Annotated Study Book for Study Design: AT3SC002

Study Design Version: 14.0

Sponsor: Sanofi Genzyme

LTE14762: An Open-Label Extension Study of Subcutaneously Administered Fitusiran in Patients with Moderate or Severe Hemophilia A or B who have Participated in a Previous Clinical Study with Fitusiran

Generated by Central Designer TM

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AT3SC002: System Screening (SCR) [frmSYSSCR]

System Screening [frmSYSSCR]

1.* ✔	Date of birth [Date of birth]	**[dtmBRTH] (DD/MM/YYYY)** Req / Req / Req (1930-2023)
2.* ✔	Sex at birth [Sex at birth]	**[lstSXBRTH]** *[A:M]* ○ Male
3.	Dummy initials *[hidden]* [Dummy initials]	**[txtINIT_SS]** A3

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: System Screening

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clSXBRTH	String		Male	M	citmSXBRTH_M	lstSXBRTH

RDE Analytics: RD_FRMSYSSCR

Data Variable RefName	RD Column Name	Column Data Type
dtmBRTH	DTMBRTH	DATE
	DTMBRTH_DTS	VARCHAR2
	DTMBRTH_ND	VARCHAR2
lstSXBRTH	LSTSXBRTH_C	VARCHAR2
	LSTSXBRTH	VARCHAR2
	LSTSXBRTH_ND	VARCHAR2
txtINIT_SS	TXTINIT_SS	VARCHAR2
	TXTINIT_SS_ND	VARCHAR2

AT3SC002: System Enrollment (ENR) [frmSYSENR]

System Enrollment [frmSYSENR]

1.* ✔	Subject signed informed consent on [Date of informed consent]	**[dtmIFC] (DD/MM/YYYY)** Req / Req / Req (2015-2023)
2.* ✔	Subject ID (3-digits) [Short Subject ID]	**[txtSHORTID]** A3
3.*	Site and Subject ID *[hidden]* [Site and Subject ID]	**[txtSUBJID]** A7

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_FRMSYSENR

Data Variable RefName	RD Column Name	Column Data Type
dtmIFC	DTMIFC	DATE
	DTMIFC_DTS	VARCHAR2
	DTMIFC_ND	VARCHAR2
txtSHORTID	TXTSHORTID	VARCHAR2
	TXTSHORTID_ND	VARCHAR2
txtSUBJID	TXTSUBJID	VARCHAR2
	TXTSUBJID_ND	VARCHAR2

AT3SC002: Date of Visit (DOV) [frmDOV]

Date of Visit [sctDOV]

1.* ✔	Date of visit [Date of visit]	**[dtmVISIT] (DD/MM/YYYY)** Req / Req / Req (2015-2023)

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_FRMDOV

Data Variable RefName	RD Column Name	Column Data Type
dtmVISIT	DTMVISIT	DATE
	DTMVISIT_DTS	VARCHAR2
	DTMVISIT_ND	VARCHAR2

DS--Disposition 'DSTERM = INFORMED CONSENT OBTAINED

AT3SC002: Demographic Data and Informed Consent Recording (DM) [frmDM] INFORMED CONSENT OBTAINED

Demographics [sctDM]

1.* ✔	Date of birth [Date of birth]	**[dtmBRTH] (DD/MM/YYYY)** Req / Req / Req (1930-2023)
2.* ✔	Subject signed informed consent on [Date of informed consent]	**[dtmIFC] (DD/MM/YYYY)** Req / Req / Req (2015-2023)
3.*	Age (calculated) *[read-only]* [Age]	**[numAGE]** N3 (years)
4.* ✔	Sex at birth [Sex at birth]	**[lstSXBRTH]** *[A:M]* Male
5.* ✔	Race [Race]	**[lstRC]** *[A:REPORTED]* **[lstRACE]** Reported, please specify: *[A:WHITE]* White *[A:BLACK]* Black or African-American *[A:ASIAN]* Asian *[A:INDIAN]* American Indian or Alaska Native *[A:HAWAIIAN]* Native Hawaiian or other Pacific Islander *[A:OTHER]* **[txtRACEOTH]** Other, please specify: A60 *[A:NOT REPORTED]* Not Available/Not Reported
6.* ✔	Ethnicity [Ethnicity]	**[lstETHNICITY]** *[A:HISPANIC OR LATINO]* Hispanic or Latino *[A:NOT HISPANIC OR LATINO]* Not Hispanic or Latino *[A:NA]* Not Available/Not Reported
7.* ✔	Part in parent study? [Part parent study]	**[lstPART]** *[A:PART B]* Part B *[A:PART C]* Part C *[A:PART D]* Part D
8.* ✔	Did the patient have an interruption between parent study and roll-over to this study? *More than a month between completion of parent study treatment and roll-over to this study will be considered an interruption.* [Subject initiates dosing]	**[lstDAYS]** *[A:Y]* Yes *[A:N]* No
9.* ✔	What is the subject's HIV status? [HIV status]	**[lstHIV]** *[A:POSITIVE]* Positive *[A:NEGATIVE]* Negative
Will the Whole Blood Clot Formation test (ROTEM) be performed at this site? [sctDYN]		
10.* ✔	Will the Whole Blood Clot Formation test (ROTEM) be performed at this site? [ROTEM available]	**[lstWBCLT]** *[A:Y]* Yes *[A:N]* No
Subject Identifiers [sctSUBID]		
11.* ✔	Subject ID (3-digits) *[read-only]* [Short Subject ID]	**[txtSHORTID1]** A3
12. ✔	Site and Subject ID from parent study [Parent study ID]	**[txtSUBJIDPS]** A7
13.*	Site and Subject ID *[hidden]* [Site and Subject ID]	**[txtSUBJID]** A7
14.	For office use only *[hidden]* [For office use only]	**[numEMAIL1]** N3
15.	For office use only *[hidden]* [For office use only]	**[numEMAIL2]** N3
16.	For office use only *[hidden]* [For office use only]	**[numEMAIL3]** N3

Key: [*] = Item is required [✔] = Source verification required
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Codelist Values Tables: Demographic Data and Informed Consent Recording

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clSXBRTH	String		Male	M	citmSXBRTH_M	lstSXBRTH
clRC	String		Reported	REPORTED	citmRC_Reported	lstRC
			Not Available/Not Reported	NOT REPORTED	citmRC_NotReported	
clRACE	String		White	WHITE	citmRACE_White	lstRACE
			Black or African-American	BLACK	citmRACE_Black	
			Asian	ASIAN	citmRACE_Asian	
			American Indian or Alaska Native	INDIAN	citmRACE_Indian	
			Native Hawaiian or other Pacific Islander	HAWAIIAN	citmRACE_Hawai	
			Other	OTHER	citmRACE_Other	
clETHNICITY	String		Hispanic or Latino	HISPANIC OR LATINO	citmETHNICITY_HispLat	lstETHNICITY
			Not Hispanic or Latino	NOT HISPANIC OR LATINO	citmETHNICITY_NotHispLat	
			Not Available/Not Reported	NA	citmETHNICITY_NA	
clPART	String		Part B	PART B	citmPART_PartB	lstPART
			Part C	PART C	citmPART_PartC	
			Part D	PART D	citmPART_PartD	
clYesNo	String		Yes	Y	citmYesNo_Y	lstDAYS, lstWBCLT
			No	N	citmYesNo_N	
clHIV	String		Positive	POSITIVE	citmHIV_Positive	lstHIV
			Negative	NEGATIVE	citmHIV_Negative	

RDE Analytics: RD_FRMDM

Data Variable RefName	RD Column Name	Column Data Type
dtmBRTH	DTMBRTH	DATE
	DTMBRTH_DTS	VARCHAR2
	DTMBRTH_ND	VARCHAR2
dtmIFC	DTMIFC	DATE
	DTMIFC_DTS	VARCHAR2
	DTMIFC_ND	VARCHAR2
numAGE	NUMAGE	NUMBER
	NUMAGE_ND	VARCHAR2
lstSXBRTH	LSTSXBRTH_C	VARCHAR2
	LSTSXBRTH	VARCHAR2
	LSTSXBRTH_ND	VARCHAR2
lstRC	LSTRC_C	VARCHAR2
	LSTRC	VARCHAR2
	LSTRC_ND	VARCHAR2
lstRC - White	LSTRACE_CITMRACEWHITE_C	VARCHAR2
	LSTRACE_CITMRACEWHITE	VARCHAR2
lstRC - Black or African-American	LSTRACE_CITMRACEBLACK_C	VARCHAR2
	LSTRACE_CITMRACEBLACK	VARCHAR2
lstRC - Asian	LSTRACE_CITMRACEASIAN_C	VARCHAR2
	LSTRACE_CITMRACEASIAN	VARCHAR2
lstRC - American Indian or Alaska Native	LSTRACE_CITMRACEINDIAN_C	VARCHAR2
	LSTRACE_CITMRACEINDIAN	VARCHAR2
lstRC - Native Hawaiian or other Pacific Islander	LSTRACE_CITMRACEHAWAI_C	VARCHAR2
	LSTRACE_CITMRACEHAWAI	VARCHAR2
lstRC - Other	LSTRACE_TXTRACEOTH_C	VARCHAR2
	LSTRACE_TXTRACEOTH	VARCHAR2
lstRC - txtRACEOTH	TXTRACEOTH	VARCHAR2
lstETHNICITY	LSTETHNICITY_C	VARCHAR2
	LSTETHNICITY	VARCHAR2
	LSTETHNICITY_ND	VARCHAR2

lstPART	LSTPART_C	VARCHAR2
	LSTPART	VARCHAR2
	LSTPART_ND	VARCHAR2
lstDAYS	LSTDAYS_C	VARCHAR2
	LSTDAYS	VARCHAR2
	LSTDAYS_ND	VARCHAR2
lstHIV	LSTHIV_C	VARCHAR2
	LSTHIV	VARCHAR2
	LSTHIV_ND	VARCHAR2
lstWBCLT	LSTWBCLT_C	VARCHAR2
	LSTWBCLT	VARCHAR2
	LSTWBCLT_ND	VARCHAR2
txtSHORTID1	TXTSHORTID1	VARCHAR2
	TXTSHORTID1_ND	VARCHAR2
txtSUBJIDPS	TXTSUBJIDPS	VARCHAR2
	TXTSUBJIDPS_ND	VARCHAR2
txtSUBJID	TXTSUBJID	VARCHAR2
	TXTSUBJID_ND	VARCHAR2
numEMAIL1	NUMEMAIL1	NUMBER
	NUMEMAIL1_ND	VARCHAR2
numEMAIL2	NUMEMAIL2	NUMBER
	NUMEMAIL2_ND	VARCHAR2
numEMAIL3	NUMEMAIL3	NUMBER
	NUMEMAIL3_ND	VARCHAR2

AT3SC002: Medical History (MHx) [frmMH]

Medical History [sctMH]

1.* ✔	Has the patient experienced any clinically relevant events or conditions? *If Yes, please report the event(s) and/or condition(s) below.* *Please record any clinically relevant events occuring between the parent study and prior to administration of the first dose in this open-label extension study.* *Please record any ongoing AE(s) from the parent study as medical history.* [Has the subject experienced a Medical History?]	**[lstMH]** *[A:Y]* ◯ Yes *[A:N]* ◯ No

	Condition	Start date	Continuing from parent study?	End date
2. ✔				

Medical History Entry [sctMHCAT]

- Please record only one condition per row.

- Please click on the Add Entry button to add rows.

- Please cross-check subject's medical/surgical history with the eligibility criteria.

2.1* ✔	Medical condition or event [Condition]	**[txtMHCOND]** A200
2.2* ✔	Start date [Start date]	**[dtmMHSTART] (DD/MM/YYYY)** Req/Unk / Req/Unk / Req/Unk (1930-2023)
2.3* ✔	Continuing from parent study? [Continuing from parent study?]	**[lstMHCATPRIOR]** *[A:Y]* ◯ Yes *[A:N]* ◯ No
2.4* ✔	End date [End date]	**[lstMHEND]** *[A:END DATE]* ◯ **[dtmMHEND] (DD/MM/YYYY)** End date, please specify Req/Unk / Req/Unk / Req/Unk (1930-2023) *[A:ONGOING]* ◯ Ongoing

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Codelist Values Tables: Medical History

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	lstMH, lstMHCATPRIOR
			No	N	citmYesNo_N	
clEND	String		End date	END DATE	citmEND_EndDate	lstMHEND
			Ongoing	ONGOING	citmEND_Ongoing	

RDE Analytics: RD_FRMMH

Data Variable RefName	RD Column Name	Column Data Type
lstMH	LSTMH_C	VARCHAR2
	LSTMH	VARCHAR2
	LSTMH_ND	VARCHAR2
RD_FRMMH_SCTMHCAT		
txtMHCOND	TXTMHCOND	VARCHAR2
	TXTMHCOND_ND	VARCHAR2
dtmMHSTART	DTMMHSTART	DATE
	DTMMHSTART_DTS	VARCHAR2
	DTMMHSTART_DTR	VARCHAR2
	DTMMHSTART_ND	VARCHAR2
lstMHCATPRIOR	LSTMHCATPRIOR_C	VARCHAR2
	LSTMHCATPRIOR	VARCHAR2
	LSTMHCATPRIOR_ND	VARCHAR2
lstMHEND	LSTMHEND_C	VARCHAR2
	LSTMHEND	VARCHAR2
	LSTMHEND_ND	VARCHAR2

lstMHEND - dtmMHEND	DTMMHEND	DATE
	DTMMHEND_DTS	VARCHAR2
	DTMMHEND_DTR	VARCHAR2

AT3SC002: Hemophilia History (HHx) [frmHHX]

Hemophilia History [sctHHx]

1.* ✔	Has the diary been provided? [Has the diary been provided?]	**[lstHH]** *[A:Y]* Yes *[A:N]* No
2.* ✔	Hemophilia type [Hemophilia type]	**[lstHTYPE]** *[A:A]* Hemophilia A *[A:B]* Hemophilia B
3.* ✔	Has biological phenotype changed from parent study? [Phenotype changed?]	**[lstBIO]** *[A:Y]* **[lstPHENO]** Yes, please complete the biological phenotype *[A:MODERATE]* Moderate (1-5%) *[A:SEVERE]* Severe (<1%) *[A:N]* No
4.* ✔	Estimated number of bleeding events (since parent study) [Number of events]	**[numBLEED]** N2
5.* ✔	Estimated number of hemophilia clinic visits (since parent study) [Number of visits]	**[numVISITS]** N3

	Date occurred	Treatment	Severity	Location	Hospitalized
6. ✔					

Bleeding Characteristics Entry [sctHHENTRY]

- Please record only one condition per row.

- Please click on the Add Entry button to add rows.

- Please record only clinically relevant events occurring between the parent study and prior to administration of the first dose of study drug in this open-label extension study.

6.1* ✔	Date bleed occurred [Date occurred]	**[dtmBLEED] (DD/MM/YYYY)** Req/Unk / Req/Unk / Req/Unk (2015-2023)
6.2* ✔	Treatment applied for this bleeding event [Treatment]	**[lstTRT]** *[A:FACTOR VIII/IX]* Treated with Factor/BPA *[A:OTHER]* **[txtTRTOTH]** Other treatment A60
6.3* ✔	Severity [Severity]	**[lstSEV]** *[A:MILD]* Mild *[A:MODERATE]* Moderate *[A:SEVERE]* Severe *[A:LIFE THREATENING]* Life threatening
6.4* ✔	Location of bleed [Location]	**[lstLOC]** *[A:JOINT]* Bleeding in joint *[A:SOFT]* Bleeding in soft tissue/muscles *[A:MOUTH]* Bleeding in mouth *[A:URINE]* Blood in urine *[A:SURFACE]* Surface bruising *[A:OTHER]* **[txtLOCOTH]** Other location A60
6.5* ✔	Hospitalized for this event? [Hospitalized]	**[lstHOSP]** *[A:Y]* **[lstDAYSHOSP]** Yes Days hospitalized *[A:NUMBER]* **[numDAYSHOSP]** Number of days hospitalized N3 *[A:UNK]* Unknown **[lstDAYSWORK]** Days missed work *[A:NUMBER]* **[numDAYSWORK]** Number of days missed work N3 *[A:UNK]* Unknown *[A:N]* No

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: Hemophilia History

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	lstHH, lstBIO, lstHOSP
			No	N	citmYesNo_N	
clHTYPE	String		Hemophilia A	A	clHTYPE_A	lstHTYPE
			Hemophilia B	B	clHTYPE_B	
clPHENO	String		Moderate (1-5%)	MODERATE	citmPHENO_MOD	lstPHENO
			Severe (<1%)	SEVERE	citmPHENO_SEV	
clBLTRT	String		Treated with Factor/BPA	FACTOR VIII/IX	citmBLTRT_Factor	lstTRT
			Other treatment	OTHER	citmBLTRT_Other	
clHHSEV	String		Mild	MILD	citmHHSEV_MILD	lstSEV
			Moderate	MODERATE	citmHHSEV_MODERATE	
			Severe	SEVERE	citmHHSEV_SEVERE	
			Life threatening	LIFE THREATENING	citmHHSEV_LIFETHREAT	
clBLLOC	String		Bleeding in joint	JOINT	citmBLLOC_Joint	lstLOC
			Bleeding in soft tissue/muscles	SOFT	citmBLLOC_Soft	
			Bleeding in mouth	MOUTH	citmBLLOC_Mouth	
			Blood in urine	URINE	citmBLLOC_Urine	
			Surface bruising	SURFACE	citmBLLOC_Surface	
			Other location	OTHER	citmBLLOC_Other	
clDAYSHOSP	String		Number of days hospitalized	NUMBER	citmDAYSHOSP_Number	lstDAYSHOSP
			Unknown	UNK	citmDAYSHOSP_Unk	
clDAYSMISSED	String		Number of days missed work	NUMBER	citmDAYSMISSED_Number	lstDAYSWORK
			Unknown	UNK	citmDAYSMISSED_Unknown	

RDE Analytics: RD_FRMHHX

Data Variable RefName	RD Column Name	Column Data Type
lstHH	LSTHH_C	VARCHAR2
	LSTHH	VARCHAR2
	LSTHH_ND	VARCHAR2
lstHTYPE	LSTHTYPE_C	VARCHAR2
	LSTHTYPE	VARCHAR2
	LSTHTYPE_ND	VARCHAR2
lstBIO	LSTBIO_C	VARCHAR2
	LSTBIO	VARCHAR2
	LSTBIO_ND	VARCHAR2
lstBIO - lstPHENO	LSTPHENO_C	VARCHAR2
	LSTPHENO	VARCHAR2
numBLEED	NUMBLEED	NUMBER
	NUMBLEED_ND	VARCHAR2
numVISITS	NUMVISITS	NUMBER
	NUMVISITS_ND	VARCHAR2
RD_FRMHHX_SCTHHENTRY		
dtmBLEED	DTMBLEED	DATE
	DTMBLEED_DTS	VARCHAR2
	DTMBLEED_DTR	VARCHAR2
	DTMBLEED_ND	VARCHAR2
lstTRT	LSTTRT_C	VARCHAR2
	LSTTRT	VARCHAR2
	LSTTRT_ND	VARCHAR2
lstTRT - txtTRTOTH	TXTTRTOTH	VARCHAR2
lstSEV	LSTSEV_C	VARCHAR2

	LSTSEV	VARCHAR2
	LSTSEV_ND	VARCHAR2
lstLOC	LSTLOC_C	VARCHAR2
	LSTLOC	VARCHAR2
	LSTLOC_ND	VARCHAR2
lstLOC - txtLOCOTH	TXTLOCOTH	VARCHAR2
lstHOSP	LSTHOSP_C	VARCHAR2
	LSTHOSP	VARCHAR2
	LSTHOSP_ND	VARCHAR2
lstHOSP - lstDAYSHOSP	LSTDAYSHOSP_C	VARCHAR2
	LSTDAYSHOSP	VARCHAR2
lstHOSP - numDAYSHOSP	NUMDAYSHOSP	NUMBER
lstHOSP - lstDAYSWORK	LSTDAYSWORK_C	VARCHAR2
	LSTDAYSWORK	VARCHAR2
lstHOSP - numDAYSWORK	NUMDAYSWORK	NUMBER

AT3SC002: Directed Physical Examination (Screening) (PE DIR) [frmPE_SCR]

Please cross-check subject's physical examination with the eligibility criteria

1.* ✔ Date collected [Date performed]

[lstASSDT]
[A:SAME DATE] Same date as visit date
[A:OTHER] **[dtmASS] (DD/MM/YYYY)**
Other date, please specify Req / Req / Req (2015-2023)

Please examine all body parts / organs and body systems and select the appropriate response: [sctPE_SCR]

If an abnormality is present at Screening, please cross-check with form MH (Medical History)

2.* ✔ Chest/Respiratory [Chest/Respiratory]

[lstRESPIRAT]
[A:NOT DONE] Not done
[A:NORMAL] Normal
[A:ABNORMAL] **[txtRESPIRAT]**
Abnormal, please specify
A200
[lstRESPIRATCS]
Is the abnormality clinically significant? *[A:Y]* Yes
[A:N] No

3.* ✔ Heart/Cardiovascular [Heart/Cardiovascular]

[lstCARDIOVA]
[A:NOT DONE] Not done
[A:NORMAL] Normal
[A:ABNORMAL] **[txtCARDIOVA]**
Abnormal, please specify
A200
[lstCARDIOVACS]
Is the abnormality clinically significant? *[A:Y]* Yes
[A:N] No

4.* ✔ Dermatological/Skin [Dermatological/Skin]

[lstSKIN]
[A:NOT DONE] Not done
[A:NORMAL] Normal
[A:ABNORMAL] **[txtSKIN]**
Abnormal, please specify
A200
[lstSKINCS]
Is the abnormality clinically significant? *[A:Y]* Yes
[A:N] No

5.* ✔ Gastrointestinal/Liver [Gastrointestinal/Liver]

[lstGASTROIN]
[A:NOT DONE] Not done
[A:NORMAL] Normal
[A:ABNORMAL] **[txtGASTROIN]**
Abnormal, please specify
A200
[lstGASTROINCS]
Is the abnormality clinically significant? *[A:Y]* Yes
[A:N] No

6.* ✔ Musculoskeletal/Extremities [Musculoskeletal/Extremities]

[lstMUSCULO]
[A:NOT DONE] Not done
[A:NORMAL] Normal
[A:ABNORMAL] **[txtMUSCULO]**
Abnormal, please specify
A200
[lstMUSCULOCS]
Is the abnormality clinically significant? *[A:Y]* Yes
[A:N] No

7. ✔ Neurologic [Neurologic]

[lstNEURO_SCR]
[A:NOT DONE] Not done
[A:NORMAL] Normal
[A:ABNORMAL] **[cmpNEURO]**
Abnormal, please specify
[txtNEURO]
A200

[lstNEUROCS]
Is the abnormality clinically significant? *[A:Y]* Yes
[A:N] No

	Other abnormalities	Other clinical significance
8. ✔		

Physical Examination Other Entry [sctPEOTH]

- If there are any other abnormalities, please record in the Add Entry section below
- Please record only one abnormality per row

8.1* ✔	Other abnormalities [Other abnormalities]	**[txtPEOTH]** A200
8.2* ✔	Is the abnormality clinically significant? [Other clinical significance]	**[lstPEOTHCS]** *[A:Y]* Yes *[A:N]* No

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Codelist Values Tables: Directed Physical Examination (Screening)

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clNDNormalAbnormal	String		Not done	NOT DONE	citmNDNormalAbnormal_ND	lstRESPIRAT, lstCARDIOVA, lstSKIN, lstGASTROIN, lstMUSCULO, lstNEURO_SCR
			Normal	NORMAL	citmNDNormalAbnormal_Normal	
			Abnormal	ABNORMAL	citmNDNormalAbnormal_Abnormal	
clYesNo	String		Yes	Y	citmYesNo_Y	lstRESPIRATCS, lstCARDIOVACS, lstSKINCS, lstGASTROINCS, lstMUSCULOCS, lstNEUROCS, lstPEOTHCS
			No	N	citmYesNo_N	

RDE Analytics: RD_FRMPE_SCR

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
lstRESPIRAT	LSTRESPIRAT_C	VARCHAR2
	LSTRESPIRAT	VARCHAR2
	LSTRESPIRAT_ND	VARCHAR2
lstRESPIRAT - txtRESPIRAT	TXTRESPIRAT	VARCHAR2
lstRESPIRAT - lstRESPIRATCS	LSTRESPIRATCS_C	VARCHAR2
	LSTRESPIRATCS	VARCHAR2
lstCARDIOVA	LSTCARDIOVA_C	VARCHAR2
	LSTCARDIOVA	VARCHAR2
	LSTCARDIOVA_ND	VARCHAR2
lstCARDIOVA - txtCARDIOVA	TXTCARDIOVA	VARCHAR2
lstCARDIOVA - lstCARDIOVACS	LSTCARDIOVACS_C	VARCHAR2
	LSTCARDIOVACS	VARCHAR2
lstSKIN	LSTSKIN_C	VARCHAR2
	LSTSKIN	VARCHAR2
	LSTSKIN_ND	VARCHAR2

lstSKIN - txtSKIN	TXTSKIN	VARCHAR2
lstSKIN - lstSKINCS	LSTSKINCS_C	VARCHAR2
	LSTSKINCS	VARCHAR2
lstGASTROIN	LSTGASTROIN_C	VARCHAR2
	LSTGASTROIN	VARCHAR2
	LSTGASTROIN_ND	VARCHAR2
lstGASTROIN - txtGASTROIN	TXTGASTROIN	VARCHAR2
lstGASTROIN - lstGASTROINCS	LSTGASTROINCS_C	VARCHAR2
	LSTGASTROINCS	VARCHAR2
lstMUSCULO	LSTMUSCULO_C	VARCHAR2
	LSTMUSCULO	VARCHAR2
	LSTMUSCULO_ND	VARCHAR2
lstMUSCULO - txtMUSCULO	TXTMUSCULO	VARCHAR2
lstMUSCULO - lstMUSCULOCS	LSTMUSCULOCS_C	VARCHAR2
	LSTMUSCULOCS	VARCHAR2
lstNEURO_SCR	LSTNEURO_SCR_C	VARCHAR2
	LSTNEURO_SCR	VARCHAR2
	LSTNEURO_SCR_ND	VARCHAR2
lstNEURO_SCR - txtNEURO	TXTNEURO	VARCHAR2
lstNEURO_SCR - lstNEUROCS	LSTNEUROCS_C	VARCHAR2
	LSTNEUROCS	VARCHAR2
RD_FRMPE_SCR_SCTPEOTH		
txtPEOTH	TXTPEOTH	VARCHAR2
	TXTPEOTH_ND	VARCHAR2
lstPEOTHCS	LSTPEOTHCS_C	VARCHAR2
	LSTPEOTHCS	VARCHAR2
	LSTPEOTHCS_ND	VARCHAR2

AT3SC002: Vital Signs (Screening) (VS SCR) [frmVS_SCR]		
1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
Weight and Height [sctANTMEASSCR]		
2.* ✔	Weight [Weight]	**[numWEIGHT]** xxx.x kg[b]
3.* ✔	Height [Height]	**[numHEIGHT]** xxx.x cm[b]
Vital Signs [sctVS]		
Should be measured in supine position after 10 minutes of rest.		
4.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
5.* ✔	Blood pressure [Blood pressure]	**[cmpBP1]** **[numSYSBP1]** **[numDIABP1]** (mmHg) N3 / N3 systolic / diastolic
6.* ✔	Heart rate [Heart rate]	**[numHR1]** N3 bpm[b]
7.* ✔	Body temperature [Body temperature]	**[numTEMP1]** xx.x C[b]
8.* ✔	Respiratory rate [Respiratory rate]	**[numRR1]** N2 breaths per minute

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.

Codelist Values Tables: Vital Signs (Screening)						
Codelist RefName	**Codelist Data Type**	**Subset**	**Label**	**Code**	**Codelist Item RefName**	**Data Variable RefName**
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	

RDE Analytics: RD_FRMVS_SCR		
Data Variable RefName	**RD Column Name**	**Column Data Type**
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
numWEIGHT	NUMWEIGHT	FLOAT
	NUMWEIGHT_U	VARCHAR2
	NUMWEIGHT_ND	VARCHAR2
numHEIGHT	NUMHEIGHT	FLOAT
	NUMHEIGHT_U	VARCHAR2
	NUMHEIGHT_ND	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
cmpBP1	CMPBP1_ND	VARCHAR2
cmpBP1 - numSYSBP1	NUMSYSBP1	NUMBER
cmpBP1 - numDIABP1	NUMDIABP1	NUMBER
numHR1	NUMHR1	NUMBER
	NUMHR1_U	VARCHAR2
	NUMHR1_ND	VARCHAR2
numTEMP1	NUMTEMP1	FLOAT

	NUMTEMP1_U	VARCHAR2
	NUMTEMP1_ND	VARCHAR2
numRR1	NUMRR1	NUMBER
	NUMRR1_ND	VARCHAR2

AT3SC002: Central Laboratory Assessments (LAB) [frmLAB]

If an abnormality is present at Screening or before first dose of study drug, please cross-check with form MH (Medical History)
Please record new clinically significant abnormalities which started after first dose of study drug on the AE form

From Month 25 to Month 48 (Year 3 and 4), carefully note that certain assessments do not need to be performed from the ICF signature for Protocol Amendment 6 onwards.

Date of sample collection [sctLABDT]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ○ Same date as visit date *[A:OTHER]* ○ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)

Laboratory sampling [sctCOLL]

2.* ✔	Were all labs obtained? [Were all labs obtained?]	**[txtLAB]** *[A:Y]* ○ Yes *[A:N]* ○ **[lstLAB]** No, please specify *[A:HEMATOLOGY]* ☐ Hematology *[A:BIOCHEMISTRY]* ☐ Biochemistry *[A:COAGULATION]* ☐ Coagulation *[A:URINALYSIS]* ☐ Urinalysis *[A:LIVER FUNCTION TEST]* ☐ Liver Function Test
3.* ✔	Kit ID number [Kit ID number]	**[txtREFNO]** A11

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: Central Laboratory Assessments

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clYesNo	String		Yes	Y	citmYesNo_Y	txtLAB
			No	N	citmYesNo_N	
clLAB	String		Hematology	HEMATOLOGY	citmLAB_Hematology	lstLAB
			Biochemistry	BIOCHEMISTRY	citmLAB_Biochemistry	
			Coagulation	COAGULATION	citmLAB_Coagulation	
			Urinalysis	URINALYSIS	citmLAB_Urinalysis	
			Liver Function Test	LIVER FUNCTION TEST	citmLAB_Liver	

RDE Analytics: RD_FRMLAB

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
txtLAB	TXTLAB_C	VARCHAR2
	TXTLAB	VARCHAR2
	TXTLAB_ND	VARCHAR2
txtLAB - Hematology	LSTLAB_CITMLABHEMATOLOGY_C	VARCHAR2
	LSTLAB_CITMLABHEMATOLOGY	VARCHAR2
txtLAB - Biochemistry	*LSTLAB_CITMLABBIOCHEMISTRY_C	VARCHAR2
	*LSTLAB_CITMLABBIOCHEMISTRY	VARCHAR2
txtLAB - Coagulation	LSTLAB_CITMLABCOAGULATION_C	VARCHAR2
	LSTLAB_CITMLABCOAGULATION	VARCHAR2
txtLAB - Urinalysis	LSTLAB_CITMLABURINALYSIS_C	VARCHAR2
	LSTLAB_CITMLABURINALYSIS	VARCHAR2
txtLAB - Liver Function Test	LSTLAB_CITMLABLIVER_C	VARCHAR2

	LSTLAB_CITMLABLIVER	VARCHAR2
txtREFNO	TXTREFNO	VARCHAR2
	TXTREFNO_ND	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different.		

AT3SC002: 12-lead ECG (Screening) (ECG SCR) [frmECG_SCR]

Assessment Date [sctASSDT]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ○ Same date as visit date *[A:OTHER]* ○ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)

12-lead Electrocardiogram [sctECG_SCR]

Supine after at least 10 minutes rest

2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
3.* ✔	Rhythm [Rhythm]	**[lstRHYTM]** *[A:NORMAL]* ○ Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* ○ Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* ○ Abnormal, Clinically Significant
4.* ✔	Ventricular rate [Ventricular rate]	**[numVR]** N3 bpm[b]
5.* ✔	PR interval [PR]	**[numPR]** N3 msec[b]
6.* ✔	QRS duration [QRS]	**[numQRS]** N3 msec[b]
7.* ✔	QT interval [QT]	**[numQT]** N3 msec[b]
8.* ✔	QTc interval [QTc]	**[numQTCF]** N3 msec[b]
9.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT]** *[A:NORMAL]* ○ Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* ○ Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* ○ Abnormal, Clinically Significant
10. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN1]** *[A:SINUS BRADYCARDIA]* ☐ Sinus Bradycardia *[A:SINUS TACHYCARDIA]* ☐ Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* ☐ Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* ☐ Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* ☐ Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* ☐ Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* ☐ Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* ☐ Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* ☐ Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* ☐ Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* ☐ Atrial Fibrillation *[A:ATRIAL PACING]* ☐ Atrial Pacing *[A:VENTRICULAR PACING]* ☐ Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* ☐ Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* ☐ 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* ☐ 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* ☐ 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* ☐ 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* ☐ Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* ☐ Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* ☐ Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* ☐ Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* ☐ Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* ☐ Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* ☐ Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* ☐ Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* ☐ Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* ☐ Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* ☐ Inferior Infarct Pattern *[A:OTHER, SPECIFY]* ☐ **[txtABNOTH1]** Other, specify A128

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.

Codelist Values Tables: 12-lead ECG (Screening)

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	lstRHYTM
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	lstOVERALLINT
			Abnormal, Not Clinically Significant	ABNORMAL, NOT CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalNCS	
			Abnormal, Clinically Significant	ABNORMAL, CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalCS	
clABN	String		Sinus Bradycardia	SINUS BRADYCARDIA	citmABN_SinusBradycardia	lstABN1
			Sinus Tachycardia	SINUS TACHYCARDIA	citmABN_SinusTachycardia	
			Atrial Tachycardia	ATRIAL TACHYCARDIA	citmABN_AtrialTachycardia	
			Ventricular Tachycardia	VENTRICULAR TACHYCARDIA	citmABN_VentricularTachycardia	
			Sick Sinus Syndrome	SICK SINUS SYNDROME	citmABN_SickSinusSyndrome	
			Premature Atrial Complexes	PREMATURE ATRIAL COMPLEXES	citmABN_PrematureAtrialComplexes	
			Premature Ventricular Complexes	PREMATURE VENTRICULAR COMPLEXES	citmABN_PrematureVentricularComplexes	
			Q Axis, Left Axis Deviation	Q AXIS LEFT AXIS DEVIATION	citmABN_QAxisLeftAxisDeviation	
			Left Atrial Abnormality	LEFT ATRIAL ABNORMALITY	citmABN_LeftAtrialAbnormality	
			Left Ventricular Hypertrophy	LEFT VENTRICULAR HYPERTROPHY	citmABN_LeftVentricularHypertrophy	
			Atrial Fibrillation	ATRIAL FIBRILLATION	citmABN_AtrialFibrillation	
			Atrial Pacing	ATRIAL PACING	citmABN_AtrialPacing	
			Ventricular Pacing	VENTRICULAR PACING	citmABN_VentricularPacing	
			Atrial Ventricular Pacing	ATRIAL VENTRICULAR PACING	citmABN_AtrialVentricularPacing	
			1st Degree A-V Block	1ST DEGREE A-V BLOCK	citmABN_1stDegreeAVBlock	
			2nd Degree A-V Block Type I	2ND DEGREE A-V BLOCK TYPE I	citmABN_2ndDegreeAVBlockTypeI	
			2nd Degree A-V Block Type II	2ND DEGREE A-V BLOCK TYPE II	citmABN_2ndDegreeAVBlockTypeII	
			3rd Degree A-V Block	3RD DEGREE A-V BLOCK	citmABN_3rdDegreeAVBlock	
			Left Bundle Branch Block	LEFT BUNDLE BRANCH BLOCK	citmABN_LeftBundleBranchBlock	
			Incomplete Left Bundle Branch Block	INCOMPLETE LEFT BUNDLE BRANCH BLOCK	citmABN_IncompleteLeftBundleBranchBlock	
			Left Anterior Hemiblock	LEFT ANTERIOR HEMIBLOCK	citmABN_LeftAnteriorHemiblock	
			Left Posterior Hemiblock	LEFT POSTERIOR HEMIBLOCK	citmABN_LeftPosteriorHemiblock	
			Right Bundle Branch Block	RIGHT BUNDLE BRANCH BLOCK	citmABN_RightBundleBranchBlock	
			Incomplete Right Bundle Branch Block	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK	citmABN_IncompleteRightBundleBranchBlock	
			Intraventricular Conduction Delay	INTRAVENTRICULAR CONDUCTION DELAY	citmABN_IntraventricularConductionDelay	
			Anteroseptal Infarct Pattern	ANTEROSEPTAL INFARCT PATTERN	citmABN_AnteroseptalInfarctPattern	
			Anterolateral Infarct Pattern	ANTEROLATERAL INFARCT PATTERN	citmABN_AnterolateralInfarctPattern	
			Lateral Infarct Pattern	LATERAL INFARCT PATTERN	citmABN_LateralInfarctPattern	
			Inferior Infarct Pattern	INFERIOR INFARCT PATTERN	citmABN_InferiorInfarctPattern	
			Other, specify	OTHER, SPECIFY	citmABN_Otherspecify	

RDE Analytics: RD_FRMECG_SCR

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2

	DTMASS_T_ND	VARCHAR2
lstRHYTM	LSTRHYTM_C	VARCHAR2
	LSTRHYTM	VARCHAR2
	LSTRHYTM_ND	VARCHAR2
numVR	NUMVR	NUMBER
	NUMVR_U	VARCHAR2
	NUMVR_ND	VARCHAR2
numPR	NUMPR	NUMBER
	NUMPR_U	VARCHAR2
	NUMPR_ND	VARCHAR2
numQRS	NUMQRS	NUMBER
	NUMQRS_U	VARCHAR2
	NUMQRS_ND	VARCHAR2
numQT	NUMQT	NUMBER
	NUMQT_U	VARCHAR2
	NUMQT_ND	VARCHAR2
numQTCF	NUMQTCF	NUMBER
	NUMQTCF_U	VARCHAR2
	NUMQTCF_ND	VARCHAR2
lstOVERALLINT	LSTOVERALLINT_C	VARCHAR2
	LSTOVERALLINT	VARCHAR2
	LSTOVERALLINT_ND	VARCHAR2
lstABN1	LSTABN1_ND	VARCHAR2
lstABN1 - Sinus Bradycardia	*LSTABN1_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN1 - Sinus Tachycardia	*LSTABN1_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN1 - Atrial Tachycardia	*LSTABN1_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN1 - Ventricular Tachycardia	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN1 - Sick Sinus Syndrome	*LSTABN1_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN1_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN1 - Premature Atrial Complexes	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN1 - Premature Ventricular Complexes	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN1 - Q Axis, Left Axis Deviation	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN1 - Left Atrial Abnormality	*LSTABN1_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN1 - Left Ventricular Hypertrophy	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN1 - Atrial Fibrillation	*LSTABN1_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN1_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN1 - Atrial Pacing	*LSTABN1_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALPACING	VARCHAR2
lstABN1 - Ventricular Pacing	*LSTABN1_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARPACING	VARCHAR2
lstABN1 - Atrial Ventricular Pacing	*LSTABN1_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN1 - 1st Degree A-V Block	*LSTABN1_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN1STDEGREEAVBLOCK	VARCHAR2

lstABN1 - 2nd Degree A-V Block Type I	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN1 - 2nd Degree A-V Block Type II	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN1 - 3rd Degree A-V Block	*LSTABN1_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN1 - Left Bundle Branch Block	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Left Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Left Anterior Hemiblock	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Left Posterior Hemiblock	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Right Bundle Branch Block	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Right Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Intraventricular Conduction Delay	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN1 - Anteroseptal Infarct Pattern	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN1 - Anterolateral Infarct Pattern	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Lateral Infarct Pattern	*LSTABN1_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Inferior Infarct Pattern	*LSTABN1_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN1 - Other, specify	LSTABN1_TXTABNOTH1_C	VARCHAR2
	LSTABN1_TXTABNOTH1	VARCHAR2
lstABN1 - txtABNOTH1	TXTABNOTH1	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: Inclusion/Exclusion Criteria (ELIG) [frmELIG]

Eligibility [sctELIG]

1.* ✔	Protocol/amendment version consented on [Protocol or amendment]	**[lstPTC]** *[A:ORIGINAL]* ◯ Original *[A:AMENDMENT 1]* ◯ Amendment 1 *[A:AMENDMENT 2]* ◯ Amendment 2 *[A:AMENDMENT 3]* ◯ Amendment 3 *[A:AMENDMENT 4]* ◯ Amendment 4 *[A:AMENDMENT 5]* ◯ Amendment 5 *[A:AMENDMENT 6]* ◯ Amendment 6 *[A:AMENDMENT 7]* ◯ Amendment 7 *[A:AMENDMENT 8]* ◯ Amendment 8 *[A:AMENDMENT 9]* ◯ Amendment 9 *[A:AMENDMENT 10]* ◯ Amendment 10
2.* ✔	Did the subject meet all eligibility criteria? [Subject meet all eligibility criteria]	**[lstELIG]** *[A:Y]* ◯ Yes *[A:N]* ◯ No
3. ✔	Failed criteria numbers [Failed criteria]	**[lstINEX]** *[A:INCLUSION CRITERION 1]* ☐ Inclusion criterion 1 *[A:INCLUSION CRITERION 2]* ☐ Inclusion criterion 2 *[A:INCLUSION CRITERION 3]* ☐ Inclusion criterion 3 *[A:INCLUSION CRITERION 4]* ☐ Inclusion criterion 4 *[A:INCLUSION CRITERION 5]* ☐ Inclusion criterion 5 *[A:EXCLUSION CRITERION 1]* ☐ Exclusion criterion 1 *[A:EXCLUSION CRITERION 2]* ☐ Exclusion criterion 2 *[A:EXCLUSION CRITERION 3]* ☐ Exclusion criterion 3 *[A:EXCLUSION CRITERION 4]* ☐ Exclusion criterion 4 *[A:EXCLUSION CRITERION 5]* ☐ Exclusion criterion 5 *[A:EXCLUSION CRITERION 6]* ☐ Exclusion criterion 6 *[A:EXCLUSION CRITERION 7]* ☐ Exclusion criterion 7 *[A:EXCLUSION CRITERION 8]* ☐ Exclusion criterion 8 *[A:EXCLUSION CRITERION 9]* ☐ Exclusion criterion 9 *[A:EXCLUSION CRITERION 10]* ☐ Exclusion criterion 10 *[A:EXCLUSION CRITERION 11]* ☐ Exclusion criterion 11
4. ✔	Was a waiver granted by the medical monitor? [Waiver]	**[lstWAIVER]** *[A:Y]* ◯ **[dtmWAIVER] (DD/MM/YYYY)** Yes, date granted Req / Req / Req (2015-2023) *[A:N]* ◯ No
5.	For office use only *[hidden]* [For office use only]	**[numEMAIL1]** N3
6.	For office use only *[hidden]* [For office use only]	**[numEMAIL2]** N3
7.	For office use only *[hidden]* [For office use only]	**[numEMAIL3]** N3

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: Inclusion/Exclusion Criteria

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clPTC	String		Original	ORIGINAL	citmPTC_Original	lstPTC
			Amendment 1	AMENDMENT 1	citmPTC_Amendment1	
			Amendment 2	AMENDMENT 2	citmPTC_Amendment2	
			Amendment 3	AMENDMENT 3	citmPTC_Amendment3	
			Amendment 4	AMENDMENT 4	citmPTC_Amendment4	
			Amendment 5	AMENDMENT 5	citmPTC_Amendment5	
			Amendment 6	AMENDMENT 6	citmPTC_Amendment6	
			Amendment 7	AMENDMENT 7	citmPTC_Amendment7	
			Amendment 8	AMENDMENT 8	citmPTC_Amendment8	

			Amendment 9	AMENDMENT 9	citmPTC_Amendment9	
			Amendment 10	AMENDMENT 10	citmPTC_Amendment10	
clYesNo	String		Yes	Y	citmYesNo_Y	lstELIG, lstWAIVER
			No	N	citmYesNo_N	
clINEX	String		Inclusion criterion 1	INCLUSION CRITERION 1	citmINEX_IN1	lstINEX
			Inclusion criterion 2	INCLUSION CRITERION 2	citmINEX_IN2	
			Inclusion criterion 3	INCLUSION CRITERION 3	citmINEX_IN3	
			Inclusion criterion 4	INCLUSION CRITERION 4	citmINEX_IN4	
			Inclusion criterion 5	INCLUSION CRITERION 5	citmINEX_IN5	
			Exclusion criterion 1	EXCLUSION CRITERION 1	citmINEX_EX1	
			Exclusion criterion 2	EXCLUSION CRITERION 2	citmINEX_EX2	
			Exclusion criterion 3	EXCLUSION CRITERION 3	citmINEX_EX3	
			Exclusion criterion 4	EXCLUSION CRITERION 4	citmINEX_EX4	
			Exclusion criterion 5	EXCLUSION CRITERION 5	citmINEX_EX5	
			Exclusion criterion 6	EXCLUSION CRITERION 6	citmINEX_EX6	
			Exclusion criterion 7	EXCLUSION CRITERION 7	citmINEX_EX7	
			Exclusion criterion 8	EXCLUSION CRITERION 8	citmINEX_EX8	
			Exclusion criterion 9	EXCLUSION CRITERION 9	citmINEX_EX9	
			Exclusion criterion 10	EXCLUSION CRITERION 10	citmINEX_EX10	
			Exclusion criterion 11	EXCLUSION CRITERION 11	citmINEX_EX11	

RDE Analytics: RD_FRMELIG

Data Variable RefName	RD Column Name	Column Data Type
lstPTC	LSTPTC_C	VARCHAR2
	LSTPTC	VARCHAR2
	LSTPTC_ND	VARCHAR2
lstELIG	LSTELIG_C	VARCHAR2
	LSTELIG	VARCHAR2
	LSTELIG_ND	VARCHAR2
lstINEX	LSTINEX_ND	VARCHAR2
lstINEX - Inclusion criterion 1	LSTINEX_CITMINEXIN1_C	VARCHAR2
	LSTINEX_CITMINEXIN1	VARCHAR2
lstINEX - Inclusion criterion 2	LSTINEX_CITMINEXIN2_C	VARCHAR2
	LSTINEX_CITMINEXIN2	VARCHAR2
lstINEX - Inclusion criterion 3	LSTINEX_CITMINEXIN3_C	VARCHAR2
	LSTINEX_CITMINEXIN3	VARCHAR2
lstINEX - Inclusion criterion 4	LSTINEX_CITMINEXIN4_C	VARCHAR2
	LSTINEX_CITMINEXIN4	VARCHAR2
lstINEX - Inclusion criterion 5	LSTINEX_CITMINEXIN5_C	VARCHAR2
	LSTINEX_CITMINEXIN5	VARCHAR2
lstINEX - Exclusion criterion 1	LSTINEX_CITMINEXEX1_C	VARCHAR2
	LSTINEX_CITMINEXEX1	VARCHAR2
lstINEX - Exclusion criterion 2	LSTINEX_CITMINEXEX2_C	VARCHAR2
	LSTINEX_CITMINEXEX2	VARCHAR2
lstINEX - Exclusion criterion 3	LSTINEX_CITMINEXEX3_C	VARCHAR2
	LSTINEX_CITMINEXEX3	VARCHAR2
lstINEX - Exclusion criterion 4	LSTINEX_CITMINEXEX4_C	VARCHAR2
	LSTINEX_CITMINEXEX4	VARCHAR2
lstINEX - Exclusion criterion 5	LSTINEX_CITMINEXEX5_C	VARCHAR2
	LSTINEX_CITMINEXEX5	VARCHAR2
lstINEX - Exclusion criterion 6	LSTINEX_CITMINEXEX6_C	VARCHAR2
	LSTINEX_CITMINEXEX6	VARCHAR2
lstINEX - Exclusion criterion 7	LSTINEX_CITMINEXEX7_C	VARCHAR2

	LSTINEX_CITMINEXEX7	VARCHAR2
lstINEX - Exclusion criterion 8	LSTINEX_CITMINEXEX8_C	VARCHAR2
	LSTINEX_CITMINEXEX8	VARCHAR2
lstINEX - Exclusion criterion 9	LSTINEX_CITMINEXEX9_C	VARCHAR2
	LSTINEX_CITMINEXEX9	VARCHAR2
lstINEX - Exclusion criterion 10	LSTINEX_CITMINEXEX10_C	VARCHAR2
	LSTINEX_CITMINEXEX10	VARCHAR2
lstINEX - Exclusion criterion 11	LSTINEX_CITMINEXEX11_C	VARCHAR2
	LSTINEX_CITMINEXEX11	VARCHAR2
lstWAIVER	LSTWAIVER_C	VARCHAR2
	LSTWAIVER	VARCHAR2
	LSTWAIVER_ND	VARCHAR2
lstWAIVER - dtmWAIVER	DTMWAIVER	DATE
	DTMWAIVER_DTS	VARCHAR2
numEMAIL1	NUMEMAIL1	NUMBER
	NUMEMAIL1_ND	VARCHAR2
numEMAIL2	NUMEMAIL2	NUMBER
	NUMEMAIL2_ND	VARCHAR2
numEMAIL3	NUMEMAIL3	NUMBER
	NUMEMAIL3_ND	VARCHAR2

AT3SC002: Concomitant Medications (CM) - Repeating Form [frmCM]

#	Row No	Medication	Indication	Continuing from parent study?	Start date and time	Stop date and time	Dose	Unit	Frequency	Route
1										

Concomitant Medications [sctCM]

Please record medication(s) ongoing from the parent study; started between parent study and present study; and any started after signing informed consent.

