Annotated Study Book for Study Design: sdGUIDEIT

Study Design Version: 7.0

Study Design

Generated by Central Designer [TM]

July 15, 2015 11:32AM

Time and Events Schedule For Study Design: sdGUIDEIT

#	Assessment	CRF	System Screening (SYSSCR) [S]	System Enrollment (SYSENR) [S]	Randomization (RANDO) [S]	DCRI only (DCRI) [S]	Cross active study (CAS) [S]	Hospitalizations (HOSP) [S/R]	Baseline (BLN) [S]	Baseline follow-up (BLNFU) [S]	2 Week visits (WKS2) [S]	2 Week follow-up (WKS2FU) [S/R]	6 Week visits (WKS6) [S]	6 Week follow-up (WKS6FU) [S/R]	3 month (MON3) [S]	3 month follow-up (MON3FU) [S/R]	6 month (MON6) [S]	6 month follow-up (MON6FU) [S/R]	9 month (MON9) [S]	9 month follow-up (MON9FU) [S/R]	12 month (MON12) [S]	12 month follow-up (MON12FU) [S/R]	15 month (MON15) [S]	15 month follow-up (MON15FU) [S/R]	18 month (MON18) [S]	18 month follow-up (MON18FU) [S/R]	21 month (MON21) [S]	21 month follow-up (MON21FU) [S/R]	24 month (MON24) [S]	24 month follow-up (MON24FU) [S/R]	Termination (EOS) [S]	DCRI Imaging (DCRIECHO) [S/R]	Investigator Signature (INVSIG) [S]
	Visit Start Hours		0	0	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
1	System Screening	SYSSCR	1																														
2	System Enrollment	SYSENR		1																													
3	RAND	RAND			1																												
4	Clinical Operations review	CLINOPS				1																											
5	Clinical Operations review of withdrawn	CLINOPSWD				2																											
6	CEC manual triggers	CECMT				3-RF																											
7	CAS Trigger form	CASTRIG					1																										
8	Adverse events	AE					2-DF-RF																										
9	Extended care	EXTCARE					3-DF-RF																										
10	Date of evaluation	DOE						1			1		1		1		1		1		1		1		1		1		1				1
11	Hospitalizations/Emergency Dept visits	HOSP						2																									
12	Acute coronary syndrome	ACS						3-DF																									
13	Hospitalization for heart failure	HF						4-DF																									
14	Subject Demographics	DEM							1																								
15	Medical History	MEDHX							2																								
16	Baseline Assessments	BASE							3																								
17	Recent Ejection Fraction	EF							4																								
18	Examination	EXAM							5	2	2-DF	2	2-DF	2	2-DF	2	2-DF	2	2-DF	2	2-DF	2	2-DF	2	2-DF	2	2-DF	2	2-DF	2			
19	Concomitant medications	MEDS							6			4-DF		4-DF		4-DF		4-DF		4-DF		4-DF		4-DF		4-DF		4-DF		4-DF			
20	Local NT-pro-BNP	PROBNP							7	4-DF	5-DF	4-DF	5-DF	4-DF	5-DF	4-DF	5-DF	4-DF	5-DF	4-DF	5-DF	4-DF	5-DF	4-DF	5-DF	4-DF	5-DF	4-DF	5-DF	4-DF			
21	Local Labs	LABS							8-DF	5-DF	6-DF	5-DF	6-DF	5-DF	6-DF	5-DF	6-DF	5-DF	6-DF	5-DF	6-DF	5-DF	6-DF	5-DF	6-DF	5-DF	6-DF	5-DF	6-DF	5-DF			
22	Biobank	BIOBANK							9-DF-RF	7-DF-RF	8-DF-RF	7-DF-RF	8-DF-RF	7-DF-RF	8-DF-RF	7-DF-RF	8-DF-RF	7-DF-RF	8-DF-RF	7-DF-RF	8-DF-RF	7-DF-RF	8-DF-RF	7-DF-RF	8-DF-RF	7-DF-RF	8-DF-RF	7-DF-RF	8-DF-RF	7-DF-RF			
23	Specimen consent	SPECCONS							10																								
24	Therapy Adjustment	ADJUST							11-DF-RF	6-DF-RF	7-DF-RF	6-DF-RF	7-DF-RF	6-DF-RF	7-DF-RF	6-DF-RF	7-DF-RF	6-DF-RF	7-DF-RF	6-DF-RF	7-DF-RF	6-DF-RF	7-DF-RF	6-DF-RF	7-DF-RF	6-DF-RF	7-DF-RF	6-DF-RF	7-DF-RF	6-DF-RF			
25	Adherence Case Review	ACR							12-DF	8-DF	9-DF	8-DF	9-DF	8-DF	9-DF	8-DF	9-DF	8-DF	9-DF	8-DF	9-DF	8-DF	9-DF	8-DF	9-DF	8-DF	9-DF	8-DF	9-DF	8-DF			
26	Adherence Review Findings	ARF							13-DF	9-DF	10-DF	9-DF	10-DF	9-DF	10-DF	9-DF	10-DF	9-DF	10-DF	9-DF	10-DF	9-DF	10-DF	9-DF	10-DF	9-DF	10-DF	9-DF	10-DF	9-DF			
27	Assessments	ASMT									3	3-DF	3	3-DF	3	3-DF	3	3-DF	3	3-DF	3	3-DF	3	3-DF	3	3-DF	3	3-DF	3			
28	Method of Contact	CONTACT										1		1		1		1		1		1		1		1							
29	End of study	EOS																														1		
30	Death	DEATH																														2-DF		
31	Echo trigger form	ECHOTRG																															2	
32	FINDINGS	FNDGS																															3-DF	
33	2-D MEASUREMENTS	MEAS2D																															4-DF	
34	M-MODE and DOPPLER MEASUREMENTS	MMDOP																															5-DF	
35	Tomtec	TOMTEC																															6-DF	
36	Signature Completion	SIGN																																1

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

sdGUIDEIT: System Screening (SYSSCR) [frSYSSCR1]

System Screening [frSYSSCR1]	
1.* Check box to screen subject into InForm system. [Check to screen subject]	**[SCRSUBJ]** *[N: 1]* ☐ Screen Subject
2. System generated initials *[hidden]* [System generated initials]	**[SUBJINIT]** A3
Key: [*] = Item is required	

sdGUIDEIT: System Enrollment (SYSENR) [frENRSYS2]

System Enrollment [frENRSYS2]	
1.* Check the box to enroll the subject into the InForm system. [Check to enroll subject]	**[ENRSUBJ]** *[N: 1]* ☐ Enroll Subject
Key: [*] = Item is required	

sdGUIDEIT: RAND (RAND) [frSIRERAND]

Randomization [stRAND1]		
1.	Patient Number *[read-only]* [Patient Number]	**[RSUBJID]** A200

Randomization Information [stRAND2]		
2.* ✔	Does subject qualify for study? [Does subject qualify for study?]	**[RNDQUAL]** *[N: 1]* ○ Yes *[N: 0]* ○ No
3.	Arm *[read-only]* [Arm]	**[ARM]** A200
4.	Site Randomization date/time *[read-only]* [Site Randomization date/time]	**[SITEDTM]** Req ✔ / Req ✔ / Req ✔ (2011-2020) Req ✔ : Req ✔ 24-hour clock
5.	Check this box if a randomization error message appears in Arm question above and the form needs to be resubmitted to populate Arm with randomization information [Re-submit]	**[RESUBMIT]** *[N: 1]* ☐ Resubmit
6.	Cohort *[hidden]*	**[COHORT]** N10

STRATA [stRAND3]		
7.	STRATA 1 *[hidden]* [STRATA 1]	**[STRATA1]** A200
8.	STRATA 2 *[hidden]* [STRATA 2]	**[STRATA2]** A200
9.	STRATA 3 *[hidden]* [STRATA 3]	**[STRATA3]** A200
10.	STRATA 4 *[hidden]* [STRATA 4]	**[STRATA4]** A200

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

sdGUIDEIT: Clinical Operations review (CLINOPS) [frCLINOPS]

Note: Entered by CRA only. Hidden to sites.

Eligibility criteria [stCLINOPS1]

1.	Per eCRF eligibility review, was subject found to be eligible? [was subject found to be eligible?]	**[INCMET]** [N: 1] ◯ Yes [N: 0] ◯ No

	Criteria	Additional comments	Was a waiver granted	Who granted waiver	Narrative	Narrative continued
2.						

Ineligible criteria Entry [rsCLINOPS2]

2.1	Criteria
	[Criteria]
		[CRITTYPE]
		[N: 1] ◯ **[INCLNOT]**
		Inclusion not met
		  [N: 1] ◯ Age > 18 years.
		  [N: 2] ◯ Hospitalization for acute decompensated HF, manifested by dyspnea at rest or on minimal exertion plus at least one sign of volume overload
		  [N: 3] ◯ Most recent documented LVEF to be <= 40% by any method within 12 months of randomization. This assessment must occur at least 12 weeks after any intervention likely to improve EF (CRT, Beta-blocker or revasc)
		  [N: 4] ◯ NT-Pro BNP > 2000 pg/mL or BNP > 400 pg/ml any time during the 30 days prior to randomization
		  [N: 5] ◯ Willing to provide informed consent
		[N: 2] ◯ **[EXCLMET]**
		Exclusion met
		  [N: 1] ◯ Acute coronary syndrome (based on clinical judgment) or cardiac revascularization procedure within 30 days
		  [N: 2] ◯ Cardiac resynchronization therapy (CRT) within prior 3 months or current plan to implant CRT device
		  [N: 3] ◯ Active myocarditis, hypertrophic obstructive cardiomyopathy, pericarditis, or restrictive cardiomyopathy
		  [N: 4] ◯ Severe stenotic valvular disease
		  [N: 5] ◯ Anticipated heart transplantation or ventricular assist device within 12 month
		  [N: 6] ◯ Chronic inotropic therapy
		  [N: 7] ◯ Complex congenital heart disease
		  [N: 8] ◯ End stage renal disease with renal replacement therapy
		  [N: 9] ◯ Non cardiac terminal illness with expected survival less than 12 months
		  [N: 10] ◯ Women who are pregnant or planning to become pregnant
		  [N: 11] ◯ Inability to comply with planned study procedures
		  [N: 12] ◯ Enrollment or planned enrollment in another clinical trial

2.2	Additional comments about eligibility criteria [Additional comments]	**[ADDELIGC]** A200
2.3	Was a waiver granted? [Was a waiver granted]	**[WAIVER]** [N: 1] ◯ **[WAIVRDT]** Yes Date Req ⌄ / Req ⌄ / Req ⌄ (2012-2025) [N: 0] ◯ No
2.4	Who granted waiver? [Who granted waiver]	**[WHOGRTWV]** A200
2.5	Reason for waiver narrative [Narrative]	**[ELIGNRT]** A200
2.6	Reason for waiver narrative continued [Narrative continued]	**[ELIGNRT1]** A200

ICF review

3.		

Informed consent Entry [rsCLINOPS3]

3.1	ICF review [ICF review]	**[ICFREVW]** [N: 1] ◯ **[ICFREVDT]** Yes ICF review complete date Req ⌄ / Req ⌄ / Req ⌄ (2012-2025) **[ICFREVWV]** ICF version A200 [N: 0] ◯ No

	Review date	Data surveillance type	Main Topic	Visit reviewed	Forms reviewed	Findings	Resolution Date
4.							

Data Surveillance Review Entry [rsCLINOPS4]

4.1	Verification review done *[hidden]*
	[Verification review done]
		[SDVDONE]
		[N: 1] ◯ **[SDVREVW]**
		Yes
		Verification review done after which visit?
		  [N: 1] ◯ Baseline
		  [N: 2] ◯ 2 week
		  [N: 3] ◯ 6 week
		  [N: 4] ◯ 3 month
		  [N: 5] ◯ 6 month
		  [N: 6] ◯ 9 month
		  [N: 7] ◯ 12 month
		  [N: 8] ◯ 15 month
		  [N: 9] ◯ 18 month
		  [N: 10] ◯ 21 month
		  [N: 11] ◯ 24 month
		  [N: 12] ◯ Participation ended
		[N: 0] ◯ No

4.2	Date of Review [Review date]	**[CORVWDT]** Req ⌄ / Req ⌄ / Req ⌄ (2012-2025)
4.3	What type of Data Surveillance was conducted? [Data surveillance type]	**[COSURVLC]** [N: 1] ◯ Data Review [N: 2] ◯ Source Document Verifcation
4.4	Main Topic [Main Topic]	**[COMNTPC]** [ctCOMNTPC] ⌄

4.5	Was visit(s) reviewed?
	[Visit reviewed]
		[COVSTRW]
		[N: 1] ◯ **[cpVSTRW]**
		Yes
		[COBSLN]
		  [N: 1] ☐ Baseline
		[CO2WK]
		  [N: 1] ☐ 2 Weeks
		[CO2WKFU]

		[N: 1] ☐ 2 Weeks Follow-up
		[CO6WK]
		[N: 1] ☐ 6 Weeks
		[CO6WKFU]
		[N: 1] ☐ 6 Weeks Follow-up
		[CO3MO]
		[N: 1] ☐ 3 Months
		[CO3MOFU]
		[N: 1] ☐ 3 Months Follow-up
		[CO6MO]
		[N: 1] ☐ 6 Months
		[CO6MOFU]
		[N: 1] ☐ 6 Months Follow-up
		[CO9MO]
		[N: 1] ☐ 9 Months
		[CO9MOFU]
		[N: 1] ☐ 9 Months Follow-up
		[CO12MO]
		[N: 1] ☐ 12 Months
		[CO12MOFU]
		[N: 1] ☐ 12 Months Follow-up
		[CO15MO]
		[N: 1] ☐ 15 Months
		[CO15MOFU]
		[N: 1] ☐ 15 Months Follow-up
		[CO18MO]
		[N: 1] ☐ 18 Months
		[CO18MOFU]
		[N: 1] ☐ 18 Months Follow-up
		[CO21MO]
		[N: 1] ☐ 21 Months
		[CO21MOFU]
		[N: 1] ☐ 21 Months Follow-up
		[CO24MO]
		[N: 1] ☐ 24 Months
		[CO24MOFU]
		[N: 1] ☐ 24 Months Follow-up
		[N: 0] ◯ No
4.6	Was form(s) reviewed? [Forms reviewed]	**[COFRMRW]** *[N: 1]* ◯ **[cpFRMRW]** Yes
		[CODEM] *[N: 1]* ☐ Demographics
		[COMEDHX] *[N: 1]* ☐ Medical History
		[COBASE] *[N: 1]* ☐ Baseline
		[COEXAM] *[N: 1]* ☐ Examination
		[COMED] *[N: 1]* ☐ Medications
		[CONTPRO] *[N: 1]* ☐ NT-proBNP
		[COLABS] *[N: 1]* ☐ Labs
		[COBIOBNK] *[N: 1]* ☐ Biobank
		[COCSNT] *[N: 1]* ☐ Consenting to Biorepository
		[COADJUST] *[N: 1]* ☐ Adjustment
		[COCONTCT] *[N: 1]* ☐ Contact
		[COASSMT] *[N: 1]* ☐ Assessment
		[COCAS] *[N: 1]* ☐ Cross Active Study Trigger Form
		[COAE] *[N: 1]* ☐ AEs/SAEs
		[COEXTND] *[N: 1]* ☐ Extended Care
		[CODOV] *[N: 1]* ☐ Date of Event
		[COHOSP] *[N: 1]* ☐ Hospitalization
		[COACS] *[N: 1]* ☐ Acute Coronary Syndrome
		[COHF] *[N: 1]* ☐ Heart Failure
		[COEOS] *[N: 1]* ☐ End of Study
		[CODEAD] *[N: 1]* ☐ Death
		[N: 0] ◯ No
4.7	Findings/Trends Discovered [Findings]	**[COFINDND]** *[N: 1]* ◯ **[COFINDNS]** Yes
		Findings/Trends Description
		A200
		[N: 0] ◯ No
4.8	Resolution Date [Resolution Date]	**[CORESLDT]** Req ▾ / Req ▾ / Req ▾ (2012-2025)

Main Category	Sub Category	IRB Reportable	IRB Acknowledgement Date	Resolution	Resolution Date
5.					

