

**Annotated Study Book for Study Design: HFNLIFE**

**Study Design Version: 10.0**

**Sponsor: NHLBI**

**Protocol: Entresto™ (LCZ696) In Advanced  
Study Design**

**Generated by Central Designer™**

**July 17, 2020 12:54PM**

Time and Events Schedule For Study Design: HFNLIFE																																				
Element	Assessment	CRF	System																																	
			evSYSSCCR (SYSSCCR) [S]	evSYSENR (SYSENR) [S]	evCLINOPS (CLINOPS) [S]	evSTATUS (STATUS) [S]	evSCREEN (SCREEN) [S]	evRUNIN (RUNIN) [S/D]	evRAND (RAND) [S/D]	evWEEK2 (WEEK2) [S/D]	evWEEK4 (WEEK4) [S/D]	evWEEK8 (WEEK8) [S/D]	evWEEK10 (WEEK10) [S/D]	evWEEK12 (WEEK12) [S/D]	evWEEK16 (WEEK16) [S/D]	evWEEK20 (WEEK20) [S/D]	evWEEK24 (WEEK24) [S/D]	evWEEK26 (WEEK26) [S/D]	evDRGLOG (DRGDOSE) [S/D]	evSFPHONE (SFPHONE) [S/D]	evINOTROPE (INOTROPE) [S/D]	evKITS (KITS) [S/D]	evREHOSP (REHOSP) [S]	evEDVISIT (OUTPTVIS) [S]	evEVENTINT (EVENTINT) [S]	evSAE (SAE) [S]	evENDPNT (ENDPNT) [S/D]	evEOS (EOS) [S/D]	evUNSCH (UNSCH) [S/D/R]	evINVSIG (INVSIG) [S/D]	evDEATH (DEATH) [S/D]					
Visit Start Hours			0	0	0	168	504	1008	1680	2688	3864	5208	6720	8400	10248	12264	14616	17136	19824	22680	25704	28896	32256	35784	39480	43344	47376	51576	54456	61656	61680					
1	frSYSSCR2	SYSSCR	1																																	
2	frENRSYS1	SYSENR		1																																
3	frCLINOPS	CLINOPS			1																															
4	frSTATUS	STATUS				1																														
5	frDEMOG	DEMOG					1																													
6	frELIG1	ELIG1						2-DF																												
7	frELIG1A	ELIG1A							3-DF																											
8	frELIG2	ELIG2							4-DF																											
9	frELIG2A	ELIG2A							5-DF																											
10	frMEDHIST1	MEDHIST1					6																													
11	frMEDHIST2	MEDHIST2					7																													
12	frMEDS	MEDS					8																													
13	frEXAM	EXAM					9	3-DF	3-DF	3-DF	3-DF			3-DF						3-DF												3-DF				
14	frKCCQ	KCCQ					10							5-DF						5-DF																
15	frLABS	LABS					11	4-DF	4-DF	5-DF	6-DF	4-DF		6-DF						6-DF												5-DF				
16	frRUNIN	RUNIN					1																													
17	frVISMEDS	VISMEDS						2-DF	2-DF	2-DF	2-DF	2-DF		2-DF						2-DF													2-DF			
18	frRAND	RAND							1																											
19	frSAMPLES	SAMPLES							5-DF	6-DF	7-DF	5-DF		7-DF						7-DF																
20	frVISIT	VISIT								1	1	1		1						1																
21	frASSESS1	ASSESS1								4-DF		3-DF																					4-DF			
22	frASSESS	ASSESS									4-DF			4-DF						4-DF																
23	frPHONE	PHONE																1			1															
24	frDRGDOSE	DRGDOSE																			1-RF															
25	frINOTROPE	INOTROPE																				1-RF														
26	frDRUGKIT	DRUGKIT																					1-RF													
27	frREHOSP	REHOSP																					1-RF													
28	frOUTPTVIS	OUTPTVIS																							1-RF											
29	frEVENTINT	EVENTINT																								1-RF										
30	frSAE	SAE																																		
31	frENDPNT	ENDPNT																																1		
32	frEOS	EOS																																1		
33	frDEATH	DEATH																															2-DF			1
34	frVISIT1	VISIT1																																1		
35	frSIGN	SIGN																																		1

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

<b>HFNLIFE: System Screening (SYSSCR) [frSYSSCR2]</b>	
<b>System Screening [frSYSSCR2]</b>	
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.	

**Study Object Descriptions: System Screening**

Type	RefName	Description
Form	frSYSSCR2	Maunal System Screening form
Item	SUBJINIT	Manual entry for subjects initials

**RDE Analytics: RD\_FRSYSSCR2**

Data Variable RefName	RD Column Name	Column Data Type
SUBJINIT	SUBJINIT	VARCHAR2
	SUBJINIT_ND	VARCHAR2

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

<b>Study Object Descriptions: System Enrollment</b>		
<b>Type</b>	<b>RefName</b>	<b>Description</b>
Form	frENRSYS1	Manual/IXRS System Enrollment form
Item	SUBJID	Subject Id created by IXRS system or manually entered into InForm

<b>RDE Analytics: RD_FRENRSYS1</b>		
<b>Data Variable RefName</b>	<b>RD Column Name</b>	<b>Column Data Type</b>
SUBJID	SUBJID	VARCHAR2
	SUBJID_ND	VARCHAR2

HFNLIFE: Clinical Operations Review (CLINOPS) [frCLINOPS]	
<b>Eligibility criteria [stCLINOPS1]</b>	
1. Per eCRF eligibility review, was subject found to be eligible? <small>[Per eCRF eligibility review, was subject found to be eligible?]</small>	[INCMET] [N:1] <input type="radio"/> Yes [N:2] <input type="radio"/> No
2. Comments <small>[Commentary]</small>	[INCCOMM] A200
<b>Ineligible Criteria</b>	
<b>Ineligible criteria Entry [rsCLINOPS2]</b>	
3.1 Criteria <small>[Ineligible Criteria]</small>	[CRITTYPE] [N:1] <input type="radio"/> [INCLNOT] Inclusion not met [N:1] <input type="radio"/> IC1 [N:2] <input type="radio"/> IC2 [N:3] <input type="radio"/> IC3 [N:4] <input type="radio"/> IC4 [N:5] <input type="radio"/> IC5 [N:6] <input type="radio"/> IC6 [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
<b>SDV Completed</b>	<b>Commentary</b>
4.1 SDV Completed <small>[SDV Completed]</small>	[SDV] [N:1] <input type="radio"/> [SDVDT] (DD/MM/YYYY) Yes Date Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021)
4.2 Comments <small>[Commentary]</small>	[SDVCOMM] A200
<b>ICD Review Completed</b>	<b>Commentary</b>
<b>ICD Review Entry [rsCLINOPS4]</b>	
5.1 ICD Review Completed <small>[ICD Review Completed]</small>	[ICD] [N:1] <input type="radio"/> [cpICDDT] [ICDDT] (DD/MM/YYYY) Yes Date Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) [ICDVERDT] (DD/MM/YYYY) Version Date of ICD Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021)
5.2 Comments <small>[Commentary]</small>	[ICDCOMM] A200
<b>Logistical Review Completed</b>	<b>Commentary</b>
<b>Logistical Review Entry [rsCLINOPS5]</b>	
6.1 Logistical Review Completed <small>[Logistical Review Completed]</small>	[LOGISTIC] [N:1] <input type="radio"/> [LOGISDT] (DD/MM/YYYY) <input type="checkbox"/> Yes Date Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021)
6.2 Comments <small>[Commentary]</small>	[LOGCOM] A128
<small>Key: [ ✓ ] = Source verification required [ ☐ ] = Item is collapsible                      Note: Source verification critical settings made in InForm will override any settings made in Central Designer.                      Note: Collapsible settings are only available to users who have the rights to edit the item.</small>	

RDE Analytics: RD_FRCLINOPS		
Data Variable RefName	RD Column Name	Column Data Type
INCMET	INCMET_C	NUMBER

	INCMET	VARCHAR2
	INCMET_ND	VARCHAR2
INCCOMM	INCCOMM	VARCHAR2
	INCCOMM_ND	VARCHAR2
<b>RD_FRCLINOPS_RSCLINOPS2</b>		
CRITTYPE	CRITTYPE_C	**NUMBER
	CRITTYPE	VARCHAR2
	CRITTYPE_ND	VARCHAR2
CRITTYPE - INCLNOT	INCLNOT_C	NUMBER
	INCLNOT	VARCHAR2
CRITTYPE - EXCLMET	EXCLMET_C	NUMBER
	EXCLMET	VARCHAR2
<b>RD_FRCLINOPS_RSCLINOPS3</b>		
SDV	SDV_C	**NUMBER
	SDV	VARCHAR2
	SDV_ND	VARCHAR2
SDV - SDVDT	SDVDT	DATE
	SDVDT_DTS	VARCHAR2
SDVCOMM	SDVCOMM	VARCHAR2
	SDVCOMM_ND	VARCHAR2
<b>RD_FRCLINOPS_RSCLINOPS4</b>		
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
<b>RD_FRCLINOPS_RSCLINOPS5</b>		
LOGISTIC	LOGISTIC_C	**NUMBER
	LOGISTIC	VARCHAR2
	LOGISTIC_ND	VARCHAR2
LOGISTIC - LOGISDT	LOGISDT	DATE
	LOGISDT_DTS	VARCHAR2
LOGCOM	LOGCOM	VARCHAR2
	LOGCOM_ND	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFNLIFE: STATUS (STATUS) [frSTATUS]	
<b>Almac Status [stSTATUS1]</b>	
1.* Subject Identifier ✓ [Subject Identifier]	[SUBJID]  A20
2.* Subject Status ✓ [Subject Status]	[SUBJSTAT] [N:1] <input type="radio"/> Consented and in Active Screening [N:2] <input type="radio"/> Screen Failure [N:3] <input type="radio"/> Randomized
3.* Date Status Updated ✓ [Date Status Updated]	[STATUSDT] (DD/MM/YYYY)  Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021)
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

Study Object Descriptions: STATUS		
Type	RefName	Description
Item	SUBJID	Subject Id created by IXRS system or manually entered into InForm

RDE Analytics: RD_FRSTATUS		
Data Variable RefName	RD Column Name	Column Data Type
SUBJID	SUBJID	VARCHAR2
	SUBJID_ND	VARCHAR2
	SUBJSTAT_C	NUMBER
SUBJSTAT	SUBJSTAT	VARCHAR2
	SUBJSTAT_ND	VARCHAR2
	STATUSDT	DATE
STATUSDT	STATUSDT_DTS	VARCHAR2
	STATUSDT_ND	VARCHAR2

HFNLIFE: INFORMED CONSENT AND DEMOGRAPHICS (DEMOG) [frDEMOG]	
Informed Consent and Demographics [stDEMOG1]	
1.* Date/Time Informed Consent Signed [Date/Time Informed Consent Signed]	[CONSDTM] (DD/MM/YYYY hh:mm) Req [v] / Req [v] / Req [v] (2015-2021) Req/Unk [v] : Req/Unk [v] 24-hour clock
2.* Under which version of the protocol is this patient being randomized? [Which version of the protocol is this patient being randomized?]	[VERSDATE] [N:1] <input type="radio"/> Version Date 1/27/17 [N:2] <input type="radio"/> Version Date 6/15/17 [N:3] <input type="radio"/> Version Date Feb/Mar 2019
3.* Date of Birth [Date of Birth]	[DOBDT] (DD/MM/YYYY) Req [v] / Req [v] / Req [v] (1912-1998)
4.* Sex [Sex]	[SEX] [N:1] <input type="radio"/> Male [N:2] <input type="radio"/> Female
5.* Ethnicity [Ethnicity]	[ETHNIC] [N:1] <input type="radio"/> Hispanic or Latino [N:2] <input type="radio"/> Not Hispanic or Latino
6.* 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
7. Update WorkFlow [Update Workflow]	[UPDTWKFL] [N:1] <input type="checkbox"/> Yes
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_FRDEMOG		
Data Variable RefName	RD Column Name	Column Data Type
CONSDTM	CONSDTM	DATE
	CONSDTM_DTS	VARCHAR2
	CONSDTM_DTR	VARCHAR2
	CONSDTM_ND	VARCHAR2
VERSDATE	VERSDATE_C	NUMBER
	VERSDATE	VARCHAR2
	VERSDATE_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
UPDTWKFL	UPDTWKFL_ND	VARCHAR2
UPDTWKFL -Yes	UPDTWKFL_CYES1_C	NUMBER
	UPDTWKFL_CYES1	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different.		

<b>HFNLIFE: INCLUSION/EXCLUSION PART 1 (ELIG1) [frELIG1]</b>	
<p><b>Inclusion [stELIG1]</b></p> <p>1.* Advanced HF/EF defined as including ALL: [Advanced HF/EF]</p>	<p><b>[INCYN1]</b> [N:1] <input type="radio"/> <b>[cpINCLVEF]</b> <b>[INCLVEF1]</b> Yes (check all criteria used to determine eligibility): [N:1] <input type="checkbox"/></p> <p><b>[cpLVEF]</b> LVEF <math>\leq</math> 35% documented during the preceding 3 months <b>[LVEF35DT] (DD/MM/YYYY)</b> Date: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2021) <b>[LVEF35VL]</b> Value: xxxxxxxxxx</p> <p><b>[GFR1]</b> [N:1] <input type="checkbox"/> <b>[cpGFR1]</b> <b>[GFR1DT] (DD/MM/YYYY)</b> Estimated GFR 20-60 mL/min/1.73m<sup>2</sup> Date: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2021) <b>[GFRVAL]</b> Value: xxxxxxxxxx</p> <p><b>[NYHAcl1]</b> [N:1] <input type="checkbox"/> NYHA class IV symptomatology for the majority of the previous month</p> <p><b>[GDMT1]</b> [N:1] <input type="checkbox"/> Minimum of 3 months GDMT for HF and/or intolerant to therapy</p> <p>[N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated</p>
<p>2.* HF <math>\geq</math> 1 symptom (dyspnea, orthopnea, or edema) and <math>\geq</math> 1 sign of congestion (rales on auscultation, ascites, peripheral edema, or pulmonary vascular congestion on chest radiography) [HF]</p>	<p><b>[INCYN2]</b> [N:1] <input type="radio"/> <b>[cpHF]</b> Yes (check all that apply)</p> <p><b>[DYSYPNEA]</b> [N:1] <input type="checkbox"/> Dyspnea</p> <p><b>[ORTHOP1]</b> [N:1] <input type="checkbox"/> Orthopnea</p> <p><b>[EDEMA1]</b> [N:1] <input type="checkbox"/> Edema</p> <p><b>[RALESASUS]</b> [N:1] <input type="checkbox"/> Rales on auscultation</p> <p><b>[PEREDEMA]</b> [N:1] <input type="checkbox"/> Peripheral Edema</p> <p><b>[ACITES]</b> [N:1] <input type="checkbox"/> Ascites</p> <p><b>[PULMCONG]</b> [N:1] <input type="checkbox"/> Pulmonary vascular congestion on chest radiography</p> <p>[N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated</p>
<p>3.* Systolic blood pressure <math>\geq</math> 90 mmHg? [Systolic blood pressure]</p>	<p><b>[INCYN3]</b> [N:1] <input type="radio"/> <b>[cpSysBld]</b> Yes <b>[SYSBPDT] (DD/MM/YYYY)</b> Date: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2021) <b>[SYSBPVAL]</b> Value: N3</p> <p>[N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated</p>
<p>4.* Serum NT-proBNP <math>\geq</math> 800 pg/mL OR BNP <math>\geq</math> 250 pg/mL? (most recent - less than 1 year old) [Serum NT-proBNP]</p>	<p><b>[INCYN4]</b> [N:1] <input type="radio"/> <b>[cpINCYN4]</b> Yes <b>[SERUMDT] (DD/MM/YYYY)</b> Date: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2021) <b>[BNPELIC1]</b> [N:1] <input type="radio"/> BNP <math>\geq</math> 250 pg/mL <b>[BNPVALE1]</b> xxxxxxxxxx</p> <p><b>[NTPROBNP]</b> [N:1] <input type="radio"/> NTproBNP <math>\geq</math> 800pg/ml <b>[NTPROVAL]</b> xxxxxxxxxx</p> <p>[N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated</p>
<p>5.* Any one or more of the following objective findings of advanced HF including: [Any one or more of the following objective findings of advanced HF including:]</p>	<p><b>[INCYN5]</b> [N:1] <input type="radio"/> <b>[cpINCYN5]</b> Yes (check all criteria used to determine eligibility):</p> <p><b>[INOTHER1]</b> <b>[INOCURR]</b> [N:1] <input type="checkbox"/> Inotropic therapy currently, or for <math>\geq</math> 5 days in the past 6 months [N:1] <input type="radio"/> Current therapy [N:2] <input type="radio"/> <math>\geq</math> 5 days in the past 6 months</p> <p><b>[HOSPHE1]</b> [N:1] <input type="checkbox"/> <math>\geq</math> 1 hospitalizations for heart failure in the past 6 months (not including the index hospitalization for inpatient subjects)</p> <p><b>[INCLVEFS]</b> [N:1] <input type="checkbox"/> LVEF <math>\leq</math> 25% (within the past 3 months)</p> <p><b>[LVEDPCW]</b> [N:1] <input type="checkbox"/> PCW or LVEDP <math>\geq</math> 20 mmHg (within the past 3 months)</p> <p><b>[PEAKV02]</b> [N:1] <input type="checkbox"/> Peak V02 &lt; 55% predicted or peak V02 <math>\leq</math> 16 for men or <math>\leq</math> 14 for women (Respiratory Exchange Ratio (RER) 1.05) (within the past 12 months)</p> <p><b>[MINWALE]</b> [N:1] <input type="checkbox"/> 6 min walk test distance &lt; 300 m (within the past 3 months)</p> <p><b>[ESTGFR]</b> [N:1] <input type="checkbox"/> Estimated GFR &lt; 45 mL/min/1.73 m<sup>2</sup> as measured by the simplified MDRD formula (within the past 12 months)</p> <p><b>[INTRAPMP]</b> [N:1] <input type="checkbox"/> <b>[INTRADT] (DD/MM/YYYY)</b> History of an intra-aortic balloon pump placement within the past 6 months Date:</p>

		Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021)
		[N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
6.* Signed Informed Consent form? [Signed Informed Consent form?]		[INCYN6] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
7.* Did subject meet all Inclusion Criteria? [Did subject meet all Inclusion Criteria?]		[ICMETYN] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
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_FRELIG1		
Data Variable RefName	RD Column Name	Column Data Type
INCYN1	INCYN1_C	**NUMBER
	INCYN1	VARCHAR2
	INCYN1_ND	VARCHAR2
INCYN1 - LVEF ≤ 35% documented during the preceding 3 months	INCLVEF1_CPLVEF_C	**NUMBER
	INCLVEF1_CPLVEF	VARCHAR2
INCYN1 - LVEF35DT	LVEF35DT	DATE
	LVEF35DT_DTS	VARCHAR2
INCYN1 - LVEF35VL	LVEF35VL	FLOAT
INCYN1 - Estimated GFR 20-60 mL/min/1.73m <sup>2</sup>	GFR1_CGFR1_C	**NUMBER
	GFR1_CGFR1	VARCHAR2
INCYN1 - GFR1DT	GFR1DT	DATE
	GFR1DT_DTS	VARCHAR2
INCYN1 - GFRVAL	GFRVAL	FLOAT
INCYN1 - NYHA class IV symptomatology for the majority of the previous month	NYHAACL1_CINYHAACL1_C	NUMBER
	NYHAACL1_CINYHAACL1	VARCHAR2
INCYN1 - Minimum of 3 months GDMT for HF and/or intolerant to therapy	GDMT1_CIGDMT1_C	NUMBER
	GDMT1_CIGDMT1	VARCHAR2
INCYN2	INCYN2_C	**NUMBER
	INCYN2	VARCHAR2
	INCYN2_ND	VARCHAR2
INCYN2 - Dyspnea	DYSPNEA_CIDYSPNEA_C	NUMBER
	DYSPNEA_CIDYSPNEA	VARCHAR2
INCYN2 - Orthopnea	ORTHOP1_CIORTHOPNEA1_C	NUMBER
	ORTHOP1_CIORTHOPNEA1	VARCHAR2
INCYN2 - Edema	EDEMA1_CIEDEMA_C	NUMBER
	EDEMA1_CIEDEMA	VARCHAR2
INCYN2 - Rales on auscultation	RALES AUS_CIRALES AUS_C	NUMBER
	RALES AUS_CIRALES AUS	VARCHAR2
INCYN2 - Peripheral Edema	PEREDEMA_CIEDEMA1_C	NUMBER
	PEREDEMA_CIEDEMA1	VARCHAR2
INCYN2 - Ascites	ACITES_CIASCITES_C	NUMBER
	ACITES_CIASCITES	VARCHAR2
INCYN2 - Pulmonary vascular congestion on chest radiography	PULMCONG_CIPULMCONG_C	NUMBER
	PULMCONG_CIPULMCONG	VARCHAR2
INCYN3	INCYN3_C	**NUMBER
	INCYN3	VARCHAR2
	INCYN3_ND	VARCHAR2
INCYN3 - SYSBPD	SYSBPD	DATE
	SYSBPD_DTS	VARCHAR2
INCYN3 - SYSBPVAL	SYSBPVAL	NUMBER
INCYN4	INCYN4_C	**NUMBER
	INCYN4	VARCHAR2
	INCYN4_ND	VARCHAR2
INCYN4 - SERUMDT	SERUMDT	DATE
	SERUMDT_DTS	VARCHAR2
INCYN4 - BNPELIG	BNPELIG_C	NUMBER
	BNPELIG	VARCHAR2
INCYN4 - BNPALEL	BNPALEL	FLOAT
INCYN4 - NTPROBNP	NTPROBNP_C	NUMBER
	NTPROBNP	VARCHAR2
INCYN4 - NTPROVAL	NTPROVAL	FLOAT
INCYN5	INCYN5_C	**NUMBER
	INCYN5	VARCHAR2
	INCYN5_ND	VARCHAR2
INCYN5 - Inotropic therapy currently, or for ≥ 5 days in the past 6 months	INOTHERP_INOCURR_C	**NUMBER
	INOTHERP_INOCURR	VARCHAR2
INCYN5 - INOCURR	INOCURR_C	NUMBER
	INOCURR	VARCHAR2
INCYN5 - ≥ 1 hospitalizations for heart failure in the past 6 months (not including the index hospitalization for inpatient subjects)	HOSP HF_CIHOSP HF_C	NUMBER
	HOSP HF_CIHOSP HF	VARCHAR2
INCYN5 - LVEF ≤ 25% (within the past 3 months)	INCLVEF5_CINCLVEF5P_C	NUMBER
	INCLVEF5_CINCLVEF5P	VARCHAR2
INCYN5 - PCW or LVEDP ≥ 20 mmHg (within the past 3 months)	LVEDPCW_CILVEDPCW_C	NUMBER
	LVEDPCW_CILVEDPCW	VARCHAR2

