PEAKPWR	PEAKPWR	NUMBER
VO2ATND	VO2ATND_C	**NUMBER
	VO2ATND	VARCHAR2
	VO2ATND_ND	VARCHAR2
VO2ATND - VO2AT	VO2AT	FLOAT
VO2ATWT	VO2ATWT	FLOAT
	VO2ATWT_ND	VARCHAR2
VEVCO2ND	VEVCO2ND_C	**NUMBER
	VEVCO2ND	VARCHAR2
	VEVCO2ND_ND	VARCHAR2
VEVCO2ND - VEVCO2	VEVCO2	FLOAT
VCO2RND	VCO2RND_C	**NUMBER
	VCO2RND	VARCHAR2
	VCO2RND_ND	VARCHAR2
VCO2RND - VEVCO2R2	VEVCO2R2	FLOAT
VO2WRKND	VO2WRKND_C	**NUMBER
	VO2WRKND	VARCHAR2
	VO2WRKND_ND	VARCHAR2
VO2WRKND - VO2WRK	VO2WRK	FLOAT
VO2WKRND	VO2WKRND_C	**NUMBER
	VO2WKRND	VARCHAR2
	VO2WKRND_ND	VARCHAR2
VO2WKRND - VO2WKR2	VO2WKR2	FLOAT
PREDICND	PREDICND_C	**NUMBER
	PREDICND	VARCHAR2
	PREDICND_ND	VARCHAR2
PREDICND - PRECPRED	PRECPRED	FLOAT
	PRECPRED_U	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HF_INDIE: ECG (ECG) [frECG]	
ECG [stECG1]	
1.* Date of ECG [Date of ECG]	[ECG] [N: 1] <input type="radio"/> [ECGDT] Req [v] / Req [v] / Req [v] (2016-2018) [N: 97] <input type="radio"/> Not Done
2.* Heart Rate [Heart Rate]	[ECGRATE] [N: 1] <input type="radio"/> [ECGHRVAL] N3 [] bpm [N: 97] <input type="radio"/> Not Done
3.* ECG Rhythm [ECG Rhythm]	[ECGRHYTH] [N: 1] <input type="radio"/> Sinus rhythm [N: 2] <input type="radio"/> Atrial fibrillation [N: 3] <input type="radio"/> Atrial flutter [N: 4] <input type="radio"/> [PACERHYT] Paced Underlying rhythm [N: 1] <input type="radio"/> Sinus [N: 2] <input type="radio"/> Atrial fibrillation [N: 3] <input type="radio"/> Atrial flutter [N: 98] <input type="radio"/> [PACEDSP] Other, specify: [A50] [N: 99] <input type="radio"/> Unknown [N: 98] <input type="radio"/> Other [N: 97] <input type="radio"/> Not Done
4.* QRS duration [QRS duration]	[ECGQRS] [N: 1] <input type="radio"/> [cpECGQRS] [ECGORSVL] xxxxxxx. [] msec [ECGORSTY] QRS complex for this measurement: [N: 1] <input type="radio"/> Intrinsic rhythm [N: 2] <input type="radio"/> Only ventricular paced QRS complexes present [N: 99] <input type="radio"/> Unknown [N: 97] <input type="radio"/> Not Done
Key: [*] = Item is required [v] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

RDE Analytics: RD_FRECG		
Data Variable RefName	RD Column Name	Column Data Type
ECG	ECG_C	**NUMBER
	ECG	VARCHAR2
	ECG_ND	VARCHAR2
ECG - ECGDT	ECGDT	DATE
	ECGDT_DTS	VARCHAR2
ECGRATE	ECGRATE_C	**NUMBER
	ECGRATE	VARCHAR2
	ECGRATE_ND	VARCHAR2
ECGRATE - ECGHRVAL	ECGHRVAL	NUMBER
ECGRHYTH	ECGRHYTH_C	NUMBER
	ECGRHYTH	VARCHAR2
	ECGRHYTH_ND	VARCHAR2
ECGRHYTH - PACERHYT	PACERHYT_C	NUMBER
	PACERHYT	VARCHAR2
ECGRHYTH - PACEDSP	PACEDSP	VARCHAR2
ECGQRS	ECGORS_C	**NUMBER
	ECGQRS	VARCHAR2
	ECGORS_ND	VARCHAR2
ECGQRS - ECGORSVL	ECGORSVL	FLOAT
ECGQRS - ECGORSTY	ECGORSTY_C	NUMBER
	ECGORSTY	VARCHAR2
Key: [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HF_INDIE: CHEMISTRY LABS (CHEM) [frCHEM]		
Chemistry [stCHEM1]		
1.* ✓	Collection Date and Time [Collection Date and Time]	[CHEMLDTM] Req [v] / Req [v] / Req [v] (2016-2018) Req/Unk [v] : Req/Unk [v] 24-hour clock
2.* ✓	Sodium [Sodium]	[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
3.* ✓	Potassium [Potassium]	[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
4.* ✓	Chloride [Chloride]	[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
5.* ✓	Carbon Dioxide [Carbon Dioxide]	[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
6.* ✓	BUN [BUN]	[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
7.* ✓	Creatinine [Creatinine]	[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
8.* ✓	ALT/SGPT [ALT/SGPT]	[ALT] [N: 1] <input type="radio"/> [cpALT] [ALTVAL] xxxxxxxx. [ALTUNT] Unit: [N: 5] <input type="radio"/> U/L [N: 6] <input type="radio"/> IU/L [N: 97] <input type="radio"/> Not Done
9.* ✓	AST/SGOT [AST/SGOT]	[AST] [N: 1] <input type="radio"/> [cpAST] [ASTVAL] xxxxxxxx. [ASTUNT] Unit: [N: 5] <input type="radio"/> U/L [N: 6] <input type="radio"/> IU/L [N: 97] <input type="radio"/> Not Done
10.* ✓	Alkaline Phosphatase [Alkaline Phosphatase]	[ALKPH] [N: 1] <input type="radio"/> [cpALKPH] [ALKPHVAL] xxxxxxxx.

		<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>[TBLI] [N:1] <input type="radio"/> [cpTBLI] [TBLIVAL] xxxxxxxx. [TBLIUNT] 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] xxxxxxxx. [GLUCUNT] [N:1] <input type="radio"/> mmol/L [N:3] <input type="radio"/> mg/dl [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>
13.* ✓	Were any of the labs above collected at a different date/time than entered in Question 1?	<p>[DIFFDTM] [N:1] <input type="radio"/> Yes (use Add Entry button) [N:0] <input type="radio"/> No</p>
14. ✓	Lab Test	Collection Date/Time
Chemistry Details Entry [rsCHEM2]		
14.1.* ✓	Lab Test: [Lab Test]	<p>[cpLABTEST] [SODIUM1] (check all that apply): [N:1] <input type="checkbox"/> Sodium [POTASUM1] [N:1] <input type="checkbox"/> Potassium [CHLORID1] [N:1] <input type="checkbox"/> Chloride [CRBONDIX] [N:1] <input type="checkbox"/> Carbon Dioxide [BUN1] [N:1] <input type="checkbox"/> BUN [CREATIN1] [N:1] <input type="checkbox"/> Creatinine [ALTSGPT1] [N:1] <input type="checkbox"/> ALT/SGPT [ASTSGOT1] [N:1] <input type="checkbox"/> AST/SGOT [ALKALINE] [N:1] <input type="checkbox"/> Alkaline Phosphatase [TOTALBIL] [N:1] <input type="checkbox"/> Total Bilirubin [GLUCOSE1] [N:1] <input type="checkbox"/> Glucose</p>
14.2.* ✓	Collection Date/Time: [Collection Date/Time]	<p>[LABDTM] Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2016-2018) Req <input type="button" value="v"/> : Req <input type="button" value="v"/> 24-hour clock</p>
<p>Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.</p>		

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
DIFFDTM	DIFFDTM_C	NUMBER
	DIFFDTM	VARCHAR2
	DIFFDTM_ND	VARCHAR2
RD_FRCHEM_RSCHM2		
cpLABTEST	CPLABTEST_ND	VARCHAR2
cpLABTEST - Sodium	SODIUM1_CISODIUM_C	NUMBER

	SODIUM1_CISODIUM	VARCHAR2
cpLABTEST - Potassium	POTASUM1_CIPOTASSIUM1_C	NUMBER
	POTASUM1_CIPOTASSIUM1	VARCHAR2
cpLABTEST - Chloride	CHLORID1_CICHLORIDE1_C	NUMBER
	CHLORID1_CICHLORIDE1	VARCHAR2
cpLABTEST - Carbon Dioxide	CRBONDIX_CICARBONDIOXIDE1_C	NUMBER
	CRBONDIX_CICARBONDIOXIDE1	VARCHAR2
cpLABTEST - BUN	BUN1_CIBUN1_C	NUMBER
	BUN1_CIBUN1	VARCHAR2
cpLABTEST - Creatinine	CREATIN1_CICREATININE1_C	NUMBER
	CREATIN1_CICREATININE1	VARCHAR2
cpLABTEST - ALT/SGPT	ALTSGPT1_CIALTSGPT1_C	NUMBER
	ALTSGPT1_CIALTSGPT1	VARCHAR2
cpLABTEST - AST/SGOT	ASTSGOT1_CIASTSGOT1_C	NUMBER
	ASTSGOT1_CIASTSGOT1	VARCHAR2
cpLABTEST - Alkaline Phosphatase	*ALKALINE_CIALKALINEPHOSPHATASE1_C	NUMBER
	*ALKALINE_CIALKALINEPHOSPHATASE1	VARCHAR2
cpLABTEST - Total Bilirubin	*TOTALBIL_CITOTALBILIRUBIN1_C	NUMBER
	*TOTALBIL_CITOTALBILIRUBIN1	VARCHAR2
cpLABTEST - Glucose	GLUCOSE1_CIGLUCOSE1_C	NUMBER
	GLUCOSE1_CIGLUCOSE1	VARCHAR2
LABDTM	LABDTM	DATE
	LABDTM_DTS	VARCHAR2
	LABDTM_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.		

HF_INDIE: CBC (CBC) [rCBC]		
CBC [stCBC1]		
1.* Collection Date and Time [Collection Date and Time]		[HEMALDTM] Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2016-2018) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <input checked="" 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:9] <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.* 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
6.* 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
7.* Were any of the labs above collected at a different date/time than entered in Question 1?		[CBCDIFF] [N:1] <input type="radio"/> Yes (use Add Entry button) [N:0] <input type="radio"/> No
8.*	Lab Test	Collection Date/Time
CBC Details Entry [rsCDC2]		
8.1.* Lab Test: [Lab Test]		[cpCBCTEST] [HEMOGLOB] (check all that apply): [N:1] <input type="checkbox"/> Hemoglobin [HEMATOCR] [N:1] <input type="checkbox"/> Hematocrit [RBC1] [N:1] <input type="checkbox"/> RBC [WBC1] [N:1] <input type="checkbox"/> WBC [PLATLET1] [N:1] <input type="checkbox"/> Platelet Count
8.2.* Collection Date/Time: [Collection Date/Time]		[CDCCLDTM] Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2016-2018) Req <input checked="" type="checkbox"/> : Req <input checked="" type="checkbox"/> 24-hour clock

Key: [*] = Item is required [✓] = Source verification required
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