Deviation Tracking Entry [rsCLINOPS5]

5.1	Main Category [Main Category]	**[MAINCAT]** *[N: 1]* ◯ Inclusion/Exclusion
		[N: 2] ◯ Informed Consent Form
		[N: 3] ◯ Laboratory Assessments
		[N: 4] ◯ Study Procedures
		[N: 5] ◯ Visit Schedule
		[N: 6] ◯ Randomization Procedures
		[N: 7] ◯ AEs/SAEs
		[N: 98] ◯ **[MANCATOT]** Other
		Other specify

		A200	

5.2	Sub Category [Sub Category]	**[SUBCAT]** A200

5.3	IRB Reportable [IRB Reportable]	**[REPORTBL]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No

5.4	IRB Acknowledgement Date [IRB Acknowledgement Date]	**[IRBACKDT]** Req ⌄ / Req ⌄ / Req ⌄ (2012-2025)

5.5	Resolution [Resolution]	**[RESOLTN]** A200

5.6	Resolution Date [Resolution Date]	**[RESLTNDT]** Req ⌄ / Req ⌄ / Req ⌄ (2012-2025)

Key: [*] – Item is required   [✔] – Source verification required

Codelist Values and Tables: Clinical Operations review

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
ctCOMNTPC	Integer	CEC Follow-Up	1	ciCEC_FU	COMNTPC
		CRF Question/Issues	2	ciCRF_Question	
		Clinical Question	3	ciClin_Question	
		Core Lab	4	ciCore_lab	
		Data Quality	5	ciData_Quality	
		GCP/ICH	6	ci_GCP_ICH	
		ICF-Major	7	ciICF_Major	
		Inc/Exc Criteria	8	ciCriteria	
		InForm eCRF Access	9	ciInformAccess	
		Other Study/Site Issues	10	ciOthIssues	
		PI Oversight	11	ciPIOversight	
		Patient Follow-Up	12	ciPatFU	
		Protocol Deviation	13	ciProtocal_Dev	
		Query Resolution	14	ciQueryRes	
		Safety Follow-up	15	ciSafetyFU	
		Site Performance	16	ciSitePerf	
		Source Documentation Verification	17	ciSourceDocVerif	
		Sub-Study	18	ciSub_study	
		Training	19	ciTraining	
		eCRF Completion	20	cieCRF_Comp	

sdGUIDEIT: Clinical Operations review of withdrawn (CLINOPSWD) [frCLINOPSWD]

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Withdrawal status [stCLINOPSWD1]

1.	Did the subject withdraw? [Subject status]	**[COWTHDR]** *[N: 1]* ○ **[COWTHDT]** Yes Date of Withdrawal Req ⌄ / Req ⌄ / Req ⌄ (2012-2025) *[N: 0]* ○ **[COWTHRK]** No At Risk for withdrawal *[N: 1]* ○ Yes *[N: 0]* ○ No
2.	Subject Agreed to Limited Participation? [Limited Participation]	**[COLTDPCT]** *[N: 1]* ○ **[cpLTDPCT]** Yes **[COMEDREC]** *[N: 1]* ☐ Medical Records Follow-up **[COMDFU]** *[N: 1]* ☐ Physician Follow-up **[COALTFU]** *[N: 1]* ☐ Alternate Contact Follow-up **[CONOEQOL]** *[N: 1]* ☐ No EQoL Follow-up **[COEQOL]** *[N: 1]* ☐ Only EQoL Follow-up **[COOTHPCT]** *[N: 1]* ☐ **[COOTHPTS]** Other Other Specify: A200 *[N: 0]* ○ No
3.	Will allow for contact to determine alive at end of study? [Contact at EOS]	**[COEOSFU]** *[N: 1]* ○ Yes *[N: 0]* ○ No

Date Updated	Current Update	IRB date
4.		

Withdrawal Entry [rsCLINOPSWD2]

4.1	Date of Current Update [Date Updated]	**[COWTHUDT]** Req ⌄ / Req ⌄ / Req ⌄ (2012-2025)
4.2	Current Update [Current Update]	**[COWTHCDT]** Req ⌄ / Req ⌄ / Req ⌄ (2012-2025)
4.3	IRB Acknowledgement Date [IRB date]	**[COIRBWDT]** Req ⌄ / Req ⌄ / Req ⌄ (2012-2025)

sdGUIDEIT: CEC manual triggers (CECMT) - Repeating Form [frCECMT]

#	Date of the unreported event	Type of event	Trigger number
1			

CEC manual triggers [stCECMT1]

1.	Date of the unreported event [Date of the unreported event]	**[MNEVNTDT]** Req ⌄ / Req ⌄ / Req ⌄ (2012-2025)
2.	Type of event [Type of event]	**[EVNTTYPE]** *[N:1]* ◯ Hospitalization *[N:2]* ◯ Death
3.	Trigger number [Trigger number]	**[MANTRIG]** A100

sdGUIDEIT: CAS Trigger form (CASTRIG) [frCASTRIG]

CAS Trigger form [frCASTRIG]	
1.* ✔ Did subject have any Serious Adverse Events or Safety Events of Interest? [AE?]	**[CASAE]** *[N: 1]* ○ Yes *[N: 0]* ○ No
2.* ✔ Did the subject have any extended care admissions? [Extended care admission?]	**[CASECF]** *[N: 1]* ○ Yes *[N: 0]* ○ No

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

sdGUIDEIT: Adverse events (AE) - Repeating Form [frAE]

#	Adverse event of interest	Onset Date and Time	End Date	Final Outcome	Severity	Serious?	Primary cause of the event	Are there any laboratory/diagnostic tests?	Lab/diagnostic test	Was the patient taking any relevant concomitant medication	Concomitant medications	SAE NARRATIVES	Form accurately displays the results of the examination	Evaluation Date and Time
1														

Adverse event [stAE1]

1.* ✔ Adverse event of interest:
[Adverse event of interest]

[AESTAT]
[N:1] ◯ Symptomatic hypotension
[N:2] ◯ Symptomatic bradycardia
[N:3] ◯ Hyperkalemia
[N:4] ◯ Worsening renal function
[N:98] ◯ **[AETERM]**
Other Adverse event
Specify Adverse event:
A100

2.* ✔ Onset Date and Time
[Onset Date and Time]

[AESTDTM]
Req/Unk ▾ / Req/Unk ▾ / Req ▾ (2012-2025)
Req/Unk ▾ : Req/Unk ▾ 24-hour clock

3.* ✔ End Date
[End Date]

[AEONGO]
[N:1] ◯ Continuing
[N:2] ◯ **[AEENDT]**
Req/Unk ▾ / Req/Unk ▾ / Req ▾ (2012-2025)

4.* ✔ Final Outcome
[Final Outcome]

[AEOUT]
[N:1] ◯ Resolved
[N:2] ◯ Resolved with sequelae
[N:3] ◯ Ongoing
[N:4] ◯ Death
[N:99] ◯ Unknown

5.* ✔ Severity
[Severity]

[AESEV]
[N:1] ◯ Mild
[N:2] ◯ Moderate
[N:3] ◯ Severe

6.* ✔ Was this adverse event serious?
[Serious?]

[AESER]
[N:1] ◯ **[AESLIFE]**
Yes
Serious criteria:
[N:1] ☐ Life threatening
[SAEPRO]
[N:1] ☐ Required prolongation of existing hospitalization
[AESDISAB]
[N:1] ☐ Persistent or significant disability
[AESCONG]
[N:1] ☐ Congenital anomaly/birth defect
[AESMIE]
[N:1] ☐ Important medical event
[N:0] ◯ No

7.* ✔ Please specify a primary cause of the event:
[Primary cause of the event]

[SAEDTLS]
[N:1] ◯ **[STDYPRC]**
Study procedure
Specify study procedure
A200

[N:2] ◯ Primary disease under study
[N:3] ◯ **[SPECILL]**
Intercurrent illness
Specify illness
A200

[N:4] ◯ **[PROBNPAE]**
NT proBNP machine
[N:1] ◯ Due to malfunction
[N:2] ◯ Due to failure
[N:3] ◯ Due to user error
[N:5] ◯ **[CONMEDAE]**
Concomitant medication (if checked, please answer question below)
Specify concomitant medication
A200

[MEDACTN]
What was the action taken with the concomitant medication?
[N:1] ◯ Dose not changed
[N:2] ◯ Dose reduced
[N:3] ◯ Drug discontinued
[N:4] ◯ **[EVNTDIM]**
Drug interrupted
If interrupted or discontinued, did the event diminish?
[N:1] ◯ Yes
[N:0] ◯ No
[MEDRESTR]
Was the drug restarted?
[N:1] ◯ Yes - event reappeared
[N:2] ◯ Yes - event did NOT reappear
[N:0] ◯ No
[N:98] ◯ **[SAEDTLOT]**
Other
Other specify
A200

8.* ✔ Are there any laboratory/diagnostic tests? (If yes, complete add entry laboratory/diagnostic tests)
[Are there any laboratory/diagnostic tests?]

[SAELAB]
[N:1] ◯ Yes
[N:0] ◯ No

Name of lab/diagnostic test	Date of test	Result	Unit	Lower limit of normal	Upper limit of normal
9.					

Lab/diagnostic test Entry [rsAE2]

9.1 ✔ Name of lab/diagnostic test (one per entry)
[Name of lab/diagnostic test]

[LABNAME]
A200

9.2 ✔ Date/time of test
[Date of test]

[LABTSTDT]
Req ▾ / Req ▾ / Req ▾ (2012-2025)
Req/Unk ▾ : Req/Unk ▾ 24-hour clock

9.3 ✔ Result
[Result]

[LABRSLTD]
[N:1] ◯ **[LABRSLT]**
A200

		[LABNRM] Was the result normal? *[N: 1]* ◯ Normal *[N: 2]* ◯ Abnormal *[N: 99]* ◯ Unknown
9.4 ✔	Unit	**[LABUNITD]** *[N: 1]* ◯ **[LABUNIT]** A50 *[N: 96]* ◯ Not applicable
9.5 ✔	Lower limit of normal [Lower limit of normal]	**[LLND]** *[N: 1]* ◯ **[LLN]** XXXXXXXX. *[N: 96]* ◯ Not applicable
9.6 ✔	Upper limit of normal [Upper limit of normal]	**[ULND]** *[N: 1]* ◯ **[ULN]** XXXXXXXX. *[N: 96]* ◯ Not applicable

Concomitant medication [stAE3]

10.* ✔	Was the patient taking any relevant concomitant medication from 30 days prior to onset of the event (If yes, complete add entry concomitant medications) [Was the patient taking any relevant concomitant medication]	**[SAEMEDS]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No

Concomitant medication	Total Daily Dose	Units	Route	Start date	Stop date	Indication for use
11.						

Concomitant medications Entry [rsAE4]

11.1 ✔	Concomitant medication (one drug per entry) [Concomitant medication]	**[AEDRUG]** A200
11.2 ✔	Total Daily Dose [Total Daily Dose]	**[TDD]** XXXXXXXX.
11.3 ✔	Units [Units]	**[DRUGUNIT]** A50
11.4 ✔	Route [Route]	**[DRUGRTE]** A50
11.5 ✔	Start date [Start date]	**[DRGSTRDT]** Req/Unk ⌄ / Req/Unk ⌄ / Req ⌄ (1995-2025)
11.6 ✔	Stop date [Stop date]	**[DRUGSTP]** *[N: 1]* ◯ **[DRGSTPDT]** Req/Unk ⌄ / Req/Unk ⌄ / Req ⌄ (2012-2025) *[N: 2]* ◯ Ongoing
11.7 ✔	Indication for use [Indication for use]	**[DRGUSE]** A200

	SAE NARRATIVES
12.	

SAE NARRATIVES Entry [rsAE5]

12.1 ✔	SAE NARRATIVES [SAE NARRATIVES]	**[SAENAR]** A200

Primary Investigator SAE Electronic Verification [stAE6]

13.	I verify that this SAE report form accurately displays the results of the examination, tests, evaluations and treatments noted within. [Form accurately displays the results of the examination]	**[MDRVW]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No
14.	Evaluation Date and Time (Electronic Verification non-enterable system generated) [Evaluation Date and Time]	**[MDRVDTM]** Req ⌄ / Req ⌄ / Req ⌄ (2012-2025) Req ⌄ : Req ⌄ *24-hour clock*

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

sdGUIDEIT: Extended care (EXTCARE) - Repeating Form [frEXTCARE]

#	Admission date	Type of extended stay facility	Was the subject discharged?
1			

Extended care [frEXTCARE]

1.*	Admission date [Admission date]	**[EXTADMDT]** Req ⌄ / Req ⌄ / Req ⌄ (2012-2025)
2.*	Type of extended stay facility [Type of extended stay facility]	**[TYPFAC]** *[N.1]* ◯ Skilled nursing *[N.2]* ◯ Rehabilitation *[N.3]* ◯ End of life facility *[N.4]* ◯ Nursing home (non-skilled)
3.*	Was the subject discharged? [Was the subject discharged?]	**[EXTDIS]** *[N.1]* ◯ **[EXTDSGDT]** Yes, Date of discharge Req ⌄ / Req ⌄ / Req ⌄ (2012-2025) **[EXTDSCHG]** Discharge disposition *[N.1]* ◯ Acute care, please complete a HOSP form *[N.2]* ◯ Extended care, please complete an additional EXTCARE form *[N.3]* ◯ Home *[N.4]* ◯ Subject died, please complete EOS and DEATH forms *[N.99]* ◯ Unknown *[N.0]* ◯ No

Key: [*] = Item is required   [🔑] = Key item

Keys (navigation)/Uniqueness: Extended care

Item	Unique	Order #
frEXTCARE (Repeating form)		
EXTADMDT	Individual	1

sdGUIDEIT: Date of evaluation (DOE) [frDOE]	
Date of evaluation [frDOE]	
1. * Date of evaluation ✔	**[EVALUDT]** Req ▼ / Req ▼ / Req ▼ (2012-2025)
2. * Type of visit ✔ [Type of visit]	**[VISTTYP]** *[N: 1]* ◯ Telephone visit *[N: 2]* ◯ In person visit
3. Delete visit - site created the visit by accident *[hidden]* [Delete visit]	**[DELETVIS]** *[N: 1]* ☐ Yes
Key: [*] = Item is required [✔] = Source verification required	

sdGUIDEIT: Hospitalizations/Emergency Dept visits (HOSP) [frHOSP]