INCYN5 - Peak V02 < 55% predicted or peak V02 ≤ 16 for men or ≤ 14 for women (Respiratory Exchange Ratio (RER) 1.05) (within the past 12 months)	PEAKV02_CIPEAKV02_C	NUMBER
	PEAKV02_CIPEAKV02	VARCHAR2
INCYN5 - 6 min walk test distance < 300 m (within the past 3 months)	MINWAL6_CIMINWL6_C	NUMBER
	MINWAL6_CIMINWL6	VARCHAR2
INCYN5 - Estimated GFR < 45 mL/min/1.73 m <sup>2</sup> as measured by the simplified MDRD formula (within the past 12 months)	ESTGFR_CIESTGFR_C	NUMBER
	ESTGFR_CIESTGFR	VARCHAR2
INCYN5 - History of an intra-aortic balloon pump placement within the past 6 months	INTRAPMP_INTRADT_C	**NUMBER
	INTRAPMP_INTRADT	VARCHAR2
INCYN5 - INTRADT	INTRADT	DATE
	INTRADT_DTS	VARCHAR2
INCYN6	INCYN6_C	NUMBER
	INCYN6	VARCHAR2
	INCYN6_ND	VARCHAR2
ICMETYN	ICMETYN_C	NUMBER
	ICMETYN	VARCHAR2
	ICMETYN_ND	VARCHAR2

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

HFNLIFE: INCLUSION/EXCLUSION PART 1 (ELIG1A) [frELIG1A]	
<p><b>Inclusion [stELIG1A]</b></p> <p>1.* Advanced HF/EF defined as including ALL: [Advanced HF/EF defined as including ALL:]</p>	<p><b>[INCYN1A]</b> [N:1] <input type="radio"/> <b>[cpINCYN1A]</b> <b>[INCLVE1A]</b> Yes (All criteria must be used to determine eligibility): [N:1] <input type="checkbox"/></p> <p><b>[cpINCLVE1A]</b> LVEF ≤ 35% documented during the preceding 12 months <b>[LVEFADT] (DD/MM/YYYY)</b> Date: Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) <b>[LVEF35VA]</b> Value: xxxxxxxx.</p> <p><b>[NYHACL1A]</b> [N:1] <input type="checkbox"/> NYHA class IV symptomatology, defined as chronic dyspnea or fatigue at rest or on minimal exertion in the previous 3 months, or patients who require chronic inotropic therapy</p> <p><b>[GDMT1A]</b> [N:1] <input type="checkbox"/> Minimum of 3 months GDMT for HF and/or intolerant to therapy</p> <p>[N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated</p>
<p>2.* Systolic blood pressure ≥ 90 mmHg? [Systolic blood pressure ≥ 90 mmHg?]</p>	<p><b>[INCYN3A]</b> [N:1] <input type="radio"/> <b>[cpINCYN3A]</b> <b>[SYSBPADT] (DD/MM/YYYY)</b> Yes Date: Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) <b>[SYSBPV1A]</b> Value: N3</p> <p>[N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated</p>
<p>3.* Serum NT-proBNP ≥ 800 pg/mL OR BNP ≥ 250 pg/mL? (most recent - less than 3 months old) [Serum NT-proBNP ≥ 800 pg/mL OR BNP ≥ 250 pg/mL? (most recent - less than 3 months old)]</p>	<p><b>[INCYN4A]</b> [N:1] <input type="radio"/> <b>[cpINCYN4A]</b> <b>[SERUMADT] (DD/MM/YYYY)</b> Yes Date: Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) <b>[BNPELIGA]</b> [N:1] <input type="checkbox"/> <b>[BNPVALEA]</b> BNP ≥ 250 pg/mL Value: xxxxxxxx.</p> <p><b>[NTPROBNA]</b> [N:1] <input type="checkbox"/> <b>[NTPROVAA]</b> NTproBNP ≥ 800 pg/mL Value: xxxxxxxx.</p> <p>[N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated</p>
<p>4.* Any one or more of the following objective findings of advanced HF including: [Any one or more of the following objective findings of advanced HF including:]</p>	<p><b>[INCYN5A]</b> [N:1] <input type="radio"/> <b>[cpINCYN51]</b> <b>[INOTHERA]</b> Yes (check all criteria used to determine eligibility): [N:1] <input type="checkbox"/></p> <p><b>[INOCURRA]</b> Inotropic therapy currently, or use of inotropes in the past 6 months [N:1] <input type="radio"/> Current therapy [N:2] <input type="radio"/> In the past 6 months</p> <p><b>[HOSPHFA]</b> [N:1] <input type="checkbox"/> ≥ 1 hospitalizations for heart failure in the past 6 months (not including the index hospitalization for inpatient subjects)</p> <p><b>[INCLVEFA]</b> [N:1] <input type="checkbox"/> LVEF ≤ 25% (within the past 12 months)</p> <p><b>[PEAKV02A]</b> [N:1] <input type="checkbox"/> Peak V02 &lt; 55% predicted or peak V02 ≤ 16 for men or ≤ 14 for women (Respiratory Exchange Ratio (RER) ≥ 1.05) (within the past 12 months)</p> <p><b>[MINWALGA]</b> [N:1] <input type="checkbox"/> 6 min walk test distance &lt; 300 m (within the past 3 months)</p> <p>[N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated</p>
<p>5.* Age ≥ 18 years and ≤ 85 years [Age ≥ 18 years and ≤ 85 years]</p>	<p><b>[ICHYN6A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No</p>
<p>6.* Signed Informed Consent form? [Signed Informed Consent form?]</p>	<p><b>[INCYN7A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated</p>
<p>7.* Did subject meet all Inclusion Criteria? [Did subject meet all Inclusion Criteria?]</p>	<p><b>[ICMETYNA]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No</p>

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

RDE Analytics: RD_FRELIG1A		
Data Variable RefName	RD Column Name	Column Data Type
INCYN1A	INCYN1A_C	**NUMBER
	INCYN1A	VARCHAR2
	INCYN1A_ND	VARCHAR2
INCYN1A - LVEF ≤ 25% documented during the preceding 12 months	INCLVE1A_CPINCLVE1A_C	**NUMBER
	INCLVE1A_CPINCLVE1A	VARCHAR2
INCYN1A - LVEFADT	LVEFADT	DATE
	LVEFADT_DTS	VARCHAR2
INCYN1A - LVEF35VA	LVEF35VA	FLOAT
INCYN1A - NYHA class IV symptomatology, defined as chronic dyspnea or fatigue at rest or on minimal exertion in the previous 3 months, or patients who require chronic inotropic therapy	NYHACL1A_CINYLACL1A_C	NUMBER
	NYHACL1A_CINYLACL1A	VARCHAR2
INCYN1A - Minimum of 3 months GDMT for HF and/or intolerant to therapy	GDMT1A_CIGDMT1A_C	NUMBER
	GDMT1A_CIGDMT1A	VARCHAR2

INCYN3A	INCYN3A_C	**NUMBER
	INCYN3A	VARCHAR2
	INCYN3A_ND	VARCHAR2
INCYN3A - SYSBPADT	SYSBPADT	DATE
	SYSBPADT_DTS	VARCHAR2
	SYSBPVLA	NUMBER
INCYN3A - SYSBPVLA INCYN4A	INCYN4A_C	**NUMBER
	INCYN4A	VARCHAR2
	INCYN4A_ND	VARCHAR2
INCYN4A - SERUMADT	SERUMADT	DATE
	SERUMADT_DTS	VARCHAR2
	BNPELIGA_BNPVALEA_C	**NUMBER
INCYN4A - BNP ≥250 pg/mL	BNPELIGA_BNPVALEA	VARCHAR2
	BNPVALEA	FLOAT
	NTPROBNA_NTPROVAA_C	**NUMBER
INCYN4A - BNPVALEA INCYN4A - NTproBNP ≥800pg/ml	NTPROBNA_NTPROVAA	VARCHAR2
	NTPROVAA	FLOAT
INCYN4A - NTPROVAA INCYN5A	INCYN5A_C	**NUMBER
	INCYN5A	VARCHAR2
	INCYN5A_ND	VARCHAR2
INCYN5A - Inotropic therapy currently, or use of inotropes in the past 6 months	INOTHERA_INOCURRA_C	**NUMBER
	INOTHERA_INOCURRA	VARCHAR2
INCYN5A - INOCURRA	INOCURRA_C	NUMBER
	INOCURRA	VARCHAR2
INCYN5A - ≥ 1 hospitalizations for heart failure in the past 6 months (not including the index hospitalization for inpatient subjects)	HOSPFA_CIHOSPFA1_C	NUMBER
	HOSPFA_CIHOSPFA1	VARCHAR2
INCYN5A - LVEF ≤ 25% (within the past 12 months)	INCLVEFA_CIIINCLVEFAN_C	NUMBER
	INCLVEFA_CIIINCLVEFAN	VARCHAR2
INCYN5A - Peak V02 < 55% predicted or peak V02 ≤ 16 for men or ≤ 14 for women (Respiratory Exchange Ratio (RER) ≥ 1.05) (within the past 12 months)	PEAKV02A_CIIPEAKV02A_C	NUMBER
	PEAKV02A_CIIPEAKV02A	VARCHAR2
INCYN5A - 6 min walk test distance < 300 m (within the past 3 months)	MINWAL6A_CIIINWAL6A_C	NUMBER
	MINWAL6A_CIIINWAL6A	VARCHAR2
ICNYN6A	ICNYN6A_C	NUMBER
	ICNYN6A	VARCHAR2
	ICNYN6A_ND	VARCHAR2
	ICNYN6A	VARCHAR2
INCYN7A	INCYN7A_C	NUMBER
	INCYN7A	VARCHAR2
	INCYN7A_ND	VARCHAR2
ICMETYNA	ICMETYNA_C	NUMBER
	ICMETYNA	VARCHAR2
	ICMETYNA_ND	VARCHAR2
Key: [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFNLIFE: INCLUSION/EXCLUSION PART 2 (ELIG2) [frELIG2]		
Exclusion [stELIG]		
1.* ✓ Currently taking Entresto™? [Entresto]	[EXCYN1] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
2.* ✓ History of hypersensitivity or intolerance to Entresto™, an ACEI or ARB as well as known or suspected contraindications to the study drugs? [Hypersensitivity]	[EXCYN2] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
3.* ✓ Age <18 years or > 85 years; co-morbid conditions that may cause death within 1 yr (e.g. cancer, chronic obstructive pulmonary disease (COPD)); and recent history of drug abuse? [ Co-morbid conditions]	[EXCYN3] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
4.* ✓ Symptomatic hypotension at randomization? [Symptomatic hypotension at randomization?]	[EXCYN4] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
5.* ✓ Serum potassium > 5.5 mmol/L? [Serum potassium]	[EXCYN5] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
6.* ✓ Severe liver dysfunction (Childs-Pugh Class C)? [Severe liver dysfunction ]	[EXCYN6] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
7.* ✓ Acute coronary syndrome within 4 weeks as defined by electrocardiographic (ECG) changes and biomarkers of myocardial necrosis (e.g. troponin) in an appropriate clinical setting (chest discomfort or original equivalent)? [Acute coronary syndrome]	[EXCYN7] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
8.* ✓ Planned or recent (≤ 4 weeks) PCI, coronary artery bypass grafting or biventricular pacing? [CABG]	[EXCYN8] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
9.* ✓ Currently hospitalized and listed 1A or 1B/1-4 for transplant? [Currently hospitalized]	[EXCYN9] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
10.* ✓ Current or scheduled for LVAD implantation within 30 days of study enrollment? [LVAD implantation]	[EXCYN10] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
11.* ✓ Active infection (current use of oral or IV antimicrobial agents)? [Active infection ]	[EXCYN11] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
12.* ✓ Primary hypertrophic or infiltrative cardiomyopathy, acute myocarditis, constrictive pericarditis or tamponade? [Primary hypertrophic]	[EXCYN12] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
13.* ✓ Complex congenital heart disease? [Complex congenital heart disease?]	[EXCYN13] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
14.* ✓ Concomitant use of aliskiren in patients with diabetes or renal impairment (eGFR < 60 mL/min/1.73m <sup>2</sup> )? [Concomitant use of aliskiren]	[EXCYN14] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
15.* ✓ Known pregnancy or anticipated pregnancy within the next 6 months or breastfeeding mothers? [Known pregnancy]	[EXCYN15] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> [ePPREG] No [EXPGDT] (DD/MM/YYYY) If no_Pregnancy Test Date Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) [PREGRES] Result [N:1] <input type="radio"/> Positive [N:2] <input type="radio"/> Negative [N:98] <input type="radio"/> N/A - Male [N:99] <input type="radio"/> N/A - Post Menopausal [N:97] <input type="radio"/> Not Evaluated	
16.* ✓ Enrollment in any other investigational clinical trial within 30 days prior to screening? [Enrollment]	[EXCYN16] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
17.* ✓ Inability to comply with study procedures?	[EXCYN17] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
18.* ✓ Did subject meet any Exclusion Criteria? [ Exclusion Criteria]	[ECHETYN] [N:1] <input type="radio"/> Yes (update WEBEZ to Screen Fail patient) [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated	
19.* ✓ Did subject withdraw consent or Investigator withdraw the subject prior to Randomization? [Did subject withdraw consent or Investigator withdraw the subject]	[ECWCYN] [N:1] <input type="radio"/> [ePOTHSPECY] Yes: [ECWCSPEC] Specify: A100 [N:0] <input type="radio"/> No [N:99] <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_FRELIG2		
Data Variable RefName	RD Column Name	Column Data Type
EXCYN1	EXCYN1_C	NUMBER
	EXCYN1	VARCHAR2
	EXCYN1_ND	VARCHAR2
EXCYN2	EXCYN2_C	NUMBER
	EXCYN2	VARCHAR2
	EXCYN2_ND	VARCHAR2
EXCYN3	EXCYN3_C	NUMBER
	EXCYN3	VARCHAR2
	EXCYN3_ND	VARCHAR2
EXCYN4	EXCYN4_C	NUMBER
	EXCYN4	VARCHAR2
	EXCYN4_ND	VARCHAR2
EXCYN5	EXCYN5_C	NUMBER
	EXCYN5	VARCHAR2
	EXCYN5_ND	VARCHAR2
EXCYN6	EXCYN6_C	NUMBER
	EXCYN6	VARCHAR2
	EXCYN6_ND	VARCHAR2
EXCYN7	EXCYN7_C	NUMBER
	EXCYN7	VARCHAR2
	EXCYN7_ND	VARCHAR2
EXCYN8	EXCYN8_C	NUMBER
	EXCYN8	VARCHAR2
	EXCYN8_ND	VARCHAR2
EXCYN9	EXCYN9_C	NUMBER
	EXCYN9	VARCHAR2
	EXCYN9_ND	VARCHAR2
EXCYN10	EXCYN10_C	NUMBER
	EXCYN10	VARCHAR2
	EXCYN10_ND	VARCHAR2
EXCYN11	EXCYN11_C	NUMBER
	EXCYN11	VARCHAR2
	EXCYN11_ND	VARCHAR2
EXCYN12	EXCYN12_C	NUMBER
	EXCYN12	VARCHAR2
	EXCYN12_ND	VARCHAR2
EXCYN13	EXCYN13_C	NUMBER
	EXCYN13	VARCHAR2
	EXCYN13_ND	VARCHAR2
EXCYN14	EXCYN14_C	NUMBER
	EXCYN14	VARCHAR2
	EXCYN14_ND	VARCHAR2
EXCYN15	EXCYN15_C	NUMBER
	EXCYN15	VARCHAR2
	EXCYN15_ND	VARCHAR2
EXCYN15 - EXPGDT	EXPGDT	DATE
	EXPGDT_DTS	VARCHAR2
EXCYN15 - PREGRES	PREGRES_C	NUMBER
	PREGRES	VARCHAR2
EXCYN16	EXCYN16_C	NUMBER
	EXCYN16	VARCHAR2
	EXCYN16_ND	VARCHAR2
EXCYN17	EXCYN17_C	NUMBER
	EXCYN17	VARCHAR2
	EXCYN17_ND	VARCHAR2
ECMETYN	ECMETYN_C	NUMBER
	ECMETYN	VARCHAR2
	ECMETYN_ND	VARCHAR2
ECWCYN	ECWCYN_C	**NUMBER
	ECWCYN	VARCHAR2
	ECWCYN_ND	VARCHAR2
ECWCYN - ECWCSPEC	ECWCSPEC	VARCHAR2

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

HFNLIFE: INCLUSION/EXCLUSION PART 2 (ELIG2A) [frELIG2A]	
Exclusion [stELIG2A]	
1.* ✓ Currently taking Entresto™? [Currently taking Entresto™?]	<b>[EXCYN1A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
2.* ✓ History of hypersensitivity or intolerance (unmodifiable) to Entresto™, an ACEI or ARB as well as known or suspected contraindications to the study drugs? [History of hypersensitivity or intolerance (unmodifiable) to Entresto™, an ACEI or ARB]	<b>[EXCYN2A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
3. Estimated glomerular filtration rate (eGFR) <20 mL/min/1.73m <sup>2</sup> at baseline? [hidden] [Estimated glomerular filtration rate]	<b>[EXCYN3A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> <b>[cpEXCYN3A]</b> No If no, GFR Date and value <b>[GFRDT1] (DD/MM/YYYY)</b> Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2021) <b>[GFRVAL1]</b> Value A100 [N:99] <input type="radio"/> Not Evaluated
4.* ✓ Estimated glomerular filtration rate (eGFR) <20 mL/min/1.73m <sup>2</sup> at baseline? [Estimated glomerular filtration rate]	<b>[EXCYN3A1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> <b>[cpEXCYN3A1]</b> No If no, GFR Date and value <b>[GFRDT1] (DD/MM/YYYY)</b> Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2021) <b>[GFRVALUE]</b> Value xxxxxxxx. [N:99] <input type="radio"/> Not Evaluated
5.* ✓ Co-morbid conditions that may interfere with completing the study protocol (e.g. recent history of drug or alcohol abuse) or cause death within 1 year? [Co-morbid conditions]	<b>[EXCYN18A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
6.* ✓ Symptomatic hypotension at randomization or systolic blood pressure < 90mmHg? [Symptomatic hypotension at randomization or systolic blood pressure]	<b>[EXCYN4A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
7.* ✓ Serum potassium > 5.5 mmol/L? [Serum potassium > 5.5 mmol/L?]	<b>[EXCYN5A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
8.* ✓ Severe liver dysfunction (Childs-Pugh Class C)? [Severe liver dysfunction (Childs-Pugh Class C)?]	<b>[EXCYN6A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
9.* ✓ Acute coronary syndrome within 4 weeks as defined by electrocardiographic (ECG) changes and biomarkers of myocardial necrosis (e.g. troponin) in an appropriate clinical setting (chest discomfort or angular equivalent)? [Acute coronary syndrome]	<b>[EXCYN7A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
10.* ✓ Planned or recent (≤ 4 weeks) PCI, coronary artery bypass grafting or biventricular pacing? [Planned or recent PCI]	<b>[EXCYN8A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
11.* ✓ Currently hospitalized and listed status 1A, 1B or 1-4 for heart transplant? [Currently hospitalized and listed status]	<b>[EXCYN9A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
12.* ✓ Current or scheduled for LVAD implantation within 30 days of study enrollment? [Current or scheduled for LVAD implantation]	<b>[EXCYN10A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
13.* ✓ Active infection (current use of oral or IV antimicrobial agents)? [Active infection (current use of oral or IV antimicrobial agents)?]	<b>[EXCYN11A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
14.* ✓ Primary hypertrophic or infiltrative cardiomyopathy, acute myocarditis, constrictive pericarditis or tamponade? [Primary hypertrophic or infiltrative cardiomyopathy, acute myocarditis, constrictive pericarditis or tamponade?]	<b>[EXCYN12A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
15.* ✓ Complex congenital heart disease? [Complex congenital heart disease?]	<b>[EXCYN13A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
16.* ✓ Concomitant use of aliskiren in patients with diabetes or renal impairment (eGFR < 60 mL/min/1.73m <sup>2</sup> )? [Concomitant use of aliskiren in patients with diabetes or renal impairment (eGFR < 60 mL/min/1.73m <sup>2</sup> )?]	<b>[EXCYN14A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
17.* ✓ Known pregnancy or anticipated pregnancy within the next 6 months or breastfeeding mothers? [Known pregnancy or anticipated pregnancy within the next 6 months or breastfeeding mothers?]	<b>[EXCYN15A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> <b>[cpEXCYN15A]</b> <b>[EXPGADT] (DD/MM/YYYY)</b> No If no, Pregnancy Test Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2021) <b>[PREGRESA]</b> Result [N:1] <input type="radio"/> Positive [N:2] <input type="radio"/> Negative [N:98] <input type="radio"/> N/A - Male [N:99] <input type="radio"/> N/A - Post Menopausal

18.* <input checked="" type="checkbox"/> Enrollment in any other investigational clinical trial within 30 days prior to screening? [Enrollment in any other investigational clinical trial within 30 days prior to screening?]	[N:97] <input type="radio"/> Not Evaluated <b>[EXCYN16A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
19.* <input checked="" type="checkbox"/> Inability to comply with study procedures? [Inability to comply with study procedures?]	<b>[EXCYN17A]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
20.* <input checked="" type="checkbox"/> Did subject meet any Exclusion Criteria? [Did subject meet any Exclusion Criteria?]	<b>[ECMETYNA]</b> [N:1] <input type="radio"/> Yes (update WEBEZ to Screen Fail patient) [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Not Evaluated
21.* <input checked="" type="checkbox"/> Did Subject withdraw consent or Investigator withdraw the subject prior to Randomization? [Subject withdrew consent or Investigator withdrew subject]	<b>[ECWCYNA]</b> [N:1] <input type="radio"/> <b>[ECWCSPA]</b> Yes Specify: A100 <input style="width: 200px;" type="text"/> [N:0] <input type="radio"/> No [N:99] <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_FRELIG2A		
Data Variable RefName	RD Column Name	Column Data Type
EXCYN1A	EXCYN1A_C	NUMBER
	EXCYN1A	VARCHAR2
	EXCYN1A_ND	VARCHAR2
EXCYN2A	EXCYN2A_C	NUMBER
	EXCYN2A	VARCHAR2
	EXCYN2A_ND	VARCHAR2
EXCYN3A	EXCYN3A_C	NUMBER
	EXCYN3A	VARCHAR2
	EXCYN3A_ND	VARCHAR2
EXCYN3A - GFRDT	GFRDT	DATE
	GFRDT_DTS	VARCHAR2
EXCYN3A - GFRVAL1	GFRVAL1	VARCHAR2
EXCYN3A1	EXCYN3A1_C	NUMBER
	EXCYN3A1	VARCHAR2
	EXCYN3A1_ND	VARCHAR2
EXCYN3A1 - GFRDT1	GFRDT1	DATE
	GFRDT1_DTS	VARCHAR2
EXCYN3A1 - GFRVALUE	GFRVALUE	FLOAT
EXCYN18A	EXCYN18A_C	NUMBER
	EXCYN18A	VARCHAR2
	EXCYN18A_ND	VARCHAR2
EXCYN4A	EXCYN4A_C	NUMBER
	EXCYN4A	VARCHAR2
	EXCYN4A_ND	VARCHAR2
EXCYN5A	EXCYN5A_C	NUMBER
	EXCYN5A	VARCHAR2
	EXCYN5A_ND	VARCHAR2
EXCYN6A	EXCYN6A_C	NUMBER
	EXCYN6A	VARCHAR2
	EXCYN6A_ND	VARCHAR2
EXCYN7A	EXCYN7A_C	NUMBER
	EXCYN7A	VARCHAR2
	EXCYN7A_ND	VARCHAR2
EXCYN8A	EXCYN8A_C	NUMBER
	EXCYN8A	VARCHAR2
	EXCYN8A_ND	VARCHAR2
EXCYN9A	EXCYN9A_C	NUMBER
	EXCYN9A	VARCHAR2
	EXCYN9A_ND	VARCHAR2
EXCYN10A	EXCYN10A_C	NUMBER
	EXCYN10A	VARCHAR2
	EXCYN10A_ND	VARCHAR2
EXCYN11A	EXCYN11A_C	NUMBER
	EXCYN11A	VARCHAR2
	EXCYN11A_ND	VARCHAR2
EXCYN12A	EXCYN12A_C	NUMBER
	EXCYN12A	VARCHAR2
	EXCYN12A_ND	VARCHAR2
EXCYN13A	EXCYN13A_C	NUMBER
	EXCYN13A	VARCHAR2
	EXCYN13A_ND	VARCHAR2
EXCYN14A	EXCYN14A_C	NUMBER
	EXCYN14A	VARCHAR2
	EXCYN14A_ND	VARCHAR2
EXCYN15A	EXCYN15A_C	NUMBER
	EXCYN15A	VARCHAR2