1.*	Row No ***(for internal use only)*** *[read-only]* [Row No]	**[numROW]** N3
2.* ✔	Medication Trade or generic name [Medication]	**[txtTRT]** A200
3.* ✔	Indication [Indication]	**[lstCMIND]** *[A:AE]* ◯ AE *[A:OTHER]* ◯ **[txtCMINDCSP]** Other indication, please specify A200
4.* ✔	Continuing from parent study? [Continuing from parent study?]	**[lstCONT]** *[A:Y]* ◯ Yes *[A:N]* ◯ No
5.* ✔	Start date and time [Start date and time]	**[dtmCMSTART] (DD/MM/YYYY hh:mm)** Req/Unk / Req/Unk / Req (1930-2023) Req/Unk : Req/Unk *24-hour clock*
6.* ✔	Stop date and time **Please complete 'Ongoing at the end of the trial' only at the end of the trial** [Stop date and time]	**[lstCMEND]** *[A:END DATE AND TIME]* ◯ **[dtmCMEND] (DD/MM/YYYY hh:mm)** Stop date and time Req/Unk / Req/Unk / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock* *[A:ONGOING]* ◯ Ongoing at the end of trial
7.* ✔	Dose per administration [Dose]	**[numDOSE]** xxxxxxxx.
8.* ✔	Unit [Unit]	**[lstDOSEU]** *[A:UNIT]* ◯ **[lstDOSEUSP]** **[clDOSEUSP]** *[A:OTHER]* ◯ **[txtDOSEUOTH]** Other, please specify A50
9.* ✔	Frequency [Frequency]	**[lstFREQ]** *[A:FREQUENCY]* ◯ **[lstFREQSP]** **[clFREQSP]** *[A:OTHER]* ◯ **[txtFREQOTH]** Other, please specify A50
10.* ✔	Route of administration [Route]	**[lstROUTE]** *[A:ROUTE]* ◯ **[lstROUTESP]** **[clROUTESP]** *[A:OTHER]* ◯ **[txtROUTEOTH]** Other, please specify A50

Key: [*] = Item is required [✔] = Source verification required [🔑] = Key item
Note: Associated form = Multiple Visits (Common CRF) / Adverse Events.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Keys (navigation) / Uniqueness: Concomitant Medications

Item	Unique	Order #
frmCM (Repeating form)		
sctCM		
numROW	Group	1
txtTRT	Group	2

Codelist Values Tables: Concomitant Medications

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clAEOther	String		AE	AE	citmAEOther_AE	lstCMIND
			Other	OTHER	citmAEOther_Other	
clYesNo	String		Yes	Y	citmYesNo_Y	lstCONT
			No	N	citmYesNo_N	
clCMEND	String		End date and time	END DATE AND TIME	citmCMEND_EndDate	lstCMEND
			Ongoing at the end of trial	ONGOING	citmCMEND_Ongoing	
clUnitOther	String		Unit	UNIT	citmUnitOther_Unit	lstDOSEU
			Other	OTHER	citmUnitOther_Other	
clDOSEUSP	String		mg	MG	citmDOSEUSP_MG	lstDOSEUSP
			ug	MICROG	citmDOSEUSP_MICROG	
			mL	ML	citmDOSEUSP_ML	
			uL	MICROL	citmDOSEUSP_MICROL	
			g	G	citmDOSEUSP_G	
			IU	IU	citmDOSEUSP_IU	
			tablet	TABLET	citmDOSEUSP_TAB	
			capsule	CAPSULE	citmDOSEUSP_CAP	
			puff	PUFF	citmDOSEUSP_PUFF	
			ampule	AMPULE	citmDOSEUSP_AMPULE	
			bolus	BOLUS	citmDOSEUSP_BOLUS	
			inhalation	INHALATION	citmDOSEUSP_INH	
			lozenge	LOZENGE	citmDOSEUSP_LOZENGE	
			patch	PATCH	citmDOSEUSP_PATCH	
			spray	SPRAY	citmDOSEUSP_SPRAY	
			suppository	SUPPOSITORY	citmDOSEUSP_SUPPOSITORY	
			Tbsp	TBSP	citmDOSEUSP_TBSP	
			tsp	TSP	citmDOSEUSP_TSP	
			oz	OZ	citmDOSEUSP_OZ	
			application	APPLICATION	citmDOSEUSP_APPLICATION	
			unknown	UNKNOWN	citmDOSEUSP_UNK	
clFrequencyOther	String		Frequency	FREQUENCY	citmFrequencyOther_Freq	lstFREQ
			Other	OTHER	citmFrequencyOther_Other	
clFREQSP	String		q.d. - once daily	QD	citmFREQSP_QD	lstFREQSP
			b.i.d. - twice daily	BID	citmFREQSP_BID	
			t.i.d. - three times daily	TID	citmFREQSP_TID	
			q.i.d. - four times daily	QID	citmFREQSP_QID	
			prn - as needed	PRN	citmFREQSP_PRN	
			qs	QS	citmFREQSP_QS	
			qm	QM	citmFREQSP_QM	
			qh	QH	citmFREQSP_QH	
			qod	QOD	citmFREQSP_QOD	
			continuous	CONTINUOUS	citmFREQSP_Continuous	
			intermittent	INTERMITTENT	citmFREQSP_Intermittent	
			once	ONCE	citmFREQSP_Once	
			unknown	UNKNOWN	citmFREQSP_Unknown	
clRouteOther	String		Route	ROUTE	citmRouteOther_Route	lstROUTE
			Other	OTHER	citmRouteOther_Other	
clROUTESP	String		PO - Oral intake	PO	citmROUTESP_PO	lstROUTESP
			IV - Intravenous	IV	citmROUTESP_IV	
			SC - Subcutaneous	SC	citmROUTESP_SC	
			TO - Topical	TO	citmROUTESP_TO	
			PA - Rectal	PA	citmROUTESP_PA	

			NA - Nasal	NA	citmROUTESP_NA	
			TD - Transdermal	TD	citmROUTESP_TD	
			INH - Inhalation	INH	citmROUTESP_INH	
			Sublingual	SUBLINGUAL	citmROUTESP_Sublingual	
			IM - Intramuscular	IM	citmROUTESP_IM	
			OC - Ocular	OC	citmROUTESP_OC	
			Unknown	UNKNOWN	citmROUTESP_Unknown	

RDE Analytics: RD_FRMCM

Data Variable RefName	RD Column Name	Column Data Type
numROW	NUMROW	NUMBER
	NUMROW_ND	VARCHAR2
txtTRT	TXTTRT	VARCHAR2
	TXTTRT_ND	VARCHAR2
lstCMIND	LSTCMIND_C	VARCHAR2
	LSTCMIND	VARCHAR2
	LSTCMIND_ND	VARCHAR2
lstCMIND - txtCMINDCSP	TXTCMINDCSP	VARCHAR2
lstCONT	LSTCONT_C	VARCHAR2
	LSTCONT	VARCHAR2
	LSTCONT_ND	VARCHAR2
dtmCMSTART	DTMCMSTART	DATE
	DTMCMSTART_DTS	VARCHAR2
	DTMCMSTART_DTR	VARCHAR2
	DTMCMSTART_ND	VARCHAR2
lstCMEND	LSTCMEND_C	VARCHAR2
	LSTCMEND	VARCHAR2
	LSTCMEND_ND	VARCHAR2
lstCMEND - dtmCMEND	DTMCMEND	DATE
	DTMCMEND_DTS	VARCHAR2
	DTMCMEND_DTR	VARCHAR2
numDOSE	NUMDOSE	FLOAT
	NUMDOSE_ND	VARCHAR2
lstDOSEU	LSTDOSEU_C	VARCHAR2
	LSTDOSEU	VARCHAR2
	LSTDOSEU_ND	VARCHAR2
lstDOSEU - lstDOSEUSP	LSTDOSEUSP_C	VARCHAR2
	LSTDOSEUSP	VARCHAR2
lstDOSEU - txtDOSEUOTH	TXTDOSEUOTH	VARCHAR2
lstFREQ	LSTFREQ_C	VARCHAR2
	LSTFREQ	VARCHAR2
	LSTFREQ_ND	VARCHAR2
lstFREQ - lstFREQSP	LSTFREQSP_C	VARCHAR2
	LSTFREQSP	VARCHAR2
lstFREQ - txtFREQOTH	TXTFREQOTH	VARCHAR2
lstROUTE	LSTROUTE_C	VARCHAR2
	LSTROUTE	VARCHAR2
	LSTROUTE_ND	VARCHAR2
lstROUTE - lstROUTESP	LSTROUTESP_C	VARCHAR2
	LSTROUTESP	VARCHAR2
lstROUTE - txtROUTEOTH	TXTROUTEOTH	VARCHAR2

AT3SC002: Directed Physical Examination (Day 1) (PE DIR) [frmPE_D1]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* Same date as visit date *[A:OTHER]* **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
Directed Physical Examination - Predose [sctPEPRE]		
If it is a new, clinically significant finding started after first dose of study drug, please also record it on the AE form		
2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
3.* ✔	Chest/Respiratory [Chest/Respiratory]	**[lstRESPIRAT]** *[A:NOT DONE]* Not done *[A:NORMAL]* Normal *[A:ABNORMAL]* **[lstRESPIRATNEW]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* No *[A:Y]* **[txtRESPIRATNEWSP]** Yes, please specify A200 **[lstRESPIRATCS]** Is the abnormality clinically significant? *[A:Y]* Yes *[A:N]* No
4.* ✔	Heart/Cardiovascular [Heart/Cardiovascular]	**[lstCARDIOVA]** *[A:NOT DONE]* Not done *[A:NORMAL]* Normal *[A:ABNORMAL]* **[lstCARDIOVANEW]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* No *[A:Y]* **[txtCARDIOVANEWSP]** Yes, please specify A200 **[lstCARDIOVACS]** Is the abnormality clinically significant? *[A:Y]* Yes *[A:N]* No
5.* ✔	Dermatological/Skin [Dermatological/Skin]	**[lstSKIN]** *[A:NOT DONE]* Not done *[A:NORMAL]* Normal *[A:ABNORMAL]* **[lstSKINNEW]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* No *[A:Y]* **[txtSKINNEWSP]** Yes, please specify A200 **[lstSKINCS]** Is the abnormality clinically significant? *[A:Y]* Yes *[A:N]* No
6.* ✔	Gastrointestinal/Liver [Gastrointestinal/Liver]	**[lstGASTROIN]** *[A:NOT DONE]* Not done *[A:NORMAL]* Normal *[A:ABNORMAL]* **[lstGASTROINNEW]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* No *[A:Y]* **[txtGASTROINNEWSP]** Yes, please specify A200 **[lstGASTROINCS]** Is the abnormality clinically significant? *[A:Y]* Yes *[A:N]* No
7.* ✔	Musculoskeletal/Extremities [Musculoskeletal/Extremities]	**[lstMUSCULO]** *[A:NOT DONE]* Not done *[A:NORMAL]* Normal *[A:ABNORMAL]* **[lstMUSCULONEW]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* No

		[A:Y] **[txtMUSCULONEWSP]** Yes, please specify A200 **[lstMUSCULOCS]** Is the abnormality clinically significant? [A:Y] Yes [A:N] No
8. ✔	Neurologic [Neurologic]	**[lstNEURO]** [A:NOT DONE] Not done [A:NORMAL] Normal [A:ABNORMAL] **[lstNEURONEW]** Abnormal, is the abnormality a new or worsened finding? [A:N] No [A:Y] **[cmpNEURONEW]** Yes, please specify **[txtNEURONEWSP]** A200 **[lstNEUROCS]** Is the abnormality clinically significant? [A:Y] Yes [A:N] No

	Other abnormalities	Other clinical significance
9. ✔		

Directed Physical Examination - Predose - Other Entry [sctPEOTHPRE]

- If there are any other abnormalities, please record in the Add Entry section below
- Please record only one abnormality per row

9.1* ✔	Other abnormalities [Other abnormalities]	**[txtPEOTH]** A200
9.2* ✔	Is the abnormality clinically significant? [Other clinical significance]	**[lstPEOTHCS]** [A:Y] Yes [A:N] No

Directed Physical Examination - 6H Postdose [sctPE6H]

If it is a new, clinically significant finding started after first dose of study drug, please also record it on the AE form

10.* ✔	Time performed [Time performed]	**[dtmASS_T2] (hh:mm)** Req : Req *24-hour clock*
11.* ✔	Chest/Respiratory [Chest/Respiratory]	**[lstRESPIRAT2]** [A:NOT DONE] Not done [A:NORMAL] Normal [A:ABNORMAL] **[lstRESPIRATNEW2]** Abnormal, is the abnormality a new or worsened finding? [A:N] No [A:Y] **[txtRESPIRATNEWSP2]** Yes, please specify A200 **[lstRESPIRATCS2]** Is the abnormality clinically significant? [A:Y] Yes [A:N] No
12.* ✔	Heart/Cardiovascular [Heart/Cardiovascular]	**[lstCARDIOVA2]** [A:NOT DONE] Not done [A:NORMAL] Normal [A:ABNORMAL] **[lstCARDIOVANEW2]** Abnormal, is the abnormality a new or worsened finding? [A:N] No [A:Y] **[txtCARDIOVANEWSP2]** Yes, please specify A200 **[lstCARDIOVACS2]** Is the abnormality clinically significant? [A:Y] Yes [A:N] No

13.* ✔	Dermatological/Skin [Dermatological/Skin]	**[lstSKIN2]** *[A:NOT DONE]* ◯ Not done *[A:NORMAL]* ◯ Normal *[A:ABNORMAL]* ◯ **[lstSKINNEW2]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* ◯ No *[A:Y]* ◯ **[txtSKINNEWSP2]** Yes, please specify A200 **[lstSKINCS2]** Is the abnormality clinically significant? *[A:Y]* ◯ Yes *[A:N]* ◯ No
14.* ✔	Gastrointestinal/Liver [Gastrointestinal/Liver]	**[lstGASTROIN2]** *[A:NOT DONE]* ◯ Not done *[A:NORMAL]* ◯ Normal *[A:ABNORMAL]* ◯ **[lstGASTROINNEW2]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* ◯ No *[A:Y]* ◯ **[txtGASTROINNEWSP2]** Yes, please specify A200 **[lstGASTROINCS2]** Is the abnormality clinically significant? *[A:Y]* ◯ Yes *[A:N]* ◯ No
15.* ✔	Musculoskeletal/Extremities [Musculoskeletal/Extremities]	**[lstMUSCULO2]** *[A:NOT DONE]* ◯ Not done *[A:NORMAL]* ◯ Normal *[A:ABNORMAL]* ◯ **[lstMUSCULONEW2]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* ◯ No *[A:Y]* ◯ **[txtMUSCULONEWSP2]** Yes, please specify A200 **[lstMUSCULOCS2]** Is the abnormality clinically significant? *[A:Y]* ◯ Yes *[A:N]* ◯ No
16. ✔	Neurologic [Neurologic]	**[lstNEURO2]** *[A:NOT DONE]* ◯ Not done *[A:NORMAL]* ◯ Normal *[A:ABNORMAL]* ◯ **[lstNEURONEW2]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* ◯ No *[A:Y]* ◯ **[cmpNEURONEW2]** Yes, please specify **[txtNEURONEWSP2]** A200 **[lstNEUROCS2]** Is the abnormality clinically significant? *[A:Y]* ◯ Yes *[A:N]* ◯ No

	Other abnormalities	Other clinical significance
17. ✔		

Directed Physical Examination - 6H Postdose - Other Entry [sctPEOTH6H]

- If there are any other abnormalities, please record in the Add Entry section below
- Please record only one abnormality per row

17.1* ✔	Other abnormalities [Other abnormalities]	**[txtPEOTH2]** A200
17.2* ✔	Is the abnormality clinically significant? [Other clinical significance]	**[lstPEOTHCS2]** *[A:Y]* ◯ Yes *[A:N]* ◯ No

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: Directed Physical Examination (Day 1)

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clNDNormalAbnormal	String		Not done	NOT DONE	citmNDNormalAbnormal_ND	lstRESPIRAT, lstCARDIOVA, lstSKIN, lstGASTROIN, lstMUSCULO, lstNEURO, lstRESPIRAT2, lstCARDIOVA2, lstSKIN2, lstGASTROIN2, lstMUSCULO2, lstNEURO2
			Normal	NORMAL	citmNDNormalAbnormal_Normal	
			Abnormal	ABNORMAL	citmNDNormalAbnormal_Abnormal	
clNoYes	String		No	N	citmNoYes_N	lstRESPIRATNEW, lstCARDIOVANEW, lstSKINNEW, lstGASTROINNEW, lstMUSCULONEW, lstNEURONEW, lstRESPIRATNEW2, lstCARDIOVANEW2, lstSKINNEW2, lstGASTROINNEW2, lstMUSCULONEW2, lstNEURONEW2
			Yes	Y	citmNoYes_Y	
clYesNo	String		Yes	Y	citmYesNo_Y	lstRESPIRATCS, lstCARDIOVACS, lstSKINCS, lstGASTROINCS, lstMUSCULOCS, lstNEUROCS, lstPEOTHCS, lstRESPIRATCS2, lstCARDIOVACS2, lstSKINCS2, lstGASTROINCS2, lstMUSCULOCS2, lstNEUROCS2, lstPEOTHCS2
			No	N	citmYesNo_N	

RDE Analytics: RD_FRMPE_D1

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
lstRESPIRAT	LSTRESPIRAT_C	VARCHAR2
	LSTRESPIRAT	VARCHAR2
	LSTRESPIRAT_ND	VARCHAR2
lstRESPIRAT - lstRESPIRATNEW	LSTRESPIRATNEW_C	VARCHAR2
	LSTRESPIRATNEW	VARCHAR2
lstRESPIRAT - txtRESPIRATNEWSP	TXTRESPIRATNEWSP	VARCHAR2
lstRESPIRAT - lstRESPIRATCS	LSTRESPIRATCS_C	VARCHAR2
	LSTRESPIRATCS	VARCHAR2
lstCARDIOVA	LSTCARDIOVA_C	VARCHAR2
	LSTCARDIOVA	VARCHAR2

	LSTCARDIOVA_ND	VARCHAR2
lstCARDIOVA - lstCARDIOVANEW	LSTCARDIOVANEW_C	VARCHAR2
	LSTCARDIOVANEW	VARCHAR2
lstCARDIOVA - txtCARDIOVANEWSP	TXTCARDIOVANEWSP	VARCHAR2
lstCARDIOVA - lstCARDIOVACS	LSTCARDIOVACS_C	VARCHAR2
	LSTCARDIOVACS	VARCHAR2
lstSKIN	LSTSKIN_C	VARCHAR2
	LSTSKIN	VARCHAR2
	LSTSKIN_ND	VARCHAR2
lstSKIN - lstSKINNEW	LSTSKINNEW_C	VARCHAR2
	LSTSKINNEW	VARCHAR2
lstSKIN - txtSKINNEWSP	TXTSKINNEWSP	VARCHAR2
lstSKIN - lstSKINCS	LSTSKINCS_C	VARCHAR2
	LSTSKINCS	VARCHAR2
lstGASTROIN	LSTGASTROIN_C	VARCHAR2
	LSTGASTROIN	VARCHAR2
	LSTGASTROIN_ND	VARCHAR2
lstGASTROIN - lstGASTROINNEW	LSTGASTROINNEW_C	VARCHAR2
	LSTGASTROINNEW	VARCHAR2
lstGASTROIN - txtGASTROINNEWSP	TXTGASTROINNEWSP	VARCHAR2
lstGASTROIN - lstGASTROINCS	LSTGASTROINCS_C	VARCHAR2
	LSTGASTROINCS	VARCHAR2
lstMUSCULO	LSTMUSCULO_C	VARCHAR2
	LSTMUSCULO	VARCHAR2
	LSTMUSCULO_ND	VARCHAR2
lstMUSCULO - lstMUSCULONEW	LSTMUSCULONEW_C	VARCHAR2
	LSTMUSCULONEW	VARCHAR2
lstMUSCULO - txtMUSCULONEWSP	TXTMUSCULONEWSP	VARCHAR2
lstMUSCULO - lstMUSCULOCS	LSTMUSCULOCS_C	VARCHAR2
	LSTMUSCULOCS	VARCHAR2
lstNEURO	LSTNEURO_C	VARCHAR2
	LSTNEURO	VARCHAR2
	LSTNEURO_ND	VARCHAR2
lstNEURO - lstNEURONEW	LSTNEURONEW_C	VARCHAR2
	LSTNEURONEW	VARCHAR2
lstNEURO - txtNEURONEWSP	TXTNEURONEWSP	VARCHAR2
lstNEURO - lstNEUROCS	LSTNEUROCS_C	VARCHAR2
	LSTNEUROCS	VARCHAR2
dtmASS_T2	DTMASS_T2	DATE
	DTMASS_T2_TMS	VARCHAR2
	DTMASS_T2_ND	VARCHAR2
lstRESPIRAT2	LSTRESPIRAT2_C	VARCHAR2
	LSTRESPIRAT2	VARCHAR2
	LSTRESPIRAT2_ND	VARCHAR2
lstRESPIRAT2 - lstRESPIRATNEW2	LSTRESPIRATNEW2_C	VARCHAR2
	LSTRESPIRATNEW2	VARCHAR2
lstRESPIRAT2 - txtRESPIRATNEWSP2	TXTRESPIRATNEWSP2	VARCHAR2
lstRESPIRAT2 - lstRESPIRATCS2	LSTRESPIRATCS2_C	VARCHAR2
	LSTRESPIRATCS2	VARCHAR2
lstCARDIOVA2	LSTCARDIOVA2_C	VARCHAR2
	LSTCARDIOVA2	VARCHAR2
	LSTCARDIOVA2_ND	VARCHAR2
lstCARDIOVA2 - lstCARDIOVANEW2	LSTCARDIOVANEW2_C	VARCHAR2

	LSTCARDIOVANEW2	VARCHAR2
lstCARDIOVA2 - txtCARDIOVANEWSP2	TXTCARDIOVANEWSP2	VARCHAR2
lstCARDIOVA2 - lstCARDIOVACS2	LSTCARDIOVACS2_C	VARCHAR2
	LSTCARDIOVACS2	VARCHAR2
lstSKIN2	LSTSKIN2_C	VARCHAR2
	LSTSKIN2	VARCHAR2
	LSTSKIN2_ND	VARCHAR2
lstSKIN2 - lstSKINNEW2	LSTSKINNEW2_C	VARCHAR2
	LSTSKINNEW2	VARCHAR2
lstSKIN2 - txtSKINNEWSP2	TXTSKINNEWSP2	VARCHAR2
lstSKIN2 - lstSKINCS2	LSTSKINCS2_C	VARCHAR2
	LSTSKINCS2	VARCHAR2
lstGASTROIN2	LSTGASTROIN2_C	VARCHAR2
	LSTGASTROIN2	VARCHAR2
	LSTGASTROIN2_ND	VARCHAR2
lstGASTROIN2 - lstGASTROINNEW2	LSTGASTROINNEW2_C	VARCHAR2
	LSTGASTROINNEW2	VARCHAR2
lstGASTROIN2 - txtGASTROINNEWSP2	TXTGASTROINNEWSP2	VARCHAR2
lstGASTROIN2 - lstGASTROINCS2	LSTGASTROINCS2_C	VARCHAR2
	LSTGASTROINCS2	VARCHAR2
lstMUSCULO2	LSTMUSCULO2_C	VARCHAR2
	LSTMUSCULO2	VARCHAR2
	LSTMUSCULO2_ND	VARCHAR2
lstMUSCULO2 - lstMUSCULONEW2	LSTMUSCULONEW2_C	VARCHAR2
	LSTMUSCULONEW2	VARCHAR2
lstMUSCULO2 - txtMUSCULONEWSP2	TXTMUSCULONEWSP2	VARCHAR2
lstMUSCULO2 - lstMUSCULOCS2	LSTMUSCULOCS2_C	VARCHAR2
	LSTMUSCULOCS2	VARCHAR2
lstNEURO2	LSTNEURO2_C	VARCHAR2
	LSTNEURO2	VARCHAR2
	LSTNEURO2_ND	VARCHAR2
lstNEURO2 - lstNEURONEW2	LSTNEURONEW2_C	VARCHAR2
	LSTNEURONEW2	VARCHAR2
lstNEURO2 - txtNEURONEWSP2	TXTNEURONEWSP2	VARCHAR2
lstNEURO2 - lstNEUROCS2	LSTNEUROCS2_C	VARCHAR2
	LSTNEUROCS2	VARCHAR2
RD_FRMPE_D1_SCTPEOTHPRE		
txtPEOTH	TXTPEOTH	VARCHAR2
	TXTPEOTH_ND	VARCHAR2
lstPEOTHCS	LSTPEOTHCS_C	VARCHAR2
	LSTPEOTHCS	VARCHAR2
	LSTPEOTHCS_ND	VARCHAR2
RD_FRMPE_D1_SCTPEOTH6H		
txtPEOTH2	TXTPEOTH2	VARCHAR2
	TXTPEOTH2_ND	VARCHAR2
lstPEOTHCS2	LSTPEOTHCS2_C	VARCHAR2
	LSTPEOTHCS2	VARCHAR2
	LSTPEOTHCS2_ND	VARCHAR2

AT3SC002: Vital Signs (Day 1) (VS D1) [frmVS_D1]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ○ Same date as visit date *[A:OTHER]* ○ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
Weight [sctANTMEAS]		
2.* ✔	Weight [Weight]	**[numWEIGHT]** xxx.x kg[b]
Vital Signs Predose [sctVSPRE]		
Should be measured in supine position after 10 minutes of rest. If it is a new, clinically significant finding started after first dose of study drug, please also record it on the AE form		
3.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
4.* ✔	Blood pressure [Blood pressure]	**[cmpBP1]** **[numSYSBP1]** **[numDIABP1]** (mmHg) N3 / N3 systolic / diastolic
5.* ✔	Heart rate [Heart rate]	**[numHR1]** N3 bpm[b]
6.* ✔	Body temperature [Body temperature]	**[numTEMP1]** xx.x C[b]
7.* ✔	Respiratory rate [Respiratory rate]	**[numRR1]** N2 breaths per minute
Vital Signs 6 Hours Postdose [sctVS6H]		
Should be measured in supine position after 10 minutes of rest. In case a new, clinically significant finding started after first dose of study drug, please also record it on the AE form.		
8.* ✔	Time performed [Time performed]	**[dtmASS_T2] (hh:mm)** Req : Req *24-hour clock*
9.* ✔	Blood pressure [Blood pressure]	**[cmpBP2]** **[numSYSBP2]** **[numDIABP2]** (mmHg) N3 / N3 systolic / diastolic
10.* ✔	Heart rate [Heart rate]	**[numHR2]** N3 bpm[b]
11.* ✔	Body temperature [Body temperature]	**[numTEMP2]** xx.x C[b]
12.* ✔	Respiratory rate [Respiratory rate]	**[numRR2]** N2 breaths per minute

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.

Codelist Values Tables: Vital Signs (Day 1)

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	

RDE Analytics: RD_FRMVS_D1

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
numWEIGHT	NUMWEIGHT	FLOAT
	NUMWEIGHT_U	VARCHAR2
	NUMWEIGHT_ND	VARCHAR2
dtmASS_T	DTMASS_T	DATE

	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
cmpBP1	CMPBP1_ND	VARCHAR2
cmpBP1 - numSYSBP1	NUMSYSBP1	NUMBER
cmpBP1 - numDIABP1	NUMDIABP1	NUMBER
numHR1	NUMHR1	NUMBER
	NUMHR1_U	VARCHAR2
	NUMHR1_ND	VARCHAR2
numTEMP1	NUMTEMP1	FLOAT
	NUMTEMP1_U	VARCHAR2
	NUMTEMP1_ND	VARCHAR2
numRR1	NUMRR1	NUMBER
	NUMRR1_ND	VARCHAR2
dtmASS_T2	DTMASS_T2	DATE
	DTMASS_T2_TMS	VARCHAR2
	DTMASS_T2_ND	VARCHAR2
cmpBP2	CMPBP2_ND	VARCHAR2
cmpBP2 - numSYSBP2	NUMSYSBP2	NUMBER
cmpBP2 - numDIABP2	NUMDIABP2	NUMBER
numHR2	NUMHR2	NUMBER
	NUMHR2_U	VARCHAR2
	NUMHR2_ND	VARCHAR2
numTEMP2	NUMTEMP2	FLOAT
	NUMTEMP2_U	VARCHAR2
	NUMTEMP2_ND	VARCHAR2
numRR2	NUMRR2	NUMBER
	NUMRR2_ND	VARCHAR2

AT3SC002: 12-lead ECG (ECG) [frmECG]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
12-lead Electrocardiogram - Predose [sctPRE]		
Supine after at least 10 minutes rest		
2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
3.* ✔	Rhythm [Rhythm]	**[lstRHYTM]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
4.* ✔	Ventricular rate [Ventricular rate]	**[numVR]** N3 bpm[b]
5.* ✔	PR interval [PR]	**[numPR]** N3 msec[b]
6.* ✔	QRS duration [QRS]	**[numQRS]** N3 msec[b]
7.* ✔	QT interval [QT]	**[numQT]** N3 msec[b]
8.* ✔	QTc interval [QTc]	**[numQTCF]** N3 msec[b]
9.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
10. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN1]** *[A:SINUS BRADYCARDIA]* ☐ Sinus Bradycardia *[A:SINUS TACHYCARDIA]* ☐ Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* ☐ Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* ☐ Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* ☐ Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* ☐ Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* ☐ Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* ☐ Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* ☐ Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* ☐ Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* ☐ Atrial Fibrillation *[A:ATRIAL PACING]* ☐ Atrial Pacing *[A:VENTRICULAR PACING]* ☐ Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* ☐ Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* ☐ 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* ☐ 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* ☐ 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* ☐ 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* ☐ Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* ☐ Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* ☐ Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* ☐ Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* ☐ Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* ☐ Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* ☐ Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* ☐ Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* ☐ Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* ☐ Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* ☐ Inferior Infarct Pattern *[A:OTHER, SPECIFY]* ☐ **[txtABNOTH1]** Other, specify A128

12-lead Electrocardiogram - 30 Minutes Postdose [sct30M]

11.* ✔	Time performed [Time performed]	**[dtmASS_T2] (hh:mm)** Req : Req *24-hour clock*
12.* ✔	Rhythm [Rhythm]	**[lstRHYTM2]** *[A:NORMAL]* Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* Abnormal, Clinically Significant
13.* ✔	Ventricular rate [Ventricular rate]	**[numVR2]** N3 bpm[b]
14.* ✔	PR interval [PR]	**[numPR2]** N3 msec[b]
15.* ✔	QRS duration [QRS]	**[numQRS2]** N3 msec[b]
16.* ✔	QT interval [QT]	**[numQT2]** N3 msec[b]
17.* ✔	QTc interval [QTc]	**[numQTCF2]** N3 msec[b]
18.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT2]** *[A:NORMAL]* Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* Abnormal, Clinically Significant
19. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN2]** *[A:SINUS BRADYCARDIA]* Sinus Bradycardia *[A:SINUS TACHYCARDIA]* Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* Atrial Fibrillation *[A:ATRIAL PACING]* Atrial Pacing *[A:VENTRICULAR PACING]* Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* Inferior Infarct Pattern *[A:OTHER, SPECIFY]* **[txtABNOTH2]** Other, specify A128
20.* ✔	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	**[lstCHANGE1]** *[A:NO SIGNIFICANT WORSENING FROM BASELINE]* No significant worsening from baseline *[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]* **[txtCHANGE1]** Clinically significant worsening from baseline, specify A128

12-lead Electrocardiogram - 2 Hours Postdose [sct2H]

21.* ✔	Time performed [Time performed]	**[dtmASS_T3] (hh:mm)** Req : Req *24-hour clock*
22.* ✔	Rhythm [Rhythm]	**[lstRHYTM3]** *[A:NORMAL]* Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* Abnormal, Clinically Significant
23.* ✔	Ventricular rate [Ventricular rate]	**[numVR3]** N3 bpm[b]
24.* ✔	PR interval [PR]	**[numPR3]** N3 msec[b]
25.* ✔	QRS duration [QRS]	**[numQRS3]** N3 msec[b]
26.* ✔	QT interval [QT]	**[numQT3]** N3 msec[b]
27.* ✔	QTc interval [QTc]	**[numQTCF3]** N3 msec[b]
28.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT3]** *[A:NORMAL]* Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* Abnormal, Clinically Significant
29. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN3]** *[A:SINUS BRADYCARDIA]* Sinus Bradycardia *[A:SINUS TACHYCARDIA]* Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* Atrial Fibrillation *[A:ATRIAL PACING]* Atrial Pacing *[A:VENTRICULAR PACING]* Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* Inferior Infarct Pattern *[A:OTHER, SPECIFY]* **[txtABNOTH3]** Other, specify A128
30.* ✔	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	**[lstCHANGE2]** *[A:NO SIGNIFICANT WORSENING FROM BASELINE]* No significant worsening from baseline *[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]* **[txtCHANGE2]** Clinically significant worsening from baseline, specify A128
12-lead Electrocardiogram - 4 Hours Postdose [sct4H]		
31.*	Time performed	**[dtmASS_T4] (hh:mm)**

✔	[Time performed]	Req : Req *24-hour clock*
32.* ✔	Rhythm [Rhythm]	**[lstRHYTM4]** *[A:NORMAL]* Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* Abnormal, Clinically Significant
33.* ✔	Ventricular rate [Ventricular rate]	**[numVR4]** N3 bpm[b]
34.* ✔	PR interval [PR]	**[numPR4]** N3 msec[b]
35.* ✔	QRS duration [QRS]	**[numQRS4]** N3 msec[b]
36.* ✔	QT interval [QT]	**[numQT4]** N3 msec[b]
37.* ✔	QTc interval [QTc]	**[numQTCF4]** N3 msec[b]
38.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT4]** *[A:NORMAL]* Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* Abnormal, Clinically Significant
39. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN4]** *[A:SINUS BRADYCARDIA]* Sinus Bradycardia *[A:SINUS TACHYCARDIA]* Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* Atrial Fibrillation *[A:ATRIAL PACING]* Atrial Pacing *[A:VENTRICULAR PACING]* Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* Inferior Infarct Pattern *[A:OTHER, SPECIFY]* **[txtABNOTH4]** Other, specify A128
40.* ✔	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	**[lstCHANGE3]** *[A:NO SIGNIFICANT WORSENING FROM BASELINE]* No significant worsening from baseline *[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]* **[txtCHANGE3]** Clinically significant worsening from baseline, specify A128

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.

Codelist Values Tables: 12-lead ECG

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	lstRHYTM, lstRHYTM2, lstRHYTM3, lstRHYTM4
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	lstOVERALLINT, lstOVERALLINT2, lstOVERALLINT3, lstOVERALLINT4
			Abnormal, Not Clinically Significant	ABNORMAL, NOT CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalNCS	
			Abnormal, Clinically Significant	ABNORMAL, CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalCS	
clABN	String		Sinus Bradycardia	SINUS BRADYCARDIA	citmABN_SinusBradycardia	lstABN1, lstABN2, lstABN3, lstABN4
			Sinus Tachycardia	SINUS TACHYCARDIA	citmABN_SinusTachycardia	
			Atrial Tachycardia	ATRIAL TACHYCARDIA	citmABN_AtrialTachycardia	
			Ventricular Tachycardia	VENTRICULAR TACHYCARDIA	citmABN_VentricularTachycardia	
			Sick Sinus Syndrome	SICK SINUS SYNDROME	citmABN_SickSinusSyndrome	
			Premature Atrial Complexes	PREMATURE ATRIAL COMPLEXES	citmABN_PrematureAtrialComplexes	
			Premature Ventricular Complexes	PREMATURE VENTRICULAR COMPLEXES	citmABN_PrematureVentricularComplexes	
			Q Axis, Left Axis Deviation	Q AXIS LEFT AXIS DEVIATION	citmABN_QAxisLeftAxisDeviation	
			Left Atrial Abnormality	LEFT ATRIAL ABNORMALITY	citmABN_LeftAtrialAbnormality	
			Left Ventricular Hypertrophy	LEFT VENTRICULAR HYPERTROPHY	citmABN_LeftVentricularHypertrophy	
			Atrial Fibrillation	ATRIAL FIBRILLATION	citmABN_AtrialFibrillation	
			Atrial Pacing	ATRIAL PACING	citmABN_AtrialPacing	
			Ventricular Pacing	VENTRICULAR PACING	citmABN_VentricularPacing	
			Atrial Ventricular Pacing	ATRIAL VENTRICULAR PACING	citmABN_AtrialVentricularPacing	
			1st Degree A-V Block	1ST DEGREE A-V BLOCK	citmABN_1stDegreeAVBlock	
			2nd Degree A-V Block Type I	2ND DEGREE A-V BLOCK TYPE I	citmABN_2ndDegreeAVBlockTypeI	
			2nd Degree A-V Block Type II	2ND DEGREE A-V BLOCK TYPE II	citmABN_2ndDegreeAVBlockTypeII	
			3rd Degree A-V Block	3RD DEGREE A-V BLOCK	citmABN_3rdDegreeAVBlock	
			Left Bundle Branch Block	LEFT BUNDLE BRANCH BLOCK	citmABN_LeftBundleBranchBlock	
			Incomplete Left Bundle Branch Block	INCOMPLETE LEFT BUNDLE BRANCH BLOCK	citmABN_IncompleteLeftBundleBranchBlock	
			Left Anterior Hemiblock	LEFT ANTERIOR HEMIBLOCK	citmABN_LeftAnteriorHemiblock	
			Left Posterior Hemiblock	LEFT POSTERIOR HEMIBLOCK	citmABN_LeftPosteriorHemiblock	
			Right Bundle Branch Block	RIGHT BUNDLE BRANCH BLOCK	citmABN_RightBundleBranchBlock	
			Incomplete Right Bundle Branch Block	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK	citmABN_IncompleteRightBundleBranchBlock	
			Intraventricular Conduction Delay	INTRAVENTRICULAR CONDUCTION DELAY	citmABN_IntraventricularConductionDelay	
			Anteroseptal Infarct Pattern	ANTEROSEPTAL INFARCT PATTERN	citmABN_AnteroseptalInfarctPattern	
			Anterolateral Infarct Pattern	ANTEROLATERAL INFARCT PATTERN	citmABN_AnterolateralInfarctPattern	
			Lateral Infarct Pattern	LATERAL INFARCT PATTERN	citmABN_LateralInfarctPattern	
			Inferior Infarct Pattern	INFERIOR INFARCT PATTERN	citmABN_InferiorInfarctPattern	
			Other, specify	OTHER, SPECIFY	citmABN_Otherspecify	
clCHANGE	String		No significant worsening from baseline	NO SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_NOSIGNIFICANTWORSENINGFROMBASELINE	lstCHANGE1
			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE	
clCHANGE_1	String		No significant worsening from baseline	NO SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_NOSIGNIFICANTWORSENINGFROMBASELINE_1	lstCHANGE2
			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE_1	
clCHANGE_1_1	String		No significant worsening from baseline	NO SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_NOSIGNIFICANTWORSENINGFROMBASELINE_1_1	lstCHANGE3
			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE_1_1	

RDE Analytics: RD_FRMECG

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE

	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
lstRHYTM	LSTRHYTM_C	VARCHAR2
	LSTRHYTM	VARCHAR2
	LSTRHYTM_ND	VARCHAR2
numVR	NUMVR	NUMBER
	NUMVR_U	VARCHAR2
	NUMVR_ND	VARCHAR2
numPR	NUMPR	NUMBER
	NUMPR_U	VARCHAR2
	NUMPR_ND	VARCHAR2
numQRS	NUMQRS	NUMBER
	NUMQRS_U	VARCHAR2
	NUMQRS_ND	VARCHAR2
numQT	NUMQT	NUMBER
	NUMQT_U	VARCHAR2
	NUMQT_ND	VARCHAR2
numQTCF	NUMQTCF	NUMBER
	NUMQTCF_U	VARCHAR2
	NUMQTCF_ND	VARCHAR2
lstOVERALLINT	LSTOVERALLINT_C	VARCHAR2
	LSTOVERALLINT	VARCHAR2
	LSTOVERALLINT_ND	VARCHAR2
lstABN1	LSTABN1_ND	VARCHAR2
lstABN1 - Sinus Bradycardia	*LSTABN1_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN1 - Sinus Tachycardia	*LSTABN1_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN1 - Atrial Tachycardia	*LSTABN1_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN1 - Ventricular Tachycardia	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN1 - Sick Sinus Syndrome	*LSTABN1_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN1_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN1 - Premature Atrial Complexes	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN1 - Premature Ventricular Complexes	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN1 - Q Axis, Left Axis Deviation	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN1 - Left Atrial Abnormality	*LSTABN1_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN1 - Left Ventricular Hypertrophy	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN1 - Atrial Fibrillation	*LSTABN1_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN1_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN1 - Atrial Pacing	*LSTABN1_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALPACING	VARCHAR2
lstABN1 - Ventricular Pacing	*LSTABN1_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARPACING	VARCHAR2
lstABN1 - Atrial Ventricular Pacing	*LSTABN1_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2

	*LSTABN1_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN1 - 1st Degree A-V Block	*LSTABN1_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN1 - 2nd Degree A-V Block Type I	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN1 - 2nd Degree A-V Block Type II	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN1 - 3rd Degree A-V Block	*LSTABN1_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN1 - Left Bundle Branch Block	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Left Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Left Anterior Hemiblock	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Left Posterior Hemiblock	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Right Bundle Branch Block	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Right Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Intraventricular Conduction Delay	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN1 - Anteroseptal Infarct Pattern	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN1 - Anterolateral Infarct Pattern	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Lateral Infarct Pattern	*LSTABN1_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Inferior Infarct Pattern	*LSTABN1_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN1 - Other, specify	LSTABN1_TXTABNOTH1_C	VARCHAR2
	LSTABN1_TXTABNOTH1	VARCHAR2
lstABN1 - txtABNOTH1	TXTABNOTH1	VARCHAR2
dtmASS_T2	DTMASS_T2	DATE
	DTMASS_T2_TMS	VARCHAR2
	DTMASS_T2_ND	VARCHAR2
lstRHYTM2	LSTRHYTM2_C	VARCHAR2
	LSTRHYTM2	VARCHAR2
	LSTRHYTM2_ND	VARCHAR2
numVR2	NUMVR2	NUMBER
	NUMVR2_U	VARCHAR2
	NUMVR2_ND	VARCHAR2
numPR2	NUMPR2	NUMBER
	NUMPR2_U	VARCHAR2
	NUMPR2_ND	VARCHAR2
numQRS2	NUMQRS2	NUMBER
	NUMQRS2_U	VARCHAR2
	NUMQRS2_ND	VARCHAR2
numQT2	NUMQT2	NUMBER
	NUMQT2_U	VARCHAR2
	NUMQT2_ND	VARCHAR2
numQTCF2	NUMQTCF2	NUMBER

	NUMQTCF2_U	VARCHAR2
	NUMQTCF2_ND	VARCHAR2
lstOVERALLINT2	LSTOVERALLINT2_C	VARCHAR2
	LSTOVERALLINT2	VARCHAR2
	LSTOVERALLINT2_ND	VARCHAR2
lstABN2	LSTABN2_ND	VARCHAR2
lstABN2 - Sinus Bradycardia	*LSTABN2_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN2 - Sinus Tachycardia	*LSTABN2_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN2 - Atrial Tachycardia	*LSTABN2_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN2 - Ventricular Tachycardia	*LSTABN2_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN2 - Sick Sinus Syndrome	*LSTABN2_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN2_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN2 - Premature Atrial Complexes	*LSTABN2_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN2_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN2 - Premature Ventricular Complexes	*LSTABN2_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN2_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN2 - Q Axis, Left Axis Deviation	*LSTABN2_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN2_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN2 - Left Atrial Abnormality	*LSTABN2_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN2_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN2 - Left Ventricular Hypertrophy	*LSTABN2_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN2_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN2 - Atrial Fibrillation	*LSTABN2_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN2_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN2 - Atrial Pacing	*LSTABN2_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN2_CITMABNATRIALPACING	VARCHAR2
lstABN2 - Ventricular Pacing	*LSTABN2_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN2_CITMABNVENTRICULARPACING	VARCHAR2
lstABN2 - Atrial Ventricular Pacing	*LSTABN2_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN2_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN2 - 1st Degree A-V Block	*LSTABN2_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN2_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN2 - 2nd Degree A-V Block Type I	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN2 - 2nd Degree A-V Block Type II	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN2 - 3rd Degree A-V Block	*LSTABN2_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN2_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN2 - Left Bundle Branch Block	*LSTABN2_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN2 - Incomplete Left Bundle Branch Block	*LSTABN2_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN2 - Left Anterior Hemiblock	*LSTABN2_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN2 - Left Posterior Hemiblock	*LSTABN2_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN2 - Right Bundle Branch Block	*LSTABN2_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN2 - Incomplete Right Bundle Branch Block	*LSTABN2_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2

	*LSTABN2_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN2 - Intraventricular Conduction Delay	*LSTABN2_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN2_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN2 - Anteroseptal Infarct Pattern	*LSTABN2_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN2 - Anterolateral Infarct Pattern	*LSTABN2_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN2 - Lateral Infarct Pattern	*LSTABN2_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN2 - Inferior Infarct Pattern	*LSTABN2_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN2 - Other, specify	LSTABN2_TXTABNOTH2_C	VARCHAR2
	LSTABN2_TXTABNOTH2	VARCHAR2
lstABN2 - txtABNOTH2	TXTABNOTH2	VARCHAR2
lstCHANGE1	LSTCHANGE1_C	VARCHAR2
	LSTCHANGE1	VARCHAR2
	LSTCHANGE1_ND	VARCHAR2
lstCHANGE1 - txtCHANGE1	TXTCHANGE1	VARCHAR2
dtmASS_T3	DTMASS_T3	DATE
	DTMASS_T3_TMS	VARCHAR2
	DTMASS_T3_ND	VARCHAR2
lstRHYTM3	LSTRHYTM3_C	VARCHAR2
	LSTRHYTM3	VARCHAR2
	LSTRHYTM3_ND	VARCHAR2
numVR3	NUMVR3	NUMBER
	NUMVR3_U	VARCHAR2
	NUMVR3_ND	VARCHAR2
numPR3	NUMPR3	NUMBER
	NUMPR3_U	VARCHAR2
	NUMPR3_ND	VARCHAR2
numQRS3	NUMQRS3	NUMBER
	NUMQRS3_U	VARCHAR2
	NUMQRS3_ND	VARCHAR2
numQT3	NUMQT3	NUMBER
	NUMQT3_U	VARCHAR2
	NUMQT3_ND	VARCHAR2
numQTCF3	NUMQTCF3	NUMBER
	NUMQTCF3_U	VARCHAR2
	NUMQTCF3_ND	VARCHAR2
lstOVERALLINT3	LSTOVERALLINT3_C	VARCHAR2
	LSTOVERALLINT3	VARCHAR2
	LSTOVERALLINT3_ND	VARCHAR2
lstABN3	LSTABN3_ND	VARCHAR2
lstABN3 - Sinus Bradycardia	*LSTABN3_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN3 - Sinus Tachycardia	*LSTABN3_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN3 - Atrial Tachycardia	*LSTABN3_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN3 - Ventricular Tachycardia	*LSTABN3_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN3 - Sick Sinus Syndrome	*LSTABN3_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN3_CITMABNSICKSINUSSYNDROME	VARCHAR2

lstABN3 - Premature Atrial Complexes	*LSTABN3_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN3_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN3 - Premature Ventricular Complexes	*LSTABN3_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN3_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN3 - Q Axis, Left Axis Deviation	*LSTABN3_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN3_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN3 - Left Atrial Abnormality	*LSTABN3_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN3_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN3 - Left Ventricular Hypertrophy	*LSTABN3_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN3_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN3 - Atrial Fibrillation	*LSTABN3_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN3_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN3 - Atrial Pacing	*LSTABN3_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN3_CITMABNATRIALPACING	VARCHAR2
lstABN3 - Ventricular Pacing	*LSTABN3_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN3_CITMABNVENTRICULARPACING	VARCHAR2
lstABN3 - Atrial Ventricular Pacing	*LSTABN3_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN3_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN3 - 1st Degree A-V Block	*LSTABN3_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN3_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN3 - 2nd Degree A-V Block Type I	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN3 - 2nd Degree A-V Block Type II	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN3 - 3rd Degree A-V Block	*LSTABN3_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN3_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN3 - Left Bundle Branch Block	*LSTABN3_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN3 - Incomplete Left Bundle Branch Block	*LSTABN3_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN3 - Left Anterior Hemiblock	*LSTABN3_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN3 - Left Posterior Hemiblock	*LSTABN3_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN3 - Right Bundle Branch Block	*LSTABN3_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN3 - Incomplete Right Bundle Branch Block	*LSTABN3_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN3 - Intraventricular Conduction Delay	*LSTABN3_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN3_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN3 - Anteroseptal Infarct Pattern	*LSTABN3_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN3_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN3 - Anterolateral Infarct Pattern	*LSTABN3_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN3_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN3 - Lateral Infarct Pattern	*LSTABN3_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN3_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN3 - Inferior Infarct Pattern	*LSTABN3_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN3_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN3 - Other, specify	LSTABN3_TXTABNOTH3_C	VARCHAR2
	LSTABN3_TXTABNOTH3	VARCHAR2
lstABN3 - txtABNOTH3	TXTABNOTH3	VARCHAR2
lstCHANGE2	LSTCHANGE2_C	VARCHAR2
	LSTCHANGE2	VARCHAR2

	LSTCHANGE2_ND	VARCHAR2
lstCHANGE2 - txtCHANGE2	TXTCHANGE2	VARCHAR2
dtmASS_T4	DTMASS_T4	DATE
	DTMASS_T4_TMS	VARCHAR2
	DTMASS_T4_ND	VARCHAR2
lstRHYTM4	LSTRHYTM4_C	VARCHAR2
	LSTRHYTM4	VARCHAR2
	LSTRHYTM4_ND	VARCHAR2
numVR4	NUMVR4	NUMBER
	NUMVR4_U	VARCHAR2
	NUMVR4_ND	VARCHAR2
numPR4	NUMPR4	NUMBER
	NUMPR4_U	VARCHAR2
	NUMPR4_ND	VARCHAR2
numQRS4	NUMQRS4	NUMBER
	NUMQRS4_U	VARCHAR2
	NUMQRS4_ND	VARCHAR2
numQT4	NUMQT4	NUMBER
	NUMQT4_U	VARCHAR2
	NUMQT4_ND	VARCHAR2
numQTCF4	NUMQTCF4	NUMBER
	NUMQTCF4_U	VARCHAR2
	NUMQTCF4_ND	VARCHAR2
lstOVERALLINT4	LSTOVERALLINT4_C	VARCHAR2
	LSTOVERALLINT4	VARCHAR2
	LSTOVERALLINT4_ND	VARCHAR2
lstABN4	LSTABN4_ND	VARCHAR2
lstABN4 - Sinus Bradycardia	*LSTABN4_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN4 - Sinus Tachycardia	*LSTABN4_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN4 - Atrial Tachycardia	*LSTABN4_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN4 - Ventricular Tachycardia	*LSTABN4_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN4 - Sick Sinus Syndrome	*LSTABN4_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN4_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN4 - Premature Atrial Complexes	*LSTABN4_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN4_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN4 - Premature Ventricular Complexes	*LSTABN4_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN4_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN4 - Q Axis, Left Axis Deviation	*LSTABN4_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN4_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN4 - Left Atrial Abnormality	*LSTABN4_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN4_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN4 - Left Ventricular Hypertrophy	*LSTABN4_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN4_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN4 - Atrial Fibrillation	*LSTABN4_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN4_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN4 - Atrial Pacing	*LSTABN4_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN4_CITMABNATRIALPACING	VARCHAR2
lstABN4 - Ventricular Pacing	*LSTABN4_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN4_CITMABNVENTRICULARPACING	VARCHAR2

lstABN4 - Atrial Ventricular Pacing	*LSTABN4_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN4_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN4 - 1st Degree A-V Block	*LSTABN4_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN4_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN4 - 2nd Degree A-V Block Type I	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN4 - 2nd Degree A-V Block Type II	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN4 - 3rd Degree A-V Block	*LSTABN4_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN4_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN4 - Left Bundle Branch Block	*LSTABN4_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN4 - Incomplete Left Bundle Branch Block	*LSTABN4_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN4 - Left Anterior Hemiblock	*LSTABN4_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN4 - Left Posterior Hemiblock	*LSTABN4_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN4 - Right Bundle Branch Block	*LSTABN4_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN4 - Incomplete Right Bundle Branch Block	*LSTABN4_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN4 - Intraventricular Conduction Delay	*LSTABN4_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN4_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN4 - Anteroseptal Infarct Pattern	*LSTABN4_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN4 - Anterolateral Infarct Pattern	*LSTABN4_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN4 - Lateral Infarct Pattern	*LSTABN4_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN4 - Inferior Infarct Pattern	*LSTABN4_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN4 - Other, specify	LSTABN4_TXTABNOTH4_C	VARCHAR2
	LSTABN4_TXTABNOTH4	VARCHAR2
lstABN4 - txtABNOTH4	TXTABNOTH4	VARCHAR2
lstCHANGE3	LSTCHANGE3_C	VARCHAR2
	LSTCHANGE3	VARCHAR2
	LSTCHANGE3_ND	VARCHAR2
lstCHANGE3 - txtCHANGE3	TXTCHANGE3	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: Whole Blood Clot Formation (ROTEM) (WBCLT) [frmWBCLT]		
1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* Same date as visit date *[A:OTHER]* **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** 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.