RDE Analytics: RD_FRCBC		
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
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
CBCDIFF	CBCDIFF_C	NUMBER
	CBCDIFF	VARCHAR2
	CBCDIFF_ND	VARCHAR2
RD_FRCBC_RS CDC2		
cpCBCTEST	CPCBCTEST_ND	VARCHAR2
cpCBCTEST - Hemoglobin	HEMOGLOB_C IHEMOGLOBIN_C	NUMBER
	HEMOGLOB_C IHEMOGLOBIN	VARCHAR2
cpCBCTEST - Hematocrit	HEMATOCR_C IHEMATOCRIT1_C	NUMBER
	HEMATOCR_C IHEMATOCRIT1	VARCHAR2
cpCBCTEST - RBC	RBC1_C IRBC1_C	NUMBER
	RBC1_C IRBC1	VARCHAR2
cpCBCTEST - WBC	WBC1_C IWBC1_C	NUMBER
	WBC1_C IWBC1	VARCHAR2
cpCBCTEST - Platelet Count	PLATLET_C IPLATLETOUNT1_C	NUMBER
	PLATLET_C IPLATLETOUNT1	VARCHAR2
CDCCLDTM	CDCCLDTM	DATE
	CDCCLDTM_DTS	VARCHAR2
	CDCCLDTM_ND	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HF_INDIE: BIOLOGICAL SAMPLES (SAMPLES) [frSAMPLES]						
Biomarkers [stSAMPLES1]						
1.* Were biomarker samples collected at this visit? [Were biomarker samples collected at this visit]	[BIOMRK] [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input type="radio"/> [BIOMNDRS] No Reason samples were not collected: [N: 1] <input type="radio"/> Too sick to perform [N: 2] <input type="radio"/> Unwilling to perform but subjectively able [N: 3] <input type="radio"/> Due to oversight or technical problem [N: 99] <input type="radio"/> [BIOMNDSP] Other, specify: A200					
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"/> / <input type="text"/> / <input type="text"/> (2016-2018) Req/Unk <input type="text"/> : <input type="text"/> / <input type="text"/> 24-hour clock					
2.2.* Number of Samples Collected [Number of Samples Collected]	[cpBI OCOLL1] [BIOMSER] [N: 1] <input type="checkbox"/> [BIOMSRNM] Serum cryovials: N2 [BIOMEDTA] [N: 1] <input type="checkbox"/> [BIOMEDNM] EDTA cryovials: N2					
2.3.* Date sent to core lab [Date sent to lab]	[BIOMSTDT] Req <input type="text"/> / <input type="text"/> / <input type="text"/> (2016-2018)					
2.4.* Date samples received [Date received]	[BIOMRCDT] Req <input type="text"/> / <input type="text"/> / <input type="text"/> (2016-2018)					
2.5.* Samples received frozen [Frozen]	[BIOMFROZ] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No					
2.6.* Number of Samples Received [Number of Samples Received]	[cpSAMPREC1] [BIOMSRRC1] [N: 1] <input type="checkbox"/> [BIOMSNUM] Serum cryovials: N2 [BIOMSUSE] Number of usable serum samples: N2 [BIOMERC1] [N: 1] <input type="checkbox"/> [BIOMENUM] EDTA cryovials: N2 [BIOMEUSE] Number of usable EDTA samples: N2					
Biorepository and Genetics [stSAMPLES3]						
3.* Were biorepository or genetics samples collected at this visit? [Were biorepository or genetics samples collected at this visit]	[BIOREP] [N: 1] <input checked="" type="radio"/> Yes [N: 0] <input type="radio"/> [BIORNDRN] No Reason samples were not collected: [N: 1] <input type="radio"/> Subject did not provide consent [N: 2] <input type="radio"/> Subject withdrew consent [N: 3] <input type="radio"/> Too sick to perform [N: 4] <input type="radio"/> Unwilling to perform test but subjectively able [N: 5] <input type="radio"/> Due to oversight or technical problem [N: 99] <input type="radio"/> [BIORNDSP] Other, specify: A200					
4.*	Collection Date/Time	Number of Samples Collected	Date sent to lab	Date received	Frozen	Number of Samples Received
Biorepository and Genetics Collection Information Entry [rsSAMPLES4]						
4.1.* Collection Date/Time: [Collection Date/Time]	[BIORPDTM] Req <input type="text"/> / <input type="text"/> / <input type="text"/> (2016-2018) Req/Unk <input type="text"/> : <input type="text"/> / <input type="text"/> 24-hour clock					
4.2.* Number of Samples Collected [Number of Samples Collected]	[cpBI OCOLL2] [BIORSER] [N: 1] <input type="checkbox"/> [BIORSRNM] Serum cryovials: N2 [BIOREDTA] [N: 1] <input type="checkbox"/> [BIOREDNM] EDTA cryovials: N2 [BIORDNA]					

		[N: 1] <input type="checkbox"/> [BIORDNUM] DNA N2
4.3	Date sent to core lab [Date sent to lab]	[BIORSTDT] Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2016-2018)
4.4	Date samples received [Date received]	[BIORRCDT] Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2016-2018)
4.5	Samples received frozen [Frozen]	[BIORFROZ] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No
4.6	Number of Samples Received (Record the number of cryovials) [Number of Samples Received]	[cpSAMPREC2] [BIORSRCD] [N: 1] <input type="checkbox"/> [BIORSNUM] Serum cryovials: N2 [BIORSUSE] Number of usable serum samples: N2 [BIORERCD] [N: 1] <input type="checkbox"/> [BIORENUM] EDTA cryovials: N2 [BIOREUSE] Number of usable EDTA samples: N2 [BIORDRCD] [N: 1] <input type="checkbox"/> [BIORDNUM] DNA N2 [BIORDUSE] Number of usable DNA samples: N2
Comments [stSAMPLES5]		
5.	Comments [Lab Comments]	[LABCOMM] A200

Key: [✓] = Source verification required
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

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
BIOMRK - BIOMNDSP	BIOMNDSP	VARCHAR2
BIOREP	BIOREP_C	NUMBER
	BIOREP	VARCHAR2
	BIOREP_ND	VARCHAR2
BIOREP - BIORNDRN	BIORNDRN_C	NUMBER
	BIORNDRN	VARCHAR2
BIOREP - BIORNDSP	BIORNDSP	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
BIORSTDT	BIORSTDT	DATE
	BIORSTDT_DTS	VARCHAR2
	BIORSTDT_ND	VARCHAR2
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.		

HF_INDIE: 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.* ✓	Date completed [Date completed]	[KCCQDT] Req [v] / Req [v] / Req [v] (2016-2018)
2.* ✓	Dressing yourself [Dressing yourself]	[KCCQ1A] [ctLimited1] [v]
3.* ✓	Showering/Bathing [Showering/Bathing]	[KCCQ1B] [ctLimited1] [v]
4.* ✓	Walking 1 block on level ground [Walking 1 block on level ground]	[KCCQ1C] [ctLimited1] [v]
5.* ✓	Doing yardwork, housework or carrying groceries [Doing yardwork, housework or carrying groceries]	[KCCQ1D] [ctLimited1] [v]
6.* ✓	Climbing a flight of stairs without stopping [Climbing a flight of stairs without stopping]	[KCCQ1E] [ctLimited1] [v]
7.* ✓	Hurrying or jogging (as if to catch a bus) [Hurrying or jogging]	[KCCQ1F] [ctLimited1] [v]
8.* ✓	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] [v]
9.* ✓	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] [v]
10.* ✓	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] [v]
11.* ✓	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] [v]
12.* ✓	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] [v]
13.* ✓	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] [v]
14.* ✓	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] [v]
15.* ✓	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] [v]
16.* ✓	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] [v]
17.* ✓	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] [v]
18.* ✓	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] [v]
19.* ✓	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] [v]
20.* ✓	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] [v]
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]		
21.* ✓	Hobbies, recreational activities [Hobbies, recreational activities]	[KCCQ15A] [ctLimited3] [v]
22.* ✓	Working or doing household chores [Working or doing household chores]	[KCCQ15B] [ctLimited3] [v]
23.* ✓	Visiting family or friends out of your home [Visiting family or friends out of your home]	[KCCQ15C] [ctLimited3] [v]
24.* ✓	Intimate relationships with loved ones [Intimate relationships with loved ones]	[KCCQ15D] [ctLimited3] [v]
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Codelist Values 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	KCCO3
		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	KCCO4
		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	KCCO5, KCCO7
		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	KCCO6
		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	KCCO8
		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	KCCO9
		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	KCCO10
		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	KCCO11
		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	KCCO12
		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	KCCO13
		2 Mostly dissatisfied	2	ciMostlyDissatisfied	
		3 Somewhat satisfied	3	ciSomewhatSatisfied	
		4 Mostly satisfied	4	ciMostlySatisfied	

		5 Completely satisfied	5	ciCompletelySatisfied	
ctHowOften	Integer	Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	KCCQ14
		1 I felt that way all of the time	1	ciAllTheTime	
		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	
ctLimited3	Integer	Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	KCCQ15A, KCCQ15B, KCCQ15C, KCCQ15D
		1 Severely limited	1	ciSeverelyLimited	
		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
KCCQDT	KCCQDT	DATE
	KCCQDT_DTS	VARCHAR2
	KCCQDT_ND	VARCHAR2
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

HF_INDIE: VISIT STATUS (VISIT) [frVISIT]

Visit Status [stVISIT1]

1.* Was the visit performed
[Visit performed]

[STATUS]
 [N: 1] **[ASSESSDT]**
 Yes
 Visit date:
 Req / Req / Req (2016-2018)

[N: 0] **[VISNDRES]**
 No
 Reason visit was not performed:
 [N: 1] Missed visit
 [N: 2] Suspected LTFU
 [N: 3] Subject no longer participating in study (died, permanently withdrew consent, etc.)
 [N: 98] **[ASESNDSP]**
 Other, specify

Key: [*] = Item is required [✓] = Source verification required
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

RDE Analytics: RD_FRVISIT

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

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

HF_INDIE: Additional Protocol Assessments (ASSESS) [frASSESS]		
Additional Protocol Assessments [stASSESS1]		
1.* ✓	Date/Time of Most Recent Study Drug Dose (prior to any visit assessments) [Date/Time of Most Recent Study Drug Dose]	[DRGDOSE] NReq <input type="checkbox"/> / NReq <input type="checkbox"/> / NReq <input type="checkbox"/> (2016-2018)
2.* ✓	Were protocol required biological samples collected (If yes, please complete SAMPLES form)? [Were protocol required biological samples collected]	[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 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: A50
3.* ✓	Were CBC Labs Drawn? (If yes, complete CBC form) [Were CBC Labs Drawn?]	[CBCDN] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> [CBCNDRS] No [N:1] <input type="radio"/> Too sick to perform [N:2] <input type="radio"/> Unwilling to perform but subjectively able [N:3] <input type="radio"/> Not done due to oversight or technical problem [N:99] <input type="radio"/> [CBCNDSP] Unknown/other Specify: A50
4.* ✓	Was Chemistry Panel Drawn? (If yes, complete CHEM form) [Was Chemistry Panel Drawn?]	[CHEMDN] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> [CHEMNDRS] No [N:1] <input type="radio"/> Too sick to perform [N:2] <input type="radio"/> Unwilling to perform but subjectively able [N:3] <input type="radio"/> Not done due to oversight or technical problem [N:99] <input type="radio"/> [CHEMNDSP] Unknown/other Specify: A50
5.* ✓	Was ECHO Performed? [Was ECHO Performed?]	[ECHODN] [N:1] <input type="radio"/> [ECHOODNT] Yes Date sent to Core Lab: Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018) [N:0] <input type="radio"/> [ECHONDRS] No [N:1] <input type="radio"/> Too sick to perform [N:2] <input type="radio"/> Unwilling to perform but subjectively able [N:3] <input type="radio"/> Not done due to oversight or technical problem [N:99] <input type="radio"/> [ECHONDSP] Unknown/other Specify: A50
6.* ✓	Was CPET Performed? (If yes, complete CPET form) [Was CPET Performed?]	[CPETDN] [N:1] <input type="radio"/> [CPETDNDT] Yes Date sent to Core Lab: Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018) [N:0] <input type="radio"/> [CPETNDRS] No [N:1] <input type="radio"/> Too sick to perform [N:2] <input type="radio"/> Unwilling to perform but subjectively able [N:3] <input type="radio"/> Not done due to oversight or technical problem [N:99] <input type="radio"/> [CPETNDSP] Unknown/other Specify: A50
7.* ✓	Was KCCO completed (If yes, complete KCCO form)? [Was KCCO completed]	[KCCODN] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> [KCCONDRS] No [N:1] <input type="radio"/> Too sick to perform [N:2] <input type="radio"/> Unwilling to perform but subjectively able [N:3] <input type="radio"/> Not done due to oversight or technical problem [N:99] <input type="radio"/> [KCCONDSP] Unknown/other Specify: A50
8.* ✓	Has the subject experienced any adverse events or events of interest since the last visit (If yes, complete AE or EVNTINT form)? [Has the subject experienced any adverse events or events of interest since the last visit]	[NEWSAE] [N:1] <input type="radio"/> [AERELATE] Yes Related to CPET? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown

9.* ✓	Has the subject been hospitalized since the last visit (If yes, complete REHOSP form)? [Has the subject been hospitalized since the last visit]	[REHOSP] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
10.* ✓	Has the subject had any emergency department visits since the last visit (If yes, complete EDVIST form)? [Has the subject had any emergency department visits since the last visit]	[EDVIST] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