Hospitalization/Facility encounter [stHOSP1]

1. * ✔	Admission or encounter date [Admission date]	**[HSPADMDT]** Req ✔ / Req ✔ / Req ✔ (2012-2025)
2. * ✔	Type of encounter [Type of encounter]	**[ENCOUNTR]** *[N:1]* ⊙ Emergency Department only *[N:2]* ⊙ Outpatient procedure without an overnight stay *[N:3]* **[cpINPATIENT]** Inpatient with an overnight stay Specify the number of nights spent in these locations **[ICUHOSP]** *[N:1]* ☐ **[ICUHSPX]** Intensive Care Unit (ICU) `N3` **[CCUHOSP]** *[N:1]* ☐ **[CCUHSPX]** Cardiac Care Unit (CCU) `N3` **[STEPHOSP]** *[N:1]* ☐ **[STEPHSPX]** Step-down care `N3` **[INPTHOSP]** *[N:1]* ☐ **[INPTHSPX]** Inpatient ward `N3` **[OBSVHOSP]** *[N:1]* ☐ **[OBSVHSPX]** Observation unit `N3`
3. * ✔	Primary reason for hospitalization [Primary reason for hospitalization]	**[HSPREAS]** *[N:1]* ⊙ Heart failure *[N:2]* ⊙ Acute Coronary Syndrome/ MI *[N:3]* ⊙ **[HSPRSOCV]** Other cardiovascular Other cardiovascular specify `A200` *[N:4]* ⊙ **[HSPRSNCV]** Non-cardiovascular Non-cardiovascular specify `A200`
4.	Were any cardiac markers drawn? *[hidden]* [Cardiac markers drawn?]	**[CMDRAWN]** *[N:1]* ⊙ **[cpCMDRAWN]** Yes **[CKDONE]** *[N:1]* ☐ **[PEAKCK]** CK Peak CK `xxxxxxxx.` **[CKULN]** CK ULN `xxxxxxxx.` **[CKMBDONE]** *[N:1]* ☐ **[PEAKCKMB]** CKMB Peak CKMB `xxxxxxxx.` **[CKMBULN]** CKMB ULN `xxxxxxxx.` **[TROPIDON]** *[N:1]* ☐ **[PKTROPI]** Troponin I Peak Troponin I `xxxxxxxx.` **[TROPIULN]** Troponin I ULN `xxxxxxxx.` **[TROPTDON]** *[N:1]* ☐ **[PKTROPT]** Troponin T Peak Troponin T `xxxxxxxx.` **[TROPTULN]** Troponin T ULN `xxxxxxxx.` **[PROBNPDN]** *[N:1]* ☐ **[PRBNPVAL]** NTproBNP proBNP value `xxxxxxxx.` **[PRBNPULN]** proBNP ULN `xxxxxxxx.` **[BNPDONE]** *[N:1]* ☐ **[BNPVAL]** BNP BNP value `xxxxxxxx.` **[BNPULN]** BNP ULN `xxxxxxxx.` *[N:0]* ⊙ No *[N:99]* ⊙ Unknown
5. *	Were any cardiac markers drawn? [Cardiac markers drawn]	**[CMDRAW2]** *[N:1]* ⊙ **[cpCMDRAWN2]** Yes **[CKDONE2]** *[N:1]* ☐ **[cpPEAKCK2]** CK **[PEAKCK2]** Peak CK `xxxxxxxx.` **[PEAKCKU2]** Peak CK units *[N:1]* ⊙ IU/L *[N:2]* ⊙ uat/L *[N:3]* ⊙ nkat/L **[CKULN2]** CK ULN `xxxxxxxx.` **[CKMBDON2]**

[N:1] ☐ **[cpCKMB2]**
CKMB
[PEAKCKM2]
Peak CKMB `xxxxxxxx.`
[PKCKMBU2]
Peak CKMB units
[N:1] ◯ IU/L
[N:2] ◯ uat/L
[N:3] ◯ nkat/L
[N:4] ◯ ng/mL or g/L
[N:5] ◯ %
[CKMBUL2]
CKMB ULN `xxxxxxxx.`

[TROPIDO2]
[N:1] ☐ **[cpTROPIDO2]**
Troponin I (ng/mL)
[PKTROPI2]
Peak Troponin I `xxxxxxxx.`
[TROPIUL2]
Troponin I ULN `xxxxxxxx.`

[TROPTDO2]
[N:1] ☐ **[cpTROPTDO2]**
Troponin T (ng/mL)
[PKTROPT2]
Peak Troponin T `xxxxxxxx.`
[TROPTUL2]
Troponin T ULN `xxxxxxxx.`

[PROBNPD2]
[N:1] ☐ **[cpPROBNPD2]**
NTproBNP
[PRBNPVA2]
NTproBNP value `xxxxxxxx.`
[PBNPUNT2]
NTproBNP units
[N:1] ◯ pg/mL
[N:2] ◯ pmol/L
[PRBNPUL2]
NTproBNP ULN `xxxxxxxx.`

[BNPDON2]
[N:1] ☐ **[cpBNPDON2]**
BNP
[BNPVAL2]
BNP value `xxxxxxx.`
[BNPUNIT2]
BNP units
[N:1] ◯ pg/mL
[N:2] ◯ pmol/L
[BNPULN2]
BNP ULN `xxxxxxxx.`

[N:0] ◯ No
[N:99] ◯ Unknown

Narrative

6.

Narrative Entry [rsHOSP2]

6.1*	Please provide a description of the symptoms, treatment, tests/procedures, and outcome of the hospitalization [Narrative]	**[HOSPDESC]** A200

Procedures performed [stHOSP3]

7.*	Was a heart catheterization performed? [Catheterization performed?]	**[PROCATH]** *[N:1]* ◯ **[LCATH]** Yes *[N:1]* ☐ Left **[RCATH]** *[N:1]* ☐ Right *[N:0]* ◯ No
8.*	Revascularization? [Revascularization?]	**[REVASC]** *[N:1]* ◯ **[CABG]** Yes *[N:1]* ☐ **[CABGDTM]** CABG Date and time of most recent CABG during this hospital stay Req ▾ / Req ▾ / Req ▾ (2012-2025) Req/Unk ▾ : Req/Unk ▾ *24-hour clock* **[PCI]** *[N:1]* ☐ **[STENT]** PCI *[N:1]* ◯ With stents *[N:2]* ◯ Without stents **[PCIDTM]** Date and time of most recent PCI during this hospital stay Req ▾ / Req ▾ / Req ▾ (2012-2025) Req/Unk ▾ : Req/Unk ▾ *24-hour clock* *[N:0]* ◯ No
9.*	Other cardiac surgery? [Other cardiac surgery?]	**[CARDSURG]** *[N:1]* ◯ **[CARDSURT]** Yes Type of other cardiac surgery A100 *[N:0]* ◯ No
10.*	Pacemaker/ICD? [Pacemaker?]	**[HOSPICD]** *[N:1]* ◯ **[PACTYPE]** Yes *[N:1]* ◯ Pacemaker (single/dual) *[N:2]* ◯ Biventricular Pacemaker with ICD *[N:3]* ◯ Biventricular Pacemaker without ICD *[N:4]* ◯ ICD only (single/dual) *[N:0]* ◯ No
11.*	Heart Transplant? [Heart Transplant?]	**[PROHTRAN]** *[N:1]* ◯ **[PRHTRDDT]** Yes Date of Transplant Req ▾ / Req ▾ / Req ▾ (2012-2025) *[N:0]* ◯ No
12.*	VAD? [VAD?]	**[VAD]** *[N:1]* ◯ **[VADREAS]** Yes Reasons for implanting VAD *[N:1]* ◯ Bridge to Transplant *[N:2]* ◯ Destination Therapy *[N:99]* ◯ Unknown *[N:0]* ◯ No

13.*	Mitral valve repair/replacement? [Mitral valve repair/replacement?]	**[MITRLVLV]** [N:1] ○ Yes [N:0] ○ No
14.*	Ablation? [Ablation?]	**[ABLATION]** [N:1] ○ **[ABLT]** Yes Reason [N:1] ○ A-fib/flutter/SVT [N:2] ○ VT [N:99] ○ Unknown [N:0] ○ No
15.*	PVD interventions? [PVD interventions?]	**[PVD]** [N:1] ○ Yes [N:0] ○ No
16.*	Mechanical ventillation [Mechanical ventillation]	**[MECHVENT]** [N:1] ○ Yes [N:0] ○ No
17.*	Ultrafiltration [Ultrafiltration]	**[ULTFILT]** [N:1] ○ Yes [N:0] ○ No
18.*	Dialysis (acute) [Dialysis (acute)]	**[DIALS]** [N:1] ○ Yes [N:0] ○ No
19.*	IV Inotropes [IV Inotropes]	**[INOTRP]** [N:1] ○ Yes [N:0] ○ No
20.	CardioMEMS HF System [CardioMEMS HF System]	**[CMEMS]** [N:1] ○ Yes [N:0] ○ No

Facility details [stHOSP4]

21.*	Hospital name [Hospital name]	**[HSPNAMED]** [N:1] ○ Enrolling facility [N:2] ○ **[HSPNAME]** Other facility A200 [N:99] ○ Unknown
22.*	Hospital location [Hospital location]	**[HSPLOCA]** [N:1] ○ **[HSPLOCAS]** City, State A200 [N:99] ○ Unknown
23.* ✔	Was the subject discharged? [Subject discharged?]	**[SUBJDIS]** [N:1] ○ **[HSPDSGDT]** Yes Date of discharge Req ⌄ / Req ⌄ / Req ⌄ (2012-2025) **[HSPDSCHG]** Discharge disposition [N:1] ○ Acute care, complete an additional HOSP form [N:2] ○ Extended care, complete EXTCARE form [N:3] ○ Subject died, complete DEATH and EOS forms [N:4] ○ Home [N:99] ○ Unknown [N:0] ○ No
24.	Trigger number [Trigger number]	**[HSPTRIG]** A100

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

sdGUIDEIT: Acute coronary syndrome (ACS) [frACS]

ACS DETAILS [stACS1]

1.*	Date and time of onset of ischemic symptoms that caused the subject to seek medical attention (day and time may be estimated) [Date and time of onset of ischemic symptoms]	**[ACSDTM]** Req ⌄ / Req ⌄ / Req ⌄ (2012-2025) Req/Unk ⌄ : Req/Unk ⌄ *24-hour clock*
2.*	Please indicate characteristics of the ischemic symptoms [Please indicate characteristics of the ischemic symptoms]	**[MIISCSYM]** *[N:1]* ◯ **[MICHESPN]** Select all that apply *[N:1]* ☐ New onset chest pain **[MIANGISC]** *[N:1]* ☐ Symptoms typical of angina/ischemia **[MIACCPAT]** *[N:1]* ☐ Accelerating pattern or frequent episodes **[MILOWACT]** *[N:1]* ☐ Chest pain that occurs with a lower activity threshold **[MISYMPTM]** *[N:1]* ☐ Symptoms at rest *[N:0]* ◯ None
3.*	Type of event [Type of event]	**[MITYPEEV]** *[N:1]* ◯ Spontaneous Myocardial Infarction *[N:2]* ◯ Myocardial Infarction following a procedure *[N:3]* ◯ Unstable angina
4.*	Longest duration of ischemic symptoms [Longest duration of ischemic symptoms]	**[LONGDUR]** *[N:0]* ◯ None *[N:1]* ◯ < = 10 minutes *[N:2]* ◯ 11-19 minutes *[N:3]* ◯ > = 20 minutes *[N:99]* ◯ Unknown
5.*	Did the participant have a cath lab visit during this event? [Did the participant have a cath lab visit during this event?]	**[MICATVIS]** *[N:1]* ◯ Yes *[N:0]* ◯ No
6.*	Were ECGs performed for ischemic episode or in follow up? (If yes, submit the ECG.) [Were ECGs performed for ischemic episode or in follow up?]	**[ECGISCEP]** *[N:1]* ◯ **[ECGISCCH]** Yes Were there new ischemic changes? *[N:1]* ◯ Yes *[N:0]* ◯ No **[ECGQWAVE]** Were new Q waves identified? *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:0]* ◯ No *[N:99]* ◯ Unknown
7.*	Was there hemodynamic instability related to this event? [Was there hemodynamic instability related to this event?]	**[EVHEMOIN]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
8.*	Was there heart failure complicating this event? [Was there heart failure complicating this event?]	**[MIHF]** *[N:1]* ◯ Yes *[N:0]* ◯ No *[N:99]* ◯ Unknown
9.*	Imaging evidence of new loss of viable myocardium? [Imaging evidence of new loss of viable myocardium?]	**[NEWLOSS]** *[N:1]* ◯ **[IMPERTYP]** Yes Type of imaging performed *[N:1]* ◯ ECHO *[N:2]* ◯ SPECT/PET *[N:3]* ◯ CMR *[N:0]* ◯ No *[N:97]* ◯ Not Done

CRA confirmation of missing ACS data (DCRI use only) [stACS2]

10.	This record was intentionally left blank. Please delete. [This record was intentionally left blank.]	**[MIUNDCON]** *[N:1]* ◯ Confirm

CEC patient profile print date [stACS3]

11.	Date/Time Patient Profile printed [Date/Time Patient Profile printed]	**[CECACS]** Req ⌄ / Req ⌄ / Req ⌄ (2012-2025) Req ⌄ : Req ⌄ *24-hour clock*

Key: [*] = Item is required

sdGUIDEIT: Hospitalization for heart failure (HF) [frHF]

HEART FAILURE [stHF1]

1.*	Indicate clinical symptoms of heart failure (Select all that apply)
	[Indicate clinical symptoms of heart failure]
		[HFNWSX]
		[N: 1] ○ **[HFDYSP]**
		  [N: 1] ☐ New or worsening dyspnea
		[HFORTH]
		  [N: 1] ☐ New or worsening orthopnea
		[HFPND]
		  [N: 1] ☐ New or worsening paroxysmal nocturnal dyspnea
		[HFEDEM]
		  [N: 1] ☐ New or worsening edema
		[HFOTHNW]
		  [N: 1] ☐ **[HFOTRNWS]**
		    Other, specify
		    A200
		[HFUNKNW]
		  [N: 1] ☐ Unknown
		[N: 0] ○ None

2.*	Indicate physical signs or objective signs of heart failure (Select all that apply)
	[Signs of heart failure]
		[HFSIGNS]
		[N: 1] ○ **[HFEDESGN]**
		  [N: 1] ☐ Edema (> 2+ lower extremity)
		[HFPULSGN]
		  [N: 1] ☐ Pulmonary crackles greater than basilar
		[HFJVSSGN]
		  [N: 1] ☐ Estimated jugular venous distension > 10 cm
		[HFTACSGN]
		  [N: 1] ☐ Tachypnea (respiratory rate > 20 breaths/minute)
		[HFWGTSGN]
		  [N: 1] ☐ Rapid weight gain
		[HFS3SGN]
		  [N: 1] ☐ S3 gallop
		[HFABDGN]
		  [N: 1] ☐ Increasing abdominal distention or ascites
		[HFHEPSGN]
		  [N: 1] ☐ Hepatojugular reflux
		[HFRADSGN]
		  [N: 1] ☐ Radiological evidence of worsening of HF
		[HFRHCSGN]
		  [N: 1] ☐ A right heart catheterization within 24 hours of admission showing an elevated pulmonary capillary wedge pressure
		[HFBNPSGN]
		  [N: 1] ☐ Elevated BNP or NTproBNP
		[HFOTRSGN]
		  [N: 1] ☐ **[HFOTSGNO]**
		    Other,
		    Other, specify
		    A200
		[HFUKNSGN]
		  [N: 1] ☐ Unknown
		[N: 0] ○ None