Codelist Values Tables: Whole Blood Clot Formation (ROTEM)

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	

RDE Analytics: RD_FRMWBCLT

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2

AT3SC002: Plasma PK Sampling (PK BLD) [frmPKBLD]

Assessment Date [sctPKBLDT]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* Same date as visit date *[A:OTHER]* **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)

Actual Time of Plasma PK Sampling [sctPKBLD1]

2.* ✔	Predose [Predose]	**[lstSAMPLE_PRE]** *[A:ACTUAL TIME]* **[dtmSAMPLE_T_PRE] (hh:mm)** Actual time Req : Req *24-hour clock* *[A:NOT COLLECTED]* Not collected
3.* ✔	30 min postdose [30 min postdose]	**[lstSAMPLE_30MIN]** *[A:ACTUAL TIME]* **[dtmSAMPLE_T_30MIN] (hh:mm)** Actual time Req : Req *24-hour clock* *[A:NOT COLLECTED]* Not collected
4.* ✔	2h postdose [2h postdose]	**[lstSAMPLE_2H]** *[A:ACTUAL TIME]* **[dtmSAMPLE_T_2H] (hh:mm)** Actual time Req : Req *24-hour clock* *[A:NOT COLLECTED]* Not collected
5.* ✔	4h postdose [4h postdose]	**[lstSAMPLE_4H]** *[A:ACTUAL TIME]* **[dtmSAMPLE_T_4H] (hh:mm)** Actual time Req : Req *24-hour clock* *[A:NOT COLLECTED]* Not collected
6.* ✔	8h postdose [8h postdose]	**[lstSAMPLE_8H]** *[A:ACTUAL TIME]* **[dtmSAMPLE_T_8H] (hh:mm)** Actual time Req : Req *24-hour clock* *[A:NOT COLLECTED]* Not collected

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: Plasma PK Sampling

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clActTimeNotCol	String		Actual Time	ACTUAL TIME	citmActTimeNotCol_ActTime	lstSAMPLE_PRE, lstSAMPLE_30MIN, lstSAMPLE_2H, lstSAMPLE_4H, lstSAMPLE_8H
			Not collected	NOT COLLECTED	citmActTimeNotCol_NotCol	

RDE Analytics: RD_FRMPKBLD

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
lstSAMPLE_PRE	LSTSAMPLE_PRE_C	VARCHAR2
	LSTSAMPLE_PRE	VARCHAR2
	LSTSAMPLE_PRE_ND	VARCHAR2
lstSAMPLE_PRE - dtmSAMPLE_T_PRE	DTMSAMPLE_T_PRE	DATE
	DTMSAMPLE_T_PRE_TMS	VARCHAR2
lstSAMPLE_30MIN	LSTSAMPLE_30MIN_C	VARCHAR2
	LSTSAMPLE_30MIN	VARCHAR2
	LSTSAMPLE_30MIN_ND	VARCHAR2
lstSAMPLE_30MIN - dtmSAMPLE_T_30MIN	DTMSAMPLE_T_30MIN	DATE
	DTMSAMPLE_T_30MIN_TMS	VARCHAR2

lstSAMPLE_2H	LSTSAMPLE_2H_C	VARCHAR2
	LSTSAMPLE_2H	VARCHAR2
	LSTSAMPLE_2H_ND	VARCHAR2
lstSAMPLE_2H - dtmSAMPLE_T_2H	DTMSAMPLE_T_2H	DATE
	DTMSAMPLE_T_2H_TMS	VARCHAR2
lstSAMPLE_4H	LSTSAMPLE_4H_C	VARCHAR2
	LSTSAMPLE_4H	VARCHAR2
	LSTSAMPLE_4H_ND	VARCHAR2
lstSAMPLE_4H - dtmSAMPLE_T_4H	DTMSAMPLE_T_4H	DATE
	DTMSAMPLE_T_4H_TMS	VARCHAR2
lstSAMPLE_8H	LSTSAMPLE_8H_C	VARCHAR2
	LSTSAMPLE_8H	VARCHAR2
	LSTSAMPLE_8H_ND	VARCHAR2
lstSAMPLE_8H - dtmSAMPLE_T_8H	DTMSAMPLE_T_8H	DATE
	DTMSAMPLE_T_8H_TMS	VARCHAR2

AT3SC002: EQ-5D Questionnaire (EQ-5D) [frmEQ5D]

From Month 25 to Month 48 (Year 3 and 4) and the EOS/ET visit, carefully note that certain assessments do not need to be performed from the ICF signature for Protocol Amendment 6 onwards.

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ○ Same date as visit date *[A:OTHER]* ○ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
3.* ✔	Language of the questionnaire [Language of the questionnaire]	**[lstLANG]** *[A:LANGUAGE]* ○ **[lstLANG_Q]** Language **[clLANG_Q]** *[A:OTHER]* ○ **[txtLANGO]** Other, please specify A100
EQ-5D [sctEQ5D]		
4.* ✔	Mobility [Mobility]	**[lstMOB]** *[A:NO PROBLEMS]* ○ I have no problems in walking about *[A:SLIGHT PROBLEMS]* ○ I have slight problems in walking about *[A:MODERATE PROBLEMS]* ○ I have moderate problems in walking about *[A:SEVERE PROBLEMS]* ○ I have severe problems in walking about *[A:UNABLE]* ○ I am unable to walk about
5.* ✔	Self-Care [Self-Care]	**[lstSELF]** *[A:NO PROBLEMS]* ○ I have no problems washing or dressing myself *[A:SLIGHT PROBLEMS]* ○ I have slight problems washing or dressing myself *[A:MODERATE PROBLEMS]* ○ I have moderate problems washing or dressing myself *[A:SEVERE PROBLEMS]* ○ I have severe problems washing or dressing myself *[A:UNABLE]* ○ I am unable to wash or dress myself
6.* ✔	Usual Activities (e.g. work, study, housework, family or leisure activities) [Usual Activities]	**[lstUSACT]** *[A:NO PROBLEMS]* ○ I have no problems doing my usual activities *[A:SLIGHT PROBLEMS]* ○ I have slight problems doing my usual activities *[A:MODERATE PROBLEMS]* ○ I have moderate problems doing my usual activities *[A:SEVERE PROBLEMS]* ○ I have severe problems doing my usual activities *[A:UNABLE]* ○ I am unable to do my usual activities
7.* ✔	Pain/Discomfort [Pain/Discomfort]	**[lstPAIN]** *[A:NO PAIN]* ○ I have no pain or discomfort *[A:SLIGHT PAIN]* ○ I have slight pain or discomfort *[A:MODERATE PAIN]* ○ I have moderate pain or discomfort *[A:SEVERE PAIN]* ○ I have severe pain or discomfort *[A:EXTREME PAIN]* ○ I have extreme pain or discomfort
8.* ✔	Anxiety/Depression [Anxiety/Depression]	**[lstANX]** *[A:NOT ANXIOUS]* ○ I am not anxious or depressed *[A:SLIGHTLY ANXIOUS]* ○ I am slightly anxious or depressed *[A:MODERATELY ANXIOUS]* ○ I am moderately anxious or depressed *[A:SEVERELY ANXIOUS]* ○ I am severely anxious or depressed *[A:EXTREMELY ANXIOUS]* ○ I am extremely anxious or depressed
9.* ✔	Your own health state today [Health State]	**[numSTATE]** N3 mm[b]

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.

Codelist Values Tables: EQ-5D Questionnaire

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clLANG	String		Language of the questionnaire	LANGUAGE	citmLANG_LANGUAGE	lstLANG
			Other, please specify	OTHER	citmLANG_OTHER	
clLANG_Q	String		Bulgarian	BULGARIAN	citmLANG_BUL	lstLANG_Q
			English (for UK)	ENGLISHUK	citmLANG_ENG_UK	
			English (for US)	ENGLISHUS	citmLANG_ENG_US	

			French (for Switzerland)	FRENCHCH	citmLANG_FRA_CH	
			German (for Switzerland)	GERMANCH	citmLANG_GER_CH	
			Russian	RUSSIAN	citm_LANG_RUS	
clMOB	String		I have no problems in walking about	NO PROBLEMS	citmMOB_NoProblems	lstMOB
			I have slight problems in walking about	SLIGHT PROBLEMS	citmMOB_SlightProblems	
			I have moderate problems in walking about	MODERATE PROBLEMS	citmMOB_ModerateProblems	
			I have severe problems in walking about	SEVERE PROBLEMS	citmMOB_SevereProblems	
			I am unable to walk about	UNABLE	citmMOB_Unable	
clSELF	String		I have no problems washing or dressing myself	NO PROBLEMS	citmSELF_NoProblems	lstSELF
			I have slight problems washing or dressing myself	SLIGHT PROBLEMS	citmSELF_SlightProblems	
			I have moderate problems washing or dressing myself	MODERATE PROBLEMS	citmSELF_ModerateProblems	
			I have severe problems washing or dressing myself	SEVERE PROBLEMS	citmSELF_SevereProblems	
			I am unable to wash or dress myself	UNABLE	citmSELF_Unable	
clUSACT	String		I have no problems doing my usual activities	NO PROBLEMS	citmUSACT_NoProblems	lstUSACT
			I have slight problems doing my usual activities	SLIGHT PROBLEMS	citmUSACT_SlightProblems	
			I have moderate problems doing my usual activities	MODERATE PROBLEMS	citmUSACT_ModerateProblems	
			I have severe problems doing my usual activities	SEVERE PROBLEMS	citmUSACT_SevereProblems	
			I am unable to do my usual activities	UNABLE	citmUSACT_Unable	
clPAIN	String		I have no pain or discomfort	NO PAIN	citmPAIN_NoPain	lstPAIN
			I have slight pain or discomfort	SLIGHT PAIN	citmPAIN_SlightPain	
			I have moderate pain or discomfort	MODERATE PAIN	citmPAIN_ModeratePain	
			I have severe pain or discomfort	SEVERE PAIN	citmPAIN_SeverePain	
			I have extreme pain or discomfort	EXTREME PAIN	citmPAIN_ExtremePain	
clANX	String		I am not anxious or depressed	NOT ANXIOUS	citmANX_NotAnxious	lstANX
			I am slightly anxious or depressed	SLIGHTLY ANXIOUS	citmANX_SlightlyAnxious	
			I am moderately anxious or depressed	MODERATELY ANXIOUS	citmANX_ModeratelyAnxious	
			I am severely anxious or depressed	SEVERELY ANXIOUS	citmANX_SeverelyAnxious	
			I am extremely anxious or depressed	EXTREMELY ANXIOUS	citmANX_ExtremelyAnxious	

RDE Analytics: RD_FRMEQ5D		
Data Variable RefName	**RD Column Name**	**Column Data Type**
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
lstLANG	LSTLANG_C	VARCHAR2
	LSTLANG	VARCHAR2
	LSTLANG_ND	VARCHAR2
lstLANG - lstLANG_Q	LSTLANG_Q_C	VARCHAR2
	LSTLANG_Q	VARCHAR2
lstLANG - txtLANGO	TXTLANGO	VARCHAR2
lstMOB	LSTMOB_C	VARCHAR2
	LSTMOB	VARCHAR2
	LSTMOB_ND	VARCHAR2
lstSELF	LSTSELF_C	VARCHAR2
	LSTSELF	VARCHAR2
	LSTSELF_ND	VARCHAR2
lstUSACT	LSTUSACT_C	VARCHAR2
	LSTUSACT	VARCHAR2

	LSTUSACT_ND	VARCHAR2
lstPAIN	LSTPAIN_C	VARCHAR2
	LSTPAIN	VARCHAR2
	LSTPAIN_ND	VARCHAR2
lstANX	LSTANX_C	VARCHAR2
	LSTANX	VARCHAR2
	LSTANX_ND	VARCHAR2
numSTATE	NUMSTATE	NUMBER
	NUMSTATE_U	VARCHAR2
	NUMSTATE_ND	VARCHAR2

AT3SC002: HAEM-A-QOL Questionnaire (HAEM-A-QOL) [frmHAEMAQOL]

From Month 25 to Month 48 (Year 3 and 4) and the EOS/ET visit, carefully note that certain assessments do not need to be performed from the ICF signature for Protocol Amendment 6 onwards.

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
3.* ✔	Language of the questionnaire [Language of the questionnaire]	**[lstLANG]** *[A:LANGUAGE]* ◯ Language **[lstLANG_Q]** **[clLANG_Q]** *[A:OTHER]* ◯ **[txtLANGO]** Other, please specify A100

1. Here we would like to find out about hemophilia and your PHYSICAL HEALTH [sctPHYHEALTH]

In the past 4 weeks ...

4.* ✔	1. ... my swellings hurt [Swelling]	**[lstSWEL]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time
5.* ✔	2. ... I had pain in my joints [Joints pain]	**[lstJOINTS]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time
6.* ✔	3. ... it was painful for me to move [Painful to move]	**[lstMOVE]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time
7.* ✔	4. ... I had difficulty walking as far as I wanted to [Difficult walking]	**[lstWALK]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time
8.* ✔	5. ... I needed more time to get ready because of my condition [More time needed]	**[lstTIME]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time

2. And now about how you have been FEELING because of your hemophilia [sctFEELING]

In the past 4 weeks ...

9.* ✔	1. ... my hemophilia was a burden for me [Burden]	**[lstBURDEN]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time
10.* ✔	2. ... my hemophilia made me angry [Angry]	**[lstANGRY]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time
11.* ✔	3. ... I was worried because of my hemophilia [Worried]	**[lstWORRIED]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time
12.* ✔	4. ... I felt excluded [Excluded]	**[lstEXCLUDED]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time

3. How does hemophilia affect your VIEW OF YOURSELF? [sctVIEW]

In the past 4 weeks ...

13.* ✔	1. ... I envied healthy people my age [Envy]	**[lstENVY]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time
14.* ✔	2. ... I felt comfortable with my body [Comfortable]	**[lstCOMFORT]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time
15.* ✔	3. ... hemophilia made my life more difficult [More difficult]	**[lstDIFFICULT]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time
16.* ✔	4. ... I felt different from others because of my hemophilia [Different]	**[lstDIFFERENT]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time
17.* ✔	5. ... I was able not to think all the time about my hemophilia [Think about]	**[lstTHINK]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time

4. These questions are about SPORTS AND LEISURE [sctSPORTS]

In the past 4 weeks ...

18.* ✔	1. ... I had to avoid sports that I like because of my hemophilia [Avoid sports]	**[lstAVOID]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time *[A:NOT APPLICABLE]* ◯ Not applicable
19.* ✔	2. ... I had to avoid sports like football [Avoid football]	**[lstFOOTBALL]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time *[A:NOT APPLICABLE]* ◯ Not applicable
20.* ✔	3. ... I played sports just as much as others [As others]	**[lstPLAYED]** *[A:NEVER]* ◯ Never *[A:RARELY]* ◯ Rarely *[A:SOMETIMES]* ◯ Sometimes *[A:OFTEN]* ◯ Often *[A:ALL THE TIME]* ◯ All the time *[A:NOT APPLICABLE]* ◯ Not applicable
	4. ... I didn't have the freedom to travel where I wanted	**[lstFREEDOM]**

21.* ✔	[Travel]	*[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time *[A:NOT APPLICABLE]* Not applicable
22.* ✔	5. ... it was necessary for me to plan everything in advance [Plan in advance]	**[lstADVANCE]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time *[A:NOT APPLICABLE]* Not applicable
5. These questions are about WORK AND SCHOOL [sctWORK]		
In the past 4 weeks ...		
23.* ✔	1. ... I was able to go to work/school regularly in spite of my hemophilia [Able to work]	**[lstWORK]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time *[A:NOT APPLICABLE]* Not applicable
24.* ✔	2. ... I was able to work/study like healthy colleagues [Healthy]	**[lstHEALTHY]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time *[A:NOT APPLICABLE]* Not applicable
25.* ✔	3. ... my everyday work/school activities were jeopardized by my hemophilia [Jeopardized]	**[lstJEOPARD]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time *[A:NOT APPLICABLE]* Not applicable
26.* ✔	4. ... I found it difficult to pay attention at work/school because I was in pain [Attention]	**[lstATTENTION]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time *[A:NOT APPLICABLE]* Not applicable
6. The next questions are about DEALING WITH HEMOPHILIA [sctDEALING]		
In the past 4 weeks ...		
27.* ✔	1. ... I tried to recognize early on when a bleed developed [Recognize early]	**[lstEARLY]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
28.* ✔	2. ... I was able to tell whether or not I was bleeding [Bleeding]	**[lstBLEEDING]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
29.* ✔	3. ... I was able to control my bleeds [Control bleeds]	**[lstCONTROL]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
7. and what about your TREATMENT? [sctTREATMENT]		
In the past 4 weeks ...		
30.* ✔	1. ... I was dependent on the factor concentrate because of my hemophilia [Dependent]	**[lstDEPENDENT]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
31.* ✔	2. ... I was dependent on physicians for the treatment of my hemophilia [Dependent on physicians]	**[lstTREATMENT]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
32.* ✔	3. ... I was annoyed about the amount of time spent having the injections [Annoyed]	**[lstANNOYED]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
33.* ✔	4. ... I felt the injections interrupted my daily activities [Daily activities interrupted]	**[lstINTERRUPTED]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
34.* ✔	5. ... I was afraid of complications [Afraid]	**[lstAFRAID]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
35.* ✔	6. ... I had problems with how my treatment was administered [Problems with administration]	**[lstPROBLEMS]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
36.* ✔	7. ... I was afraid that in case of emergency, other doctors wouldn't know how to treat hemophilia [Emergency]	**[lstTREAT]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
37.* ✔	8. ... I was satisfied with the hemophilia center [Satisfied]	**[lstSATISFIED]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
8. What do you think about the FUTURE? [sctFUTURE]		
Recently ...		
38.* ✔	1. ... I have been thinking that it will be difficult for me to lead a normal life [Normal life]	**[lstTHINKING]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
39.* ✔	2. ... I have been expecting that things will get better in the future [Better in future]	**[lstBETTER]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
40.* ✔	3. ... I have been worrying that my condition is worsening [Worsening condition]	**[lstWORSENING]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
41.* ✔	4. ... my life plans have been influenced by my hemophilia [Life plans]	**[lstLIFE]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
42.* ✔	5. ... I have been afraid that I will need a wheelchair [Wheelchair]	**[lstWHEELCHAIR]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
9. The next questions are about hemophilia and your FAMILY PLANNING [sctFAMILY]		
Recently ...		
43.* ✔	1. ... I have had difficulties having children [Difficult having children]	**[lstCHILDREN]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time *[A:NOT APPLICABLE]* Not applicable
	2. ... I have been afraid that I cannot have children	

44.* ✔	[Afraid cannot have children]	**[lstAFRAIDCHILD]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time *[A:NOT APPLICABLE]* Not applicable
45.* ✔	3. ... I have been afraid that I will not be able to take care of my children [Not able to take care]	**[lstNOCARE]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time *[A:NOT APPLICABLE]* Not applicable
46.* ✔	4. ... I worry about not being able to raise a family [Worry]	**[lstWORRY]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time *[A:NOT APPLICABLE]* Not applicable
10. What about PARTNERSHIP AND SEXUALITY? [sctPARTNER]		
Recently ...		
47.* ✔	1. ... I have been finding it difficult to date because of my hemophilia [Difficult to date]	**[lstDATE]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
48.* ✔	2. ... I have been insecure in my intimate relationships because of my hemophilia [Insecure]	**[lstINSECURE]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time
49.* ✔	3. ... I haven't been able to have a normal relationship because of my hemophilia [No normal relationship]	**[lstNOREL]** *[A:NEVER]* Never *[A:RARELY]* Rarely *[A:SOMETIMES]* Sometimes *[A:OFTEN]* Often *[A:ALL THE TIME]* All the time

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: HAEM-A-QOL Questionnaire

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clLANG	String		Language of the questionnaire	LANGUAGE	citmLANG_LANGUAGE	lstLANG
			Other, please specify	OTHER	citmLANG_OTHER	
clLANG_Q	String		Bulgarian	BULGARIAN	citmLANG_BUL	lstLANG_Q
			English (for UK)	ENGLISHUK	citmLANG_ENG_UK	
			English (for US)	ENGLISHUS	citmLANG_ENG_US	
			French (for Switzerland)	FRENCHCH	citmLANG_FRA_CH	
			German (for Switzerland)	GERMANCH	citmLANG_GER_CH	
			Russian	RUSSIAN	citm_LANG_RUS	
clHAEM1	String		Never	NEVER	citmHAEM1_Never	lstSWEL, lstJOINTS, lstMOVE, lstWALK, lstTIME, lstBURDEN, lstANGRY, lstWORRIED, lstEXCLUDED, lstENVY, lstCOMFORT, lstDIFFICULT, lstDIFFERENT, lstTHINK, lstEARLY, lstBLEEDING, lstCONTROL, lstDEPENDENT, lstTREATMENT, lstANNOYED, lstINTERRUPTED, lstAFRAID, lstPROBLEMS, lstTREAT, lstSATISFIED, lstTHINKING, lstBETTER, lstWORSENING, lstLIFE, lstWHEELCHAIR, lstDATE, lstINSECURE, lstNOREL
			Rarely	RARELY	citmHAEM1_Rarely	
			Sometimes	SOMETIMES	citmHAEM1_Sometimes	
			Often	OFTEN	citmHAEM1_Often	
			All the time	ALL THE TIME	citmHAEM1_Allthetime	
clHAEM2	String		Never	NEVER	citmHAEM2_Never	lstAVOID, lstFOOTBALL, lstPLAYED, lstFREEDOM, lstADVANCE, lstWORK, lstHEALTHY,
			Rarely	RARELY	citmHAEM2_Rarely	
			Sometimes	SOMETIMES	citmHAEM2_Sometimes	

			Often	OFTEN	citmHAEM2_Often	lstJEOPARD, lstATTENTION, lstCHILDREN, lstAFRAIDCHILD, lstNOCARE, lstWORRY
			All the time	ALL THE TIME	citmHAEM2_Allthetime	
			Not applicable	NOT APPLICABLE	citmHAEM2_Notapplicable	

RDE Analytics: RD_FRMHAEMAQOL		
Data Variable RefName	**RD Column Name**	**Column Data Type**
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
lstLANG	LSTLANG_C	VARCHAR2
	LSTLANG	VARCHAR2
	LSTLANG_ND	VARCHAR2
lstLANG - lstLANG_Q	LSTLANG_Q_C	VARCHAR2
	LSTLANG_Q	VARCHAR2
lstLANG - txtLANGO	TXTLANGO	VARCHAR2
lstSWEL	LSTSWEL_C	VARCHAR2
	LSTSWEL	VARCHAR2
	LSTSWEL_ND	VARCHAR2
lstJOINTS	LSTJOINTS_C	VARCHAR2
	LSTJOINTS	VARCHAR2
	LSTJOINTS_ND	VARCHAR2
lstMOVE	LSTMOVE_C	VARCHAR2
	LSTMOVE	VARCHAR2
	LSTMOVE_ND	VARCHAR2
lstWALK	LSTWALK_C	VARCHAR2
	LSTWALK	VARCHAR2
	LSTWALK_ND	VARCHAR2
lstTIME	LSTTIME_C	VARCHAR2
	LSTTIME	VARCHAR2
	LSTTIME_ND	VARCHAR2
lstBURDEN	LSTBURDEN_C	VARCHAR2
	LSTBURDEN	VARCHAR2
	LSTBURDEN_ND	VARCHAR2
lstANGRY	LSTANGRY_C	VARCHAR2
	LSTANGRY	VARCHAR2
	LSTANGRY_ND	VARCHAR2
lstWORRIED	LSTWORRIED_C	VARCHAR2
	LSTWORRIED	VARCHAR2
	LSTWORRIED_ND	VARCHAR2
lstEXCLUDED	LSTEXCLUDED_C	VARCHAR2
	LSTEXCLUDED	VARCHAR2
	LSTEXCLUDED_ND	VARCHAR2
lstENVY	LSTENVY_C	VARCHAR2
	LSTENVY	VARCHAR2
	LSTENVY_ND	VARCHAR2
lstCOMFORT	LSTCOMFORT_C	VARCHAR2
	LSTCOMFORT	VARCHAR2

	LSTCOMFORT_ND	VARCHAR2
lstDIFFICULT	LSTDIFFICULT_C	VARCHAR2
	LSTDIFFICULT	VARCHAR2
	LSTDIFFICULT_ND	VARCHAR2
lstDIFFERENT	LSTDIFFERENT_C	VARCHAR2
	LSTDIFFERENT	VARCHAR2
	LSTDIFFERENT_ND	VARCHAR2
lstTHINK	LSTTHINK_C	VARCHAR2
	LSTTHINK	VARCHAR2
	LSTTHINK_ND	VARCHAR2
lstAVOID	LSTAVOID_C	VARCHAR2
	LSTAVOID	VARCHAR2
	LSTAVOID_ND	VARCHAR2
lstFOOTBALL	LSTFOOTBALL_C	VARCHAR2
	LSTFOOTBALL	VARCHAR2
	LSTFOOTBALL_ND	VARCHAR2
lstPLAYED	LSTPLAYED_C	VARCHAR2
	LSTPLAYED	VARCHAR2
	LSTPLAYED_ND	VARCHAR2
lstFREEDOM	LSTFREEDOM_C	VARCHAR2
	LSTFREEDOM	VARCHAR2
	LSTFREEDOM_ND	VARCHAR2
lstADVANCE	LSTADVANCE_C	VARCHAR2
	LSTADVANCE	VARCHAR2
	LSTADVANCE_ND	VARCHAR2
lstWORK	LSTWORK_C	VARCHAR2
	LSTWORK	VARCHAR2
	LSTWORK_ND	VARCHAR2
lstHEALTHY	LSTHEALTHY_C	VARCHAR2
	LSTHEALTHY	VARCHAR2
	LSTHEALTHY_ND	VARCHAR2
lstJEOPARD	LSTJEOPARD_C	VARCHAR2
	LSTJEOPARD	VARCHAR2
	LSTJEOPARD_ND	VARCHAR2
lstATTENTION	LSTATTENTION_C	VARCHAR2
	LSTATTENTION	VARCHAR2
	LSTATTENTION_ND	VARCHAR2
lstEARLY	LSTEARLY_C	VARCHAR2
	LSTEARLY	VARCHAR2
	LSTEARLY_ND	VARCHAR2
lstBLEEDING	LSTBLEEDING_C	VARCHAR2
	LSTBLEEDING	VARCHAR2
	LSTBLEEDING_ND	VARCHAR2
lstCONTROL	LSTCONTROL_C	VARCHAR2
	LSTCONTROL	VARCHAR2
	LSTCONTROL_ND	VARCHAR2
lstDEPENDENT	LSTDEPENDENT_C	VARCHAR2
	LSTDEPENDENT	VARCHAR2
	LSTDEPENDENT_ND	VARCHAR2
lstTREATMENT	LSTTREATMENT_C	VARCHAR2
	LSTTREATMENT	VARCHAR2
	LSTTREATMENT_ND	VARCHAR2
lstANNOYED	LSTANNOYED_C	VARCHAR2

	LSTANNOYED	VARCHAR2
	LSTANNOYED_ND	VARCHAR2
lstINTERRUPTED	LSTINTERRUPTED_C	VARCHAR2
	LSTINTERRUPTED	VARCHAR2
	LSTINTERRUPTED_ND	VARCHAR2
lstAFRAID	LSTAFRAID_C	VARCHAR2
	LSTAFRAID	VARCHAR2
	LSTAFRAID_ND	VARCHAR2
lstPROBLEMS	LSTPROBLEMS_C	VARCHAR2
	LSTPROBLEMS	VARCHAR2
	LSTPROBLEMS_ND	VARCHAR2
lstTREAT	LSTTREAT_C	VARCHAR2
	LSTTREAT	VARCHAR2
	LSTTREAT_ND	VARCHAR2
lstSATISFIED	LSTSATISFIED_C	VARCHAR2
	LSTSATISFIED	VARCHAR2
	LSTSATISFIED_ND	VARCHAR2
lstTHINKING	LSTTHINKING_C	VARCHAR2
	LSTTHINKING	VARCHAR2
	LSTTHINKING_ND	VARCHAR2
lstBETTER	LSTBETTER_C	VARCHAR2
	LSTBETTER	VARCHAR2
	LSTBETTER_ND	VARCHAR2
lstWORSENING	LSTWORSENING_C	VARCHAR2
	LSTWORSENING	VARCHAR2
	LSTWORSENING_ND	VARCHAR2
lstLIFE	LSTLIFE_C	VARCHAR2
	LSTLIFE	VARCHAR2
	LSTLIFE_ND	VARCHAR2
lstWHEELCHAIR	LSTWHEELCHAIR_C	VARCHAR2
	LSTWHEELCHAIR	VARCHAR2
	LSTWHEELCHAIR_ND	VARCHAR2
lstCHILDREN	LSTCHILDREN_C	VARCHAR2
	LSTCHILDREN	VARCHAR2
	LSTCHILDREN_ND	VARCHAR2
lstAFRAIDCHILD	LSTAFRAIDCHILD_C	VARCHAR2
	LSTAFRAIDCHILD	VARCHAR2
	LSTAFRAIDCHILD_ND	VARCHAR2
lstNOCARE	LSTNOCARE_C	VARCHAR2
	LSTNOCARE	VARCHAR2
	LSTNOCARE_ND	VARCHAR2
lstWORRY	LSTWORRY_C	VARCHAR2
	LSTWORRY	VARCHAR2
	LSTWORRY_ND	VARCHAR2
lstDATE	LSTDATE_C	VARCHAR2
	LSTDATE	VARCHAR2
	LSTDATE_ND	VARCHAR2
lstINSECURE	LSTINSECURE_C	VARCHAR2
	LSTINSECURE	VARCHAR2
	LSTINSECURE_ND	VARCHAR2
lstNOREL	LSTNOREL_C	VARCHAR2
	LSTNOREL	VARCHAR2
	LSTNOREL_ND	VARCHAR2

AT3SC002: Study Drug Administration - ALN-AT3SC (ALN-AT3SC) [frmADM]

1.* ✔	Were predose LFT results obtained in a central and/or local lab? (Please complete in an unscheduled visit) [Were predose LFT results obtained in a central and/or local lab?]	**[lstLABLFT]** *[A:CENTRAL]* ☐ Central lab *[A:LOCAL]* ☐ Local lab *[A:NOT APPLICABLE]* ☐ Not applicable (from year 3 onwards, the frequency of predose LFT monitoring may be decreased for patients who have negative hep C antibody and meet the specific criteria as per protocol)
2.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
3.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
4.* ✔	Was this conducted in the clinic or during a home visit? [Administration at clinic or home?]	**[lstADMHC]** *[A:CLINIC]* ◯ Clinic - administered by a healthcare professional *[A:HOME]* ◯ Home - administered by a healthcare professional *[A:HOMEPAT]* ◯ Home - administered by patient *[A:HOMECARE]* ◯ Home - administered by caregiver *[A:CLINICPAT]* ◯ Clinic - administered by patient *[A:CLINICCARE]* ◯ Clinic - administered by caregiver
5. ✔	Planned dose (weight based) [Planned dose (weight based)]	**[numADM]** x.xxx mg/kg
6. ✔	Fixed dose [Fixed dose]	**[numADM2]** xxxx. mg
7.* ✔	Type of dispensed kit [Type of dispensed kit]	**[lstKITTYPE]** *[A:VIAL]* ◯ Vial *[A:PFS]* ◯ Pre-filled syringe (PFS) *[A:NOT APPLICABLE]* ◯ Not applicable
8.* ✔	Total volume administered at this visit [Volume administered]	**[numVOLADM]** xxxx. mL
9.* ✔	Was the full dose successfully administered? [Dose administered?]	**[lstDOSEADM]** *[A:Y]* ◯ Yes *[A:N]* ◯ **[txtDOSEADMNO]** No, provide the reason for partial dose A128
10.* ✔	Injection site location [Injection site]	**[lstINJSITE]** *[A:RIGHT UPPER QUADRANT]* ◯ Right upper quadrant *[A:LIGHT UPPER QUADRANT]* ◯ Left upper quadrant *[A:RIGHT LOWER QUANDRANT]* ◯ Right lower quadrant *[A:LEFT LOWER QUADRANT]* ◯ Left lower quadrant *[A:RIGHT UPPER ARM HIGH]* ◯ Right upper arm high *[A:LEFT UPPER ARM HIGH]* ◯ Left upper arm high *[A:RIGHT UPPER ARM LOW]* ◯ Right upper arm low *[A:LEFT UPPER ARM LOW]* ◯ Left upper arm low *[A:RIGHT UPPER THIGH]* ◯ Right upper thigh *[A:LEFT UPPER THIGH]* ◯ Left upper thigh *[A:RIGHT LOWER THIGH]* ◯ Right lower thigh *[A:LEFT LOWER THIGH]* ◯ Left lower thigh *[A:OTHER]* ◯ **[txtINJSITEOTH]** Other site location A128
11.* ✔	Was a 29 gauge needle used? [Was a 29 gauge needle used?]	**[lstNEEDLE]** *[A:Y]* ◯ Yes *[A:N]* ◯ No
12.* ✔	Was the Dose Injection associated with an Adverse Event? [Injection linked with AE?]	**[txtISRAE]** *[A:Y]* ◯ **[cmpAE]** Yes Please specify AE#(s) - as recorded on AE form **[numAESEQ1] [numAESEQ2] [numAESEQ3] [numAESEQ4] [numAESEQ5] [numAESEQ6]** N3 N3 N3 N3 N3 N3 *[A:N]* ◯ No
13.	For office use only *[hidden]*	**[numEMAIL1]**

	[For office use only]	N3
14.	For office use only *[hidden]* [For office use only]	**[numEMAIL2]** N3
15.	For office use only *[hidden]* [For office use only]	**[numEMAIL3]** N3

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: Study Drug Administration - ALN-AT3SC

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clLABLFT	String		Central lab	CENTRAL	citmLABLFT_CENTRAL	lstLABLFT
			Local lab	LOCAL	citmLABLFT_LOCAL	
			Not applicable (from year 3 onwards, the frequency of predose LFT monitoring may be decreased for patients who have negative hep C antibody and meet the specific criteria as per protocol)	NOT APPLICABLE	citmLABLFT_NOTAPPLICABLE	
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clADMHC	String		Clinic - administered by a healthcare professional	CLINIC	citmADMHC_CLINIC	lstADMHC
			Home - administered by a healthcare professional	HOME	citmADMHC_HOME	
			Home - administered by patient	HOMEPAT	citmADMHC_HOMEPAT	
			Home - administered by caregiver	HOMECARE	citmADMHC_HOMECARE	
			Clinic - administered by patient	CLINICPAT	citmADMHC_CLINICPAT	
			Clinic - administered by caregiver	CLINICCARE	citmADMHC_CLINICCARE	
clKITTYPE	String		Vial	VIAL	citmKITTYPE_VIAL	lstKITTYPE
			Pre-filled syringe (PFS)	PFS	citmKITTYPE_PFS	
			Not applicable	NOT APPLICABLE	citmKITTYPE_NOTAPPLICABLE	
clYesNo	String		Yes	Y	citmYesNo_Y	lstDOSEADM, lstNEEDLE, txtISRAE
			No	N	citmYesNo_N	
clINJSITE	String		Right upper quadrant	RIGHT UPPER QUADRANT	citmINJSITE_RUQ	lstINJSITE
			Left upper quadrant	LIGHT UPPER QUADRANT	citmINJSITE_LUQ	
			Right lower quadrant	RIGHT LOWER QUANDRANT	citmINJSITE_RLQ	
			Left lower quadrant	LEFT LOWER QUADRANT	citmINJSITE_LLQ	
			Right upper arm high	RIGHT UPPER ARM HIGH	citmINJSITE_RUAH	
			Left upper arm high	LEFT UPPER ARM HIGH	citmINJSITE_LUAH	
			Right upper arm low	RIGHT UPPER ARM LOW	citmINJSITE_RUAL	
			Left upper arm low	LEFT UPPER ARM LOW	citmINJSITE_LUAL	
			Right upper thigh	RIGHT UPPER THIGH	citmINJSITE_RUT	
			Left upper thigh	LEFT UPPER THIGH	citmINJSITE_LUT	
			Right lower thigh	RIGHT LOWER THIGH	citmINJSITE_RLT	
			Left lower thigh	LEFT LOWER THIGH	citmINJSITE_LLT	
			Other	OTHER	citmINJSITE_OTHER	

RDE Analytics: RD_FRMADM

Data Variable RefName	RD Column Name	Column Data Type
lstLABLFT	LSTLABLFT_ND	VARCHAR2
lstLABLFT - Central lab	*LSTLABLFT_CITMLABLFTCENTRAL_C	VARCHAR2
	*LSTLABLFT_CITMLABLFTCENTRAL	VARCHAR2
lstLABLFT - Local lab	LSTLABLFT_CITMLABLFTLOCAL_C	VARCHAR2
	LSTLABLFT_CITMLABLFTLOCAL	VARCHAR2
lstLABLFT - Not applicable (from year 3 onwards, the frequency of predose LFT monitoring may be decreased for patients who have negative hep C antibody and meet the specific criteria as per protocol)	*LSTLABLFT_CITMLABLFTNOTAPPLICABLE_C	VARCHAR2
	*LSTLABLFT_CITMLABLFTNOTAPPLICABLE	VARCHAR2
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2

	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
lstADMHC	LSTADMHC_C	VARCHAR2
	LSTADMHC	VARCHAR2
	LSTADMHC_ND	VARCHAR2
numADM	NUMADM	FLOAT
	NUMADM_ND	VARCHAR2
numADM2	NUMADM2	FLOAT
	NUMADM2_ND	VARCHAR2
lstKITTYPE	LSTKITTYPE_C	VARCHAR2
	LSTKITTYPE	VARCHAR2
	LSTKITTYPE_ND	VARCHAR2
numVOLADM	NUMVOLADM	FLOAT
	NUMVOLADM_ND	VARCHAR2
lstDOSEADM	LSTDOSEADM_C	VARCHAR2
	LSTDOSEADM	VARCHAR2
	LSTDOSEADM_ND	VARCHAR2
lstDOSEADM - txtDOSEADMNO	TXTDOSEADMNO	VARCHAR2
lstINJSITE	LSTINJSITE_C	VARCHAR2
	LSTINJSITE	VARCHAR2
	LSTINJSITE_ND	VARCHAR2
lstINJSITE - txtINJSITEOTH	TXTINJSITEOTH	VARCHAR2
	LSTINJSITE_ND	VARCHAR2
lstINJSITE - txtINJSITEOTH	TXTINJSITEOTH	VARCHAR2
lstNEEDLE	LSTNEEDLE_C	VARCHAR2
	LSTNEEDLE	VARCHAR2
	LSTNEEDLE_ND	VARCHAR2
txtISRAE	TXTISRAE_C	VARCHAR2
	TXTISRAE	VARCHAR2
	TXTISRAE_ND	VARCHAR2
txtISRAE - numAESEQ1	NUMAESEQ1	NUMBER
txtISRAE - numAESEQ2	NUMAESEQ2	NUMBER
txtISRAE - numAESEQ3	NUMAESEQ3	NUMBER
txtISRAE - numAESEQ4	NUMAESEQ4	NUMBER
txtISRAE - numAESEQ5	NUMAESEQ5	NUMBER
txtISRAE - numAESEQ6	NUMAESEQ6	NUMBER
numEMAIL1	NUMEMAIL1	NUMBER
	NUMEMAIL1_ND	VARCHAR2
numEMAIL2	NUMEMAIL2	NUMBER
	NUMEMAIL2_ND	VARCHAR2
numEMAIL3	NUMEMAIL3	NUMBER
	NUMEMAIL3_ND	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: Adverse Events (AE) - Repeating Form [frmAE]

#	Row No	AE	Start date and time	Stop date and time	Severity	Relationship to ALN-AT3SC	If 'Unlikely related', 'Possibly related' or 'Definitely related', related to	Action taken	Medication taken	Outcome	Was this event an injection site reaction?	Event of Clinical Interest?	Event of Special Interest?	Seriousness
1														

Adverse Events [sctAE]

1.*	Row No ***(for internal use only)*** *[read-only]* [Row No]	**[numROW]** N3
2.*	Adverse event [AE]	**[txtAE]** A200
3.*	Start date and time [Start date and time]	**[dtmSTART] (DD/MM/YYYY hh:mm)** Req/Unk / Req/Unk / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock*
4.*	Stop date and time **Please complete 'Ongoing at the end of the trial' only at the end of the trial** [Stop date and time]	**[lstAEEND]** *[A:END DATE AND TIME]* **[dtmEND] (DD/MM/YYYY hh:mm)** Stop date and time Req/Unk / Req/Unk / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock* *[A:ONGOING]* Ongoing at the end of trial *[A:UNKNOWN]* Unknown
5.*	Severity [Severity]	**[lstAEINT]** *[A:MILD]* Mild *[A:MODERATE]* Moderate *[A:SEVERE]* Severe
6.*	Relationship to ALN-AT3SC? [Relationship to ALN-AT3SC]	**[lstAEREL]** *[A:NOT RELATED]* Not related *[A:UNLIKELY RELATED]* Unlikely related *[A:POSSIBLY RELATED]* Possibly related *[A:DEFINITELY RELATED]* Definitely related
7.	If 'Unlikely related', 'Possibly related' or 'Definitely related', please complete if related to **Only to be completed from the ICF signature for Protocol Amendment 6 onwards** [If 'Unlikely related', 'Possibly related' or 'Definitely related', related to]	**[lstAEREL2]** *[A:VIAL]* Vial *[A:PFS]* PFS *[A:UNKNOWN]* Unknown
8.*	Action taken with ALN-AT3SC? [Action taken]	**[lstACT]** *[A:DOSE NOT CHANGED]* Dose not changed *[A:DRUG WITHDRAWN]* Drug withdrawn *[A:DOSE REDUCED]* Dose reduced *[A:DRUG INTERRUPTED]* Drug interrupted *[A:NOT APPLICABLE]* Not applicable *[A:UNKNOWN]* Unknown
9.*	Concomitant therapy taken for this AE? [Medication taken]	**[lstAETRT]** *[A:Y]* Yes *[A:N]* No
10.*	Outcome [Outcome]	**[lstAEOUT]** *[A:RECOVERED/RESOLVED]* Recovered / Resolved *[A:RECOVERED/RESOLVED WITH SEQUELAE]* Recovered / Resolved with sequelae *[A:RECOVERING/RESOLVING]* Recovering / Resolving *[A:NOT RECOVERED/NOT RESOLVED]* Not recovered / Not resolved *[A:FATAL]* Fatal *[A:UNKNOWN]* Unknown
11.*	Was this event an injection site reaction? [Was this event an injection site reaction?]	**[lstAEINJ]** *[A:Y]* **[lstSYMPREYN]** Yes, was the reaction measurable? *[A:Y]* **[numSYMPRE]** Yes, size of reaction (mm): N3 *[A:N]* No *[A:N]* No
12.	Is this event an adverse event of Clinical Interest? [Event of Clinical Interest?]	**[lstAECI]** *[A:Y]* **[lstAECIS]**

		Yes, please specify: *[A:ISR]* Severe or serious ISRs, please complete the Supplemental Adverse Event of Clinical Interest form *[A:LFT]* ALT or AST elevations >3× ULN. Please create an Unscheduled Visit and complete the 'Hepatic Assessments in Patients who Experience LFT Elevations' form *[A:THROMBO]* **[lstTHROMBO]** Thrombosis. If Imaging and/or D-Dimer analysis was performed to diagnose thrombosis, please create an Unscheduled Visit and complete the respective assessment. *[A:CONFIRMED]* Confirmed thrombosis *[A:SUSPECTED]* Suspected thrombosis *[A:N]* No
13.* ✔	Is this event an adverse event of Special Interest? **If Yes, please complete the AESI Report Form and submit to PSI CRO within 24 hours, and update the Medical History and Concomitant Medications CRFs as necessary.** [Event of Special Interest?]	**[lstAESI]** *[A:Y]* **[lstAESIS]** Yes, please specify *[A:ISR]* Severe or serious ISRs, please complete the Supplemental Adverse Event of Special Interest form *[A:LFT]* ALT or AST elevations >3× ULN. Please create an Unscheduled Visit and complete the 'Hepatic Assessments in Patients who Experience LFT Elevations' form *[A:THROMBO]* **[lstTHROMBO2]** Thrombosis. If Imaging and/or D-Dimer analysis was performed to diagnose thrombosis, please create an Unscheduled Visit and complete the respective assessment. *[A:CONFIRMED]* Confirmed thrombosis *[A:SUSPECTED]* Suspected thrombosis *[A:IAR]* Systemic injection associated reactions (IARs), defined as hypersensitivity reactions which are related or possibly related to IMP *[A:CHOLEC]* Cholecystitis *[A:CHOLEL]* Cholelithiasis *[A:N]* No
Serious AE [sctAESER]		
14.* ✔	Is the AE serious? **If Yes, please complete the SAE Report Form and submit to PSI CRO within 24 hours, and update the Medical History and Concomitant Medications CRFs as necessary.** [Seriousness]	**[lstAESER]** *[A:Y]* **[lstDEATH]** Yes Results in death? *[A:Y]* Yes *[A:N]* No **[lstTHREAT]** Is life-threatening? *[A:Y]* Yes *[A:N]* No **[lstHOSPI]** Requires in-patient hospitalization or prolongation of existing hospitalization? *[A:Y]* Yes *[A:N]* No **[lstDIS]** Results in persistent or significant disability or incapacity? *[A:Y]* Yes *[A:N]* No **[lstCONG]** Is a congenital abnormality or birth defect? *[A:Y]* Yes *[A:N]* No **[lstMIE]** Is an important medical event? *[A:Y]* Yes *[A:N]* No *[A:N]* No
15.	SAE reference number *[hidden]* [SAE reference number]	**[txtSAEREFNO]** A50
16.	For office use only *[hidden]* [For office use only]	**[numEMAIL1]** N3
17.	For office use only *[hidden]* [For office use only]	**[numEMAIL2]** N3
18.	For office use only *[hidden]* [For office use only]	**[numEMAIL3]** N3
19.	For office use only *[hidden]* [For office use only]	**[numEMAIL4]** N3