RDE Analytics: RD_FRASSESS		
Data Variable RefName	RD Column Name	Column Data Type
DRGDOSE	DRGDOSE	DATE
	DRGDOSE_DTS	VARCHAR2
	DRGDOSE_DTR	VARCHAR2
	DRGDOSE_ND	VARCHAR2
BIOSAMP	BIOSAMP_C	NUMBER
	BIOSAMP	VARCHAR2
	BIOSAMP_ND	VARCHAR2
BIOSAMP - BIONDRSN	BIONDRSN_C	NUMBER
	BIONDRSN	VARCHAR2
BIOSAMP - BIONDSP	BIONDSP	VARCHAR2
CBCDN	CBCDN_C	NUMBER
	CBCDN	VARCHAR2
	CBCDN_ND	VARCHAR2
CBCDN - CBCNDRS	CBCNDRS_C	NUMBER
	CBCNDRS	VARCHAR2
CBCDN - CBCNDSP	CBCNDSP	VARCHAR2
CHEMDN	CHEMDN_C	NUMBER
	CHEMDN	VARCHAR2
	CHEMDN_ND	VARCHAR2
CHEMDN - CHEMNDRS	CHEMNDRS_C	NUMBER
	CHEMNDRS	VARCHAR2
CHEMDN - CHEMNDRS	CHEMNDRS	VARCHAR2
CHEMDN - CHEMNDRS	CHEMNDRS	VARCHAR2
ECHODN	ECHODN_C	**NUMBER
	ECHODN	VARCHAR2
	ECHODN_ND	VARCHAR2
ECHODN - ECHODNDT	ECHODNDT	DATE
	ECHODNDT_DTS	VARCHAR2
ECHODN - ECHONDRS	ECHONDRS_C	NUMBER
	ECHONDRS	VARCHAR2
ECHODN - ECHONDRS	ECHONDRS	VARCHAR2
CPETDN	CPETDN_C	**NUMBER
	CPETDN	VARCHAR2
	CPETDN_ND	VARCHAR2
CPETDN - CPETDNDT	CPETDNDT	DATE
	CPETDNDT_DTS	VARCHAR2
CPETDN - CPETNDRS	CPETNDRS_C	NUMBER
	CPETNDRS	VARCHAR2
CPETDN - CPETNDRS	CPETNDRS	VARCHAR2
KCCODN	KCCODN_C	NUMBER
	KCCODN	VARCHAR2
	KCCODN_ND	VARCHAR2
KCCODN - KCCONDRS	KCCONDRS_C	NUMBER
	KCCONDRS	VARCHAR2
KCCODN - KCCONDRS	KCCONDRS	VARCHAR2
NEWSAE	NEWSAE_C	**NUMBER
	NEWSAE	VARCHAR2
	NEWSAE_ND	VARCHAR2
NEWSAE - AERELATE	AERELATE_C	NUMBER
	AERELATE	VARCHAR2
REHOSP	REHOSP_C	NUMBER
	REHOSP	VARCHAR2
	REHOSP_ND	VARCHAR2
EDVIST	EDVIST_C	NUMBER
	EDVIST	VARCHAR2

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

HF_INDIE: ECHO RESULTS (ECHOLAB) [frECHOLAB]	
TO BE COMPLETED BY ECHO CORE LAB: [stECHOLAB1]	
1. Echo Date [Echo Date]	[CECHODT] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018)
2. 2D PLAX: IVS systolic dimension [2D PLAX: IVS systolic dimension]	[IVSDD] [N: 1] <input type="radio"/> [IVSD] xxxxxxxx. cm [N: 2] <input type="radio"/> [IVVSD] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
3. 2D PLAX: PW systolic dimension [2D PLAX: PW systolic dimension]	[PWSDD] [N: 1] <input type="radio"/> [PWS] xxxxxxxx. cm [N: 2] <input type="radio"/> [VPWS] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
4. 2D PLAX: LV systolic dimension [2D PLAX: LV systolic dimension]	[LVSDD] [N: 1] <input type="radio"/> [LVSD] xxxxxxxx. cm [N: 2] <input type="radio"/> [VLVS] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
5. 2D PLAX: IVS diastolic dimension [2D PLAX: IVS diastolic dimension]	[IVSDDD] [N: 1] <input type="radio"/> [IVSDDD] xxxxxxxx. cm [N: 2] <input type="radio"/> [IVSDD] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
6. 2D PLAX: PW diastolic dimension [2D PLAX: PW diastolic dimension]	[PWDDD] [N: 1] <input type="radio"/> [PWDD] xxxxxxxx. cm [N: 2] <input type="radio"/> [VPWDD] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
7. 2D PLAX: LV diastolic dimension [2D PLAX: LV diastolic dimension]	[LVDDD] [N: 1] <input type="radio"/> [LVDD] xxxxxxxx. cm [N: 2] <input type="radio"/> [VLVD] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
8. Final conclusion Ejection Fraction [Final conclusion Ejection Fraction]	[FEJFCTND] [N: 1] <input type="radio"/> [FEJFCTNV] xxxxxxxx. % [N: 97] <input type="radio"/> Not Done
9. MV Inflow: E velocity at leaf tip [MV Inflow: E velocity at leaf tip]	[EVELOCD] [N: 1] <input type="radio"/> [EVELOC] xxxxxxxx. m/sec [N: 2] <input type="radio"/> [VEVELOC] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
10. Peak TR velocity [Peak TR velocity]	[PKTRVELD] [N: 1] <input type="radio"/> [PEAKVELC] xxxxxxxx. m/sec [N: 2] <input type="radio"/> [VPEAKTR] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
11. RA Pressure (est) - If no IVC is recorded 10 mmHg will be used for RA Pressure [RA Pressure (est) - If no IVC is recorded 10 mmHg will be used for RA Pressure]	[RAPRESSD] [N: 1] <input type="radio"/> [RAPRESS] xxxxxxxx. mmHg [N: 97] <input type="radio"/> Not Done
12. RETIRED ITEM: LA Area [hidden] [LA Area]	[LAAREAD] [N: 1] <input type="radio"/> [LAAREA] xxxxxxxx. cm ² [N: 2] <input type="radio"/> [VLAAREA] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent [N: 3] <input type="radio"/> Not clinically indicated
13. Mitral Medial Annulus e [Mitral Medial Annulus e]	[MEDMIED] [N: 1] <input type="radio"/> [MEDMIE] xxxxxxxx. m/sec [N: 2] <input type="radio"/> [VMEDMIE] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views

		<p><input type="radio"/> Views Absent</p> <p>[N: 2] <input type="radio"/></p>
14.	Mitral Medial Annulus a [Mitral Medial Annulus a]	<p>[MEDMIAD]</p> <p>[N: 1] <input type="radio"/> [MEDMIA] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VMEDMIA] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>
15.	RETIRED ITEM. DTI Medial Annulus e [hidden] [DTI Medial Annulus e]	<p>[DTIMEDED]</p> <p>[N: 1] <input type="radio"/> [DTIMEDE] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VDTIMEDE] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>
16.	Mitral Medial Annulus s [Mitral Medial Annulus s]	<p>[DTIME SDS]</p> <p>[N: 1] <input type="radio"/> [DTIME S] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VDTIME S] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>
17.	Mitral Lateral Annulus e [Mitral Lateral Annulus e]	<p>[LATMIAED]</p> <p>[N: 1] <input type="radio"/> [LATMIAE] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VLATMIAE] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>
18.	Mitral Lateral Annulus a [Mitral Lateral Annulus a]	<p>[LATMIAD]</p> <p>[N: 1] <input type="radio"/> [LATMIAA] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VLATMIAA] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>
19.	RETIRED ITEM. DTI Lateral Annulus e [hidden] [DTI Lateral Annulus e]	<p>[DTILATED]</p> <p>[N: 1] <input type="radio"/> [DTILATE] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VDTILATE] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>
20.	Mitral Lateral Annulus s [Mitral Lateral Annulus s]	<p>[DTILATSD]</p> <p>[N: 1] <input type="radio"/> [DTILATS] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VDTILATS] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>
21.	Tricuspid Lateral Annulus e [Tricuspid Lateral Annulus e]	<p>[DTITRIED]</p> <p>[N: 1] <input type="radio"/> [DTITRIE] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VDTITRIE] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>
22.	Tricuspid Lateral Annulus s [Tricuspid Lateral Annulus s]	<p>[DTITRISD]</p> <p>[N: 1] <input type="radio"/> [DTITRIS] xxxxxxxx. <input type="text"/> m/sec</p> <p>[N: 2] <input type="radio"/> [VDTITRIS] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>
23.	LA 4c Area [LA 4c Area]	<p>[LACAREAD]</p> <p>[N: 1] <input type="radio"/> [LACAREA] xxxxxxxx. <input type="text"/> cm²</p> <p>[N: 2] <input type="radio"/> [VLACAREA] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>
24.	LA 4c Length [LA 4c Length]	<p>[LACLEND]</p> <p>[N: 1] <input type="radio"/> [LACLEN] xxxxxxxx. <input type="text"/> cm</p> <p>[N: 2] <input type="radio"/> [VLACLEN] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent</p>
25.	LA 2ch Area [LA 2ch Area]	<p>[LACHARD]</p> <p>[N: 1] <input type="radio"/> [LACHAREA] xxxxxxxx. <input type="text"/> cm²</p> <p>[N: 2] <input type="radio"/> [VLACHARE]</p>

		Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent
26. LA 2c Length [LA 2c Length]	[LALEND] [N: 1] <input type="radio"/> [LALEN] <input type="text" value="xxxxxxx"/> cm [N: 2] <input type="radio"/> [VLALEN] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent	
27. Apical 4 Chamber - LA Volume (ml) [Apical 4 Chamber - LA Volume (ml)]	[A4CLAD] [N: 1] <input type="radio"/> [A4CLA] <input type="text" value="xxxxxxx"/> ml [N: 2] <input type="radio"/> [VA4CLA] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent	
28. Apical 2 Chamber - LA Volume (ml) [Apical 2 Chamber - LA Volume (ml)]	[A2CLAD] [N: 1] <input type="radio"/> [A2CLA] <input type="text" value="xxxxxxx"/> ml [N: 2] <input type="radio"/> [VA2CLA] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent	
29. TAPSE [TAPSE]	[TAPSEND] [N: 1] <input type="radio"/> [TAPSE] <input type="text" value="xxxxxxx"/> cm [N: 2] <input type="radio"/> [VTAPSE] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent	
30. Apical 4 Chamber - RV focused view function [Apical 4 Chamber - RV focused view function]	[A4CRVWV] [N: 1] <input type="radio"/> Normal [N: 2] <input type="radio"/> Mild-Moderate [N: 3] <input type="radio"/> Severe [N: 97] <input type="radio"/> Not Done	
31. Apical 4c - RV focused view: Tricuspid annulus tissue Doppler velocity (s') from RV lateral annulus [Apical 4c - RV focused view: Tricuspid annulus tissue Doppler velocity (s') from RV lateral annulus]	[A4CDOPD] [N: 1] <input type="radio"/> [A4CDOP] <input type="text" value="xxxxxxx"/> m/sec [N: 2] <input type="radio"/> [VA4CDOP] Missing - indicate view quality: [N: 1] <input type="radio"/> Poor Views [N: 2] <input type="radio"/> Views Absent	
32. Additional Comments [Additional Comments]	[ECHOCOM] A200	

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

RDE Analytics: RD_FRECHOLAB		
Data Variable RefName	RD Column Name	Column Data Type
CECHODT	CECHODT	DATE
	CECHODT_DTS	VARCHAR2
	CECHODT_ND	VARCHAR2
IVSDD	IVSDD_C	**NUMBER
	IVSDD	VARCHAR2
	IVSDD_ND	VARCHAR2
IVSDD - IVSD	IVSD	FLOAT
IVSDD - VIVSD	VIVSD_C	NUMBER
	VIVSD	VARCHAR2
PWSD	PWSD_C	**NUMBER
	PWSD	VARCHAR2
	PWSD_ND	VARCHAR2
PWSD - PWSD	PWSD	FLOAT
PWSD - VPWSD	VPWSD_C	NUMBER
	VPWSD	VARCHAR2
LVSDD	LVSDD_C	**NUMBER
	LVSDD	VARCHAR2
	LVSDD_ND	VARCHAR2
LVSDD - LVSD	LVSD	FLOAT
LVSDD - VLVSDD	VLVSDD_C	NUMBER
	VLVSDD	VARCHAR2
IVSDDDN	IVSDDDN_C	**NUMBER
	IVSDDDN	VARCHAR2