3.*	Initiation of, or an increase in, treatment directed of heart failure (Select all that apply)
	[Initiation of, or an increase in, treatment directed of heart failure]
		[HFINCTHX]
		[N: 1] ○ **[HFDIUTHX]**
		  [N: 1] ☐ Initiation of IV diuretic, inotrope, or vasodilator therapy or significant augmentation of therapy
		[HFUPTTHX]
		  [N: 1] ☐ Uptitration of IV therapy, if already on therapy
		[HFMECTHX]
		  [N: 1] ☐ Initiation of mechanical or surgical intervention
		[HFOTRTHX]
		  [N: 1] ☐ **[HFOTTHXS]**
		    Other,
		    Other, specify
		    A200
		[HFUKNTHX]
		  [N: 1] ☐ Unknown
		[N: 0] ○ None

CRA confirmation of missing HF data (DCRI use only) [stHF2]

4.	This record was intentionally left blank. Please delete. [Please delete.]	**[HFNDCON]** *[N: 1]* ○ Confirm

CEC patient profile print date [stHF3]

5.	Date/Time Patient Profile printed [Time profile printed]	**[CECHFDTM]** Req ▼ / Req ▼ / Req ▼ *(2012-2025)* Req ▼ : Req ▼ *24-hour clock*

Key: [*] = Item is required

sdGUIDEIT: Subject Demographics (DEM) [frDEM]

Subject Demographics [frDEM]

1.	Update Workflow *[hidden]* [Update Workflow]	**[UPDTWKFL]** *[N:1]* ☐ Yes
2.	Update subject number [Update subject number]	**[SUBJID]** A50
3.* ✔	Date of birth [Date of birth]	**[DOBDT]** Req ▾ / Req ▾ / Req ▾ (1900-2008)
4.*	Gender [Gender]	**[GENDER]** *[N:1]* ○ Male *[N:2]* ○ Female
5.*	Ethnicity [Ethnicity]	**[ETHNIC]** *[N:1]* ○ Hispanic or Latino *[N:2]* ○ Not Hispanic or Latino *[N:99]* ○ Unknown

6.*	Race	**[RACE]**
		[N:1] ○ **[cpRACE]**
		Select all the races that apply in the list
		  [AMERIND]
		  [N:1] ☐ American Indian or Alaska Native
		  [ASIAN]
		  [N:1] ☐ Asian
		  [BLACK]
		  [N:1] ☐ Black or African American
		  [NATHWN]
		  [N:1] ☐ Native Hawaiian or other Pacific Islander
		  [WHITE]
		  [N:1] ☐ White/Caucasian
		  [OTHRACE]
		  [N:1] ☐ **[RACESP]**
		  Other Race
		  Specify Other
		  A50
		[N:99] ○ Unknown

7.*	Height [Height]	**[HTDONE]** *[N:1]* ○ **[HEIGHT]** XXXXXXXX. ○ in [b] ○ cm *[N:97]* ○ Not Done
8.	Weight *[hidden]* [Weight]	**[WGHTDN]** *[N:1]* ○ **[WGHT]** XXXXXXXX. ○ lbs [b] ○ kg *[N:97]* ○ Not Done

Informed Consent [stDEM2]

9.* ✔	Date and time of consent [Date and time of consent]	**[CNSNTDTM]** Req ▾ / Req ▾ / Req ▾ (2012-2025) Req/Unk ▾ : Req/Unk ▾ *24-hour clock*

10.* ✔	Qualifying NT-proBNP or BNP value:
	[Qualifying NT-proBNP or BNP value:]
		[INDXMRKR]
		[N:1] ○ **[cpBNP]**
		BNP
		  [NDXBNPDT]
		  Req ▾ / Req ▾ / Req ▾ (2000-2025)
		  [INDXBNP]
		  XXXXXXXX.
		[N:2] ○ **[cpNTPROBNP]**
		NT-proBNP
		  [NDXPBNDT]
		  Req ▾ / Req ▾ / Req ▾ (2000-2025)
		  [INDXPBNP]
		  XXXXXXXX.

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

sdGUIDEIT: Medical History (MEDHX) [frMEDHX]

Medical History [frMEDHX]

1.* ✔	What is the primary etiology of the heart failure?	**[HFETIOL]** [N:1] ◉ Ischemic
		 [N:2] ◉ **[NISETIOL]** Non-ischemic
		    [N:1] ◯ Dilated/ Idiopathic
		    [N:2] ◯ Hypertensive
		    [N:3] ◯ Valvular
		    [N:98] ◉ **[NISETIO]** Other
		      A200

2.*	Duration of heart failure (number of months) [Duration of heart failure]	**[HFDURKNW]** [N:1] ◯ **[HFDUR]** N3 [N:99] ◯ Unknown

3.*	Has the subject had any hospitalizations for heart failure?
	 [Has the subject had any hospitalizations for heart failure]
		[HFHOSP] [N:1] ◯ **[LSTHOSDT]** Yes,
		 Date of the last hospitalization for heart failure
		 Req/Unk ▾ / Req/Unk ▾ / Req ▾ (1980-2025)
		 [HSPHFMXD]
		 Number of hospitalizations with a primary diagnosis of heart failure in the past 12 months
		    [N:1] ◯ **[HSPHFMX]** N3
		    [N:99] ◯ Unknown
		 [N:0] ◯ No

Indicate if the subject has had a history of the following [stMEDHX2]

4.*	Coronary artery disease (CAD) [Coronary artery disease (CAD)]	**[CAD]** [N:1] ◯ Yes [N:0] ◯ No

5.* ✔	Prior revascularization (If yes, check all that apply)
	 [Prior revascularization]
		[CABGS] [N:1] ◯ **[cpCABGS]** Yes
		    [PPCI] [N:1] ☐ PCI
		    [PCABG] [N:1] ☐ CABG
		 [N:0] ◯ No

6.* ✔	Valve surgery (If yes, check all that apply)
	 [Valve surgery]
		[HRTSURG] [N:1] ◯ **[cpHRTSURG]** Yes
		    [AORVLV] [N:1] ☐ Aortic valve replacement
		    [MITRVLV] [N:1] ☐ Mitral valve replacement/repair
		    [OTHVLVSG] [N:1] ☐ **[OTVLVSRG]** Other valve surgery
		      Specify other valve sugery
		      A200
		 [N:0] ◯ No

7.* ✔	Prior implantable cardioverter defibrillator (ICD)/ Pacemaker implantation
	 [Prior implantable cardioverter defibrillator (ICD)]
		[ICDDONE] [N:1] ◯ **[ICD]** Yes
		    [N:1] ◯ ICD Only
		    [N:2] ◯ Pacemaker only
		    [N:3] ◯ Biventricular pacer only
		    [N:4] ◯ Biventricular pacer and ICD
		 [N:0] ◯ No

8.*	Myocardial infarction (MI)
	 [Myocardial infarction (MI)]
		[MI] [N:1] ◯ **[MIDT]** Yes,
		 Year of most recent
		    [N:1] ◯ **[MIYR]** Req ▾ (1980-2025)
		    [N:99] ◯ Unknown
		 [N:0] ◯ No

9.*	Prior left heart catheterization
	 [Prior left heart catheterization]
		[LHC] [N:1] ◯ **[LHCSTENO]** Yes
		 Did any vessel have >70% stenosis?
		    [N:1] ◯ Yes
		    [N:0] ◯ No
		    [N:99] ◯ Unknown
		 [N:0] ◯ No

10.*	Atrial fibrillation/flutter [Atrial fibrillation]	**[AFIB]** [N:1] ◯ Yes [N:0] ◯ No
11.*	Ventricular tachycardia/fibrillation [Ventricular tachycardia]	**[VFIB]** [N:1] ◯ Yes [N:0] ◯ No
12.*	Peripheral arterial vascular disease [Peripheral arterial vascular disease]	**[PAVD]** [N:1] ◯ Yes [N:0] ◯ No
13.*	Stroke [Stroke]	**[STROKE]** [N:1] ◯ Yes [N:0] ◯ No
14.*	Hypertension [Hypertension]	**[HIPRESSR]** [N:1] ◯ Yes [N:0] ◯ No
15.*	Diabetes mellitus	**[DIABETES]** [N:1] ◯ Yes [N:0] ◯ No
16.*	Chronic respiratory disease (e.g. COPD) [Chronic respiratory disease]	**[COPD]** [N:1] ◯ Yes [N:0] ◯ No
17.*	Chronic liver disease [Chronic liver disease]	**[LIVER]** [N:1] ◯ Yes [N:0] ◯ No
18.*	Cancer within past 5 years, excluding skin cancer [Cancer within past 5 years]	**[CANCER]** [N:1] ◯ Yes [N:0] ◯ No

19. * ✔	Cigarette smoking [Cigarette smoking]	[SMOKEHX] [N:1] ◯ Yes [N:0] ◯ No
20. *	Alcohol abuse [Alcohol abuse]	[ALCOHOL] [N:1] ◯ Yes [N:0] ◯ No
21. * ✔	Depression treated with medications [Depression]	[DPRSNMED] [N:1] ◯ Yes [N:0] ◯ No
22. *	Drug abuse [Drug abuse]	[DRUG] [N:1] ◯ Yes [N:0] ◯ No
23. *	Hyperlipidemia [Hyperlipidemia]	[FAT] [N:1] ◯ Yes [N:0] ◯ No
24. * ✔	Sleep apnea [Sleep apnea]	[APNEA] [N:1] ◯ Yes [N:0] ◯ No
25. * ✔	Renal disease [Renal disease]	[KIDNEY] [N:1] ◯ Yes [N:0] ◯ No
26.	CardioMEMS HF System [CardioMEMS HF System]	[CMEMSMHX] [N:1] ◯ Yes [N:0] ◯ No

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

sdGUIDEIT: Baseline Assessments (BASE) [frBASE]

Index hospitalization discharge [stBASE1]

1.* ✔	Date of qualifying event [Date of discharge]	**[NDXDSCDT]** Req ∨ / Req ∨ / Req ∨ (2012-2025)

2.* ✔	Type of qualifying event
	[Type of qualifying event]
		[QLFYNTYP]
		[N: 1] ◯ Hospitalization for HF
		[N: 2] ◯ Treatment in the emergency department of equivalent
		[N: 3] ◯ **[OUTPT1V]**
		Outpatient treatment with IV diuretics
		   [N: 1] ◯ **[OTPT1VDT]**
		   Date of outpatient treatment with IV diuretics
		   Req ∨ / Req ∨ / Req ∨ (2012-2025)
		[N: 99] ◯ Unknown

Assessments [stBASE2]

3.* ✔	Date of baseline assessment [Date of baseline assessment]	**[BASASCDT]** Req ∨ / Req ∨ / Req ∨ (2012-2025)
4.* ✔	Were local labs performed? (If yes, please complete LABS form) [Were local labs performed?]	**[STDYLAB1]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No *[N: 2]* ◯ Subject refused
5.* ✔	Were protocol required biological samples collected? (If yes, please complete BIOBANK form)	**[BIOLOG1]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No *[N: 2]* ◯ Subject refused

6.* ✔	Was 6-minute walk performed?	**[WALKDONE]**
		[N: 1] ◯ **[WALKKN]**
		Yes,
		Distance walked (meters)
		   [N: 1] ◯ **[WALKDIST]**
		   xxxxxxx.
		   [N: 99] ◯ Unknown
		[N: 0] ◯ **[WLKNDRSN]**
		No
		Reason test was not performed:
		   [N: 1] ◯ Too sick to perform
		   [N: 2] ◯ Unwilling to perform but subjectively able
		   [N: 3] ◯ Not done due to oversight
		   [N: 4] ◯ Cannot walk for technical reasons (e.g., amputee, orthopedic)
		   [N: 5] ◯ Neurological reasons
		   [N: 99] ◯ Unknown

7.* ✔	Were baseline QOL forms administered? [Were baseline QOL forms administered?]	**[QOLFORMS]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No

8.* ✔	Did the subject have an echo performed?
	(Applicable for Echo Sub-Study Participating Sites ONLY. Expected answer of No, if not participating.)
	[Did the subject have an echo performed?]
		[ECHODN]
		[N: 1] ◯ **[ECHOSUBM]**
		Yes
		Date submitted to DCRI
		   [N: 97] ◯ Not Done
		   [N: 1] ◯ **[ECHSUBDT]**
		   Req ∨ / Req ∨ / Req ∨ (2012-2025)
		[N: 0] ◯ No

9.* ✔	Was therapy adjusted? (If yes, please complete ADJUST form)
	[Was therapy adjusted?]
		[PBNPADJ1]
		[N: 1] ◯ Yes
		[N: 0] ◯ **[NOBNPAD1]**
		No
		Why was therapy not adjusted?
		   [N: 1] ◯ NTproBNP already at target range
		   [N: 2] ◯ Already at maximally tolerated therapy
		   [N: 3] ◯ Already at guideline recommended target doses
		   [N: 4] ◯ **[MDDCSNO1]**
		   Other clinician decision
		   Other specify
		   A100
		   [N: 5] ◯ **[PTPREFO1]**
		   Patient preference
		   Other specify
		   A100
		   [N: 98] ◯ **[NOBNADO1]**
		   Other
		   Other specify
		   A100

Key: [*] – Item is required [✔] – Source verification required

sdGUIDEIT: Recent Ejection Fraction (EF) [frEF]

Recent Ejection Fraction [frEF]

1.* ✔	Most recent ejection fraction date [ejection fraction date]	**[EFDT]** Req ▾ / Req ▾ / Req ▾ (1995-2025)
2.* ✔	Value of most recent LVEF (Enter description only if EF value unavailable) [Value of most recent LVEF]	**[LVEF]** [N: 1] ○ **[LVEFVAL]** EF ⃞ xxxxxxxx. [N: 2] ○ Normal [N: 3] ○ Mild dysfunction [N: 4] ○ Moderate dysfunction [N: 5] ○ Severe dysfunction
3.*	Method of assessment of LV function [Method of assessment of LV function]	**[METHLV]** [N: 1] ○ Radionuclide ventriculogram [N: 2] ○ Left ventriculogram by cardiac catheterization [N: 3] ○ Echocardiogram [N: 4] ○ MRI [N: 98] ○ **[OMETHLV]** Other specify ⃞ A50

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

sdGUIDEIT: Examination (EXAM) [frEXAM]

Update to historical findings [stEXAM1]

1.*	New York Heart Association Class [New York Heart Association Class]	**[NYHACD]** *[N:1]* ○ I *[N:2]* ○ II *[N:3]* ○ III *[N:4]* ○ IV *[N:97]* ○ Not Done
2.*	Orthopnea (Number of pillows at 10 cm/pillow) [Orthopnea (Number of pillows at 10 cm/pillow)]	**[ORTHODN]** *[N:0]* ○ 0 *[N:1]* ○ 1 *[N:2]* ○ 2 *[N:3]* ○ >=3 *[N:97]* ○ Not Done