	EXCYN15A_ND	VARCHAR2
EXCYN15A - EXPGADT	EXPGADT	DATE
	EXPGADT_DTS	VARCHAR2
EXCYN15A - PREGRESA	PREGRESA_C	NUMBER
	PREGRESA	VARCHAR2
EXCYN16A	EXCYN16A_C	NUMBER
	EXCYN16A	VARCHAR2
	EXCYN16A_ND	VARCHAR2
EXCYN17A	EXCYN17A_C	NUMBER
	EXCYN17A	VARCHAR2
	EXCYN17A_ND	VARCHAR2
ECMETYNA	ECMETYNA_C	NUMBER
	ECMETYNA	VARCHAR2
	ECMETYNA_ND	VARCHAR2
ECWCYNA	ECWCYNA_C	**NUMBER
	ECWCYNA	VARCHAR2
	ECWCYNA_ND	VARCHAR2
ECWCYNA - ECWCSPEA	ECWCSPEA	VARCHAR2

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

HFNLIFE: 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] (MM/YYYY) Req/Unk <input checked="" type="checkbox"/> / Req/Unk <input type="checkbox"/> (1920-2021)
2.* ✓ Total number of hospitalizations with primary diagnosis of heart failure within prior 6 months, not including the index hospitalization for inpatient participants (provide best estimate if exact number is unknown) [Total number of hospitalizations within prior 6 months]	[HOSPVAL] N3 <input type="text"/>
3. Number of hospitalizations with primary diagnosis of heart failure within past 6 months (provide best estimate if exact number is unknown): [hidden] [Number of hospitalizations with primary diagnosis of heart failure within past 6 months]	[NUMHFHSP] N3 <input type="text"/>
4.* ✓ Number of outpatient heart failure visits within past 6 months (provide best estimate if exact number is unknown): [Number of outpatient heart failure visits]	[OUTPVIST] N3 <input type="text"/>
5.* ✓ Has LV function been assessed per protocol? [Has LV function been assessed per protocol?]	[LVASSESS] [N:1] <input type="radio"/> Yes <input checked="" type="radio"/> No If Yes: date of last LVEF: [LVASSDT] (DD/MM/YYYY) Date: Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) [LVEF] Value of last LVEF: [N:1] <input type="text"/> [LVEFEF] % xxxxxxxxx % [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
6.* ✓ 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
7.* ✓ 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
8.* ✓ Has the subject had a percutaneous coronary intervention (PCI)? [Has the subject had a percutaneous coronary intervention (PCI)]	[PCIHK] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
9.* ✓ 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
10.* ✓ 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 [IDIORIS] [N:1] <input type="checkbox"/> Idiopathic restrictive cardiomyopathy [PERIPRT] [N:1] <input type="checkbox"/> Peripartum [VALVUL] [N:1] <input type="checkbox"/> Valvular [HCM] [N:1] <input type="checkbox"/> HCM [MYOOTH] [N:1] <input type="checkbox"/> [MYOPSP] Other/uncertain Specify A100 [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown

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
HOSPVAL	HOSPVAL	NUMBER
	HOSPVAL_ND	VARCHAR2
NUMHFHSP	NUMHFHSP	NUMBER
	NUMHFHSP_ND	VARCHAR2
OUTPVIST	OUTPVIST	NUMBER
	OUTPVIST_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.

HFNLIFE: 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 type="radio"/> [cpVALVULAR] Yes (check all that apply) [MSTENOS] [N:1] <input type="checkbox"/> Mitral stenosis [MREGURG] [N:1] <input type="checkbox"/> Mitral regurgitation [ATSTENOS] [N:1] <input type="checkbox"/> Aortic stenosis [AREGURG] [N:1] <input type="checkbox"/> Aortic regurgitation [TSTENOS] [N:1] <input type="checkbox"/> Tricuspid stenosis [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]	[PVALSURG] [N:1] <input type="radio"/> [cpPVALSURG] 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 type="radio"/> [cpARRHYTHM] Yes (check all that apply) [ATRIALFB] [N:1] <input type="checkbox"/> Atrial fibrillation [ARRHOTH] [N:1] <input type="checkbox"/> [ARRSPEC] Other Specify A100 [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
7.* ✓ Pacemaker/ICD [Pacemaker/ICD]	[PACEICD] [N:1] <input type="radio"/> [PACICDTY] Yes [N:1] <input type="radio"/> Pacemaker (single/dual) [N:2] <input type="radio"/> Biventricular Pacemaker with ICD [N:3] <input type="radio"/> Biventricular Pacemaker without ICD [N:4] <input type="radio"/> ICD only (single/dual) [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
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.* ✓ Malignancy (past 5 years other than skin) [Malignancy (past 5 years other than skin)]	[MALIG] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
14.* ✓ Depression (treated with prescription medication) [Depression]	[DEPRESS] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
Chronic alcohol use	

15.* ✓	[Chronic alcohol use]	[ALCOHOL] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
16.* ✓	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
17.* ✓	Hyperlipidemia [Hyperlipidemia]	[HYPLRLIP] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
18.* ✓	Obstructive sleep apnea [Obstructive sleep apnea]	[OSA] <input type="radio"/> [OSATX] [N:1] Yes Treated: [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
<p>Key: [*] = Item is required [✓] = Source verification required                  Note: Source verification critical settings made in InForm will override any settings made in Central Designer.</p>		

RDE Analytics: RD_FRMEDHIST2		
Data Variable RefName	RD Column Name	Column Data Type
VALVULAR	VALVULAR_C	**NUMBER
	VALVULAR	VARCHAR2
	VALVULAR_ND	VARCHAR2
VALVULAR - Mitral stenosis	MSTENOS_CIMITRALSTENOSIS_C	NUMBER
	MSTENOS_CIMITRALSTENOSIS	VARCHAR2
VALVULAR - Mitral regurgitation	*MREGURG_CIMITRALREGURGITATION_C	NUMBER
	*MREGURG_CIMITRALREGURGITATION	VARCHAR2
VALVULAR - Aortic stenosis	ATSTENOS_CIAORTICSTENOSIS_C	NUMBER
	ATSTENOS_CIAORTICSTENOSIS	VARCHAR2
VALVULAR - Aortic regurgitation	*AREGURG_CIAORTICREGURGITATION_C	NUMBER
	*AREGURG_CIAORTICREGURGITATION	VARCHAR2
VALVULAR - Tricuspid stenosis	*TSTENOS_CITRICUSPIDSTENOSIS_C	NUMBER
	*TSTENOS_CITRICUSPIDSTENOSIS	VARCHAR2
VALVULAR - Tricuspid regurgitation	*TREGURG_CITRICUSPIDREGURGITATION_C	NUMBER
	*TREGURG_CITRICUSPIDREGURGITATION	VARCHAR2
PVALSRG	PVALSRG_C	**NUMBER
	PVALSRG	VARCHAR2
	PVALSRG_ND	VARCHAR2
PVALSRG - Mitral	MITSURG_CIMITRAL_C	NUMBER
	MITSURG_CIMITRAL	VARCHAR2
PVALSRG - Aortic	AORSURG_CIAORTIC_C	NUMBER
	AORSURG_CIAORTIC	VARCHAR2
PVALSRG - Tricuspid	TRISURG_CITRICUSPID_C	NUMBER
	TRISURG_CITRICUSPID	VARCHAR2
PVALSRG - Pulmonic	PULSURG_CIPULMONIC_C	NUMBER
	PULSURG_CIPULMONIC	VARCHAR2
HYPRTESN	HYPRTESN_C	NUMBER
	HYPRTESN	VARCHAR2
	HYPRTESN_ND	VARCHAR2
TIA	TIA_C	NUMBER
	TIA	VARCHAR2
	TIA_ND	VARCHAR2
STROKE	STROKE_C	NUMBER
	STROKE	VARCHAR2
	STROKE_ND	VARCHAR2
ARRHYTHM	ARRHYTHM_C	**NUMBER
	ARRHYTHM	VARCHAR2
	ARRHYTHM_ND	VARCHAR2
ARRHYTHM - Atrial fibrillation	*ATRIALFB_CIATRIALFIBRILLATION_C	NUMBER
	*ATRIALFB_CIATRIALFIBRILLATION	VARCHAR2
ARRHYTHM - Unknown/Other	ARRHOTH_ARRSPEC_C	**NUMBER
	ARRHOTH_ARRSPEC	VARCHAR2
ARRHYTHM - ARRSPEC	ARRSPEC	VARCHAR2
PACEICD	PACEICD_C	**NUMBER
	PACEICD	VARCHAR2
	PACEICD_ND	VARCHAR2
PACEICD - PACICDXY	PACICDXY_C	NUMBER
	PACICDXY	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
MALIG	MALIG_C	NUMBER
	MALIG	VARCHAR2
	MALIG_ND	VARCHAR2
DEPRESS	DEPRESS_C	NUMBER
	DEPRESS	VARCHAR2
	DEPRESS_ND	VARCHAR2
ALCOHOL	ALCOHOL_C	NUMBER
	ALCOHOL	VARCHAR2
	ALCOHOL_ND	VARCHAR2
SMOKING	SMOKING_C	NUMBER
	SMOKING	VARCHAR2
	SMOKING_ND	VARCHAR2
HYPRLIP	HYPRLIP_C	NUMBER
	HYPRLIP	VARCHAR2
	HYPRLIP_ND	VARCHAR2
OSA	OSA_C	**NUMBER
	OSA	VARCHAR2
	OSA_ND	VARCHAR2
OSA - OSATX	OSATX_C	NUMBER
	OSATX	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different. [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFNLIFE: MEDICATIONS (MEDS) [frMEDS]	
Medications [stMEDS1]	
1.* ✓ ACE inhibitor [ACE inhibitor]	[ACE] <input type="radio"/> Yes [N:1] [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.* ✓ Valsartan [Valsartan]	[VAL] <input type="radio"/> Yes [N:1] [N:0] <input type="radio"/> [VALCONT] 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.* ✓ Angiotensin receptor blocker (Other than Valsartan) [Angiotensin receptor blocker]	[ARB] <input type="radio"/> Yes [N:1] [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
4.* ✓ Was the patient on ACE inhibitor or Angiotensin Receptor Blocker at time of consent? [the patient on ACE inhibitor or Angiotensin Receptor Blocker at time of consent]	[ACEICONS] <input type="radio"/> Yes [N:1] [N:0] <input type="radio"/> [ACEOTHSP] No If No, patient was not on ACE, ARB and Valsartan, provide reason: AZ00 <input type="text"/>
5.* ✓ Beta Blocker [Beta Blocker]	[BETAB] <input type="radio"/> Yes [N:1] [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
6.* ✓ Aldosterone antagonist [Aldosterone antagonist]	[ALDOS] <input type="radio"/> Yes [N:1] [N:0] <input type="radio"/> [ALDOCONT] No If no: Is there documented evidence of contraindication? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
7.* ✓ Hydralazine [Hydralazine]	[HYDR] <input type="radio"/> Yes [N:1] [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
8.* ✓ Nitrates (long acting) [Nitrates]	[NITR] <input type="radio"/> Yes [N:1] [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
9.* ✓ Calcium channel blocker [Calcium channel blocker]	[CCB] <input type="radio"/> Yes [N:1] [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
10.* ✓ Antiplatelets [Antiplatelets]	[ANTIPLT] <input type="radio"/> [cANTIPLTY] [N:1] Yes (check all that apply) [ANTIPASP] <input type="checkbox"/> [N:1] Aspirin (taken daily) [ANTIPHPH] <input type="checkbox"/> [N:1] Thienopyridines (eg: ticlopidine, clopidogrel, prasugrel) [ANTIPOTH] <input type="checkbox"/> [N:1] Other [N:0] <input 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
11.* ✓ Anticoagulants [Anticoagulants]	[ANTICAG] <input type="radio"/> [cANTICAGY] [N:1] Yes (check all that apply) [ANTICWAR] <input type="checkbox"/> [N:1] Warfarin [ANTHEP] <input type="checkbox"/> [N:1] Heparin [ANTICFCX] <input type="checkbox"/> [N:1] Factor Xa Inhibitor [ANTICDTH] <input type="checkbox"/> [N:1] Direct Thrombin Inhibitor [ANTICOTH] <input type="checkbox"/> [N:1] Other [N:0] <input type="radio"/> [ANTICACI] No

		<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>
12.* ✓	Digoxin [Digoxin]	<p><b>[DIGGX]</b></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.* ✓	Amiodarone [Amiodarone]	<p><b>[AMIOD]</b></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>
14.* ✓	Statin [Statin]	<p><b>[STATIN]</b></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>
15.* ✓	Lipid lowering agent (other than statin) [Lipid lowering agent]	<p><b>[LLIPID]</b></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>
16.* ✓	Insulin [Insulin]	<p><b>[INSULIN]</b></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>
17.* ✓	Oral diabetic agent [Oral diabetic agent]	<p><b>[ODIAGT]</b></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>
18.* ✓	Antidepressant [Antidepressant]	<p><b>[DEPRES]</b></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>
19.* ✓	Aiskiren [Aiskiren]	<p><b>[ALI]</b></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>
20.* ✓	Sacubitril/Valsartan (Entresto) [Sacubitril/Valsartan (Entresto)]	<p><b>[ENTRESTO]</b></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>
21.* ✓	Ivabradine (Corlanor) [Ivabradine (Corlanor)]	<p><b>[IVABRAD]</b></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>
22.* ✓	Metolazone [Metolazone]	<p><b>[METAZ]</b> <b>[METZFRQ]</b></p> <p>[N:1] <input type="radio"/> Yes  <input type="radio"/> Chronic (&gt;=1x/week)  <input type="radio"/> PRN (&lt;1x/week)</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:99] <input type="radio"/> Unknown</p>
23.* ✓	HCTZ [HCTZ]	<p><b>[HCTZ]</b> <b>[HCTZFRQ]</b></p> <p>[N:1] <input type="radio"/> Yes  <input type="radio"/> Chronic (&gt;=1x/week)  <input type="radio"/> PRN (&lt;1x/week)</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:99] <input type="radio"/> Unknown</p>
24.* ✓	Furosemide [Furosemide]	<p><b>[FURO]</b></p> <p>[N:1] <input type="radio"/> <b>[FURODOSE]</b>  Yes  Daily Dose (mg): _____  xxxxxxxx.</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:99] <input type="radio"/> Unknown</p>
25.* ✓	Torsemide [Torsemide]	<p><b>[TORS]</b></p> <p>[N:1] <input type="radio"/> <b>[TORSDOSE]</b>  Yes  Daily Dose (mg): _____  xxxxxxxx.</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:99] <input type="radio"/> Unknown</p>
26.* ✓	Bumetanide [Bumetanide]	<p><b>[BUME]</b> <b>[BUMDOSE]</b></p> <p>[N:1] <input type="radio"/> Yes  Daily Dose (mg): _____  xxxxxxxx.</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:99] <input type="radio"/> Unknown</p>
27.* ✓	Chlorothiazide [Chlorothiazide]	<p><b>[CHLORTH]</b> <b>[CHLORDSE]</b></p> <p>[N:1] <input type="radio"/> Yes  Total Daily Dose (mg): _____  xxxxxxxx.</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:99] <input type="radio"/> Unknown</p>
28.* ✓	Chlorthalidone [Chlorthalidone]	<p><b>[THALID]</b> <b>[THALIDOS]</b></p> <p>[N:1] <input type="radio"/> Yes  Total Daily Dose (mg): _____  xxxxxxxx.</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:99] <input type="radio"/> Unknown</p>
	Spirolactone	<p><b>[SPIROUSE]</b></p>

29.* ✓ [Spirinolactone]	[N:1] <input type="radio"/> [SPIRDOSE] Yes Total Daily Dose (mg): xxxxxxxx. [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
30.* ✓ Eplerenone [Eplerenone]	[EPLUSE] [N:1] <input type="radio"/> [EPLEDOSE] Yes Total Daily Dose (mg): xxxxxxxx. [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
31.* ✓ Potassium [Potassium]	[KUSE] [N:1] <input type="radio"/> [KD0SE] Yes Total Daily Dose (mEq): xxxxxxxxxxxx.xx [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
32.* ✓ Magnesium [Magnesium]	[MAGUSE] [N:1] <input type="radio"/> [MAGDOSE] Yes Total Daily Dose (mg): xxxxxxxx. [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
33.* ✓ IV Inotropes [IV Inotropes]	[VINOTRO] [N:1] <input type="radio"/> Yes (If yes, complete INOTROPE form) [N:0] <input type="radio"/> No [N:99] <input 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.</p>	

RDE Analytics: RD_FRMEDI		
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
VAL	VAL_C	NUMBER
	VAL	VARCHAR2
	VAL_ND	VARCHAR2
VAL - VALCONT	VALCONT_C	NUMBER
	VALCONT	VARCHAR2
ARB	ARB_C	NUMBER
	ARB	VARCHAR2
	ARB_ND	VARCHAR2
ARB - ARBCONT	ARBCONT_C	NUMBER
	ARBCONT	VARCHAR2
ACEICONS	ACEICONS_C	NUMBER
	ACEICONS	VARCHAR2
	ACEICONS_ND	VARCHAR2
ACEICONS - ACEOTHSP	ACEOTHSP	VARCHAR2
BETAB	BETAB_C	NUMBER
	BETAB	VARCHAR2
	BETAB_ND	VARCHAR2
	BETACONT_C	NUMBER
BETAB - BETACONT	BETACONT	VARCHAR2
ALDOS	ALDOS_C	NUMBER
	ALDOS	VARCHAR2
	ALDOS_ND	VARCHAR2
	ALDOCONT_C	NUMBER
ALDOS - ALDOCONT	ALDOCONT	VARCHAR2
HYDR	HYDR_C	NUMBER
	HYDR	VARCHAR2
	HYDR_ND	VARCHAR2
NITR	NITR_C	NUMBER
	NITR	VARCHAR2
	NITR_ND	VARCHAR2
CCB	CCB_C	NUMBER
	CCB	VARCHAR2
	CCB_ND	VARCHAR2
	ANTIPLT	ANTIPLT_C
ANTIPLT - Aspirin (taken daily)	ANTIPLT	VARCHAR2
	ANTIPLT_ND	VARCHAR2
	*ANTIPASP_CIASPIRINTAKENDAILY_C	NUMBER
ANTIPLT - Thienopyridines (eg: ticlopidine, clopidogrel, prasugrel)	*ANTIPASP_CIASPIRINTAKENDAILY	VARCHAR2
	*ANTIPTHL_CITHIENOPYRIDINES_C	NUMBER
	*ANTIPTHL_CITHIENOPYRIDINES	VARCHAR2
ANTIPLT - Other	ANTIPOTH_C10THER1_C	NUMBER
	ANTIPOTH_C10THER1	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 - Heparin	ANTIHEP_CANTIHEP_C	NUMBER
	ANTIHEP_CANTIHEP	VARCHAR2
	*ANTICFCX_CIFACTORXINHIBITOR_C	NUMBER
ANTICAG - Factor Xa Inhibitor	*ANTICFCX_CIFACTORXINHIBITOR	VARCHAR2
	*ANTICDTH_CIDIRECTTHROMBININHIBITOR_C	NUMBER
ANTICAG - Direct Thrombin Inhibitor	*ANTICDTH_CIDIRECTTHROMBININHIBITOR	VARCHAR2
	ANTICOTH_CIOTHER1_C	NUMBER
ANTICAG - Other	ANTICOTH_CIOTHER1	VARCHAR2
	ANTICACI_C	NUMBER
ANTICAG - ANTICACI	ANTICACI	VARCHAR2
	DIGX_C	NUMBER
DIGX	DIGX	VARCHAR2
	DIGX_ND	VARCHAR2
	AMIOD_C	NUMBER
AMIOD	AMIOD	VARCHAR2
	AMIOD_ND	VARCHAR2
	STATIN_C	NUMBER
STATIN	STATIN	VARCHAR2
	STATIN_ND	VARCHAR2
	LLIPID_C	NUMBER
LLIPID	LLIPID	VARCHAR2
	LLIPID_ND	VARCHAR2
	INSULIN_C	NUMBER
INSULIN	INSULIN	VARCHAR2
	INSULIN_ND	VARCHAR2
ODIAGT	ODIAGT_C	NUMBER
	ODIAGT	VARCHAR2
	ODIAGT_ND	VARCHAR2
DEPRES	DEPRES_C	NUMBER
	DEPRES	VARCHAR2
	DEPRES_ND	VARCHAR2
ALI	ALI_C	NUMBER
	ALI	VARCHAR2
	ALI_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 - METZAFRQ	METAZFRQ_C	NUMBER
HCTZ	METAZFRQ	VARCHAR2
	HCTZ_C	**NUMBER
	HCTZ	VARCHAR2
HCTZ - HCCTZFRQ	HCTZ_ND	VARCHAR2
	HCCTZFRQ_C	NUMBER
FURO	HCCTZFRQ	VARCHAR2
	FURO_C	**NUMBER
	FURO	VARCHAR2
FURO - FURODOSE	FURO_ND	VARCHAR2
	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 - THALIDOS	THALIDOS	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
IVINOTRO	IVINOTRO_C	NUMBER
	IVINOTRO	VARCHAR2
	IVINOTRO_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.		

HFNLIFE: EXAMINATION (EXAM) [frEXAM]	
Examination [stEXAM1]	
1.* ✓ Date of Exam [Date of Exam]	<b>[EXDN]</b> [N:1] <input type="radio"/> [EXDT] (DD/MM/YYYY) Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) [N:97] <input type="radio"/> Not Done
2.* ✓ Heart Rate (sitting or resting) [Heart Rate]	<b>[HRATE]</b> [N:1] <input type="radio"/> [HRATEVAL] N3 <input type="text"/> bpm [N:97] <input type="radio"/> Not Done
3.* ✓ Blood Pressure (sitting or resting) [Blood Pressure]	<b>[BPDONE]</b> [N:1] <input type="radio"/> [cpBPP] [BPPSYS] [BPDIA] mmHg N3 <input type="text"/> / N3 <input type="text"/> [N:97] <input type="radio"/> Not Done
4.* ✓ SpO2 [SpO2]	<b>[SPO2]</b> [N:1] <input type="radio"/> [SPO2VAL] <input type="text"/> % <sup>[b]</sup> xxxxxxxxxx. [N:97] <input type="radio"/> Not Done
5.* ✓ Height (at Screening visit only) [Height]	<b>[HEIGHT]</b> [N:1] <input type="radio"/> [cpHEIGHT] [HGTVAL] xxxxxxxxxx. [HGTUNIT] Unit [N:1] <input type="radio"/> in [N:2] <input type="radio"/> cm [N:97] <input type="radio"/> Not Done
6.* ✓ Weight [Weight]	<b>[WEIGHT]</b> [N:1] <input type="radio"/> [cpWEIGHT] [WGTVAL] xxxxxxxxxx. [WGTUNIT] Unit [N:1] <input type="radio"/> lb [N:2] <input type="radio"/> kg [N:97] <input type="radio"/> Not Done
7.* ✓ JVP [JVP]	<b>[JVP]</b> [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]	<b>[RALES]</b> [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]	<b>[S3AUS]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:97] <input type="radio"/> Not Done
10.* ✓ Hepatomegaly [Hepatomegaly]	<b>[HEPATO]</b> [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]	<b>[ASCITES]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:97] <input type="radio"/> Not Done
12.* ✓ Peripheral edema [Peripheral edema]	<b>[EDEMA]</b> [N:1] <input type="radio"/> None [N:2] <input type="radio"/> Trace [N:3] <input type="radio"/> Mild (1+) [N:4] <input type="radio"/> Moderate (2+, 3+) [N:97] <input type="radio"/> Not Done
13.* ✓ Current NYHA heart failure classification [Current NYHA heart failure classification]	<b>[NYHA]</b> [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]	<b>[ORTHOP]</b> [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.