	IVSDDN_ND	VARCHAR2
IVSDDN - IVSDD	IVSDD	FLOAT
IVSDDN - VIVSDD	VIVSDD_C	NUMBER
	VIVSDD	VARCHAR2
PWDD	PWDD_C	**NUMBER
	PWDD	VARCHAR2
	PWDD_ND	VARCHAR2
PWDD - PWDD	PWDD	FLOAT
PWDD - VPWDD	VPWDD_C	NUMBER
	VPWDD	VARCHAR2
LVDD	LVDD_C	**NUMBER
	LVDD	VARCHAR2
	LVDD_ND	VARCHAR2
LVDD - LVDD	LVDD	FLOAT
LVDD - VLVDD	VLVDD_C	NUMBER
	VLVDD	VARCHAR2
FEJCTND	FEJCTND_C	**NUMBER
	FEJCTND	VARCHAR2
	FEJCTND_ND	VARCHAR2
FEJCTND - FEJCTNV	FEJCTNV	FLOAT
EVELOCD	EVELOCD_C	**NUMBER
	EVELOCD	VARCHAR2
	EVELOCD_ND	VARCHAR2
EVELOCD - EVELOC	EVELOC	FLOAT
EVELOCD - VEVELOC	VEVELOC_C	NUMBER
	VEVELOC	VARCHAR2
PKTRVELD	PKTRVELD_C	**NUMBER
	PKTRVELD	VARCHAR2
	PKTRVELD_ND	VARCHAR2
PKTRVELD - PEAKVELC	PEAKVELC	FLOAT
PKTRVELD - VPEAKTR	VPEAKTR_C	NUMBER
	VPEAKTR	VARCHAR2
RAPRESSD	RAPRESSD_C	**NUMBER
	RAPRESSD	VARCHAR2
	RAPRESSD_ND	VARCHAR2
RAPRESSD - RAPRESS	RAPRESS	FLOAT
LAAREAD	LAAREAD_C	**NUMBER
	LAAREAD	VARCHAR2
	LAAREAD_ND	VARCHAR2
LAAREAD - LAAREA	LAAREA	FLOAT
LAAREAD - VLAAREA	VLAAREA_C	NUMBER
	VLAAREA	VARCHAR2
MEDMIED	MEDMIED_C	**NUMBER
	MEDMIED	VARCHAR2
	MEDMIED_ND	VARCHAR2
MEDMIED - MEDMIE	MEDMIE	FLOAT
MEDMIED - VMEDMIE	VMEDMIE_C	NUMBER
	VMEDMIE	VARCHAR2
MEDMIAD	MEDMIAD_C	**NUMBER
	MEDMIAD	VARCHAR2
	MEDMIAD_ND	VARCHAR2
MEDMIAD - MEDMIA	MEDMIA	FLOAT
MEDMIAD - VMEDMIA	VMEDMIA_C	NUMBER
	VMEDMIA	VARCHAR2
DTIMEDED	DTIMEDED_C	**NUMBER
	DTIMEDED	VARCHAR2
	DTIMEDED_ND	VARCHAR2
DTIMEDED - DTIMEDE	DTIMEDE	FLOAT
DTIMEDED - VDTIMEDE	VDTIMEDE_C	NUMBER
	VDTIMEDE	VARCHAR2
DTIMEDSD	DTIMEDSD_C	**NUMBER
	DTIMEDSD	VARCHAR2
	DTIMEDSD_ND	VARCHAR2
DTIMEDSD - DTIMEDS	DTIMEDS	FLOAT
DTIMEDSD - VDTIMEDS	VDTIMEDS_C	NUMBER
	VDTIMEDS	VARCHAR2

LATMIAED	LATMIAED_C	**NUMBER
	LATMIAED	VARCHAR2
	LATMIAED_ND	VARCHAR2
LATMIAED - LATMIAE	LATMIAE	FLOAT
LATMIAED - VLATMIAE	VLATMIAE_C	NUMBER
	VLATMIAE	VARCHAR2
LATMIAD	LATMIAD_C	**NUMBER
	LATMIAD	VARCHAR2
	LATMIAD_ND	VARCHAR2
LATMIAD - LATMIAA	LATMIAA	FLOAT
LATMIAD - VLATMIAA	VLATMIAA_C	NUMBER
	VLATMIAA	VARCHAR2
DTILATED	DTILATED_C	**NUMBER
	DTILATED	VARCHAR2
	DTILATED_ND	VARCHAR2
DTILATED - DTILATE	DTILATE	FLOAT
DTILATED - VDTILATE	VDTILATE_C	NUMBER
	VDTILATE	VARCHAR2
DTILATSD	DTILATSD_C	**NUMBER
	DTILATSD	VARCHAR2
	DTILATSD_ND	VARCHAR2
DTILATSD - DTILATS	DTILATS	FLOAT
DTILATSD - VDTILATS	VDTILATS_C	NUMBER
	VDTILATS	VARCHAR2
DTITRIED	DTITRIED_C	**NUMBER
	DTITRIED	VARCHAR2
	DTITRIED_ND	VARCHAR2
DTITRIED - DTITRIE	DTITRIE	FLOAT
DTITRIED - VDTITRIE	VDTITRIE_C	NUMBER
	VDTITRIE	VARCHAR2
DTITRISD	DTITRISD_C	**NUMBER
	DTITRISD	VARCHAR2
	DTITRISD_ND	VARCHAR2
DTITRISD - DTITRIS	DTITRIS	FLOAT
DTITRISD - VDTITRIS	VDTITRIS_C	NUMBER
	VDTITRIS	VARCHAR2
LACAREAD	LACAREAD_C	**NUMBER
	LACAREAD	VARCHAR2
	LACAREAD_ND	VARCHAR2
LACAREAD - LACAREA	LACAREA	FLOAT
LACAREAD - VLACAREA	VLACAREA_C	NUMBER
	VLACAREA	VARCHAR2
LACLEND	LACLEND_C	**NUMBER
	LACLEND	VARCHAR2
	LACLEND_ND	VARCHAR2
LACLEND - LACLEN	LACLEN	FLOAT
LACLEND - VLACLEN	VLACLEN_C	NUMBER
	VLACLEN	VARCHAR2
LACHARD	LACHARD_C	**NUMBER
	LACHARD	VARCHAR2
	LACHARD_ND	VARCHAR2
LACHARD - LACHAREA	LACHAREA	FLOAT
LACHARD - VLACHARE	VLACHARE_C	NUMBER
	VLACHARE	VARCHAR2
LALEND	LALEND_C	**NUMBER
	LALEND	VARCHAR2
	LALEND_ND	VARCHAR2
LALEND - LALEN	LALEN	FLOAT
LALEND - VLALLEN	VLALLEN_C	NUMBER
	VLALLEN	VARCHAR2
A4CLAD	A4CLAD_C	**NUMBER
	A4CLAD	VARCHAR2
	A4CLAD_ND	VARCHAR2
A4CLAD - A4CLA	A4CLA	FLOAT
A4CLAD - VA4CLA	VA4CLA_C	NUMBER
	VA4CLA	VARCHAR2

A2CLAD	A2CLAD_C	**NUMBER
	A2CLAD	VARCHAR2
	A2CLAD_ND	VARCHAR2
A2CLAD - A2CLA	A2CLA	FLOAT
A2CLAD - VA2CLA	VA2CLA_C	NUMBER
	VA2CLA	VARCHAR2
TAPSEND	TAPSEND_C	**NUMBER
	TAPSEND	VARCHAR2
	TAPSEND_ND	VARCHAR2
TAPSEND - TAPSE	TAPSE	FLOAT
TAPSEND - VTAPSE	VTAPSE_C	NUMBER
	VTAPSE	VARCHAR2
A4CRVWW	A4CRVWW_C	NUMBER
	A4CRVWW	VARCHAR2
	A4CRVWW_ND	VARCHAR2
A4CDOPD	A4CDOPD_C	**NUMBER
	A4CDOPD	VARCHAR2
	A4CDOPD_ND	VARCHAR2
A4CDOPD - A4CDOP	A4CDOP	FLOAT
A4CDOPD - OA4CDOP	OA4CDOP_C	NUMBER
	OA4CDOP	VARCHAR2
ECHOCOM	ECHOCOM	VARCHAR2
	ECHOCOM_ND	VARCHAR2
Key: [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HF_INDIE: PATIENT PREFERENCE (PREF) [frPREF]	
Patient Preference [stPREF1]	
1. * <input checked="" type="checkbox"/> Patient response to question during which study phase did you feel better? [Patient response to question during which study phase did you feel better]	[PTPREF] [N: 1] <input type="radio"/> Phase 1 [N: 2] <input type="radio"/> Phase 2 [N: 3] <input type="radio"/> No Preference [N: 97] <input type="radio"/> Not Done
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

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

HF_INDIE: WEEK 15 PATIENT RESPONSE (RESPONSE) [frRESPONSE]		
Patient Response [stRESPONSE1]		
1.* ✓	Since you have had 2 weeks to think about this, in which study phase did you feel better? [In which study phase did you feel better]	[STYPHS] [N: 1] <input type="radio"/> Phase 1 [N: 2] <input type="radio"/> Phase 2 [N: 3] <input type="radio"/> No Preference [N: 97] <input type="radio"/> Not Done
2.* ✓	As compared to the phase that you felt better in how do you feel now? (choose 1) [How do you feel now]	[PTRS] [N: 1] <input type="radio"/> Much worse [N: 2] <input type="radio"/> Slightly worse [N: 3] <input type="radio"/> Same [N: 4] <input type="radio"/> Slightly better [N: 5] <input type="radio"/> Much better [N: 97] <input type="radio"/> Not Done
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

RDE Analytics: RD_FRRESPONSE		
Data Variable RefName	RD Column Name	Column Data Type
STYPHS	STYPHS_C	NUMBER
	STYPHS	VARCHAR2
	STYPHS_ND	VARCHAR2
PTRS	PTRS_C	NUMBER
	PTRS	VARCHAR2
	PTRS_ND	VARCHAR2

HF_INDIE: PHONE VISIT LOG (PHONE) - Repeating Form [frPHONE]	
#	Phone Visit Performed
1	Phone Visit Date
Phone Visit [stPHONE1]	
1.* ☑	<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> Phone Visit Performed [Phone Visit Performed] </div> <div style="width: 48%;"> [PHONEVT] [N: 99] <input type="radio"/> Screen Failure 2-Week Follow-Up Call [N: 1] <input type="radio"/> Phase 1: Day 4-7 Telephone Visit [N: 2] <input type="radio"/> Phase 1: Day 11-14 Telephone Visit [N: 3] <input type="radio"/> Phase 1: Day 17 Telephone Visit [N: 4] <input type="radio"/> Phase 1: Day 18-21 Telephone Visit [N: 5] <input type="radio"/> Phase 1: Day 23-24 Telephone Visit [N: 6] <input type="radio"/> Phase 1: Day 25-28 Telephone Visit [N: 7] <input type="radio"/> Phase 1: Day 32-35 Telephone Visit [N: 8] <input type="radio"/> Phase 1: Day 38-41 Telephone Visit [N: 9] <input type="radio"/> Phase 2: Day 4-7 Telephone Visit [N: 10] <input type="radio"/> Phase 2: Day 11-14 Telephone Visit [N: 11] <input type="radio"/> Phase 2: Day 17 Telephone Visit [N: 12] <input type="radio"/> Phase 2: Day 18-21 Telephone Visit [N: 13] <input type="radio"/> Phase 2: Day 23-24 Telephone Visit [N: 14] <input type="radio"/> Phase 2: Day 25-28 Telephone Visit [N: 15] <input type="radio"/> Phase 2: Day 32-35 Telephone Visit [N: 16] <input type="radio"/> Phase 2: Day 38-41 Telephone Visit </div> </div>
2.* ☑	<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> Phone Visit Date [Phone Visit Date] </div> <div style="width: 48%;"> [PHONDT] Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2016-2018) </div> </div>
Key: [*] - Item is required [☑] - Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

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

HF_INDIE: STUDY DRUG DOSING LOG (DRGDOSE) [frDRGDOSE]				
1. ✓	Start Date/Time	Phase	Dose	Primary Reason for Dose Change
Drug Dosing Log Entry [rsDRGDOSE1]				
1.1 ✓	Dose Change Date/Time [Start Date/Time]			[SDSTDT] Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2016-2018) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock
1.2 ✓	Current study phase [Phase]			[STDYPHSE] [N:1] <input type="radio"/> Phase 1 [N:2] <input type="radio"/> Phase 2
1.3 ✓	Dose [Dose]			[SDRGDOSE] [N:1] <input type="radio"/> 46 mg [N:2] <input type="radio"/> 80 mg [N:3] <input type="radio"/> End of Study Phase [N:4] <input type="radio"/> Temporary discontinuation [N:5] <input type="radio"/> Study drug stopped prior to end of phase [N:98] <input type="radio"/> [DRGDSOTS] Other, specify: <input type="text" value="A100"/>
1.4 ✓	Primary Reason for Dose Change or Discontinuation [Primary Reason for Dose Change]			[CHGREAS] [N:2] <input type="radio"/> Per protocol [N:3] <input type="radio"/> [AERXSP] Adverse reaction, specify (complete AE or EVNTINT Form): <input type="text" value="A12B"/> [DRGSAE] Is this a Serious Adverse event? [N:1] <input type="radio"/> [DRGSAENO] Yes SAE Number (from SAE form) <input type="text" value="A4"/> [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown [N:98] <input type="radio"/> [CHGRSSP] Other, specify: <input type="text" value="A100"/>

Key: [*] = Item is required [✓] = Source verification required
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

RDE Analytics: RD_FRDRGDOSE		
Data Variable RefName	RD Column Name	Column Data Type
RD_FRDRGDOSE_RSDRGDOSE1		
SDSTDT	SDSTDT	DATE
	SDSTDT_DTS	VARCHAR2
	SDSTDT_DTR	VARCHAR2
	SDSTDT_ND	VARCHAR2
STDYPHSE	STDYPHSE_C	NUMBER
	STDYPHSE	VARCHAR2
	STDYPHSE_ND	VARCHAR2
SDRGDOSE	SDRGDOSE_C	NUMBER
	SDRGDOSE	VARCHAR2
	SDRGDOSE_ND	VARCHAR2
SDRGDOSE - DRGDSOTS	DRGDSOTS	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.