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

Note: Associated form = Multiple Visits (Common CRF) / Concomitant Medications.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Keys (navigation) / Uniqueness: Adverse Events		
Item	**Unique**	**Order #**

frmAE (Repeating form)		
sctAE		
numROW	Group	1
txtAE	Group	2
dtmSTART	Group	3

Codelist Values Tables: Adverse Events

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clAEEND	String		End date and time	END DATE AND TIME	citmAEEND_EndDate	lstAEEND
			Ongoing at the end of trial	ONGOING	citmAEEND_Ongoing	
			Unknown	UNKNOWN	citmAEEND_Unknown	
clAEINT	String		Mild	MILD	citmAEINT_MILD	lstAEINT
			Moderate	MODERATE	citmAEINT_MODERATE	
			Severe	SEVERE	citmAEINT_SEVERE	
clAEREL	String		Not related	NOT RELATED	citmAEREL_NotRelated	lstAEREL
			Unlikely related	UNLIKELY RELATED	citmAEREL_UnlikelyRelated	
			Possibly related	POSSIBLY RELATED	citmAEREL_PossiblyRelated	
			Definitely related	DEFINITELY RELATED	citmAEREL_DefinitelyRelated	
clAEREL2	String		Vial	VIAL	citmAEREL2_VIAL	lstAEREL2
			PFS	PFS	citmAEREL2_PFS	
			Unknown	UNKNOWN	citmAEREL2_UNKNOWN	
clAETRT	String		Dose not changed	DOSE NOT CHANGED	citmAETRT_DoseNotChanged	lstACT
			Drug withdrawn	DRUG WITHDRAWN	citmAETRT_DrugWithdrawn	
			Dose reduced	DOSE REDUCED	citmAETRT_DoseReduced	
			Drug interrupted	DRUG INTERRUPTED	citmAETRT_DrugInterrupted	
			Not applicable	NOT APPLICABLE	citmAETRT_NoApplicable	
			Unknown	UNKNOWN	citmAETRT_Unknown	
clYesNo	String		Yes	Y	citmYesNo_Y	lstAETRT, lstAEINJ, lstSYMPREYN, lstAECI, lstAESI, lstAESER, lstDEATH, lstTHREAT, lstHOSPI, lstDIS, lstCONG, lstMIE
			No	N	citmYesNo_N	
clAEOUT	String		Recovered / Resolved	RECOVERED/RESOLVED	citmAEOUT_RecRes	lstAEOUT
			Recovered / Resolved with sequelae	RECOVERED/RESOLVED WITH SEQUELAE	citmAEOUT_RecResSeq	
			Recovering / Resolving	RECOVERING/RESOLVING	citmAEOUT_RecResIng	
			Not recovered / Not resolved	NOT RECOVERED/NOT RESOLVED	citmAEOUT_NotRecNotRes	
			Fatal	FATAL	citmAEOUT_Fatal	
			Unknown	UNKNOWN	citmAEOUT_Unknown	
clAECIS	String		Severe or serious ISRs, please complete the Supplemental Adverse Event of Clinical Interest form	ISR	citmAECIS_ISR	lstAECIS
			ALT or AST elevations >3× ULN. Please create an Unscheduled Visit and complete the 'Hepatic Assessments in Patients who Experience LFT Elevations' form	LFT	citmAECIS_LFT	
			Thrombosis	THROMBO	citmAECIS_THROMBO	
clTHROMBO	String		Confirmed thrombosis	CONFIRMED	citmTHROMBO_CONFIRMED	lstTHROMBO, lstTHROMBO2
			Suspected thrombosis	SUSPECTED	citmTHROMBO_SUSPECTED	
clAESIS	String		Severe or serious ISRs, please complete the Supplemental Adverse Event of Special Interest form	ISR	citmAESIS_ISR	lstAESIS
			ALT or AST elevations >3× ULN. Please create an Unscheduled Visit and complete the 'Hepatic Assessments in Patients who Experience LFT Elevations' form	LFT	citmAESIS_LFT	
			Thrombosis	THROMBO	citmAESIS_THROMBO	
			Systemic injection associated reactions (IARs), defined as hypersensitivity reactions which are related or possibly related to IMP	IAR	citmAESIS_IAR	
			Cholecystitis	CHOLEC	citmAESIS_CHOLEC	

			Cholelithiasis	CHOLEL	citmAESIS_CHOLEL	

RDE Analytics: RD_FRMAE		
Data Variable RefName	**RD Column Name**	**Column Data Type**
numROW	NUMROW	NUMBER
	NUMROW_ND	VARCHAR2
txtAE	TXTAE	VARCHAR2
	TXTAE_ND	VARCHAR2
dtmSTART	DTMSTART	DATE
	DTMSTART_DTS	VARCHAR2
	DTMSTART_DTR	VARCHAR2
	DTMSTART_ND	VARCHAR2
lstAEEND	LSTAEEND_C	VARCHAR2
	LSTAEEND	VARCHAR2
	LSTAEEND_ND	VARCHAR2
lstAEEND - dtmEND	DTMEND	DATE
	DTMEND_DTS	VARCHAR2
	DTMEND_DTR	VARCHAR2
lstAEINT	LSTAEINT_C	VARCHAR2
	LSTAEINT	VARCHAR2
	LSTAEINT_ND	VARCHAR2
lstAEREL	LSTAEREL_C	VARCHAR2
	LSTAEREL	VARCHAR2
	LSTAEREL_ND	VARCHAR2
lstAEREL2	LSTAEREL2_C	VARCHAR2
	LSTAEREL2	VARCHAR2
	LSTAEREL2_ND	VARCHAR2
lstACT	LSTACT_C	VARCHAR2
	LSTACT	VARCHAR2
	LSTACT_ND	VARCHAR2
lstAETRT	LSTAETRT_C	VARCHAR2
	LSTAETRT	VARCHAR2
	LSTAETRT_ND	VARCHAR2
lstAEOUT	LSTAEOUT_C	VARCHAR2
	LSTAEOUT	VARCHAR2
	LSTAEOUT_ND	VARCHAR2
lstAEINJ	LSTAEINJ_C	VARCHAR2
	LSTAEINJ	VARCHAR2
	LSTAEINJ_ND	VARCHAR2
lstAEINJ - lstSYMPREYN	LSTSYMPREYN_C	VARCHAR2
	LSTSYMPREYN	VARCHAR2
lstAEINJ - numSYMPRE	NUMSYMPRE	NUMBER
lstAECI	LSTAECI_C	VARCHAR2
	LSTAECI	VARCHAR2
	LSTAECI_ND	VARCHAR2
lstAECI - lstAECIS	LSTAECIS_C	VARCHAR2
	LSTAECIS	VARCHAR2
lstAECI - lstTHROMBO	LSTTHROMBO_C	VARCHAR2
	LSTTHROMBO	VARCHAR2
lstAESI	LSTAESI_C	VARCHAR2
	LSTAESI	VARCHAR2
	LSTAESI_ND	VARCHAR2
lstAESI - lstAESIS	LSTAESIS_C	VARCHAR2

	LSTAESIS	VARCHAR2
lstAESI - lstTHROMBO2	LSTTHROMBO2_C	VARCHAR2
	LSTTHROMBO2	VARCHAR2
lstAESER	LSTAESER_C	VARCHAR2
	LSTAESER	VARCHAR2
	LSTAESER_ND	VARCHAR2
lstAESER - lstDEATH	LSTDEATH_C	VARCHAR2
	LSTDEATH	VARCHAR2
lstAESER - lstTHREAT	LSTTHREAT_C	VARCHAR2
	LSTTHREAT	VARCHAR2
lstAESER - lstHOSPI	LSTHOSPI_C	VARCHAR2
	LSTHOSPI	VARCHAR2
lstAESER - lstDIS	LSTDIS_C	VARCHAR2
	LSTDIS	VARCHAR2
lstAESER - lstCONG	LSTCONG_C	VARCHAR2
	LSTCONG	VARCHAR2
lstAESER - lstMIE	LSTMIE_C	VARCHAR2
	LSTMIE	VARCHAR2
txtSAEREFNO	TXTSAEREFNO	VARCHAR2
	TXTSAEREFNO_ND	VARCHAR2
numEMAIL1	NUMEMAIL1	NUMBER
	NUMEMAIL1_ND	VARCHAR2
numEMAIL2	NUMEMAIL2	NUMBER
	NUMEMAIL2_ND	VARCHAR2
numEMAIL3	NUMEMAIL3	NUMBER
	NUMEMAIL3_ND	VARCHAR2
numEMAIL4	NUMEMAIL4	NUMBER
	NUMEMAIL4_ND	VARCHAR2

AT3SC002: ISR Signs and Symptoms (ISRSS) - Repeating Form [frmISRSS]

#	Row No	AE number	Size	Signs and symptoms	Other signs/symptoms
1					

sctISRSS [sctISRSS]

1.*	Row No ***(for internal use only)*** *[read-only]* [Row No]	**[numROW]** N3
2.* ✔	Corresponding Adverse Event number [AE number]	**[numSYMPAE]** N3
3.* ✔	Size of reaction [Size]	**[numSYMPRE]** N3 mm
4.* ✔	What were the associated signs/symptoms of the injection site reaction? [Signs and symptoms]	**[lstSYMP]** *[A:ERYTHEMA]* ☐ Erythema *[A:INDURATION]* ☐ Induration *[A:PRURITUS]* ☐ Pruritus *[A:OEDEMA]* ☐ Oedema *[A:PHLEBITIS]* ☐ Phlebitis *[A:PALLOR AND PIGMENT CHANGE]* ☐ Pallor and pigment change *[A:LIPODYSTROPHY]* ☐ Lipodystrophy *[A:ULCERATION]* ☐ Ulceration *[A:PAIN]* ☐ Pain *[A:TENDERNESS]* ☐ Tenderness *[A:OTHER]* ☐ Other

	Other
5. ✔	

Other signs/symptoms Entry [sctISRSSOTH]

5.1* ✔	Other, specify [Other]	**[txtSYMP]** A128

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

Keys (navigation)/Uniqueness: ISR Signs and Symptoms

Item	Unique	Order #
frmISRSS (Repeating form)		
sctISRSS		
numROW	Group	1

Codelist Values Tables: ISR Signs and Symptoms

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clSYMP	String		Erythema	ERYTHEMA	citmSYMP_Erythema	lstSYMP
			Induration	INDURATION	citmSYMP_Induration	
			Pruritus	PRURITUS	citmSYMP_Pruritus	
			Oedema	OEDEMA	citmSYMP_Oedema	
			Phlebitis	PHLEBITIS	citmSYMP_Phlebitis	
			Pallor and pigment change	PALLOR AND PIGMENT CHANGE	citmSYMP_Pallorandpigmentchange	
			Lipodystrophy	LIPODYSTROPHY	citmSYMP_Lipodystrophy	
			Ulceration	ULCERATION	citmSYMP_Ulceration	
			Pain	PAIN	citmSYMP_Pain	
			Tenderness	TENDERNESS	citmSYMP_Tenderness	
			Other	OTHER	citmSYMP_Other	

RDE Analytics: RD_FRMISRSS

Data Variable RefName	RD Column Name	Column Data Type
numROW	NUMROW	NUMBER
	NUMROW_ND	VARCHAR2

numSYMPAE	NUMSYMPAE	NUMBER
	NUMSYMPAE_ND	VARCHAR2
numSYMPRE	NUMSYMPRE	NUMBER
	NUMSYMPRE_ND	VARCHAR2
lstSYMP	LSTSYMP_ND	VARCHAR2
lstSYMP - Erythema	LSTSYMP_CITMSYMPERYTHEMA_C	VARCHAR2
	LSTSYMP_CITMSYMPERYTHEMA	VARCHAR2
lstSYMP - Induration	*LSTSYMP_CITMSYMPINDURATION_C	VARCHAR2
	*LSTSYMP_CITMSYMPINDURATION	VARCHAR2
lstSYMP - Pruritus	LSTSYMP_CITMSYMPPRURITUS_C	VARCHAR2
	LSTSYMP_CITMSYMPPRURITUS	VARCHAR2
lstSYMP - Oedema	LSTSYMP_CITMSYMPOEDEMA_C	VARCHAR2
	LSTSYMP_CITMSYMPOEDEMA	VARCHAR2
lstSYMP - Phlebitis	LSTSYMP_CITMSYMPPHLEBITIS_C	VARCHAR2
	LSTSYMP_CITMSYMPPHLEBITIS	VARCHAR2
lstSYMP - Pallor and pigment change	*LSTSYMP_CITMSYMPPALLORANDPIGMENTCHANGE_C	VARCHAR2
	*LSTSYMP_CITMSYMPPALLORANDPIGMENTCHANGE	VARCHAR2
lstSYMP - Lipodystrophy	*LSTSYMP_CITMSYMPLIPODYSTROPHY_C	VARCHAR2
	*LSTSYMP_CITMSYMPLIPODYSTROPHY	VARCHAR2
lstSYMP - Ulceration	*LSTSYMP_CITMSYMPULCERATION_C	VARCHAR2
	*LSTSYMP_CITMSYMPULCERATION	VARCHAR2
lstSYMP - Pain	LSTSYMP_CITMSYMPPAIN_C	VARCHAR2
	LSTSYMP_CITMSYMPPAIN	VARCHAR2
lstSYMP - Tenderness	*LSTSYMP_CITMSYMPTENDERNESS_C	VARCHAR2
	*LSTSYMP_CITMSYMPTENDERNESS	VARCHAR2
lstSYMP - Other	LSTSYMP_CITMSYMPOTHER_C	VARCHAR2
	LSTSYMP_CITMSYMPOTHER	VARCHAR2
RD_FRMISRSS_SCTISRSSOTH		
txtSYMP	TXTSYMP	VARCHAR2
	TXTSYMP_ND	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: Supplemental Adverse Event of Clinical Interest (AE CI) - Repeating Form [frmAECI]

#	Row No	AE number	Type of ISR	any follow-up actions taken for this AECI ISR	Check all follow-up actions taken for this AECI ISR
1					

Supplemental Adverse Event of Clinical Interest [sctAECI]

1.* 🔗	Row No ***(for internal use only)*** *[read-only]* [Row No]	**[numROW]** N3
2.* ✔	Corresponding Adverse Event number [AE number]	**[numSYMPAE]** N3
3.	Corresponding ISRSS number *[hidden]* [ISRSS number]	**[numISR]** N3
4.* ✔	The patient experienced an ISR or series of ISRs and should meet at least one of the following criteria: (Check all that apply) [Type of ISR]	**[lstISR]** *[A:SEVERE]* ☐ ISRs that are recurrent and/or demonstrate a pattern of increasing severity *[A:RECALL]* ☐ ISR that is determined to be severe and/or a cause for study drug discontinuation *[A:INTERRUPT]* ☐ ISR that, in the opinion of the Investigator, requires further medical evaluation or treatment
5.* ✔	Were any follow-up actions taken for this AECI ISR? [any follow-up actions taken for this AECI ISR]	**[lstAECIFUYN]** *[A:Y]* ◯ Yes *[A:N]* ◯ No
6. ✔	If 'Yes', check all follow-up actions taken for this AECI ISR [Check all follow-up actions taken for this AECI ISR]	**[lstAECIFU]** *[A:PHOTO]* ☐ Photograph *[A:DERMATO]* ☐ Dermatologic consult *[A:SKIN BIOPSY]* ☐ Skin biopsy *[A:SPEC LAB]* ☐ Specialty labs *[A:OTHER]* ☐ **[txtAECIFUO]** Other, specify A200
7.	For office use only *[hidden]* [For office use only]	**[numEMAIL1]** N3
8.	For office use only *[hidden]* [For office use only]	**[numEMAIL2]** N3
9.	For office use only *[hidden]* [For office use only]	**[numEMAIL3]** N3

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

Keys (navigation) / Uniqueness: Supplemental Adverse Event of Clinical Interest

Item	Unique	Order #
frmAECI (Repeating form)		
sctAECI		
numROW	Group	1

Codelist Values Tables: Supplemental Adverse Event of Clinical Interest

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clISR	String		ISRs that are recurrent and/or demonstrate a pattern of increasing severity	SEVERE	citmISR_SEVERE	lstISR
			ISR that is determined to be severe and/or a cause for study drug discontinuation	RECALL	citmISR_RECALL	
			ISR that, in the opinion of the Investigator, requires further medical evaluation or treatment	INTERRUPT	citmISR_INTERRUPT	
clYesNo	String		Yes	Y	citmYesNo_Y	lstAECIFUYN
			No	N	citmYesNo_N	
clAECIFU	String		Photograph	PHOTO	citmAECIFU_PHOTO	lstAECIFU
			Dermatologic consult	DERMATO	citmAECIFU_DERMATO	
			Skin biopsy	SKIN BIOPSY	citmAECIFU_SKINBIOP	
			Specialty labs	SPEC LAB	citmAECIFU_SPECLAB	
			Other	OTHER	citmAECIFU_OTHER	

RDE Analytics: RD_FRMAECI

Data Variable RefName	RD Column Name	Column Data Type
numROW	NUMROW	NUMBER
	NUMROW_ND	VARCHAR2
numSYMPAE	NUMSYMPAE	NUMBER
	NUMSYMPAE_ND	VARCHAR2
numISR	NUMISR	NUMBER
	NUMISR_ND	VARCHAR2
lstISR	LSTISR_ND	VARCHAR2
lstISR - ISRs that are recurrent and/or demonstrate a pattern of increasing severity	LSTISR_CITMISRSEVERE_C	VARCHAR2
	LSTISR_CITMISRSEVERE	VARCHAR2
lstISR - ISR that is determined to be severe and/or a cause for study drug discontinuation	LSTISR_CITMISRRECALL_C	VARCHAR2
	LSTISR_CITMISRRECALL	VARCHAR2
lstISR - ISR that, in the opinion of the Investigator, requires further medical evaluation or treatment	LSTISR_CITMISRINTERRUPT_C	VARCHAR2
	LSTISR_CITMISRINTERRUPT	VARCHAR2
lstAECIFUYN	LSTAECIFUYN_C	VARCHAR2
	LSTAECIFUYN	VARCHAR2
	LSTAECIFUYN_ND	VARCHAR2
lstAECIFU	LSTAECIFU_ND	VARCHAR2
lstAECIFU - Photograph	LSTAECIFU_CITMAECIFUPHOTO_C	VARCHAR2
	LSTAECIFU_CITMAECIFUPHOTO	VARCHAR2
lstAECIFU - Dermatologic consult	*LSTAECIFU_CITMAECIFUDERMATO_C	VARCHAR2
	*LSTAECIFU_CITMAECIFUDERMATO	VARCHAR2
lstAECIFU - Skin biopsy	*LSTAECIFU_CITMAECIFUSKINBIOP_C	VARCHAR2
	*LSTAECIFU_CITMAECIFUSKINBIOP	VARCHAR2
lstAECIFU - Specialty labs	*LSTAECIFU_CITMAECIFUSPECLAB_C	VARCHAR2
	*LSTAECIFU_CITMAECIFUSPECLAB	VARCHAR2
lstAECIFU - Other	LSTAECIFU_TXTAECIFUO_C	VARCHAR2
	LSTAECIFU_TXTAECIFUO	VARCHAR2
lstAECIFU - txtAECIFUO	TXTAECIFUO	VARCHAR2
numEMAIL1	NUMEMAIL1	NUMBER
	NUMEMAIL1_ND	VARCHAR2
numEMAIL2	NUMEMAIL2	NUMBER
	NUMEMAIL2_ND	VARCHAR2
numEMAIL3	NUMEMAIL3	NUMBER
	NUMEMAIL3_ND	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: Supplemental Adverse Event of Special Interest (AE SI) - Repeating Form [frmAESI]

#	Row No	AE number	Type of ISR	Any follow-up actions taken for this AESI ISR	Check all follow-up actions taken for this AESI ISR
1					

This form only needs to be completed from **Protocol Amendment 5** onwards.

Supplemental Adverse Event of Special Interest [sctAESI]

1.* 🔗	Row No ***(for internal use only)*** *[read-only]* [Row No]	**[numROW]** N3
2.* ✔	Corresponding Adverse Event number [AE number]	**[numSYMPAE]** N3
3.* ✔	The patient experienced an ISR or series of ISRs and should meet at least one of the following criteria: (Check all that apply) [Type of ISR]	**[lstISR]** *[A:SEVERE]* ☐ ISRs that are recurrent and/or demonstrate a pattern of increasing severity *[A:RECALL]* ☐ ISR that is determined to be severe and/or a cause for study drug discontinuation *[A:INTERRUPT]* ☐ ISR that, in the opinion of the Investigator, requires further medical evaluation or treatment
4.* ✔	Were any follow-up actions taken for this AESI ISR? [Any follow-up actions taken for this AESI ISR]	**[lstAESIFUYN]** *[A:Y]* ◯ Yes *[A:N]* ◯ No
5. ✔	If 'Yes', check all follow-up actions taken for this AESI ISR [Check all follow-up actions taken for this AESI ISR]	**[lstAESIFU]** *[A:PHOTO]* ☐ Photograph *[A:DERMATO]* ☐ Dermatologic consult *[A:SKIN BIOPSY]* ☐ Skin biopsy *[A:SPEC LAB]* ☐ Specialty labs *[A:OTHER]* ☐ **[txtAESIFUO]** Other, specify A200
6.	For office use only *[hidden]* [For office use only]	**[numEMAIL1]** N3
7.	For office use only *[hidden]* [For office use only]	**[numEMAIL2]** N3
8.	For office use only *[hidden]* [For office use only]	**[numEMAIL3]** N3

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

Keys (navigation) / Uniqueness: Supplemental Adverse Event of Special Interest

Item	Unique	Order #
frmAESI (Repeating form)		
sctAESI		
numROW	Group	1

Codelist Values Tables: Supplemental Adverse Event of Special Interest

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clISR	String		ISRs that are recurrent and/or demonstrate a pattern of increasing severity	SEVERE	citmISR_SEVERE	lstISR
			ISR that is determined to be severe and/or a cause for study drug discontinuation	RECALL	citmISR_RECALL	
			ISR that, in the opinion of the Investigator, requires further medical evaluation or treatment	INTERRUPT	citmISR_INTERRUPT	
clYesNo	String		Yes	Y	citmYesNo_Y	lstAESIFUYN
			No	N	citmYesNo_N	
clAECIFU	String		Photograph	PHOTO	citmAECIFU_PHOTO	lstAESIFU
			Dermatologic consult	DERMATO	citmAECIFU_DERMATO	
			Skin biopsy	SKIN BIOPSY	citmAECIFU_SKINBIOP	
			Specialty labs	SPEC LAB	citmAECIFU_SPECLAB	
			Other	OTHER	citmAECIFU_OTHER	

RDE Analytics: RD_FRMAESI

Data Variable RefName	RD Column Name	Column Data Type
numROW	NUMROW	NUMBER
	NUMROW_ND	VARCHAR2
numSYMPAE	NUMSYMPAE	NUMBER
	NUMSYMPAE_ND	VARCHAR2
lstISR	LSTISR_ND	VARCHAR2
lstISR - ISRs that are recurrent and/or demonstrate a pattern of increasing severity	LSTISR_CITMISRSEVERE_C	VARCHAR2
	LSTISR_CITMISRSEVERE	VARCHAR2
lstISR - ISR that is determined to be severe and/or a cause for study drug discontinuation	LSTISR_CITMISRRECALL_C	VARCHAR2
	LSTISR_CITMISRRECALL	VARCHAR2
lstISR - ISR that, in the opinion of the Investigator, requires further medical evaluation or treatment	LSTISR_CITMISRINTERRUPT_C	VARCHAR2
	LSTISR_CITMISRINTERRUPT	VARCHAR2
lstAESIFUYN	LSTAESIFUYN_C	VARCHAR2
	LSTAESIFUYN	VARCHAR2
	LSTAESIFUYN_ND	VARCHAR2
lstAESIFU	LSTAESIFU_ND	VARCHAR2
lstAESIFU - Photograph	LSTAESIFU_CITMAECIFUPHOTO_C	VARCHAR2
	LSTAESIFU_CITMAECIFUPHOTO	VARCHAR2
lstAESIFU - Dermatologic consult	*LSTAESIFU_CITMAECIFUDERMATO_C	VARCHAR2
	*LSTAESIFU_CITMAECIFUDERMATO	VARCHAR2
lstAESIFU - Skin biopsy	*LSTAESIFU_CITMAECIFUSKINBIOP_C	VARCHAR2
	*LSTAESIFU_CITMAECIFUSKINBIOP	VARCHAR2
lstAESIFU - Specialty labs	*LSTAESIFU_CITMAECIFUSPECLAB_C	VARCHAR2
	*LSTAESIFU_CITMAECIFUSPECLAB	VARCHAR2
lstAESIFU - Other	LSTAESIFU_TXTAESIFUO_C	VARCHAR2
	LSTAESIFU_TXTAESIFUO	VARCHAR2
lstAESIFU - txtAESIFUO	TXTAESIFUO	VARCHAR2
numEMAIL1	NUMEMAIL1	NUMBER
	NUMEMAIL1_ND	VARCHAR2
numEMAIL2	NUMEMAIL2	NUMBER
	NUMEMAIL2_ND	VARCHAR2
numEMAIL3	NUMEMAIL3	NUMBER
	NUMEMAIL3_ND	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: Bleeding Management Plan (BLEED MAN) - Repeating Form [frmBLEEDMAN]

#	Row No	Preperation date	Start date	End date	Medication	Medication name	Recommended dose	Maximum dose
1								

Bleeding Management Plan [sctBLEEDMAN]

1.* 🔑	Row No ***(for internal use only)*** *[read-only]* [Row No]	**[numROW]** N3
2.* ✔	Bleed management plan preparation date [Preperation date]	**[dBLDPREP] (DD/MM/YYYY)** Req / Req / Req (2015-2023)

Bleeding Management Plan Duration [sctBLEEDDUR]

3.* ✔ 🔑	Start date [Start date]	**[dBLDDURST] (DD/MM/YYYY)** Req / Req / Req (2015-2023)
4.* ✔	End date **Please complete 'Ongoing at the end of the trial' only at the end of the trial** [End date]	**[lstBLDDUREN]** *[A:END DATE AND TIME]* ○ **[dBLDDUREN] (DD/MM/YYYY)** End date Req / Req / Req (2015-2023) *[A:ONGOING]* ○ Ongoing at the end of trial

Bleeding Management Plan Medication [sctBLEEDMED]

5.* ✔	Medication [Medication]	**[lstBLDMED]** *[A:µg]* ○ mcg of rFVIIa *[A:IU FVIII]* ○ Units of FVIII *[A:IU FIX]* ○ Units of FIX *[A:U]* ○ Units of aPCC
6.* ✔	Medication name [Medication name]	**[txtBLDMED]** A200
7.* ✔	Recommended treatment dose [Recommended dose]	**[numBLDDSREC]** N5
8.* ✔	Maximum treatment dose [Maximum dose]	**[numBLDDSMAX]** N5

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

Keys (navigation) / Uniqueness: Bleeding Management Plan

Item	Unique	Order #
frmBLEEDMAN (Repeating form)		
sctBLEEDMAN		
numROW	Group	1
sctBLEEDDUR		
dBLDDURST	Group	2

Codelist Values Tables: Bleeding Management Plan

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clCMEND	String		End date and time	END DATE AND TIME	citmCMEND_EndDate	lstBLDDUREN
			Ongoing at the end of trial	ONGOING	citmCMEND_Ongoing	
clBLDMED	String		mcg of rFVIIa	µg	citmBLDMED_RFVIIA	lstBLDMED
			Units of FVIII	IU FVIII	citmBLDMED_FVIII	
			Units of FIX	IU FIX	citmBLDMED_FIX	
			Units of aPCC	U	citmBLDMED_APCC	

RDE Analytics: RD_FRMBLEEDMAN

Data Variable RefName	RD Column Name	Column Data Type
numROW	NUMROW	NUMBER
	NUMROW_ND	VARCHAR2

dBLDPREP	DBLDPREP	DATE
	DBLDPREP_DTS	VARCHAR2
	DBLDPREP_ND	VARCHAR2
dBLDDURST	DBLDDURST	DATE
	DBLDDURST_DTS	VARCHAR2
	DBLDDURST_ND	VARCHAR2
lstBLDDUREN	LSTBLDDUREN_C	VARCHAR2
	LSTBLDDUREN	VARCHAR2
	LSTBLDDUREN_ND	VARCHAR2
lstBLDDUREN - dBLDDUREN	DBLDDUREN	DATE
	DBLDDUREN_DTS	VARCHAR2
lstBLDMED	LSTBLDMED_C	VARCHAR2
	LSTBLDMED	VARCHAR2
	LSTBLDMED_ND	VARCHAR2
txtBLDMED	TXTBLDMED	VARCHAR2
	TXTBLDMED_ND	VARCHAR2
numBLDDSREC	NUMBLDDSREC	NUMBER
	NUMBLDDSREC_ND	VARCHAR2
numBLDDSMAX	NUMBLDDSMAX	NUMBER
	NUMBLDDSMAX_ND	VARCHAR2

AT3SC002: 12-lead ECG (24H Postdose) (ECG 24H) [frmECG24H]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
12-lead Electrocardiogram [sctECG24H]		
Supine after at least 10 minutes rest		
2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
3.* ✔	Rhythm [Rhythm]	**[lstRHYTM]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
4.* ✔	Ventricular rate [Ventricular rate]	**[numVR]** N3 bpm[b]
5.* ✔	PR interval [PR]	**[numPR]** N3 msec[b]
6.* ✔	QRS duration [QRS]	**[numQRS]** N3 msec[b]
7.* ✔	QT interval [QT]	**[numQT]** N3 msec[b]
8.* ✔	QTc interval [QTc]	**[numQTCF]** N3 msec[b]
9.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
10. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN1]** *[A:SINUS BRADYCARDIA]* ☐ Sinus Bradycardia *[A:SINUS TACHYCARDIA]* ☐ Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* ☐ Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* ☐ Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* ☐ Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* ☐ Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* ☐ Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* ☐ Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* ☐ Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* ☐ Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* ☐ Atrial Fibrillation *[A:ATRIAL PACING]* ☐ Atrial Pacing *[A:VENTRICULAR PACING]* ☐ Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* ☐ Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* ☐ 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* ☐ 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* ☐ 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* ☐ 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* ☐ Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* ☐ Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* ☐ Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* ☐ Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* ☐ Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* ☐ Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* ☐ Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* ☐ Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* ☐ Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* ☐ Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* ☐ Inferior Infarct Pattern *[A:OTHER, SPECIFY]* ☐ **[txtABNOTH1]** Other, specify A128

11.* ✔	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	**[lstCHANGE1]** *[A:NO SIGNIFICANT WORSENING FROM BASELINE]* ◯ No significant worsening from baseline *[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]* ◯ **[txtCHANGE1]** Clinically significant worsening from baseline, specify A128

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.

Codelist Values Tables: 12-lead ECG (24H Postdose)

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	lstRHYTM
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	lstOVERALLINT
			Abnormal, Not Clinically Significant	ABNORMAL, NOT CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalNCS	
			Abnormal, Clinically Significant	ABNORMAL, CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalCS	
clABN	String		Sinus Bradycardia	SINUS BRADYCARDIA	citmABN_SinusBradycardia	lstABN1
			Sinus Tachycardia	SINUS TACHYCARDIA	citmABN_SinusTachycardia	
			Atrial Tachycardia	ATRIAL TACHYCARDIA	citmABN_AtrialTachycardia	
			Ventricular Tachycardia	VENTRICULAR TACHYCARDIA	citmABN_VentricularTachycardia	
			Sick Sinus Syndrome	SICK SINUS SYNDROME	citmABN_SickSinusSyndrome	
			Premature Atrial Complexes	PREMATURE ATRIAL COMPLEXES	citmABN_PrematureAtrialComplexes	
			Premature Ventricular Complexes	PREMATURE VENTRICULAR COMPLEXES	citmABN_PrematureVentricularComplexes	
			Q Axis, Left Axis Deviation	Q AXIS LEFT AXIS DEVIATION	citmABN_QAxisLeftAxisDeviation	
			Left Atrial Abnormality	LEFT ATRIAL ABNORMALITY	citmABN_LeftAtrialAbnormality	
			Left Ventricular Hypertrophy	LEFT VENTRICULAR HYPERTROPHY	citmABN_LeftVentricularHypertrophy	
			Atrial Fibrillation	ATRIAL FIBRILLATION	citmABN_AtrialFibrillation	
			Atrial Pacing	ATRIAL PACING	citmABN_AtrialPacing	
			Ventricular Pacing	VENTRICULAR PACING	citmABN_VentricularPacing	
			Atrial Ventricular Pacing	ATRIAL VENTRICULAR PACING	citmABN_AtrialVentricularPacing	
			1st Degree A-V Block	1ST DEGREE A-V BLOCK	citmABN_1stDegreeAVBlock	
			2nd Degree A-V Block Type I	2ND DEGREE A-V BLOCK TYPE I	citmABN_2ndDegreeAVBlockTypeI	
			2nd Degree A-V Block Type II	2ND DEGREE A-V BLOCK TYPE II	citmABN_2ndDegreeAVBlockTypeII	
			3rd Degree A-V Block	3RD DEGREE A-V BLOCK	citmABN_3rdDegreeAVBlock	
			Left Bundle Branch Block	LEFT BUNDLE BRANCH BLOCK	citmABN_LeftBundleBranchBlock	
			Incomplete Left Bundle Branch Block	INCOMPLETE LEFT BUNDLE BRANCH BLOCK	citmABN_IncompleteLeftBundleBranchBlock	
			Left Anterior Hemiblock	LEFT ANTERIOR HEMIBLOCK	citmABN_LeftAnteriorHemiblock	
			Left Posterior Hemiblock	LEFT POSTERIOR HEMIBLOCK	citmABN_LeftPosteriorHemiblock	
			Right Bundle Branch Block	RIGHT BUNDLE BRANCH BLOCK	citmABN_RightBundleBranchBlock	
			Incomplete Right Bundle Branch Block	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK	citmABN_IncompleteRightBundleBranchBlock	
			Intraventricular Conduction Delay	INTRAVENTRICULAR CONDUCTION DELAY	citmABN_IntraventricularConductionDelay	
			Anteroseptal Infarct Pattern	ANTEROSEPTAL INFARCT PATTERN	citmABN_AnteroseptalInfarctPattern	
			Anterolateral Infarct Pattern	ANTEROLATERAL INFARCT PATTERN	citmABN_AnterolateralInfarctPattern	
			Lateral Infarct Pattern	LATERAL INFARCT PATTERN	citmABN_LateralInfarctPattern	
			Inferior Infarct Pattern	INFERIOR INFARCT PATTERN	citmABN_InferiorInfarctPattern	
			Other, specify	OTHER, SPECIFY	citmABN_Otherspecify	
clCHANGE	String		No significant worsening from baseline	NO SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_NOSIGNIFICANTWORSENINGFROMBASELINE	lstCHANGE1
			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE	

RDE Analytics: RD_FRMECG24H

Data Variable RefName	RD Column Name	Column Data Type

lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
lstRHYTM	LSTRHYTM_C	VARCHAR2
	LSTRHYTM	VARCHAR2
	LSTRHYTM_ND	VARCHAR2
numVR	NUMVR	NUMBER
	NUMVR_U	VARCHAR2
	NUMVR_ND	VARCHAR2
numPR	NUMPR	NUMBER
	NUMPR_U	VARCHAR2
	NUMPR_ND	VARCHAR2
numQRS	NUMQRS	NUMBER
	NUMQRS_U	VARCHAR2
	NUMQRS_ND	VARCHAR2
numQT	NUMQT	NUMBER
	NUMQT_U	VARCHAR2
	NUMQT_ND	VARCHAR2
numQTCF	NUMQTCF	NUMBER
	NUMQTCF_U	VARCHAR2
	NUMQTCF_ND	VARCHAR2
lstOVERALLINT	LSTOVERALLINT_C	VARCHAR2
	LSTOVERALLINT	VARCHAR2
	LSTOVERALLINT_ND	VARCHAR2
lstABN1	LSTABN1_ND	VARCHAR2
lstABN1 - Sinus Bradycardia	*LSTABN1_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN1 - Sinus Tachycardia	*LSTABN1_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN1 - Atrial Tachycardia	*LSTABN1_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN1 - Ventricular Tachycardia	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN1 - Sick Sinus Syndrome	*LSTABN1_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN1_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN1 - Premature Atrial Complexes	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN1 - Premature Ventricular Complexes	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN1 - Q Axis, Left Axis Deviation	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN1 - Left Atrial Abnormality	*LSTABN1_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN1 - Left Ventricular Hypertrophy	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN1 - Atrial Fibrillation	*LSTABN1_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN1_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN1 - Atrial Pacing	*LSTABN1_CITMABNATRIALPACING_C	VARCHAR2

	*LSTABN1_CITMABNATRIALPACING	VARCHAR2
lstABN1 - Ventricular Pacing	*LSTABN1_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARPACING	VARCHAR2
lstABN1 - Atrial Ventricular Pacing	*LSTABN1_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN1 - 1st Degree A-V Block	*LSTABN1_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN1 - 2nd Degree A-V Block Type I	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN1 - 2nd Degree A-V Block Type II	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN1 - 3rd Degree A-V Block	*LSTABN1_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN1 - Left Bundle Branch Block	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Left Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Left Anterior Hemiblock	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Left Posterior Hemiblock	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Right Bundle Branch Block	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Right Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Intraventricular Conduction Delay	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN1 - Anteroseptal Infarct Pattern	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN1 - Anterolateral Infarct Pattern	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Lateral Infarct Pattern	*LSTABN1_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Inferior Infarct Pattern	*LSTABN1_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN1 - Other, specify	LSTABN1_TXTABNOTH1_C	VARCHAR2
	LSTABN1_TXTABNOTH1	VARCHAR2
lstABN1 - txtABNOTH1	TXTABNOTH1	VARCHAR2
lstCHANGE1	LSTCHANGE1_C	VARCHAR2
	LSTCHANGE1	VARCHAR2
	LSTCHANGE1_ND	VARCHAR2
lstCHANGE1 - txtCHANGE1	TXTCHANGE1	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: Plasma PK Sampling (PK BLD24H) [frmPKBLD24H]

Assessment Date [sctPKBLDT]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* Same date as visit date *[A:OTHER]* **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)

Actual Time of Plasma PK Sampling [sctPKBLD2]

2.* ✔	24h postdose [24h postdose]	**[lstSAMPLE_24H]** *[A:ACTUAL TIME]* **[dtmSAMPLE_T_24H] (hh:mm)** Actual time Req : Req *24-hour clock* *[A:NOT COLLECTED]* Not collected

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: Plasma PK Sampling

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clActTimeNotCol	String		Actual Time	ACTUAL TIME	citmActTimeNotCol_ActTime	lstSAMPLE_24H
			Not collected	NOT COLLECTED	citmActTimeNotCol_NotCol	

RDE Analytics: RD_FRMPKBLD24H

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
lstSAMPLE_24H	LSTSAMPLE_24H_C	VARCHAR2
	LSTSAMPLE_24H	VARCHAR2
	LSTSAMPLE_24H_ND	VARCHAR2
lstSAMPLE_24H - dtmSAMPLE_T_24H	DTMSAMPLE_T_24H	DATE
	DTMSAMPLE_T_24H_TMS	VARCHAR2

AT3SC002: Directed Physical Examination (PE DIR) [frmPE]

From Month 25 to Month 48 (Year 3 and 4), carefully note that certain assessments do not need to be performed from the ICF signature for Protocol Amendment 6 onwards.

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
Please examine all body parts / organs and body systems and select the appropriate response: [sctPE]		
If it is a new, clinically significant finding started after first dose of study drug, please also record it on the AE form		
2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
3.* ✔	Chest/Respiratory [Chest/Respiratory]	**[lstRESPIRAT]** *[A:NOT DONE]* ◯ Not done *[A:NORMAL]* ◯ Normal *[A:ABNORMAL]* ◯ **[lstRESPIRATNEW]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* ◯ No *[A:Y]* ◯ **[txtRESPIRATNEWSP]** Yes, please specify A200 **[lstRESPIRATCS]** Is the abnormality clinically significant? *[A:Y]* ◯ Yes *[A:N]* ◯ No
4.* ✔	Heart/Cardiovascular [Heart/Cardiovascular]	**[lstCARDIOVA]** *[A:NOT DONE]* ◯ Not done *[A:NORMAL]* ◯ Normal *[A:ABNORMAL]* ◯ **[lstCARDIOVANEW]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* ◯ No *[A:Y]* ◯ **[txtCARDIOVANEWSP]** Yes, please specify A200 **[lstCARDIOVACS]** Is the abnormality clinically significant? *[A:Y]* ◯ Yes *[A:N]* ◯ No
5.* ✔	Dermatological/Skin [Dermatological/Skin]	**[lstSKIN]** *[A:NOT DONE]* ◯ Not done *[A:NORMAL]* ◯ Normal *[A:ABNORMAL]* ◯ **[lstSKINNEW]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* ◯ No *[A:Y]* ◯ **[txtSKINNEWSP]** Yes, please specify A200 **[lstSKINCS]** Is the abnormality clinically significant? *[A:Y]* ◯ Yes *[A:N]* ◯ No
6.* ✔	Gastrointestinal/Liver [Gastrointestinal/Liver]	**[lstGASTROIN]** *[A:NOT DONE]* ◯ Not done *[A:NORMAL]* ◯ Normal *[A:ABNORMAL]* ◯ **[lstGASTROINNEW]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* ◯ No *[A:Y]* ◯ **[txtGASTROINNEWSP]** Yes, please specify A200 **[lstGASTROINCS]** Is the abnormality clinically significant? *[A:Y]* ◯ Yes *[A:N]* ◯ No
7.* ✔	Musculoskeletal/Extremities [Musculoskeletal/Extremities]	**[lstMUSCULO]** *[A:NOT DONE]* ◯ Not done *[A:NORMAL]* ◯ Normal *[A:ABNORMAL]* ◯ **[lstMUSCULONEW]**

		Abnormal, is the abnormality a new or worsened finding? *[A:N]* ◯ No *[A:Y]* ◯ **[txtMUSCULONEWSP]** Yes, please specify A200 **[lstMUSCULOCS]** Is the abnormality clinically significant? *[A:Y]* ◯ Yes *[A:N]* ◯ No
8.* ✔	Neurologic [Neurologic]	**[lstNEURO3]** *[A:NOT DONE]* ◯ Not done *[A:NORMAL]* ◯ Normal *[A:ABNORMAL]* ◯ **[lstNEURONEW]** Abnormal, is the abnormality a new or worsened finding? *[A:N]* ◯ No *[A:Y]* ◯ **[cmpNEURONEW]** Yes, please specify **[txtNEURONEWSP]** A200 **[lstNEUROCS]** Is the abnormality clinically significant? *[A:Y]* ◯ Yes *[A:N]* ◯ No

	Other abnormalities	Other clinical significance
9. ✔		

Physical Examination Other Entry [sctPEOTH]

- If there are any other abnormalities, please record in the Add Entry section below
- Please record only one abnormality per row

9.1* ✔	Other abnormalities [Other abnormalities]	**[txtPEOTH]** A200
9.2* ✔	Is the abnormality clinically significant? [Other clinical significance]	**[lstPEOTHCS]** *[A:Y]* ◯ Yes *[A:N]* ◯ No

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: Directed Physical Examination

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clNDNormalAbnormal	String		Not done	NOT DONE	citmNDNormalAbnormal_ND	lstRESPIRAT, lstCARDIOVA, lstSKIN, lstGASTROIN, lstMUSCULO, lstNEURO3
			Normal	NORMAL	citmNDNormalAbnormal_Normal	
			Abnormal	ABNORMAL	citmNDNormalAbnormal_Abnormal	
clNoYes	String		No	N	citmNoYes_N	lstRESPIRATNEW, lstCARDIOVANEW, lstSKINNEW, lstGASTROINNEW, lstMUSCULONEW, lstNEURONEW
			Yes	Y	citmNoYes_Y	
clYesNo	String		Yes	Y	citmYesNo_Y	lstRESPIRATCS, lstCARDIOVACS, lstSKINCS, lstGASTROINCS, lstMUSCULOCS, lstNEUROCS, lstPEOTHCS
			No	N	citmYesNo_N	

RDE Analytics: RD_FRMPE

Data Variable RefName	RD Column Name	Column Data Type

lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
lstRESPIRAT	LSTRESPIRAT_C	VARCHAR2
	LSTRESPIRAT	VARCHAR2
	LSTRESPIRAT_ND	VARCHAR2
lstRESPIRAT - lstRESPIRATNEW	LSTRESPIRATNEW_C	VARCHAR2
	LSTRESPIRATNEW	VARCHAR2
lstRESPIRAT - txtRESPIRATNEWSP	TXTRESPIRATNEWSP	VARCHAR2
lstRESPIRAT - lstRESPIRATCS	LSTRESPIRATCS_C	VARCHAR2
	LSTRESPIRATCS	VARCHAR2
lstCARDIOVA	LSTCARDIOVA_C	VARCHAR2
	LSTCARDIOVA	VARCHAR2
	LSTCARDIOVA_ND	VARCHAR2
lstCARDIOVA - lstCARDIOVANEW	LSTCARDIOVANEW_C	VARCHAR2
	LSTCARDIOVANEW	VARCHAR2
lstCARDIOVA - txtCARDIOVANEWSP	TXTCARDIOVANEWSP	VARCHAR2
lstCARDIOVA - lstCARDIOVACS	LSTCARDIOVACS_C	VARCHAR2
	LSTCARDIOVACS	VARCHAR2
lstSKIN	LSTSKIN_C	VARCHAR2
	LSTSKIN	VARCHAR2
	LSTSKIN_ND	VARCHAR2
lstSKIN - lstSKINNEW	LSTSKINNEW_C	VARCHAR2
	LSTSKINNEW	VARCHAR2
lstSKIN - txtSKINNEWSP	TXTSKINNEWSP	VARCHAR2
lstSKIN - lstSKINCS	LSTSKINCS_C	VARCHAR2
	LSTSKINCS	VARCHAR2
lstGASTROIN	LSTGASTROIN_C	VARCHAR2
	LSTGASTROIN	VARCHAR2
	LSTGASTROIN_ND	VARCHAR2
lstGASTROIN - lstGASTROINNEW	LSTGASTROINNEW_C	VARCHAR2
	LSTGASTROINNEW	VARCHAR2
lstGASTROIN - txtGASTROINNEWSP	TXTGASTROINNEWSP	VARCHAR2
lstGASTROIN - lstGASTROINCS	LSTGASTROINCS_C	VARCHAR2
	LSTGASTROINCS	VARCHAR2
lstMUSCULO	LSTMUSCULO_C	VARCHAR2
	LSTMUSCULO	VARCHAR2
	LSTMUSCULO_ND	VARCHAR2
lstMUSCULO - lstMUSCULONEW	LSTMUSCULONEW_C	VARCHAR2
	LSTMUSCULONEW	VARCHAR2
lstMUSCULO - txtMUSCULONEWSP	TXTMUSCULONEWSP	VARCHAR2
lstMUSCULO - lstMUSCULOCS	LSTMUSCULOCS_C	VARCHAR2
	LSTMUSCULOCS	VARCHAR2
lstNEURO3	LSTNEURO3_C	VARCHAR2
	LSTNEURO3	VARCHAR2
	LSTNEURO3_ND	VARCHAR2
lstNEURO3 - lstNEURONEW	LSTNEURONEW_C	VARCHAR2
	LSTNEURONEW	VARCHAR2

lstNEURO3 - txtNEURONEWSP	TXTNEURONEWSP	VARCHAR2
lstNEURO3 - lstNEUROCS	LSTNEUROCS_C	VARCHAR2
	LSTNEUROCS	VARCHAR2
RD_FRMPE_SCTPEOTH		
txtPEOTH	TXTPEOTH	VARCHAR2
	TXTPEOTH_ND	VARCHAR2
lstPEOTHCS	LSTPEOTHCS_C	VARCHAR2
	LSTPEOTHCS	VARCHAR2
	LSTPEOTHCS_ND	VARCHAR2

AT3SC002: Vital Signs (VS) [frmVS]

From Month 25 to Month 48 (Year 3 and 4), carefully note that certain assessments do not need to be performed from the ICF signature for Protocol Amendment 6 onwards.

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
Weight [sctANTMEAS]		
2.* ✔	Weight [Weight]	**[numWEIGHT]** xxx.x kg[b]
Vital Signs [sctVS]		
Should be measured in supine position after 10 minutes of rest.		
3.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
4.* ✔	Blood pressure [Blood pressure]	**[cmpBP1]** **[numSYSBP1]** **[numDIABP1]** (mmHg) N3 / N3 systolic / diastolic
5.* ✔	Heart rate [Heart rate]	**[numHR1]** N3 bpm[b]
6.* ✔	Body temperature [Body temperature]	**[numTEMP1]** xx.x C[b]
7.* ✔	Respiratory rate [Respiratory rate]	**[numRR1]** N2 breaths per minute

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.

Codelist Values Tables: Vital Signs

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	

RDE Analytics: RD_FRMVS

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
numWEIGHT	NUMWEIGHT	FLOAT
	NUMWEIGHT_U	VARCHAR2
	NUMWEIGHT_ND	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
cmpBP1	CMPBP1_ND	VARCHAR2
cmpBP1 - numSYSBP1	NUMSYSBP1	NUMBER
cmpBP1 - numDIABP1	NUMDIABP1	NUMBER
numHR1	NUMHR1	NUMBER
	NUMHR1_U	VARCHAR2
	NUMHR1_ND	VARCHAR2
numTEMP1	NUMTEMP1	FLOAT
	NUMTEMP1_U	VARCHAR2
	NUMTEMP1_ND	VARCHAR2
numRR1	NUMRR1	NUMBER
	NUMRR1_ND	VARCHAR2

AT3SC002: Central Laboratory Assessments (LAB) [frmLAB2]

If an abnormality is present at Screening or before first dose of study drug, please cross-check with form MH (Medical History)
Please record new clinically significant abnormalities which started after first dose of study drug on the AE form

From Month 25 to Month 48 (Year 3 and 4), carefully note that certain assessments do not need to be performed from the ICF signature for Protocol Amendment 6 onwards.