Physician Findings [stEXAM2]

3.*	Weight [Weight]	**[WEIGHTD]** *[N:1]* ○ **[WEIGHT]** XXXXXXXX. ○ lbs [b] ○ kg *[N:97]* ○ Not Done
4.*	Heart Rate (sitting or resting) (beats/min) [Heart Rate]	**[HRDONE]** *[N:1]* ○ **[HRVALUE]** XXXXXXXX. *[N:97]* ○ Not Done
5.*	Respiratory Rate (sitting or resting) (breaths per min) [Respiratory Rate]	**[RSDONE]** *[N:1]* ○ **[RSVALUE]** XXXXXXXX. *[N:97]* ○ Not Done
6.*	Blood Pressure (sitting or resting) (mmHg) [Blood Pressure]	**[BPDONE]** *[N:1]* ○ **[cpBP]** **[BPSYS]** **[BPDIA]** N3 / N3 *[N:97]* ○ Not Done
7.*	Is the patient currently in atrial fibrillation or atrial flutter? [Is the patient currently in atrial fibrillation or atrial flutter?]	**[CRHYTM]** *[N:1]* ○ Yes *[N:0]* ○ No
8.*	SpO2 (%) [SpO2 (%)]	**[SPO2DONE]** *[N:1]* ○ **[SPO2]** XXXXXXXX. *[N:97]* ○ Not Done
9.*	Jugular venous pressure (cm) [Jugular venous pressure (cm)]	**[JVPDONE]** *[N:1]* ○ **[JVP]** Yes *[N:1]* ○ < 8 *[N:2]* ○ 8-12 *[N:3]* ○ 13-16 *[N:4]* ○ > 16 *[N:97]* ○ Not Done
10.*	Rales [Rales]	**[RALESDN]** *[N:1]* ○ **[RALES]** Yes *[N:1]* ○ < 1/3 *[N:2]* ○ 1/3-2/3 *[N:3]* ○ > 2/3 *[N:0]* ○ No *[N:97]* ○ Not Done
11.*	S3 auscultation [S3 auscultation]	**[S3AUSC]** *[N:1]* ○ Yes *[N:0]* ○ No *[N:97]* ○ Not Done
12.*	Hepatomegaly [Hepatomegaly]	**[HEPAT]** *[N:1]* ○ Yes *[N:0]* ○ No *[N:97]* ○ Not Done
13.*	Ascites [Ascites]	**[ASCITES]** *[N:1]* ○ Yes *[N:0]* ○ No *[N:97]* ○ Not Done
14.*	Peripheral edema [Peripheral edema]	**[EDEMADN]** *[N:1]* ○ **[EDEMA]** Yes *[N:1]* ○ Trace *[N:2]* ○ Moderate *[N:3]* ○ Severe *[N:0]* ○ No *[N:97]* ○ Not Done

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

sdGUIDEIT: Concomitant medications (MEDS) [frMEDS]
Medications [STMEDS1]

1. * ✔ ACE inhibitor
[ACE inhibitor]

[ACE]
[N:1] ○ **[ACEAGENT]**
Yes
Specify agent
[N: 1] ○ Benazepril
[N: 2] ○ Captopril
[N: 3] ○ Enalapril
[N: 4] ○ Fosinopril
[N: 5] ○ Lisinopril
[N: 6] ○ Quinapril
[N: 7] ○ Ramipril
[N: 8] ○ Trandolapril
[N: 98] ○ **[ACEOTHR]**
Other
Other specifiy
A100

[ACEDOSED]
Total daily dose (mg)
[N: 1] ○ **[ACEDOSE]**
xxxxxxxx.
[N: 99] ○ Unknown
[N:0] ○ No
[N: 99] ○ Unknown

2. * ✔ Aldosterone antagonist
[Aldosterone antagonist]

[ALDOS]
[N:1] ○ **[ALDAGENT]**
Yes
Specify agent
[N: 1] ○ Epleronone
[N: 2] ○ Spironolactone
[N: 98] ○ **[ALDOTHR]**
Other
Other specifiy
A100

[ALDDOSED]
Total daily dose (mg)
[N: 1] ○ **[ALDODOSE]**
xxxxxxxx.
[N: 99] ○ Unknown
[N:0] ○ No
[N: 99] ○ Unknown

3. * ✔ Angiotensin receptor blocker
[Angiotensin receptor blocker]

[ARB]
[N:1] ○ **[ARBAGENT]**
Yes
Specify agent
[N: 1] ○ Candesartan
[N: 2] ○ Irbesartan
[N: 3] ○ Losartan
[N: 4] ○ Valsartan
[N: 98] ○ **[ANGOTHR]**
Other
Other specifiy
A100

[ARBDOSED]
[N: 1] ○ **[ARBDOSE]**
Total daily dose (mg)

xxxxxxxx.
[N: 99] ○ Unknown
[N:0] ○ No
[N: 99] ○ Unknown

4. * ✔ Beta Blocker
[Beta Blocker]

[BETAB]
[N: 1] ○ **[BBAGENT]**
Yes
Specify agent
[N: 1] ○ Atenolol
[N: 2] ○ Bisoprolol
[N: 3] ○ Carvedilol
[N: 4] ○ Metoprolol immediate release
[N: 5] ○ Metoprolol XL
[N: 98] ○ **[BBOTHR]**
Other
Other specifiy
A100

[BBDOSED]
[N: 1] ○ **[BBDOSE]**
Total daily dose (mg) xxxxxxxx.
[N: 99] ○ Unknown
[N:0] ○ No
[N: 99] ○ Unknown

5. * ✔ Loop diuretic

[LOOPDIU]
[N: 1] ○ **[cpAGENT]**
Yes
[FUROS]
[N: 1] ☐ **[FUROSND]**
Furosemide
Total daily dose (mg)
[N: 1] ○ **[FUROSE]**
xxxxxxxx.
[N: 2] ○ PRN
[N: 99] ○ Unknown
[BUMETA]
[N: 1] ☐ **[BUMETAND]**
Bumetanide
Total daily dose (mg)
[N: 1] ○ **[BUMETDD]**
xxxxxxxx.
[N: 2] ○ PRN
[N: 99] ○ Unknown
[TORSE]
[N: 1] ☐ **[TORSEND]**
Torsemide
Total daily dose (mg)
[N: 1] ○ **[TORSEDD]**
xxxxxxxx.
[N: 2] ○ PRN
[N: 99] ○ Unknown
[N:0] ○ No
[N: 99] ○ Unknown

6. Other loop diuretic
[Other loop diuretic]

[LDOTHR]

✔		*[N:1]* ☐ **[LPOTHRSP]** Other Other Specify A100 **[LPDOSED]** Total daily dose (mg) *[N:1]* ○ **[LPDOSE]** XXXXXXXX. *[N:2]* ○ PRN *[N:99]* ○ Unknown
7.* ✔	PDE5 Inhibitors [PDE5 Inhibitors]	**[PDE5I]** *[N:1]* ○ **[PDE5IA]** Yes Specify agent *[N:1]* ○ Sildenafil *[N:2]* ○ Tadalafil *[N:3]* ○ Vardenafil *[N:98]* ○ **[PDE5IO]** Other Other specify A100 *[N:0]* ○ No *[N:99]* ○ Unknown
8.* ✔	Metolazone [Metolazone]	**[METAZ]** *[N:1]* ○ **[METZAFRQ]** Yes *[N:1]* ○ Chronic (>=1x/week) *[N:2]* ○ PRN (<1x/week) *[N:0]* ○ No *[N:99]* ○ Unknown
9.* ✔	HCTZ [HCTZ]	**[HCTZ]** *[N:1]* ○ **[HCCTZFRQ]** Yes *[N:1]* ○ Chronic (>=1x/week) *[N:2]* ○ PRN (<1x/week) *[N:0]* ○ No *[N:99]* ○ Unknown
10.* ✔	Ambulatory IV Inotropes [Ambulatory IV Inotropes]	**[IVINOTRP]** *[N:1]* ○ Yes *[N:0]* ○ No *[N:99]* ○ Unknown
11.*	Hydralazine [Hydralazine]	**[HYDR]** *[N:1]* ○ Yes *[N:0]* ○ No *[N:99]* ○ Unknown
12.*	Nitrates (long lasting) [Nitrates (long lasting)]	**[NITR]** *[N:1]* ○ Yes *[N:0]* ○ No *[N:99]* ○ Unknown
13.*	Calcium channel blocker [Calcium channel blocker]	**[CCB]** *[N:1]* ○ Yes *[N:0]* ○ No *[N:99]* ○ Unknown
14.*	Antiplatelets [Antiplatelets]	**[ANTIPLT]** *[N:1]* ○ **[ANTPASPR]** Yes *[N:1]* ☐ Aspirin (taken daily) **[ANTPTHIE]** *[N:1]* ☐ Thienopyridines (e.g., ticlopidine, clopidogrel, prasugrel) **[ANTP2Y12]** *[N:1]* ☐ P2Y12 inhibitors (e.g., ticagrelor) **[ANTPOTHR]** *[N:1]* ☐ **[ANTIPLSP]** Other Other (specify) A50 *[N:0]* ○ No *[N:99]* ○ Unknown
15.*	Anticoagulants [Anticoagulants]	**[ANTICAG]** *[N:1]* ○ **[cpANTICAG]** **[ANTIWARF]** Yes *[N:1]* ☐ Warfarin **[ANTIFXA]** *[N:1]* ☐ Factor Xa Inhibitor **[ANTITI]** *[N:1]* ☐ Direct Thrombin Inhibitor **[ANTIOTH]** *[N:1]* ☐ **[ANTICASP]** Other Other (specify) A50 *[N:0]* ○ No *[N:99]* ○ Unknown
16.* ✔	Digoxin	**[DIGX]** *[N:1]* ○ Yes *[N:0]* ○ No *[N:99]* ○ Unknown
17.* ✔	Amiodarone	**[AMIOD]** *[N:1]* ○ Yes *[N:0]* ○ No *[N:99]* ○ Unknown
18.* ✔	Other antiarrhythmic [Other antiarrhythmic]	**[OARRH]** *[N:1]* ○ Yes *[N:0]* ○ No *[N:99]* ○ Unknown
19.*	Statin [Statin]	**[STATIN]** *[N:1]* ○ Yes *[N:0]* ○ No *[N:99]* ○ Unknown
20.*	Lipid lowering agent (other than statin) [Lipid lowering agent (other than statin)]	**[LLIPID]** *[N:1]* ○ Yes *[N:0]* ○ No *[N:99]* ○ Unknown
21.*	Insulin [Insulin]	**[INSULIN]** *[N:1]* ○ Yes *[N:0]* ○ No *[N:99]* ○ Unknown

22.*	Oral anti-diabetic agent [Oral anti-diabetic agent]	**[ODIAGT]** *[N:1]* ○Yes *[N:0]* ○No *[N:99]* ○Unknown
23.*	Antidepressant [Antidepressant]	**[DEPRES]** *[N:1]* ○Yes *[N:0]* ○No *[N:99]* ○Unknown
24.*	Allopurinol [Allopurinol]	**[ALLOPUR]** *[N:1]* ○Yes *[N:0]* ○No *[N:99]* ○Unknown
25.*	Bronchodilator (long lasting) [Bronchodilator (long lasting)]	**[BRONCHDR]** *[N:1]* ○ **[B2AGNT]** Yes Type of Bronchodilator *[N:1]* ☐ Beta 2 agonist **[ACH]** *[N:1]* ☐ Anticholinergic **[BRONCDRO]** *[N:1]* ☐ **[BRNCDROS]** Other Other (specify) A100 *[N:0]* ○No *[N:99]* ○Unknown
26.	Valsartan/sacubitril [Valsartan/sacubitril]	**[LCZ696YN]** *[N:1]* ○Yes *[N:0]* ○No *[N:99]* ○Unknown
27.	Ivabradine [Ivabradine]	**[IVABRDYN]** *[N:1]* ○Yes *[N:0]* ○No *[N:99]* ○Unknown
Key: [*] = Item is required [✔] = Source verification required		

sdGUIDEIT: Local NT-pro-BNP (PROBNP) [frPROBNP]

NT-proBNP result [stPROBNP1]

1. * ✔	NT-proBNP testing date [NT-proBNP testing date]	**[PBNPDT]** Req ▾ / Req ▾ / Req ▾ (2012-2025)
2. * ✔	NT-proBNP result (pg/mL) [NT-proBNP result (pg/mL)]	**[PBNPRSTD]** *[N: 1]* ◯ **[PBNPRSLT]** XXXXXXXX. *[N: 99]* ◯ Unknown
3. ✔	ClinOps discussed results with site [ClinOps discussed results with site]	**[CLNOPADJ]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No
4. ✔	Adherence Committee discussed results with site [Adherence Committee discussed results with site]	**[ACADJ]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No

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

sdGUIDEIT: Local Labs (LABS) [frLABS]

Chemistry [stLABS1]

1.* ✔	Date of Chemistry Labs [Date of Chemistry Labs]	**[CLABDT]** Req/Unk ▾ / Req/Unk ▾ / Req ▾ (2012-2025)
2.* ✔	Sodium [Sodium]	**[SODIUM]** *[N:1]* ○ **[SODVAL]** Value: xxxxxxxx. **[SODUNIT]** *[N:1]* ○ mmol/L *[N:2]* ○ mEq/L *[N:97]* ○ Not Done
3.* ✔	Potassium [Potassium]	**[POTASS]** *[N:1]* ○ **[POTVAL]** Value: xxxxxxxx. **[POTASUNT]** *[N:1]* ○ mmol/L *[N:2]* ○ mEq/L *[N:97]* ○ Not Done
4.* ✔	BUN/Urea [BUN]	**[BUNUR]** *[N:1]* ○ **[BUNVAL]** Value: xxxxxxxx. **[BUNUNIT]** *[N:1]* ○ mmol/L *[N:3]* ○ mg/dL *[N:97]* ○ Not Done
5.* ✔	Creatinine [Creatinine]	**[CREAT]** *[N:1]* ○ **[CREATVAL]** Value: xxxxxxxx. **[CREAUNIT]** *[N:3]* ○ mg/dL *[N:4]* ○ umol/L *[N:97]* ○ Not Done
6.* ✔	Total Cholesterol [Total Cholesterol]	**[TCHOL]** *[N:1]* ○ **[TCHOLVAL]** Value: xxxxxxxx. **[TCHOLUNIT]** *[N:1]* ○ mmol/L *[N:3]* ○ mg/dL *[N:97]* ○ Not Done
7.* ✔	Uric acid [Uric acid]	**[URIC]** *[N:1]* ○ **[URICVAL]** Value: xxxxxxxx. **[URICUNIT]** *[N:1]* ○ mmol/L *[N:3]* ○ mg/dL *[N:4]* ○ umol/L *[N:97]* ○ Not Done

Hematology [stLABS2]