HF_INDIE: DRUG KIT DISPENSING (DRUGKIT) - Repeating Form [frDRUGKIT]			
#	Date dispensed	Kit #	Reason dispensed
1			
Drug Kit dispensed [stDRUGKIT1]			
1.* ✓	Date kit dispensed [Date dispensed]	[DISPDT] Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2016-2018)	
2.* ✓	Kit number [Kit #]	[KITNUM] N5	
3.* ✓	Reason dispensed: [Reason dispensed]	[DISPREAS] [N: 1] <input type="radio"/> Study Visit 1 (Baseline) [N: 3] <input type="radio"/> Study Visit 2 [N: 2] <input checked="" 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 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.			

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

HF_INDIE: ACCELEROMETER LOG (AXM) [frAXM]							
Accelerometer [stAXM1]							
1.* ✓	Was accelerometer dispensed? [Was accelerometer dispensed]			[ACCDISP] [N: 1] <input type="radio"/> Yes (click Add Entry to record each Accelerometer dispensed) [N: 0] <input checked="" type="radio"/> [ACCNDRSN] No If No, specify reason: [N: 1] <input type="radio"/> Subject withdrew consent [N: 98] <input checked="" type="radio"/> [ACCNDSP] Other Specify: A200			
	Serial Number 1	Serial Number 2	Accelerometer Dispense Date	Phase	Replaced	Accelerometer Returned	Received by Core Lab
2. ✓							
Accelerometer Details Entry [rsAXM2]							
2.1* ✓	Accelerometer Serial Number #1 [Serial Number 1]			[ACCSN1] A20			
2.2* ✓	Accelerometer Serial Number #2 [Serial Number 2]			[ACCSN2] A20			
2.3* ✓	Accelerometer Dispense Date [Accelerometer Dispense Date]			[ACCDSDT] Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018)			
2.4 ✓	Phase Dispensed [Phase]			[RPCPHASE] [N: 1] <input type="radio"/> Phase 1 [N: 2] <input type="radio"/> Phase 2			
2.5 ✓	Was this an unscheduled/replacement device? [Replaced]			[ACCRPLC] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No			
2.6 ✓	Was Accelerometer Returned? [Accelerometer Returned]			[ACCRT] [N: 1] <input checked="" type="radio"/> [cpACDT] Yes [ACCRDT] Date Returned: Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018) [ACSDTDT] Date Sent to Core Lab: Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018) [FEDEXNUM] Fed Ex tracking number: A20 [N: 0] <input type="radio"/> No			
2.7	Received by Core Lab? [Received by Core Lab]			[ACCCDT] [N: 1] <input checked="" type="radio"/> [ACCRCDT] Yes Date Received: Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018) [N: 0] <input type="radio"/> No			
2.8	Comments [Lab Comments]			[ACCCOMM] A200			
Key: [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.							

RDE Analytics: RD_FRAXM		
Data Variable RefName	RD Column Name	Column Data Type
ACCDISP	ACCDISP_C	NUMBER
	ACCDISP	VARCHAR2
	ACCDISP_ND	VARCHAR2
ACCDISP - ACCNDRSN	ACCNDRSN_C	NUMBER
	ACCNDRSN	VARCHAR2
ACCDISP - ACCNDSP	ACCNDSP	VARCHAR2
RD_FRAXM_RSAXM2		
ACCSN1	ACCSN1	VARCHAR2
	ACCSN1_ND	VARCHAR2
ACCSN2	ACCSN2	VARCHAR2
	ACCSN2_ND	VARCHAR2
ACCDSDT	ACCDSDT	DATE
	ACCDSDT_DTS	VARCHAR2
	ACCDSDT_ND	VARCHAR2
RPCPHASE	RPCPHASE_C	NUMBER
	RPCPHASE	VARCHAR2
	RPCPHASE_ND	VARCHAR2
ACCRPLC	ACCRPLC_C	NUMBER

	ACCRPLC	VARCHAR2
	ACCRPLC_ND	VARCHAR2
ACCRT	ACCRT_C	**NUMBER
	ACCRT	VARCHAR2
	ACCRT_ND	VARCHAR2
ACCRT - ACCRTDT	ACCRTDT	DATE
	ACCRTDT_DTS	VARCHAR2
	ACCRTDT_DTR	VARCHAR2
ACCRT - ACSDTDT	ACSDTDT	DATE
	ACSDTDT_DTS	VARCHAR2
	ACSDTDT_DTR	VARCHAR2
ACCRT - FEDEXNUM	FEDEXNUM	VARCHAR2
ACCCDT	ACCCDT_C	**NUMBER
	ACCCDT	VARCHAR2
	ACCCDT_ND	VARCHAR2
ACCCDT - ACCRCDT	ACCRCDT	DATE
	ACCRCDT_DTS	VARCHAR2
	ACCRCDT_DTR	VARCHAR2
ACCCOMM	ACCCOMM	VARCHAR2
	ACCCOMM_ND	VARCHAR2
Key: [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HF_INDIE: NEBULIZER LOG (NEB) [frNEB]										
Nebulizer [stNEB1]										
1. *	Was nebulizer dispensed? [Was nebulizer dispensed]				[NEBDISP] [N: 1] <input checked="" type="radio"/> Yes (click Add Entry to record each Nebulizer dispensed) [N: 0] <input type="radio"/> [NEBDRSN] No If No, specify reason: [N: 1] <input type="radio"/> Subject withdrew consent [N: 98] <input type="radio"/> [NEBNDSP] Other Specify: A200					
2. *	Nebulizer Serial Number	Nebulizer Dispense Date	Replaced	Nebulizer Returned	Adherence data downloaded at Visit 2	Estimated Phase 1 Compliance	Adherence data downloaded at Visit 3	Estimated Phase 2 Compliance	Date Phase 2 downloaded	Date Phase 3 downloaded
Nebulizer Details Entry [rsNEB2]										
2.1 *	Nebulizer Serial Number [Nebulizer Serial Number]				[NEBSN] A20					
2.2 *	Nebulizer Dispense Date [Nebulizer Dispense Date]				[NEBDSDT] Req [v] / Req [v] / Req [v] (2016-2018)					
2.3	Was this an unscheduled/replacement Nebulizer? [Replaced]				[NEBRPLC] [N: 1] <input type="radio"/> [NEBRPCPH] Yes During which phase was the Unscheduled/Replacement device provided? [N: 1] <input type="radio"/> Phase 1 [N: 2] <input type="radio"/> Phase 2 [N: 0] <input type="radio"/> No					
2.4	Was Nebulizer Returned? [Nebulizer Returned]				[NEBRT] [N: 1] <input type="radio"/> [NEBRTDT] Yes Date Returned: Req/Unk [v] / Req [v] / Req [v] (2016-2018) [N: 0] <input type="radio"/> No					
2.5	Was adherence data downloaded at Visit 2? [Adherence data downloaded at Visit 2]				[DATADWN2] [N: 1] <input type="radio"/> [cpDATADWN2] Yes [DOWN2DT] Date of download: Req [v] / Req [v] / Req [v] (2016-2018) [DCC2DT] Date submitted to DCC: Req [v] / Req [v] / Req [v] (2016-2018) [N: 0] <input type="radio"/> [DATANO2] No Reason: [N: 1] <input type="radio"/> Subject did not bring device [N: 2] <input type="radio"/> Unwilling to perform but subjectively able [N: 98] <input type="radio"/> [DATASPF2] Other, specify: A200					
2.6	Estimated Phase 1 Compliance [Estimated Phase 1 Compliance]				[PHSE1COM] [N: 1] <input type="radio"/> Not at all compliant [N: 2] <input type="radio"/> Somewhat compliant [N: 3] <input type="radio"/> Very compliant					
2.7	Was adherence data downloaded at Visit 3? [Adherence data downloaded at Visit 3]				[DATADWN3] [N: 1] <input type="radio"/> [cpDATADWN3] Yes [DOWN3DT] Date of download: Req [v] / Req [v] / Req [v] (2016-2018) [DCC3DT] Date submitted to DCC: Req [v] / Req [v] / Req [v] (2016-2018) [N: 0] <input type="radio"/> [DATANO3] No Reason: [N: 1] <input type="radio"/> Subject did not bring device [N: 2] <input type="radio"/> Unwilling to perform but subjectively able [N: 98] <input type="radio"/> [DATASPF3] Other, specify: A200					
2.8	Estimated Phase 2 Compliance [Estimated Phase 2 Compliance]				[PHSE2COM] [N: 1] <input type="radio"/> Not at all compliant [N: 2] <input type="radio"/> Somewhat compliant [N: 3] <input type="radio"/> Very compliant					

2.9	Date Phase 2 adherence data downloaded: [Date Phase 2 downloaded]	[PH2DWNDT] Req [v] / Req [v] / Req [v] (2016-2018)
2.10	Date Phase 3 adherence data downloaded: [Date Phase 3 downloaded]	[PH3DWNDT] Req [v] / Req [v] / Req [v] (2016-2018)
Key: [v] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

RDE Analytics: RD_FRNEB		
Data Variable RefName	RD Column Name	Column Data Type
NEBDISP	NEBDISP_C	NUMBER
	NEBDISP	VARCHAR2
	NEBDISP_ND	VARCHAR2
NEBDISP - NEBDRSN	NEBDRSN_C	NUMBER
	NEBDRSN	VARCHAR2
NEBDISP - NEBNDSP	NEBNDSP	VARCHAR2
RD_FRNEB_RSNEB2		
NEBSN	NEBSN	VARCHAR2
	NEBSN_ND	VARCHAR2
NEBDSDT	NEBDSDT	DATE
	NEBDSDT_DTS	VARCHAR2
	NEBDSDT_ND	VARCHAR2
NEBRPLC	NEBRPLC_C	**NUMBER
	NEBRPLC	VARCHAR2
	NEBRPLC_ND	VARCHAR2
NEBRPLC - NEBRPCPH	NEBRPCPH_C	NUMBER
	NEBRPCPH	VARCHAR2
NEBRT	NEBRT_C	**NUMBER
	NEBRT	VARCHAR2
	NEBRT_ND	VARCHAR2
NEBRT - NEBRDT	NEBRDT	DATE
	NEBRDT_DTS	VARCHAR2
	NEBRDT_DTR	VARCHAR2
DATADWN2	DATADWN2_C	**NUMBER
	DATADWN2	VARCHAR2
	DATADWN2_ND	VARCHAR2
DATADWN2 - DOWN2DT	DOWN2DT	DATE
	DOWN2DT_DTS	VARCHAR2
DATADWN2 - DCC2DT	DCC2DT	DATE
	DCC2DT_DTS	VARCHAR2
DATADWN2 - DATANO2	DATANO2_C	NUMBER
	DATANO2	VARCHAR2
DATADWN2 - DATASPF2	DATASPF2	VARCHAR2
PHSE1COM	PHSE1COM_C	NUMBER
	PHSE1COM	VARCHAR2
	PHSE1COM_ND	VARCHAR2
DATADWN3	DATADWN3_C	**NUMBER
	DATADWN3	VARCHAR2
	DATADWN3_ND	VARCHAR2
DATADWN3 - DOWN3DT	DOWN3DT	DATE
	DOWN3DT_DTS	VARCHAR2
DATADWN3 - DCC3DT	DCC3DT	DATE
	DCC3DT_DTS	VARCHAR2
DATADWN3 - DATANO3	DATANO3_C	NUMBER
	DATANO3	VARCHAR2
DATADWN3 - DATASPF3	DATASPF3	VARCHAR2
PHSE2COM	PHSE2COM_C	NUMBER
	PHSE2COM	VARCHAR2
	PHSE2COM_ND	VARCHAR2
PH2DWNDT	PH2DWNDT	DATE
	PH2DWNDT_DTS	VARCHAR2
	PH2DWNDT_ND	VARCHAR2
PH3DWNDT	PH3DWNDT	DATE
	PH3DWNDT_DTS	VARCHAR2
	PH3DWNDT_ND	VARCHAR2

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

HF_INDIE: DEVICE DEFICIENCY (DEVDEF) - Repeating Form [frDEVDEF]						
#	Device Deficiency #	Nebulizer Serial #	Deficiency Date	Deficiency Type	Medical Effect	Narrative
1						
Device Information [stDEVDEF1]						
1.*	Device Deficiency Number (non-enterable field) [Device Deficiency #]			[DEVDFNUM] A4		
2.*	Nebulizer Serial Number [Nebulizer Serial #]			[NEBSRNUM] A20		
3.*	Date deficiency occurred [Deficiency Date]			[DEFDT] Req/Unk / Req/Unk / Req (2016-2018)		
4.*	Type of device deficiency [Deficiency Type]			[DEVFAIL] [N: 1] [DEVFAILS] Device Delivery Failure Specify: A100 [N: 7] [DEVFOSP] Other, specify A100		
5.*	Medical occurrence, disease or injury [Medical Effect]			[cpODI] [ODINON] [N: 1] <input type="checkbox"/> None [ODISUB] [N: 1] <input type="checkbox"/> [DEVAELNK] Affecting subject (complete AE Form) Adverse Event #: A4 [ODIOTH] [N: 1] <input type="checkbox"/> [ODIOTHSP] Other, specify A100		
6.*	Narrative [Narrative]			[DEVNARR] A200		