		3 Moderately bothersome	3	ciModerately	
		4 Slightly bothersome	4	ciSlightly	
		5 Not at all bothersome	5	ciNotAtAll4	
		6 I have had no swelling	6	ciNone6	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctTimesLimited	Integer	1 All of the time	1	ciAllTime	KCCQ5, KCCQ7
		2 Several times per day	2	ciSeveralTimesPerDay	
		3 At least once a day	3	ciAtLeastOnceDay	
		4 3 or more times per week but not every day	4	ci3MoreTimesPerWeek4	
		5 1-2 times a week	5	ci1to2TimesPerWeek5	
		6 Less than once a week	6	ciLessThanOnceWeek6	
		7 Never over the past 2 weeks	7	ciNeverOverPast2Weeks	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctMuchBothered1	Integer	1 Extremely bothersome	1	ciExtremely	KCCQ6
		2 Quite a bit bothersome	2	ciQuiteBit2	
		3 Moderately bothersome	3	ciModerately	
		4 Slightly bothersome	4	ciSlightly	
		5 Not at all bothersome	5	ciNotAtAll4	
		6 I have had no fatigue	6	ciNoFatigue	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctMuchBothered2	Integer	1 Extremely bothersome	1	ciExtremely	KCCQ8
		2 Quite a bit bothersome	2	ciQuiteBit2	
		3 Moderately bothersome	3	ciModerately	
		4 Slightly bothersome	4	ciSlightly	
		5 Not at all bothersome	5	ciNotAtAll4	
		6 I have had no shortness of breath	6	ciNoShortnessBreath	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctTimesSleepUpright	Integer	1 Every night	1	ciEveryNight	KCCQ9
		2 3 or more times a week, but not every night	2	ci3xWeekNotEveryNight	
		3 1-2 times a week	3	ci1to2TimesPerWeek3	
		4 Less than once a week	4	ciLessThanOnceWeek4	
		5 Never over the past 2 weeks	5	ciNeverOverPast2Weeks5	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctHowSure	Integer	1 Not at all sure	1	ciNotAtAllSure	KCCQ10
		2 Not very sure	2	ciNotVerySure	
		3 Somewhat sure	3	ciSomewhatSure	
		4 Mostly sure	4	ciMostlySure	
		5 Completely sure	5	ciCompletelySure	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctHowWellUnderstand	Integer	1 Do not understand at all	1	ciDoNotUnderstandAtAll	KCCQ11
		2 Do not understand very well	2	ciDoNotUnderstandVeryWell	
		3 Somewhat understand	3	ciSomewhatUnderstand	
		4 Mostly understand	4	ciMostlyUnderstand	
		5 Completely understand	5	ciCompletelyUnderstand	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctLimited2	Integer	1 It has extremely limited my enjoyment of life	1	ciExtremelyLimited1	KCCQ12
		2 It has limited my enjoyment of life quite a bit	2	ciQuiteBitLimited2	
		3 It has moderately limited my enjoyment of life	3	ciModeratelyLimited3	
		4 It has slightly limited my enjoyment of life	4	ciSlightlyLimited4	
		5 It has not limited my enjoyment of life at all	5	ciNotAtAllLimited5	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctSatisfaction	Integer	1 Not at all satisfied	1	ciNotAtAllSatisfied	KCCQ13
		2 Mostly dissatisfied	2	ciMostlyDissatisfied	
		3 Somewhat satisfied	3	ciSomewhatSatisfied	
		4 Mostly satisfied	4	ciMostlySatisfied	
		5 Completely satisfied	5	ciCompletelySatisfied	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctHowOften	Integer	1 I felt that way all of the time	1	ciAllTheTime	KCCQ14
		2 I felt that way most of the time	2	ciMostTime	
		3 I occasionally felt that way	3	ciOccasionally2	
		4 I rarely felt that way	4	ciRarely	
		5 I never felt that way	5	ciNever5	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	
ctLimited3	Integer	1 Severely limited	1	ciSeverelyLimited	KCCQ15A, KCCQ15B, KCCQ15C, KCCQ15D
		2 Limited quite a bit	2	ciLimitedQuiteBit	
		3 Moderately limited	3	ciModeratelyLimited2	
		4 Slightly limited	4	ciSlightlyLimited3	
		5 Did not limit at all	5	ciDidNotLimitAtAll	
		6 Does not apply or did not do for other reasons	6	ciDoesNotApply	
		Unknown/Subject did not answer	99	ciUnkSubjectNotAnswer	

RDE Analytics: RD_FRKCCQ		
Data Variable RefName	RD Column Name	Column Data Type
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

HFNLIFE: LABS (LABS) [frLABS]	
Labs [stLABS]	
1.* ✓ Collection Date and Time [Collection Date and Time]	<b>[CHEMLDTM] (DD/MM/YYYY hh:mm)</b> [Req] [ ] / [Req] [ ] / [Req] [ ] (2015-2021) [Req/Unk] [ ] : [Req/Unk] [ ] 24-hour clock
2.* ✓ Sodium [Sodium]	<b>[SODIUM]</b> [N:1] <input type="radio"/> [cpSODIUM] [SODVAL] _____ xxxxxxxxxx. <b>[SODUNT]</b> 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]	<b>[POTAS]</b> [N:1] <input type="radio"/> [cpPOTAS] [POTASVAL] _____ xxxxxxxxxx. <b>[POTASUNT]</b> 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]	<b>[CHLORIDE]</b> [N:1] <input type="radio"/> [cpCHLORIDE] [CHLORVAL] _____ xxxxxxxxxx. <b>[CHLORUNT]</b> Unit: [N:1] <input type="radio"/> mmol/L [N:2] <input type="radio"/> mEq/L [N:97] <input type="radio"/> Not Done
5.* ✓ CO2/Bicarbonate [CO2/Bicarbonate]	<b>[CO2]</b> [N:1] <input type="radio"/> [cpCO2] [CO2VAL] _____ xxxxxxxxxx. <b>[CO2UNT]</b> Unit: [N:1] <input type="radio"/> mmol/L [N:2] <input type="radio"/> mEq/L [N:97] <input type="radio"/> Not Done
6.* ✓ BUN/UREA [BUN/UREA]	<b>[BUN]</b> [N:1] <input type="radio"/> [cpBUN] [BUNVAL] _____ xxxxxxxxxx. <b>[BUNUNT]</b> 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]	<b>[CREAT]</b> [N:1] <input type="radio"/> [cpCREAT] [CREATVAL] _____ xxxxxxxxxx. <b>[CREATUNT]</b> Unit: [N:3] <input type="radio"/> mg/dl [N:4] <input type="radio"/> umol/L [N:97] <input type="radio"/> Not Done
8.* ✓ Total calcium [Total calcium]	<b>[CALC]</b> [N:1] <input type="radio"/> [cpCALC] [CALCVAL] _____ xxxxxxxxxx. <b>[CALCUNT]</b> Unit: [N:1] <input type="radio"/> mmol/L [N:2] <input type="radio"/> mEq/L [N:3] <input type="radio"/> mg/dL [N:97] <input type="radio"/> Not Done
9.* ✓ Magnesium [Magnesium]	<b>[MAG]</b> [N:1] <input type="radio"/> [cpMAG] [MAGVAL] _____ xxxxxxxxxx. <b>[MAGUNT]</b> Unit: [N:1] <input type="radio"/> mmol/L [N:2] <input type="radio"/> mEq/L [N:3] <input type="radio"/> mg/dL [N:97] <input type="radio"/> Not Done
10.* ✓ BNP [BNP]	<b>[BNP]</b> [N:1] <input type="radio"/> [cpBNP] [BNPVAL] _____ xxxxxxxxxx. <b>[BNPUNT]</b> Unit: [N:17] <input type="radio"/> pg/mL [N:18] <input type="radio"/> ng/L [N:97] <input type="radio"/> Not Done
11.* ✓ NT-proBNP	<b>[NTBPNP]</b> [N:1] <input type="radio"/> [cpNTBPNP] [NTBPNPVAL] _____ xxxxxxxxxx. <b>[NTBPNPUNT]</b> Unit: [N:17] <input type="radio"/> pg/mL [N:18] <input type="radio"/> ng/L [N:97] <input type="radio"/> Not Done
12.* ✓ Were any of the labs above collected at a different date/time than entered in Question 1? [Were any of the labs above collected at a different date/time]	<b>[DIFFDTM]</b> [N:1] Yes (use Add Entry button)

Lab Test		Collection Date/Time
13.1	Lab Test: [Lab Test]	[N:0] <input type="radio"/> No [cpLABTEST] [SODIUM1] <input type="checkbox"/> Sodium [POTASUM1] <input type="checkbox"/> Potassium [CHLORID1] <input type="checkbox"/> Chloride [CARBOND1] <input type="checkbox"/> CO2/Bicarbonat [BUN1] <input type="checkbox"/> BUN/Urea [CREATIN1] <input type="checkbox"/> Creatinine [TCALC1] <input type="checkbox"/> Total calcium [BNP1] <input type="checkbox"/> BNP [NTPBNP1] <input type="checkbox"/> NT-proBNP [MAG1] <input type="checkbox"/> Magnesium
13.2	Collection Date/Time: [Collection Date/Time]	[LABDTM] (DD/MM/YYYY hh:mm) Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2015-2021) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <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_FRLABS		
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
	SODUNT_ND	VARCHAR2
POTAS	POTAS_C	**NUMBER
	POTAS	VARCHAR2
	POTAS_ND	VARCHAR2
POTAS - POTASVAL	POTASVAL	FLOAT
POTAS - POTASUNT	POTASUNT_C	NUMBER
	POTASUNT	VARCHAR2
	POTASUNT_ND	VARCHAR2
CHLORIDE	CHLORIDE_C	**NUMBER
	CHLORIDE	VARCHAR2
	CHLORIDE_ND	VARCHAR2
CHLORIDE - CHLORVAL	CHLORVAL	FLOAT
CHLORIDE - CHLORUNT	CHLORUNT_C	NUMBER
	CHLORUNT	VARCHAR2
	CHLORUNT_ND	VARCHAR2
CO2	CO2_C	**NUMBER
	CO2	VARCHAR2
	CO2_ND	VARCHAR2
CO2 - CO2VAL	CO2VAL	FLOAT
CO2 - CO2unit	CO2UNIT_C	NUMBER
	CO2UNIT	VARCHAR2
	CO2UNIT_ND	VARCHAR2
BUN	BUN_C	**NUMBER
	BUN	VARCHAR2
	BUN_ND	VARCHAR2
BUN - BUNVAL	BUNVAL	FLOAT
BUN - BUNUNT	BUNUNT_C	NUMBER
	BUNUNT	VARCHAR2
	BUNUNT_ND	VARCHAR2
CREAT	CREAT_C	**NUMBER
	CREAT	VARCHAR2
	CREAT_ND	VARCHAR2
CREAT - CREATVAL	CREATVAL	FLOAT
CREAT - CREATUNT	CREATUNT_C	NUMBER
	CREATUNT	VARCHAR2
	CREATUNT_ND	VARCHAR2
CALC	CALC_C	**NUMBER
	CALC	VARCHAR2
	CALC_ND	VARCHAR2
CALC - CALCVAL	CALCVAL	FLOAT
CALC - CALCUNT	CALCUNT_C	NUMBER
	CALCUNT	VARCHAR2
	CALCUNT_ND	VARCHAR2
MAG	MAG_C	**NUMBER
	MAG	VARCHAR2

	MAG_ND	VARCHAR2
MAG - MAGVAL	MAGVAL	FLOAT
MAG - MAGUNT	MAGUNT_C	NUMBER
	MAGUNT	VARCHAR2
BNP	BNP_C	**NUMBER
	BNP	VARCHAR2
	BNP_ND	VARCHAR2
BNP - BNPVAL	BNPVAL	FLOAT
BNP - BNPUNT	BNPUNT_C	NUMBER
	BNPUNT	VARCHAR2
NTBNP	NTBNP_C	**NUMBER
	NTBNP	VARCHAR2
	NTBNP_ND	VARCHAR2
NTBNP - NTBNPVAL	NTBNPVAL	FLOAT
NTBNP - NTBNPUNT	NTBNPUNT_C	NUMBER
	NTBNPUNT	VARCHAR2
DIFFDTM	DIFFDTM_C	NUMBER
	DIFFDTM	VARCHAR2
	DIFFDTM_ND	VARCHAR2
<b>RD_FRLABS_RSLABS2</b>		
cpLABTEST	CPLABTEST_ND	VARCHAR2
cpLABTEST - Sodium	SODIUM1_CISODIUM_C	NUMBER
	SODIUM1_CISODIUM	VARCHAR2
cpLABTEST - Potassium	POTASUM1_CIPOTASSIUM_C	NUMBER
	POTASUM1_CIPOTASSIUM	VARCHAR2
cpLABTEST - Chloride	CHLORID1_CICHLORIDEN_C	NUMBER
	CHLORID1_CICHLORIDEN	VARCHAR2
cpLABTEST - CO2/Bicarbonat	CRBONDIX_CICO2_C	NUMBER
	CRBONDIX_CICO2	VARCHAR2
cpLABTEST - BUN/Urea	BUN1_CIBUNUREA_C	NUMBER
	BUN1_CIBUNUREA	VARCHAR2
cpLABTEST - Creatinine	CREATIN1_CICREATININE2_C	NUMBER
	CREATIN1_CICREATININE2	VARCHAR2
cpLABTEST - Total calcium	TCALC1_CITOTCALCIUM_C	NUMBER
	TCALC1_CITOTCALCIUM	VARCHAR2
cpLABTEST - BNP	BNP1_CIBNPNEW_C	NUMBER
	BNP1_CIBNPNEW	VARCHAR2
cpLABTEST - NT-proBNP	NTBPNP1_CINTPROBNP_C	NUMBER
	NTBPNP1_CINTPROBNP	VARCHAR2
cpLABTEST - Magnesium	MAG1_CIMAGNESIUM_C	NUMBER
	MAG1_CIMAGNESIUM	VARCHAR2
LABDTM	LABDTM	DATE
	LABDTM_DTS	VARCHAR2
	LABDTM_DTR	VARCHAR2
	LABDTM_ND	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFNLIFE: RUNIN DOSE (RUNIN) [fr-RUNIN]						
Run-in Dose [stRUNIN]						
1.*	Were the screening visit and run-in visit combined? If yes, then Run-in VISMEDS, EXAM and LABS not required [Were the screening visit and run-in visit combined]			[SCREENRI] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No		
2.*	Did the subject die after consent and during the run-in phase (up through the Randomization or Screen Failure Phone Visit, as applicable)? [Did the subject die]			[RUNINDTH] [N:1] <input type="radio"/> Yes (If yes, complete DEATH form) [N:0] <input type="radio"/> No		
3.*	Was the subject on ACEI within 7 days prior to run-in? [Was the subject on ACEI within 7 days prior to run-in?]			[ACEYN] <input type="radio"/> [ACEDTTM] (DD/MM/YYYY hh:mm) [N:1] <input type="radio"/> Yes If yes, provide last dose date and time Req <input type="text"/> / <input type="text"/> / <input type="text"/> (2015-2021) Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock [N:0] <input type="radio"/> No - Subject not on ACE in prior 7 days		
4.*	Indicate the ACEI dose taken within prior 7 days, or else check "not applicable" [Indicate the ACEI dose taken within prior 7 days]			[ACEYN1] <input type="radio"/> [ACIDOSE] [N:1] <input type="radio"/> Yes - Subject was on ACE in prior 7 days If yes: [N:1] <input type="radio"/> Low Dose [N:2] <input type="radio"/> Greater than Low Dose [N:0] <input type="radio"/> No - Not applicable		
5.*	Was the subject on ARB within 7 days prior to run-in? [Was the subject on ARB within 7 days prior to run-in?]			[ACE1YN] <input type="radio"/> [ACEIDTTM] (DD/MM/YYYY hh:mm) [N:1] <input type="radio"/> Yes If yes, provide last dose date and time Req <input type="text"/> / <input type="text"/> / <input type="text"/> (2015-2021) Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock [N:0] <input type="radio"/> No - Subject not on ARB in prior 7 days		
6.*	Indicate the ARB dose taken within prior 7 days, or else check "not applicable" [Indicate the ARB dose taken within prior 7 days]			[ARBYN1] <input type="radio"/> [ARBDOSE] [N:1] <input type="radio"/> Yes - Subject was on ARB in prior 7 days If yes: [N:1] <input type="radio"/> Low Dose [N:2] <input type="radio"/> Greater than Low Dose [N:0] <input type="radio"/> No - Not applicable		
7.*	Was the Run-In dose administered? [Was the Run-In dose administered?]			[RUNYN] <input type="radio"/> Yes [N:0] <input type="radio"/> No		
8.*	Did the subject experience any events of interest during the run-in phase? (If yes, complete EVTINT form?) [Did the subject experience any events of interest during the run-in phase? (If yes, complete EVTINT form?)]			[NEWEVENT] <input type="radio"/> Yes [N:0] <input type="radio"/> No		
9.*	Did the subject experience any serious adverse events during the run-in phase? (If yes, complete SAE form?) [Did the subject experience any serious adverse events during the run-in phase? (If yes, complete SAE form?)]			[NEWSAE] <input type="radio"/> Yes [N:0] <input type="radio"/> No		
10.	<b>Bottle number</b>	<b>Start Date and Time</b>	<b>Stop Date</b>	<b>Any doses missed</b>	<b>Tablets Remaining</b>	<b>Was the Run-In dose tolerated?</b>
10.1*	Bottle number [Bottle number]					
<b>Bottle Information Entry [rsRUNIN2]</b>						
10.1*	Bottle number [Bottle number]			[BOTNUM] NS		
10.2*	Start Date and Time [Start Date and Time]			[RUNSTD] (DD/MM/YYYY hh:mm) Req <input type="text"/> / <input type="text"/> / <input type="text"/> (2015-2021) Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock		
10.3*	Stop Date [Stop Date]			[RUNSPD] (DD/MM/YYYY) Req/Unk <input type="text"/> / <input type="text"/> / <input type="text"/> (2015-2021)		
10.4*	Were any doses missed? [Any doses missed]			[DOSMISYN] <input type="radio"/> [DOSENUM] [N:1] <input type="radio"/> Yes If yes, how many? NS <input type="text"/> [N:0] <input type="radio"/> No		
10.5*	Tablets Remaining [Tablets Remaining]			[TABREM] N10		
10.6*	Was the Run-In dose tolerated? [hidden] [Run-In dose tolerated?]			[RUNTOLYN] <input type="radio"/> Yes [N:0] <input type="radio"/> [RNRGRS] No If No, specify reason: [N:1] <input type="radio"/> Symptomatic hypotension [N:2] <input type="radio"/> Creatinine < 2.0 [N:3] <input type="radio"/> Systolic blood pressure < 90 [N:98] <input type="radio"/> [RNRGRSP] Other Specify: A200		
10.7*	Was the Run-In dose tolerated? [Was the Run-In dose tolerated?]			[RUNTOL1] <input type="radio"/> Yes [N:0] <input type="radio"/> [cpRUNINREA] No If No, specify reasons: Select all that apply: [SYSTOBP1] <input type="checkbox"/> [N:1] <input type="checkbox"/> Systolic blood pressure <90 [SYMHPYP1] <input type="checkbox"/> [N:1] <input type="checkbox"/> Symptomatic hypotension [CREAT1] <input type="checkbox"/> [N:1] <input type="checkbox"/> Renal Dysfunction (e.g., Creatinine > 2.0) [RUNOTH1] <input type="checkbox"/> [N:1] <input type="checkbox"/> [RNRGRSP] Other Specify: A200		

Patient Eligibility Verification [stRUNIN3]		
11.*	Investigator has confirmed subject is eligible to be Randomized [Investigator has confirmed subject is eligible ]	[ELIGVER] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
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_FRRUNIN		
Data Variable RefName	RD Column Name	Column Data Type
SCREENRI	SCREENRI_C	NUMBER
	SCREENRI	VARCHAR2
	SCREENRI_ND	VARCHAR2
RUNINDTH	RUNINDTH_C	NUMBER
	RUNINDTH	VARCHAR2
	RUNINDTH_ND	VARCHAR2
ACEYN	ACEYN_C	**NUMBER
	ACEYN	VARCHAR2
	ACEYN_ND	VARCHAR2
ACEYN - ACEDTTM	ACEDTTM	DATE
	ACEDTTM_DTS	VARCHAR2
	ACEDTTM_DTR	VARCHAR2
ACEYN1	ACEYN1_C	**NUMBER
	ACEYN1	VARCHAR2
	ACEYN1_ND	VARCHAR2
ACEYN1 - ACIDOSE	ACIDOSE_C	NUMBER
	ACIDOSE	VARCHAR2
ACE1YN	ACE1YN_C	**NUMBER
	ACE1YN	VARCHAR2
	ACE1YN_ND	VARCHAR2
ACE1YN - ACE1DTM	ACE1DTM	DATE
	ACE1DTM_DTS	VARCHAR2
	ACE1DTM_DTR	VARCHAR2
ARBYN1	ARBYN1_C	**NUMBER
	ARBYN1	VARCHAR2
	ARBYN1_ND	VARCHAR2
ARBYN1 - ARBDOSE	ARBDOSE_C	NUMBER
	ARBDOSE	VARCHAR2
RUNYN	RUNYN_C	NUMBER
	RUNYN	VARCHAR2
	RUNYN_ND	VARCHAR2
NEWEVENT	NEWEVENT_C	NUMBER
	NEWEVENT	VARCHAR2
	NEWEVENT_ND	VARCHAR2
NEWSAE	NEWSAE_C	NUMBER
	NEWSAE	VARCHAR2
	NEWSAE_ND	VARCHAR2
ELIGVER	ELIGVER_C	NUMBER
	ELIGVER	VARCHAR2
	ELIGVER_ND	VARCHAR2
RD_FRRUNIN_RSUNIN2		
BOTNUM	BOTNUM	NUMBER
	BOTNUM_ND	VARCHAR2
RUNSTD	RUNSTD	DATE
	RUNSTD_DTS	VARCHAR2
	RUNSTD_DTR	VARCHAR2
	RUNSTD_ND	VARCHAR2
RUNSPDT	RUNSPDT	DATE
	RUNSPDT_DTS	VARCHAR2
	RUNSPDT_DTR	VARCHAR2
	RUNSPDT_ND	VARCHAR2
DOSMISYN	DOSMISYN_C	**NUMBER
	DOSMISYN	VARCHAR2
	DOSMISYN_ND	VARCHAR2
DOSMISYN - DOSENUM	DOSENUM	NUMBER
TABREM	TABREM	NUMBER
	TABREM_ND	VARCHAR2
RUNTOLYN	RUNTOLYN_C	NUMBER
	RUNTOLYN	VARCHAR2
	RUNTOLYN_ND	VARCHAR2
RUNTOLYN - RNRGRS	RNRGRS_C	NUMBER
RUNTOLYN - RNRGRSP	RNRGRSP	VARCHAR2
RUNTOL1	RUNTOL1_C	NUMBER
	RUNTOL1	VARCHAR2
	RUNTOL1_ND	VARCHAR2
RUNTOL1 - Systolic blood pressure <90	SYSTOBP1_CISYSTOBP1_C	NUMBER
	SYSTOBP1_CISYSTOBP1	VARCHAR2
RUNTOL1 - Symptomatic hypotension	SYMPHYYP1_CISYMPHYYP1_C	NUMBER
	SYMPHYYP1_CISYMPHYYP1	VARCHAR2