Date of sample collection [sctLABDT]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ○ Same date as visit date *[A:OTHER]* ○ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)

Laboratory sampling [sctCOLL2]

2.* ✔	Were all labs obtained? [Were all labs obtained?]	**[txtLAB]** *[A:Y]* ○ Yes *[A:N]* ○ **[lstLAB2]** No, please specify *[A:HEMATOLOGY]* ☐ Hematology *[A:BIOCHEMISTRY]* ☐ Biochemistry *[A:COAGULATION]* ☐ Coagulation *[A:URINALYSIS]* ☐ Urinalysis *[A:LIVER FUNCTION TEST]* ☐ Liver Function Test
3.* ✔	Kit ID number [Kit ID number]	**[txtREFNO]** A11

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: Central Laboratory Assessments

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clYesNo	String		Yes	Y	citmYesNo_Y	txtLAB
			No	N	citmYesNo_N	
clLAB2	String		Hematology	HEMATOLOGY	citmLAB2_Hematology	lstLAB2
			Biochemistry	BIOCHEMISTRY	citmLAB2_Biochemistry	
			Coagulation	COAGULATION	citmLAB2_Coagulation	
			Urinalysis	URINALYSIS	citmLAB2_Urinalysis	
			Liver Function Test	LIVER FUNCTION TEST	citmLAB2_Liver	

RDE Analytics: RD_FRMLAB2

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
txtLAB	TXTLAB_C	VARCHAR2
	TXTLAB	VARCHAR2
	TXTLAB_ND	VARCHAR2
txtLAB - Hematology	*LSTLAB2_CITMLAB2HEMATOLOGY_C	VARCHAR2
	*LSTLAB2_CITMLAB2HEMATOLOGY	VARCHAR2
txtLAB - Biochemistry	*LSTLAB2_CITMLAB2BIOCHEMISTRY_C	VARCHAR2
	*LSTLAB2_CITMLAB2BIOCHEMISTRY	VARCHAR2
txtLAB - Coagulation	*LSTLAB2_CITMLAB2COAGULATION_C	VARCHAR2
	*LSTLAB2_CITMLAB2COAGULATION	VARCHAR2
txtLAB - Urinalysis	*LSTLAB2_CITMLAB2URINALYSIS_C	VARCHAR2
	*LSTLAB2_CITMLAB2URINALYSIS	VARCHAR2
txtLAB - Liver Function Test	LSTLAB2_CITMLAB2LIVER_C	VARCHAR2

	LSTLAB2_CITMLAB2LIVER	VARCHAR2
txtREFNO	TXTREFNO	VARCHAR2
	TXTREFNO_ND	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: Study Drug Administration - ALN-AT3SC (ALN-AT3SC) [frmADM2]

1.* ✔	Were predose LFT results obtained in a central and/or local lab? (Please complete in an unscheduled visit) [Were predose LFT results obtained in a central and/or local lab?]	**[lstLABLFT]** *[A:CENTRAL]* ☐ Central lab *[A:LOCAL]* ☐ Local lab *[A:NOT APPLICABLE]* ☐ Not applicable (from year 3 onwards, the frequency of predose LFT monitoring may be decreased for patients who have negative hep C antibody and meet the specific criteria as per protocol)
2.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
3.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
4.* ✔	Was this conducted in the clinic or during a home visit? [Administration at clinic or home?]	**[lstADMHC]** *[A:CLINIC]* ◯ Clinic - administered by a healthcare professional *[A:HOME]* ◯ Home - administered by a healthcare professional *[A:HOMEPAT]* ◯ Home - administered by patient *[A:HOMECARE]* ◯ Home - administered by caregiver *[A:CLINICPAT]* ◯ Clinic - administered by patient *[A:CLINICCARE]* ◯ Clinic - administered by caregiver
5. ✔	Planned dose (weight based) [Planned dose (weight based)]	**[numADM]** x.xxx mg/kg
6. ✔	Fixed dose [Fixed dose]	**[numADM2]** xxxx. mg
7.* ✔	Type of dispensed kit [Type of dispensed kit]	**[lstKITTYPE]** *[A:VIAL]* ◯ Vial *[A:PFS]* ◯ Pre-filled syringe (PFS) *[A:NOT APPLICABLE]* ◯ Not applicable
8.* ✔	Total volume administered at this visit [Volume administered]	**[numVOLADM]** xxxx. mL
9.* ✔	Was the full dose successfully administered? [Dose administered?]	**[lstDOSEADM]** *[A:Y]* ◯ Yes *[A:N]* ◯ **[txtDOSEADMNO]** No, provide the reason for partial dose A128
10.* ✔	Injection site location [Injection site]	**[lstINJSITE]** *[A:RIGHT UPPER QUADRANT]* ◯ Right upper quadrant *[A:LIGHT UPPER QUADRANT]* ◯ Left upper quadrant *[A:RIGHT LOWER QUANDRANT]* ◯ Right lower quadrant *[A:LEFT LOWER QUADRANT]* ◯ Left lower quadrant *[A:RIGHT UPPER ARM HIGH]* ◯ Right upper arm high *[A:LEFT UPPER ARM HIGH]* ◯ Left upper arm high *[A:RIGHT UPPER ARM LOW]* ◯ Right upper arm low *[A:LEFT UPPER ARM LOW]* ◯ Left upper arm low *[A:RIGHT UPPER THIGH]* ◯ Right upper thigh *[A:LEFT UPPER THIGH]* ◯ Left upper thigh *[A:RIGHT LOWER THIGH]* ◯ Right lower thigh *[A:LEFT LOWER THIGH]* ◯ Left lower thigh *[A:OTHER]* ◯ **[txtINJSITEOTH]** Other site location A128
11.* ✔	Was a 29 gauge needle used? [Was a 29 gauge needle used?]	**[lstNEEDLE]** *[A:Y]* ◯ Yes *[A:N]* ◯ No
12.* ✔	Was the Dose Injection associated with an Adverse Event? [Injection linked with AE?]	**[txtISRAE]** *[A:Y]* ◯ **[cmpAE]** Yes Please specify AE#(s) - as recorded on AE form **[numAESEQ1] [numAESEQ2] [numAESEQ3] [numAESEQ4] [numAESEQ5] [numAESEQ6]** N3 N3 N3 N3 N3 N3 *[A:N]* ◯ No
13.	For office use only *[hidden]*	**[numEMAIL1]**

	[For office use only]	N3
14.	For office use only *[hidden]* [For office use only]	**[numEMAIL2]** N3
15.	For office use only *[hidden]* [For office use only]	**[numEMAIL3]** N3

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: Study Drug Administration - ALN-AT3SC

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clLABLFT	String		Central lab	CENTRAL	citmLABLFT_CENTRAL	lstLABLFT
			Local lab	LOCAL	citmLABLFT_LOCAL	
			Not applicable (from year 3 onwards, the frequency of predose LFT monitoring may be decreased for patients who have negative hep C antibody and meet the specific criteria as per protocol)	NOT APPLICABLE	citmLABLFT_NOTAPPLICABLE	
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clADMHC	String		Clinic - administered by a healthcare professional	CLINIC	citmADMHC_CLINIC	lstADMHC
			Home - administered by a healthcare professional	HOME	citmADMHC_HOME	
			Home - administered by patient	HOMEPAT	citmADMHC_HOMEPAT	
			Home - administered by caregiver	HOMECARE	citmADMHC_HOMECARE	
			Clinic - administered by patient	CLINICPAT	citmADMHC_CLINICPAT	
			Clinic - administered by caregiver	CLINICCARE	citmADMHC_CLINICCARE	
clKITTYPE	String		Vial	VIAL	citmKITTYPE_VIAL	lstKITTYPE
			Pre-filled syringe (PFS)	PFS	citmKITTYPE_PFS	
			Not applicable	NOT APPLICABLE	citmKITTYPE_NOTAPPLICABLE	
clYesNo	String		Yes	Y	citmYesNo_Y	lstDOSEADM, lstNEEDLE, txtISRAE
			No	N	citmYesNo_N	
clINJSITE	String		Right upper quadrant	RIGHT UPPER QUADRANT	citmINJSITE_RUQ	lstINJSITE
			Left upper quadrant	LIGHT UPPER QUADRANT	citmINJSITE_LUQ	
			Right lower quadrant	RIGHT LOWER QUANDRANT	citmINJSITE_RLQ	
			Left lower quadrant	LEFT LOWER QUADRANT	citmINJSITE_LLQ	
			Right upper arm high	RIGHT UPPER ARM HIGH	citmINJSITE_RUAH	
			Left upper arm high	LEFT UPPER ARM HIGH	citmINJSITE_LUAH	
			Right upper arm low	RIGHT UPPER ARM LOW	citmINJSITE_RUAL	
			Left upper arm low	LEFT UPPER ARM LOW	citmINJSITE_LUAL	
			Right upper thigh	RIGHT UPPER THIGH	citmINJSITE_RUT	
			Left upper thigh	LEFT UPPER THIGH	citmINJSITE_LUT	
			Right lower thigh	RIGHT LOWER THIGH	citmINJSITE_RLT	
			Left lower thigh	LEFT LOWER THIGH	citmINJSITE_LLT	
			Other	OTHER	citmINJSITE_OTHER	

RDE Analytics: RD_FRMADM2

Data Variable RefName	RD Column Name	Column Data Type
lstLABLFT	LSTLABLFT_ND	VARCHAR2
lstLABLFT - Central lab	*LSTLABLFT_CITMLABLFTCENTRAL_C	VARCHAR2
	*LSTLABLFT_CITMLABLFTCENTRAL	VARCHAR2
lstLABLFT - Local lab	LSTLABLFT_CITMLABLFTLOCAL_C	VARCHAR2
	LSTLABLFT_CITMLABLFTLOCAL	VARCHAR2
lstLABLFT - Not applicable (from year 3 onwards, the frequency of predose LFT monitoring may be decreased for patients who have negative hep C antibody and meet the specific criteria as per protocol)	*LSTLABLFT_CITMLABLFTNOTAPPLICABLE_C	VARCHAR2
	*LSTLABLFT_CITMLABLFTNOTAPPLICABLE	VARCHAR2
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2

	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
lstADMHC	LSTADMHC_C	VARCHAR2
	LSTADMHC	VARCHAR2
	LSTADMHC_ND	VARCHAR2
numADM	NUMADM	FLOAT
	NUMADM_ND	VARCHAR2
numADM2	NUMADM2	FLOAT
	NUMADM2_ND	VARCHAR2
lstKITTYPE	LSTKITTYPE_C	VARCHAR2
	LSTKITTYPE	VARCHAR2
	LSTKITTYPE_ND	VARCHAR2
numVOLADM	NUMVOLADM	FLOAT
	NUMVOLADM_ND	VARCHAR2
lstDOSEADM	LSTDOSEADM_C	VARCHAR2
	LSTDOSEADM	VARCHAR2
	LSTDOSEADM_ND	VARCHAR2
lstDOSEADM - txtDOSEADMNO	TXTDOSEADMNO	VARCHAR2
lstINJSITE	LSTINJSITE_C	VARCHAR2
	LSTINJSITE	VARCHAR2
	LSTINJSITE_ND	VARCHAR2
lstINJSITE - txtINJSITEOTH	TXTINJSITEOTH	VARCHAR2
lstNEEDLE	LSTNEEDLE_C	VARCHAR2
	LSTNEEDLE	VARCHAR2
	LSTNEEDLE_ND	VARCHAR2
txtISRAE	TXTISRAE_C	VARCHAR2
	TXTISRAE	VARCHAR2
	TXTISRAE_ND	VARCHAR2
txtISRAE - numAESEQ1	NUMAESEQ1	NUMBER
txtISRAE - numAESEQ2	NUMAESEQ2	NUMBER
txtISRAE - numAESEQ3	NUMAESEQ3	NUMBER
txtISRAE - numAESEQ4	NUMAESEQ4	NUMBER
txtISRAE - numAESEQ5	NUMAESEQ5	NUMBER
txtISRAE - numAESEQ6	NUMAESEQ6	NUMBER
numEMAIL1	NUMEMAIL1	NUMBER
	NUMEMAIL1_ND	VARCHAR2
numEMAIL2	NUMEMAIL2	NUMBER
	NUMEMAIL2_ND	VARCHAR2
numEMAIL3	NUMEMAIL3	NUMBER
	NUMEMAIL3_ND	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: Telephone call (TEL) [frmTEL]

Telephone call [sctTEL]

1.* ✔	Was a telephone call done for the at-home administration of ALN-AT3SC? [Was a telephone call done?]	**[lstTEL]** *[A:Y]* **[dtTEL] (DD/MM/YYYY hh:mm)** Yes Date and Time of telephone call Req / Req / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock* *[A:N]* No

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: Telephone call

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	lstTEL
			No	N	citmYesNo_N	

RDE Analytics: RD_FRMTEL

Data Variable RefName	RD Column Name	Column Data Type
lstTEL	LSTTEL_C	VARCHAR2
	LSTTEL	VARCHAR2
	LSTTEL_ND	VARCHAR2
lstTEL - dtTEL	DTTEL	DATE
	DTTEL_DTS	VARCHAR2
	DTTEL_DTR	VARCHAR2

AT3SC002: 12-lead ECG (ECG M12M24) [frmECG_M12M24]

Assessment Date [sctECGDT]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)

12-lead Electrocardiogram - Predose [sctPRE_M12M24]

Supine after at least 10 minutes rest

2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
3.* ✔	Rhythm [Rhythm]	**[lstRHYTM]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
4.* ✔	Ventricular rate [Ventricular rate]	**[numVR]** N3 bpm[b]
5.* ✔	PR interval [PR]	**[numPR]** N3 msec[b]
6.* ✔	QRS duration [QRS]	**[numQRS]** N3 msec[b]
7.* ✔	QT interval [QT]	**[numQT]** N3 msec[b]
8.* ✔	QTc interval [QTc]	**[numQTCF]** N3 msec[b]
9.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
10. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN1]** *[A:SINUS BRADYCARDIA]* ☐ Sinus Bradycardia *[A:SINUS TACHYCARDIA]* ☐ Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* ☐ Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* ☐ Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* ☐ Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* ☐ Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* ☐ Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* ☐ Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* ☐ Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* ☐ Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* ☐ Atrial Fibrillation *[A:ATRIAL PACING]* ☐ Atrial Pacing *[A:VENTRICULAR PACING]* ☐ Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* ☐ Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* ☐ 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* ☐ 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* ☐ 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* ☐ 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* ☐ Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* ☐ Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* ☐ Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* ☐ Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* ☐ Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* ☐ Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* ☐ Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* ☐ Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* ☐ Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* ☐ Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* ☐ Inferior Infarct Pattern *[A:OTHER, SPECIFY]* ☐ **[txtABNOTH1]** Other, specify A128

11.* ✔	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	**[lstCHANGE4]** *[A:NO SIGNIFICANT WORSENING FROM BASELINE]* ◯ No significant worsening from baseline *[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]* ◯ **[txtCHANGE4]** Clinically significant worsening from baseline, specify A128
12-lead Electrocardiogram - 30 Minutes Postdose [sct30M]		
12.* ✔	Time performed [Time performed]	**[dtmASS_T2] (hh:mm)** Req : Req *24-hour clock*
13.* ✔	Rhythm [Rhythm]	**[lstRHYTM2]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
14.* ✔	Ventricular rate [Ventricular rate]	**[numVR2]** N3 bpm[b]
15.* ✔	PR interval [PR]	**[numPR2]** N3 msec[b]
16.* ✔	QRS duration [QRS]	**[numQRS2]** N3 msec[b]
17.* ✔	QT interval [QT]	**[numQT2]** N3 msec[b]
18.* ✔	QTc interval [QTc]	**[numQTCF2]** N3 msec[b]
19.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT2]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
20. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN2]** *[A:SINUS BRADYCARDIA]* ☐ Sinus Bradycardia *[A:SINUS TACHYCARDIA]* ☐ Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* ☐ Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* ☐ Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* ☐ Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* ☐ Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* ☐ Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* ☐ Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* ☐ Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* ☐ Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* ☐ Atrial Fibrillation *[A:ATRIAL PACING]* ☐ Atrial Pacing *[A:VENTRICULAR PACING]* ☐ Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* ☐ Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* ☐ 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* ☐ 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* ☐ 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* ☐ 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* ☐ Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* ☐ Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* ☐ Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* ☐ Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* ☐ Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* ☐ Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* ☐ Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* ☐ Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* ☐ Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* ☐ Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* ☐ Inferior Infarct Pattern *[A:OTHER, SPECIFY]* ☐ **[txtABNOTH2]** Other, specify A128
21.*	Change from baseline (Day 1, Pre-Dose) ECG	**[lstCHANGE1]**

✔	[Change from baseline]	*[A:NO SIGNIFICANT WORSENING FROM BASELINE]* ○ No significant worsening from baseline *[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]* ○ **[txtCHANGE1]** Clinically significant worsening from baseline, specify: A128
12-lead Electrocardiogram - 2 Hours Postdose [sct2H]		
22.* ✔	Time performed [Time performed]	**[dtmASS_T3] (hh:mm)** Req : Req *24-hour clock*
23.* ✔	Rhythm [Rhythm]	**[lstRHYTM3]** *[A:NORMAL]* ○ Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* ○ Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* ○ Abnormal, Clinically Significant
24.* ✔	Ventricular rate [Ventricular rate]	**[numVR3]** N3 bpm[b]
25.* ✔	PR interval [PR]	**[numPR3]** N3 msec[b]
26.* ✔	QRS duration [QRS]	**[numQRS3]** N3 msec[b]
27.* ✔	QT interval [QT]	**[numQT3]** N3 msec[b]
28.* ✔	QTc interval [QTc]	**[numQTCF3]** N3 msec[b]
29.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT3]** *[A:NORMAL]* ○ Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* ○ Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* ○ Abnormal, Clinically Significant
30. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN3]** *[A:SINUS BRADYCARDIA]* ☐ Sinus Bradycardia *[A:SINUS TACHYCARDIA]* ☐ Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* ☐ Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* ☐ Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* ☐ Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* ☐ Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* ☐ Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* ☐ Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* ☐ Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* ☐ Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* ☐ Atrial Fibrillation *[A:ATRIAL PACING]* ☐ Atrial Pacing *[A:VENTRICULAR PACING]* ☐ Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* ☐ Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* ☐ 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* ☐ 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* ☐ 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* ☐ 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* ☐ Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* ☐ Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* ☐ Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* ☐ Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* ☐ Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* ☐ Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* ☐ Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* ☐ Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* ☐ Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* ☐ Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* ☐ Inferior Infarct Pattern *[A:OTHER, SPECIFY]* ☐ **[txtABNOTH3]** Other, specify: A128
31.* ✔	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	**[lstCHANGE2]** *[A:NO SIGNIFICANT WORSENING FROM BASELINE]* ○ No significant worsening from baseline

		[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE] ◯ **[txtCHANGE2]** Clinically significant worsening from baseline, specify A128
12-lead Electrocardiogram - 4 Hours Postdose [sct4H]		
32.* ✔	Time performed [Time performed]	**[dtmASS_T4] (hh:mm)** Req : Req *24-hour clock*
33.* ✔	Rhythm [Rhythm]	**[lstRHYTM4]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
34.* ✔	Ventricular rate [Ventricular rate]	**[numVR4]** N3 bpm[b]
35.* ✔	PR interval [PR]	**[numPR4]** N3 msec[b]
36.* ✔	QRS duration [QRS]	**[numQRS4]** N3 msec[b]
37.* ✔	QT interval [QT]	**[numQT4]** N3 msec[b]
38.* ✔	QTc interval [QTc]	**[numQTCF4]** N3 msec[b]
39.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT4]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
40. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN4]** *[A:SINUS BRADYCARDIA]* ☐ Sinus Bradycardia *[A:SINUS TACHYCARDIA]* ☐ Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* ☐ Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* ☐ Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* ☐ Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* ☐ Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* ☐ Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* ☐ Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* ☐ Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* ☐ Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* ☐ Atrial Fibrillation *[A:ATRIAL PACING]* ☐ Atrial Pacing *[A:VENTRICULAR PACING]* ☐ Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* ☐ Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* ☐ 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* ☐ 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* ☐ 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* ☐ 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* ☐ Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* ☐ Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* ☐ Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* ☐ Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* ☐ Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* ☐ Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* ☐ Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* ☐ Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* ☐ Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* ☐ Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* ☐ Inferior Infarct Pattern *[A:OTHER, SPECIFY]* ☐ **[txtABNOTH4]** Other, specify A128
41.* ✔	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	**[lstCHANGE3]** *[A:NO SIGNIFICANT WORSENING FROM BASELINE]* ◯ No significant worsening from baseline *[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]* ◯ **[txtCHANGE3]**

Clinically significant worsening from baseline, specify

A128

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.

Codelist Values Tables: 12-lead ECG

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	lstRHYTM, lstRHYTM2, lstRHYTM3, lstRHYTM4
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	lstOVERALLINT, lstOVERALLINT2, lstOVERALLINT3, lstOVERALLINT4
			Abnormal, Not Clinically Significant	ABNORMAL, NOT CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalNCS	
			Abnormal, Clinically Significant	ABNORMAL, CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalCS	
clABN	String		Sinus Bradycardia	SINUS BRADYCARDIA	citmABN_SinusBradycardia	lstABN1, lstABN2, lstABN3, lstABN4
			Sinus Tachycardia	SINUS TACHYCARDIA	citmABN_SinusTachycardia	
			Atrial Tachycardia	ATRIAL TACHYCARDIA	citmABN_AtrialTachycardia	
			Ventricular Tachycardia	VENTRICULAR TACHYCARDIA	citmABN_VentricularTachycardia	
			Sick Sinus Syndrome	SICK SINUS SYNDROME	citmABN_SickSinusSyndrome	
			Premature Atrial Complexes	PREMATURE ATRIAL COMPLEXES	citmABN_PrematureAtrialComplexes	
			Premature Ventricular Complexes	PREMATURE VENTRICULAR COMPLEXES	citmABN_PrematureVentricularComplexes	
			Q Axis, Left Axis Deviation	Q AXIS LEFT AXIS DEVIATION	citmABN_QAxisLeftAxisDeviation	
			Left Atrial Abnormality	LEFT ATRIAL ABNORMALITY	citmABN_LeftAtrialAbnormality	
			Left Ventricular Hypertrophy	LEFT VENTRICULAR HYPERTROPHY	citmABN_LeftVentricularHypertrophy	
			Atrial Fibrillation	ATRIAL FIBRILLATION	citmABN_AtrialFibrillation	
			Atrial Pacing	ATRIAL PACING	citmABN_AtrialPacing	
			Ventricular Pacing	VENTRICULAR PACING	citmABN_VentricularPacing	
			Atrial Ventricular Pacing	ATRIAL VENTRICULAR PACING	citmABN_AtrialVentricularPacing	
			1st Degree A-V Block	1ST DEGREE A-V BLOCK	citmABN_1stDegreeAVBlock	
			2nd Degree A-V Block Type I	2ND DEGREE A-V BLOCK TYPE I	citmABN_2ndDegreeAVBlockTypeI	
			2nd Degree A-V Block Type II	2ND DEGREE A-V BLOCK TYPE II	citmABN_2ndDegreeAVBlockTypeII	
			3rd Degree A-V Block	3RD DEGREE A-V BLOCK	citmABN_3rdDegreeAVBlock	
			Left Bundle Branch Block	LEFT BUNDLE BRANCH BLOCK	citmABN_LeftBundleBranchBlock	
			Incomplete Left Bundle Branch Block	INCOMPLETE LEFT BUNDLE BRANCH BLOCK	citmABN_IncompleteLeftBundleBranchBlock	
			Left Anterior Hemiblock	LEFT ANTERIOR HEMIBLOCK	citmABN_LeftAnteriorHemiblock	
			Left Posterior Hemiblock	LEFT POSTERIOR HEMIBLOCK	citmABN_LeftPosteriorHemiblock	
			Right Bundle Branch Block	RIGHT BUNDLE BRANCH BLOCK	citmABN_RightBundleBranchBlock	
			Incomplete Right Bundle Branch Block	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK	citmABN_IncompleteRightBundleBranchBlock	
			Intraventricular Conduction Delay	INTRAVENTRICULAR CONDUCTION DELAY	citmABN_IntraventricularConductionDelay	
			Anteroseptal Infarct Pattern	ANTEROSEPTAL INFARCT PATTERN	citmABN_AnteroseptalInfarctPattern	
			Anterolateral Infarct Pattern	ANTEROLATERAL INFARCT PATTERN	citmABN_AnterolateralInfarctPattern	
			Lateral Infarct Pattern	LATERAL INFARCT PATTERN	citmABN_LateralInfarctPattern	
			Inferior Infarct Pattern	INFERIOR INFARCT PATTERN	citmABN_InferiorInfarctPattern	
			Other, specify	OTHER, SPECIFY	citmABN_Otherspecify	
clCHANGE_2	String		No significant worsening from baseline	NO SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_NOSIGNIFICANTWORSENINGFROMBASELINE_2	lstCHANGE4
			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE_2	
clCHANGE	String		No significant worsening from baseline	NO SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_NOSIGNIFICANTWORSENINGFROMBASELINE	lstCHANGE1
			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE	
clCHANGE_1	String		No significant worsening from baseline	NO SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_NOSIGNIFICANTWORSENINGFROMBASELINE_1	lstCHANGE2
			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE_1	
clCHANGE_1_1	String		No significant worsening from baseline	NO SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_NOSIGNIFICANTWORSENINGFROMBASELINE_1_1	lstCHANGE3

			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE_1_1	

RDE Analytics: RD_FRMECG_M12M24		
Data Variable RefName	**RD Column Name**	**Column Data Type**
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
lstRHYTM	LSTRHYTM_C	VARCHAR2
	LSTRHYTM	VARCHAR2
	LSTRHYTM_ND	VARCHAR2
numVR	NUMVR	NUMBER
	NUMVR_U	VARCHAR2
	NUMVR_ND	VARCHAR2
numPR	NUMPR	NUMBER
	NUMPR_U	VARCHAR2
	NUMPR_ND	VARCHAR2
numQRS	NUMQRS	NUMBER
	NUMQRS_U	VARCHAR2
	NUMQRS_ND	VARCHAR2
numQT	NUMQT	NUMBER
	NUMQT_U	VARCHAR2
	NUMQT_ND	VARCHAR2
numQTCF	NUMQTCF	NUMBER
	NUMQTCF_U	VARCHAR2
	NUMQTCF_ND	VARCHAR2
lstOVERALLINT	LSTOVERALLINT_C	VARCHAR2
	LSTOVERALLINT	VARCHAR2
	LSTOVERALLINT_ND	VARCHAR2
lstABN1	LSTABN1_ND	VARCHAR2
lstABN1 - Sinus Bradycardia	*LSTABN1_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN1 - Sinus Tachycardia	*LSTABN1_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN1 - Atrial Tachycardia	*LSTABN1_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN1 - Ventricular Tachycardia	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN1 - Sick Sinus Syndrome	*LSTABN1_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN1_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN1 - Premature Atrial Complexes	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN1 - Premature Ventricular Complexes	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN1 - Q Axis, Left Axis Deviation	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN1 - Left Atrial Abnormality	*LSTABN1_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN1 - Left Ventricular Hypertrophy	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2

	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN1 - Atrial Fibrillation	*LSTABN1_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN1_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN1 - Atrial Pacing	*LSTABN1_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALPACING	VARCHAR2
lstABN1 - Ventricular Pacing	*LSTABN1_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARPACING	VARCHAR2
lstABN1 - Atrial Ventricular Pacing	*LSTABN1_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN1 - 1st Degree A-V Block	*LSTABN1_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN1 - 2nd Degree A-V Block Type I	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN1 - 2nd Degree A-V Block Type II	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN1 - 3rd Degree A-V Block	*LSTABN1_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN1 - Left Bundle Branch Block	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Left Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Left Anterior Hemiblock	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Left Posterior Hemiblock	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Right Bundle Branch Block	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Right Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Intraventricular Conduction Delay	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN1 - Anteroseptal Infarct Pattern	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN1 - Anterolateral Infarct Pattern	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Lateral Infarct Pattern	*LSTABN1_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Inferior Infarct Pattern	*LSTABN1_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN1 - Other, specify	LSTABN1_TXTABNOTH1_C	VARCHAR2
	LSTABN1_TXTABNOTH1	VARCHAR2
lstABN1 - txtABNOTH1	TXTABNOTH1	VARCHAR2
lstCHANGE4	LSTCHANGE4_C	VARCHAR2
	LSTCHANGE4	VARCHAR2
	LSTCHANGE4_ND	VARCHAR2
lstCHANGE4 - txtCHANGE4	TXTCHANGE4	VARCHAR2
dtmASS_T2	DTMASS_T2	DATE
	DTMASS_T2_TMS	VARCHAR2
	DTMASS_T2_ND	VARCHAR2
lstRHYTM2	LSTRHYTM2_C	VARCHAR2
	LSTRHYTM2	VARCHAR2
	LSTRHYTM2_ND	VARCHAR2
numVR2	NUMVR2	NUMBER

	NUMVR2_U	VARCHAR2
	NUMVR2_ND	VARCHAR2
numPR2	NUMPR2	NUMBER
	NUMPR2_U	VARCHAR2
	NUMPR2_ND	VARCHAR2
numQRS2	NUMQRS2	NUMBER
	NUMQRS2_U	VARCHAR2
	NUMQRS2_ND	VARCHAR2
numQT2	NUMQT2	NUMBER
	NUMQT2_U	VARCHAR2
	NUMQT2_ND	VARCHAR2
numQTCF2	NUMQTCF2	NUMBER
	NUMQTCF2_U	VARCHAR2
	NUMQTCF2_ND	VARCHAR2
lstOVERALLINT2	LSTOVERALLINT2_C	VARCHAR2
	LSTOVERALLINT2	VARCHAR2
	LSTOVERALLINT2_ND	VARCHAR2
lstABN2	LSTABN2_ND	VARCHAR2
lstABN2 - Sinus Bradycardia	*LSTABN2_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN2 - Sinus Tachycardia	*LSTABN2_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN2 - Atrial Tachycardia	*LSTABN2_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN2 - Ventricular Tachycardia	*LSTABN2_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN2 - Sick Sinus Syndrome	*LSTABN2_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN2_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN2 - Premature Atrial Complexes	*LSTABN2_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN2_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN2 - Premature Ventricular Complexes	*LSTABN2_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN2_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN2 - Q Axis, Left Axis Deviation	*LSTABN2_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN2_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN2 - Left Atrial Abnormality	*LSTABN2_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN2_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN2 - Left Ventricular Hypertrophy	*LSTABN2_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN2_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN2 - Atrial Fibrillation	*LSTABN2_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN2_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN2 - Atrial Pacing	*LSTABN2_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN2_CITMABNATRIALPACING	VARCHAR2
lstABN2 - Ventricular Pacing	*LSTABN2_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN2_CITMABNVENTRICULARPACING	VARCHAR2
lstABN2 - Atrial Ventricular Pacing	*LSTABN2_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN2_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN2 - 1st Degree A-V Block	*LSTABN2_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN2_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN2 - 2nd Degree A-V Block Type I	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN2 - 2nd Degree A-V Block Type II	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN2 - 3rd Degree A-V Block	*LSTABN2_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2

	*LSTABN2_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN2 - Left Bundle Branch Block	*LSTABN2_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN2 - Incomplete Left Bundle Branch Block	*LSTABN2_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN2 - Left Anterior Hemiblock	*LSTABN2_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN2 - Left Posterior Hemiblock	*LSTABN2_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN2 - Right Bundle Branch Block	*LSTABN2_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN2 - Incomplete Right Bundle Branch Block	*LSTABN2_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN2 - Intraventricular Conduction Delay	*LSTABN2_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN2_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN2 - Anteroseptal Infarct Pattern	*LSTABN2_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN2 - Anterolateral Infarct Pattern	*LSTABN2_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN2 - Lateral Infarct Pattern	*LSTABN2_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN2 - Inferior Infarct Pattern	*LSTABN2_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN2 - Other, specify	LSTABN2_TXTABNOTH2_C	VARCHAR2
	LSTABN2_TXTABNOTH2	VARCHAR2
lstABN2 - txtABNOTH2	TXTABNOTH2	VARCHAR2
lstCHANGE1	LSTCHANGE1_C	VARCHAR2
	LSTCHANGE1	VARCHAR2
	LSTCHANGE1_ND	VARCHAR2
lstCHANGE1 - txtCHANGE1	TXTCHANGE1	VARCHAR2
dtmASS_T3	DTMASS_T3	DATE
	DTMASS_T3_TMS	VARCHAR2
	DTMASS_T3_ND	VARCHAR2
lstRHYTM3	LSTRHYTM3_C	VARCHAR2
	LSTRHYTM3	VARCHAR2
	LSTRHYTM3_ND	VARCHAR2
numVR3	NUMVR3	NUMBER
	NUMVR3_U	VARCHAR2
	NUMVR3_ND	VARCHAR2
numPR3	NUMPR3	NUMBER
	NUMPR3_U	VARCHAR2
	NUMPR3_ND	VARCHAR2
numQRS3	NUMQRS3	NUMBER
	NUMQRS3_U	VARCHAR2
	NUMQRS3_ND	VARCHAR2
numQT3	NUMQT3	NUMBER
	NUMQT3_U	VARCHAR2
	NUMQT3_ND	VARCHAR2
numQTCF3	NUMQTCF3	NUMBER
	NUMQTCF3_U	VARCHAR2
	NUMQTCF3_ND	VARCHAR2
lstOVERALLINT3	LSTOVERALLINT3_C	VARCHAR2
	LSTOVERALLINT3	VARCHAR2

	LSTOVERALLINT3_ND	VARCHAR2
lstABN3	LSTABN3_ND	VARCHAR2
lstABN3 - Sinus Bradycardia	*LSTABN3_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN3 - Sinus Tachycardia	*LSTABN3_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN3 - Atrial Tachycardia	*LSTABN3_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN3 - Ventricular Tachycardia	*LSTABN3_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN3 - Sick Sinus Syndrome	*LSTABN3_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN3_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN3 - Premature Atrial Complexes	*LSTABN3_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN3_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN3 - Premature Ventricular Complexes	*LSTABN3_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN3_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN3 - Q Axis, Left Axis Deviation	*LSTABN3_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN3_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN3 - Left Atrial Abnormality	*LSTABN3_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN3_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN3 - Left Ventricular Hypertrophy	*LSTABN3_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN3_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN3 - Atrial Fibrillation	*LSTABN3_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN3_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN3 - Atrial Pacing	*LSTABN3_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN3_CITMABNATRIALPACING	VARCHAR2
lstABN3 - Ventricular Pacing	*LSTABN3_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN3_CITMABNVENTRICULARPACING	VARCHAR2
lstABN3 - Atrial Ventricular Pacing	*LSTABN3_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN3_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN3 - 1st Degree A-V Block	*LSTABN3_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN3_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN3 - 2nd Degree A-V Block Type I	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN3 - 2nd Degree A-V Block Type II	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN3 - 3rd Degree A-V Block	*LSTABN3_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN3_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN3 - Left Bundle Branch Block	*LSTABN3_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN3 - Incomplete Left Bundle Branch Block	*LSTABN3_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN3 - Left Anterior Hemiblock	*LSTABN3_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN3 - Left Posterior Hemiblock	*LSTABN3_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN3 - Right Bundle Branch Block	*LSTABN3_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN3 - Incomplete Right Bundle Branch Block	*LSTABN3_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN3 - Intraventricular Conduction Delay	*LSTABN3_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN3_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN3 - Anteroseptal Infarct Pattern	*LSTABN3_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2

	*LSTABN3_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN3 - Anterolateral Infarct Pattern	*LSTABN3_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN3_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN3 - Lateral Infarct Pattern	*LSTABN3_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN3_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN3 - Inferior Infarct Pattern	*LSTABN3_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN3_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN3 - Other, specify	LSTABN3_TXTABNOTH3_C	VARCHAR2
	LSTABN3_TXTABNOTH3	VARCHAR2
lstABN3 - txtABNOTH3	TXTABNOTH3	VARCHAR2
lstCHANGE2	LSTCHANGE2_C	VARCHAR2
	LSTCHANGE2	VARCHAR2
	LSTCHANGE2_ND	VARCHAR2
lstCHANGE2 - txtCHANGE2	TXTCHANGE2	VARCHAR2
dtmASS_T4	DTMASS_T4	DATE
	DTMASS_T4_TMS	VARCHAR2
	DTMASS_T4_ND	VARCHAR2
lstRHYTM4	LSTRHYTM4_C	VARCHAR2
	LSTRHYTM4	VARCHAR2
	LSTRHYTM4_ND	VARCHAR2
numVR4	NUMVR4	NUMBER
	NUMVR4_U	VARCHAR2
	NUMVR4_ND	VARCHAR2
numPR4	NUMPR4	NUMBER
	NUMPR4_U	VARCHAR2
	NUMPR4_ND	VARCHAR2
numQRS4	NUMQRS4	NUMBER
	NUMQRS4_U	VARCHAR2
	NUMQRS4_ND	VARCHAR2
numQT4	NUMQT4	NUMBER
	NUMQT4_U	VARCHAR2
	NUMQT4_ND	VARCHAR2
numQTCF4	NUMQTCF4	NUMBER
	NUMQTCF4_U	VARCHAR2
	NUMQTCF4_ND	VARCHAR2
lstOVERALLINT4	LSTOVERALLINT4_C	VARCHAR2
	LSTOVERALLINT4	VARCHAR2
	LSTOVERALLINT4_ND	VARCHAR2
lstABN4	LSTABN4_ND	VARCHAR2
lstABN4 - Sinus Bradycardia	*LSTABN4_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN4 - Sinus Tachycardia	*LSTABN4_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN4 - Atrial Tachycardia	*LSTABN4_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN4 - Ventricular Tachycardia	*LSTABN4_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN4 - Sick Sinus Syndrome	*LSTABN4_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN4_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN4 - Premature Atrial Complexes	*LSTABN4_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN4_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN4 - Premature Ventricular Complexes	*LSTABN4_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN4_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2

lstABN4 - Q Axis, Left Axis Deviation	*LSTABN4_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN4_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN4 - Left Atrial Abnormality	*LSTABN4_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN4_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN4 - Left Ventricular Hypertrophy	*LSTABN4_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN4_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN4 - Atrial Fibrillation	*LSTABN4_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN4_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN4 - Atrial Pacing	*LSTABN4_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN4_CITMABNATRIALPACING	VARCHAR2
lstABN4 - Ventricular Pacing	*LSTABN4_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN4_CITMABNVENTRICULARPACING	VARCHAR2
lstABN4 - Atrial Ventricular Pacing	*LSTABN4_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN4_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN4 - 1st Degree A-V Block	*LSTABN4_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN4_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN4 - 2nd Degree A-V Block Type I	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN4 - 2nd Degree A-V Block Type II	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN4 - 3rd Degree A-V Block	*LSTABN4_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN4_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN4 - Left Bundle Branch Block	*LSTABN4_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN4 - Incomplete Left Bundle Branch Block	*LSTABN4_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN4 - Left Anterior Hemiblock	*LSTABN4_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN4 - Left Posterior Hemiblock	*LSTABN4_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN4 - Right Bundle Branch Block	*LSTABN4_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN4 - Incomplete Right Bundle Branch Block	*LSTABN4_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN4 - Intraventricular Conduction Delay	*LSTABN4_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN4_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN4 - Anteroseptal Infarct Pattern	*LSTABN4_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN4 - Anterolateral Infarct Pattern	*LSTABN4_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN4 - Lateral Infarct Pattern	*LSTABN4_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN4 - Inferior Infarct Pattern	*LSTABN4_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN4 - Other, specify	LSTABN4_TXTABNOTH4_C	VARCHAR2
	LSTABN4_TXTABNOTH4	VARCHAR2
lstABN4 - txtABNOTH4	TXTABNOTH4	VARCHAR2
lstCHANGE3	LSTCHANGE3_C	VARCHAR2
	LSTCHANGE3	VARCHAR2
	LSTCHANGE3_ND	VARCHAR2
lstCHANGE3 - txtCHANGE3	TXTCHANGE3	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: PK Subset Question (PK QUEST) [frmPKQUEST]

PK Subset Question [sctPKQUEST]

1.* ✔	Will the subject participate in a PK substudy? [Will the subject participate in a PK substudy?]	**[lstPKSUB]** *[A:Y]* ◯ Yes *[A:N]* ◯ No

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: PK Subset Question

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	lstPKSUB
			No	N	citmYesNo_N	

RDE Analytics: RD_FRMPKQUEST

Data Variable RefName	RD Column Name	Column Data Type
lstPKSUB	LSTPKSUB_C	VARCHAR2
	LSTPKSUB	VARCHAR2
	LSTPKSUB_ND	VARCHAR2

AT3SC002: Urine PK Sampling (PK UR) [frmPK_UR]		
0h - 6h urine collection interval [sctPKUR_OH6H]		
1.* ✔	Start date and time [Start date and time]	**[dPKUR_ST] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req : Req *24-hour clock*
2.* ✔	End date and time [End date and time]	**[dPKUR_EN0H6H] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req : Req *24-hour clock*
3.* ✔	Total volume urine collected [Total volume urine collected]	**[numPKUR_V0H6H]** xxxxx. mL
6h - 12h urine collection interval [sctPKUR_6H12H]		
4.* ✔	End date and time [End date and time]	**[dPKUR_EN6H12H] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req : Req *24-hour clock*
5.* ✔	Total volume urine collected [Total volume urine collected]	**[numPKUR_V6H12H]** xxxxx. mL
12h - 24h urine collection interval [sctPKUR_12H24H]		
6.* ✔	End date and time [End date and time]	**[dPKUR_EN12H24H] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req : Req *24-hour clock*
7.* ✔	Total volume urine collected [Total volume urine collected]	**[numPKUR_V12H24H]** xxxxx. mL

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_FRMPK_UR		
Data Variable RefName	**RD Column Name**	**Column Data Type**
dPKUR_ST	DPKUR_ST	DATE
	DPKUR_ST_DTS	VARCHAR2
	DPKUR_ST_ND	VARCHAR2
dPKUR_EN0H6H	DPKUR_EN0H6H	DATE
	DPKUR_EN0H6H_DTS	VARCHAR2
	DPKUR_EN0H6H_ND	VARCHAR2
numPKUR_V0H6H	NUMPKUR_V0H6H	FLOAT
	NUMPKUR_V0H6H_ND	VARCHAR2
dPKUR_EN6H12H	DPKUR_EN6H12H	DATE
	DPKUR_EN6H12H_DTS	VARCHAR2
	DPKUR_EN6H12H_ND	VARCHAR2
numPKUR_V6H12H	NUMPKUR_V6H12H	FLOAT
	NUMPKUR_V6H12H_ND	VARCHAR2
dPKUR_EN12H24H	DPKUR_EN12H24H	DATE
	DPKUR_EN12H24H_DTS	VARCHAR2
	DPKUR_EN12H24H_ND	VARCHAR2
numPKUR_V12H24H	NUMPKUR_V12H24H	FLOAT
	NUMPKUR_V12H24H_ND	VARCHAR2

AT3SC002: 12-lead ECG (ECG) [frmECG_PRE]

Assessment Date [sctASSDT]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)

12-lead Electrocardiogram - Predose [sctECG_UNS]

Supine after at least 10 minutes rest

2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
3.* ✔	Rhythm [Rhythm]	**[lstRHYTM]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
4.* ✔	Ventricular rate [Ventricular rate]	**[numVR]** N3 bpm[b]
5.* ✔	PR interval [PR]	**[numPR]** N3 msec[b]
6.* ✔	QRS duration [QRS]	**[numQRS]** N3 msec[b]
7.* ✔	QT interval [QT]	**[numQT]** N3 msec[b]
8.* ✔	QTc interval [QTc]	**[numQTCF]** N3 msec[b]
9.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
10. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN1]** *[A:SINUS BRADYCARDIA]* ☐ Sinus Bradycardia *[A:SINUS TACHYCARDIA]* ☐ Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* ☐ Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* ☐ Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* ☐ Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* ☐ Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* ☐ Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* ☐ Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* ☐ Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* ☐ Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* ☐ Atrial Fibrillation *[A:ATRIAL PACING]* ☐ Atrial Pacing *[A:VENTRICULAR PACING]* ☐ Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* ☐ Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* ☐ 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* ☐ 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* ☐ 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* ☐ 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* ☐ Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* ☐ Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* ☐ Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* ☐ Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* ☐ Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* ☐ Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* ☐ Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* ☐ Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* ☐ Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* ☐ Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* ☐ Inferior Infarct Pattern *[A:OTHER, SPECIFY]* ☐ **[txtABNOTH1]** Other, specify A128

11.* ✔	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	**[lstCHANGE1]** *[A:NO SIGNIFICANT WORSENING FROM BASELINE]* ◯ No significant worsening from baseline *[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]* ◯ **[txtCHANGE1]** Clinically significant worsening from baseline, specify A128

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.

Codelist Values Tables: 12-lead ECG

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	lstRHYTM
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	lstOVERALLINT
			Abnormal, Not Clinically Significant	ABNORMAL, NOT CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalNCS	
			Abnormal, Clinically Significant	ABNORMAL, CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalCS	
clABN	String		Sinus Bradycardia	SINUS BRADYCARDIA	citmABN_SinusBradycardia	lstABN1
			Sinus Tachycardia	SINUS TACHYCARDIA	citmABN_SinusTachycardia	
			Atrial Tachycardia	ATRIAL TACHYCARDIA	citmABN_AtrialTachycardia	
			Ventricular Tachycardia	VENTRICULAR TACHYCARDIA	citmABN_VentricularTachycardia	
			Sick Sinus Syndrome	SICK SINUS SYNDROME	citmABN_SickSinusSyndrome	
			Premature Atrial Complexes	PREMATURE ATRIAL COMPLEXES	citmABN_PrematureAtrialComplexes	
			Premature Ventricular Complexes	PREMATURE VENTRICULAR COMPLEXES	citmABN_PrematureVentricularComplexes	
			Q Axis, Left Axis Deviation	Q AXIS LEFT AXIS DEVIATION	citmABN_QAxisLeftAxisDeviation	
			Left Atrial Abnormality	LEFT ATRIAL ABNORMALITY	citmABN_LeftAtrialAbnormality	
			Left Ventricular Hypertrophy	LEFT VENTRICULAR HYPERTROPHY	citmABN_LeftVentricularHypertrophy	
			Atrial Fibrillation	ATRIAL FIBRILLATION	citmABN_AtrialFibrillation	
			Atrial Pacing	ATRIAL PACING	citmABN_AtrialPacing	
			Ventricular Pacing	VENTRICULAR PACING	citmABN_VentricularPacing	
			Atrial Ventricular Pacing	ATRIAL VENTRICULAR PACING	citmABN_AtrialVentricularPacing	
			1st Degree A-V Block	1ST DEGREE A-V BLOCK	citmABN_1stDegreeAVBlock	
			2nd Degree A-V Block Type I	2ND DEGREE A-V BLOCK TYPE I	citmABN_2ndDegreeAVBlockTypeI	
			2nd Degree A-V Block Type II	2ND DEGREE A-V BLOCK TYPE II	citmABN_2ndDegreeAVBlockTypeII	
			3rd Degree A-V Block	3RD DEGREE A-V BLOCK	citmABN_3rdDegreeAVBlock	
			Left Bundle Branch Block	LEFT BUNDLE BRANCH BLOCK	citmABN_LeftBundleBranchBlock	
			Incomplete Left Bundle Branch Block	INCOMPLETE LEFT BUNDLE BRANCH BLOCK	citmABN_IncompleteLeftBundleBranchBlock	
			Left Anterior Hemiblock	LEFT ANTERIOR HEMIBLOCK	citmABN_LeftAnteriorHemiblock	
			Left Posterior Hemiblock	LEFT POSTERIOR HEMIBLOCK	citmABN_LeftPosteriorHemiblock	
			Right Bundle Branch Block	RIGHT BUNDLE BRANCH BLOCK	citmABN_RightBundleBranchBlock	
			Incomplete Right Bundle Branch Block	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK	citmABN_IncompleteRightBundleBranchBlock	
			Intraventricular Conduction Delay	INTRAVENTRICULAR CONDUCTION DELAY	citmABN_IntraventricularConductionDelay	
			Anteroseptal Infarct Pattern	ANTEROSEPTAL INFARCT PATTERN	citmABN_AnteroseptalInfarctPattern	
			Anterolateral Infarct Pattern	ANTEROLATERAL INFARCT PATTERN	citmABN_AnterolateralInfarctPattern	
			Lateral Infarct Pattern	LATERAL INFARCT PATTERN	citmABN_LateralInfarctPattern	
			Inferior Infarct Pattern	INFERIOR INFARCT PATTERN	citmABN_InferiorInfarctPattern	
			Other, specify	OTHER, SPECIFY	citmABN_Otherspecify	
clCHANGE	String		No significant worsening from baseline	NO SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_NOSIGNIFICANTWORSENINGFROMBASELINE	lstCHANGE1
			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE	

RDE Analytics: RD_FRMECG_PRE

Data Variable RefName	RD Column Name	Column Data Type

lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
lstRHYTM	LSTRHYTM_C	VARCHAR2
	LSTRHYTM	VARCHAR2
	LSTRHYTM_ND	VARCHAR2
numVR	NUMVR	NUMBER
	NUMVR_U	VARCHAR2
	NUMVR_ND	VARCHAR2
numPR	NUMPR	NUMBER
	NUMPR_U	VARCHAR2
	NUMPR_ND	VARCHAR2
numQRS	NUMQRS	NUMBER
	NUMQRS_U	VARCHAR2
	NUMQRS_ND	VARCHAR2
numQT	NUMQT	NUMBER
	NUMQT_U	VARCHAR2
	NUMQT_ND	VARCHAR2
numQTCF	NUMQTCF	NUMBER
	NUMQTCF_U	VARCHAR2
	NUMQTCF_ND	VARCHAR2
lstOVERALLINT	LSTOVERALLINT_C	VARCHAR2
	LSTOVERALLINT	VARCHAR2
	LSTOVERALLINT_ND	VARCHAR2
lstABN1	LSTABN1_ND	VARCHAR2
lstABN1 - Sinus Bradycardia	*LSTABN1_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN1 - Sinus Tachycardia	*LSTABN1_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN1 - Atrial Tachycardia	*LSTABN1_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN1 - Ventricular Tachycardia	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN1 - Sick Sinus Syndrome	*LSTABN1_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN1_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN1 - Premature Atrial Complexes	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN1 - Premature Ventricular Complexes	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN1 - Q Axis, Left Axis Deviation	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN1 - Left Atrial Abnormality	*LSTABN1_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN1 - Left Ventricular Hypertrophy	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN1 - Atrial Fibrillation	*LSTABN1_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN1_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN1 - Atrial Pacing	*LSTABN1_CITMABNATRIALPACING_C	VARCHAR2

	*LSTABN1_CITMABNATRIALPACING	VARCHAR2
lstABN1 - Ventricular Pacing	*LSTABN1_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARPACING	VARCHAR2
lstABN1 - Atrial Ventricular Pacing	*LSTABN1_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN1 - 1st Degree A-V Block	*LSTABN1_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN1 - 2nd Degree A-V Block Type I	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN1 - 2nd Degree A-V Block Type II	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN1 - 3rd Degree A-V Block	*LSTABN1_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN1 - Left Bundle Branch Block	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Left Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Left Anterior Hemiblock	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Left Posterior Hemiblock	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Right Bundle Branch Block	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Right Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Intraventricular Conduction Delay	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN1 - Anteroseptal Infarct Pattern	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN1 - Anterolateral Infarct Pattern	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Lateral Infarct Pattern	*LSTABN1_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Inferior Infarct Pattern	*LSTABN1_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN1 - Other, specify	LSTABN1_TXTABNOTH1_C	VARCHAR2
	LSTABN1_TXTABNOTH1	VARCHAR2
lstABN1 - txtABNOTH1	TXTABNOTH1	VARCHAR2
lstCHANGE1	LSTCHANGE1_C	VARCHAR2
	LSTCHANGE1	VARCHAR2
	LSTCHANGE1_ND	VARCHAR2
lstCHANGE1 - txtCHANGE1	TXTCHANGE1	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: Visit Purpose (VISPUR) [frmVISPUR]

Visit Purpose [sctVISPUR]

1.* ✔ Indicate the dosing schedule at this visit
[Indicate the dosing schedule at this visit]

[lstVIS]
- *[A:50 QM]* ○ 50mg QM
- *[A:50 Q2M]* ○ **[lstDOSING]** 50mg Q2M
  - *[A:DOSING]* ○ Dosing
  - *[A:NO DOSING]* ○ No Dosing
- *[A:80 QM]* ○ 80mg QM

2. ✔ In case the old visit schedule is resumed after signing the Informed Consent for protocol amendment 8 and this visit is part of the first 6 months after resuming dose, was additional lab collected?
[Lab collected for the first 6 months after resuming dose?]