Key: [*] = Item is required [✓] = Source verification required
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RDE Analytics: RD_FRDEVDEF		
Data Variable RefName	RD Column Name	Column Data Type
DEVDFNUM	DEVDFNUM	VARCHAR2
	DEVDFNUM_ND	VARCHAR2
NEBSRNUM	NEBSRNUM	VARCHAR2
	NEBSRNUM_ND	VARCHAR2
DEFDT	DEFDT	DATE
	DEFDT_DTS	VARCHAR2
	DEFDT_DTR	VARCHAR2
	DEFDT_ND	VARCHAR2
DEVFAIL	DEVFAIL_C	**NUMBER
	DEVFAIL	VARCHAR2
	DEVFAIL_ND	VARCHAR2
DEVFAIL - DEVFAILS	DEVFAILS	VARCHAR2
DEVFAIL - DEVFOSP	DEVFOSP	VARCHAR2
cpODI	CPODI_ND	VARCHAR2
cpODI - None	ODINON_CINONE_C	NUMBER
	ODINON_CINONE	VARCHAR2
cpODI - Yes	ODISUB_DEVAELNK_C	**NUMBER
	ODISUB_DEVAELNK	VARCHAR2
cpODI - DEVAELNK	DEVAELNK	VARCHAR2
cpODI - ODIOTHSP	ODIOTH_ODIOTHSP_C	**NUMBER
	ODIOTH_ODIOTHSP	VARCHAR2
cpODI - ODIOTHSP	ODIOTHSP	VARCHAR2
DEVNARR	DEVNARR	VARCHAR2
	DEVNARR_ND	VARCHAR2

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

HF_INDIE: REHOSPITALIZATION (REHOSP) - Repeating Form [frREHOSP]													
#	Admission Date	Unplanned?	Discharge Date	Primary reason for admission	Contributing causes	Clinical manifestations	Biomarker or radiographic evidence	Pharmacologic or mechanical interventions	Heart Cath?	Revascularization	Pacemaker/ICD	Heart Transplant	LVAD
Please ensure a corresponding Event of Interest or AE/SAE is entered on the applicable form.													
Hospitalization Information [stREHOSP1]													
1.*	Admission Date [Admission Date]					[ADMITDT] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018)							
2.*	Was this an unplanned hospitalization? [Unplanned?]					[ELECTAD] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No							
3.*	Discharge Date [Discharge Date]					[INREHOSP] [N: 1] <input type="radio"/> [REDCDGT] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018) [N: 2] <input type="radio"/> Remains hospitalized [N: 3] <input type="radio"/> Subject died while hospitalized							
4.*	Primary reason for admission [Primary reason for admission]					[HOSPRS] [N: 1] <input type="radio"/> Heart failure [N: 2] <input type="radio"/> Acute coronary syndrome [N: 3] <input type="radio"/> Cerebral Vascular Accident (CVA)/stroke [N: 4] <input type="radio"/> Atrial arrhythmia [N: 5] <input type="radio"/> Ventricular arrhythmia [N: 6] <input type="radio"/> Sudden death with resuscitation [N: 7] <input type="radio"/> [PRMCRDSP] Other cardiovascular Specify: A100 [N: 8] <input type="radio"/> [PRMNCSP] Other non-cardiovascular Specify: A100							
5.	Contributing causes (check all that apply) [Contributing causes]					[epCONCAUS] [CONHF] [N: 1] <input type="checkbox"/> Heart failure [CONACS] [N: 1] <input type="checkbox"/> Acute coronary syndrome [CONCVA] [N: 1] <input type="checkbox"/> Cerebral Vascular Accident (CVA)/stroke [CONARRH] [N: 1] <input type="checkbox"/> Atrial arrhythmia [CONVENTA] [N: 1] <input type="checkbox"/> Ventricular arrhythmia [RENFAIL] [N: 1] <input type="checkbox"/> Renal Failure [CONSDTH] [N: 1] <input type="checkbox"/> Sudden death with resuscitation [CONOTHC] [N: 1] <input type="checkbox"/> Other cardiovascular [CONOTHNC] [N: 1] <input type="checkbox"/> Other non-cardiovascular							
6.*	Indicate any clinical manifestations of heart failure that occurred during this hospitalization (check all that apply) [Clinical manifestations]					[MANIFEST] [N: 1] <input type="radio"/> [epMANIFEST] [HFDYSP] [N: 1] <input type="checkbox"/> Dyspnea [HFORTHO] [N: 1] <input type="checkbox"/> Orthopnea [HFNOCVYS] [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"/> Heart sound gallop rhythm [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 type="radio"/> None							
7.*	Indicate any Biomarker or radiographic evidence consistent with heart failure during this hospitalization (check all that apply)					[RADIOEV] [N: 1] <input type="radio"/> [epRADIOEV]							

	[Biomarker or radiographic evidence]	<p>[I NCBNP] <i>[N: 1]</i> <input type="checkbox"/> Documented increased or increasing levels of a natriuretic peptide (BNP or NTproBNP)</p> <p>[HFIMGING] <i>[N: 1]</i> <input type="checkbox"/> Documented worsening pulmonary congestion or pulmonary edema on chest X-ray or other generally recognized imaging pattern.</p> <p>[BIOOTH] <i>[N: 1]</i> <input type="checkbox"/> [BIOOTHSP] Other, specify <input type="text" value="A100"/></p> <p>[BIOUNK] <i>[N: 1]</i> <input type="checkbox"/> Unknown <i>[N: 0]</i> <input type="radio"/> None</p>
8.* ✓	Indicate any additional or increased pharmacologic or mechanical interventions directed at the treatment of heart failure during this hospitalization (check all that apply) [Pharmacologic or mechanical interventions]	<p>[PHARMINT] <i>[N: 1]</i> <input checked="" type="radio"/> [cpPHARMINT] [I NITHRPPY] <i>[N: 1]</i> <input type="checkbox"/> Initiation of intravenous diuretic, inotropic, or vasodilator therapy</p> <p>[ORLTHPPY] <i>[N: 1]</i> <input type="checkbox"/> Significant addition or increase in oral heart failure therapy</p> <p>[UPTI TRTE] <i>[N: 1]</i> <input type="checkbox"/> Up-titration of intravenous therapy, if already on therapy</p> <p>[MECHSURG] <i>[N: 1]</i> <input type="checkbox"/> Initiation of mechanical or surgical intervention to improve cardiac function), or the use of ultrafiltration, hemofiltration, or dialysis that is specifically directed at treatment of heart failure.</p> <p>[OTHINTVN] <i>[N: 1]</i> <input type="checkbox"/> [INTVNSP] Other, specify <input type="text" value="A100"/></p> <p>[INTVUNK] <i>[N: 1]</i> <input type="checkbox"/> Unknown <i>[N: 0]</i> <input type="radio"/> None</p>
9.* ✓	Was a heart catheterization performed? [Heart Cath?]	<p>[PROCATH] <i>[N: 1]</i> <input checked="" type="radio"/> [cpPROCATH] Yes [LCATH] <i>[N: 1]</i> <input type="checkbox"/> Left [RCATH] <i>[N: 1]</i> <input type="checkbox"/> Right <i>[N: 0]</i> <input type="radio"/> No <i>[N: 99]</i> <input checked="" type="radio"/> Unknown</p>
10.* ✓	Revascularization [Revascularization]	<p>[REVASC] <i>[N: 1]</i> <input checked="" type="radio"/> [cpREVASC] Yes [CABG] <i>[N: 1]</i> <input type="checkbox"/> CABG [PCI] <i>[N: 1]</i> <input type="checkbox"/> PCI <i>[N: 0]</i> <input type="radio"/> No <i>[N: 99]</i> <input checked="" type="radio"/> Unknown</p>
11.* ✓	Pacemaker/ICD [Pacemaker/ICD]	<p>[HOSPID] <i>[N: 1]</i> <input checked="" type="radio"/> [PACTYPE] Yes <i>[N: 1]</i> <input type="radio"/> Pacemaker (single/dual) <i>[N: 2]</i> <input type="radio"/> Biventricular Pacemaker with ICD <i>[N: 3]</i> <input type="radio"/> Biventricular Pacemaker without ICD <i>[N: 4]</i> <input type="radio"/> ICD only (single/dual) <i>[N: 0]</i> <input type="radio"/> No <i>[N: 99]</i> <input checked="" type="radio"/> Unknown</p>
12.* ✓	Heart Transplant [Heart Transplant]	<p>[PROHTRAN] <i>[N: 1]</i> <input checked="" type="radio"/> [PRHTRDDT] Yes Date of Transplant: Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (2016-2018) <i>[N: 0]</i> <input type="radio"/> No <i>[N: 99]</i> <input checked="" type="radio"/> Unknown</p>
13.* ✓	LVAD [LVAD]	<p>[LVAD] <i>[N: 1]</i> <input checked="" type="radio"/> [LVADDT] Yes Date of Implant: Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (2016-2018) <i>[N: 0]</i> <input type="radio"/> No <i>[N: 99]</i> <input checked="" type="radio"/> Unknown</p>

Key: [*] = Item is required [✓] = Source verification required
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

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	VARCHAR2
	ELECTAD_ND	VARCHAR2
INREHOSP	INREHOSP_C	**NUMBER
	INREHOSP	VARCHAR2
	INREHOSP_ND	VARCHAR2
INREHOSP - REDCHGDT	REDCHGDT	DATE
	REDCHGDT_DTS	VARCHAR2
	REDCHGDT_DTR	VARCHAR2
HOSPRS	HOSPRS_C	NUMBER
	HOSPRS	VARCHAR2
	HOSPRS_ND	VARCHAR2
HOSPRS - PRMCRDSP	PRMCRDSP	VARCHAR2
HOSPRS - PRMNCSP	PRMNCSP	VARCHAR2
cpCONCAUS	CPCONCAUS_ND	VARCHAR2
cpCONCAUS - Heart failure	CONHF_CIHEARTFAILURE_C	NUMBER
	CONHF_CIHEARTFAILURE	VARCHAR2
cpCONCAUS - Acute coronary syndrome	*CONACS_CIACUTECORONARYSYNDROME1_C	NUMBER
	*CONACS_CIACUTECORONARYSYNDROME1	VARCHAR2
cpCONCAUS - Cerebral Vascular Accident (CVA)/stroke	*CONCVA_CICEREBRALVASCULARACCIDENT1_C	NUMBER
	*CONCVA_CICEREBRALVASCULARACCIDENT1	VARCHAR2
cpCONCAUS - Atrial arrhythmia	*CONARRH_CIATRIALARRHYTHMIA1_C	NUMBER
	*CONARRH_CIATRIALARRHYTHMIA1	VARCHAR2
cpCONCAUS - Ventricular arrhythmia	*CONVENTA_CIVENTRICULARARRHYTHMIA1_C	NUMBER
	*CONVENTA_CIVENTRICULARARRHYTHMIA1	VARCHAR2
cpCONCAUS - Renal Failure	RENFAIL_CIRENALFAILURE_C	NUMBER
	RENFAIL_CIRENALFAILURE	VARCHAR2
cpCONCAUS - Sudden death with resuscitation	*CONSDTH_CISUDDENDEATHRESUSCITATION1_C	NUMBER
	*CONSDTH_CISUDDENDEATHRESUSCITATION1	VARCHAR2
cpCONCAUS - Other cardiovascular	*CONOTH_CCIOTHERCARDIOVASCULAR1_C	NUMBER
	*CONOTH_CCIOTHERCARDIOVASCULAR1	VARCHAR2
cpCONCAUS - Other non-cardiovascular	*CONOTHNC_CIOTHERNONCARDIOVASCULAR1_C	NUMBER
	*CONOTHNC_CIOTHERNONCARDIOVASCULAR1	VARCHAR2
MANIFEST	MANIFEST_C	**NUMBER
	MANIFEST	VARCHAR2
	MANIFEST_ND	VARCHAR2
MANIFEST - Dyspnea	HFDYSP_CIDYSPNEA_C	NUMBER
	HFDYSP_CIDYSPNEA	VARCHAR2
MANIFEST - Orthopnea	HFORTHO_CIORTHOPNEA1_C	NUMBER
	HFORTHO_CIORTHOPNEA1	VARCHAR2
MANIFEST - Paroxysmal nocturnal dyspnea	*HFNOCDYS_CIPAROXYSMALNOCTURNALDYSPNEA1_C	NUMBER
	*HFNOCDYS_CIPAROXYSMALNOCTURNALDYSPNEA1	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 - Heart sound gallop rhythm	*HFGALLOP_CIHEARTSOUNDGALLOPRHYTHM_C	NUMBER
	*HFGALLOP_CIHEARTSOUNDGALLOPRHYTHM	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_CIINCREASEDNATRIURETICPEPTIDE_C	NUMBER
	*INCBNP_CIINCREASEDNATRIURETICPEPTIDE	VARCHAR2
RADIOEV - Documented worsening pulmonary congestion or pulmonary edema on chest X-ray or other generally recognized imaging pattern.	*HFIMGING_CIDOCWORSENINGPULMONARYCONGESTION_C	NUMBER
	*HFIMGING_CIDOCWORSENINGPULMONARYCONGESTION	VARCHAR2
RADIOEV - Other	BIOOTH_BIOOTHSP_C	**NUMBER