RUNTOL1 - Renal Dysfunction (e.g., Creatinine > 2.0)	CREAT1_CICREAT1_C	NUMBER
	CREAT1_CICREAT1	VARCHAR2
RUNTOL1 - Other	RUNOTH1_RNRGRSP_C	**NUMBER
	RUNOTH1_RNRGRSP	VARCHAR2
RUNTOL1 - RNRGRSP	RNRGRSP	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFNLIFE: VISIT MEDICATIONS (VISMEDS) [frVISMEDS]		
Medications [stMEDS]		
1.* ✓	ACE inhibitor [ACE inhibitor]	<b>[ACE1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
2.* ✓	Open Label Valsartan [Open Label Valsartan]	<b>[OPVAL1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
3.* ✓	Angiotensin receptor blocker (Other than Valsartan) [Angiotensin receptor blocker]	<b>[ARB1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
4.* ✓	Beta Blocker [Beta Blocker]	<b>[BETAB1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
5.* ✓	Aldosterone antagonist [Aldosterone antagonist]	<b>[ALDOS1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
6.* ✓	Hydralazine [Hydralazine]	<b>[HYDR1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
7.* ✓	Nitrates (long acting) [Nitrates]	<b>[NITR1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
8.* ✓	Calcium channel blocker [Calcium channel blocker]	<b>[CCB1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
9.* ✓	Antiplatelets [Antiplatelets]	<b>[ANTIPLT1]</b> [N:1] <input type="radio"/> <b>[cpANTIPLY1]</b> Yes (check all that apply) <b>[ANTIPAS1]</b> [N:1] <input type="checkbox"/> Aspirin (taken daily) <b>[ANTIPT1]</b> [N:1] <input type="checkbox"/> Thienopyridines (eg: ticlopidine, clopidogrel, prasugrel) <b>[ANTIPOT1]</b> [N:1] <input type="checkbox"/> Other [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
10.* ✓	Anticoagulants [Anticoagulants]	<b>[ANTICAG1]</b> [N:1] <input type="radio"/> <b>[cpANTICAGY1]</b> Yes (check all that apply) <b>[ATICWAR1]</b> [N:1] <input type="checkbox"/> Warfarin <b>[ANTHEP1]</b> [N:1] <input type="checkbox"/> Heparin <b>[ATICFCX1]</b> [N:1] <input type="checkbox"/> Factor Xa Inhibitor <b>[ATICOTH1]</b> [N:1] <input type="checkbox"/> Direct Thrombin Inhibitor <b>[ATICOTH1]</b> [N:1] <input type="checkbox"/> Other [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
11.* ✓	Digoxin [Digoxin]	<b>[DIGX1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
12.* ✓	Amiodarone [Amiodarone]	<b>[AMIOD1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
13.* ✓	Statin [Statin]	<b>[STATIN1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
14.* ✓	Lipid lowering agent (other than statin) [Lipid lowering agent]	<b>[LLIPID1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
15.* ✓	Insulin [Insulin]	<b>[INSULIN1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
16.* ✓	Oral diabetic agent [Oral diabetic agent]	<b>[ODIAGT1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
17.* ✓	Antidepressant [Antidepressant]	<b>[DEPRES1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
18.* ✓	Aliskiren [Aliskiren]	<b>[ALISK1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown

19.* ✓	Open Label Sacubitril/Valsartan (Entresto) [Sacubitril/Valsartan (Entresto)]	<b>[ENTRES1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
20.* ✓	Ivabradine (Corlanor) [Ivabradine (Corlanor)]	<b>[IVABRAD1]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
21.* ✓	Metolazone [Metolazone]	<b>[METAZ1]</b> [N:1] <input type="radio"/> Yes [N:1] <input type="radio"/> Chronic (>= 1x/week) [N:2] <input type="radio"/> PRN (<1x/week) [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
22.* ✓	HCTZ [HCTZ]	<b>[HCTZ1]</b> [N:1] <input type="radio"/> Yes <b>[HCTZFR1]</b> Yes [N:1] <input type="radio"/> Chronic (>= 1x/week) [N:2] <input type="radio"/> PRN (<1x/week) [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
23.* ✓	Furosemide [Furosemide]	<b>[FURO1]</b> [N:1] <input type="radio"/> Yes Daily Dose (mg): _____ xxxxxxxx. [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
24.* ✓	Torsemide [Torsemide]	<b>[TORS1]</b> [N:1] <input type="radio"/> Yes Daily Dose (mg): _____ xxxxxxxx. [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
25.* ✓	Bumetanide [Bumetanide]	<b>[BUME1]</b> [N:1] <input type="radio"/> Yes Daily Dose (mg): _____ xxxxxxxx. [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
26.* ✓	Chlorothiazide [Chlorothiazide]	<b>[CHLORT1]</b> [N:1] <input type="radio"/> Yes Daily Dose (mg): _____ xxxxxxxx. [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
27.* ✓	Chlorthalidone [Chlorthalidone]	<b>[THALID1]</b> [N:1] <input type="radio"/> Yes Daily Dose (mg): _____ xxxxxxxx. [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
28.* ✓	Spirolactone [Spirolactone]	<b>[SPIROU1]</b> [N:1] <input type="radio"/> Yes Daily Dose (mg): _____ xxxxxxxx. [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
29.* ✓	Eplerenone [Eplerenone]	<b>[EPLUSE1]</b> [N:1] <input type="radio"/> Yes Daily Dose (mg): _____ xxxxxxxx. [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
30.* ✓	Potassium [Potassium]	<b>[KUSE1]</b> [N:1] <input type="radio"/> Yes Total Daily Dose (mEq): _____ xxxxxxxx. [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
31.* ✓	Magnesium [Magnesium]	<b>[MAGUSE1]</b> [N:1] <input type="radio"/> Yes Total Daily Dose (mg): _____ xxxxxxxx. [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
32.* ✓	IV Inotropes [IV Inotropes]	<b>[IVINOTR1]</b> [N:1] <input type="radio"/> Yes (If IV Inotropes, complete INOTROPE) [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_FRVISMEDS		
Data Variable RefName	RD Column Name	Column Data Type
ACE1	ACE1_C	NUMBER
	ACE1	VARCHAR2

	ACE1_ND	VARCHAR2
OPVAL1	OPVAL1_C	NUMBER
	OPVAL1	VARCHAR2
	OPVAL1_ND	VARCHAR2
ARB1	ARB1_C	NUMBER
	ARB1	VARCHAR2
	ARB1_ND	VARCHAR2
BETAB1	BETAB1_C	NUMBER
	BETAB1	VARCHAR2
	BETAB1_ND	VARCHAR2
ALDOS1	ALDOS1_C	NUMBER
	ALDOS1	VARCHAR2
	ALDOS1_ND	VARCHAR2
HYDR1	HYDR1_C	NUMBER
	HYDR1	VARCHAR2
	HYDR1_ND	VARCHAR2
NITR1	NITR1_C	NUMBER
	NITR1	VARCHAR2
	NITR1_ND	VARCHAR2
CCB1	CCB1_C	NUMBER
	CCB1	VARCHAR2
	CCB1_ND	VARCHAR2
ANTIPLT1	ANTIPLT1_C	**NUMBER
	ANTIPLT1	VARCHAR2
	ANTIPLT1_ND	VARCHAR2
ANTIPLT1 - Aspirin (taken daily)	*ANTIPAS1_CIASPIRINTAKENDAILY_C	NUMBER
	*ANTIPAS1_CIASPIRINTAKENDAILY	VARCHAR2
ANTIPLT1 - Thienopyridines (eg: ticlopidine, clopidogrel, prasugrel)	*ANTIPTH1_CITHIENOPYRIDINES_C	NUMBER
	*ANTIPTH1_CITHIENOPYRIDINES	VARCHAR2
ANTIPLT1 - Other	ANTIPLT1_COTHER11_C	NUMBER
	ANTIPLT1_COTHER11	VARCHAR2
ANTICAG1	ANTICAG1_C	**NUMBER
	ANTICAG1	VARCHAR2
	ANTICAG1_ND	VARCHAR2
ANTICAG1 - Warfarin	ATICWAR1_CIWARFARIN_C	NUMBER
	ATICWAR1_CIWARFARIN	VARCHAR2
ANTICAG1 - Heparin	ANTIHEP1_CANTHEP_C	NUMBER
	ANTIHEP1_CANTHEP	VARCHAR2
ANTICAG1 - Factor Xa Inhibitor	*ATICFCX1_CIFACTORXAINHIBITOR_C	NUMBER
	*ATICFCX1_CIFACTORXAINHIBITOR	VARCHAR2
ANTICAG1 - Direct Thrombin Inhibitor	*ATICDTH1_CIDIRECTTHROMBININHIBITOR_C	NUMBER
	*ATICDTH1_CIDIRECTTHROMBININHIBITOR	VARCHAR2
ANTICAG1 - Other	ATICOTH1_COTHER1_C	NUMBER
	ATICOTH1_COTHER1	VARCHAR2
DIGX1	DIGX1_C	NUMBER
	DIGX1	VARCHAR2
	DIGX1_ND	VARCHAR2
AMIOD1	AMIOD1_C	NUMBER
	AMIOD1	VARCHAR2
	AMIOD1_ND	VARCHAR2
STATIN1	STATIN1_C	NUMBER
	STATIN1	VARCHAR2
	STATIN1_ND	VARCHAR2
LLIPID1	LLIPID1_C	NUMBER
	LLIPID1	VARCHAR2
	LLIPID1_ND	VARCHAR2
INSULIN1	INSULIN1_C	NUMBER
	INSULIN1	VARCHAR2
	INSULIN1_ND	VARCHAR2
ODIAGT1	ODIAGT1_C	NUMBER
	ODIAGT1	VARCHAR2
	ODIAGT1_ND	VARCHAR2
DEPRES1	DEPRES1_C	NUMBER
	DEPRES1	VARCHAR2
	DEPRES1_ND	VARCHAR2
ALISK1	ALISK1_C	NUMBER
	ALISK1	VARCHAR2
	ALISK1_ND	VARCHAR2
ENTRES1	ENTRES1_C	NUMBER
	ENTRES1	VARCHAR2
	ENTRES1_ND	VARCHAR2
IVABRAD1	IVABRAD1_C	NUMBER
	IVABRAD1	VARCHAR2
	IVABRAD1_ND	VARCHAR2
METAZ1	METAZ1_C	**NUMBER
	METAZ1	VARCHAR2
	METAZ1_ND	VARCHAR2
METAZ1 - METZAFR1	METAZAFR1_C	NUMBER

	METZAFR1	VARCHAR2
HCTZ1	HCTZ1_C	**NUMBER
	HCTZ1	VARCHAR2
	HCTZ1_ND	VARCHAR2
HCTZ1 - HCCTZFR1	HCCTZFR1_C	NUMBER
	HCCTZFR1	VARCHAR2
FURO1	FURO1_C	**NUMBER
	FURO1	VARCHAR2
	FURO1_ND	VARCHAR2
FURO1 - FURDOS1	FURDOS1	FLOAT
TORS1	TORS1_C	**NUMBER
	TORS1	VARCHAR2
	TORS1_ND	VARCHAR2
TORS1 - TORSDOS1	TORSDOS1	FLOAT
BUME1	BUME1_C	**NUMBER
	BUME1	VARCHAR2
	BUME1_ND	VARCHAR2
BUME1 - BUMDOSE1	BUMDOSE1	FLOAT
CHLORTH1	CHLORTH1_C	**NUMBER
	CHLORTH1	VARCHAR2
	CHLORTH1_ND	VARCHAR2
CHLORTH1 - CHLORDS1	CHLORDS1	FLOAT
THALID1	THALID1_C	**NUMBER
	THALID1	VARCHAR2
	THALID1_ND	VARCHAR2
THALID1 - THALIDO1	THALIDO1	FLOAT
SPIROUS1	SPIROUS1_C	**NUMBER
	SPIROUS1	VARCHAR2
	SPIROUS1_ND	VARCHAR2
SPIROUS1 - SPIRDOS1	SPIRDOS1	FLOAT
EPLUSE1	EPLUSE1_C	**NUMBER
	EPLUSE1	VARCHAR2
	EPLUSE1_ND	VARCHAR2
EPLUSE1 - EPLEDOS1	EPLEDOS1	FLOAT
KUSE1	KUSE1_C	**NUMBER
	KUSE1	VARCHAR2
	KUSE1_ND	VARCHAR2
KUSE1 - KDOSE1	KDOSE1	FLOAT
MAGUSE1	MAGUSE1_C	**NUMBER
	MAGUSE1	VARCHAR2
	MAGUSE1_ND	VARCHAR2
MAGUSE1 - MAGDOSE1	MAGDOSE1	FLOAT
IVINOTR1	IVINOTR1_C	NUMBER
	IVINOTR1	VARCHAR2
	IVINOTR1_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.		

HFNLIFE: RANDOMIZATION AND BIOMARKER CONSENT (RAND) [frRAND]	
Randomization and Biomarker Consent [stRAND1]	
1.* <input checked="" type="checkbox"/> Date and Time of Randomization <small>[Date and Time of Randomization]</small>	[RANDDTM] (DD/MM/YYYY hh:mm) Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) Req <input type="checkbox"/> : Req <input type="checkbox"/> 24-hour clock
2.* <input checked="" type="checkbox"/> Did the subject agree to participate in the biorepository substudy <small>[Did the subject agree to participate]</small>	[BIORPSTY] [N:1] <input type="radio"/> [BIORPCDT] (DD/MM/YYYY) Yes Date consent obtained Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Site not participating
3. <input type="checkbox"/> Did the subject agree to participate in the pharmacogenomics (genetics) substudy <i>[hidden]</i> <small>[Did the subject agree to participate in the pharmacogenomics (genetics) substudy]</small>	[GENETICS] [N:1] <input type="radio"/> [GENCONDT] (DD/MM/YYYY) Yes Date consent obtained Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Site not participating
4.* <input checked="" type="checkbox"/> Location of randomization <small>[Location of randomization]</small>	[RANDLOC] [N:1] <input type="radio"/> [DISCHDT] (DD/MM/YYYY) Inpatient If inpatient, provide date of discharge Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) [N:0] <input type="radio"/> Outpatient

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
RANDLOC	RANDLOC_C	**NUMBER
	RANDLOC	VARCHAR2
	RANDLOC_ND	VARCHAR2
RANDLOC - DISCHDT	DISCHDT	DATE
	DISCHDT_DTS	VARCHAR2

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

HFNLIFE: BIOLOGICAL SAMPLES (SAMPLES) [frSAMPLES]						
Biomarkers [tsSAMPLES1]						
To be completed by site						
1.* Were biomarker samples collected at this visit? [Were biomarker samples collected at this visit]	<input type="checkbox"/> [BIOMRK] [N:1] <input 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"/> Not done due to oversight or technical problem [N:99] <input type="radio"/> [BIOMNDSP] Other, specify: <input type="text" value="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]	<input type="checkbox"/> [BIOMKDTM] (DD/MM/YYYY hh:mm) Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) Req/Unk <input type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock					
2.2.* Number of Samples Collected [Number of Samples Collected]	<input type="checkbox"/> [cpBIOCOLL1] <input type="checkbox"/> [BIOMSER] [N:1] <input type="checkbox"/> [BIOMSRNM] Serum Cryovials: <input type="text" value="N2"/> <input type="checkbox"/> [BIOMEDTA] [N:1] <input type="checkbox"/> [BIOMEDNM] EDTA Cryovials: <input type="text" value="N2"/>					
2.3.* Date sent to core lab [Date sent to lab]	<input type="checkbox"/> [BIOMSTDT] (DD/MM/YYYY) Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021)					
2.4 Date samples received [Date received]	<input type="checkbox"/> [BIOMRCDT] (DD/MM/YYYY) Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021)					
2.5 Samples received frozen [Frozen]	<input type="checkbox"/> [BIOMFROZ] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No					
2.6 Number of Samples Received [Number of Samples Received]	<input type="checkbox"/> [cpSAMPREC1] <input type="checkbox"/> [BIOMSRC0] [N:1] <input type="checkbox"/> [cpSAMPREC] Serum Cryovials <input type="text" value="N2"/> <input type="checkbox"/> [BIOMSEUSE] Number of usable serum samples: <input type="text" value="N2"/> <input type="checkbox"/> [BIOMERC0] [N:1] <input type="checkbox"/> [cpSMPREC1] EDTA Cryovials <input type="text" value="N2"/> <input type="checkbox"/> [BIOMEUSE] Number of usable EDTA samples: <input type="text" value="N2"/>					
Biorepository [tsSAMPLES3]						
3.* Were biorepository samples collected at this visit? [Were biorepository samples collected at this visit]	<input type="checkbox"/> [BIOREP] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> [BIORNDRN] No Reason samples were not collected: [N:4] <input type="radio"/> Subject did not provide consent [N:5] <input type="radio"/> Subject withdrew consent [N:1] <input type="radio"/> Too sick to perform [N:6] <input type="radio"/> Site not participating [N:2] <input type="radio"/> Unwilling to perform test but subjectively able [N:3] <input type="radio"/> Due to oversight or technical problem [N:99] <input type="radio"/> [BIORNDSP] Other, specify: <input type="text" value="A200"/>					
4.*	Collection Date/Time	Number of Samples Collected	Date received	Frozen	Number of Samples Received	
Biorepository Collection Information Entry [rsSAMPLES4]						
4.1.* Collection Date/Time: [Collection Date/Time]	<input type="checkbox"/> [BIORPDTM] (DD/MM/YYYY hh:mm) Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) Req/Unk <input type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock					
4.2 Number of Samples Collected (hidden) [Number of Samples Collected]	<input type="checkbox"/> [cpBIOCOLL2] <input type="checkbox"/> [BIORSER] [N:1] <input type="checkbox"/> [BIOSRNM] Serum Cryovials: <input type="text" value="N2"/> <input type="checkbox"/> [BIOREDTA] [N:1] <input type="checkbox"/> [BIOREDNM] EDTA Cryovials: <input type="text" value="N2"/> <input type="checkbox"/> [BIORDNA] [N:1] <input type="checkbox"/> [BIORDNUM] DNA <input type="text" value="N2"/>					
4.3.* Number of Samples Collected [Number of Samples Collected]	<input type="checkbox"/> [cpBIOSAMPLE] <input type="checkbox"/> [BIOSER1] [N:1] <input type="checkbox"/> [BIOSERN1] Serum Cryovials <input type="text" value="N2"/>					

		<p><b>[BIOEDTA1]</b>                  [N:1] <input type="checkbox"/> <b>[EDTAV1]</b>                  EDTA Cryovials                  N2</p>
4.4	Date samples received [Date received]	<p><b>[BIORCDT] (DD/MM/YYYY)</b>                  Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2015-2021)</p>
4.5	Samples received frozen [Frozen]	<p><b>[BIORFROZ]</b>                  [N:1] <input type="radio"/> Yes                  [N:0] <input type="radio"/> No</p>
4.6	Number of Samples Received [Number of Samples Received]	<p><b>[cpBIOSAMPLE2]</b>  <b>[BIOER2]</b>                  [N:1] <input type="checkbox"/> <b>[cpSESample]</b>  <b>[BIOERN2]</b>                  Serum Cryovials                  N2  <b>[BIOUSE2]</b>                  Number of usable serum samples: N2</p> <p><b>[BIOCROY2]</b>                  [N:1] <input type="checkbox"/> <b>[cpEDTASample]</b>  <b>[BIOVLE2]</b>                  EDTA Cryovials                  N2  <b>[BIOUSE2]</b>                  Number of usable EDTA samples: N2</p>
4.7	Number of Samples Received <i>[hidden]</i> [Number of Samples Received]	<p><b>[cpSAMPREC2]</b>  <b>[BIORSRCD]</b>                  [N:1] <input type="checkbox"/> <b>[cpBIORSNUM]</b>                  Serum Cryovials  <b>[BIORSUSE]</b>                  N2  <b>[BIORSNUM]</b>                  Number of usable serum samples: N2</p> <p><b>[BIORERCD]</b>                  [N:1] <input type="checkbox"/> <b>[cpBIORENUM]</b>                  EDTA Cryovials  <b>[BIORENUM]</b>                  N2  <b>[BIOREUSE]</b>                  Number of usable EDTA samples: N2</p> <p><b>[BIORDRCD]</b>                  [N:1] <input type="checkbox"/> <b>[cpBIORNUM]</b>                  DNA  <b>[BIORNUM]</b>                  N2  <b>[BIORDUSE]</b>                  Number of usable DNA samples: N2</p>
<b>Comments [stSAMPLES]</b>		
5.	Comments [Lab Comments]	<p><b>[LABCOMM]</b>                  A200</p>
<p>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.</p>		

RDE Analytics: RD_FRSSAMPLES		
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
	BIOMNDRS_ND	VARCHAR2
BIOMRK - BIOMNDSP	BIOMNDSP	VARCHAR2
	BIOREP_C	NUMBER
	BIOREP	VARCHAR2
BIOREP - BIORNDRN	BIOREP_ND	VARCHAR2
	BIORNDRN_C	NUMBER
	BIORNDRN	VARCHAR2
BIOREP - BIORNDSP	BIORNDSP	VARCHAR2
	LABCOMM	VARCHAR2
	LABCOMM_ND	VARCHAR2
RD_FRSSAMPLES_RSSAMPLES2		
BIOMKDTM	BIOMKDTM	DATE
	BIOMKDTM_DTS	VARCHAR2
	BIOMKDTM_DTR	VARCHAR2
	BIOMKDTM_ND	VARCHAR2
	CPBIOCOLL1_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_CPSAMPREC1_C	**NUMBER
	BIOMSRCD_CPSAMPREC1N	VARCHAR2
cpSAMPREC1 - BIOMSNUM	BIOMSNUM	NUMBER
cpSAMPREC1 - BIOMSUSE	BIOMSUSE	NUMBER
cpSAMPREC1 - EDTA	BIOMERCD_CPSMPREC1_C	**NUMBER
	BIOMERCD_CPSMPREC1N	VARCHAR2
cpSAMPREC1 - BIOMENUM	BIOMENUM	NUMBER
cpSAMPREC1 - BIOMEUSE	BIOMEUSE	NUMBER
<b>RD_FRSAMPLES_RSSAMPLES4</b>		
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_BIREDNM_C	**NUMBER
	BIOREDTA_BIREDNM	VARCHAR2
cpBIOCOLL2 - BIOREDNM	BIOREDNM	NUMBER
cpBIOCOLL2 - DNA	BIORDNA_BIORDNUM_C	**NUMBER
	BIORDNA_BIORDNUM	VARCHAR2
cpBIOCOLL2 - BIORDNUM	BIORDNUM	NUMBER
cpBIOSAMPLE	CPBIOSAMPLE_ND	VARCHAR2
cpBIOSAMPLE - Serum	BIOSER1_BIOSERN1_C	**NUMBER
	BIOSER1_BIOSERN1	VARCHAR2
cpBIOSAMPLE - BIOSERN1	BIOSERN1	NUMBER
cpBIOSAMPLE - EDTA	BIOEDTA1_EDTAV1_C	**NUMBER
	BIOEDTA1_EDTAV1	VARCHAR2
cpBIOSAMPLE - EDTAV1	EDTAV1	NUMBER
BIORRCDT	BIORRCDT	DATE
	BIORRCDT_DTS	VARCHAR2
	BIORRCDT_ND	VARCHAR2
BIORFROZ	BIORFROZ_C	NUMBER
	BIORFROZ	VARCHAR2
	BIORFROZ_ND	VARCHAR2
cpBIOSAMPLE2	CPBIOSAMPLE2_ND	VARCHAR2
cpBIOSAMPLE2 - Serum	BIOSER2_CPSESAMPLE_C	**NUMBER
	BIOSER2_CPSESAMPLE	VARCHAR2
cpBIOSAMPLE2 - BIOSERN2	BIOSERN2	NUMBER
cpBIOSAMPLE2 - BIOUSE2	BIOUSE2	NUMBER
cpBIOSAMPLE2 - EDTA	BIOCRYO2_CPEDTASAMPLE_C	**NUMBER
	BIOCRYO2_CPEDTASAMPLE	VARCHAR2
cpBIOSAMPLE2 - BIOVILE2	BIOVILE2	NUMBER
cpBIOSAMPLE2 - BIOUSED2	BIOUSED2	NUMBER
cpSAMPREC2	CPSAMPREC2_ND	VARCHAR2
cpSAMPREC2 - Serum	BIORSRCD_CPBIORSNUM_C	**NUMBER
	BIORSRCD_CPBIORSNUM	VARCHAR2
cpSAMPREC2 - BIORSUSE	BIORSUSE	NUMBER
cpSAMPREC2 - BIORSNUM	BIORSNUM	NUMBER
cpSAMPREC2 - EDTA	BIORERCD_CPBIORENUM_C	**NUMBER
	BIORERCD_CPBIORENUM	VARCHAR2
cpSAMPREC2 - BIORENUM	BIORENUM	NUMBER
cpSAMPREC2 - BIOREUSE	BIOREUSE	NUMBER
cpSAMPREC2 - DNA	BIORDRCD_CPBIORNUM_C	**NUMBER
	BIORDRCD_CPBIORNUM	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.		