[lstLAB6M]
- *[A:Y]* ○ Yes
- *[A:N]* ○ No

3.* ✔ Choose the current visit
[Choose the current visit]

[lstCURVIS]
[clVISIT]

4.* ✔ Please indicate for this visit if dose level was not changed/escalated/de-escalated or if treatment was discontinued?
[Dose level not changed/escalated/de-escalated/treatment discontinued?]

[lstDOSECHANGE]

[A:DOSE LEVEL NOT CHANGED] ○ **[lstNOTCHANGED]** Dose level not changed, please specify reason
- *[A:SAME DOSE]* ○ Participant eligible to continue on original dosing
- *[A:CRITERIA NOT MET]* ○ **[lstCRITNOTMET]** Protocol dose change criteria not met
  - *[A:NOT A PROTOCOL-SPECIFIED VISIT FOR POTENTIAL DOSE CHANGE]* ○ Not a protocol-specified visit for potential dose change
  - *[A:WITHOUT AT GREATER THAN 35 OR LESS THAN 15]* ○ Without two previous predose AT levels from central lab testing > 35% or < 15% at a protocol-specified visit for potential dose change
- *[A:AT GREATER THAN 35]* ○ **[lstAT35]** Two previous predose AT levels from central lab testing > 35% at a protocol-specified visit for potential dose change
  - *[A:NOT ELIGIBLE TO RE-ESCALATE]* ○ Participant previously had more than 1 AT level < 15% at the 50mg QM or 80mg QM dose level and is not eligible to re-escalate to the same dose level
  - *[A:OTHER]* ○ **[txtAT35O]** Other, please specify: A200
- *[A:AT LESS THAN 15]* ○ **[txtAT15O]** Two previous predose AT levels from central lab testing < 15%, please specify reason: A200
- *[A:OTHER]* ○ **[txtNOTCHOTH]** Other, please specify: A200

[A:DOSE LEVEL ESCALATED] ○ **[lstESCAL]** Dose level escalated, please specify reason
- *[A:AT LEVELS GREATER THAN 35]* ○ Two previous predose AT levels from central lab testing > 35%
- *[A:OTHER]* ○ **[txtESCALO]** Other, please specify: A200

[A:DOSE LEVEL DE-ESCALATED] ○ **[txtDEESCALO]** Dose level de-escalated, please specify reason: A200

[A:TREATMENT DISCONTINUED] ○ **[lstDISCONT]** Treatment discontinued, please specify reason
- *[A:AT LEVELS LESS THAN 15]* ○ Two previous predose AT levels from central lab testing < 15%
- *[A:OTHER]* ○ **[txtDISCONTO]** Other, please specify: A200

5. ✔	AT 1 [AT 1]	**[cmpAT1]** **[lstVISITAT1]** **[dAT1] (DD/MM/YYYY)** **[numAT1]** Visit AT1 **[clVISITAT]** Date of assessment AT1 Req / Req / Req (2015-2023) AT value 1 xxx.x %[b]
6. ✔	AT 2 [AT 2]	**[cmpAT2]** **[lstVISITAT2]** **[dAT2] (DD/MM/YYYY)** **[numAT2]** Visit AT2 **[clVISITAT]** Date of assessment AT2 Req / Req / Req (2015-2023) AT value 2 xxx.x %[b]
7. ✔	AT 3 [AT 3]	**[cmpAT3]** **[lstVISITAT3]** **[dAT3] (DD/MM/YYYY)** **[numAT3]** Visit AT3 **[clVISITAT]** Date of assessment AT3 Req / Req / Req (2015-2023) AT value 3 xxx.x %[b]

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.

Codelist Values Tables: Visit Purpose

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDOSE	String		50mg QM	50 QM	citmDOSE_50QM	lstVIS
			50mg Q2M	50 Q2M	citmDOSE_50Q2M	
			80mg QM	80 QM	citmDOSE_80QM	
clDOSING	String		Dosing	DOSING	citmDOSING_DOSING	lstDOSING
			No Dosing	NO DOSING	citmDOSING_NODOSING	
clYesNo	String		Yes	Y	citmYesNo_Y	lstLAB6M
			No	N	citmYesNo_N	
clVISIT	String		PR Day 1	PRD1	citmVISIT_PRD1	lstCURVIS
			PR Month 1	PRM1	citmVISIT_PRM1	
			PR Month 2	PRM2	citmVISIT_PRM2	
			PR Month 3	PRM3	citmVISIT_PRM3	
			PR Month 4	PRM4	citmVISIT_PRM4	
			PR Month 5	PRM5	citmVISIT_PRM5	
			PR Month 6	PRM6	citmVISIT_PRM6	
			PR Month 7	PRM7	citmVISIT_PRM7	
			PR Month 8	PRM8	citmVISIT_PRM8	
			PR Month 9	PRM9	citmVISIT_PRM9	
			PR Month 10	PRM10	citmVISIT_PRM10	
			PR Month 11	PRM11	citmVISIT_PRM11	
			PR Month 12	PRM12	citmVISIT_PRM12	
			PR Month 13	PRM13	citmVISIT_PRM13	
			PR Month 14	PRM14	citmVISIT_PRM14	
			PR Month 15	PRM15	citmVISIT_PRM15	
			PR Month 16	PRM16	citmVISIT_PRM16	
			PR Month 17	PRM17	citmVISIT_PRM17	
			PR Month 18	PRM18	citmVISIT_PRM18	
			PR Month 19	PRM19	citmVISIT_PRM19	
			PR Month 20	PRM20	citmVISIT_PRM20	
			PR Month 21	PRM21	citmVISIT_PRM21	
			PR Month 22	PRM22	citmVISIT_PRM22	
			PR Month 23	PRM23	citmVISIT_PRM23	
			PR Month 24	PRM24	citmVISIT_PRM24	
			PR Month 25	PRM25	citmVISIT_PRM25	
			PR Month 26	PRM26	citmVISIT_PRM26	
			PR Month 27	PRM27	citmVISIT_PRM27	
			PR Month 28	PRM28	citmVISIT_PRM28	
			PR Month 29	PRM29	citmVISIT_PRM29	
			PR Month 30	PRM30	citmVISIT_PRM30	
			PR Month 31	PRM31	citmVISIT_PRM31	
			PR Month 32	PRM32	citmVISIT_PRM32	

			PR Month 33	PRM33	citmVISIT_PRM33	
			PR Month 34	PRM34	citmVISIT_PRM34	
			PR Month 35	PRM35	citmVISIT_PRM35	
			PR Month 36	PRM36	citmVISIT_PRM36	
			Month 40	M40	citmVISIT_M40	
			Month 41	M41	citmVISIT_M41	
			Month 42	M42	citmVISIT_M42	
			Month 43	M43	citmVISIT_M43	
			Month 44	M44	citmVISIT_M44	
			Month 45	M45	citmVISIT_M45	
			Month 46	M46	citmVISIT_M46	
			Month 47	M47	citmVISIT_M47	
			Month 48	M48	citmVISIT_M48	
			Month 49	M49	citmVISIT_M49	
			Month 50	M50	citmVISIT_M50	
			Month 51	M51	citmVISIT_M51	
			Month 52	M52	citmVISIT_M52	
			Month 53	M53	citmVISIT_M53	
			Month 54	M54	citmVISIT_M54	
			Month 55	M55	citmVISIT_M55	
			Month 56	M56	citmVISIT_M56	
			Month 57	M57	citmVISIT_M57	
			Month 58	M58	citmVISIT_M58	
			Month 59	M59	citmVISIT_M59	
			Month 60	M60	citmVISIT_M60	
			Month 61	M61	citmVISIT_M61	
			Month 62	M62	citmVISIT_M62	
			Month 63	M63	citmVISIT_M63	
			Month 64	M64	citmVISIT_M64	
			Month 65	M65	citmVISIT_M65	
			Month 66	M66	citmVISIT_M66	
			Month 67	M67	citmVISIT_M67	
			Month 68	M68	citmVISIT_M68	
			Month 69	M69	citmVISIT_M69	
			Month 70	M70	citmVISIT_M70	
			Month 71	M71	citmVISIT_M71	
			Month 72	M72	citmVISIT_M72	
			Month 73	M73	citmVISIT_M73	
			Month 74	M74	citmVISIT_M74	
			Month 75	M75	citmVISIT_M75	
			Month 76	M76	citmVISIT_M76	
			Month 77	M77	citmVISIT_M77	
			Month 78	M78	citmVISIT_M78	
			Month 79	M79	citmVISIT_M79	
			Month 80	M80	citmVISIT_M80	
			Month 81	M81	citmVISIT_M81	
			Month 82	M82	citmVISIT_M82	
			Month 83	M83	citmVISIT_M83	
			EOT	EOT	citmVISIT_EOT	
clDOSECHANGE	String		Dose level not changed	DOSE LEVEL NOT CHANGED	citmDOSECHANGE_NOTCHANGED	lstDOSECHANGE
			Dose level escalated	DOSE LEVEL ESCALATED	citmDOSECHANGE_ESCALATED	
			Dose level de-escalated	DOSE LEVEL DE-ESCALATED	citmDOSECHANGE_DEESCALATED	
			Treatment discontinued	TREATMENT DISCONTINUED	citmDOSECHANGE_DISCONTINUED	

clNOTCHANGED	String		Participant eligible to continue on original dosing	SAME DOSE	citmNOTCHANGED_SAMEDOSE	lstNOTCHANGED
			Protocol dose change criteria not met	CRITERIA NOT MET	citmNOTCHANGED_CRITERIANOTMET	
			Two previous predose AT levels from central lab testing > 35% at a protocol-specified visit for potential dose change	AT GREATER THAN 35	citmNOTCHANGED_AT35	
			Two previous predose AT levels from central lab testing < 15%	AT LESS THAN 15	citmNOTCHANGED_AT15	
			Other	OTHER	citmNOTCHANGED_OTH	
clCRITNOTMET	String		Not a protocol-specified visit for potential dose change	NOT A PROTOCOL-SPECIFIED VISIT FOR POTENTIAL DOSE CHANGE	citmCRITNOTMET_VISIT	lstCRITNOTMET
			Without two previous predose AT levels from central lab testing > 35% or < 15% at a protocol-specified visit for potential dose change	WITHOUT AT GREATER THAN 35 OR LESS THAN 15	citmCRITNOTMET_AT	
clAT35	String		Participant previously had more than 1 AT level < 15% at the 50mg QM or 80mg QM dose level and is not eligible to re-escalate to the same dose level	NOT ELIGIBLE TO RE-ESCALATE	citmAT35_NOTELIGIBLE	lstAT35
			Other	OTHER	citmAT35_OTHER	
clESCAL	String		Two previous predose AT levels from central lab testing > 35%	AT LEVELS GREATER THAN 35	citmESCAL_AT	lstESCAL
			OTHER	OTHER	citmESCAL_OTHER	
clDISCONT	String		Two previous predose AT levels from central lab testing < 15%	AT LEVELS LESS THAN 15	citmDISCONT_AT	lstDISCONT
			Other	OTHER	citmDISCONT_OTHER	
clVISITAT	String		PR Day 1	PRD1	citmVISITAT_PRD1	lstVISITAT1, lstVISITAT2, lstVISITAT3
			PR Month 1	PRM1	citmVISITAT_PRM1	
			PR Month 2	PRM2	citmVISITAT_PRM2	
			PR Month 3	PRM3	citmVISITAT_PRM3	
			PR Month 4	PRM4	citmVISITAT_PRM4	
			PR Month 5	PRM5	citmVISITAT_PRM5	
			PR Month 6	PRM6	citmVISITAT_PRM6	
			PR Month 7	PRM7	citmVISITAT_PRM7	
			PR Month 8	PRM8	citmVISITAT_PRM8	
			PR Month 9	PRM9	citmVISITAT_PRM9	
			PR Month 10	PRM10	citmVISITAT_PRM10	
			PR Month 11	PRM11	citmVISITAT_PRM11	
			PR Month 12	PRM12	citmVISITAT_PRM12	
			PR Month 13	PRM13	citmVISITAT_PRM13	
			PR Month 14	PRM14	citmVISITAT_PRM14	
			PR Month 15	PRM15	citmVISITAT_PRM15	
			PR Month 16	PRM16	citmVISITAT_PRM16	
			PR Month 17	PRM17	citmVISITAT_PRM17	
			PR Month 18	PRM18	citmVISITAT_PRM18	
			PR Month 19	PRM19	citmVISITAT_PRM19	
			PR Month 20	PRM20	citmVISITAT_PRM20	
			PR Month 21	PRM21	citmVISITAT_PRM21	
			PR Month 22	PRM22	citmVISITAT_PRM22	
			PR Month 23	PRM23	citmVISITAT_PRM23	
			PR Month 24	PRM24	citmVISITAT_PRM24	
			PR Month 25	PRM25	citmVISITAT_PRM25	
			PR Month 26	PRM26	citmVISITAT_PRM26	
			PR Month 27	PRM27	citmVISITAT_PRM27	
			PR Month 28	PRM28	citmVISITAT_PRM28	
			PR Month 29	PRM29	citmVISITAT_PRM29	
			PR Month 30	PRM30	citmVISITAT_PRM30	
			PR Month 31	PRM31	citmVISITAT_PRM31	
			PR Month 32	PRM32	citmVISITAT_PRM32	
			PR Month 33	PRM33	citmVISITAT_PRM33	
			PR Month 34	PRM34	citmVISITAT_PRM34	
			PR Month 35	PRM35	citmVISITAT_PRM35	
			PR Month 36	PRM36	citmVISITAT_PRM36	
			Day 1	D1	citmVISITAT_D1	

Month 1	M1	citmVISITAT_M1
Month 2	M2	citmVISITAT_M2
Month 3	M3	citmVISITAT_M3
Month 4	M4	citmVISITAT_M4
Month 5	M5	citmVISITAT_M5
Month 6	M6	citmVISITAT_M6
Month 7	M7	citmVISITAT_M7
Month 8	M8	citmVISITAT_M8
Month 9	M9	citmVISITAT_M9
Month 10	M10	citmVISITAT_M10
Month 11	M11	citmVISITAT_M11
Month 12	M12	citmVISITAT_M12
Month 13	M13	citmVISITAT_M13
Month 14	M14	citmVISITAT_M14
Month 15	M15	citmVISITAT_M15
Month 16	M16	citmVISITAT_M16
Month 17	M17	citmVISITAT_M17
Month 18	M18	citmVISITAT_M18
Month 19	M19	citmVISITAT_M19
Month 20	M20	citmVISITAT_M20
Month 21	M21	citmVISITAT_M21
Month 22	M22	citmVISITAT_M22
Month 23	M23	citmVISITAT_M23
Month 24	M24	citmVISITAT_M24
Month 25	M25	citmVISITAT_M25
Month 26	M26	citmVISITAT_M26
Month 27	M27	citmVISITAT_M27
Month 28	M28	citmVISITAT_M28
Month 29	M29	citmVISITAT_M29
Month 30	M30	citmVISITAT_M30
Month 31	M31	citmVISITAT_M31
Month 32	M32	citmVISITAT_M32
Month 33	M33	citmVISITAT_M33
Month 34	M34	citmVISITAT_M34
Month 35	M35	citmVISITAT_M35
Month 36	M36	citmVISITAT_M36
Month 37	M37	citmVISITAT_M37
Month 38	M38	citmVISITAT_M38
Month 39	M39	citmVISITAT_M39
Month 40	M40	citmVISITAT_M40
Month 41	M41	citmVISITAT_M41
Month 42	M42	citmVISITAT_M42
Month 43	M43	citmVISITAT_M43
Month 44	M44	citmVISITAT_M44
Month 45	M45	citmVISITAT_M45
Month 46	M46	citmVISITAT_M46
Month 47	M47	citmVISITAT_M47
Month 48	M48	citmVISITAT_M48
Month 49	M49	citmVISITAT_M49
Month 50	M50	citmVISITAT_M50
Month 51	M51	citmVISITAT_M51
Month 52	M52	citmVISITAT_M52
Month 53	M53	citmVISITAT_M53

				M54	citmVISITAT_M54	
			Month 55	M55	citmVISITAT_M55	
			Month 56	M56	citmVISITAT_M56	
			Month 57	M57	citmVISITAT_M57	
			Month 58	M58	citmVISITAT_M58	
			Month 59	M59	citmVISITAT_M59	
			Month 60	M60	citmVISITAT_M60	
			Month 61	M61	citmVISITAT_M61	
			Month 62	M62	citmVISITAT_M62	
			Month 63	M63	citmVISITAT_M63	
			Month 64	M64	citmVISITAT_M64	
			Month 65	M65	citmVISITAT_M65	
			Month 66	M66	citmVISITAT_M66	
			Month 67	M67	citmVISITAT_M67	
			Month 68	M68	citmVISITAT_M68	
			Month 69	M69	citmVISITAT_M69	
			Month 70	M70	citmVISITAT_M70	
			Month 71	M71	citmVISITAT_M71	
			Month 72	M72	citmVISITAT_M72	
			Month 73	M73	citmVISITAT_M73	
			Month 74	M74	citmVISITAT_M74	
			Month 75	M75	citmVISITAT_M75	
			Month 76	M76	citmVISITAT_M76	
			Month 77	M77	citmVISITAT_M77	
			Month 78	M78	citmVISITAT_M78	
			Month 79	M79	citmVISITAT_M79	
			Month 80	M80	citmVISITAT_M80	
			Month 81	M81	citmVISITAT_M81	
			Month 82	M82	citmVISITAT_M82	
			Month 83	M83	citmVISITAT_M83	
			EOT	EOT	citmVISITAT_EOT	
			Unscheduled	UNS	citmVISITAT_UNS	

RDE Analytics: RD_FRMVISPUR		
Data Variable RefName	**RD Column Name**	**Column Data Type**
lstVIS	LSTVIS_C	VARCHAR2
	LSTVIS	VARCHAR2
	LSTVIS_ND	VARCHAR2
lstVIS - lstDOSING	LSTDOSING_C	VARCHAR2
	LSTDOSING	VARCHAR2
lstLAB6M	LSTLAB6M_C	VARCHAR2
	LSTLAB6M	VARCHAR2
	LSTLAB6M_ND	VARCHAR2
lstCURVIS	LSTCURVIS_C	VARCHAR2
	LSTCURVIS	VARCHAR2
	LSTCURVIS_ND	VARCHAR2
lstDOSECHANGE	LSTDOSECHANGE_C	VARCHAR2
	LSTDOSECHANGE	VARCHAR2
	LSTDOSECHANGE_ND	VARCHAR2
lstDOSECHANGE - lstNOTCHANGED	LSTNOTCHANGED_C	VARCHAR2
	LSTNOTCHANGED	VARCHAR2
lstDOSECHANGE - lstCRITNOTMET	LSTCRITNOTMET_C	VARCHAR2
	LSTCRITNOTMET	VARCHAR2

lstDOSECHANGE - lstAT35	LSTAT35_C	VARCHAR2
	LSTAT35	VARCHAR2
lstDOSECHANGE - txtAT35O	TXTAT35O	VARCHAR2
lstDOSECHANGE - txtAT15O	TXTAT15O	VARCHAR2
lstDOSECHANGE - txtNOTCHOTH	TXTNOTCHOTH	VARCHAR2
lstDOSECHANGE - lstESCAL	LSTESCAL_C	VARCHAR2
	LSTESCAL	VARCHAR2
lstDOSECHANGE - txtESCALO	TXTESCALO	VARCHAR2
lstDOSECHANGE - txtDEESCALO	TXTDEESCALO	VARCHAR2
lstDOSECHANGE - lstDISCONT	LSTDISCONT_C	VARCHAR2
	LSTDISCONT	VARCHAR2
lstDOSECHANGE - txtDISCONTO	TXTDISCONTO	VARCHAR2
cmpAT1	CMPAT1_ND	VARCHAR2
cmpAT1 - lstVISITAT1	LSTVISITAT1_C	VARCHAR2
	LSTVISITAT1	VARCHAR2
cmpAT1 - dAT1	DAT1	DATE
	DAT1_DTS	VARCHAR2
cmpAT1 - numAT1	NUMAT1	FLOAT
	NUMAT1_U	VARCHAR2
cmpAT2	CMPAT2_ND	VARCHAR2
cmpAT2 - lstVISITAT2	LSTVISITAT2_C	VARCHAR2
	LSTVISITAT2	VARCHAR2
cmpAT2 - dAT2	DAT2	DATE
	DAT2_DTS	VARCHAR2
cmpAT2 - numAT2	NUMAT2	FLOAT
	NUMAT2_U	VARCHAR2
cmpAT3	CMPAT3_ND	VARCHAR2
cmpAT3 - lstVISITAT3	LSTVISITAT3_C	VARCHAR2
	LSTVISITAT3	VARCHAR2
cmpAT3 - dAT3	DAT3	DATE
	DAT3_DTS	VARCHAR2
cmpAT3 - numAT3	NUMAT3	FLOAT
	NUMAT3_U	VARCHAR2

AT3SC002: 12-lead ECG (Escalation) (ECG ESC) [frmECG_ESC]

Assessment Date [sctECGDT]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)

12-lead Electrocardiogram - Predose [sctPRE_M12M24]

Supine after at least 10 minutes rest

2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
3.* ✔	Rhythm [Rhythm]	**[lstRHYTM]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
4.* ✔	Ventricular rate [Ventricular rate]	**[numVR]** N3 bpm[b]
5.* ✔	PR interval [PR]	**[numPR]** N3 msec[b]
6.* ✔	QRS duration [QRS]	**[numQRS]** N3 msec[b]
7.* ✔	QT interval [QT]	**[numQT]** N3 msec[b]
8.* ✔	QTc interval [QTc]	**[numQTCF]** N3 msec[b]
9.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
10. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN1]** *[A:SINUS BRADYCARDIA]* ☐ Sinus Bradycardia *[A:SINUS TACHYCARDIA]* ☐ Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* ☐ Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* ☐ Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* ☐ Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* ☐ Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* ☐ Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* ☐ Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* ☐ Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* ☐ Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* ☐ Atrial Fibrillation *[A:ATRIAL PACING]* ☐ Atrial Pacing *[A:VENTRICULAR PACING]* ☐ Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* ☐ Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* ☐ 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* ☐ 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* ☐ 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* ☐ 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* ☐ Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* ☐ Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* ☐ Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* ☐ Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* ☐ Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* ☐ Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* ☐ Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* ☐ Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* ☐ Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* ☐ Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* ☐ Inferior Infarct Pattern *[A:OTHER, SPECIFY]* ☐ **[txtABNOTH1]** Other, specify A128

11.* ✔	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	**[lstCHANGE4]** *[A:NO SIGNIFICANT WORSENING FROM BASELINE]* ◯ No significant worsening from baseline *[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]* ◯ **[txtCHANGE4]** Clinically significant worsening from baseline, specify A128
12-lead Electrocardiogram - 30 Minutes Postdose [sct30M]		
This section should only be completed for subjects under Amendment 8		
12.* ✔	Time performed [Time performed]	**[dtmASS_T2] (hh:mm)** Req : Req *24-hour clock*
13.* ✔	Rhythm [Rhythm]	**[lstRHYTM2]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
14.* ✔	Ventricular rate [Ventricular rate]	**[numVR2]** N3 bpm[b]
15.* ✔	PR interval [PR]	**[numPR2]** N3 msec[b]
16.* ✔	QRS duration [QRS]	**[numQRS2]** N3 msec[b]
17.* ✔	QT interval [QT]	**[numQT2]** N3 msec[b]
18.* ✔	QTc interval [QTc]	**[numQTCF2]** N3 msec[b]
19.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT2]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
20. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN2]** *[A:SINUS BRADYCARDIA]* ☐ Sinus Bradycardia *[A:SINUS TACHYCARDIA]* ☐ Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* ☐ Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* ☐ Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* ☐ Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* ☐ Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* ☐ Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* ☐ Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* ☐ Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* ☐ Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* ☐ Atrial Fibrillation *[A:ATRIAL PACING]* ☐ Atrial Pacing *[A:VENTRICULAR PACING]* ☐ Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* ☐ Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* ☐ 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* ☐ 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* ☐ 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* ☐ 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* ☐ Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* ☐ Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* ☐ Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* ☐ Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* ☐ Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* ☐ Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* ☐ Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* ☐ Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* ☐ Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* ☐ Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* ☐ Inferior Infarct Pattern *[A:OTHER, SPECIFY]* ☐ **[txtABNOTH2]** Other, specify A128

21.* ✔	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	**[lstCHANGE1]** *[A:NO SIGNIFICANT WORSENING FROM BASELINE]* ◯ No significant worsening from baseline *[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]* ◯ **[txtCHANGE1]** Clinically significant worsening from baseline, specify A128
12-lead Electrocardiogram - 4 Hours Postdose [sct4H]		
This section should only be completed for subjects under Amendment 8		
22.* ✔	Time performed [Time performed]	**[dtmASS_T4] (hh:mm)** Req : Req *24-hour clock*
23.* ✔	Rhythm [Rhythm]	**[lstRHYTM4]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
24.* ✔	Ventricular rate [Ventricular rate]	**[numVR4]** N3 bpm[b]
25.* ✔	PR interval [PR]	**[numPR4]** N3 msec[b]
26.* ✔	QRS duration [QRS]	**[numQRS4]** N3 msec[b]
27.* ✔	QT interval [QT]	**[numQT4]** N3 msec[b]
28.* ✔	QTc interval [QTc]	**[numQTCF4]** N3 msec[b]
29.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT4]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
30. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN4]** *[A:SINUS BRADYCARDIA]* ☐ Sinus Bradycardia *[A:SINUS TACHYCARDIA]* ☐ Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* ☐ Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* ☐ Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* ☐ Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* ☐ Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* ☐ Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* ☐ Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* ☐ Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* ☐ Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* ☐ Atrial Fibrillation *[A:ATRIAL PACING]* ☐ Atrial Pacing *[A:VENTRICULAR PACING]* ☐ Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* ☐ Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* ☐ 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* ☐ 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* ☐ 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* ☐ 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* ☐ Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* ☐ Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* ☐ Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* ☐ Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* ☐ Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* ☐ Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* ☐ Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* ☐ Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* ☐ Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* ☐ Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* ☐ Inferior Infarct Pattern *[A:OTHER, SPECIFY]* ☐ **[txtABNOTH4]** Other, specify A128

31.* ✔	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	**[lstCHANGE3]** *[A:NO SIGNIFICANT WORSENING FROM BASELINE]* ◯ No significant worsening from baseline *[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]* ◯ **[txtCHANGE3]** Clinically significant worsening from baseline, specify A128

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.

Codelist Values Tables: 12-lead ECG (Escalation)

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	lstRHYTM, lstRHYTM2, lstRHYTM4
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	lstOVERALLINT, lstOVERALLINT2, lstOVERALLINT4
			Abnormal, Not Clinically Significant	ABNORMAL, NOT CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalNCS	
			Abnormal, Clinically Significant	ABNORMAL, CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalCS	
clABN	String		Sinus Bradycardia	SINUS BRADYCARDIA	citmABN_SinusBradycardia	lstABN1, lstABN2, lstABN4
			Sinus Tachycardia	SINUS TACHYCARDIA	citmABN_SinusTachycardia	
			Atrial Tachycardia	ATRIAL TACHYCARDIA	citmABN_AtrialTachycardia	
			Ventricular Tachycardia	VENTRICULAR TACHYCARDIA	citmABN_VentricularTachycardia	
			Sick Sinus Syndrome	SICK SINUS SYNDROME	citmABN_SickSinusSyndrome	
			Premature Atrial Complexes	PREMATURE ATRIAL COMPLEXES	citmABN_PrematureAtrialComplexes	
			Premature Ventricular Complexes	PREMATURE VENTRICULAR COMPLEXES	citmABN_PrematureVentricularComplexes	
			Q Axis, Left Axis Deviation	Q AXIS LEFT AXIS DEVIATION	citmABN_QAxisLeftAxisDeviation	
			Left Atrial Abnormality	LEFT ATRIAL ABNORMALITY	citmABN_LeftAtrialAbnormality	
			Left Ventricular Hypertrophy	LEFT VENTRICULAR HYPERTROPHY	citmABN_LeftVentricularHypertrophy	
			Atrial Fibrillation	ATRIAL FIBRILLATION	citmABN_AtrialFibrillation	
			Atrial Pacing	ATRIAL PACING	citmABN_AtrialPacing	
			Ventricular Pacing	VENTRICULAR PACING	citmABN_VentricularPacing	
			Atrial Ventricular Pacing	ATRIAL VENTRICULAR PACING	citmABN_AtrialVentricularPacing	
			1st Degree A-V Block	1ST DEGREE A-V BLOCK	citmABN_1stDegreeAVBlock	
			2nd Degree A-V Block Type I	2ND DEGREE A-V BLOCK TYPE I	citmABN_2ndDegreeAVBlockTypeI	
			2nd Degree A-V Block Type II	2ND DEGREE A-V BLOCK TYPE II	citmABN_2ndDegreeAVBlockTypeII	
			3rd Degree A-V Block	3RD DEGREE A-V BLOCK	citmABN_3rdDegreeAVBlock	
			Left Bundle Branch Block	LEFT BUNDLE BRANCH BLOCK	citmABN_LeftBundleBranchBlock	
			Incomplete Left Bundle Branch Block	INCOMPLETE LEFT BUNDLE BRANCH BLOCK	citmABN_IncompleteLeftBundleBranchBlock	
			Left Anterior Hemiblock	LEFT ANTERIOR HEMIBLOCK	citmABN_LeftAnteriorHemiblock	
			Left Posterior Hemiblock	LEFT POSTERIOR HEMIBLOCK	citmABN_LeftPosteriorHemiblock	
			Right Bundle Branch Block	RIGHT BUNDLE BRANCH BLOCK	citmABN_RightBundleBranchBlock	
			Incomplete Right Bundle Branch Block	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK	citmABN_IncompleteRightBundleBranchBlock	
			Intraventricular Conduction Delay	INTRAVENTRICULAR CONDUCTION DELAY	citmABN_IntraventricularConductionDelay	
			Anteroseptal Infarct Pattern	ANTEROSEPTAL INFARCT PATTERN	citmABN_AnteroseptalInfarctPattern	
			Anterolateral Infarct Pattern	ANTEROLATERAL INFARCT PATTERN	citmABN_AnterolateralInfarctPattern	
			Lateral Infarct Pattern	LATERAL INFARCT PATTERN	citmABN_LateralInfarctPattern	
			Inferior Infarct Pattern	INFERIOR INFARCT PATTERN	citmABN_InferiorInfarctPattern	
			Other, specify	OTHER, SPECIFY	citmABN_Otherspecify	
clCHANGE_2	String		No significant worsening from baseline	NO SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_NOSIGNIFICANTWORSENINGFROMBASELINE_2	lstCHANGE4
			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE_2	
clCHANGE	String		No significant worsening from baseline	NO SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_NOSIGNIFICANTWORSENINGFROMBASELINE	lstCHANGE1
			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE	
clCHANGE_1_1	String		No significant worsening from baseline	NO SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_NOSIGNIFICANTWORSENINGFROMBASELINE_1_1	lstCHANGE3

			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE_1_1	

RDE Analytics: RD_FRMECG_ESC		
Data Variable RefName	**RD Column Name**	**Column Data Type**
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
lstRHYTM	LSTRHYTM_C	VARCHAR2
	LSTRHYTM	VARCHAR2
	LSTRHYTM_ND	VARCHAR2
numVR	NUMVR	NUMBER
	NUMVR_U	VARCHAR2
	NUMVR_ND	VARCHAR2
numPR	NUMPR	NUMBER
	NUMPR_U	VARCHAR2
	NUMPR_ND	VARCHAR2
numQRS	NUMQRS	NUMBER
	NUMQRS_U	VARCHAR2
	NUMQRS_ND	VARCHAR2
numQT	NUMQT	NUMBER
	NUMQT_U	VARCHAR2
	NUMQT_ND	VARCHAR2
numQTCF	NUMQTCF	NUMBER
	NUMQTCF_U	VARCHAR2
	NUMQTCF_ND	VARCHAR2
lstOVERALLINT	LSTOVERALLINT_C	VARCHAR2
	LSTOVERALLINT	VARCHAR2
	LSTOVERALLINT_ND	VARCHAR2
lstABN1	LSTABN1_ND	VARCHAR2
lstABN1 - Sinus Bradycardia	*LSTABN1_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN1 - Sinus Tachycardia	*LSTABN1_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN1 - Atrial Tachycardia	*LSTABN1_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN1 - Ventricular Tachycardia	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN1 - Sick Sinus Syndrome	*LSTABN1_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN1_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN1 - Premature Atrial Complexes	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN1 - Premature Ventricular Complexes	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN1 - Q Axis, Left Axis Deviation	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN1 - Left Atrial Abnormality	*LSTABN1_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN1 - Left Ventricular Hypertrophy	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2

	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN1 - Atrial Fibrillation	*LSTABN1_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN1_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN1 - Atrial Pacing	*LSTABN1_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALPACING	VARCHAR2
lstABN1 - Ventricular Pacing	*LSTABN1_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARPACING	VARCHAR2
lstABN1 - Atrial Ventricular Pacing	*LSTABN1_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN1 - 1st Degree A-V Block	*LSTABN1_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN1 - 2nd Degree A-V Block Type I	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN1 - 2nd Degree A-V Block Type II	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN1 - 3rd Degree A-V Block	*LSTABN1_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN1 - Left Bundle Branch Block	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Left Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Left Anterior Hemiblock	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Left Posterior Hemiblock	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Right Bundle Branch Block	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Right Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Intraventricular Conduction Delay	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN1 - Anteroseptal Infarct Pattern	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN1 - Anterolateral Infarct Pattern	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Lateral Infarct Pattern	*LSTABN1_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Inferior Infarct Pattern	*LSTABN1_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN1 - Other, specify	LSTABN1_TXTABNOTH1_C	VARCHAR2
	LSTABN1_TXTABNOTH1	VARCHAR2
lstABN1 - txtABNOTH1	TXTABNOTH1	VARCHAR2
lstCHANGE4	LSTCHANGE4_C	VARCHAR2
	LSTCHANGE4	VARCHAR2
	LSTCHANGE4_ND	VARCHAR2
lstCHANGE4 - txtCHANGE4	TXTCHANGE4	VARCHAR2
dtmASS_T2	DTMASS_T2	DATE
	DTMASS_T2_TMS	VARCHAR2
	DTMASS_T2_ND	VARCHAR2
lstRHYTM2	LSTRHYTM2_C	VARCHAR2
	LSTRHYTM2	VARCHAR2
	LSTRHYTM2_ND	VARCHAR2
numVR2	NUMVR2	NUMBER

	NUMVR2_U	VARCHAR2
	NUMVR2_ND	VARCHAR2
numPR2	NUMPR2	NUMBER
	NUMPR2_U	VARCHAR2
	NUMPR2_ND	VARCHAR2
numQRS2	NUMQRS2	NUMBER
	NUMQRS2_U	VARCHAR2
	NUMQRS2_ND	VARCHAR2
numQT2	NUMQT2	NUMBER
	NUMQT2_U	VARCHAR2
	NUMQT2_ND	VARCHAR2
numQTCF2	NUMQTCF2	NUMBER
	NUMQTCF2_U	VARCHAR2
	NUMQTCF2_ND	VARCHAR2
lstOVERALLINT2	LSTOVERALLINT2_C	VARCHAR2
	LSTOVERALLINT2	VARCHAR2
	LSTOVERALLINT2_ND	VARCHAR2
lstABN2	LSTABN2_ND	VARCHAR2
lstABN2 - Sinus Bradycardia	*LSTABN2_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN2 - Sinus Tachycardia	*LSTABN2_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN2 - Atrial Tachycardia	*LSTABN2_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN2 - Ventricular Tachycardia	*LSTABN2_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN2 - Sick Sinus Syndrome	*LSTABN2_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN2_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN2 - Premature Atrial Complexes	*LSTABN2_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN2_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN2 - Premature Ventricular Complexes	*LSTABN2_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN2_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN2 - Q Axis, Left Axis Deviation	*LSTABN2_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN2_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN2 - Left Atrial Abnormality	*LSTABN2_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN2_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN2 - Left Ventricular Hypertrophy	*LSTABN2_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN2_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN2 - Atrial Fibrillation	*LSTABN2_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN2_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN2 - Atrial Pacing	*LSTABN2_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN2_CITMABNATRIALPACING	VARCHAR2
lstABN2 - Ventricular Pacing	*LSTABN2_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN2_CITMABNVENTRICULARPACING	VARCHAR2
lstABN2 - Atrial Ventricular Pacing	*LSTABN2_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN2_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN2 - 1st Degree A-V Block	*LSTABN2_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN2_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN2 - 2nd Degree A-V Block Type I	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN2 - 2nd Degree A-V Block Type II	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN2 - 3rd Degree A-V Block	*LSTABN2_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2

	*LSTABN2_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN2 - Left Bundle Branch Block	*LSTABN2_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN2 - Incomplete Left Bundle Branch Block	*LSTABN2_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN2 - Left Anterior Hemiblock	*LSTABN2_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN2 - Left Posterior Hemiblock	*LSTABN2_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN2 - Right Bundle Branch Block	*LSTABN2_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN2 - Incomplete Right Bundle Branch Block	*LSTABN2_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN2 - Intraventricular Conduction Delay	*LSTABN2_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN2_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN2 - Anteroseptal Infarct Pattern	*LSTABN2_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN2 - Anterolateral Infarct Pattern	*LSTABN2_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN2 - Lateral Infarct Pattern	*LSTABN2_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN2 - Inferior Infarct Pattern	*LSTABN2_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN2 - Other, specify	LSTABN2_TXTABNOTH2_C	VARCHAR2
	LSTABN2_TXTABNOTH2	VARCHAR2
lstABN2 - txtABNOTH2	TXTABNOTH2	VARCHAR2
lstCHANGE1	LSTCHANGE1_C	VARCHAR2
	LSTCHANGE1	VARCHAR2
	LSTCHANGE1_ND	VARCHAR2
lstCHANGE1 - txtCHANGE1	TXTCHANGE1	VARCHAR2
dtmASS_T4	DTMASS_T4	DATE
	DTMASS_T4_TMS	VARCHAR2
	DTMASS_T4_ND	VARCHAR2
lstRHYTM4	LSTRHYTM4_C	VARCHAR2
	LSTRHYTM4	VARCHAR2
	LSTRHYTM4_ND	VARCHAR2
numVR4	NUMVR4	NUMBER
	NUMVR4_U	VARCHAR2
	NUMVR4_ND	VARCHAR2
numPR4	NUMPR4	NUMBER
	NUMPR4_U	VARCHAR2
	NUMPR4_ND	VARCHAR2
numQRS4	NUMQRS4	NUMBER
	NUMQRS4_U	VARCHAR2
	NUMQRS4_ND	VARCHAR2
numQT4	NUMQT4	NUMBER
	NUMQT4_U	VARCHAR2
	NUMQT4_ND	VARCHAR2
numQTCF4	NUMQTCF4	NUMBER
	NUMQTCF4_U	VARCHAR2
	NUMQTCF4_ND	VARCHAR2
lstOVERALLINT4	LSTOVERALLINT4_C	VARCHAR2
	LSTOVERALLINT4	VARCHAR2

	LSTOVERALLINT4_ND	VARCHAR2
lstABN4	LSTABN4_ND	VARCHAR2
lstABN4 - Sinus Bradycardia	*LSTABN4_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN4 - Sinus Tachycardia	*LSTABN4_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN4 - Atrial Tachycardia	*LSTABN4_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN4 - Ventricular Tachycardia	*LSTABN4_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN4 - Sick Sinus Syndrome	*LSTABN4_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN4_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN4 - Premature Atrial Complexes	*LSTABN4_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN4_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN4 - Premature Ventricular Complexes	*LSTABN4_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN4_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN4 - Q Axis, Left Axis Deviation	*LSTABN4_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN4_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN4 - Left Atrial Abnormality	*LSTABN4_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN4_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN4 - Left Ventricular Hypertrophy	*LSTABN4_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN4_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN4 - Atrial Fibrillation	*LSTABN4_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN4_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN4 - Atrial Pacing	*LSTABN4_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN4_CITMABNATRIALPACING	VARCHAR2
lstABN4 - Ventricular Pacing	*LSTABN4_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN4_CITMABNVENTRICULARPACING	VARCHAR2
lstABN4 - Atrial Ventricular Pacing	*LSTABN4_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN4_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN4 - 1st Degree A-V Block	*LSTABN4_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN4_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN4 - 2nd Degree A-V Block Type I	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN4 - 2nd Degree A-V Block Type II	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN4 - 3rd Degree A-V Block	*LSTABN4_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN4_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN4 - Left Bundle Branch Block	*LSTABN4_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN4 - Incomplete Left Bundle Branch Block	*LSTABN4_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN4 - Left Anterior Hemiblock	*LSTABN4_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN4 - Left Posterior Hemiblock	*LSTABN4_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN4 - Right Bundle Branch Block	*LSTABN4_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN4 - Incomplete Right Bundle Branch Block	*LSTABN4_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN4 - Intraventricular Conduction Delay	*LSTABN4_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN4_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN4 - Anteroseptal Infarct Pattern	*LSTABN4_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2

	*LSTABN4_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN4 - Anterolateral Infarct Pattern	*LSTABN4_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN4 - Lateral Infarct Pattern	*LSTABN4_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN4 - Inferior Infarct Pattern	*LSTABN4_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN4 - Other, specify	LSTABN4_TXTABNOTH4_C	VARCHAR2
	LSTABN4_TXTABNOTH4	VARCHAR2
lstABN4 - txtABNOTH4	TXTABNOTH4	VARCHAR2
lstCHANGE3	LSTCHANGE3_C	VARCHAR2
	LSTCHANGE3	VARCHAR2
	LSTCHANGE3_ND	VARCHAR2
lstCHANGE3 - txtCHANGE3	TXTCHANGE3	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: Additional Visits (ADDVIS) [frmADDVIS]

Additional Visits [sctADDVIS]

1.* ✔	Will the subject need additional visits? (Only applicable from Protocol Amendment 9 onwards) [Will the subject need additional visits? (Only applicable from Protocol Amendment 9 onwards)]	**[lstADDVIS]** *[A:Y]* ◯ Yes *[A:N]* ◯ No

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: Additional Visits

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	lstADDVIS
			No	N	citmYesNo_N	

RDE Analytics: RD_FRMADDVIS

Data Variable RefName	RD Column Name	Column Data Type
lstADDVIS	LSTADDVIS_C	VARCHAR2
	LSTADDVIS	VARCHAR2
	LSTADDVIS_ND	VARCHAR2

AT3SC002: End of Study Question (EOS QUEST) [frmEOSQUEST]		
1.* ✔	Please specify the type of this visit [Type of visit]	**[lstEOSQUEST]** *[A:M25]* ◯ End of Study *[A:EARLY TERMINATION]* ◯ Early Termination

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: End of Study Question

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clEOSQUEST	String		End of Study	M25	citmEOSQUEST_M25	lstEOSQUEST
			Early Termination	EARLY TERMINATION	citmEOSQUEST_ET	

RDE Analytics: RD_FRMEOSQUEST

Data Variable RefName	RD Column Name	Column Data Type
lstEOSQUEST	LSTEOSQUEST_C	VARCHAR2
	LSTEOSQUEST	VARCHAR2
	LSTEOSQUEST_ND	VARCHAR2

AT3SC002: 12-lead ECG (Unscheduled) (ECG UNS) [frmECG_UNS]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
12-lead Electrocardiogram [sctECG_UNS]		
Supine after at least 10 minutes rest		
2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
3.* ✔	Rhythm [Rhythm]	**[lstRHYTM]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
4.* ✔	Ventricular rate [Ventricular rate]	**[numVR]** N3 bpm[b]
5.* ✔	PR interval [PR]	**[numPR]** N3 msec[b]
6.* ✔	QRS duration [QRS]	**[numQRS]** N3 msec[b]
7.* ✔	QT interval [QT]	**[numQT]** N3 msec[b]
8.* ✔	QTc interval [QTc]	**[numQTCF]** N3 msec[b]
9.* ✔	Overall interpretation [Overall interpretation]	**[lstOVERALLINT]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]* ◯ Abnormal, Not Clinically Significant *[A:ABNORMAL, CLINICALLY SIGNIFICANT]* ◯ Abnormal, Clinically Significant
10. ✔	If abnormal, please specify by checking all that apply [Abnormal]	**[lstABN1]** *[A:SINUS BRADYCARDIA]* ☐ Sinus Bradycardia *[A:SINUS TACHYCARDIA]* ☐ Sinus Tachycardia *[A:ATRIAL TACHYCARDIA]* ☐ Atrial Tachycardia *[A:VENTRICULAR TACHYCARDIA]* ☐ Ventricular Tachycardia *[A:SICK SINUS SYNDROME]* ☐ Sick Sinus Syndrome *[A:PREMATURE ATRIAL COMPLEXES]* ☐ Premature Atrial Complexes *[A:PREMATURE VENTRICULAR COMPLEXES]* ☐ Premature Ventricular Complexes *[A:Q AXIS LEFT AXIS DEVIATION]* ☐ Q Axis, Left Axis Deviation *[A:LEFT ATRIAL ABNORMALITY]* ☐ Left Atrial Abnormality *[A:LEFT VENTRICULAR HYPERTROPHY]* ☐ Left Ventricular Hypertrophy *[A:ATRIAL FIBRILLATION]* ☐ Atrial Fibrillation *[A:ATRIAL PACING]* ☐ Atrial Pacing *[A:VENTRICULAR PACING]* ☐ Ventricular Pacing *[A:ATRIAL VENTRICULAR PACING]* ☐ Atrial Ventricular Pacing *[A:1ST DEGREE A-V BLOCK]* ☐ 1st Degree A-V Block *[A:2ND DEGREE A-V BLOCK TYPE I]* ☐ 2nd Degree A-V Block Type I *[A:2ND DEGREE A-V BLOCK TYPE II]* ☐ 2nd Degree A-V Block Type II *[A:3RD DEGREE A-V BLOCK]* ☐ 3rd Degree A-V Block *[A:LEFT BUNDLE BRANCH BLOCK]* ☐ Left Bundle Branch Block *[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]* ☐ Incomplete Left Bundle Branch Block *[A:LEFT ANTERIOR HEMIBLOCK]* ☐ Left Anterior Hemiblock *[A:LEFT POSTERIOR HEMIBLOCK]* ☐ Left Posterior Hemiblock *[A:RIGHT BUNDLE BRANCH BLOCK]* ☐ Right Bundle Branch Block *[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]* ☐ Incomplete Right Bundle Branch Block *[A:INTRAVENTRICULAR CONDUCTION DELAY]* ☐ Intraventricular Conduction Delay *[A:ANTEROSEPTAL INFARCT PATTERN]* ☐ Anteroseptal Infarct Pattern *[A:ANTEROLATERAL INFARCT PATTERN]* ☐ Anterolateral Infarct Pattern *[A:LATERAL INFARCT PATTERN]* ☐ Lateral Infarct Pattern *[A:INFERIOR INFARCT PATTERN]* ☐ Inferior Infarct Pattern *[A:OTHER, SPECIFY]* ☐ **[txtABNOTH1]** Other, specify A128

11.* ✔	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	**[lstCHANGE1]** *[A:NO SIGNIFICANT WORSENING FROM BASELINE]* ◯ No significant worsening from baseline *[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]* ◯ **[txtCHANGE1]** Clinically significant worsening from baseline, specify A128

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.