	BIOOTH_BIOOTHSP	VARCHAR2
RADIOEV - BIOOTHSP	BIOOTHSP	VARCHAR2
RADIOEV - Unknown	BIOUNK_CIUNKNOWN1_C	NUMBER
	BIOUNK_CIUNKNOWN1	VARCHAR2
PHARMINT	PHARMINT_C	**NUMBER
	PHARMINT	VARCHAR2
	PHARMINT_ND	VARCHAR2
PHARMINT - Initiation of intravenous diuretic, inotropic, or vasodilator therapy	*INITHRPY_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_CIUPTITRATIONINTRAVENOUSTHERAPY_C	NUMBER
	*UPTITRTE_CIUPTITRATIONINTRAVENOUSTHERAPY	VARCHAR2
PHARMINT - Initiation of mechanical or surgical intervention to improve cardiac function), or the use of ultrafiltration, hemofiltration, or dialysis that is specifically directed at treatment of heart failure.	*MECHSURG_CIINITIATIONMECHSURGICALINTERVENTION_C	NUMBER
	*MECHSURG_CIINITIATIONMECHSURGICALINTERVENTION	VARCHAR2
PHARMINT - Other	OTHINTVN_INTVNSP_C	**NUMBER
	OTHINTVN_INTVNSP	VARCHAR2
	INTVNSP	VARCHAR2
PHARMINT - INTVNSP	INTVNSP	VARCHAR2
PHARMINT - Unknown	INTVUNK_CIUNKNOWN1_C	NUMBER
	INTVUNK_CIUNKNOWN1	VARCHAR2
PROCATH	PROCATH_C	**NUMBER
	PROCATH	VARCHAR2
	PROCATH_ND	VARCHAR2
PROCATH - Left	LCATH_CILEFT_C	NUMBER
	LCATH_CILEFT	VARCHAR2
PROCATH - Right	RCATH_CIRIGHT_C	NUMBER
	RCATH_CIRIGHT	VARCHAR2
REVASC	REVASC_C	**NUMBER
	REVASC	VARCHAR2
	REVASC_ND	VARCHAR2
REVASC - CABG	CABG_CICABG_C	NUMBER
	CABG_CICABG	VARCHAR2
REVASC - PCI	PCI_CIPCI_C	NUMBER
	PCI_CIPCI	VARCHAR2
HOSPICD	HOSPICD_C	**NUMBER
	HOSPICD	VARCHAR2
	HOSPICD_ND	VARCHAR2
HOSPICD - PACTYPE	PACTYPE_C	NUMBER
	PACTYPE	VARCHAR2
PROHTRAN	PROHTRAN_C	**NUMBER
	PROHTRAN	VARCHAR2
	PROHTRAN_ND	VARCHAR2
PROHTRAN - PRHTRDDT	PRHTRDDT	DATE
	PRHTRDDT_DTS	VARCHAR2
	PRHTRDDT_DTR	VARCHAR2
LVAD	LVAD_C	**NUMBER
	LVAD	VARCHAR2
	LVAD_ND	VARCHAR2
LVAD - LVADDT	LVADDT	DATE
	LVADDT_DTS	VARCHAR2
	LVADDT_DTR	VARCHAR2
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.		

HF_INDIE: EMERGENCY DEPARTMENT VISIT (EDVISIT) - Repeating Form [frEDVISIT]	
#	Encounter Date Primary reason for emergency department visit
1	
Please ensure a corresponding Event of Interest or AE/SAE is entered on the applicable form.	
ED Visit Information [stEDVISIT1]	
1.* <input checked="" type="checkbox"/> Encounter Date [Encounter Date]	[UNSCHDT] Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2018)
2.* <input checked="" type="checkbox"/> 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"/> [OTHCRDSP] Other cardiovascular Specify: <input style="width: 250px; height: 15px;" type="text"/> A100 [N:3] <input type="radio"/> [OTHNONSP] Other non-cardiovascular Specify: <input style="width: 250px; height: 15px;" type="text"/> A100
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

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
UNSCREAS - OTHCRDSP	OTHCRDSP	VARCHAR2
UNSCREAS - OTHNONSP	OTHNONSP	VARCHAR2

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

HF_INDIE: EVENTS OF INTEREST (EVNTINT) - Repeating Form [frEVNTINT]

#	Anticipated, disease-related event:	Onset Date
1		
Anticipated Disease Related Events [stEVNTINT1]		
1.* ✓	Anticipated, disease-related event: [Anticipated, disease-related event:]	<p>[EVNTTYPE]</p> <p>[N: 1] <input checked="" type="radio"/> [ARRHYTYP] Arrhythmias Type of Arrhythmia: [A50]</p> <p>[N: 3] <input type="radio"/> Acute coronary syndrome</p> <p>[N: 4] <input type="radio"/> Unplanned hospitalization, ER visit or clinic visit for worsening heart failure</p> <p>[N: 5] <input type="radio"/> Cerebrovascular event</p> <p>[N: 6] <input type="radio"/> Venous thromboembolism</p> <p>[N: 8] <input type="radio"/> Worsening renal function</p>
2.* ✓	Onset Date [Onset Date]	<p>[EVNTDT]</p> <p>Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2016-2018)</p>
<p>Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.</p>		

RDE Analytics: RD_FREVNTINT

Data Variable RefName	RD Column Name	Column Data Type
EVNTTYPE	EVNTTYPE_C	**NUMBER
	EVNTTYPE	VARCHAR2
	EVNTTYPE_ND	VARCHAR2
EVNTTYPE - ARRHYTYP	ARRHYTYP	VARCHAR2
EVNTDT	EVNTDT	DATE
	EVNTDT_DTS	VARCHAR2
	EVNTDT_DTR	VARCHAR2
	EVNTDT_ND	VARCHAR2

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

HF_INDIE: Adverse Event (AE) - Repeating Form [frAE]																						
#	AE #	Onset Date/Time	Severity	Relationship to Study Drug	Relationship to Device	Device Deficiency	Device Deficiency Details	Outcome	Stop Date	Date/Time of Last Dose of Study Drug	Action Taken	AE diminish/abate	AE reappear	Possible alternate causes	Serious	AE Summary	Relevant Labs	Relevant Laboratory and Diagnostic Tests Details	On concomitant medications	Con Med Details	SAE verify	Evaluation date/time
1																						
If this is an anticipated disease related event, please do not complete this form. Instead, please complete the EVNTINT form.																						
Adverse Event/Serious Adverse Event [stAE1]																						
1.*	AE Number (non-enterable field) [read-only] [AE #]											[AENUM] A4										
2.*	AE Term [AE]											[AETERM] A100										
3.*	AE Onset Date and Time [Onset Date/Time]											[AESTDTC] Req/Unk / Req / Req (2016-2018) Req/Unk : Req/Unk 24-hour clock										
4.*	AE Severity [Severity]											[AESEV] [N:1] <input type="radio"/> Mild [N:2] <input type="radio"/> Moderate [N:3] <input type="radio"/> Severe										
5.*	Relationship of AE to Study Drug [Relationship to Study Drug]											[AEREL] [N:1] <input type="radio"/> Not related [N:2] <input type="radio"/> Unlikely related [N:3] <input type="radio"/> [PRRATREL] Possibly Related Rationale A100 [N:4] <input type="radio"/> [RRATREL] Related Rationale A100										
6.*	Relationship of AE to Device [Relationship to Device]											[DEVNTREL] [N:1] <input type="radio"/> Not related [N:2] <input type="radio"/> Unlikely related [N:3] <input type="radio"/> [DEVPSREL] Possibly Related Rationale A100 [N:4] <input type="radio"/> [DEVREL] Related Rationale A100										
Device Deficiency [stAE2]																						
7.*	Was this event the result of a device deficiency (Delivery Failure, Malfunction, User Error, Inadequate Labeling, Improper/Inadequate Design, Manufacturer Error)? [Device Deficiency]											[AEDEVDEF] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No										
8.*	Device Deficiency #:																					
Device Deficiency Details Entry [rsAE3]																						
8.1*	Device Deficiency # (refer to Question 1 on DEVDEF form). [Device Deficiency #:]											[AEDEFNUM] Device Deficiency #: A4										
Additional AE Information [stAE4]																						
9.*	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										
10.*	AE Stop Date and Time [Stop Date]											[AEONGO] [N:1] <input type="radio"/> [AEENDTC] Req/Unk / Req/Unk / Req/Unk (2016-2018) Req/Unk : Req/Unk 24-hour clock [N:2] <input type="radio"/> Ongoing										
11.*	Date/Time of Last Dose of Study Drug (prior to Onset of AE) [Date/Time of Last Dose of Study Drug]											[TOOKDRUG] [N:1] <input type="radio"/> [AELSTDTC] Req/Unk / Req/Unk / Req/Unk (2016-2018) Req/Unk : Req/Unk 24-hour clock [N:2] <input type="radio"/> Never took drug										
12.*	Action taken regarding study drug [Action Taken]											[AEACN] [N:1] <input type="radio"/> None [N:2] <input type="radio"/> Dose reduced [N:3] <input type="radio"/> Dose increased [N:4] <input type="radio"/> [AEDINRD]										

		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 checked="" 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 [N: 0] <input type="radio"/> No [N: 96] <input type="radio"/> Not Applicable [N: 99] <input type="radio"/> Unknown [N: 96] <input type="radio"/> Not Applicable										
13.*	If study drug was discontinued, interrupted, or reduced (dechallenged), did AE diminish/abate? [AE diminish/abate]	[AEDIMTD] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 96] <input type="radio"/> Not Applicable										
14.*	If study drug was restarted (Rechallenge), did AE recur? [AE reappear]	[AERAPR] [N: 1] <input type="radio"/> Yes [N: 0] <input type="radio"/> No [N: 96] <input type="radio"/> Not Applicable										
15.*	Possible alternate causes of the AE (check all that apply): [Possible alternate causes]	[cpALTC AUS] [PRIMDIS] [N: 1] <input type="checkbox"/> Primary disease under study [CONCOMIL] [N: 1] <input type="checkbox"/> [LILNSPEC] Concomitant illness Specify: A200 [CONCOMED] [N: 1] <input type="checkbox"/> [CONSPEM] Concomitant medication Specify: A100 [OTHCAUS] [N: 1] <input type="checkbox"/> [OTHSPC] Other known or suspected cause Specify: A200 [ALTNONE] [N: 1] <input type="checkbox"/> None (Only applicable if study drug related and considered only cause of AE)										
16.*	Was this event serious? (If Yes, check all that apply) [Serious]	[AESER] [N: 1] <input checked="" type="radio"/> [cpSERICRIT] Yes [AESDTH] [N: 1] <input type="checkbox"/> Death [AESLIFE] [N: 1] <input type="checkbox"/> Life-Threatening [AESHOSP] [N: 1] <input type="checkbox"/> Hospitalization required or prolongation of existing hospitalization [AESDISAB] [N: 1] <input type="checkbox"/> Persistent or significant disability/incapacity [AESCONG] [N: 1] <input type="checkbox"/> Congenital anomaly or birth defect [AESMIE] [N: 1] <input type="checkbox"/> Important medical event [N: 0] <input type="radio"/> No										
Serious Adverse Event Summary												
17.*												
AE Summary Entry [rsAE5]												
17.1*	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. Subject's status at time of report and/or final outcome, as applicable [Serious Adverse Event Summary]	[NARSYMP] A200										
Relevant Laboratory and Diagnostic Tests [stAE6]												
18.*	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										
19.*	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:15%;">Date</th> <th style="width:20%;">Test</th> <th style="width:20%;">Result</th> <th style="width:10%;">Unit</th> <th style="width:35%;">Normal Range or Value</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Date	Test	Result	Unit	Normal Range or Value						
Date	Test	Result	Unit	Normal Range or Value								
Relevant Laboratory and Diagnostic Tests Details Entry [rsAE7]												
19.1*	Date and time [Date]	[DRAWDTM] Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (2016-2018) Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock										
19.2*	Test [Test]	[TESTNAM] A200										