**HFNLIFE: VISIT STATUS (VISIT) [fr-VISIT]**

**Visit Status [stVISIT1]**

1.\* Was the visit performed  
 [Visit performed]

**[STATUS]**  
 [N:1]  **[ASSESSDT] (DD/MM/YYYY)**  
 Yes  
 Visit date:  
 Req  / Req  / Req  (2015-2021)

[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  
 A200

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\_FRVISIT**

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

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

HFNLIFE: ASSESS1 (ASSESS1) [frASSESS1]	
Protocol Assessments [stASSESS1]	
1.* Were local labs performed (If yes, please complete LAB form)? [Were local labs performed]	[LABSDON1] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> [LABNDRS1] 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"/> [LABNDSP1] <input type="checkbox"/> Unknown/other Specify: A100
2.* Were protocol required biological samples collected (If yes, please complete SAMPLES form)? [Were protocol required biological samples collected]	[BIOSAMP1] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> [BIONDRS1] <input type="checkbox"/> 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"/> [BIONDSP1] <input type="checkbox"/> Unknown/other Specify: A100
3.* Has the subject experienced an Event of Interest (not an AE or SAE) since the last assessment (If yes, complete EVTINT form)? [SAE]	[NEWEVNT1] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
4.* Has the subject experienced any SAE's since the last assessment (If yes, complete SAE form)? [New SAE]	[NEWSAE1] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
5.* Has the subject been hospitalized since the last assessment (If yes, complete REHOSP form)? [Experienced SAE]	[REHOSP1] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
6.* Was there an unscheduled clinic visit, Emergency Department Visit, or observational unit stay since the last assessment (if Yes, Complete the OUTPTVIS form)? [Unschedule clinic visit]	[OUTPTVS1] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
7.* Has subject reported a pregnancy since the last assessment? [Has subject reported a pregnancy]	[POSPREG1] [N:1] <input type="radio"/> Yes (If yes, complete paper Pregnancy tracking form) [N:0] <input type="radio"/> No [N:96] <input type="radio"/> Not Applicable
8.* Did the study drug dose change since the last assessment (if Yes, Complete the DRGDOSE form)? [Did the study drug dose change]	[DRGVIS1] [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 [☐] = Item is collapsible Note: Source verification critical settings made in Inform will override any settings made in Central Designer. Note: Collapsible settings are only available to users who have the rights to edit the item.	

RDE Analytics: RD_FRASSESS1			
Data Variable RefName	RD Column Name	Column	Data Type
LABSDON1	LABSDON1_C		NUMBER
	LABSDON1		VARCHAR2
	LABSDON1_ND		VARCHAR2
LABSDON1 - LABNDRS1	LABNDRS1_C		NUMBER
	LABNDRS1		VARCHAR2
LABSDON1 - LABNDSP1	LABNDSP1		VARCHAR2
BIOSAMP1	BIOSAMP1_C		NUMBER
	BIOSAMP1		VARCHAR2
	BIOSAMP1_ND		VARCHAR2
BIOSAMP1 - BIONDRS1	BIONDRS1_C		NUMBER
	BIONDRS1		VARCHAR2
BIOSAMP1 - BIONDSP1	BIONDSP1		VARCHAR2
NEWEVNT1	NEWEVNT1_C		NUMBER
	NEWEVNT1		VARCHAR2
	NEWEVNT1_ND		VARCHAR2
NEWSAE1	NEWSAE1_C		NUMBER
	NEWSAE1		VARCHAR2
	NEWSAE1_ND		VARCHAR2
REHOSP1	REHOSP1_C		NUMBER
	REHOSP1		VARCHAR2
	REHOSP1_ND		VARCHAR2
OUTPTVS1	OUTPTVS1_C		NUMBER
	OUTPTVS1		VARCHAR2
	OUTPTVS1_ND		VARCHAR2
POSPREG1	POSPREG1_C		NUMBER
	POSPREG1		VARCHAR2
	POSPREG1_ND		VARCHAR2
DRGVIS1	DRGVIS1_C		NUMBER
	DRGVIS1		VARCHAR2
	DRGVIS1_ND		VARCHAR2



HFNLIFE: Protocol Assessments (ASSESS) [frASSESS]	
Protocol Assessments [stASSESS]	
1.* <input checked="" type="checkbox"/> Were local labs performed (If yes, please complete ROUTINE lab form)? [Were local labs performed]	[LABSDONE] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> [LABNDRSN] No [N:1] <input type="radio"/> Too sick to perform [N:2] <input type="radio"/> Unwilling to perform but subjectively able [N:3] <input type="radio"/> Not done due to oversight or technical problem [N:99] <input type="radio"/> [LcpSpecify1] [LABNDSP] Unknown/other Specify: A100
2.* <input checked="" type="checkbox"/> 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"/> [LcpSpecify2] [BIONDSP] Unknown/other Specify: A100
3.* <input checked="" type="checkbox"/> Was KCCQ completed (If yes, complete KCCQ form)? [Was KCCQ completed]	[KCCQDN] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> [KCCQNDRS] No [N:1] <input type="radio"/> Too sick to perform [N:2] <input type="radio"/> Unwilling to perform but subjectively able [N:3] <input type="radio"/> Not done due to oversight or technical problem [N:99] <input type="radio"/> [LcpSpecify3] [KCCQNDSP] Unknown/other Specify: A100
4.* <input checked="" type="checkbox"/> Has the subject experienced an Event of Interest (not an AE or SAE) since the last assessment (If yes, complete EVTINT form)? [SAE]	[NEWEVNT] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
5.* <input checked="" type="checkbox"/> Has the subject experienced any SAE's since the last assessment (If yes, complete SAE form)? [New SAE]	[NEWSAEVN] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
6.* <input checked="" type="checkbox"/> Has the subject been hospitalized since the last assessment (If yes, complete REHOSP form)? [Experienced SAE]	[REHOSP] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
7.* <input checked="" type="checkbox"/> Was there an unscheduled clinic visit, Emergency Department Visit, or observational unit stay since the last assessment (if Yes, Complete the OUTPTVIS form)? [Unschedule clinic visit]	[OUTPTVIS] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown
8.* <input checked="" type="checkbox"/> Has subject reported a pregnancy since the last assessment? [Has subject reported a pregnancy]	[POSREG] [N:1] <input type="radio"/> Yes (If yes, complete paper Pregnancy tracking form) [N:0] <input type="radio"/> No [N:96] <input type="radio"/> Not Applicable
9.* <input checked="" type="checkbox"/> Did the study drug dose change since the last assessment (if Yes, Complete the DRGDOSE form)? [Did the study drug dose change]	[DRGVIS] [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
LABSDONE	LABSDONE_C	NUMBER
	LABSDONE	VARCHAR2
	LABSDONE_ND	VARCHAR2
LABSDONE - LABNDRSN	LABNDRSN_C	NUMBER
	LABNDRSN	VARCHAR2
LABSDONE - LABNDSP	LABNDSP	VARCHAR2
BIOSAMP	BIOSAMP_C	NUMBER
	BIOSAMP	VARCHAR2
	BIOSAMP_ND	VARCHAR2
BIOSAMP - BIONDRSN	BIONDRSN_C	NUMBER
	BIONDRSN	VARCHAR2
BIOSAMP - BIONDSP	BIONDSP	VARCHAR2
KCCQDN	KCCQDN_C	NUMBER
	KCCQDN	VARCHAR2
	KCCQDN_ND	VARCHAR2
KCCQDN - KCCQNDRS	KCCQNDRS_C	NUMBER
	KCCQNDRS	VARCHAR2
KCCQDN - KCCQNDSP	KCCQNDSP	VARCHAR2
NEWEVNT	NEWEVNT_C	NUMBER
	NEWEVNT	VARCHAR2
	NEWEVNT_ND	VARCHAR2

NEWSAEYN	NEWSAEYN_C	NUMBER
	NEWSAEYN	VARCHAR2
	NEWSAEYN_ND	VARCHAR2
REHOSP	REHOSP_C	NUMBER
	REHOSP	VARCHAR2
	REHOSP_ND	VARCHAR2
OUTPTVIS	OUTPTVIS_C	NUMBER
	OUTPTVIS	VARCHAR2
	OUTPTVIS_ND	VARCHAR2
POSPREG	POSPREG_C	NUMBER
	POSPREG	VARCHAR2
	POSPREG_ND	VARCHAR2
DRGVIS	DRGVIS_C	NUMBER
	DRGVIS	VARCHAR2
	DRGVIS_ND	VARCHAR2

HFNLIFE: PHONE VISIT (PHONE) [frPHONE]	
<b>Phone Visit [stPHONE1]</b>	
1.* Phone Visit Performed <input checked="" type="checkbox"/> [Phone Visit Performed]	<b>[PHONEVT]</b> [N:1] <input type="radio"/> <b>[PHONDT] (DD/MM/YYYY)</b> Yes Visit date: Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2015-2021) [N:0] <input type="radio"/> <b>[PHVISND]</b> No Reason phone visit was not performed: [N:1] <input type="radio"/> Missed visit [N:2] <input type="radio"/> Suspected LTFU [N:3] <input type="radio"/> Subject no longer participating in study (died, permanently withdrew consent, etc). [N:98] <input type="radio"/> <b>[cpPHSPECY]</b> Other, specify <b>[PHVNDSP]</b> A100
2.* Has the subject experienced an Event of Interest (not an AE or SAE) since the last assessment (If yes, complete the EVTINT form)? <input checked="" type="checkbox"/> [Event of Interest]	<b>[PHEVNTYN]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
3.* Has the subject experienced any SAEs since the last assessment (If yes, complete the SAE form)? <input checked="" type="checkbox"/> [Has the subject experienced any SAEs]	<b>[PHSAEYN]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
4.* Was the subject hospitalized since the last assessment (If yes, complete REHOSP form)? <input checked="" type="checkbox"/> [Was the subject hospitalized]	<b>[PHREHSYN]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
5.* Was there an unscheduled clinic visit, Emergency Department Visit, or observational unit stay since the last assessment (If yes, complete the OUTPTVIS form)? <input checked="" type="checkbox"/> [Was there an unscheduled clinic visit]	<b>[PHOUTYN]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
6.* Has subject reported a pregnancy since the last assessment? <input checked="" type="checkbox"/> [Reported pregnancy]	<b>[PHSPREG]</b> [N:1] <input type="radio"/> Yes (If yes, complete paper Pregnancy tracking form) [N:0] <input type="radio"/> No [N:96] <input type="radio"/> Not Applicable
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
PHONEVT - PHONDT	PHONDT	DATE
	PHONDT_DTS	VARCHAR2
PHONEVT - PHVISND	PHVISND_C	NUMBER
	PHVISND	VARCHAR2
PHONEVT - PHVNDSP	PHVNDSP	VARCHAR2
PHEVNTYN	PHEVNTYN_C	NUMBER
	PHEVNTYN	VARCHAR2
	PHEVNTYN_ND	VARCHAR2
PHSAEYN	PHSAEYN_C	NUMBER
	PHSAEYN	VARCHAR2
	PHSAEYN_ND	VARCHAR2
PHREHSYN	PHREHSYN_C	NUMBER
	PHREHSYN	VARCHAR2
	PHREHSYN_ND	VARCHAR2
PHOUTYN	PHOUTYN_C	NUMBER
	PHOUTYN	VARCHAR2
	PHOUTYN_ND	VARCHAR2
PHSPREG	PHSPREG_C	NUMBER
	PHSPREG	VARCHAR2
	PHSPREG_ND	VARCHAR2

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

HFNLIFE: STUDY DRUG DOSING (DRGDOSE) - Repeating Form [frDRGDOSE]			
#	Date of Dose Change	New Dose	Primary Reason for Dose Change
1			
<b>STUDY DRUG DOSING [frDRGDOSE]</b>			
1.*	Date of Dose Change [Date of Dose Change]		[SDCHGDT] (DD/MM/YYYY) [Req/Unk] / [Req] / [Req] (2015-2021)
2.*	New Dose [New Dose]		[SDRGDOSE] [N:1] <input type="radio"/> 50 mg LCZ696 / 40 mg Valsartan (Low) [N:2] <input type="radio"/> 100 mg LCZ696 / 80 mg Valsartan (Med) [N:3] <input type="radio"/> 200 mg LCZ696 / 160 mg Valsartan (High) [N:98] <input type="radio"/> [DRGDOSSP] Other Specify A30 [N:4] <input type="radio"/> Temporary discontinuation [N:5] <input type="radio"/> Permanent discontinuation
3.	Primary Reason for Dose Change [hidden] [Primary Reason for Dose Change]		[CHGREAS] [N:1] <input type="radio"/> Initial dose [N:2] <input type="radio"/> Protocol specified up-titration [N:3] <input type="radio"/> [DRGSAE] Adverse reaction Is this a Serious Adverse event? [N:1] <input type="radio"/> [DRGSAENO] SAE Number (from SAE form) A4 [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown [N:4] <input type="radio"/> Adverse reaction [N:98] <input type="radio"/> [CHGRSSP] Other, specify: A200
4.*	Primary Reason for Dose Change [Primary Reason for Dose Change]		[CHGREASX] [N:4] <input type="radio"/> Initial Dose [N:1] <input type="radio"/> Protocol specified up-titration [N:2] <input type="radio"/> Protocol specified down-titration [N:3] <input type="radio"/> [DRGSAEX] Adverse reaction Is this a Serious Adverse event? [N:1] <input type="radio"/> [DRGSAENX] SAE Number (from SAE form) A4 [N:0] <input type="radio"/> No [N:99] <input type="radio"/> Unknown [N:98] <input type="radio"/> [CHGRSSPX] Other, specify: A200

Key: [\*] = Item is required [v] = Source verification required  
Notes: 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
SDCHGDT	SDCHGDT	DATE
	SDCHGDT_DTS	VARCHAR2
	SDCHGDT_DTR	VARCHAR2
	SDCHGDT_ND	VARCHAR2
	SDRGDOSE	NUMBER
SDRGDOSE - DRGDOSSP	SDRGDOSE_C	VARCHAR2
	SDRGDOSE	VARCHAR2
	SDRGDOSE_ND	VARCHAR2
CHGREAS	DRGDOSSP	VARCHAR2
	CHGREAS_C	NUMBER
	CHGREAS	VARCHAR2
CHGREAS - DRGSAE	CHGREAS_ND	VARCHAR2
	DRGSAE_C	**NUMBER
	DRGSAE	VARCHAR2
CHGREAS - DRGSAENO	DRGSAENO	VARCHAR2
CHGREAS - CHGRSSP	CHGRSSP	VARCHAR2
CHGREASX	CHGREASX_C	NUMBER
	CHGREASX	VARCHAR2
	CHGREASX_ND	VARCHAR2
CHGREASX - DRGSAEX	CHGREASX_C	**NUMBER
	DRGSAEX	VARCHAR2
	CHGREASX - DRGSAENX	DRGSAENX
CHGREASX - CHGRSSPX	CHGRSSPX	VARCHAR2

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

HFNLIFE: IV INOTROPES (INOTROPES) - Repeating Form [frINOTROPES]			
#	IV Inotrope	Start Date	Stop Date
1			
<b>IV INOTROPE Details [stINOTROPES1]</b>			
1.*	IV Inotrope [IV Inotrope]	[INTRPDET] [[ctINOTROPES] ▼]	
2.*	Start Date [Start Date]	[INTPSTD] (DD/MM/YYYY) Req/Unk ▼ / Req/Unk ▼ / Req/Unk ▼ (2015-2021)	
3.	Stop Date [hidden] [Stop Date]	[INTPSPDT] (DD/MM/YYYY) Req/Unk ▼ / Req/Unk ▼ / Req/Unk ▼ (2015-2021)	
4.*	Stop Date [Stop Date]	[INTPONG1] [N:1] <input type="radio"/> [INPSPDT] (DD/MM/YYYY) Req/Unk ▼ / Req/Unk ▼ / Req/Unk ▼ (2015-2021) [N:2] <input type="radio"/> Ongoing	

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: IV INOTROPES						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
ctINOTROPE	Integer		Dobutamine	1	ciDobutamine	INTRPDET
			Milrinone	2	ciMilrinone	
			Dopamine	3	ciDopamine	

RDE Analytics: RD_FRINOTROPES		
Data Variable RefName	RD Column Name	Column Data Type
INTRPDET	INTRPDET_C	NUMBER
	INTRPDET	VARCHAR2
	INTRPDET_ND	VARCHAR2
INTPSTD	INTPSTD	DATE
	INTPSTD_DTS	VARCHAR2
	INTPSTD_DTR	VARCHAR2
	INTPSTD_ND	VARCHAR2
INTPSPDT	INTPSPDT	DATE
	INTPSPDT_DTS	VARCHAR2
	INTPSPDT_DTR	VARCHAR2
	INTPSPDT_ND	VARCHAR2
INTPONG1	INTPONG1_C	**NUMBER
	INTPONG1	VARCHAR2
	INTPONG1_ND	VARCHAR2
INTPONG1 - INPSPDT	INPSPDT	DATE
	INPSPDT_DTS	VARCHAR2
	INPSPDT_DTR	VARCHAR2

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

HFNLIFE: DRUG KIT DISPENSING AND COMPLIANCE (DRUGKIT) - Repeating Form [frDRUGKIT]							
#	Date kit dispensed	Kit number	Dosing level dispensed:	Is this dispensed kit unscheduled?	Tablets remain	Tablets remain	Commentary
1							
<b>Blinded Drug Kit Dispensed [stDRUGKIT]</b>							
1.*	Date kit dispensed [Date kit dispensed]						[DISPDT] (DD/MM/YYYY) Req [v] / Req [v] / Req [v] (2015-2021)
2.*	Kit number [Kit number]						[KITNUM] A10
3.*	Dosing level dispensed: [Dosing level dispensed:]						[DISPREAS] [N:1] <input type="radio"/> Low Dose [N:2] <input type="radio"/> Med/High Dose
4.*	Is this dispensed kit unscheduled? [Is this dispensed kit unscheduled?]						[DISPUNSC] [N:1] <input type="radio"/> [REASCHNG] Yes (reason) [N:1] <input type="radio"/> Dose change [N:2] <input type="radio"/> Lost kit [N:3] <input type="radio"/> Damaged kit [N:4] <input type="radio"/> Subject ran out of drug [N:5] <input type="radio"/> Mis-use by subject [N:98] <input type="radio"/> [DISSPEC] Other, specify A200  [N:0] <input type="radio"/> No
5.*	How many tablets remain upon final return? [Tablets remain]						[BOTTLEA] [N:1] <input type="radio"/> [TABANUM] Bottle 1 N2 [N:2] <input type="radio"/> Bottle not returned
6.*	How many tablets remain upon final return? [Tablets remain]						[BOTTLEB] [N:1] <input type="radio"/> [TABBNUM] Bottle 2 N2 [N:2] <input type="radio"/> Bottle not returned
7.	Comments [Commentary]						[KITCOMM] A200
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_FRDRUGKIT		
Data Variable RefName	RD Column Name	Column Data Type
DISPDT	DISPDT	DATE
	DISPDT_DTS	VARCHAR2
	DISPDT_ND	VARCHAR2
KITNUM	KITNUM	VARCHAR2
	KITNUM_ND	VARCHAR2
DISPREAS	DISPREAS_C	NUMBER
	DISPREAS	VARCHAR2
	DISPREAS_ND	VARCHAR2
DISPUNSC	DISPUNSC_C	**NUMBER
	DISPUNSC	VARCHAR2
	DISPUNSC_ND	VARCHAR2
DISPUNSC - REASCHNG	REASCHNG_C	NUMBER
	REASCHNG	VARCHAR2
DISPUNSC - DISSPEC	DISSPEC	VARCHAR2
BOTTLEA	BOTTLEA_C	**NUMBER
	BOTTLEA	VARCHAR2
	BOTTLEA_ND	VARCHAR2
BOTTLEA - TABANUM	TABANUM	NUMBER
BOTTLEB	BOTTLEB_C	**NUMBER
	BOTTLEB	VARCHAR2
	BOTTLEB_ND	VARCHAR2
BOTTLEB - TABBNUM	TABBNUM	NUMBER
KITCOMM	KITCOMM	VARCHAR2
	KITCOMM_ND	VARCHAR2