Codelist Values Tables: 12-lead ECG (Unscheduled)

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	lstRHYTM
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	lstOVERALLINT
			Abnormal, Not Clinically Significant	ABNORMAL, NOT CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalNCS	
			Abnormal, Clinically Significant	ABNORMAL, CLINICALLY SIGNIFICANT	citmOVERALLINT_AbnormalCS	
clABN	String		Sinus Bradycardia	SINUS BRADYCARDIA	citmABN_SinusBradycardia	lstABN1
			Sinus Tachycardia	SINUS TACHYCARDIA	citmABN_SinusTachycardia	
			Atrial Tachycardia	ATRIAL TACHYCARDIA	citmABN_AtrialTachycardia	
			Ventricular Tachycardia	VENTRICULAR TACHYCARDIA	citmABN_VentricularTachycardia	
			Sick Sinus Syndrome	SICK SINUS SYNDROME	citmABN_SickSinusSyndrome	
			Premature Atrial Complexes	PREMATURE ATRIAL COMPLEXES	citmABN_PrematureAtrialComplexes	
			Premature Ventricular Complexes	PREMATURE VENTRICULAR COMPLEXES	citmABN_PrematureVentricularComplexes	
			Q Axis, Left Axis Deviation	Q AXIS LEFT AXIS DEVIATION	citmABN_QAxisLeftAxisDeviation	
			Left Atrial Abnormality	LEFT ATRIAL ABNORMALITY	citmABN_LeftAtrialAbnormality	
			Left Ventricular Hypertrophy	LEFT VENTRICULAR HYPERTROPHY	citmABN_LeftVentricularHypertrophy	
			Atrial Fibrillation	ATRIAL FIBRILLATION	citmABN_AtrialFibrillation	
			Atrial Pacing	ATRIAL PACING	citmABN_AtrialPacing	
			Ventricular Pacing	VENTRICULAR PACING	citmABN_VentricularPacing	
			Atrial Ventricular Pacing	ATRIAL VENTRICULAR PACING	citmABN_AtrialVentricularPacing	
			1st Degree A-V Block	1ST DEGREE A-V BLOCK	citmABN_1stDegreeAVBlock	
			2nd Degree A-V Block Type I	2ND DEGREE A-V BLOCK TYPE I	citmABN_2ndDegreeAVBlockTypeI	
			2nd Degree A-V Block Type II	2ND DEGREE A-V BLOCK TYPE II	citmABN_2ndDegreeAVBlockTypeII	
			3rd Degree A-V Block	3RD DEGREE A-V BLOCK	citmABN_3rdDegreeAVBlock	
			Left Bundle Branch Block	LEFT BUNDLE BRANCH BLOCK	citmABN_LeftBundleBranchBlock	
			Incomplete Left Bundle Branch Block	INCOMPLETE LEFT BUNDLE BRANCH BLOCK	citmABN_IncompleteLeftBundleBranchBlock	
			Left Anterior Hemiblock	LEFT ANTERIOR HEMIBLOCK	citmABN_LeftAnteriorHemiblock	
			Left Posterior Hemiblock	LEFT POSTERIOR HEMIBLOCK	citmABN_LeftPosteriorHemiblock	
			Right Bundle Branch Block	RIGHT BUNDLE BRANCH BLOCK	citmABN_RightBundleBranchBlock	
			Incomplete Right Bundle Branch Block	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK	citmABN_IncompleteRightBundleBranchBlock	
			Intraventricular Conduction Delay	INTRAVENTRICULAR CONDUCTION DELAY	citmABN_IntraventricularConductionDelay	
			Anteroseptal Infarct Pattern	ANTEROSEPTAL INFARCT PATTERN	citmABN_AnteroseptalInfarctPattern	
			Anterolateral Infarct Pattern	ANTEROLATERAL INFARCT PATTERN	citmABN_AnterolateralInfarctPattern	
			Lateral Infarct Pattern	LATERAL INFARCT PATTERN	citmABN_LateralInfarctPattern	
			Inferior Infarct Pattern	INFERIOR INFARCT PATTERN	citmABN_InferiorInfarctPattern	
			Other, specify	OTHER, SPECIFY	citmABN_Otherspecify	
clCHANGE	String		No significant worsening from baseline	NO SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_NOSIGNIFICANTWORSENINGFROMBASELINE	lstCHANGE1
			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE	

RDE Analytics: RD_FRMECG_UNS

Data Variable RefName	RD Column Name	Column Data Type

lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
lstRHYTM	LSTRHYTM_C	VARCHAR2
	LSTRHYTM	VARCHAR2
	LSTRHYTM_ND	VARCHAR2
numVR	NUMVR	NUMBER
	NUMVR_U	VARCHAR2
	NUMVR_ND	VARCHAR2
numPR	NUMPR	NUMBER
	NUMPR_U	VARCHAR2
	NUMPR_ND	VARCHAR2
numQRS	NUMQRS	NUMBER
	NUMQRS_U	VARCHAR2
	NUMQRS_ND	VARCHAR2
numQT	NUMQT	NUMBER
	NUMQT_U	VARCHAR2
	NUMQT_ND	VARCHAR2
numQTCF	NUMQTCF	NUMBER
	NUMQTCF_U	VARCHAR2
	NUMQTCF_ND	VARCHAR2
lstOVERALLINT	LSTOVERALLINT_C	VARCHAR2
	LSTOVERALLINT	VARCHAR2
	LSTOVERALLINT_ND	VARCHAR2
lstABN1	LSTABN1_ND	VARCHAR2
lstABN1 - Sinus Bradycardia	*LSTABN1_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSBRADYCARDIA	VARCHAR2
lstABN1 - Sinus Tachycardia	*LSTABN1_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSTACHYCARDIA	VARCHAR2
lstABN1 - Atrial Tachycardia	*LSTABN1_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNATRIALTACHYCARDIA	VARCHAR2
lstABN1 - Ventricular Tachycardia	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
lstABN1 - Sick Sinus Syndrome	*LSTABN1_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN1_CITMABNSICKSINUSSYNDROME	VARCHAR2
lstABN1 - Premature Atrial Complexes	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
lstABN1 - Premature Ventricular Complexes	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
lstABN1 - Q Axis, Left Axis Deviation	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
lstABN1 - Left Atrial Abnormality	*LSTABN1_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
lstABN1 - Left Ventricular Hypertrophy	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
lstABN1 - Atrial Fibrillation	*LSTABN1_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN1_CITMABNATRIALFIBRILLATION	VARCHAR2
lstABN1 - Atrial Pacing	*LSTABN1_CITMABNATRIALPACING_C	VARCHAR2

	*LSTABN1_CITMABNATRIALPACING	VARCHAR2
lstABN1 - Ventricular Pacing	*LSTABN1_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARPACING	VARCHAR2
lstABN1 - Atrial Ventricular Pacing	*LSTABN1_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALVENTRICULARPACING	VARCHAR2
lstABN1 - 1st Degree A-V Block	*LSTABN1_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN1STDEGREEAVBLOCK	VARCHAR2
lstABN1 - 2nd Degree A-V Block Type I	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
lstABN1 - 2nd Degree A-V Block Type II	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
lstABN1 - 3rd Degree A-V Block	*LSTABN1_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
lstABN1 - Left Bundle Branch Block	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Left Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Left Anterior Hemiblock	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Left Posterior Hemiblock	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
lstABN1 - Right Bundle Branch Block	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Incomplete Right Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
lstABN1 - Intraventricular Conduction Delay	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
lstABN1 - Anteroseptal Infarct Pattern	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
lstABN1 - Anterolateral Infarct Pattern	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Lateral Infarct Pattern	*LSTABN1_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNLATERALINFARCTPATTERN	VARCHAR2
lstABN1 - Inferior Infarct Pattern	*LSTABN1_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
lstABN1 - Other, specify	LSTABN1_TXTABNOTH1_C	VARCHAR2
	LSTABN1_TXTABNOTH1	VARCHAR2
lstABN1 - txtABNOTH1	TXTABNOTH1	VARCHAR2
lstCHANGE1	LSTCHANGE1_C	VARCHAR2
	LSTCHANGE1	VARCHAR2
	LSTCHANGE1_ND	VARCHAR2
lstCHANGE1 - txtCHANGE1	TXTCHANGE1	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: Date of Repeating Visit (DOV REP) [frmDOV_REP]

Date of Repeating Visit [sctDOV_UNS]

1.* ✔	Date and time of visit [Date and time of visit]	**[dtmVISIT_DT_UNS] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock*
2.	Should this visit be marked as deleted? *[hidden]* [Should this visit be marked as deleted?]	**[lstVISDELETED]** *[A:Y]* ☐ Yes

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: Date of Repeating Visit

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYes	String		Yes	Y	citmYes_Y	lstVISDELETED

RDE Analytics: RD_FRMDOV_REP

Data Variable RefName	RD Column Name	Column Data Type
dtmVISIT_DT_UNS	DTMVISIT_DT_UNS	DATE
	DTMVISIT_DT_UNS_DTS	VARCHAR2
	DTMVISIT_DT_UNS_DTR	VARCHAR2
	DTMVISIT_DT_UNS_ND	VARCHAR2
lstVISDELETED	LSTVISDELETED_ND	VARCHAR2
lstVISDELETED - Yes	LSTVISDELETED_CITMYESY_C	VARCHAR2
	LSTVISDELETED_CITMYESY	VARCHAR2

AT3SC002: Protocol Version for AT Follow-Up Visit (PROTATFU) [frmPROTATFU]

Protocol Version for AT Follow-Up Visit [sctPROTATFU]

1.* ✔	Which Protocol Amendment Version is effective for this subject for this AT Follow-Up Visit? [Protocol Amendment Version effective?]	**[lstPROTATFU]** *[A:PROTAM5]* ◯ Protocol Amendment 5 (or lower) *[A:PROTAM6]* ◯ Protocol Amendment 6 (or higher)

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: Protocol Version for AT Follow-Up Visit

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clPROTATFU	String		Protocol Amendment 5 (or lower)	PROTAM5	citmPROTATFU_PROTAM5	lstPROTATFU
			Protocol Amendment 6 (or higher)	PROTAM6	citmPROTATFU_PROTAM6	

RDE Analytics: RD_FRMPROTATFU

Data Variable RefName	RD Column Name	Column Data Type
lstPROTATFU	LSTPROTATFU_C	VARCHAR2
	LSTPROTATFU	VARCHAR2
	LSTPROTATFU_ND	VARCHAR2

AT3SC002: Vital Signs (VS EXW) [frmVS_EXW]

Assessment Date [sctASSDT]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ○ Same date as visit date *[A:OTHER]* ○ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)

Vital Signs [sctVS]

2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*
3.* ✔	Blood pressure [Blood pressure]	**[cmpBP1]** **[numSYSBP1] [numDIABP1]** (mmHg) N3 / N3 systolic / diastolic
4.* ✔	Heart rate [Heart rate]	**[numHR1]** N3 bpm[b]
5.* ✔	Body temperature [Body temperature]	**[numTEMP1]** xx.x C[b]
6.* ✔	Respiratory rate [Respiratory rate]	**[numRR1]** N2 breaths per minute

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.

Codelist Values Tables: Vital Signs

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	

RDE Analytics: RD_FRMVS_EXW

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
cmpBP1	CMPBP1_ND	VARCHAR2
cmpBP1 - numSYSBP1	NUMSYSBP1	NUMBER
cmpBP1 - numDIABP1	NUMDIABP1	NUMBER
numHR1	NUMHR1	NUMBER
	NUMHR1_U	VARCHAR2
	NUMHR1_ND	VARCHAR2
numTEMP1	NUMTEMP1	FLOAT
	NUMTEMP1_U	VARCHAR2
	NUMTEMP1_ND	VARCHAR2
numRR1	NUMRR1	NUMBER
	NUMRR1_ND	VARCHAR2

AT3SC002: AT Follow-Up Visit Question (ATFUPQ) [frmATFUPQ]

Laboratory sampling [sctLABDT]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* Same date as visit date *[A:OTHER]* **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)

AT Follow-Up Visit Question [sctATFUQ]

2.* ✔	Has the Antithrombin level returned to >= 60% value? [Antithrombin level returned to >= 60% value?]	**[lstPDMARK]** *[A:Y]* Yes *[A:N]* No, please complete another AT Follow-Up Visit a month from now

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: AT Follow-Up Visit Question

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clPDMARK	String		Yes	Y	citmPDMARK_Y	lstPDMARK
			No, please complete another AT Follow-Up Visit a month from now	N	citmPDMARK_N	

RDE Analytics: RD_FRMATFUPQ

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
lstPDMARK	LSTPDMARK_C	VARCHAR2
	LSTPDMARK	VARCHAR2
	LSTPDMARK_ND	VARCHAR2

AT3SC002: Date of Surgery Visit (DOV SURG) [frmDOV_SURG]

Date of Unscheduled Visit [sctDOV_UNS]

1.* ✔	Date and time of visit [Date and time of visit]	**[dtmVISIT_DT_UNS] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock*
2.	Should this visit be marked as deleted? *[hidden]* [Should this visit be marked as deleted?]	**[lstVISDELETED]** *[A:Y]* ☐ Yes

Surgery number [sctSURGN]

3.* ✔	Surgery number [Surgery number]	**[numSURG]** N2

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: Date of Surgery Visit

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYes	String		Yes	Y	citmYes_Y	lstVISDELETED

RDE Analytics: RD_FRMDOV_SURG

Data Variable RefName	RD Column Name	Column Data Type
dtmVISIT_DT_UNS	DTMVISIT_DT_UNS	DATE
	DTMVISIT_DT_UNS_DTS	VARCHAR2
	DTMVISIT_DT_UNS_DTR	VARCHAR2
	DTMVISIT_DT_UNS_ND	VARCHAR2
lstVISDELETED	LSTVISDELETED_ND	VARCHAR2
lstVISDELETED - Yes	LSTVISDELETED_CITMYESY_C	VARCHAR2
	LSTVISDELETED_CITMYESY	VARCHAR2
numSURG	NUMSURG	NUMBER
	NUMSURG_ND	VARCHAR2

AT3SC002: Central Laboratory Assessments (LAB POP) [frmLAB_POP]

Laboratory sampling [sctCOLL_POP]

1.* ✔	Visit performed at [Visit performed at]	**[lstSURGLOC]** *[A:STUDY CENTER]* ◯ Study center *[A:OTHER LOCATION/SITE]* ◯ Other location/site
2. ✔	Date performed [Date performed]	**[lstASSDT_POP]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
3. ✔	Kit ID number [Kit ID number]	**[txtREFNO_POP]** A11

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: Central Laboratory Assessments

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clSURGLOC	String		Study center	STUDY CENTER	citmSURGLOC_STUDYC	lstSURGLOC
			Other location/site	OTHER LOCATION/SITE	citmSURGLOC_OTHER	
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT_POP
			Other	OTHER	citmDateOther_Other	

RDE Analytics: RD_FRMLAB_POP

Data Variable RefName	RD Column Name	Column Data Type
lstSURGLOC	LSTSURGLOC_C	VARCHAR2
	LSTSURGLOC	VARCHAR2
	LSTSURGLOC_ND	VARCHAR2
lstASSDT_POP	LSTASSDT_POP_C	VARCHAR2
	LSTASSDT_POP	VARCHAR2
	LSTASSDT_POP_ND	VARCHAR2
lstASSDT_POP - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
txtREFNO_POP	TXTREFNO_POP	VARCHAR2
	TXTREFNO_POP_ND	VARCHAR2

AT3SC002: Hemostatic/Thromboprophylaxis Treatment Plan (TREATMENT PLAN) - Repeating Form [frmTREAT]

#	Row No	Date	Time	Treatment name	Dose	Unit	Frequency
1							

Please provide details on the **planned** hemostatic and/or thromboprophylaxis treatment for each day during the preoperative, intraoperative and postoperative periods

1.*	Row No ***(for internal use only)*** *[read-only]* [Row No]	**[numROW]** N3
2.* ✔	Date [Date]	**[dSURGDAY] (DD/MM/YYYY)** Req / Req / Req (2015-2023)
3.* ✔	Time [Time]	**[tSURGDAY] (hh:mm)** Req/Unk : Req/Unk *24-hour clock*
4.* ✔	Treatment name [Treatment name]	**[txtTREAT]** A50
5.* ✔	Dose [Dose]	**[numTRTDOSE]** xxxxxxxxx.
6.* ✔	Unit [Unit]	**[lstDOSEU]** *[A:UNIT]* ○ Unit specification **[lstDOSEUSP]** **[clDOSEUSP]** *[A:OTHER]* ○ **[txtDOSEUOTH]** Other, please specify A50
7.* ✔	Frequency [Frequency]	**[lstFREQ]** *[A:FREQUENCY]* ○ Frequency specification **[lstFREQSP]** **[clFREQSP]** *[A:OTHER]* ○ **[txtFREQOTH]** Other, please specify A50

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

Keys (navigation)/Uniqueness: Hemostatic/Thromboprophylaxis Treatment Plan

Item	Unique	Order #
frmTREAT (Repeating form)		
sctTREAT		
numROW	Group	1
txtTREAT	Group	2

Codelist Values Tables: Hemostatic/Thromboprophylaxis Treatment Plan

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clUnitOther	String		Unit	UNIT	citmUnitOther_Unit	lstDOSEU
			Other	OTHER	citmUnitOther_Other	
clDOSEUSP	String		mg	MG	citmDOSEUSP_MG	lstDOSEUSP
			ug	MICROG	citmDOSEUSP_MICROG	
			mL	ML	citmDOSEUSP_ML	
			uL	MICROL	citmDOSEUSP_MICROL	
			g	G	citmDOSEUSP_G	
			IU	IU	citmDOSEUSP_IU	
			tablet	TABLET	citmDOSEUSP_TAB	
			capsule	CAPSULE	citmDOSEUSP_CAP	
			puff	PUFF	citmDOSEUSP_PUFF	
			ampule	AMPULE	citmDOSEUSP_AMPULE	
			bolus	BOLUS	citmDOSEUSP_BOLUS	
			inhalation	INHALATION	citmDOSEUSP_INH	
			lozenge	LOZENGE	citmDOSEUSP_LOZENGE	
			patch	PATCH	citmDOSEUSP_PATCH	
			spray	SPRAY	citmDOSEUSP_SPRAY	

			suppository	SUPPOSITORY	citmDOSEUSP_SUPPOSITORY	
			Tbsp	TBSP	citmDOSEUSP_TBSP	
			tsp	TSP	citmDOSEUSP_TSP	
			oz	OZ	citmDOSEUSP_OZ	
			application	APPLICATION	citmDOSEUSP_APPLICATION	
			unknown	UNKNOWN	citmDOSEUSP_UNK	
clFrequencyOther	String		Frequency	FREQUENCY	citmFrequencyOther_Freq	lstFREQ
			Other	OTHER	citmFrequencyOther_Other	
clFREQSP	String		q.d. - once daily	QD	citmFREQSP_QD	lstFREQSP
			b.i.d. - twice daily	BID	citmFREQSP_BID	
			t.i.d. - three times daily	TID	citmFREQSP_TID	
			q.i.d. - four times daily	QID	citmFREQSP_QID	
			prn - as needed	PRN	citmFREQSP_PRN	
			qs	QS	citmFREQSP_QS	
			qm	QM	citmFREQSP_QM	
			qh	QH	citmFREQSP_QH	
			qod	QOD	citmFREQSP_QOD	
			continuous	CONTINUOUS	citmFREQSP_Continuous	
			intermittent	INTERMITTENT	citmFREQSP_Intermittent	
			once	ONCE	citmFREQSP_Once	
			unknown	UNKNOWN	citmFREQSP_Unknown	

RDE Analytics: RD_FRMTREAT

Data Variable RefName	RD Column Name	Column Data Type
numROW	NUMROW	NUMBER
	NUMROW_ND	VARCHAR2
dSURGDAY	DSURGDAY	DATE
	DSURGDAY_DTS	VARCHAR2
	DSURGDAY_ND	VARCHAR2
tSURGDAY	TSURGDAY	DATE
	TSURGDAY_TMS	VARCHAR2
	TSURGDAY_TMR	VARCHAR2
	TSURGDAY_ND	VARCHAR2
txtTREAT	TXTTREAT	VARCHAR2
	TXTTREAT_ND	VARCHAR2
numTRTDOSE	NUMTRTDOSE	FLOAT
	NUMTRTDOSE_ND	VARCHAR2
lstDOSEU	LSTDOSEU_C	VARCHAR2
	LSTDOSEU	VARCHAR2
	LSTDOSEU_ND	VARCHAR2
lstDOSEU - lstDOSEUSP	LSTDOSEUSP_C	VARCHAR2
	LSTDOSEUSP	VARCHAR2
lstDOSEU - txtDOSEUOTH	TXTDOSEUOTH	VARCHAR2
lstFREQ	LSTFREQ_C	VARCHAR2
	LSTFREQ	VARCHAR2
	LSTFREQ_ND	VARCHAR2
lstFREQ - lstFREQSP	LSTFREQSP_C	VARCHAR2
	LSTFREQSP	VARCHAR2
lstFREQ - txtFREQOTH	TXTFREQOTH	VARCHAR2

AT3SC002: Surgery procedure (SURG PROC) [frmSURG_PROC]

Surgery procedure [sctSURG_PROC]

1.* ✔	Start date and time of surgery [Start date and time of surgery]	**[dtSURG_ST] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock*
2.* ✔	End date and time of surgery [End date and time of surgery]	**[dtSURG_EN] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock*
3.* ✔	Name of procedure [Name of procedure]	**[txtPROC]** A200

For a non-hemophilic patient undergoing the same type of procedure: [sctSURGBLD]

4.* ✔	What is the typical blood loss expected? [What is the typical blood loss expected?]	**[numBLDLOSS]** N4 mL
5.* ✔	Will blood component transfusions be required for this procedure? [Will blood component transfusions be required for this procedure?]	**[lstTRANSF]** *[A:Y]* ◯ **[lstTRANSTP]** Yes What type of blood component transfusion and how much is anticipated? *[A:RBC]* ☐ **[numRBC]** Red blood cell (RBCs): Amount (mL) N4 *[A:PL]* ☐ **[numPL]** Platelets : Amount (mL) N4 *[A:FFP]* ☐ **[numFFP]** Fresh frozen plasma (FFP): Amount (mL) N4 *[A:CRYO]* ☐ **[numCRYO]** Cryoprecipitate: Amount (mL) N4 *[A:N]* ◯ No

Surgery [sctSURG]

6.* ✔	Type of surgery [Type of surgery]	**[lstSURG]** *[A:ELEC]* ◯ Elective surgery *[A:EMERGE]* ◯ Emergency surgery
7.* ✔	Minor/Major surgery [Minor/Major surgery]	**[lstSURGMM]** *[A:MINOR]* ◯ Minor surgery *[A:MAJOR]* ◯ Major surgery
8.* ✔	Treatment paused [Treatment paused]	**[lstTPAU]** *[A:Y]* ◯ Yes *[A:N]* ◯ No

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: Surgery procedure

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	lstTRANSF, lstTPAU
			No	N	citmYesNo_N	
clTRANSTP	String		Red blood cell (RBCs)	RBC	citmTRANSP_RBC	lstTRANSTP
			Platelets	PL	citmTRANSP_PL	
			Fresh frozen plasma (FFP)	FFP	citmTRANSP_FFP	
			Cryoprecipitate	CRYO	citmTRANSP_CRYO	
clSURG	String		Elective surgery	ELEC	citmSURG_ELEC	lstSURG
			Emergency surgery	EMERGE	citmSURG_EMERG	
clSURGMM	String		Minor surgery	MINOR	citmSURGMM_MINOR	lstSURGMM
			Major surgery	MAJOR	citmSURGMM_MAJOR	

RDE Analytics: RD_FRMSURG_PROC

Data Variable RefName	RD Column Name	Column Data Type
dtSURG_ST	DTSURG_ST	DATE

	DTSURG_ST_DTS	VARCHAR2
	DTSURG_ST_DTR	VARCHAR2
	DTSURG_ST_ND	VARCHAR2
dtSURG_EN	DTSURG_EN	DATE
	DTSURG_EN_DTS	VARCHAR2
	DTSURG_EN_DTR	VARCHAR2
	DTSURG_EN_ND	VARCHAR2
txtPROC	TXTPROC	VARCHAR2
	TXTPROC_ND	VARCHAR2
numBLDLOSS	NUMBLDLOSS	NUMBER
	NUMBLDLOSS_ND	VARCHAR2
lstTRANSF	LSTTRANSF_C	VARCHAR2
	LSTTRANSF	VARCHAR2
	LSTTRANSF_ND	VARCHAR2
lstTRANSF - Red blood cell (RBCs)	LSTTRANSTP_NUMRBC_C	VARCHAR2
	LSTTRANSTP_NUMRBC	VARCHAR2
lstTRANSF - numRBC	NUMRBC	NUMBER
lstTRANSF - Platelets	LSTTRANSTP_NUMPL_C	VARCHAR2
	LSTTRANSTP_NUMPL	VARCHAR2
lstTRANSF - numPL	NUMPL	NUMBER
lstTRANSF - Fresh frozen plasma (FFP)	LSTTRANSTP_NUMFFP_C	VARCHAR2
	LSTTRANSTP_NUMFFP	VARCHAR2
lstTRANSF - numFFP	NUMFFP	NUMBER
lstTRANSF - Cryoprecipitate	LSTTRANSTP_NUMCRYO_C	VARCHAR2
	LSTTRANSTP_NUMCRYO	VARCHAR2
lstTRANSF - numCRYO	NUMCRYO	NUMBER
lstSURG	LSTSURG_C	VARCHAR2
	LSTSURG	VARCHAR2
	LSTSURG_ND	VARCHAR2
lstSURGMM	LSTSURGMM_C	VARCHAR2
	LSTSURGMM	VARCHAR2
	LSTSURGMM_ND	VARCHAR2
lstTPAU	LSTTPAU_C	VARCHAR2
	LSTTPAU	VARCHAR2
	LSTTPAU_ND	VARCHAR2

AT3SC002: Factor or BPA Sample Collection (LAB FAC/BPA) [frmLAB_BPA]

Factor or BPA Sample Collection [sctLAB_BPA]

1.* ✔ Did factor or BPA administration occur at the study center?
[Administration at the study center]

[lstLAB_BPA]

[A:Y] ○ **[cmpLAB_BPA]** Yes

[lstLAB_PRE]
Lab sample collection predose to administration of factor or BPA: *[A:ACTUAL TIME]* ○ **[tLAB_PRE] (hh:mm)** Actual time Req : Req *24-hour clock*
[A:NOT COLLECTED] ○ Not collected

[tINTAKE] (hh:mm)
Time of factor/BPA intake: Req : Req *24-hour clock*

[lstLAB_10M]
Lab sample collection 10 min postdose to administration of factor or BPA (+/-5min): *[A:ACTUAL TIME]* ○ **[tLAB_10M] (hh:mm)** Actual time Req : Req *24-hour clock*
[A:NOT COLLECTED] ○ Not collected

[lstLAB_60M]
Lab sample collection 60 min postdose to administration of factor or BPA (+/-5min): *[A:ACTUAL TIME]* ○ **[tLAB_60M] (hh:mm)** Actual time Req : Req *24-hour clock*
[A:NOT COLLECTED] ○ Not collected

[A:N] ○ No

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: Factor or BPA Sample Collection

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	lstLAB_BPA
			No	N	citmYesNo_N	
clActTimeNotCol	String		Actual Time	ACTUAL TIME	citmActTimeNotCol_ActTime	lstLAB_PRE, lstLAB_10M, lstLAB_60M
			Not collected	NOT COLLECTED	citmActTimeNotCol_NotCol	

RDE Analytics: RD_FRMLAB_BPA

Data Variable RefName	RD Column Name	Column Data Type
lstLAB_BPA	LSTLAB_BPA_C	VARCHAR2
	LSTLAB_BPA	VARCHAR2
	LSTLAB_BPA_ND	VARCHAR2
lstLAB_BPA - lstLAB_PRE	LSTLAB_PRE_C	VARCHAR2
	LSTLAB_PRE	VARCHAR2
lstLAB_BPA - tLAB_PRE	TLAB_PRE	DATE
	TLAB_PRE_TMS	VARCHAR2
lstLAB_BPA - tINTAKE	TINTAKE	DATE
	TINTAKE_TMS	VARCHAR2
lstLAB_BPA - lstLAB_10M	LSTLAB_10M_C	VARCHAR2
	LSTLAB_10M	VARCHAR2
lstLAB_BPA - tLAB_10M	TLAB_10M	DATE
	TLAB_10M_TMS	VARCHAR2
lstLAB_BPA - lstLAB_60M	LSTLAB_60M_C	VARCHAR2
	LSTLAB_60M	VARCHAR2
lstLAB_BPA - tLAB_60M	TLAB_60M	DATE
	TLAB_60M_TMS	VARCHAR2

AT3SC002: Perioperative Questionnaire (POPQ) [frmPOPQ_SV]

Assessment date and time [sctPOPQDT]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*

Perioperative Questionnaire [sctPOPQ_SV]

3.* ✔	What was the estimated blood loss for this patient? [Estimated blood loss]	**[numBLDLOSSP]** N4 mL
4.* ✔	Were blood component transfusions required? [Transfusions required?]	**[lstTRANSFU_SV]** *[A:N]* ◯ No *[A:Y]* ◯ **[lstTRANSTPP]** Yes What type of blood component transfusion and how much was needed? *[A:RBC]* ☐ **[numRBC]** Red blood cell (RBCs): Amount (mL) N4 *[A:PL]* ☐ **[numPL]** Platelets : Amount (mL) N4 *[A:FFP]* ☐ **[numFFP]** Fresh frozen plasma (FFP): Amount (mL) N4 *[A:CRYO]* ☐ **[numCRYO]** Cryoprecipitate: Amount (mL) N4
5.* ✔	How would you rate the patient's hemostasis? [Patient's hemostasis?]	**[lstHERS]** *[A:EXC]* ◯ Excellent *[A:GOOD]* ◯ Good *[A:MOD]* ◯ Moderate *[A:NONE]* ◯ None

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: Perioperative Questionnaire

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clNoYes	String		No	N	citmNoYes_N	lstTRANSFU_SV
			Yes	Y	citmNoYes_Y	
clTRANSTP	String		Red blood cell (RBCs)	RBC	citmTRANSP_RBC	lstTRANSTPP
			Platelets	PL	citmTRANSP_PL	
			Fresh frozen plasma (FFP)	FFP	citmTRANSP_FFP	
			Cryoprecipitate	CRYO	citmTRANSP_CRYO	
clHERS	String		Excellent	EXC	citmHERS_EXC	lstHERS
			Good	GOOD	citmHERS_GOOD	
			Moderate	MOD	citmHERS_MOD	
			None	NONE	citmHERS_NONE	

RDE Analytics: RD_FRMPOPQ_SV

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2

numBLDLOSSP	NUMBLDLOSSP	NUMBER
	NUMBLDLOSSP_ND	VARCHAR2
lstTRANSFU_SV	LSTTRANSFU_SV_C	VARCHAR2
	LSTTRANSFU_SV	VARCHAR2
	LSTTRANSFU_SV_ND	VARCHAR2
lstTRANSFU_SV - Red blood cell (RBCs)	LSTTRANSTPP_NUMRBC_C	VARCHAR2
	LSTTRANSTPP_NUMRBC	VARCHAR2
lstTRANSFU_SV - numRBC	NUMRBC	NUMBER
lstTRANSFU_SV - Platelets	LSTTRANSTPP_NUMPL_C	VARCHAR2
	LSTTRANSTPP_NUMPL	VARCHAR2
lstTRANSFU_SV - numPL	NUMPL	NUMBER
lstTRANSFU_SV - Fresh frozen plasma (FFP)	LSTTRANSTPP_NUMFFP_C	VARCHAR2
	LSTTRANSTPP_NUMFFP	VARCHAR2
lstTRANSFU_SV - numFFP	NUMFFP	NUMBER
lstTRANSFU_SV - Cryoprecipitate	LSTTRANSTPP_NUMCRYO_C	VARCHAR2
	LSTTRANSTPP_NUMCRYO	VARCHAR2
lstTRANSFU_SV - numCRYO	NUMCRYO	NUMBER
lstHERS	LSTHERS_C	VARCHAR2
	LSTHERS	VARCHAR2
	LSTHERS_ND	VARCHAR2

AT3SC002: Perioperative Questionnaire (POPQ) [frmPOPQ]

Assessment date and time [sctPOPQDT]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
2.* ✔	Time performed [Time performed]	**[dtmASS_T] (hh:mm)** Req : Req *24-hour clock*

Perioperative Questionnaire [sctPOPQ]

3.* ✔	Were blood component transfusions required since the last visit? [Transfusions required?]	**[lstTRANSFU]** *[A:N]* ◯ No *[A:Y]* ◯ **[lstTRANSTPP]** Yes What type of blood component transfusion and how much was needed? *[A:RBC]* ☐ **[numRBC]** Red blood cell (RBCs): Amount (mL) N4 *[A:PL]* ☐ **[numPL]** Platelets : Amount (mL) N4 *[A:FFP]* ☐ **[numFFP]** Fresh frozen plasma (FFP): Amount (mL) N4 *[A:CRYO]* ☐ **[numCRYO]** Cryoprecipitate: Amount (mL) N4
4.* ✔	How would you rate the patient's hemostasis since the last visit? [Patient's hemostasis?]	**[lstHERS_PO]** *[A:EXC]* ◯ Excellent *[A:GOOD]* ◯ Good *[A:MOD]* ◯ Moderate *[A:NONE]* ◯ None

Key: [*] = Item is required [✔] = Source verification required
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Codelist Values Tables: Perioperative Questionnaire

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clNoYes	String		No	N	citmNoYes_N	lstTRANSFU
			Yes	Y	citmNoYes_Y	
clTRANSTP	String		Red blood cell (RBCs)	RBC	citmTRANSP_RBC	lstTRANSTPP
			Platelets	PL	citmTRANSP_PL	
			Fresh frozen plasma (FFP)	FFP	citmTRANSP_FFP	
			Cryoprecipitate	CRYO	citmTRANSP_CRYO	
clHERS	String		Excellent	EXC	citmHERS_EXC	lstHERS_PO
			Good	GOOD	citmHERS_GOOD	
			Moderate	MOD	citmHERS_MOD	
			None	NONE	citmHERS_NONE	

RDE Analytics: RD_FRMPOPQ

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
lstTRANSFU	LSTTRANSFU_C	VARCHAR2
	LSTTRANSFU	VARCHAR2

	LSTTRANSFU_ND	VARCHAR2
lstTRANSFU - Red blood cell (RBCs)	LSTTRANSTPP_NUMRBC_C	VARCHAR2
	LSTTRANSTPP_NUMRBC	VARCHAR2
lstTRANSFU - numRBC	NUMRBC	NUMBER
lstTRANSFU - Platelets	LSTTRANSTPP_NUMPL_C	VARCHAR2
	LSTTRANSTPP_NUMPL	VARCHAR2
lstTRANSFU - numPL	NUMPL	NUMBER
lstTRANSFU - Fresh frozen plasma (FFP)	LSTTRANSTPP_NUMFFP_C	VARCHAR2
	LSTTRANSTPP_NUMFFP	VARCHAR2
lstTRANSFU - numFFP	NUMFFP	NUMBER
lstTRANSFU - Cryoprecipitate	LSTTRANSTPP_NUMCRYO_C	VARCHAR2
	LSTTRANSTPP_NUMCRYO	VARCHAR2
lstTRANSFU - numCRYO	NUMCRYO	NUMBER
lstHERS_PO	LSTHERS_PO_C	VARCHAR2
	LSTHERS_PO	VARCHAR2
	LSTHERS_PO_ND	VARCHAR2

AT3SC002: Completion of Hemostatic Treatment Coverage (COMP POPV2) [frmCOMP_POPV2]

Completion of Hemostatic Treatment Coverage [sctCOMP_POPV2]

1.* ✔	Was the perioperative treatment coverage and the thromboprophylaxis coverage completed at this visit? [Was the perioperative treatment coverage and the thromboprophylaxis coverage completed at this visit?]	**[lstCOVCOMP]** *[A:Y]* ◯ **[cmpCOMP_POPV2]** Yes **[dtSTART] (DD/MM/YYYY hh:mm)** Completion of perioperative treatment coverage Start date and time Req/Unk / Req/Unk / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock* **[dtEND] (DD/MM/YYYY hh:mm)** End date and time Req/Unk / Req/Unk / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock* **[lstTHROM]** Completion of thromboprophylaxis coverage *[A:DATE]* ◯ **[cmpTHROM]** **[dTHROM] (DD/MM/YYYY hh:mm)** Yes, Start date and time Req / Req / Req (2015-2023) Req : Req *24-hour clock* **[dTHROM_EN] (DD/MM/YYYY hh:mm)** End date and time Req / Req / Req (2015-2023) Req : Req *24-hour clock* *[A:NAP]* ◯ Not Applicable *[A:N]* ◯ No, please complete Postoperative visit 3

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: Completion of Hemostatic Treatment Coverage

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clCOVCOMP	String		Yes	Y	citmCOVCOMP_Y	lstCOVCOMP
			No, please complete Postoperative visit 3	N	citmCOVCOMP_N	
clTHROMDT	String		Date	DATE	citmTHROMDT_DATE	lstTHROM
			Not Applicable	NAP	citmTHROMDT_NAP	

RDE Analytics: RD_FRMCOMP_POPV2

Data Variable RefName	RD Column Name	Column Data Type
lstCOVCOMP	LSTCOVCOMP_C	VARCHAR2
	LSTCOVCOMP	VARCHAR2
	LSTCOVCOMP_ND	VARCHAR2
lstCOVCOMP - dtSTART	DTSTART	DATE
	DTSTART_DTS	VARCHAR2
	DTSTART_DTR	VARCHAR2
lstCOVCOMP - dtEND	DTEND	DATE
	DTEND_DTS	VARCHAR2
	DTEND_DTR	VARCHAR2
lstCOVCOMP - lstTHROM	LSTTHROM_C	VARCHAR2
	LSTTHROM	VARCHAR2
lstCOVCOMP - dTHROM	DTHROM	DATE
	DTHROM_DTS	VARCHAR2
lstCOVCOMP - dTHROM_EN	DTHROM_EN	DATE
	DTHROM_EN_DTS	VARCHAR2

AT3SC002: Completion of Hemostatic Treatment Coverage (COMP POP) [frmCOMP_POP]

Assessment Date [sctASSDT]

1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ○ Same date as visit date *[A:OTHER]* ○ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)

Completion of Hemostatic Treatment Coverage [sctCOMP_POP]

2.* ✔	How would you rate the patient's hemostasis since the last visit? [Patient's hemostasis?]	**[lstHERS_PO]** *[A:EXC]* ○ Excellent *[A:GOOD]* ○ Good *[A:MOD]* ○ Moderate *[A:NONE]* ○ None
3.* ✔	Completion of perioperative treatment coverage [Completion of perioperative treatment coverage]	**[cmpCOMP_POP]** **[dtSTART] (DD/MM/YYYY hh:mm)** Start date and time Req/Unk / Req/Unk / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock* **[dtEND] (DD/MM/YYYY hh:mm)** End date and time Req/Unk / Req/Unk / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock*
4.* ✔	Completion of thromboprophylaxis coverage [Completion of thromboprophylaxis coverage]	**[lstTHROM]** *[A:DATE]* ○ **[dTHROM] (DD/MM/YYYY hh:mm)** Start date and time Req / Req / Req (2015-2023) Req : Req *24-hour clock* **[dTHROM_EN] (DD/MM/YYYY hh:mm)** End date and time Req / Req / Req (2015-2023) Req : Req *24-hour clock* *[A:NAP]* ○ 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.

Codelist Values Tables: Completion of Hemostatic Treatment Coverage

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clHERS	String		Excellent	EXC	citmHERS_EXC	lstHERS_PO
			Good	GOOD	citmHERS_GOOD	
			Moderate	MOD	citmHERS_MOD	
			None	NONE	citmHERS_NONE	
clTHROMDT	String		Date	DATE	citmTHROMDT_DATE	lstTHROM
			Not Applicable	NAP	citmTHROMDT_NAP	

RDE Analytics: RD_FRMCOMP_POP

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
lstHERS_PO	LSTHERS_PO_C	VARCHAR2
	LSTHERS_PO	VARCHAR2
	LSTHERS_PO_ND	VARCHAR2
cmpCOMP_POP	CMPCOMP_POP_ND	VARCHAR2
cmpCOMP_POP - dtSTART	DTSTART	DATE
	DTSTART_DTS	VARCHAR2

	DTSTART_DTR	VARCHAR2
cmpCOMP_POP - dtEND	DTEND	DATE
	DTEND_DTS	VARCHAR2
	DTEND_DTR	VARCHAR2
lstTHROM	LSTTHROM_C	VARCHAR2
	LSTTHROM	VARCHAR2
	LSTTHROM_ND	VARCHAR2
lstTHROM - dTHROM	DTHROM	DATE
	DTHROM_DTS	VARCHAR2
lstTHROM - dTHROM_EN	DTHROM_EN	DATE
	DTHROM_EN_DTS	VARCHAR2

AT3SC002: Telephone Calls (TEL) [frmTEL2]

	Timepoint	Date and Time	Dosing schedule	Actual visit
1. ✔				

Scheduled Telephone Calls Entry [sctTELSCHED]

Please add all Scheduled Telephone Calls in the Add Entry section below

1.1* ✔ 🔑	Telephone call timepoint [Timepoint]	**[lstTELSCHED]** **[clTELSCHED]**
1.2* ✔	Date and Time of telephone call [Date and Time]	**[dtTELSCHED] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock*
1.3 ✔	Dosing schedule *(Only to be completed for PR visits)* *[Dosing schedule]*	**[lstDOSE]** *[A:50 QM]* 50mg QM *[A:50 Q2M]* 50mg Q2M *[A:80 QM]* 80mg QM
1.4 ✔	Actual visit *(Only to be completed for PR visits)* *[Actual visit]*	**[lstACTVIS]** **[clACVIS]**

	Date and Time
2. ✔	

Telephone call(s) 2 weeks after scheduled AT Follow-up visit(s) Entry [sctTELATFU]

Please add all telephone call(s) 2 weeks after scheduled AT Follow-up visit(s) in the Add Entry section below

2.1* ✔	Date and Time of telephone call [Date and Time]	**[dtTELAFU] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock*

	Date and Time
3. ✔	

Unscheduled Telephone Calls Entry [sctTELUNS]

Please add all Unscheduled Telephone Calls in the Add Entry section below

3.1* ✔	Date and Time of telephone call [Date and Time]	**[dtTELUNS] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock*

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

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

Keys (navigation) / Uniqueness: Telephone Calls

Item	Unique	Order #
sctTELSCHED (Repeating section)		
lstTELSCHED	Individual	1

Codelist Values Tables: Telephone Calls

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clTELSCHED	String		2 Weeks post Month 1 visit	M1	citmTELSCHED_M1	lstTELSCHED
			2 Weeks post Month 2 visit	M2	citmTELSCHED_M2	
			2 Weeks post Month 3 visit	M3	citmTELSCHED_M3	
			2 Weeks post Month 4 visit	M4	citmTELSCHED_M4	
			2 Weeks post Month 5 visit	M5	citmTELSCHED_M5	
			2 Weeks post Month 6 visit	M6	citmTELSCHED_M6	
			2 Weeks post Month 7 visit	M7	citmTELSCHED_M7	
			2 Weeks post Month 8 visit	M8	citmTELSCHED_M8	
			2 Weeks post Month 9 visit	M9	citmTELSCHED_M9	
			2 Weeks post Month 10 visit	M10	citmTELSCHED_M10	

2 Weeks post Month 11 visit	M11	citmTELSCHED_M11
2 Weeks post Month 12 visit	M12	citmTELSCHED_M12
2 Weeks post Month 13 visit	M13	citmTELSCHED_M13
2 Weeks post Month 14 visit	M14	citmTELSCHED_M14
2 Weeks post Month 15 visit	M15	citmTELSCHED_M15
2 Weeks post Month 16 visit	M16	citmTELSCHED_M16
2 Weeks post Month 17 visit	M17	citmTELSCHED_M17
2 Weeks post Month 18 visit	M18	citmTELSCHED_M18
2 Weeks post Month 19 visit	M19	citmTELSCHED_M19
2 Weeks post Month 20 visit	M20	citmTELSCHED_M20
2 Weeks post Month 21 visit	M21	citmTELSCHED_M21
2 Weeks post Month 22 visit	M22	citmTELSCHED_M22
2 Weeks post Month 23 visit	M23	citmTELSCHED_M23
2 Weeks post Month 24 visit	M24	citmTELSCHED_M24
2 Weeks post Month 25 visit	M25	citmTELSCHED_M25
2 Weeks post Month 26 visit	M26	citmTELSCHED_M26
2 Weeks post Month 27 visit	M27	citmTELSCHED_M27
2 Weeks post Month 28 visit	M28	citmTELSCHED_M28
2 Weeks post Month 29 visit	M29	citmTELSCHED_M29
2 Weeks post Month 30 visit	M30	citmTELSCHED_M30
2 Weeks post Month 31 visit	M31	citmTELSCHED_M31
2 Weeks post Month 32 visit	M32	citmTELSCHED_M32
2 Weeks post Month 33 visit	M33	citmTELSCHED_M33
2 Weeks post Month 34 visit	M34	citmTELSCHED_M34
2 Weeks post Month 35 visit	M35	citmTELSCHED_M35
2 Weeks post Month 36 visit	M36	citmTELSCHED_M36
2 Weeks post Month 37 visit	M37	citmTELSCHED_M37
2 Weeks post Month 38 visit	M38	citmTELSCHED_M38
2 Weeks post Month 39 visit	M39	citmTELSCHED_M39
2 Weeks post Month 40 visit	M40	citmTELSCHED_M40
2 Weeks post Month 41 visit	M41	citmTELSCHED_M41
2 Weeks post Month 42 visit	M42	citmTELSCHED_M422
2 Weeks post Month 43 visit	M43	citmTELSCHED_M43
2 Weeks post Month 44 visit	M44	citmTELSCHED_M44
2 Weeks post Month 45 visit	M45	citmTELSCHED_M45
2 Weeks post Month 46 visit	M46	citmTELSCHED_M46
2 Weeks post Month 47 visit	M47	citmTELSCHED_M47
2 Weeks post Month 48 visit	M48	citmTELSCHED_M48
2 Weeks post Month 49 visit	EOS	citmTELSCHED_EOS
2 Weeks post Month 50 visit	M50	citmTELSCHED_M50
2 Weeks post Month 51 visit	M51	citmTELSCHED_M51
2 Weeks post Month 52 visit	M52	citmTELSCHED_M52
2 Weeks post Month 53 visit	M53	citmTELSCHED_M53
2 Weeks post Month 54 visit	M54	citmTELSCHED_M54
2 Weeks post Month 55 visit	M55	citmTELSCHED_M55
2 Weeks post Month 56 visit	M56	citmTELSCHED_M56
2 Weeks post Month 57 visit	M57	citmTELSCHED_M57
2 Weeks post Month 58 visit	M58	citmTELSCHED_M58
2 Weeks post Month 59 visit	M59	citmTELSCHED_M59
2 Weeks post Month 60 visit	M60	citmTELSCHED_M60
2 Weeks post Month 61 visit	M61	citmTELSCHED_M61
2 Weeks post Month 62 visit	M62	citmTELSCHED_M62
2 Weeks post Month 63 visit	M63	citmTELSCHED_M63

				M64	citmTELSCHED_M64	
			2 Weeks post Month 65 visit	M65	citmTELSCHED_M65	
			2 Weeks post Month 66 visit	M66	citmTELSCHED_M66	
			2 Weeks post Month 67 visit	M67	citmTELSCHED_M67	
			2 Weeks post Month 68 visit	M68	citmTELSCHED_M68	
			2 Weeks post Month 69 visit	M69	citmTELSCHED_M69	
			2 Weeks post Month 70 visit	M70	citmTELSCHED_M70	
			2 Weeks post Month 71 visit	M71	citmTELSCHED_M71	
			2 Weeks post Month 72 (EOT) visit	M72	citmTELSCHED_M72	
			2 Weeks post Month 73 (EOS) visit	M73	citmTELSCHED_M73	
			2 Weeks post Month 74 visit	M74	citmTELSCHED_M74	
			2 Weeks post Month 75 visit	M75	citmTELSCHED_M75	
			2 Weeks post Month 76 visit	M76	citmTELSCHED_M76	
			2 Weeks post Month 77 visit	M77	citmTELSCHED_M77	
			2 Weeks post Month 78 visit	M78	citmTELSCHED_M78	
			2 Weeks post Month 79 visit	M79	citmTELSCHED_M79	
			2 Weeks post Month 80 visit	M80	citmTELSCHED_M80	
			2 Weeks post Month 81 visit	M81	citmTELSCHED_M81	
			2 Weeks post Month 82 visit	M82	citmTELSCHED_M82	
			2 Weeks post Month 83 visit	M83	citmTELSCHED_M83	
			2 Weeks post Month 84 (EOT) visit	M84	citmTELSCHED_M84	
			2 Weeks post Month 85 (EOS) visit	M85	citmTELSCHED_M85	
			2 Weeks post ET visit	ET	citmTELSCHED_ET	
			2 Weeks post Follow-Up 1	FU1	citmTELSCHED_FU1	
			2 Weeks post Follow-Up 2	FU2	citmTELSCHED_FU2	
clDOSE	String		50mg QM	50 QM	citmDOSE_50QM	lstDOSE
			50mg Q2M	50 Q2M	citmDOSE_50Q2M	
			80mg QM	80 QM	citmDOSE_80QM	
clACVIS	String		PR Day1	PRD1	citmACVIS_PRD1	lstACTVIS
			PR Month 1	PRM1	citmACVIS_PRM1	
			PR Month 2	PRM2	citmACVIS_PRM2	
			PR Month 3	PRM3	citmACVIS_PRM3	
			PR Month 4	PRM4	citmACVIS_PRM4	
			PR Month 5	PRM5	citmACVIS_PRM5	
			PR Month 6	PRM6	citmACVIS_PRM6	
			PR Month 7	PRM7	citmACVIS_PRM7	
			PR Month 8	PRM8	citmACVIS_PRM8	
			PR Month 9	PRM9	citmACVIS_PRM9	
			PR Month 10	PRM10	citmACVIS_PRM10	
			PR Month 11	PRM11	citmACVIS_PRM11	
			PR Month 12	PRM12	citmACVIS_PRM12	
			PR Month 13	PRM13	citmACVIS_PRM13	
			PR Month 14	PRM14	citmACVIS_PRM14	
			PR Month 15	PRM15	citmACVIS_PRM15	
			PR Month 16	PRM16	citmACVIS_PRM16	
			PR Month 17	PRM17	citmACVIS_PRM17	
			PR Month 18	PRM18	citmACVIS_PRM18	
			PR Month 19	PRM19	citmACVIS_PRM19	
			PR Month 20	PRM20	citmACVIS_PRM20	
			PR Month 21	PRM21	citmACVIS_PRM21	
			PR Month 22	PRM22	citmACVIS_PRM22	
			PR Month 23	PRM23	citmACVIS_PRM23	
			PR Month 24	PRM24	citmACVIS_PRM24	

			PR Month 25	PRM25	citmACVIS_PRM25	
			PR Month 26	PRM26	citmACVIS_PRM26	
			PR Month 27	PRM27	citmACVIS_PRM27	
			PR Month 28	PRM28	citmACVIS_PRM28	
			PR Month 29	PRM29	citmACVIS_PRM29	
			PR Month 30	PRM30	citmACVIS_PRM30	
			PR Month 31	PRM31	citmACVIS_PRM31	
			PR Month 32	PRM32	citmACVIS_PRM32	
			PR Month 33	PRM33	citmACVIS_PRM33	
			PR Month 34	PRM34	citmACVIS_PRM34	
			PR Month 35	PRM35	citmACVIS_PRM35	
			PR Month 36	PRM36	citmACVIS_PRM36	
			PR EOT	PREOT	citmACVIS_PREOT	
			PR EOS	PREOS	citmACVIS_PREOS	
			PR ET	PRET	citmACVIS_PRET	

RDE Analytics: RD_FRMTEL2		
Data Variable RefName	**RD Column Name**	**Column Data Type**
RD_FRMTEL2_SCTTELSCHED		
lstTELSCHED	LSTTELSCHED_C	VARCHAR2
	LSTTELSCHED	VARCHAR2
	LSTTELSCHED_ND	VARCHAR2
dtTELSCHED	DTTELSCHED	DATE
	DTTELSCHED_DTS	VARCHAR2
	DTTELSCHED_DTR	VARCHAR2
	DTTELSCHED_ND	VARCHAR2
lstDOSE	LSTDOSE_C	VARCHAR2
	LSTDOSE	VARCHAR2
	LSTDOSE_ND	VARCHAR2
lstACTVIS	LSTACTVIS_C	VARCHAR2
	LSTACTVIS	VARCHAR2
	LSTACTVIS_ND	VARCHAR2
RD_FRMTEL2_SCTTELATFU		
dtTELAFU	DTTELAFU	DATE
	DTTELAFU_DTS	VARCHAR2
	DTTELAFU_DTR	VARCHAR2
	DTTELAFU_ND	VARCHAR2
RD_FRMTEL2_SCTTELUNS		
dtTELUNS	DTTELUNS	DATE
	DTTELUNS_DTS	VARCHAR2
	DTTELUNS_DTR	VARCHAR2
	DTTELUNS_ND	VARCHAR2