8.* ✔	Date of Hematology Labs [Date of Hematology Labs]	**[HLABDT]** Req/Unk ▾ / Req/Unk ▾ / Req ▾ (2012-2025)
9.* ✔	Hemoglobin [Hemoglobin]	**[HEMO]** *[N:1]* ○ **[HEMOVAL]** Value: xxxxxxxx. **[HEMOUNIT]** *[N:7]* ○ g/dL *[N:8]* ○ g/L *[N:1]* ○ mmol/L *[N:97]* ○ Not Done
10.* ✔	Hematocrit [Hematocrit]	**[HEMAT]** *[N:1]* ○ **[HEMATVAL]** Value: xxxxxxxx. **[HEMUNIT]** *[N:12]* ○ L/L *[N:11]* ○ % *[N:97]* ○ Not Done
11.* ✔	Platelets [Platelets]	**[PLATELET]** *[N:1]* ○ **[PLATVAL]** Value: xxxxxxxx. **[PLATUNIT]** *[N:9]* ○ 10^9/L or 10^3/mm^3 *[N:10]* ○ /mm^3 *[N:97]* ○ Not Done
12.* ✔	WBC [WBC]	**[WBC]** *[N:1]* ○ **[WBCVAL]** Value: xxxxxxxx. **[WBCUNIT]** *[N:9]* ○ 10^9/L or 10^3/mm^3 *[N:10]* ○ /mm^3 *[N:97]* ○ Not Done
13.* ✔	Lymphocytes (%) [Lymphocytes]	**[LYMPH]** *[N:1]* ○ **[LYMPVAL]** Value: xxxxxxxx. *[N:97]* ○ Not Done

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

sdGUIDEIT: Biobank (BIOBANK) - Repeating Form [frBIOBANK]

#	Sample Collection Date/Time	Was subject fasting?	Sample Collected	Date/Time Processing Initiated	Date/Time Frozen	Date sent to core lab
1						

Biobank [frBIOBANK]

1.* ✔	Sample Collection Date/Time [Sample Collection Date/Time]	**[SMPLDTM]** Req ∨ / Req ∨ / Req ∨ (2012-2025) Req/Unk ∨ : Req/Unk ∨ _24-hour clock_

2.* ✔	Was subject fasting? [Was subject fasting?]	**[FASTING]** _[N: 1]_ ⊙ **[FASTSTAT]** Yes Last time subject had anything to eat/drink containing calories Req/Unk ∨ / Req/Unk ∨ / Req/Unk ∨ (2012-2025) Req/Unk ∨ : Req/Unk ∨ _24-hour clock_ _[N: 0]_ ⊙ No

3.	Sample Collected (Record the number of cryovials) _[hidden]_ [Sample Collected]	**[cpSAMPCOL]** **[DNABLD]** _[N: 1]_ ☐ **[DNABLDV]** DNA - whole blood N3 **[SERUM]** _[N: 1]_ ☐ **[SERUMV]** Serum N3 **[PLSM6]** _[N: 1]_ ☐ **[PLSM6V]** Plasma - 6 ml N3 **[PLSM5]** _[N: 1]_ ☐ **[PLSM5V]** Plasma - 0.5 ml N3 **[PROBNP]** _[N: 1]_ ☐ **[PROBNPV]** NT-pro-BNP N3

4.* ✔	Sample Collected (Record the number of cryovials) [Sample Collected]	**[cpSAMPCOL2]** **[DNABLD2]** _[N: 1]_ ☐ **[DNABLDV2]** Whole blood, EDTA N3 **[SERUM2]** _[N: 1]_ ☐ **[SERUMV2]** Serum, Gold Top (cryovials) N3 **[PROBNP2]** _[N: 1]_ ☐ **[PROBNPV2]** NT-pro-BNP (2 mL Plasma) (cryovials) N3 **[PLSM102]** _[N: 1]_ ☐ **[PLSM10V2]** Plasma, EDTA - 10 mL (cryovials) N3 **[PLSM32]** _[N: 1]_ ☐ **[PLSM3V2]** Plasma, Lithium Heparin - 3 ml (cryovials) N3

5.* ✔	Date/Time Processing Initiated [Date/Time Processing Initiated]	**[PRCSDTM]** Req ∨ / Req ∨ / Req ∨ (2012-2025) Req/Unk ∨ : Req/Unk ∨ _24-hour clock_

6.* ✔	Date/Time Frozen [Date/Time Frozen]	**[FRZDTM]** Req ∨ / Req ∨ / Req ∨ (2012-2025) Req/Unk ∨ : Req/Unk ∨ _24-hour clock_

7.* ✔	Date sent to core lab [Date sent to core lab]	**[CORELDT]** Req ∨ / Req ∨ / Req ∨ (2012-2025)

Key: [*] – Item is required [✔] – Source verification required

sdGUIDEIT: Specimen consent (SPECCONS) [frSPECCONS]

Specimen consent [frSPECCONS]

1.* ✔	Biorepository Sample consented [Biorepository Sample consented]	**[GBSCON]** *[N: 1]* ○ **[GBSCNDT]** Yes Consent Date *Req* ⌄ / *Req* ⌄ / *Req* ⌄ (2012-2025) *[N: 0]* ○ No
2.	Biorepository Sample consent withdrawn [Biorepository Sample consent withdrawn]	**[GBSCWTD]** *[N: 1]* ☐ **[GBSWTDT]** Yes Withdrawal Date *Req/Unk* ⌄ / *Req/Unk* ⌄ / *Req* ⌄ (2012-2025)
3.* ✔	DNA consented [DNA consented]	**[DNACON]** *[N: 1]* ○ **[DNACNDT]** Yes Consent Date *Req/Unk* ⌄ / *Req/Unk* ⌄ / *Req* ⌄ (2012-2025) *[N: 0]* ○ No
4.	DNA consent withdrawn [DNA consent withdrawn]	**[DNACWTD]** *[N: 1]* ☐ **[DNAWTDT]** Yes Withdrawal Date *Req/Unk* ⌄ / *Req/Unk* ⌄ / *Req* ⌄ (2012-2025)
5.	RNA consented *[hidden]* [RNA consented]	**[RNACON]** *[N: 1]* ○ **[RNACNDT]** Yes Consent Date *Req* ⌄ / *Req* ⌄ / *Req* ⌄ (2012-2025) *[N: 0]* ○ No
6.	RNA consent withdrawn *[hidden]* [RNA consent withdrawn]	**[RNACWTD]** *[N: 1]* ☐ **[RNAWTDT]** Yes Withdrawal Date *Req* ⌄ / *Req* ⌄ / *Req* ⌄ (2012-2025)

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

sdGUIDEIT: Therapy Adjustment (ADJUST) - Repeating Form [frADJUST]

#	Date of therapy adjustment	Hospitalization	ACE-inhibitor	ARB	Beta-blocker	Digoxin	Hydralazine-nitrates	Ivabradine	Loop diuretic	Mineralocorticoid receptor antagonist	Oral thiazide diuretic	Valsartan/sacubitril	Cardioversion or rate control for a-fib	Referral for or optimization of cardiac resynchronization therapy	Recommend exercise training or cardiac rehab	Provide additional HF Education	Any other therapy changes?	Other adjustment
1																		

Therapy Adjustment [frADJUST]

| 1. * ✔ | Date of therapy adjustment [Date of therapy adjustment] | [ADJMNTDT] Req ⌄ / Req ⌄ / Req ⌄ (2012-2025) |

Indicate the therapy adjustment(s) on this date [stADJUST2]

| 2. ✔ | Hospitalization (Complete a HOSP form) [Hospitalization] | [HOSADJ] [N:1] ☐ Yes |

| 3. ✔ | Angiotensin Converting Enzyme (ACE)-inhibitor [ACE-inhibitor] | [ACEADJ] [ACECHG] [N:1] ☐ Yes |

How was the therapy adjusted?
- [N:1] ○ Added
- [N:2] ○ Stopped
- [N:3] ○ Increased
- [N:4] ○ Decreased
- [N:5] ○ Switched to another agent in class

[ACEADJR]
Rationale for the adjustment
- [N:1] ○ Decompensated HF
- [N:2] ○ Clinical indication without decompensated HF
- [N:3] ○ Decrease in NT-ProBNP
- [N:4] ○ Increase in NT-ProBNP
- [N:5] ○ [ACEADROT]
  Other investigator decision
  Other specify
  A100
- [N:6] ○ Side effects or intolerance
- [N:98] ○ [ACEADJRO]
  Other
  Other specify
  A100

| 4. ✔ | ARB [ARB] | [ARBADJ] [ARBCHG] [N:1] ☐ Yes |

How was the therapy adjusted?
- [N:1] ○ Added
- [N:2] ○ Stopped
- [N:3] ○ Increased
- [N:4] ○ Decreased
- [N:5] ○ Switched to another agent in class

[ARBADJR]
Rationale for the adjustment
- [N:1] ○ Decompensated HF
- [N:2] ○ Clinical indication without decompensated HF
- [N:3] ○ Decrease in NT-ProBNP
- [N:4] ○ Increase in NT-ProBNP
- [N:5] ○ [ARBADJRO]
  Other investigator decision
  Other specify
  A100
- [N:6] ○ Side effects or intolerance
- [N:98] ○ [OARBADRO]
  Other
  Other specify
  A100

| 5. ✔ | Beta-blocker [Beta-blocker] | [BBADJ] [BBCHG] [N:1] ☐ Yes |

How was the therapy adjusted?
- [N:1] ○ Added
- [N:2] ○ Stopped
- [N:3] ○ Increased
- [N:4] ○ Decreased
- [N:5] ○ Switched to another agent in class

[BBADJR]
Rationale for the adjustment
- [N:1] ○ Decompensated HF
- [N:2] ○ Clinical indication without decompensated HF
- [N:3] ○ Decrease in NT-ProBNP
- [N:4] ○ Increase in NT-ProBNP
- [N:5] ○ [BBADJRO]
  Other investigator decision
  Other specify
  A100
- [N:6] ○ Side effects or intolerance
- [N:98] ○ [OBBADJRO]
  Other
  Other specify
  A100

| 6. ✔ | Digoxin [Digoxin] | [DIGADJ] [DIGCHG] [N:1] ☐ Yes |

How was the therapy adjusted?
- [N:1] ○ Added
- [N:2] ○ Stopped
- [N:3] ○ Increased
- [N:4] ○ Decreased
- [N:5] ○ Switched to another agent in class

[DIGADJR]
Rationale for the adjustment
- [N:1] ○ Decompensated HF
- [N:2] ○ Clinical indication without decompensated HF
- [N:3] ○ Decrease in NT-ProBNP
- [N:4] ○ Increase in NT-ProBNP
- [N:5] ○ [DIGADJRO]
  Other investigator decision
  Other specify
  A100
- [N:6] ○ Side effects or intolerance
- [N:98] ○ [ODIGADRO]
  Other
  Other specify
  A100

| 7. | Hydralazine-nitrates | [HNADJ] |

✔	[Hydralazine-nitrates]	**[N:1]** ☐ **[HNCHG]** Yes

How was the therapy adjusted?
- *[N:1]* ◯ Added
- *[N:2]* ◯ Stopped
- *[N:3]* ◯ Increased
- *[N:4]* ◯ Decreased
- *[N:5]* ◯ Switched to another agent in class

[HNADJR]
Rationale for the adjustment
- *[N:1]* ◯ Decompensated HF
- *[N:2]* ◯ Clinical indication without decompensated HF
- *[N:3]* ◯ Decrease in NT-ProBNP
- *[N:4]* ◯ Increase in NT-ProBNP
- *[N:5]* ◯ **[HNADJRO]** Other investigator decision

  Other specify

  A100

- *[N:6]* ◯ Side effects or intolerance
- *[N:98]* ◯ **[OHNADJRO]** Other

  Other specify

  A100

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8. Ivabradine

✔ [Ivabradine]

[IVBADJ]
[N:1] ☐ **[IVBCHG]** Yes

How was the therapy adjusted?
- *[N:1]* ◯ Added
- *[N:2]* ◯ Stopped
- *[N:3]* ◯ Increased
- *[N:4]* ◯ Decreased
- *[N:5]* ◯ Switched to another agent in class

[IVBADJR]
Rationale for the adjustment
- *[N:1]* ◯ Decompensated HF
- *[N:2]* ◯ Clinical indication without decompensated HF
- *[N:3]* ◯ Decrease in NT-ProBNP
- *[N:4]* ◯ Increase in NT-ProBNP
- *[N:5]* ◯ **[IVBADJRO]** Other investigator decision

  Other specify

  A100

- *[N:6]* ◯ Side effects or intolerance
- *[N:98]* ◯ **[OIVADJRO]** Other

  Other specify

  A100

---

9. Loop diuretic

✔ [Loop diuretic]

[DIUADJ]
[N:1] ☐ **[DIUCHG]** Yes

How was the therapy adjusted?
- *[N:1]* ◯ Added
- *[N:2]* ◯ Stopped
- *[N:3]* ◯ Increased
- *[N:4]* ◯ Decreased
- *[N:5]* ◯ Switched to another agent in class

[DIUADJR]
Rationale for the adjustment
- *[N:1]* ◯ Decompensated HF
- *[N:2]* ◯ Clinical indication without decompensated HF
- *[N:3]* ◯ Decrease in NT-ProBNP
- *[N:4]* ◯ Increase in NT-ProBNP
- *[N:5]* ◯ **[DIUADJRO]** Other investigator decision

  Other specify

  A100

- *[N:6]* ◯ Side effects or intolerance
- *[N:98]* ◯ **[ODIUADRO]** Other

  Other specify

  A100

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10. Mineralocorticoid receptor antagonist (spironolactone or eplerenone)

✔ [Mineralocorticoid receptor antagonist]

[MRAADJ]
[N:1] ☐ **[MRACHG]** Yes

How was the therapy adjusted?
- *[N:1]* ◯ Added
- *[N:2]* ◯ Stopped
- *[N:3]* ◯ Increased
- *[N:4]* ◯ Decreased
- *[N:5]* ◯ Switched to another agent in class

[MRAADJR]
Rationale for the adjustment
- *[N:1]* ◯ Decompensated HF
- *[N:2]* ◯ Clinical indication without decompensated HF
- *[N:3]* ◯ Decrease in NT-ProBNP
- *[N:4]* ◯ Increase in NT-ProBNP
- *[N:5]* ◯ **[MRAADJRO]** Other investigator decision

  Other specify

  A100

- *[N:6]* ◯ Side effects or intolerance
- *[N:98]* ◯ **[OMRAADRO]** Other

  Other specify

  A100

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11. Oral thiazide diuretic

✔ [Oral thiazide diuretic]

[THZADJ]
[N:1] ☐ **[THZCHG]** Yes

How was the therapy adjusted?
- *[N:1]* ◯ Added
- *[N:2]* ◯ Stopped
- *[N:3]* ◯ Increased
- *[N:4]* ◯ Decreased
- *[N:5]* ◯ Switched to another agent in class

[THZADJR]
Rationale for the adjustment
- *[N:1]* ◯ Decompensated HF
- *[N:2]* ◯ Clinical indication without decompensated HF
- *[N:3]* ◯ Decrease in NT-ProBNP