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

HFNLIFE: REHOSPITALIZATION (REHOSP) - Repeating Form [frEHOSP]															
#	Admission Date	Associated AE Number(s)	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	
<b>Hospitalization Information [stREHOSP1]</b>															
1.*	Admission Date [Admission Date]						<b>[ADMITDT] (DD/MM/YYYY)</b> Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021)								
2.	If related to a Serious Adverse Event, indicate the associated AE number(s) as applicable (e.g., AE1): [Associated AE Number(s)]					<b>[cpAENUMS]</b> <b>[AENUM1]</b> A4 <b>[AENUM2]</b> A4 <b>[AENUM3]</b> A4 <b>[AENUM4]</b> A4 <b>[AENUM5]</b> A4									
3.*	Was this an unplanned hospitalization? [Unplanned?]					<b>[ELECTAD]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No									
4.*	Discharge Date [Discharge Date]					<b>[INREHOSP]</b> [N:1] <input type="radio"/> <b>[REDCHBDT] (DD/MM/YYYY)</b> req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021) [N:2] <input type="radio"/> Remains hospitalized [N:3] <input type="radio"/> Subject died while hospitalized (complete DEATH form and SAE form as applicable)									
5.*	Primary reason for admission (If an anticipated disease related event, please also complete Events of Interest form) [Primary reason for admission]					<b>[HOSPRE]</b> [N:1] <input type="radio"/> Heart failure (complete EVNTINT, if applicable) [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"/> <b>[PRMCRDSP]</b> <input type="checkbox"/> Other cardiovascular Specify: A200  [N:8] <input type="radio"/> <b>[PRHNCSP]</b> <input type="checkbox"/> Other non-cardiovascular (complete SAE form as applicable) Specify: A200									
6.*	Contributing causes (check all that apply) [Contributing causes]					<b>[cpCONCAUS]</b> <b>[CONHF]</b> [N:1] <input type="checkbox"/> Heart failure (complete EVNTINT, if applicable) <b>[CONACS]</b> [N:1] <input type="checkbox"/> Acute coronary syndrome <b>[CONCVA]</b> [N:1] <input type="checkbox"/> Cerebral Vascular Accident (CVA)/stroke <b>[CONARRH]</b> [N:1] <input type="checkbox"/> Atrial arrhythmia <b>[CONVENTA]</b> [N:1] <input type="checkbox"/> Ventricular arrhythmia <b>[RENFALL]</b> [N:1] <input type="checkbox"/> Renal Failure <b>[CONSDTH]</b> [N:1] <input type="checkbox"/> Sudden death with resuscitation <b>[CONOTHC]</b> [N:1] <input type="checkbox"/> Other cardiovascular <b>[CONOTHNC]</b> [N:1] <input type="checkbox"/> Other non-cardiovascular									
7.*	Indicate any clinical manifestations of heart failure that occurred during this hospitalization (check all that apply) [Clinical manifestations]					<b>[MANIFEST]</b> [N:1] <input type="radio"/> <b>[cpMANIFEST]</b> <b>[HFDYSP]</b> [N:1] <input type="checkbox"/> Dyspnea <b>[HFORTHQ]</b> [N:1] <input type="checkbox"/> Orthopnea <b>[HFNOCNYS]</b> [N:1] <input type="checkbox"/> Paroxysmal nocturnal dyspnea <b>[HFEDEMA]</b> [N:1] <input type="checkbox"/> Edema <b>[HFRALES]</b> [N:1] <input type="checkbox"/> Pulmonary rales <b>[HFJVD]</b> [N:1] <input type="checkbox"/> Jugular venous distension <b>[HFGALLOP]</b> [N:1] <input type="checkbox"/> Heart sound gallop rhythm <b>[HFHYPO]</b> [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 <b>[HFEVDNCE]</b> [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) <b>[HFOTHR]</b> [N:1] <input type="checkbox"/> <b>[HFOTHRSP]</b> <input type="checkbox"/> Other, specify A200  <b>[HFUNK]</b> [N:1] <input type="checkbox"/> Unknown [N:0] <input type="radio"/> None									
8.*	Indicate any Biomarker or radiographic evidence consistent with heart failure during this hospitalization (check all that apply)					<b>[RADIOEV]</b>									

<p>✓ [Biomarker or radiographic evidence]</p>	<p>[N:1] <input type="radio"/> [cpRADIOEV]</p> <p>[INCBNP]</p> <p>[N:1] <input type="checkbox"/> Documented increased or increasing levels of a natriuretic peptide (BNP or NTproBNP)</p> <p>[HEFMINGC]</p> <p>[N:1] <input type="checkbox"/> Documented worsening pulmonary congestion or pulmonary edema on chest X-ray or other generally recognized imaging pattern.</p> <p>[BIOOTH]</p> <p>[N:1] <input type="checkbox"/> [BIOOTHSP] <input type="checkbox"/></p> <p>Other, specify</p> <p>A200</p> <p>[BIOUNK]</p> <p>[N:1] <input type="checkbox"/> Unknown</p> <p>[N:0] <input type="radio"/> None</p>
<p>9.* ✓ Indicate any additional or increased pharmacologic or mechanical interventions directed at the treatment of heart failure during this hospitalization (check all that apply) [Pharmacologic or mechanical interventions]</p>	<p>[N:1] <input type="radio"/> [cpPHARMINT]</p> <p>[INITHRPV]</p> <p>[N:1] <input type="checkbox"/> Initiation of intravenous inotropic or vasodilator therapy</p> <p>[INITDIUR]</p> <p>[N:1] <input type="checkbox"/> Initiation of intravenous diuretic therapy</p> <p>[OBLTHPY]</p> <p>[N:1] <input type="checkbox"/> Significant addition or increase in oral heart failure therapy</p> <p>[UPTITRTE]</p> <p>[N:1] <input type="checkbox"/> Up-titration of intravenous therapy, if already on therapy</p> <p>[MECHSURG]</p> <p>[N:1] <input type="checkbox"/> Initiation of mechanical or surgical intervention to improve cardiac function), or the use of ultrafiltration, hemofiltration, or dialysis that is specifically directed at treatment of heart failure.</p> <p>[OTHINTVN]</p> <p>[N:1] <input type="checkbox"/> [INTVNSP] <input type="checkbox"/></p> <p>Other, specify</p> <p>A200</p> <p>[INTVUNK]</p> <p>[N:1] <input type="checkbox"/> Unknown</p> <p>[N:0] <input type="radio"/> None</p>
<p>10.* ✓ Was a heart catheterization performed? [Heart Cath?]</p>	<p>[PROCATH]</p> <p>[N:1] <input type="radio"/> [cpPROCATH] <input type="checkbox"/></p> <p>Yes</p> <p>[LCATH]</p> <p>[N:1] <input type="checkbox"/> Left</p> <p>[RCATH]</p> <p>[N:1] <input type="checkbox"/> Right</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:99] <input type="radio"/> Unknown</p>
<p>11.* ✓ Revascularization [Revascularization]</p>	<p>[REVASC]</p> <p>[N:1] <input type="radio"/> [cpREVASC] <input type="checkbox"/></p> <p>Yes</p> <p>[CABG]</p> <p>[N:1] <input type="checkbox"/> CABG</p> <p>[PCI]</p> <p>[N:1] <input type="checkbox"/> PCI</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:99] <input type="radio"/> Unknown</p>
<p>12.* ✓ Pacemaker/ICD [Pacemaker/ICD]</p>	<p>[HOSPICD]</p> <p>[N:1] <input type="radio"/> [cpPACTYPE] <input type="checkbox"/></p> <p>Yes</p> <p>[PACTYPE]</p> <p>[N:1] <input type="radio"/> Pacemaker (single/dual)</p> <p>[N:2] <input type="radio"/> Biventricular Pacemaker with ICD</p> <p>[N:3] <input type="radio"/> Biventricular Pacemaker without ICD</p> <p>[N:4] <input type="radio"/> ICD only (single/dual)</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:99] <input type="radio"/> Unknown</p>
<p>13.* ✓ Heart Transplant [Heart Transplant]</p>	<p>[PROHTRAN]</p> <p>[N:1] <input type="radio"/> [LPRHRODT] (DD/MM/YYYY)</p> <p>Yes (complete EVNTINT, if applicable)</p> <p>Date of Transplant:</p> <p>Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021)</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:99] <input type="radio"/> Unknown</p>
<p>14.* ✓ LVAD [LVAD]</p>	<p>[LVAD]</p> <p>[N:1] <input type="radio"/> [LVADDT] (DD/MM/YYYY)</p> <p>Yes (complete EVNTINT, if applicable)</p> <p>Date of Implant:</p> <p>Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021)</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:99] <input type="radio"/> Unknown</p>

Key: [\*] = Item is required [✓] = Source verification required [ ] = Item is collapsible  
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.  
 Note: Collapsible settings are only available to users who have the rights to edit the item.

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
cpAENUMS	CPAENUMS_ND	VARCHAR2
cpAENUMS - AENUM1	AENUM1	VARCHAR2
cpAENUMS - AENUM2	AENUM2	VARCHAR2
cpAENUMS - AENUM3	AENUM3	VARCHAR2
cpAENUMS - AENUM4	AENUM4	VARCHAR2
cpAENUMS - AENUM5	AENUM5	VARCHAR2
ELECTAD	ELECTAD_C	NUMBER

	ELECTAD	VARCHAR2
	ELECTAD_ND	VARCHAR2
INREHOSP	INREHOSP_C	**NUMBER
	INREHOSP	VARCHAR2
	INREHOSP_ND	VARCHAR2
INREHOSP - REDCHGDT	REDCHGDT	DATE
	REDCHGDT_DTS	VARCHAR2
	REDCHGDT_DTR	VARCHAR2
HOSPRS	HOSPRS_C	NUMBER
	HOSPRS	VARCHAR2
	HOSPRS_ND	VARCHAR2
HOSPRS - PRMCRDSP	PRMCRDSP	VARCHAR2
HOSPRS - PRMNCSP	PRMNCSP	VARCHAR2
cpCONCAUS	CPCONCAUS_ND	VARCHAR2
cpCONCAUS - Heart failure	CONHF_CHEARTFAILURE_C	NUMBER
	CONHF_CHEARTFAILURE	VARCHAR2
cpCONCAUS - Acute coronary syndrome	*CONACS_CIACTECORONARYSYNDROME1_C	NUMBER
	*CONACS_CIACTECORONARYSYNDROME1	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	RENFAL_CIRENALFAILURE_C	NUMBER
	RENFAL_CIRENALFAILURE	VARCHAR2
cpCONCAUS - Sudden death with resuscitation	*CONSDTH_CISUDDENDEATHRESUSCITATION1_C	NUMBER
	*CONSDTH_CISUDDENDEATHRESUSCITATION1	VARCHAR2
cpCONCAUS - Other cardiovascular	*CONOTH_CIOOTHERCARDIOVASCULAR1_C	NUMBER
	*CONOTH_CIOOTHERCARDIOVASCULAR1	VARCHAR2
cpCONCAUS - Other non-cardiovascular	*CONOTHNC_CIOTHERNONCARDIOVASCULAR1_C	NUMBER
	*CONOTHNC_CIOTHERNONCARDIOVASCULAR1	VARCHAR2
MANIFEST	MANIFEST_C	**NUMBER
	MANIFEST	VARCHAR2
	MANIFEST_ND	VARCHAR2
MANIFEST - Dyspnea	HFDYSP_CIDYSNPEA_C	NUMBER
	HFDYSP_CIDYSNPEA	VARCHAR2
MANIFEST - Orthopnea	HFORTH_CIORTHOPNEA1_C	NUMBER
	HFORTH_CIORTHOPNEA1	VARCHAR2
MANIFEST - Paroxysmal nocturnal dyspnea	*HFNOCDYS_CIPAROXYSMALNOCTURNALDYSNPEA1_C	NUMBER
	*HFNOCDYS_CIPAROXYSMALNOCTURNALDYSNPEA1	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_CIHFGALLOP_C	NUMBER
	HFGALLOP_CIHFGALLOP	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_CIOETHCLINICALEVIDENCE_C	NUMBER
	*HFEVDNCE_CIOETHCLINICALEVIDENCE	VARCHAR2
MANIFEST - Other	HFOTHR_HFOTHRSP_C	**NUMBER
	HFOTHR_HFOTHRSP	VARCHAR2
MANIFEST - HFOTHRSP	HFOTHRSP	VARCHAR2
MANIFEST - Unknown	HFUNK_CIUKNOWN1_C	NUMBER
	HFUNK_CIUKNOWN1	VARCHAR2
RADIOEV	RADIOEV_C	**NUMBER
	RADIOEV	VARCHAR2
	RADIOEV_ND	VARCHAR2
RADIOEV - Documented increased or increasing levels of a natriuretic peptide (BNP or NTproBNP)	*INCBNP_CIIINCREASEDNATRIURETICPEPTIDE_C	NUMBER
	*INCBNP_CIIINCREASEDNATRIURETICPEPTIDE	VARCHAR2
RADIOEV - Documented worsening pulmonary congestion or pulmonary edema on chest X-ray or other generally recognized imaging pattern.	*HFIMGING_CIDOCWORSENINGPULMONARYCONGESTION_C	NUMBER
	*HFIMGING_CIDOCWORSENINGPULMONARYCONGESTION	VARCHAR2
RADIOEV - Other	BIOOTH_BIOOTHSP_C	**NUMBER
	BIOOTH_BIOOTHSP	VARCHAR2
RADIOEV - BIOOTHSP	BIOOTHSP	VARCHAR2
RADIOEV - Unknown	BIOUNK_CIUKNOWN1_C	NUMBER
	BIOUNK_CIUKNOWN1	VARCHAR2
PHARMINT	PHARMINT_C	**NUMBER
	PHARMINT	VARCHAR2
	PHARMINT_ND	VARCHAR2
PHARMINT - Initiation of intravenous inotropic or vasodilator therapy	*INITHRPHY_CIIINITIATIONOFTHERAPY_C	NUMBER
	*INITHRPHY_CIIINITIATIONOFTHERAPY	VARCHAR2
PHARMINT - Initiation of intravenous diuretic therapy	INITDIUR_CINITDIUR_C	NUMBER
	INITDIUR_CINITDIUR	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_CIUPTITRATIONINTRAVENOUTHERAPY_C	NUMBER
	*UPTITRTE_CIUPTITRATIONINTRAVENOUTHERAPY	VARCHAR2
PHARMINT - Initiation of mechanical or surgical intervention to improve cardiac function), or the use of ultrafiltration, hemofiltration, or dialysis that is specifically directed at treatment of heart failure.	*MECHSURG_CIIINITIATIONMECHSURGICALINTERVENTION_C	NUMBER
	*MECHSURG_CIIINITIATIONMECHSURGICALINTERVENTION	VARCHAR2
PHARMINT - Other	OTHINTVN_INTVNSP_C	**NUMBER
	OTHINTVN_INTVNSP	VARCHAR2
PHARMINT - INTVNSP	INTVNSP	VARCHAR2
PHARMINT - Unknown	INTVUNK_CIUNKOWN1_C	NUMBER
	INTVUNK_CIUNKOWN1	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
LVAD	LVAD_C	**NUMBER
	LVAD	VARCHAR2
	LVAD_ND	VARCHAR2
LVAD - LVADDT	LVADDT	DATE
	LVADDT_DTS	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.

HFNLIFE: OUTPATIENT VISIT (OUTPTVIS) - Repeating Form [frOUTPTVIS]			
#	Encounter Date:	Visit Type:	Primary reason for visit:
1			
<b>Outpatient Visit Information [stOUTPTVIS]</b>			
Please ensure a corresponding Event of Interest or SAE is entered on the applicable form.			
1.*	Encounter Date: [Encounter Date:]	[UNSCHDT] (DD/MM/YYYY) [Req] / [Req] / [Req] (2015-2021)	
2.*	Visit Type: [Visit Type:]	[OTPTYPE] [N:1] <input type="radio"/> Unscheduled Clinic [N:2] <input type="radio"/> Emergency Department (non-admission) [N:3] <input type="radio"/> Observational Unit (short stay)	
3.*	Primary reason for visit: [Primary reason for visit:]	[UNSCREAS] [N:1] <input type="radio"/> [DECOMP] Heart failure Signs or symptoms indicating decompensated heart failure [N:1] <input type="radio"/> Yes (complete EVNTINT, if applicable) [N:0] <input type="radio"/> No [OUTIVDIR] Did subject receive IV diuretics? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [OTHIVTX] Did subject receive other IV treatment? [N:1] <input type="radio"/> [OTHIVSP] Yes (if IV Inotropes, complete INOTROPE) Specify: <input type="text" value="A200"/> [N:0] <input type="radio"/> No [N:2] <input type="radio"/> Other cardiovascular [N:3] <input type="radio"/> Other non-cardiovascular	
Key: [*] = Item is required [v] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.			

RDE Analytics: RD_FROUTPTVIS		
Data Variable RefName	RD Column Name	Column Data Type
UNSCHDT	UNSCHDT	DATE
	UNSCHDT_DTS	VARCHAR2
	UNSCHDT_ND	VARCHAR2
OTPTYPE	OTPTYPE_C	NUMBER
	OTPTYPE	VARCHAR2
	OTPTYPE_ND	VARCHAR2
UNSCREAS	UNSCREAS_C	**NUMBER
	UNSCREAS	VARCHAR2
	UNSCREAS_ND	VARCHAR2
UNSCREAS - DECOMP	DECOMP_C	NUMBER
	DECOMP	VARCHAR2
UNSCREAS - OUTIVDIR	OUTIVDIR_C	NUMBER
	OUTIVDIR	VARCHAR2
UNSCREAS - OTHIVTX	OTHIVTX_C	**NUMBER
	OTHIVTX	VARCHAR2
UNSCREAS - OTHIVSP	OTHIVSP	VARCHAR2

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

HFNLIFE: EVNTINT (EVNTINT) - Repeating Form [frEVNTINT]			
#	Anticipated, disease-related event	eGFR Value	Onset Date
1			
<b>EVNTINT [frEVNTINT]</b>			
1.* Anticipated, disease-related event: <input checked="" type="checkbox"/> [Anticipated, disease-related event]		<b>[EVNTTYPE]</b> [N:1] <input type="radio"/> <b>[ARRHTYPE]</b> Arrhythmias Type of Arrhythmia: <input type="text" value="A100"/>	
		[N:2] <input type="radio"/> Acute coronary syndrome [N:3] <input type="radio"/> Unplanned hospitalization, ER visit or clinic visit for worsening HF [N:4] <input type="radio"/> LVAD implantation [N:5] <input type="radio"/> Cerebrovascular event [N:6] <input type="radio"/> Cardiac Transplantation [N:7] <input type="radio"/> Hyperkalemia ( ≥ 6) [N:8] <input type="radio"/> Hyperkalemia ( 5.5 -5.9) [N:9] <input type="radio"/> Angioedema [N:10] <input type="radio"/> Acute renal failure with serum creatinine > 2.5 mg/dL [N:11] <input type="radio"/> Venous thromboembolism [N:12] <input type="radio"/> <b>[EVSYSBP]</b> Symptomatic hypotension Provide systolic blood pressure mmHG <input type="text" value="N10"/>	
2. <input checked="" type="checkbox"/> If the patient was diagnosed with worsening renal function, please provide eGFR value used in the diagnosis: [eGFR Value]		<b>[GFRVAL2]</b> <input type="text" value="xxxxxxx"/> ml/min/1.73 m <sup>2</sup>	
3.* <input checked="" type="checkbox"/> Onset Date <input checked="" type="checkbox"/> [Onset Date]		<b>[EVNTDT] (DD/MM/YYYY)</b> Req/Unk <input checked="" type="checkbox"/> / Req/Unk <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2015-2021)	
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\_FREVTINT**

Data Variable RefName	RD Column Name	Column Data Type
EVNTTYPE	EVNTTYPE_C	**NUMBER
	EVNTTYPE	VARCHAR2
	EVNTTYPE_ND	VARCHAR2
EVNTTYPE - ARRHTYPE	ARRHTYPE	VARCHAR2
EVNTTYPE - EVSYSBP	EVSYSBP	NUMBER
GFRVAL2	GFRVAL2	FLOAT
	GFRVAL2_ND	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.

HFNLIFE: SERIOUS ADVERSE EVENTS (SAE) - Repeating Form [fr:SAE]																																							
#	SAE #	SAE Term	Search Text	LLT	LLT Code	PREF	PREF Code	HLT	HLT Code	HLGT	HLGT Code	SOC	SOC Code	Dict Ver	SAE Onset Date/Time	Severity	Relationship	Outcome	Serious Criteria	SAE Stop Date/Time	Action Taken	SAE diminish/abate	SAE reappear	Possible alternate causes	Unexpected?	SAE Summary	Relevant Labs	Relevant Laboratory and Diagnostic Tests Details	On concomitant medications	Con Med Details	SAE verify	Evaluation date/time							
<b>Serious Adverse Events [stSAE1]</b>																																							
If this is an anticipated disease related event, please do not complete this form. Instead, please complete the EVNTINT form.																																							
1.	SAE #	SAE Number (non-enterable field) <i>[read-only]</i>																			[AENUM]																		
2.	Event Term	Event Term																			[AETERM]																		
3.	(Hidden) Previous AETERM Value	(Hidden) Previous AETERM Value																			[NDB_AETERMCOMP]																		
4.	Search Text	Search Text																			[AESERTXT]																		
5.	Lower Level Term - Term	Lower Level Term - Term																			[LLT]																		
6.	Lower Level Term - Code	Lower Level Term - Code																			[LLTC]																		
7.	Preferred Term - Term	Preferred Term - Term																			[PREF]																		
8.	Preferred Term - Code	Preferred Term - Code																			[PREFC]																		
9.	High Level Term - Term	High Level Term - Term																			[HLT]																		
10.	High Level Term - Code	High Level Term - Code																			[HLTC]																		
11.	High Level Group Term - Term	High Level Group Term - Term																			[HLGT]																		
12.	High Level Group Term - Code	High Level Group Term - Code																			[HLGTC]																		
13.	System Organ Class - Term	System Organ Class - Term																			[SOC]																		
14.	System Organ Class - Code	System Organ Class - Code																			[SOCC]																		
15.	MedDRA dictionary version	MedDRA dictionary version																			[DICTVER]																		