19.3 [*] ✓	Result [Result]	[TESTRST] A200
19.4 [*] ✓	Unit (applicable for labs only) [Unit]	[TESTUNT] A200
19.5 [*] ✓	Normal range or value [Normal Range or Value]	[NRANGE] A200

Concomitant Medications [stAE8]

20. ✓	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												
21. ✓	<table border="1"> <thead> <tr> <th>Med Name</th> <th>Med Start Date</th> <th>Med Stop Date</th> <th>Medication Total Daily Dose</th> <th>Medication Unit</th> <th>Medication Indication</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Med Name	Med Start Date	Med Stop Date	Medication Total Daily Dose	Medication Unit	Medication Indication							
Med Name	Med Start Date	Med Stop Date	Medication Total Daily Dose	Medication Unit	Medication Indication									

Con Med Details Entry [rsAE9]

21.1 [*] ✓	Medication Name [Med Name]	[SAECMED] A50
21.2 [*] ✓	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
21.3 [*] ✓	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
21.4 [*] ✓	Medication Total Daily Dose [Medication Total Daily Dose]	[CONDOSE] xxxxxxx.
21.5 [*] ✓	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
21.6 [*] ✓	Indication [Medication Indication]	[MEDIIND] A200

Investigator Verification [stAE10]

22. ✓	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="radio"/> Yes
23. ✓	Evaluation date and time (electronic verification non-enterable system generated) [read-only] [Evaluation date/time]	[PI DATE] Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2013-2018) Req <input type="button" value="v"/> : Req <input type="button" value="v"/> 24-hour clock

Key: [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

RDE Analytics: RD_FRAE

Data Variable RefName	RD Column Name	Column Data Type
AENUM	AENUM	VARCHAR2
	AENUM_ND	VARCHAR2
AETERM	AETERM	VARCHAR2
	AETERM_ND	VARCHAR2
AESTDTC	AESTDTC	DATE
	AESTDTC_DTS	VARCHAR2
	AESTDTC_DTR	VARCHAR2
	AESTDTC_ND	VARCHAR2
AESEV	AESEV_C	NUMBER
	AESEV	VARCHAR2
	AESEV_ND	VARCHAR2
AEREL	AEREL_C	NUMBER
	AEREL	VARCHAR2

	AEREL_ND	VARCHAR2
AEREL - PRATREL	PRATREL	VARCHAR2
AEREL - RRATREL	RRATREL	VARCHAR2
DEVNTREL	DEVNTREL_C	NUMBER
	DEVNTREL	VARCHAR2
	DEVNTREL_ND	VARCHAR2
DEVNTREL - DEVPSREL	DEVPSREL	VARCHAR2
DEVNTREL - DEVREL	DEVREL	VARCHAR2
AEDEVDEF	AEDEVDEF_C	NUMBER
	AEDEVDEF	VARCHAR2
	AEDEVDEF_ND	VARCHAR2
AEOUT	AEOUT_C	NUMBER
	AEOUT	VARCHAR2
	AEOUT_ND	VARCHAR2
AEONGO	AEONGO_C	**NUMBER
	AEONGO	VARCHAR2
	AEONGO_ND	VARCHAR2
AEONGO - AEENDTC	AEENDTC	DATE
	AEENDTC_DTS	VARCHAR2
	AEENDTC_DTR	VARCHAR2
TOOKDRUG	TOOKDRUG_C	**NUMBER
	TOOKDRUG	VARCHAR2
	TOOKDRUG_ND	VARCHAR2
TOOKDRUG - AELSTDTM	AELSTDTM	DATE
	AELSTDTM_DTS	VARCHAR2
	AELSTDTM_DTR	VARCHAR2
AEACN	AEACN_C	NUMBER
	AEACN	VARCHAR2
	AEACN_ND	VARCHAR2
AEACN - AEDINRD	AEDINRD_C	NUMBER
	AEDINRD	VARCHAR2
AEACN - DCDTAE	DCDTAE_C	NUMBER
	DCDTAE	VARCHAR2
AEDIMTD	AEDIMTD_C	NUMBER
	AEDIMTD	VARCHAR2
	AEDIMTD_ND	VARCHAR2
	AERAPR	NUMBER
AERAPR	AERAPR_C	NUMBER
	AERAPR	VARCHAR2
	AERAPR_ND	VARCHAR2
cpALTCASUS	CPALTCASUS_ND	VARCHAR2
cpALTCASUS - Primary disease under study	*PRIMDIS_CIPRIMARYDISEASEUNDERSTUDY_C	NUMBER
	*PRIMDIS_CIPRIMARYDISEASEUNDERSTUDY	VARCHAR2
cpALTCASUS - Concomitant illness	CONCOMIL_INILSPEC_C	**NUMBER
	CONCOMIL_INILSPEC	VARCHAR2
cpALTCASUS - INILSPEC	INILSPEC	VARCHAR2
cpALTCASUS - Concomitant medication	CONCOMED_CONSPEC_C	**NUMBER
	CONCOMED_CONSPEC	VARCHAR2
cpALTCASUS - CONSPEC	CONSPEC	VARCHAR2
cpALTCASUS - Other	OTHCAUS_OTHSPEC_C	**NUMBER
	OTHCAUS_OTHSPEC	VARCHAR2
cpALTCASUS - OTHSPEC	OTHSPEC	VARCHAR2
cpALTCASUS - None (Only applicable if study drug related and considered only cause of AE)	ALTNONE_CISAECAUSENONE_C	NUMBER
	ALTNONE_CISAECAUSENONE	VARCHAR2
AESER	AESER_C	**NUMBER
	AESER	VARCHAR2
	AESER_ND	VARCHAR2
AESER - Death	AESDTH_CIDEATH1_C	NUMBER
	AESDTH_CIDEATH1	VARCHAR2
AESER - Life-Threatening	AESLIFE_CILIFETHREATENING_C	NUMBER
	AESLIFE_CILIFETHREATENING	VARCHAR2
AESER - Hospitalization required or prolongation of existing hospitalization	*AESHOSP_CIREQUIREINPATIENTHOSP_C	NUMBER
	*AESHOSP_CIREQUIREINPATIENTHOSP	VARCHAR2
AESER - Persistent or significant disability/incapacity	*AESDISAB_CIPERSISTENTSIGNIFICANTDISABILITY_C	NUMBER
	*AESDISAB_CIPERSISTENTSIGNIFICANTDISABILITY	VARCHAR2
AESER - Congenital anomaly or birth defect	*AESCONG_CICONGENITALANOMALYBIRTHDEFECT_C	NUMBER
	*AESCONG_CICONGENITALANOMALYBIRTHDEFECT	VARCHAR2

AESER - Important medical event	*AESMIE_CIIMPORTANTMEDICALEVENT_C	NUMBER
	*AESMIE_CIIMPORTANTMEDICALEVENT	VARCHAR2
SAELABYN	SAELABYN_C	NUMBER
	SAELABYN	VARCHAR2
	SAELABYN_ND	VARCHAR2
SAECMYN	SAECMYN_C	NUMBER
	SAECMYN	VARCHAR2
	SAECMYN_ND	VARCHAR2
PIVER	PIVER_C	NUMBER
	PIVER	VARCHAR2
	PIVER_ND	VARCHAR2
PIDATE	PIDATE	DATE
	PIDATE_DTS	VARCHAR2
	PIDATE_ND	VARCHAR2
RD_FRAE_RSAE3		
AEDEFNUM	AEDEFNUM	VARCHAR2
	AEDEFNUM_ND	VARCHAR2
RD_FRAE_RSAE5		
NARSYMP	NARSYMP	VARCHAR2
	NARSYMP_ND	VARCHAR2
RD_FRAE_RSAE7		
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_FRAE_RSAE9		
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
<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>		

HF_INDIE: 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 checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2016-2018)
2. RETIRED ITEM: Status at time of last contact [hidden] [Status at time of last contact]	[CMPLTD] [N: 1] <input type="radio"/> Died, please complete DEATH form [N: 2] <input type="radio"/> Completed protocol [N: 3] <input type="radio"/> Subject lost to follow-up [N: 4] <input type="radio"/> Subject withdrew consent for study participation [N: 5] <input type="radio"/> Subject withdrawn from the study by site investigator [N: 98] <input type="radio"/> [CMPTOSP] Other, specify A100
3. <input checked="" type="checkbox"/> Status at time of last contact [Status at time of last contact]	[CMPLTD2] [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"/> [CMPLTDSP] Subject withdrew consent for study participation, Specify A200 [N: 5] <input type="radio"/> Subject withdrawn from the study by site investigator [N: 98] <input type="radio"/> [CMPTSP2] Other, specify A100
Key: [*] - Item is required [<input checked="" type="checkbox"/>] - Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

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
CMPLTD2	CMPLTD2_C	NUMBER
	CMPLTD2	VARCHAR2
	CMPLTD2_ND	VARCHAR2
CMPLTD2 - CMPLTDSP	CMPLTDSP	VARCHAR2
CMPLTD2 - CMPTSP2	CMPTSP2	VARCHAR2

HF_INDIE: DEATH (DEATH) [frDEATH]	
Death [stDEATH1]	
1.* ✓ Location of Death [Location of Death]	[DEATHLOC] [N: 1] <input type="radio"/> Inpatient/ER [N: 2] <input type="radio"/> Outpatient
2.* ✓ Date of Death [Date of Death]	[DEATHDT] Req/Unk <input type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> (2016-2018)
3.* ✓ Cause of Death [Cause of Death]	[DTHCAUSE] [N: 1] <input type="radio"/> [DTHCARD] Cardiovascular [N: 1] <input type="radio"/> Myocardial infarction [N: 2] <input type="radio"/> Heart failure/Pump failure/Cardiogenic Shock [N: 3] <input type="radio"/> [SDNDTHW] Sudden Death [N: 1] <input type="radio"/> Witnessed [N: 2] <input type="radio"/> Not Witnessed [N: 4] <input type="radio"/> Stroke [N: 5] <input type="radio"/> [DTHCVPR] CV Procedure [N: 1] <input type="radio"/> CABG [N: 2] <input type="radio"/> PCI/Stenting [N: 3] <input type="radio"/> Valvular [N: 98] <input type="radio"/> Other CV Procedure [N: 6] <input type="radio"/> Pulmonary Embolism [N: 98] <input type="radio"/> [DTHCRDSP] Other CV, specify: A100 <input type="text"/>
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

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
	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
DTHCAUSE - NCRDSP	NCRDSP	VARCHAR2

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

HF_INDIE: Signature Completion (SIGN) [frSIGN]

Casebook Ready for Signature [stSIGN]

1. *	Casebook Ready for Signature [Casebook Ready for Signature]	[PISIGN] [N: 1] <input checked="" type="radio"/> Yes
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Key: [*] = Item is required
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

RDE Analytics: RD_FRSIGN

Data Variable RefName	RD Column Name	Column Data Type
PISIGN	PISIGN_C	NUMBER
	PISIGN	VARCHAR2
	PISIGN_ND	VARCHAR2

InForm Special Properties For Study Design: HF_INDIE			
InForm Special Property	Property Type	Data Object RefName	Data Object Path RefName
Screening	Visit	evSYSSCR	evSYSSCR
Enrollment	Visit	evSYSENR	evSYSENR
Screening	Form	frSYSSCR2	evSYSSCR.frSYSSCR2
Enrollment	Form	frENRSYS1	evSYSENR.frENRSYS1
Patient Identification	Form	frSTATUS	evSTATUS.frSTATUS
Study Completion	Form	Unassigned	Unassigned
Reg Docs	Form	Unassigned	Unassigned
Visit Report	Form	Unassigned	Unassigned
Initials (Screening)	Item	SUBJINIT	evSYSSCR.frSYSSCR2.SUBJINIT
DOB (Screening)	Item	Unassigned	Unassigned
Screening date (Screening)	Item	Unassigned	Unassigned
Patient No. (Enrollment)	Item	SUBJID	evSTATUS.frSTATUS.stSTATUS1.SUBJID evSYSENR.frENRSYS1.SUBJID
Initials (Patient Identification)	Item	SUBINIT	evSTATUS.frSTATUS.stSTATUS1.SUBINIT
Completion status (Study Completion)	Item	Unassigned	Unassigned
Drop out reason (Study Completion)	Item	Unassigned	Unassigned
DOV (Date of Visit)	Item	Unassigned	Unassigned
Randomization field (Randomization)	Item	Unassigned	Unassigned

Personal/Protected Health Information Table: HF_INDIE		
Item RefName	Section RefName	Form RefName
No Items have been defined as "Personal/Protected Health Information".		
Please note: emails sent from the trial server by the InForm application are not encrypted. If you are subject to HIPAA requirements, you should identify and block all Personal/Protected Health Information items that may be included in email notifications.		

Review States for Study: HF_INDIE

No Review States have been defined.

In-place Revisions Summary Table: HF_INDIE

No in-place revisions have been defined.
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