		[N: 4] ◯ Increase in NT-ProBNP
		[N: 5] **[THZADJRO]**
		Other investigator decision
		Other specify
		A100
		[N: 6] ◯ Side effects or intolerance
		[N: 98] **[OTHZADRO]**
		Other
		Other specify
		A100
12. ✔	Valsartan/sacubitril [Valsartan/sacubitril]	**[LCZADJ]** [N: 1] ☐ **[LCZCHG]** Yes How was the therapy adjusted? [N: 1] ◯ Added [N: 2] ◯ Stopped [N: 3] ◯ Increased [N: 4] ◯ Decreased [N: 5] ◯ Switched to another agent in class **[LCZADJR]** Rationale for the adjustment [N: 1] ◯ Decompensated HF [N: 2] ◯ Clinical indication without decompensated HF [N: 3] ◯ Decrease in NT-ProBNP [N: 4] ◯ Increase in NT-ProBNP [N: 5] **[LCZADJRO]** Other investigator decision Other specify A100 [N: 6] ◯ Side effects or intolerance [N: 98] **[OLCZADRO]** Other Other specify A100
13. ✔	Cardioversion or rate control for a-fib [Cardioversion or rate control for a-fib]	**[RCADJ]** [N: 1] ☐ **[RCADJR]** Yes Rationale for the adjustment [N: 1] ◯ Decompensated HF [N: 2] ◯ Clinical indication without decompensated HF [N: 3] ◯ Decrease in NT-ProBNP [N: 4] ◯ Increase in NT-ProBNP [N: 5] **[RCADJRO]** Other investigator decision Other specify A100 [N: 6] ◯ Side effects or intolerance [N: 98] **[ORCADRO]** Other Other specify A100
14. ✔	Referral for or optimization of cardiac resynchronization therapy [Referral for or optimization of cardiac resynchronization therapy]	**[CRTADJ]** [N: 1] ☐ **[CRTADJR]** Yes Rationale for the adjustment [N: 1] ◯ Decompensated HF [N: 2] ◯ Clinical indication without decompensated HF [N: 3] ◯ Decrease in NT-ProBNP [N: 4] ◯ Increase in NT-ProBNP [N: 5] ◯ **[CRTADJRO]** Other investigator decision Other specify A100 [N: 6] ◯ Side effects or intolerance [N: 98] ◯ **[OCRTADRO]** Other Other specify A100
15. ✔	Recommend exercise training or cardiac rehab [Recommend exercise training or cardiac rehab]	**[EXERCZ]** [N: 1] ☐ **[EXERCZR]** Yes Rationale for the adjustment [N: 1] ◯ Decompensated HF [N: 2] ◯ Clinical indication without decompensated HF [N: 3] ◯ Decrease in NT-ProBNP [N: 4] ◯ Increase in NT-ProBNP [N: 5] ◯ **[EXERCZRO]** Other investigator decision Other specify A100 [N: 6] ◯ Side effects or intolerance [N: 98] ◯ **[OEXERCRO]** Other Other specify A100
16. ✔	Provide additional HF Education [Provide additional HF Education]	**[HFED]** [N: 1] ☐ **[HFEDR]** Yes Rationale for the adjustment [N: 1] ◯ Decompensated HF [N: 2] ◯ Clinical indication without decompensated HF [N: 3] ◯ Decrease in NT-ProBNP [N: 4] ◯ Increase in NT-ProBNP [N: 5] ◯ **[HFEDRO]** Other investigator decision Other specify A100 [N: 6] ◯ Side effects or intolerance [N: 98] ◯ **[OHFERO]** Other Other specify A100
17. * ✔	Did the subject have any other therapy changes? [Any other therapy changes?]	**[OTRTHRP]** [N: 1] ◯ Yes [N: 0] ◯ No
	Other adjustment	How was the therapy adjusted?	Rationale for the adjustment

18.			
Other adjustment Entry [rsADJUST3]			

18.1	Other adjustment [Other adjustment]	**[OTHADJ]** A100

18.2	How was the therapy adjusted? [How was the therapy adjusted?]	**[OTHCHG]** [N:1] ○ Added [N:2] ○ Stopped [N:3] ○ Increased [N:4] ○ Decreased [N:5] ○ Switched to another agent in class [N:96] ○ Not applicable

18.3	Rationale for the adjustment [Rationale for the adjustment]	**[OTHADJR]** [N:1] ○ Decompensated HF [N:2] ○ Clinical indication without decompensated HF [N:3] ○ Decrease in NT-ProBNP [N:4] ○ Increase in NT-ProBNP [N:5] ○ **[OTHADJRO]** Other investigator decision Other specify A100 [N:6] ○ Side effects or intolerance [N:98] ○ **[OOTHADRO]** Other Other specify A100

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

sdGUIDEIT: Adherence Case Review (ACR) [frACR]

Adherence Case Review [stACR1]

1.*	Did the Adherence Committee Reviewer adjudicate this case? [Did the Adherence Committee Reviewer adjudicate this case?]	**[ACRDONE]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No

Key: [*] = Item is required

sdGUIDEIT: Adherence Review Findings (ARF) [frARF]

Adherence Review Findings [stARF1]

1.*	Reviewer identifier [Reviewer identifier]	**[AHCRVWR]** *[N: 1]* ◯ 1 *[N: 2]* ◯ 2 *[N: 3]* ◯ 3 *[N: 4]* ◯ 4 *[N: 5]* ◯ 5 *[N: 6]* ◯ 6
2.*	Were the adjustment efforts approved? [Were the adjustment efforts approved?]	**[ARFDONE]** *[N: 1]* ◯ **[ARFAPPVD]** Yes *[N: 1]* ◯ Subject died *[N: 2]* ◯ Subject is non compliant with medications *[N: 3]* ◯ Very sick patient with little room for adjustments *[N: 98]* ◯ **[OARFAPVD]** Other: Other specify A200 *[N: 0]* ◯ **[ARFINDNG]** No What were the findings of the reviewer of the case? For this case, the site should have *[N: 1]* ◯ Committee recognizes dosing efforts, but have concerns with compliance (reducing NTproBNP <1000) and using appropriate doses of evidence based medications *[N: 2]* ◯ Committee suggested consider decreasing diuretic to allow for use of evidence based medications *[N: 3]* ◯ Contact the site and stress they must review and follow the protocol specifically, using evidence based medications to lower NTproBNP value < 1000 *[N: 4]* ◯ Site needs to consider increasing doses of evidence based medications *[N: 5]* ◯ Committee felt this patient needs to be reviewed by the PI. Patient is not on evidence based medications. No adjustments are being made. *[N: 6]* ◯ Committee felt there was room for adjustment. FU with site to make adjustments per guidelines. *[N: 7]* ◯ Committee felt already at max tolerated therapy was not a valid reason for no adjustment *[N: 8]* ◯ Committee felt doses not at max and could increase beta blocker and/or ACE/ARB *[N: 9]* ◯ OK with rationale since patient is non-compliant with medications: continue to work on compliance *[N: 10]* ◯ On low dose of evidence-based medicine including BB or ACE/ARB and should be increasing medications and not decreasing them *[N: 98]* ◯ **[OARFINDN]** Other: Other specify A200
3.*	Clinical Operations contacted site to discuss issue [Clinical Operations contacted site to discuss issue]	**[COTALKD]** *[N: 1]* ◯ **[cpContactQuery]** Yes Contact method **[TALKWPPL]** *[N: 1]* ☐ Contacted/ emailed the PI about concerns **[TALKQRY]** *[N: 1]* ☐ Issued a query *[N: 0]* ◯ No
4.*	Adherence Committee contacted site to discuss issue [Adherence Committee contacted site to discuss issue]	**[AHCTALKD]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No
5.*	Would the reviewer like to discuss on an Adherence Committee Call? [Would the reviewer like to discuss on an Adherence Committee Call]	**[ACFOLOUP]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No
	Comments	
6.		

Comments from Adherence Review Entry [rsARF2]

6.1	Comments [Comments]	**[ACCOMMT]** A200

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

sdGUIDEIT: Assessments (ASMT) [frASMT]

Note: If subject had an AE, SAE or extended care facility admission, complete the appropriate form in the CAS visit. [stASMT1]

1.* ✔	Were local labs performed? (If yes, please complete LABS form) [Were local labs performed?]	**[STDYLAB2]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No *[N: 2]* ◯ Subject refused
2.* ✔	Were protocol required biological samples collected? (If yes, please complete BIOBANK form) [Were protocol required biological samples collected?]	**[BIOLOG2]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No *[N: 2]* ◯ Subject refused
3.* ✔	Was local NT-proBNP measured? (If yes, please complete PROBNP form) [Question only expected for biomarker guided arm] [Was local NT-proBNP measured?]	**[NTPROM5]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No *[N: 2]* ◯ Subject refused
4.* ✔	Has the subject had an inpatient hospitalization, outpatient procedure or emergency department visit? (If yes, complete new HOSP visit) [Has the subject had an inpatient hospitalization, outpatient procedure or emergency department visit?]	**[HOSPADMT]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No
5.* ✔	Did the subject have an echo performed? (Applicable for Echo Sub-Study Participating Sites ONLY. Expected answer of No, if not participating.) [Subject have an echo performed since the last visit]	**[ECHODONE]** *[N: 1]* ◯ **[ECHOSHIP]** Yes Date submitted to DCRI *[N: 97]* ◯ Not Done *[N: 1]* ◯ **[ECHOSPDT]** Req ⌄ / Req ⌄ / Req ⌄ (2012-2025) *[N: 0]* ◯ No
6.* ✔	Was therapy adjusted? (If yes, please complete ADJUST form) [Was therapy adjusted?]	**[PBNPADJ]** *[N: 1]* ◯ Yes *[N: 0]* ◯ **[NOPBNPAD]** No *[N: 1]* ◯ NTproBNP already at target range *[N: 2]* ◯ Already at maximally tolerated therapy *[N: 3]* ◯ Already at guideline recommended target doses *[N: 4]* ◯ **[MDDCSNO]** Other clinician decision Other specify [A200 ....] *[N: 5]* ◯ **[PTPREFO]** Patient preference Other specify [A200 ....] *[N: 98]* ◯ **[NOPBNADO]** Other Other specify [A200 ....]
7.	Specify reason already at maximally tolerated therapy [Specify reason already at maximally tolerated therapy]	**[MAXTLDS]** [A200 ....]

Resource use [stASMT2]

8.*	Has the subject been seen as an outpatient by a clinician since the last visit? [Has the subject been seen as an outpatient by a clinician?]	**[OPTVST]** *[N: 1]* ◯ **[OPTVSTCV]** Yes Specify the number of cardiovascular visits [N3] **[OPTVTNCV]** Specify the number of non-cardiovascular visits [N3] *[N: 0]* ◯ No

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

sdGUIDEIT: Method of Contact (CONTACT) [frCONTACT]

Method of Contact [frCONTACT]

1.* ✔	Was this visit performed?
	[Visit performed?]
		[VIST]
		[N: 1] ○ **[VSITDT]**
		    Yes, Date of visit
		    Req ⌄ / Req ⌄ / Req ⌄ (2012-2025)
		[N: 0] ○ **[NOVISRSN]**
		    No
		    Reason visit not performed
		    [N: 2] ○ Missed visit, continuing in study
		    [N: 3] ○ Suspected lost to follow-up
		    [N: 1] ○ Subject no longer participating in study (died, permanently withdrew consent, LT : please complete EOS form)

2.	Delete visit - site created the visit by accident *[hidden]* [Delete visit]	**[DELETVST]** *[N: 1]* ☐ Yes

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

sdGUIDEIT: End of study (EOS) [frEOS]

End of study [frEOS]	
1. * ✔ Date of last study contact [Date of last study contact]	**[LSTTLKDT]** Req/Unk ⌄ / Req/Unk ⌄ / Req ⌄ (2012–2025)
2. * ✔ Status at end of contact [Status at end of contact]	**[CMPLTD]** *[N: 1]* ◯ Died, please complete DEATH form *[N: 2]* ◯ Completed protocol *[N: 3]* ◯ Subject lost to follow-up *[N: 4]* ◯ Subject withdrew consent for study participation *[N: 5]* ◯ Subject withdrawn from the study by site investigator *[N: 6]* ◯ Received a procedure with effect on NT-Pro-BNP (e.g. LVAD, Dialysis, Heart Transplant)

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

sdGUIDEIT: Death (DEATH) [frDEATH]

Death [frDEATH]

1. * ✔	Date and time of death [Date and time of death]	**[DEADDTM]** Req/Unk ⌄ / Req/Unk ⌄ / Req ⌄ (2012-2025) Req/Unk ⌄ : Req/Unk ⌄ *24-hour clock*
2. * ✔	Was the subject hospitalized or was at an extended care facility at the time of death. (If yes, complete a HOSP or EXTCARE form) [Hospitalized at time of death]	**[DEADLOC]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No *[N: 99]* ◯ Unknown
3. * ✔	Was the death witnessed? [Was the death witnessed]	**[WITNESS]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No *[N: 99]* ◯ Unknown
4.	Was an autopsy performed? *[hidden]* [Was an autopsy performed]	**[AUTOPSY]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No *[N: 99]* ◯ Unknown
5.	Primary cause of death *[hidden]* [Primary cause of death]	**[DEATHCAU]** *[N: 1]* ◯ Heart failure *[N: 2]* ◯ Sudden cardiac death *[N: 3]* ◯ Other cardiovascular *[N: 4]* ◯ Non-cardiovascular *[N: 99]* ◯ Unknown
6. * ✔	Was an autopsy performed? [Autopsy performed]	**[AUTOPSY2]** *[N: 1]* ◯ **[AUTPSDTL]** Yes Record relevant findings from the autopsy ┌─────────────┐ │ A200 │ └─────────────┘ *[N: 0]* ◯ No *[N: 99]* ◯ Unknown
7. * ✔	Primary cause of death [Primary cause of death]	**[DEATHCA2]** *[N: 1]* ◯ Heart Failure/Cardiogenic Shock *[N: 2]* ◯ Acute Coronary Syndrome/ MI *[N: 3]* ◯ **[DTHRSOC2]** Other cardiovascular Other cardiovascular specify ┌─────────────┐ │ A200 │ └─────────────┘ *[N: 4]* ◯ **[DTHRSNC2]** Non-cardiovascular Non-cardiovascular specify ┌─────────────┐ │ A200 │ └─────────────┘ *[N: 5]* ◯ Sudden Cardiac Death *[N: 99]* ◯ Unknown/ Undetermined
8.	Trigger number [Trigger number]	**[DTTRIG]** A100
	What were the relevant medical events leading up to the death	
9.		