<p>[Dict Ver]</p>	<p>A255</p>
<p>16.* SAE Onset Date/Time [SAE Onset Date/Time]</p>	<p><b>[AESTDTM] (DD/MM/YYYY hh:mm)</b> Req/Unk [v] / Req [v] / Req [v] (2015-2021) Req/Unk [v] : Req/Unk [v] 24-hour clock</p>
<p>17.* SAE Severity [Severity]</p>	<p><b>[SEVERITY]</b> [N:1] <input type="radio"/> Mild [N:2] <input type="radio"/> Moderate [N:3] <input type="radio"/> Severe</p>
<p>18.* What is the causal relationship to study drug? [Relationship]</p>	<p><b>[AEREL]</b> [N:1] <input type="radio"/> Not related [N:2] <input type="radio"/> Unlikely related [N:3] <input type="radio"/> <b>[PRRTREL]</b> Possibly related Rationale for positive relationship: A100 [N:4] <input type="radio"/> <b>[RRATREL]</b> Related Rationale for positive relationship: A100</p>
<p>19.* Outcome [Outcome]</p>	<p><b>[AEOUT]</b> [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 (complete DEATH form) [N:99] <input type="radio"/> Unknown</p>
<p>20.* Serious Criteria [Serious Criteria]</p>	<p><b>[cPSEICRIT]</b> <b>[SAEDEATH]</b> Check all that apply: [N:1] <input type="checkbox"/> Death <b>[SAELIFE]</b> [N:1] <input type="checkbox"/> Life-Threatening <b>[SAEHOSP]</b> [N:1] <input type="checkbox"/> Hospitalization required or prolongation of existing hospitalization <b>[SAEDIS]</b> [N:1] <input type="checkbox"/> Persistent or significant disability/incapacity <b>[SAEANOM]</b> [N:1] <input type="checkbox"/> Congenital anomaly or birth defect <b>[SAEIMPNT]</b> [N:1] <input type="checkbox"/> Important medical event</p>
<p>21.* SAE Stop Date/Time [SAE Stop Date/Time]</p>	<p><b>[AEONGO]</b> [N:1] <input type="radio"/> <b>[AESPDTM] (DD/MM/YYYY hh:mm)</b> Req/Unk [v] / Req/Unk [v] / Req/Unk [v] (2015-2021) Req/Unk [v] : Req/Unk [v] 24-hour clock [N:2] <input type="radio"/> Ongoing</p>
<p>22. (Hidden) Admin Fields for Email Alerts [hidden] [Alert Stuff]</p>	<p><b>[ALRTSTUF]</b> <b>[ALRTTYPE]</b> (Hidden) Email Alert Type (Hidden) Alert Count (ALRTCNT) (Hidden) Alert Count History (ALRTCNT2) (Hidden) Narrative Alert Count (ALRTNARCNT) [N:1] <input type="radio"/> Initial N10 N10 N10 [N:2] <input type="radio"/> Update [N:3] <input type="radio"/> Downgrade [N:4] <input type="radio"/> Upgrade [N:0] <input type="radio"/> -</p>
<p>23.* Action Taken Regarding Study Drug [Action Taken]</p>	<p><b>[AEACN]</b> [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"/> <b>[INTDTAE]</b> Drug Interrupted If study drug was interrupted, is this adverse event the primary reason for study drug interruption? [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:5] <input type="radio"/> <b>[DCDTAE]</b> 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</p>
<p>24.* If study drug was discontinued, interrupted, or reduced (dechallenged), did SAE diminish/abate? [SAE diminish/abate]</p>	<p><b>[AEDIMTD]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:96] <input type="radio"/> Not Applicable</p>
<p>25.* If study drug was restarted (Rechallenge), did SAE recur? [SAE reappear]</p>	<p><b>[AERAPR]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:96] <input type="radio"/> Not Applicable</p>
<p>26.* Possible alternate causes of the SAE (check all that apply) [Possible alternate causes]</p>	<p><b>[cPPRIMDIS]</b> <b>[PRIMDIS]</b> [N:1] <input type="checkbox"/> Primary disease under study <b>[INTERILL]</b> [N:1] <input type="checkbox"/> <b>[INILSPEC]</b> Concomitant illness Specify: A200 <b>[CONCOM]</b> [N:1] <input type="checkbox"/> <b>[CONSPEC]</b> Concomitant medication Specify:</p>

		A100					
		<input type="checkbox"/> [OKNWN] [N:1] <input type="checkbox"/> [OTHSPEC] Other known or suspected cause Specify: A200					
		<input type="checkbox"/> [ALTNONE] [N:1] <input type="checkbox"/> None (Only applicable if study drug related and considered only cause of AE)					
		<input type="checkbox"/> [UNKNOWN] [N:1] <input type="checkbox"/> Unknown					
27. ✓	Was this event unexpected per product labeling? [Unexpected?]	<input type="checkbox"/> [SAEUNEX] [N:1] <input type="radio"/> Yes <input type="radio"/> No [N:0]					
<b>SAE Summary</b>							
<b>SAE Summary Entry [rsAESAE2]</b>							
28. ✓	Provide a summary, in chronological order, of the clinical course of this SAE from onset through resolution. 1. Presenting signs and symptoms; 2. Treatments and response to treatments 3. Subject's status at time of report and/or final outcome, as applicable [SAE Summary]	<input type="checkbox"/> [SAENAR] A200					
<b>Relevant Laboratory and Diagnostic Tests [stAESAE3]</b>							
29. ✓	Were there any relevant laboratory or diagnostic tests for this SAE? [Relevant Labs]	<input type="checkbox"/> [SAELABYN] [N:1] <input type="radio"/> Yes <input type="radio"/> No [N:0]					
30. ✓		<b>Date</b>	<b>Test</b>	<b>Result</b>	<b>Unit</b>	<b>Normal Range or Value</b>	
<b>Relevant Laboratory and Diagnostic Tests Details Entry [rsAESAE4]</b>							
30.1. ✓	Date and time [Date]	<input type="checkbox"/> [DRAWDTM] (DD/MM/YYYY hh:mm) Req [v] / Req [v] / Req [v] (2015-2021) Req/Unk [v] : Req/Unk [v] 24-hour clock					
30.2. ✓	Test [Test]	<input type="checkbox"/> [TESTNAM] A200					
30.3. ✓	Result [Result]	<input type="checkbox"/> [TESTRST] A200					
30.4. ✓	Unit (applicable for labs only) [Unit]	<input type="checkbox"/> [TESTUNT] A200					
30.5. ✓	Normal range or value [Normal Range or Value]	<input type="checkbox"/> [NRANGE] A200					
<b>Concomitant Medications [stAESAE5]</b>							
31. ✓	Was the subject on any relevant concomitant medications within 30 days prior to onset of this SAE? If yes, list all concomitant medications: [On concomitant medications]	<input type="checkbox"/> [SAECHYN] [N:1] <input type="radio"/> Yes <input type="radio"/> No [N:0]					
32. ✓		<b>Med Name</b>	<b>Med Start Date</b>	<b>Med Stop Date</b>	<b>Medication Total Daily Dose</b>	<b>Medication Unit</b>	<b>Medication Indication</b>
<b>Con Med Details Entry [rsAESAE6]</b>							
32.1. ✓	Medication Name [Med Name]	<input type="checkbox"/> [SAECMED] A50					
32.2. ✓	Relevant Medication Start Date [Med Start Date]	<input type="checkbox"/> [CONSTRDT] (DD/MM/YYYY hh:mm) Req/Unk [v] / Req/Unk [v] / Req/Unk [v] (1914-2021) Req/Unk [v] : Req/Unk [v] 24-hour clock					
32.3. ✓	Relevant Medication Stop Date [Med Stop Date]	<input type="checkbox"/> [CONSTP] [N:1] <input type="radio"/> [CONSTPDT] (DD/MM/YYYY hh:mm) Req/Unk [v] / Req/Unk [v] / Req/Unk [v] (1914-2021) Req/Unk [v] : Req/Unk [v] 24-hour clock <input type="radio"/> [N:2] Ongoing					
32.4. ✓	Medication Total Daily Dose [Medication Total Daily Dose]	<input type="checkbox"/> [CONDOSE] xxxxxxxx.					
32.5. ✓	Unit [Medication Unit]	<input type="checkbox"/> [CONUNIT] [N:1] <input type="radio"/> mg <input type="radio"/> g [N:2] <input type="radio"/> mL [N:3] <input type="radio"/> cc [N:4] <input type="radio"/> [CONUNIT] [N:99] Other unit specify: A20					
32.6. ✓	Indication [Medication Indication]	<input type="checkbox"/> [MEDIND] A200					
<b>Investigator Verification [stAESAE7]</b>							
33. ✓	I verify that this SAE report form accurately displays the results of the examination, tests, evaluations and treatments noted within. [SAE verify]	<input type="checkbox"/> [PICONFRM] [N:1] <input type="checkbox"/> Yes					

34.	Evaluation date and time (electronic verification non-enterable system generated) [read-only] [Evaluation date/time]	[PDATE] (DD/MM/YYYY hh:mm) Req / / / / / (2015-2021) Req : Req 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.		

**Coding Summary: SERIOUS ADVERSE EVENTS**

Verbatim RefName: AETERM  
 Dictionary: MedDRA Verbatim Type:

Coding Item RefName	Level	Level Type
SOC	System Organ Class	Term
SOCC	System Organ Class	Code
HLGT	High Level Group Term	Term
HLGTC	High Level Group Term	Code
HLT	High Level Term	Term
HLTC	High Level Term	Code
PREF	Preferred Term	Term
PREFC	Preferred Term	Code
LLT	Low Level Term	Term
LLTC	Low Level Term	Code
DICTVER	Dictionary	Term
AESERTXT	SearchText	Term

**RDE Analytics: RD\_FRSAE**

Data Variable RefName	RD Column Name	Column Data Type
AENUM	AENUM	VARCHAR2
	AENUM_ND	VARCHAR2
AETERM	AETERM	VARCHAR2
	AETERM_ND	VARCHAR2
NDB_AETERMCOMP	NDB_AETERMCOMP	VARCHAR2
	NDB_AETERMCOMP_ND	VARCHAR2
AESERTXT	AESERTXT	VARCHAR2
	AESERTXT_ND	VARCHAR2
LLT	LLT	VARCHAR2
	LLT_ND	VARCHAR2
LLTC	LLTC	VARCHAR2
	LLTC_ND	VARCHAR2
PREF	PREF	VARCHAR2
	PREF_ND	VARCHAR2
PREFC	PREFC	VARCHAR2
	PREFC_ND	VARCHAR2
HLT	HLT	VARCHAR2
	HLT_ND	VARCHAR2
HLTC	HLTC	VARCHAR2
	HLTC_ND	VARCHAR2
HLGT	HLGT	VARCHAR2
	HLGT_ND	VARCHAR2
HLGTC	HLGTC	VARCHAR2
	HLGTC_ND	VARCHAR2
SOC	SOC	VARCHAR2
	SOC_ND	VARCHAR2
SOCC	SOCC	VARCHAR2
	SOCC_ND	VARCHAR2
DICTVER	DICTVER	VARCHAR2
	DICTVER_ND	VARCHAR2
AESTDTM	AESTDTM	DATE
	AESTDTM_DTS	VARCHAR2
	AESTDTM_DTR	VARCHAR2
	AESTDTM_ND	VARCHAR2
SEVERITY	SEVERITY_C	NUMBER
	SEVERITY	VARCHAR2
	SEVERITY_ND	VARCHAR2
AEREL	AEREL_C	NUMBER
	AEREL	VARCHAR2
	AEREL_ND	VARCHAR2
AEREL - PRRATREL	PRRATREL	VARCHAR2
AEREL - RRATREL	RRATREL	VARCHAR2
AEOUT	AEOUT_C	NUMBER
	AEOUT	VARCHAR2
	AEOUT_ND	VARCHAR2
cpSERICRIT	CPSERICRIT_ND	VARCHAR2
cpSERICRIT - Death	SAEDEATH_CIDEATH1_C	NUMBER
	SAEDEATH_CIDEATH1	VARCHAR2
cpSERICRIT - Life-Threatening	SAELIFE_CILIFETHREATENING_C	NUMBER
	SAELIFE_CILIFETHREATENING	VARCHAR2
cpSERICRIT - Hospitalization required or prolongation of existing hospitalization	*SAEHOSP_CIREQUIREINPATIENTHOSP_C	NUMBER
	*SAEHOSP_CIREQUIREINPATIENTHOSP	VARCHAR2
cpSERICRIT - Persistent or significant disability/incapacity	*SAEDIS_CIPERSISTENTSIGNIFICANTDISABILITY_C	NUMBER
	*SAEDIS_CIPERSISTENTSIGNIFICANTDISABILITY	VARCHAR2

cpSERICRIT - Congenital anomaly or birth defect	*SAEANO_CICONGENTLANOMALYBIRTHDEFECT_C	NUMBER
	*SAEANO_CICONGENTLANOMALYBIRTHDEFECT	VARCHAR2
cpSERICRIT - Important medical event	*SAEIMPNT_CIIMPORTANTMEDICALEVENT_C	NUMBER
	*SAEIMPNT_CIIMPORTANTMEDICALEVENT	VARCHAR2
AEONGO	AEONGO_C	**NUMBER
	AEONGO	VARCHAR2
	AEONGO_ND	VARCHAR2
AEONGO ^AESPTM	AESPTM	DATE
	AESPTM_DTS	VARCHAR2
	AESPTM_DTR	VARCHAR2
ALRTSTUF	ALRTSTUF_ND	VARCHAR2
ALRTSTUF - ALRTTYPE	ALRTTYPE_C	NUMBER
	ALRTTYPE	VARCHAR2
ALRTSTUF - ALRTCNT	ALRTCNT	NUMBER
ALRTSTUF - ALRTCNT2	ALRTCNT2	NUMBER
ALRTSTUF - ALRTNARCNT	ALRTNARCNT	NUMBER
AEACN	AEACN_C	NUMBER
	AEACN	VARCHAR2
	AEACN_ND	VARCHAR2
AEACN - INTDTAE	INTDTAE_C	NUMBER
	INTDTAE	VARCHAR2
AEACN - DCDTAE	DCDTAE_C	NUMBER
	DCDTAE	VARCHAR2
AEDIMTD	AEDIMTD_C	NUMBER
	AEDIMTD	VARCHAR2
	AEDIMTD_ND	VARCHAR2
AERAPR	AERAPR_C	NUMBER
	AERAPR	VARCHAR2
	AERAPR_ND	VARCHAR2
cpPRIMDIS	CPPRIMDIS_ND	VARCHAR2
cpPRIMDIS - Primary disease under study	PRIMDIS_CIPRIM_C	NUMBER
	PRIMDIS_CIPRIM	VARCHAR2
cpPRIMDIS - Concomitant illness	INTERILL_INILSPEC_C	**NUMBER
	INTERILL_INILSPEC	VARCHAR2
cpPRIMDIS - INILSPEC	INILSPEC	VARCHAR2
cpPRIMDIS - Concomitant medication	CONCOM_CONSPEC_C	**NUMBER
	CONCOM_CONSPEC	VARCHAR2
cpPRIMDIS - CONSPEC	CONSPEC	VARCHAR2
cpPRIMDIS - Other known or suspected cause	OKNWN_OTHSPEC_C	**NUMBER
	OKNWN_OTHSPEC	VARCHAR2
cpPRIMDIS - OTHSPEC	OTHSPEC	VARCHAR2
cpPRIMDIS - None (Only applicable if study drug related and considered only cause of AE)	ALTNONE_CIALTNONE_C	NUMBER
	ALTNONE_CIALTNONE	VARCHAR2
cpPRIMDIS - Unknown	UNKNOWN_CIUNKNOWN1_C	NUMBER
	UNKNOWN_CIUNKNOWN1	VARCHAR2
SAEUNEX	SAEUNEX_C	NUMBER
	SAEUNEX	VARCHAR2
	SAEUNEX_ND	VARCHAR2
SAELABYN	SAELABYN_C	NUMBER
	SAELABYN	VARCHAR2
	SAELABYN_ND	VARCHAR2
SAECMYN	SAECMYN_C	NUMBER
	SAECMYN	VARCHAR2
	SAECMYN_ND	VARCHAR2
PICONFRM	PICONFRM_ND	VARCHAR2
PICONFRM - Yes	PICONFRM_CIYES1_C	NUMBER
	PICONFRM_CIYES1	VARCHAR2
PIDATE	PIDATE	DATE
	PIDATE_DTS	VARCHAR2
	PIDATE_ND	VARCHAR2
<b>RD_FRSAE_RSAESAE2</b>		
SAENAR	SAENAR	VARCHAR2
	SAENAR_ND	VARCHAR2
<b>RD_FRSAE_RSAESAE4</b>		
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
<b>RD_FRSAE_RSAESAE6</b>		
SAECMED	SAECMED	VARCHAR2

	SAECMED_ND	VARCHAR2
CONSTRDT	CONSTRDT	DATE
	CONSTRDT_DTS	VARCHAR2
	CONSTRDT_DTR	VARCHAR2
	CONSTRDT_ND	VARCHAR2
CONSTP	CONSTP_C	**NUMBER
	CONSTP	VARCHAR2
	CONSTP_ND	VARCHAR2
CONSTP - CONSTPDT	CONSTPDT	DATE
	CONSTPDT_DTS	VARCHAR2
	CONSTPDT_DTR	VARCHAR2
CONDOSE	CONDOSE	FLOAT
	CONDOSE_ND	VARCHAR2
CONUNIT	CONUNIT_C	NUMBER
	CONUNIT	VARCHAR2
	CONUNIT_ND	VARCHAR2
CONUNIT - CONUNIT	CONUNIT	VARCHAR2
MEDIND	MEDIND	VARCHAR2
	MEDIND_ND	VARCHAR2

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

HFNLIFE: ENDPOINT (ENDPNT) [frENDPNT]	
Endpoint Information [stENDPNT]	
1.* Date decision made to schedule subject for LVAD [LVAD Date]	<b>[LVADC]</b> [N:1] <input type="radio"/> [LVADCDT] (DD/MM/YYYY) Req/Unk <input checked="" type="checkbox"/> / Req/Unk <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2015-2021) [N:96] <input type="radio"/> NA
2.* Date listed for transplant status 1a, or 1b or 1-4 [Transplant Date]	<b>[TRANSP]</b> [N:1] <input type="radio"/> [TRANSPDT] (DD/MM/YYYY) Req/Unk <input checked="" type="checkbox"/> / Req/Unk <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2015-2021) [N:96] <input type="radio"/> NA
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_FRENDPNT		
Data Variable RefName	RD Column Name	Column Data Type
LVADC	LVADC_C	**NUMBER
	LVADC	VARCHAR2
	LVADC_ND	VARCHAR2
LVADC - LVADCDT	LVADCDT	DATE
	LVADCDT_DTS	VARCHAR2
	LVADCDT_DTR	VARCHAR2
TRANSP	TRANSP_C	**NUMBER
	TRANSP	VARCHAR2
	TRANSP_ND	VARCHAR2
TRANSP - TRANSPDT	TRANSPDT	DATE
	TRANSPDT_DTS	VARCHAR2
	TRANSPDT_DTR	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

HFNLIFE: END OF STUDY (EOS) [frEOS]	
End of Study Participation [stEOS1]	
1.* Date of last contact <input checked="" type="checkbox"/> [Date of last contact]	[LSTCONDT] (DD/MM/YYYY) <input checked="" type="checkbox"/> / <input checked="" type="checkbox"/> / <input checked="" type="checkbox"/> (2015-2021)
2.* Status at time of last contact <input checked="" type="checkbox"/> [Status at time of last contact]	[CMLPTD] [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 checked="" type="radio"/> [WTCONSP] 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"/> [CMPTOSP] <input type="checkbox"/> Other, specify A200 _____ _____
Key: [*] = Item is required [✓] = Source verification required [☐] = Item is collapsible Note: Source verification critical settings made in InForm will override any settings made in Central Designer. Note: Collapsible settings are only available to users who have the rights to edit the item.	

RDE Analytics: RD_FREOS		
Data Variable RefName	RD Column Name	Column Data Type
LSTCONDT	LSTCONDT	DATE
	LSTCONDT_DTS	VARCHAR2
	LSTCONDT_ND	VARCHAR2
CMLPTD	CMLPTD_C	NUMBER
	CMLPTD	VARCHAR2
	CMLPTD_ND	VARCHAR2
CMLPTD - WTCONSP	WTCONSP	VARCHAR2
CMLPTD - CMPTOSP	CMPTOSP	VARCHAR2

HFNLIFE: DEATH (DEATH) [frDEATH]	
Please record any applicable SAEs on the SAE form	
<b>Death [stDEATH1]</b>	
1.* Location of Death ✓ [Location of Death]	<b>[DEATHLOC]</b> [N:1] <input type="radio"/> Inpatient/ER [N:2] <input type="radio"/> Outpatient
2.* Date of Death ✓ [Date of Death]	<b>[DEATHDT] (DD/MM/YYYY)</b> Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2015-2021)
3.* Cause of Death ✓ [Cause of Death]	<b>[DTHCAUSE]</b> [N:1] <input type="radio"/> <b>[cpDTHCARD]</b> Cardiovascular <b>[DTHCARD]</b> [N:1] <input type="radio"/> Myocardial infarction [N:2] <input type="radio"/> Heart failure/Pump failure/Cardiogenic Shock [N:3] <input type="radio"/> <b>[cpSDNDTHW]</b> Sudden Death <b>[SDNDTHW]</b> [N:1] <input type="radio"/> Witnessed [N:2] <input type="radio"/> Not Witnessed [N:4] <input type="radio"/> Stroke [N:5] <input type="radio"/> <b>[cpDTHCVPRO]</b> CV Procedure <b>[DTHCVPR]</b> [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"/> <b>[cpDTHCRDSP]</b> Other CV, specify: <b>[DTHCRDSP]</b> A200  [N:2] <input type="radio"/> <b>[cpNCRDSP]</b> Non-Cardiovascular <b>[NCRDSP]</b> A200  [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_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_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.

HFNLIFE: UNSCHEDULED VISIT (VISIT1) [fr-VISIT1]	
<b>Visit Status [stVISIT1A]</b>	
1.* Visit date ✓ [Visit date]	<b>[ASSESDT] (DD/MM/YYYY)</b> Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2015-2021)
2.* Was the unscheduled visit performed? ✓ [Was the unscheduled visit performed?]	<b>[STATUS1]</b> [N:1] <input type="radio"/> Yes (Check all forms to be completed) <b>[VISITMED]</b> [N:1] <input type="checkbox"/> Visit Meds <b>[EXAM]</b> [N:1] <input type="checkbox"/> Examination <b>[ASSESS]</b> [N:1] <input type="checkbox"/> Additional Protocol Assessments <b>[LABS]</b> [N:1] <input type="checkbox"/> Labs [N:0] <input type="radio"/> No
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_FRVISIT1		
Data Variable RefName	RD Column Name	Column Data Type
ASSESDT	ASSESDT	DATE
	ASSESDT_DTS	VARCHAR2
	ASSESDT_ND	VARCHAR2
STATUS1	STATUS1_C	**NUMBER
	STATUS1	VARCHAR2
	STATUS1_ND	VARCHAR2
STATUS1 - Visit Meds	VISITMED_CIVISITMED_C	NUMBER
	VISITMED_CIVISITMED	VARCHAR2
STATUS1 - Examination	EXAM_CIEXAMIN_C	NUMBER
	EXAM_CIEXAMIN	VARCHAR2
STATUS1 - Additional Protocol Assessments	ASSESS_CIADPPA_C	NUMBER
	ASSESS_CIADPPA	VARCHAR2
STATUS1 - Labs	LABS_CILABS_C	NUMBER
	LABS_CILABS	VARCHAR2
Key: [**] = In some versions of InForm and Reporting the data type will be reported as VARCHAR2.		

HFNLIFE: Signature Completion (SIGN) [frSIGN]	
<b>Casebook Ready for Signature [stSIGN]</b>	
1. Casebook Ready for Signature <i>[hidden]</i> [Casebook Ready for Signature]	[PISIGN] [N10]
2.* CasebookReady for Signature [CasebookReady for Signature]	[PISIGN1] [N:1] <input type="checkbox"/> Yes
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_FRSIGN		
Data Variable RefName	RD Column Name	Column Data Type
PISIGN	PISIGN	NUMBER
	PISIGN_ND	VARCHAR2
PISIGN1	PISIGN1_ND	VARCHAR2
PISIGN1 - Yes	PISIGN1_CIYES1_C	NUMBER
	PISIGN1_CIYES1	VARCHAR2

<b>InForm Special Properties For Study Design: HFNLIFE</b>			
<b>InForm Special Property</b>	<b>Property Type</b>	<b>Data Object RefName</b>	<b>Data Object Path RefName</b>
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	Unassigned	Unassigned
Completion status (Study Completion)	Item	Unassigned	Unassigned
Drop out reason (Study Completion)	Item	Unassigned	Unassigned
DOV (Date of Visit)	Item	ASSESDT	evUNSCH.frVISIT1.stVISIT1A.ASES EDT
Randomization field (Randomization)	Item	Unassigned	Unassigned

**Unit Conversions For Study Design: HFNLIFE**

No unit conversion data.