NARRATIVE Entry [rsDEATH2]

9.1 * ✔	What were the relevant medical events leading up to the death (e.g., hospitalized, at home, palliative care, contributing co-morbidities, witness account)? [What were the relevant medical events leading up to the death]	**[DEATNARR]** A200

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

sdGUIDEIT: Echo trigger form (ECHOTRG) [frECHOTRG]

Echo trigger form [stECHOTRG1]

1.*	Tracking Number [Tracking Number]	**[ECOTRGNM]** A50

2.*	Visit
	[Visit]
		[ECHOVIST]
		[N: 1] ◯ Baseline
		[N: 2] ◯ 12-Month
		[N: 3] ◯ **[ECHOWGTD]**
		Unscheduled
		    [N: 1] ◯ **[ECHOWGT]**
		      Weight xxxxxxxx.
		    [N: 97] ◯ Not Done

3.*	Was a 2D Echo Digiview Protocol completed for this visit? [Was a 2D Echo Digiview Protocol completed for this visit?]	**[TRG2DECO]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No
4.*	Was a Tomtec Echo eCRF completed for this visit? [Was a Tomtec Echo eCRF completed for this visit?]	**[TOMTEC]** *[N: 1]* ◯ Yes *[N: 0]* ◯ No

Key: [*] = Item is required

sdGUIDEIT: FINDINGS (FNDGS) [frFNDGS]

Hemodynamic Findings: [stFNDGS1]

1.*	Systolic BP [Systolic BP]	**[SYSBP2DD]** [N:1] ○ **[SYSBP2DR]** XXXXXXXX. [N:96] ○ NA
2.*	Diastolic BP [Diastolic BP]	**[DIABD2DD]** [N:1] ○ **[DIABP2DR]** XXXXXXXX. [N:96] ○ NA
3.*	Heart Rate [Heart Rate]	**[HRT2DD]** [N:1] ○ **[HRT2DR]** XXXXXXXX. [N:96] ○ NA

Machine Settings: [stFNDGS2]

4.*	Nyquist Limit [Nyquist Limit]	**[NYQLMTD]** [N:1] ○ **[NYQLMTR]** XXXXXXXX. [N:96] ○ NA
5.*	Depth [Depth]	**[DEPTHD]** [N:1] ○ **[DEPTHR]** XXXXXXXX. [N:96] ○ NA
6.*	Color Gain [Color Gain]	**[COLORGD]** [N:1] ○ **[COLORGR]** XXXXXXXX. [N:96] ○ NA
7.*	Frame Rate [Frame Rate]	**[FRMRTD]** [N:1] ○ **[FRMRTR]** XXXXXXXX. [N:96] ○ NA
8.*	AV Regurg [AV Regurg]	**[AVREGURG]** [N:1] ○ None [N:2] ○ Trivial [N:3] ○ Mild [N:4] ○ Moderate [N:5] ○ Severe [N:96] ○ NA
9.*	MV Regurg [MV Regurg]	**[MVREGURG]** [N:1] ○ None [N:2] ○ Trivial [N:3] ○ Mild [N:4] ○ Moderate [N:5] ○ Severe [N:96] ○ NA
10.*	TV Regurg [TV Regurg]	**[TVREGURG]** [N:1] ○ None [N:2] ○ Trivial [N:3] ○ Mild [N:4] ○ Moderate [N:5] ○ Severe [N:96] ○ NA
11.*	Visual LVEF [Visual LVEF]	**[VISLEFD]** [N:1] ○ **[VISLEFDR]** XXXXXXXX. [N:96] ○ NA
12.*	Diastolic Fxn Score [Diastolic Fxn Score]	**[DIAFXSCR]** [N:0] ○ 0 [N:1] ○ 1 [N:2] ○ 2 [N:3] ○ 3 or 4 [N:4] ○ Indeterminate [N:96] ○ NA
13.*	Pulm Vein Dom [Pulm Vein Dom]	**[PULVNDOM]** [N:1] ○ Systole [N:2] ○ Diastole [N:3] ○ Equivocal [N:96] ○ NA
14.*	Qual RV Fxn [Qual RV Fxn]	**[QLTRVFX]** [N:1] ○ Normal [N:2] ○ Mildly Impaired [N:3] ○ Moderately Impaired [N:4] ○ Severely Impaired [N:96] ○ NA
15.*	Thrombus [Thrombus]	**[THROMASS]** [N:96] ○ NA [N:2] ○ Absent [N:1] ○ **[THRMRSLT]** Present If present, thrombus type [N:96] ○ NA [N:1] ○ LA [N:2] ○ LV [N:3] ○ RA [N:4] ○ RV [N:99] ○ **[THRMRSSP]** Other ThrombusOther (specify) A200
	2D Echo Digiview comments	
16.		

2D Echo Digiview comments Entry [rsFNDGS3]

16.1*	2D Echo Digiview comments [2D Echo Digiview comments]	**[DIGCOMTD]** [N:1] ○ **[DIGCOMTS]** Yes A200 [N:0] ○ No
	2D Echo Digiview additional findings	
17.		

2D Echo Digiview additional findings Entry [rsFNDGS4]

17.1*	2D Echo Digiview additional findings [2D Echo Digiview additional findings]	**[DIGFNDGD]** *[N: 1]* ○ **[DIGFNDGS]** Yes
		A200
		[N:0] ○ No

Key: [*] – Item is required

sdGUIDEIT: 2-D MEASUREMENTS (MEAS2D) [frMEAS2D]

	LVID Dias Diam	LVPW Dias Thick	IVS Dias Thick	LV Mass
1.				

LV Mass ASE Entry [rsMEAS2D1]

1.1*	LVID Dias Diam [LVID Dias Diam]	[LVIDDDD] [N:1] ○[LVIDDDR] XXXXXXXX. [N:96] ○NA
1.2*	LVPW Dias Thick [LVPW Dias Thick]	[LVPWDTD] [N:1] ○[LVPWDTR] XXXXXXXX. [N:96] ○NA
1.3*	IVS Dias Thick [IVS Dias Thick]	[IVSDTD] [N:1] ○[IVSDTR] XXXXXXXX. [N:96] ○NA
1.4*	LV Mass [LV Mass]	[LVMD] [N:1] ○[LVMR] XXXXXXXX. [N:96] ○NA

	LVID sys dimen
2.	

Left Ventricle: Sys Dimen Entry [rsMEAS2D2]

| 2.1* | LVID sys dimen [LVID sys dimen] | [LVIDSDD] [N:1] ○[LVIDSDDR] XXXXXXXX. [N:96] ○NA |

	LVOT sys dimen
3.	

LVOT Dimen Entry [rsMEAS2D3]

| 3.1* | LVOT sys dimen [LVOT sys dimen] | [LVOTSDD] [N:1] ○[LVOTSDDR] XXXXXXXX. [N:96] ○NA |

	4ch LV Length
4.	

4ch LV Length Entry [rsMEAS2D4]

| 4.1* | 4ch LV Length [4ch LV Length] | [LV4EDDDD] [N:1] ○[LV4EDDDR] XXXXXXXX. [N:96] ○NA |

	2ch LV Length
5.	

2ch LV Length Entry [rsMEAS2D5]

| 5.1* | 2ch LV Length [2ch LV Length] | [LV2EDDDD] [N:1] ○[LV2EDDDR] XXXXXXXX. [N:96] ○NA |

	LV Dias volume	LV Sys volume	2D Stroke vol	Ejection Fraction	Heart Rate	Card Out
6.						

LV EF Biplane Entry [rsMEAS2D6]

6.1*	LV Dias volume [LV Dias volume]	[LVEDVD] [N:1] ○[LVEDVR] XXXXXXXX. [N:96] ○NA
6.2*	LV Sys volume [LV Sys volume]	[LVESVD] [N:1] ○[LVESVR] XXXXXXXX. [N:96] ○NA
6.3*	2D Stroke vol [2D Stroke vol]	[SV2DD] [N:1] ○[SV2DR] XXXXXXXX. [N:96] ○NA
6.4*	Ejection Fraction [Ejection Fraction]	[LVBEFD] [N:1] ○[LVBEFR] XXXXXXXX. [N:96] ○NA
6.5*	Heart Rate [Heart Rate]	[HRDN] [N:1] ○[HRR] XXXXXXXX. [N:96] ○NA
6.6*	Card Out [Card Out]	[CO2DD] [N:1] ○[CO2DR] XXXXXXXX. [N:96] ○NA

	LA Sys Area 4ch
7.	

Left Atrium: LA Sys Area 4ch Entry [rsMEAS2D7]

| 7.1* | LA Sys Area 4ch [LA Sys Area 4ch] | [LASYSAD] [N:1] ○[LASYSAR] XXXXXXXX. [N:96] ○NA |

	LA volume
8.	

LA vol Biplane: LA vol Entry [rsMEAS2D8]

| 8.1* | LA volume [LA volume] | [LASYSVD] [N:1] ○[LASYSVR] XXXXXXXX. [N:96] ○NA |

	RA Sys Area 4ch
9.	

Right Atrium: RA Sys Area 4ch Entry [rsMEAS2D9]

| 9.1* | RA Sys Area 4ch [RA Sys Area 4ch] | [RAAREAD] [N:1] ○[RAAREAR] XXXXXXXX. [N:96] ○NA |

	RV Basal Width
10.	

RV Basal Width Entry [rsMEAS2D10]

10.1*	RV Basal Width [RV Basal Width]		[RVIDBDD] [N: 1] ○[RVIDBDR] XXXXXXXX. [N: 96] ○NA
		RV Mid Width	
11.			
RV Mid Width Entry [rsMEAS2D11]			
11.1*	RV Mid Width [RV Mid Width]		[RVIDMDD] [N: 1] ○[RVIDMDR] XXXXXXXX. [N: 96] ○NA
		RV Long Length	
12.			
RV Long Length Entry [rsMEAS2D12]			
12.1*	RV Long Length [RV Long Length]		[RVIDLDD] [N: 1] ○[RVIDLDR] XXXXXXXX. [N: 96] ○NA

Key: [*] = Item is required

sdGUIDEIT: M-MODE and DOPPLER MEASUREMENTS (MMDOP) [frMMDOP]

	TAPSE
1.	

RV TAPSE Entry [rsMMDOP1]

1.1*	TAPSE (cm) [TAPSE]	[TAPSED] [N:1] ⊙ [TAPSER] XXXXXXXX. [N:96] ⊙ NA

TI Jet Vel	Sys Press TV
2.	

RA PA Sys Press Entry [rsMMDOP2]

2.1*	TI Jet Vel [TI Jet Vel]	[PKTRVELD] [N:1] ⊙ [PKTRVELR] XXXXXXXX. [N:96] ⊙ NA
2.2*	Sys Press TV [Sys Press TV]	[RVSPD] [N:1] ⊙ [RVSPR] XXXXXXXX. [N:96] ⊙ NA

	Pk E Vel
3.	

Mitral Valve: Peak E Vel Entry [rsMMDOP3]

3.1*	Pk E Vel [Pk E Vel]	[PEAKED] [N:1] ⊙ [PEAKER] XXXXXXXX. [N:96] ⊙ NA

	Pk A Vel
4.	

Mitral Valve: Peak A Vel Entry [rsMMDOP4]

4.1*	Pk A Vel [Pk A Vel]	[PEAKAD] [N:1] ⊙ [PEAKAR] XXXXXXXX. [N:96] ⊙ NA

	Decel Time
5.	

MV Decel Time Entry [rsMMDOP5]

5.1*	Decel Time [Decel Time]	[MVDTD] [N:1] ⊙ [MVDTR] XXXXXXXX. [N:96] ⊙ NA

	Septal TDI é
6.	

Septal TDI é Entry [rsMMDOP6]

6.1*	Septal TDI é [Septal TDI é]	[SEPTDIPD] [N:1] ⊙ [SEPTDIPR] XXXXXXXX. [N:96] ⊙ NA

	LVOT TVI
7.	

LVOT Forward Flow Entry [rsMMDOP7]

7.1*	LVOT TVI [LVOT TVI]	[TVID] [N:1] ⊙ [TVIR] XXXXXXXX. [N:96] ⊙ NA

Key: [*] = Item is required

sdGUIDEIT: Tomtec (TOMTEC) [frTOMTEC]

Tomtec [frTOMTEC]

1.*	Apical 4-Ch Frame Rate [Apical 4-Ch Frame Rate]	**[A4CFRD]** *[N: 1]* ◯ **[A4CFR]** xxxxxxxx. *[N: 96]* ◯ NA
2.*	Apical 2-Ch Frame Rate [Apical 2-Ch Frame Rate]	**[A2CFRD]** *[N: 1]* ◯ **[A2CFR]** xxxxxxxx. *[N: 96]* ◯ NA
3.*	Apical 3-Ch Frame Rate [Apical 3-Ch Frame Rate]	**[A3CFRD]** *[N: 1]* ◯ **[A3CFR]** xxxxxxxx. *[N: 96]* ◯ NA

Global Longitudinal LV strain [stTOMTEC1]

4.*	Apical 4-Ch Global Long LV [Apical 4-Ch Global Long LV]	**[A4CGLLVD]** *[N: 1]* ◯ **[A4CGLLVR]** xxxxxxxx. *[N: 96]* ◯ NA
5.*	Apical 2-Ch Global Long LV [Apical 2-Ch Global Long LV]	**[A2CGLLVD]** *[N: 1]* ◯ **[A2CGLLVR]** xxxxxxxx. *[N: 96]* ◯ NA
6.*	Apical 3-Ch Global Long LV [Apical 3-Ch Global Long LV]	**[A3CGLLVD]** *[N: 1]* ◯ **[A3CGLLVR]** xxxxxxxx. *[N: 96]* ◯ NA

Longitudinal RV strain [stTOMTEC2]

7.*	Basal 4-Ch Long RV [Basal 4-Ch Long RV]	**[B4LRVSD]** *[N: 1]* ◯ **[B4LRVSR]** xxxxxxxx. *[N: 96]* ◯ NA
8.*	Mid 4-Ch Long RV [Mid 4-Ch Long RV]	**[M4LRVSD]** *[N: 1]* ◯ **[M4LRVSR]** xxxxxxxx. *[N: 96]* ◯ NA
9.*	Apical 4-Ch Long RV [Apical 4-Ch Long RV]	**[A4LRVSD]** *[N: 1]* ◯ **[A4LRVSR]** xxxxxxxx. *[N: 96]* ◯ NA
	Tomtec comments?	
10.		

Tomtec comments Entry [rsTOMTEC3]

10.1*	Tomtec comments? [Tomtec comments?]	**[TTCOMTND]** *[N: 1]* ◯ **[TTCOMTNS]** Yes A200 *[N: 0]* ◯ No

Key: [*] = Item is required

sdGUIDEIT: frSIGN (SIGN) [frSIGN]
frSIGN [frSIGN]

		[PISIGN]
1.* ✔	Casebook Ready for Signature [Casebook Ready for Signature]	[N: 1] ☐ Yes

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

InForm Special Properties For Study Design: sdGUIDEIT

InForm Special Property	Property Type	Data Object RefName	Data Object Path RefName
Screening	Visit	evSYSSCR	evSYSSCR
Enrollment	Visit	evSYSENR	evSYSENR
Screening	Form	frSYSSCR1	evSYSSCR.frSYSSCR1
Enrollment	Form	frENRSYS2	evSYSENR.frENRSYS2
Patient Identification	Form	frDEM	evBLN.frDEM
Study Completion	Form	Unassigned	Unassigned
Reg Docs	Form	Unassigned	Unassigned
Visit Report	Form	Unassigned	Unassigned
Initials (Screening)	Item	SUBJINIT	evSYSSCR.frSYSSCR1.SUBJINIT
DOB (Screening)	Item	Unassigned	Unassigned
Screening date (Screening)	Item	Unassigned	Unassigned
Patient No. (Enrollment)	Item	SUBJID	evBLN.frDEM.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	EVALUDT	evBLNFU.frDOE.EVALUDT evWKS2FU.frDOE.EVALUDT evDCRIECHO.frDOE.EVALUDT evMON18FU.frDOE.EVALUDT evWKS6FU.frDOE.EVALUDT evMON24FU.frDOE.EVALUDT evMON21FU.frDOE.EVALUDT evMON15FU.frDOE.EVALUDT evHOSP.frDOE.EVALUDT evMON9FU.frDOE.EVALUDT evMON6FU.frDOE.EVALUDT evMON3FU.frDOE.EVALUDT evMON12FU.frDOE.EVALUDT
Randomization field (Randomization)	Item	Unassigned	Unassigned