AT3SC002: Telephone Calls by Subject (SUBJ TEL) [frmTEL3]

	Date and Time	Symptoms of bleed?
1. ✔		

Telephone Calls by Subject Entry [sctTELSUBJ]

Please add all Telephone Calls from the Subject to the Site in the Add Entry section below

1.1* ✔	Date and Time of telephone call [Date and Time]	**[dtTELUNS] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock*
1.2* ✔	Was your patient calling to discuss symptoms of a potential or existing bleed? [Symptoms of bleed?]	**[lstBLEEDYN]** *[A:Y]* **[lstTREATYN]** Yes, Did the symptoms require treatment with Factor VIII, Factor IX, aPCC, rFVIIa, or Antifibrinolytics? *[A:Y]* **[lstTREATBEF]** Yes, Was treatment for these symptoms started before this phone call? *[A:Y]* **[lstTREATNUM]** Yes, this treatment was: **[clTREATNUM]** *[A:N]* No *[A:N]* No *[A:N]* No

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: Telephone Calls by Subject

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	lstBLEEDYN, lstTREATYN, lstTREATBEF
			No	N	citmYesNo_N	
clTREATNUM	String		The First Treatment	FIRST TREATMENT	citmTREATNUM_FIRST	lstTREATNUM
			The Second Treatment	SECOND TREATMENT	citmTREATNUM_SECOND	
			The Third Treatment	THIRD TREATMENT	citmTREATNUM_THIRD	
			A Later Treatment	LATER TREATMENT	citmTREATNUM_LATER	

RDE Analytics: RD_FRMTEL3

Data Variable RefName	RD Column Name	Column Data Type
RD_FRMTEL3_SCTTELSUBJ		
dtTELUNS	DTTELUNS	DATE
	DTTELUNS_DTS	VARCHAR2
	DTTELUNS_DTR	VARCHAR2
	DTTELUNS_ND	VARCHAR2
lstBLEEDYN	LSTBLEEDYN_C	VARCHAR2
	LSTBLEEDYN	VARCHAR2
	LSTBLEEDYN_ND	VARCHAR2
lstBLEEDYN - lstTREATYN	LSTTREATYN_C	VARCHAR2
	LSTTREATYN	VARCHAR2
lstBLEEDYN - lstTREATBEF	LSTTREATBEF_C	VARCHAR2
	LSTTREATBEF	VARCHAR2
lstBLEEDYN - lstTREATNUM	LSTTREATNUM_C	VARCHAR2
	LSTTREATNUM	VARCHAR2

AT3SC002: Central Laboratory Assessments (Bleeding Episode) (LAB BLEED) [frmLAB_BLEED]

If an abnormality is present at Screening or before first dose of study drug, please cross-check with form MH (Medical History)
Please record new clinically significant abnormalities which started after first dose of study drug on the AE form

Date of sample collection [sctLABDT]		
1.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
Kit ID number [sctKITNUM]		
2.* ✔	Kit ID number [Kit ID number]	**[txtREFNO]** A11
Actual Time of Sampling [sctCOLL_BLD]		
3.* ✔	Predose to administration of factor or BPA [Predose]	**[lstLAB_PRE]** *[A:ACTUAL TIME]* ◯ **[tLAB_PRE] (hh:mm)** Actual time Req : Req *24-hour clock* *[A:NOT COLLECTED]* ◯ Not collected
4. ✔	Predose Kit ID number [Predose Kit ID number]	**[txtREFNO1]** A11
5.* ✔	Time of factor/BPA intake [Time of factor/BPA intake]	**[tINTAKE] (hh:mm)** Req : Req *24-hour clock*
6.* ✔	10 min postdose to administration of factor or BPA (+/-5min) [10 min postdose]	**[lstLAB_10M]** *[A:ACTUAL TIME]* ◯ **[tLAB_10M] (hh:mm)** Actual time Req : Req *24-hour clock* *[A:NOT COLLECTED]* ◯ Not collected
7. ✔	10 min postdose Kit ID number [10 min postdose Kit ID number]	**[txtREFNO2]** A11
8.* ✔	60 min postdose to administration of factor or BPA (+/-5min) [60 min postdose]	**[lstLAB_60M]** *[A:ACTUAL TIME]* ◯ **[tLAB_60M] (hh:mm)** Actual time Req : Req *24-hour clock* *[A:NOT COLLECTED]* ◯ Not collected
9. ✔	60 min postdose Kit ID number [60 min postdose Kit ID number]	**[txtREFNO3]** A11

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: Central Laboratory Assessments (Bleeding Episode)

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT
			Other	OTHER	citmDateOther_Other	
clActTimeNotCol	String		Actual Time	ACTUAL TIME	citmActTimeNotCol_ActTime	lstLAB_PRE, lstLAB_10M, lstLAB_60M
			Not collected	NOT COLLECTED	citmActTimeNotCol_NotCol	

RDE Analytics: RD_FRMLAB_BLEED

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
txtREFNO	TXTREFNO	VARCHAR2
	TXTREFNO_ND	VARCHAR2
lstLAB_PRE	LSTLAB_PRE_C	VARCHAR2
	LSTLAB_PRE	VARCHAR2
	LSTLAB_PRE_ND	VARCHAR2
lstLAB_PRE - tLAB_PRE	TLAB_PRE	DATE

	TLAB_PRE_TMS	VARCHAR2
txtREFNO1	TXTREFNO1	VARCHAR2
	TXTREFNO1_ND	VARCHAR2
tINTAKE	TINTAKE	DATE
	TINTAKE_TMS	VARCHAR2
	TINTAKE_ND	VARCHAR2
lstLAB_10M	LSTLAB_10M_C	VARCHAR2
	LSTLAB_10M	VARCHAR2
	LSTLAB_10M_ND	VARCHAR2
lstLAB_10M - tLAB_10M	TLAB_10M	DATE
	TLAB_10M_TMS	VARCHAR2
txtREFNO2	TXTREFNO2	VARCHAR2
	TXTREFNO2_ND	VARCHAR2
lstLAB_60M	LSTLAB_60M_C	VARCHAR2
	LSTLAB_60M	VARCHAR2
	LSTLAB_60M_ND	VARCHAR2
lstLAB_60M - tLAB_60M	TLAB_60M	DATE
	TLAB_60M_TMS	VARCHAR2
txtREFNO3	TXTREFNO3	VARCHAR2
	TXTREFNO3_ND	VARCHAR2

AT3SC002: Optional Imaging (IMAG) [frmIMAG]

Optional Imaging Question [sctIMAGQ]

1.* ✔	Was optional imaging performed to confirm bleeding episode? [Optional imaging performed?]	**[lstIMAG]** *[A:Y]* ◯ Yes *[A:N]* ◯ No
2.	For office use only *[hidden]* [For office use only]	**[numEMAIL1]** N3
3.	For office use only *[hidden]* [For office use only]	**[numEMAIL2]** N3

	Method of imaging	Date of imaging	Did this imaging confirm the presence of an acute bleed?
4. ✔			

Optional Imaging Entry [sctIMAG]

Please record all performed imaging in the Add Entry section below

4.1* ✔	Method of imaging [Method of imaging]	**[lstIMAGSP]** *[A:ULTRASOUND]* ◯ Ultrasound *[A:CT SCAN]* ◯ CT Imaging *[A:MRI]* ◯ MRI Imaging *[A:OTHER]* ◯ **[txtIMAGOTH]** Other, please specify A128
4.2* ✔	Date of imaging [Date of imaging]	**[dIMAG] (DD/MM/YYYY)** Req / Req / Req (2015-2023)
4.3* ✔	Did this imaging confirm the presence of an acute bleed? [Did this imaging confirm the presence of an acute bleed?]	**[lstACTBLD]** *[A:Y]* ◯ Yes *[A:N]* ◯ No *[A:INDETERMINATE]* ◯ Indeterminate

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: Optional Imaging

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	lstIMAG
			No	N	citmYesNo_N	
clIMAGSP	String		Ultrasound	ULTRASOUND	citmIMAGSP_ULTRASOUND	lstIMAGSP
			CT Imaging	CT SCAN	citmIMAGSP_CT	
			MRI Imaging	MRI	citmIMAGSP_MRI	
			Other	OTHER	itmIMAGSP_OTHER	
clACTBLD	String		Yes	Y	citmACTBLD_Y	lstACTBLD
			No	N	citmACTBLD_N	
			Indeterminate	INDETERMINATE	citmACTBLD_INDET	

RDE Analytics: RD_FRMIMAG

Data Variable RefName	RD Column Name	Column Data Type
lstIMAG	LSTIMAG_C	VARCHAR2
	LSTIMAG	VARCHAR2
	LSTIMAG_ND	VARCHAR2
numEMAIL1	NUMEMAIL1	NUMBER
	NUMEMAIL1_ND	VARCHAR2
numEMAIL2	NUMEMAIL2	NUMBER
	NUMEMAIL2_ND	VARCHAR2
RD_FRMIMAG_SCTIMAG		
lstIMAGSP	LSTIMAGSP_C	VARCHAR2
	LSTIMAGSP	VARCHAR2
	LSTIMAGSP_ND	VARCHAR2

lstIMAGSP - txtIMAGOTH	TXTIMAGOTH	VARCHAR2
dIMAG	DIMAG	DATE
	DIMAG_DTS	VARCHAR2
	DIMAG_ND	VARCHAR2
lstACTBLD	LSTACTBLD_C	VARCHAR2
	LSTACTBLD	VARCHAR2
	LSTACTBLD_ND	VARCHAR2

AT3SC002: Date of Unscheduled Visit (DOV UNS) [frmDOV_UNS]

Date of Unscheduled Visit [sctDOV_UNS]

1.* ✔	Date and time of visit [Date and time of visit]	**[dtmVISIT_DT_UNS] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req/Unk : Req/Unk *24-hour clock*
2.	Should this visit be marked as deleted? *[hidden]* [Should this visit be marked as deleted?]	**[lstVISDELETED]** *[A:Y]* ☐ Yes

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: Date of Unscheduled Visit

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYes	String		Yes	Y	citmYes_Y	lstVISDELETED

RDE Analytics: RD_FRMDOV_UNS

Data Variable RefName	RD Column Name	Column Data Type
dtmVISIT_DT_UNS	DTMVISIT_DT_UNS	DATE
	DTMVISIT_DT_UNS_DTS	VARCHAR2
	DTMVISIT_DT_UNS_DTR	VARCHAR2
	DTMVISIT_DT_UNS_ND	VARCHAR2
lstVISDELETED	LSTVISDELETED_ND	VARCHAR2
lstVISDELETED - Yes	LSTVISDELETED_CITMYESY_C	VARCHAR2
	LSTVISDELETED_CITMYESY	VARCHAR2

AT3SC002: Unscheduled Assessments (ASS UNS) [frmASS_UNS]

Unscheduled Assessments [sctASS_UNS]

1.* ✔	Check the assessments to be completed at this unscheduled visit [Performed assessments during visit]	**[lstASS_UNS]** *[A:IMAG]* ☐ Imaging *[A:LAB]* ☐ Central Laboratory Assessments *[A:ECG]* ☐ 12-lead Electrocardiogram *[A:EQ5D]* ☐ EQ-5D Questionnaire *[A:HAEMAQOL]* ☐ HAEM-A-QOL Questionnaire *[A:DIRECTED PE]* ☐ Directed Physical Examination *[A:PKBLD]* ☐ Plasma PK Sampling *[A:VITAL SIGNS]* ☐ Vital Signs *[A:WHOLE BLOOD CLOT]* ☐ Whole Blood Clot Formation (ROTEM) *[A:LOCLAB]* ☐ Local Laboratory Assessments *[A:HEPATIC]* ☐ Hepatic Assessments in Patients who Experience LFT Elevations *[A:FIBRO]* ☐ FibroTest/FibroScan

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: Unscheduled Assessments

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clASS_UNS	String		Imaging	IMAG	citmASS_UNS_IMAG	lstASS_UNS
			Central Laboratory Assessments	LAB	citmASS_UNS_LAB	
			12-lead Electrocardiogram	ECG	citmASS_UNS_ECG	
			EQ-5D Questionnaire	EQ5D	citmASS_UNS_EQ5D	
			HAEM-A-QOL Questionnaire	HAEMAQOL	citmASS_UNS_HAEMAQOL	
			Directed Physical Examination	DIRECTED PE	citmASS_UNS_PE	
			Plasma PK Sampling	PKBLD	citmASS_UNS_PKBLD	
			Vital Signs	VITAL SIGNS	citmASS_UNS_VS	
			Whole Blood Clot Formation (ROTEM)	WHOLE BLOOD CLOT	citmASS_UNS_WBCLT	
			Local Laboratory Assessments	LOCLAB	citmASS_UNS_LOCLAB	
			Hepatic Assessments in Patients who Experience LFT Elevations	HEPATIC	citmASS_UNS_HEPATIC	
			FibroTest/FibroScan	FIBRO	citmASS_UNS_FIBRO	

RDE Analytics: RD_FRMASS_UNS

Data Variable RefName	RD Column Name	Column Data Type
lstASS_UNS	LSTASS_UNS_ND	VARCHAR2
lstASS_UNS - Imaging	LSTASS_UNS_CITMASSUNSIMAG_C	VARCHAR2
	LSTASS_UNS_CITMASSUNSIMAG	VARCHAR2
lstASS_UNS - Central Laboratory Assessments	LSTASS_UNS_CITMASSUNSLAB_C	VARCHAR2
	LSTASS_UNS_CITMASSUNSLAB	VARCHAR2
lstASS_UNS - 12-lead Electrocardiogram	LSTASS_UNS_CITMASSUNSECG_C	VARCHAR2
	LSTASS_UNS_CITMASSUNSECG	VARCHAR2
lstASS_UNS - EQ-5D Questionnaire	LSTASS_UNS_CITMASSUNSEQ5D_C	VARCHAR2
	LSTASS_UNS_CITMASSUNSEQ5D	VARCHAR2
lstASS_UNS - HAEM-A-QOL Questionnaire	*LSTASS_UNS_CITMASSUNSHAEMAQOL_C	VARCHAR2
	*LSTASS_UNS_CITMASSUNSHAEMAQOL	VARCHAR2
lstASS_UNS - Directed Physical Examination	LSTASS_UNS_CITMASSUNSPE_C	VARCHAR2
	LSTASS_UNS_CITMASSUNSPE	VARCHAR2
lstASS_UNS - Plasma PK Sampling	*LSTASS_UNS_CITMASSUNSPKBLD_C	VARCHAR2
	*LSTASS_UNS_CITMASSUNSPKBLD	VARCHAR2
lstASS_UNS - Vital Signs	LSTASS_UNS_CITMASSUNSVS_C	VARCHAR2
	LSTASS_UNS_CITMASSUNSVS	VARCHAR2
lstASS_UNS - Whole Blood Clot Formation (ROTEM)	*LSTASS_UNS_CITMASSUNSWBCLT_C	VARCHAR2
	*LSTASS_UNS_CITMASSUNSWBCLT	VARCHAR2
lstASS_UNS - Local Laboratory Assessments	*LSTASS_UNS_CITMASSUNSLOCLAB_C	VARCHAR2

	*LSTASS_UNS_CITMASSUNSLOCLAB	VARCHAR2
lstASS_UNS - Hepatic Assessments in Patients who Experience LFT Elevations	*LSTASS_UNS_CITMASSUNSHEPATIC_C	VARCHAR2
	*LSTASS_UNS_CITMASSUNSHEPATIC	VARCHAR2
lstASS_UNS - FibroTest/FibroScan	*LSTASS_UNS_CITMASSUNSFIBRO_C	VARCHAR2
	*LSTASS_UNS_CITMASSUNSFIBRO	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different.		

AT3SC002: Imaging (IMAG) [frmIMAG_UNS]

Imaging [sctIMAG_UNS]

1.* ✔	Date of imaging [Date of imaging]	**[lstASSDT_IMAG]** *[A:SAME DATE]* ◯ Same date as visit date *[A:OTHER]* ◯ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
2.* ✔	Method(s) of imaging [Method(s) of imaging]	**[lstIMAG_UNS]** *[A:ULTRASOUND]* ☐ Ultrasound *[A:CT SCAN]* ☐ CT Imaging *[A:MRI]* ☐ MRI Imaging *[A:OTHER]* ☐ **[txtIMAGOTH]** Other, please specify A128
3.	For office use only *[hidden]* [For office use only]	**[numEMAIL1]** N3
4.	For office use only *[hidden]* [For office use only]	**[numEMAIL2]** N3

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: Imaging

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT_IMAG
			Other	OTHER	citmDateOther_Other	
clIMAGSP	String		Ultrasound	ULTRASOUND	citmIMAGSP_ULTRASOUND	lstIMAG_UNS
			CT Imaging	CT SCAN	citmIMAGSP_CT	
			MRI Imaging	MRI	citmIMAGSP_MRI	
			Other	OTHER	itmIMAGSP_OTHER	

RDE Analytics: RD_FRMIMAG_UNS

Data Variable RefName	RD Column Name	Column Data Type
lstASSDT_IMAG	LSTASSDT_IMAG_C	VARCHAR2
	LSTASSDT_IMAG	VARCHAR2
	LSTASSDT_IMAG_ND	VARCHAR2
lstASSDT_IMAG - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
lstIMAG_UNS	LSTIMAG_UNS_ND	VARCHAR2
lstIMAG_UNS - Ultrasound	*LSTIMAG_UNS_CITMIMAGSPULTRASOUND_C	VARCHAR2
	*LSTIMAG_UNS_CITMIMAGSPULTRASOUND	VARCHAR2
lstIMAG_UNS - CT Imaging	LSTIMAG_UNS_CITMIMAGSPCT_C	VARCHAR2
	LSTIMAG_UNS_CITMIMAGSPCT	VARCHAR2
lstIMAG_UNS - MRI Imaging	LSTIMAG_UNS_CITMIMAGSPMRI_C	VARCHAR2
	LSTIMAG_UNS_CITMIMAGSPMRI	VARCHAR2
lstIMAG_UNS - Other	LSTIMAG_UNS_TXTIMAGOTH_C	VARCHAR2
	LSTIMAG_UNS_TXTIMAGOTH	VARCHAR2
lstIMAG_UNS - txtIMAGOTH	TXTIMAGOTH	VARCHAR2
numEMAIL1	NUMEMAIL1	NUMBER
	NUMEMAIL1_ND	VARCHAR2
numEMAIL2	NUMEMAIL2	NUMBER
	NUMEMAIL2_ND	VARCHAR2

Key: [*] = The column and/or table name in the actual RDE extract may be different.

AT3SC002: Plasma PK Sampling (PK UNS) [frmPKBLD_UNS]		
Actual Time of Plasma PK Sampling [sctPKBLD_UNS]		
1.* ✔	Actual time [Actual time]	**[dtmSAMPLE_T_UNS] (hh:mm)** 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.		

RDE Analytics: RD_FRMPKBLD_UNS		
Data Variable RefName	**RD Column Name**	**Column Data Type**
dtmSAMPLE_T_UNS	DTMSAMPLE_T_UNS	DATE
	DTMSAMPLE_T_UNS_TMS	VARCHAR2
	DTMSAMPLE_T_UNS_ND	VARCHAR2

AT3SC002: Local Laboratory Assessments (LOCLAB) [frmLOCLAB]

Sample collection [sctLOCLAB]

1.* ✔	Time of collection [Time of collection]	**[tLOCLAB] (hh:mm)** Req : Req *24-hour clock*
2.* ✔	Local Laboratory name [Local Laboratory name]	**[txtLOCLAB]** A200
3. ✔	Remarks regarding sample collection, if any [Remarks]	**[txtREM]** A200

	Tests	Value	Unit	Interpretation	Normal Range
4. ✔					

LFT tests Entry [sctLFT]

4.1* ✔	Tests [Tests]	**[lstTESTS_LFT]** *[A:ALT]* Alanine Transaminase *[A:AST]* Aspartate Aminotransferase *[A:ALP]* Alkaline Phosphatase *[A:GGT]* Gamma Glutamyl Transferase *[A:TBIL]* Total bilirubin *[A:DBIL]* Direct bilirubin
4.2* ✔	Value [Value]	**[txtVALUE_LFT]** A100
4.3* ✔	Unit [Unit]	**[lstUNIT_LFT]** *[A:UNIT]* **[lstUNITS_LFT]** Units **[clUNIT]** *[A:OTHER]* **[txtUNITO_LFT]** Other A50
4.4* ✔	Interpretation [Interpretation]	**[lstCSLAB_LFT]** *[A:NORMAL]* Normal *[A:ABNORMAL NCS]* Abnormal, not clinically significant *[A:ABNORMAL CS]* **[txtINTP_LFT]** Abnormal, clinically significant, please specify A50
4.5* ✔	Normal Range	**[cmpNR_LFT]** **[txtNRLL_LFT]** Normal range - lower limit A40 **[txtNRUL_LFT]** Normal range - upper limit A40 **[txtNRTB_LFT]** Normal range - text based A40

	Type of sample	Lab test	Value	Unit	Interpretation	Normal Range
5. ✔						

Local Laboratory Tests Entry [sctTEST_UNS]

5.1* ✔	Type of sample [Type of sample]	**[lstTYPE]** *[A:BLOOD]* Blood (blood, serum, plasma) *[A:URINE]* Urine
5.2* ✔	Lab test [Lab test]	**[lstTEST]** *[A:TEST]* **[lstTESTS]** Tests **[clTESTS_UNS]** *[A:OTHER]* **[txtTESTO]** Other, please specify A50
5.3* ✔	Value [Value]	**[txtVALUE]**

		A100
5.4* ✔	Unit [Unit]	**[lstUNIT]** *[A:UNIT]* Units **[lstUNITS]** **[clUNIT]** *[A:OTHER]* **[txtUNITO]** Other, please specify A50
5.5* ✔	Interpretation [Interpretation]	**[lstCSLAB]** *[A:NORMAL]* Normal *[A:ABNORMAL NCS]* Abnormal, not clinically significant *[A:ABNORMAL CS]* **[txtINTP]** Abnormal, clinically significant, please specify A50
5.6* ✔	Normal Range [Normal Range]	**[cmpNR]** **[txtNRLL]** Normal range - lower limit A40 **[txtNRUL]** Normal range - upper limit A40 **[txtNRTB]** Normal range - text based A40

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

Keys (navigation) / Uniqueness: Local Laboratory Assessments

Item	Unique	Order #
sctLFT (Repeating section)		
lstTESTS_LFT	Group	1

Codelist Values Tables: Local Laboratory Assessments

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clTESTSLFT_UNS	String		Alanine Transaminase	ALT	citmTESTS_ALT	lstTESTS_LFT
			Aspartate Aminotransferase	AST	citmTESTS_AST	
			Alkaline Phosphatase	ALP	citmTESTS_ALP	
			Gamma Glutamyl Transferase	GGT	citmTESTS_GGT	
			Total bilirubin	TBIL	citmTESTS_TBIL	
			Direct bilirubin	DBIL	citmTESTS_DBIL	
clUnitOther	String		Unit	UNIT	citmUnitOther_Unit	lstUNIT_LFT, lstUNIT
			Other	OTHER	citmUnitOther_Other	
clUNIT	String		%	%	citmUNIT_PER	lstUNITS_LFT, lstUNITS
			/pL	/pL	citmUNIT_PL	
			fL	fL	citmUNIT_FL	
			/µL	/µL	citmUNIT_UL	
			µg/dL	µg/dL	citmUNIT_UGDL	
			µkat/L	µkat/L	citmUNIT_UKATL	
			µmol/L	µmol/L	citmUNIT_UMOLL	
			absolute	absolute	citmUNIT_ABS	
			g/dL	g/dL	citmUNIT_GDL	
			g/L	g/L	citmUNIT_GL	
			IU/L	IU/L	citmUNIT_IUL	
			KU/L	KU/L	citmUNIT_KUL	
			L/L	L/L	citmUNIT_LL	
			mEq/L	mEq/L	citmUNIT_MEQL	
			mg/dL	mg/dL	citmUNIT_MGDL	
			mg/L	mg/L	citmUNIT_MGL	
			mIU/L	mIU/L	citmUNIT_MIUL	
			mmol/L	mmol/L	citmUNIT_MMOLL	

			mU/L	mU/L	citmUNIT_MUL	
			ng/dL	ng/dL	citmUNIT_NGDL	
			nmol/L	nmol/L	citmUNIT_NMOLL	
			pg	pg	citmUNIT_PG	
			pg/cell	pg/cell	citmUNIT_PGCELL	
			pg/dL	pg/dL	citmUNIT_PGDL	
			pmol/L	pmol/L	citmUNIT_PMOLL	
			units/L	units/L	citmUNIT_UNITSL	
			x10E12/L	x10E12/L	citmUNIT_10E12	
			x10E9/L	x10E9/L	citmUNIT_10E9	
			Ratio	Ratio	citmUNIT_RATIO	
			Sec	Sec	citmUNIT_SEC	
			µg/L	µg/L	citmUNIT_UGL	
clCSLAB	String		Normal	NORMAL	citmCSLAB_NORM	lstCSLAB_LFT, lstCSLAB
			Abnormal, not clinically significant	ABNORMAL NCS	citmCSLAB_ABNCS	
			Abnormal, clinically significant	ABNORMAL CS	citmCSLAB_ABCS	
clTYPE	String		Blood (blood, serum, plasma)	BLOOD	citmTYPE_BLOOD	lstTYPE
			Urine	URINE	citmTYPE_URINE	
clTEST	String		Test	TEST	citmTEST_TEST	lstTEST
			Other	OTHER	citmTEST_OTHER	
clTESTS_UNS	String		Hepatitis A virus antibody (IgG)	HEP A IGG	citmTESTS_HEPAIGG	lstTESTS
			Hepatitis E virus antibody (IgG)	HEP E IGG	citmTESTS_HEPEIGG	
			Hepatitis B surface antibody	HEP B SURF AB	citmTESTS_HEPBSURFAB	
			Hepatitis B core antibody Total	HEP B AB TOT	citmTESTS_HEPBABTOT	
			Prothrombin fragment 1,2	PF12	citmTEST_PF12	
			INR	INR	citmTESTS_INR	
			Hepatitis A viral load	HEP A	citmTESTS_HEPA	
			Hepatitis A Virus antibody (IgM)	HEP A IGM	citmTESTS_HEPAIGM	
			Hepatitis B viral load	HEP B	citmTESTS_HEPB	
			Hepatitis B surface antigen	HEP B SURF	citmTESTS_HEPBSURF	
			Hepatitis B core antibody (IgM)	HEP B IGM	citmTESTS_HEPBIGM	
			Hepatitis B core antibody (IgG)	HEP B IGG	citmTESTS_HEPBIGG	
			Hepatitis C viral load	HEB C	citmTESTS_HEPC	
			Hepatitis C Virus antibody (IgM)	HEP C IGM	citmTESTS_HEPCIGM	
			Hepatitis C Virus antibody (IgG)	HEP C IGG	citmTESTS_HEPCIGG	
			Hepatitis E viral load	HEP E	citmTESTS_HEPE	
			Hepatitis E Virus antibody (IgM)	HEP E IGM	citmTESTS_HEPEIGM	
			Herpes Simplex Virus 1 antibody (IgM)	HSV1 IGM	citmTESTS_HSV1IGM	
			Herpes Simplex Virus 1 antibody (IgG)	HSV1 IGG	citmTESTS_HSV1IGG	
			Herpes Simplex Virus 2 antibody (IgM)	HSV2 IGM	citmTESTS_HSV2IGM	
			Herpes Simplex Virus 2 antibody (IgG)	HSV2 IGG	citmTESTS_HSV2IGG	
			Herpes zoster virus (HZV) antibodies (IgM)	HZV IGM	citmTESTS_HZVIGM	
			Herpes zoster virus (HZV) antibodies (IgG)	HZV IGG	citmTESTS_HZVIGG	
			HIV 1 viral load	HIV 1	citmTESTS_HIV1	
			HIV 2a viral load	HIV 2A	citmTESTS_HIV2A	
			Human herpesvirus 6 (HHV-6) antibody (IgM)	HHV 6 IGM	citmTESTS_HHV6IGM	
			Human herpesvirus 6 (HHV-6) antibody (IgG)	HHV 6 IGG	citmTESTS_HHV6IGG	
			Cytomegalovirus (CMV) antibody (IgM)	CMV IGM	citmTESTS_CMVIGM	
			Cytomegalovirus (CMV) antibody (IgG) (	CMV IGG	citmTESTS_CMVIGG	
			Epstein-Barr virus (EBV) viral capsid antibody (IgM)	EBVM	citmTESTS_EBVM	
			Epstein-Barr virus (EBV) viral capsid antibody (IgG)	EBVG	citmTESTS_EBVG	
			Anti-nuclear antibodies (ANA)	ANA	citmTESTS_ANA	
			Anti-mitochondrial antibodies (AMA)	AMA	citmTESTS_AMA	

Anti-smooth muscle antibody (anti-SMA)	ASMA	citmTESTS_ASMA
Anti-centromere antibody	ACA	citmTESTS_ACA
Anti-liver kidney microsomal (anti-LKM) antibody	ALKM	citmTESTS_ALKM
Erythrocytes	RBC	citmTESTS_RBC
Leukocytes	WBC	citmTESTS_WBC
Hematocrit	HTC	citmTESTS_HTC
Hemoglobin	HGB	citmTESTS_HGB
Ery. Mean Corpuscular Hemoglobin	MC HGB	citmTESTS_MCHGB
Ery. Mean Corpuscular HGB Concentration	MC HGB C	citmTESTS_MCHGBC
Ery. Mean Corpuscular Volume	MC VOL	citmTESTS_MCVOL
Neutrophils	NEU	citmTESTS_NEU
Lymphocytes	LYM	citmTESTS_LYM
Monocytes	MON	citmTESTS_MON
Eosinophils	EOS	citmTESTS_EOS
Basophils	BAS	citmTESTS_BAS
Platelets	PLAT	citmTESTS_PLAT
Sodium	NA	citmTESTS_NA
Potassium	K	citmTESTS_K
Blood Urea Nitrogen	BUN	citmTESTS_BUN
Creatinine	CRE	citmTESTS_CRE
Albumin	ALB	citmTESTS_ALB
Calcium	CAL	citmTESTS_CAL
Phosphate	PHO	citmTESTS_PHO
Glucose	GLUC	citmTESTS_GLUC
C Reactive Protein	PRC	citmTESTS_PRC
Carbon Dioxide	CO2	citmTESTS_CO2
Protein	PROT	citmTESTS_PROT
Uric Acid	UA	citmTESTS_UA
Lactate Dehydrogenase	LDH	citmTESTS_LDH
Chloride	CL	citmTESTS_CL
Prothrombin Time	PT	citmTESTS_PT
Activated Partial Thromboplastin Time	APTT	citmTESTS_APTT
D-Dimer	DD	citmTESTS_DD
Fibrinogen	FIB	citmTESTS_FIB
Urobilinogen	UBIL	citmTESTS_UBIL
Ketones	KET	citmTESTS_KET
pH	PH	citmTESTS_PH
Nitrite	NIT	citmTESTS_NIT
Specific Gravity	SGRAV	citmTESTS_SGRAV
Appearance	APP	citmTESTS_APP
Color	COLOR	citmTESTS_COLOR

RDE Analytics: RD_FRMLOCLAB		
Data Variable RefName	**RD Column Name**	**Column Data Type**
tLOCLAB	TLOCLAB	DATE
	TLOCLAB_TMS	VARCHAR2
	TLOCLAB_ND	VARCHAR2
txtLOCLAB	TXTLOCLAB	VARCHAR2
	TXTLOCLAB_ND	VARCHAR2
txtREM	TXTREM	VARCHAR2
	TXTREM_ND	VARCHAR2
RD_FRMLOCLAB_SCTLFT		
lstTESTS_LFT	LSTTESTS_LFT_C	VARCHAR2

	LSTTESTS_LFT	VARCHAR2
	LSTTESTS_LFT_ND	VARCHAR2
txtVALUE_LFT	TXTVALUE_LFT	VARCHAR2
	TXTVALUE_LFT_ND	VARCHAR2
lstUNIT_LFT	LSTUNIT_LFT_C	VARCHAR2
	LSTUNIT_LFT	VARCHAR2
	LSTUNIT_LFT_ND	VARCHAR2
lstUNIT_LFT - lstUNITS_LFT	LSTUNITS_LFT_C	VARCHAR2
	LSTUNITS_LFT	VARCHAR2
lstUNIT_LFT - txtUNITO_LFT	TXTUNITO_LFT	VARCHAR2
lstCSLAB_LFT	LSTCSLAB_LFT_C	VARCHAR2
	LSTCSLAB_LFT	VARCHAR2
	LSTCSLAB_LFT_ND	VARCHAR2
lstCSLAB_LFT - txtINTP_LFT	TXTINTP_LFT	VARCHAR2
cmpNR_LFT	CMPNR_LFT_ND	VARCHAR2
cmpNR_LFT - txtNRLL_LFT	TXTNRLL_LFT	VARCHAR2
cmpNR_LFT - txtNRUL_LFT	TXTNRUL_LFT	VARCHAR2
cmpNR_LFT - txtNRTB_LFT	TXTNRTB_LFT	VARCHAR2
RD_FRMLOCLAB_SCTTEST_UNS		
lstTYPE	LSTTYPE_C	VARCHAR2
	LSTTYPE	VARCHAR2
	LSTTYPE_ND	VARCHAR2
lstTEST	LSTTEST_C	VARCHAR2
	LSTTEST	VARCHAR2
	LSTTEST_ND	VARCHAR2
lstTEST - lstTESTS	LSTTESTS_C	VARCHAR2
	LSTTESTS	VARCHAR2
lstTEST - txtTESTO	TXTTESTO	VARCHAR2
txtVALUE	TXTVALUE	VARCHAR2
	TXTVALUE_ND	VARCHAR2
lstUNIT	LSTUNIT_C	VARCHAR2
	LSTUNIT	VARCHAR2
	LSTUNIT_ND	VARCHAR2
lstUNIT - lstUNITS	LSTUNITS_C	VARCHAR2
	LSTUNITS	VARCHAR2
lstUNIT - txtUNITO	TXTUNITO	VARCHAR2
lstCSLAB	LSTCSLAB_C	VARCHAR2
	LSTCSLAB	VARCHAR2
	LSTCSLAB_ND	VARCHAR2
lstCSLAB - txtINTP	TXTINTP	VARCHAR2
cmpNR	CMPNR_ND	VARCHAR2
cmpNR - txtNRLL	TXTNRLL	VARCHAR2
cmpNR - txtNRUL	TXTNRUL	VARCHAR2
cmpNR - txtNRTB	TXTNRTB	VARCHAR2

AT3SC002: Hepatic Assessments in Patients who Experience LFT Elevations (HEP ASS) [frmHEPASS]

1.* ✔	Corresponding Adverse Event number [AE number]	**[numSYMPAE]** N3
Extended hepatic panel [sctLFTLAB]		
2.* ✔	Date collected [Date performed]	**[lstASSDT]** *[A:SAME DATE]* ○ Same date as visit date *[A:OTHER]* ○ **[dtmASS] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
3.* ✔	Kit ID number [Kit ID number]	**[txtREFNO]** A11
Imaging [sctLFTIMAGE]		
4.* ✔	Date imaging performed [Date imaging performed]	**[lstASSDTIM]** *[A:SAME DATE]* ○ Same date as visit date *[A:OTHER]* ○ **[dtmASSIM] (DD/MM/YYYY)** Other date, please specify Req / Req / Req (2015-2023)
5.* ✔	Type of imaging [Type of imaging]	**[lstIMAGE]** *[A:ULTRASOUND]* ○ Ultrasound with Doppler flow *[A:CT]* ○ CT *[A:MRI]* ○ MRI
6.* ✔	Result [Result]	**[txtIMAGE]** A200
Focused Medical and Travel History [sctLFTHX]		
7.* ✔	Use of any potentially hepatotoxic concomitant medications, including over the counter medications and herbal remedies? *If yes, please complete the Concomitant Medication form* [concomitant medications]	**[lstLFTCM]** *[A:Y]* ○ Yes *[A:N]* ○ No
8.* ✔	Other potentially hepatotoxic agents including any work-related exposures? [Hepatotoxic agents]	**[lstAGENTS]** *[A:Y]* ○ Yes *[A:N]* ○ No
9.	Does the patient drink alcohol? *Beer: 1 unit = 1/2 pint* *Wine: 1 unit = 1 glass (125 mL)* *Distilled spirits: 1 unit = 1 measure [hidden]* *[Alcohol consumption]*	**[lstALCOHOL]** *[A:N]* ○ No *[A:Y]* ○ **[lstALCWEEK]** Yes Taking the past month into account, please indicate maximum alcohol consumption per week *[A:BEER]* ○ **[numBEER]** Beer (units/week): xxx. *[A:WINE]* ○ **[numWINE]** Wine (units/week): xxx. *[A:DISTILLED SPIRITS]* ○ **[numDISTIL]** Distilled spirits (units/week): xxx. **[lstALCDAY]** Taking the past month into account, please indicate maximum alcohol consumption per day *[A:BEER]* ○ **[numBEERDAY]** Beer (units/day): xxx. *[A:WINE]* ○ **[numWINEDAY]** Wine (units/day): xxx. *[A:DISTILLED SPIRITS]* ○ **[numDISTILDAY]** Distilled spirits (units/day): xxx.
10.* ✔	Does the patient drink alcohol? *Beer: 1 unit = 1/2 pint* *Wine: 1 unit = 1 glass (125 mL)* *Distilled spirits: 1 unit = 1 measure* *[Alcohol consumption]*	**[lstALCOHOL2]** *[A:N]* ○ No *[A:Y]* ○ **[lstALCWEEK2]** Yes Taking the past month into account, please indicate maximum alcohol consumption per week *[A:BEER]* ☐ **[numBEER2]** Beer (units/week): xxx. *[A:WINE]* ☐ **[numWINE2]** Wine (units/week): xxx. *[A:DISTILLED SPIRITS]* ☐ **[numDISTIL2]** Distilled spirits (units/week): xxx. **[lstALCDAY2]** Taking the past month into account, please indicate maximum alcohol consumption per day

		[A:BEER]	☐ **[numBEERDAY2]** Beer (units/day): xxx.
		[A:WINE]	☐ **[numWINEDAY2]** Wine (units/day): xxx.
		[A:DISTILLED SPIRITS]	☐ **[numDISTILDAY2]** Distilled spirits (units/day): xxx.
11.* ✔	Recent travel to areas where hepatitis A or E is endemic? [Travel]	**[lstTRAVEL]** *[A:Y]* ◯ Yes *[A:N]* ◯ No	

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: Hepatic Assessments in Patients who Experience LFT Elevations

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	lstASSDT, lstASSDTIM
			Other	OTHER	citmDateOther_Other	
clIMAGE	String		Ultrasound with Doppler flow	ULTRASOUND	citmtIMAGE_ULTRASOUND	lstIMAGE
			CT	CT	citmtIMAGE_CT	
			MRI	MRI	citmtIMAGE_MRI	
clYesNo	String		Yes	Y	citmYesNo_Y	lstLFTCM, lstAGENTS, lstTRAVEL
			No	N	citmYesNo_N	
clNoYes	String		No	N	citmNoYes_N	lstALCOHOL, lstALCOHOL2
			Yes	Y	citmNoYes_Y	
clALCTYP	String		Beer	BEER	citmALCTYP_BEER	lstALCWEEK, lstALCDAY, lstALCWEEK2, lstALCDAY2
			Wine	WINE	citmALCTYP_WINE	
			Distilled spirits	DISTILLED SPIRITS	citmALCTYP_DISTILLED	

RDE Analytics: RD_FRMHEPASS

Data Variable RefName	RD Column Name	Column Data Type
numSYMPAE	NUMSYMPAE	NUMBER
	NUMSYMPAE_ND	VARCHAR2
lstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
lstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
txtREFNO	TXTREFNO	VARCHAR2
	TXTREFNO_ND	VARCHAR2
lstASSDTIM	LSTASSDTIM_C	VARCHAR2
	LSTASSDTIM	VARCHAR2
	LSTASSDTIM_ND	VARCHAR2
lstASSDTIM - dtmASSIM	DTMASSIM	DATE
	DTMASSIM_DTS	VARCHAR2
lstIMAGE	LSTIMAGE_C	VARCHAR2
	LSTIMAGE	VARCHAR2
	LSTIMAGE_ND	VARCHAR2
txtIMAGE	TXTIMAGE	VARCHAR2
	TXTIMAGE_ND	VARCHAR2
lstLFTCM	LSTLFTCM_C	VARCHAR2
	LSTLFTCM	VARCHAR2
	LSTLFTCM_ND	VARCHAR2
lstAGENTS	LSTAGENTS_C	VARCHAR2
	LSTAGENTS	VARCHAR2
	LSTAGENTS_ND	VARCHAR2

lstALCOHOL	LSTALCOHOL_C	VARCHAR2
	LSTALCOHOL	VARCHAR2
	LSTALCOHOL_ND	VARCHAR2
lstALCOHOL - lstALCWEEK	LSTALCWEEK_C	VARCHAR2
	LSTALCWEEK	VARCHAR2
lstALCOHOL - numBEER	NUMBEER	FLOAT
lstALCOHOL - numWINE	NUMWINE	FLOAT
lstALCOHOL - numDISTIL	NUMDISTIL	FLOAT
lstALCOHOL - lstALCDAY	LSTALCDAY_C	VARCHAR2
	LSTALCDAY	VARCHAR2
lstALCOHOL - numBEERDAY	NUMBEERDAY	FLOAT
lstALCOHOL - numWINEDAY	NUMWINEDAY	FLOAT
lstALCOHOL - numDISTILDAY	NUMDISTILDAY	FLOAT
lstALCOHOL2	LSTALCOHOL2_C	VARCHAR2
	LSTALCOHOL2	VARCHAR2
	LSTALCOHOL2_ND	VARCHAR2
lstALCOHOL2 - Beer	LSTALCWEEK2_NUMBEER2_C	VARCHAR2
	LSTALCWEEK2_NUMBEER2	VARCHAR2
lstALCOHOL2 - numBEER2	NUMBEER2	FLOAT
lstALCOHOL2 - Wine	LSTALCWEEK2_NUMWINE2_C	VARCHAR2
	LSTALCWEEK2_NUMWINE2	VARCHAR2
lstALCOHOL2 - numWINE2	NUMWINE2	FLOAT
lstALCOHOL2 - Distilled spirits	LSTALCWEEK2_NUMDISTIL2_C	VARCHAR2
	LSTALCWEEK2_NUMDISTIL2	VARCHAR2
lstALCOHOL2 - numDISTIL2	NUMDISTIL2	FLOAT
lstALCOHOL2 - Beer	LSTALCDAY2_NUMBEERDAY2_C	VARCHAR2
	LSTALCDAY2_NUMBEERDAY2	VARCHAR2
lstALCOHOL2 - numBEERDAY2	NUMBEERDAY2	FLOAT
lstALCOHOL2 - Wine	LSTALCDAY2_NUMWINEDAY2_C	VARCHAR2
	LSTALCDAY2_NUMWINEDAY2	VARCHAR2
lstALCOHOL2 - numWINEDAY2	NUMWINEDAY2	FLOAT
lstALCOHOL2 - Distilled spirits	LSTALCDAY2_NUMDISTILDAY2_C	VARCHAR2
	LSTALCDAY2_NUMDISTILDAY2	VARCHAR2
lstALCOHOL2 - numDISTILDAY2	NUMDISTILDAY2	FLOAT
lstTRAVEL	LSTTRAVEL_C	VARCHAR2
	LSTTRAVEL	VARCHAR2
	LSTTRAVEL_ND	VARCHAR2

AT3SC002: FibroTest/FibroScan (FIBRO) [frmFIBRO]		
FibroScan [sctFIBROSCAN]		
1.* ✔	Date performed [Date performed]	**[dFIBS] (DD/MM/YYYY)** Req / Req / Req (2015-2023)
2.* ✔	Score/result [Score/result]	**[numFIBS]** xxxx. (kPa)
FibroTest and APRI [sctFIBROTEST]		
3.* ✔	Was a sample collected and sent to central lab? [Sample collected]	**[lstFIBT]** *[A:Y]* Yes *[A:N]* No

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: FibroTest/FibroScan

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	lstFIBT
			No	N	citmYesNo_N	

RDE Analytics: RD_FRMFIBRO

Data Variable RefName	RD Column Name	Column Data Type
dFIBS	DFIBS	DATE
	DFIBS_DTS	VARCHAR2
	DFIBS_ND	VARCHAR2
numFIBS	NUMFIBS	FLOAT
	NUMFIBS_ND	VARCHAR2
lstFIBT	LSTFIBT_C	VARCHAR2
	LSTFIBT	VARCHAR2
	LSTFIBT_ND	VARCHAR2

DS--Disposition
RELREC--Related Records

AT3SC002: Drug Termination (DRUG TERM) [frmDRUGTERM]

Study Drug Completion / Termination [sctDRUGTERM]

1.* ✔	Date of study drug termination [Date of study drug termination]	**[dtmDRUGTERM] (DD/MM/YYYY)** Req / Req / Req (2015-2023) DSTERM='COMPLETED'. If LSTDRUGCOMP_C = 'COMPLETED' then DSTERM='COMPLETED
2.* ✔	Please specify if the patient completed the entire course of ALN-AT3SC treatment as specified in the protocol or if the patient discontinued ALN-AT3SC early [Please specify if the patient completed the entire course of ALN-AT3SC treatment]	**[lstDRUGCOMP]** *[A:COMPLETED]* =DSTERM='COMPLETED' *[A:DISCONTINUED]* DISTERM=DISCONTINUED Discontinued - please specify the primary reason for early termination *[A:ADVERSE EVENT]* DISTERM=ADVERSE EVENT = AVDERSE EVENT Adverse Event Please specify AE#(s) - as recorded on AE form **[numAESEQ1] [numAESEQ2] [numAESEQ3] [numAESEQ4] [numAESEQ5] [numAESEQ6]** N3 N3 N3 N3 N3 N3 *[A:DEATH]* DISTERM=DEATH DSTERM= DEATH *[A:LOST TO FOLLOW-UP]* DISTERM=LOST TO FOLLOW-UP LUW-UP *[A:NON-COMPLIANT]* DISTERM=NON-COMPLIANT rug *[A:PHYSICIAN DECISION]* DISTERM=PHYSICIAN DECISION Physician Decision, please specify DSTERM= TXTDISCPHYSDEC A200 *[A:PROTOCOL VIOLATION]* DISTERM=PROTOCOL VIOLATION Protocol Violation, please specify A200 *[A:STUDY TERMINATED]* DISTERM=STUDY TERMINATED *[A:SUBJECT WITHDREW CONSENT]* DISTERM=SUBJECT WITHDREW CONSENT *[A:OTHER]* DISTERM=OTHER **[SCOTH]** Other, please specify A200 *[A:AT]* DISTERM=AT More than 1 AT measurement <15% *[A:EMERGENCY]* DISTERM=EMERGENCY tinuation due to a regional or national emergency
3.* ✔	Will the patient continue to use commercially available fitusiran? [Will the patient continue to use commercially available fitusiran?]	**[lstCOMMERC]** *[A:Y]* Yes *[A:N]* No
4.	For office use only *[hidden]* [For office use only]	**[numEMAIL1]** N3
5.	For office use only *[hidden]* [For office use only]	**[numEMAIL2]** N3
6.	For office use only *[hidden]* [For office use only]	**[numEMAIL3]** N3

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: Drug Termination

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clCompDisc	String		Completed	COMPLETED	citmCompDisc_Comp	lstDRUGCOMP
			Discontinued	DISCONTINUED	citmCompDisc_Disc	
clDISCRS	String		Adverse Event	ADVERSE EVENT	citmDISCRS_AE	lstDISCRS
			Death	DEATH	citmDISCRS_Death	
			Lost to follow-up	LOST TO FOLLOW-UP	citmDISCRS_LostFU	
			Non-Compliance with Study Drug	NON-COMPLIANT	citmDISCRS_NonCompliant	
			Physician Decision	PHYSICIAN DECISION	citmDISCRS_PhysDec	
			Protocol Violation	PROTOCOL VIOLATION	citmDISCRS_PV	
			Study Terminated by Sponsor	STUDY TERMINATED	citmDISCRS_StudyTerm	
			Subject Withdrew Consent	SUBJECT WITHDREW CONSENT	citmDISCRS_WDConsent	
			Other	OTHER	citmDISCRS_Other	
			More than 1 AT measurement <15%	AT	citmDISCRS_AT	
			Temporary discontinuation due to a regional or national emergency	EMERGENCY	citmDISCRS_EMERGENCY	
clYesNo	String		Yes	Y	citmYesNo_Y	lstCOMMERC

			No	N	citmYesNo_N	

RDE Analytics: RD_FRMDRUGTERM		
Data Variable RefName	**RD Column Name**	**Column Data Type**
dtmDRUGTERM	DTMDRUGTERM	DATE
	DTMDRUGTERM_DTS	VARCHAR2
	DTMDRUGTERM_ND	VARCHAR2
lstDRUGCOMP	LSTDRUGCOMP_C	VARCHAR2
	LSTDRUGCOMP	VARCHAR2
	LSTDRUGCOMP_ND	VARCHAR2
lstDRUGCOMP - lstDISCRS	LSTDISCRS_C	VARCHAR2
	LSTDISCRS	VARCHAR2
lstDRUGCOMP - numAESEQ1	NUMAESEQ1	NUMBER
lstDRUGCOMP - numAESEQ2	NUMAESEQ2	NUMBER
lstDRUGCOMP - numAESEQ3	NUMAESEQ3	NUMBER
lstDRUGCOMP - numAESEQ4	NUMAESEQ4	NUMBER
lstDRUGCOMP - numAESEQ5	NUMAESEQ5	NUMBER
lstDRUGCOMP - numAESEQ6	NUMAESEQ6	NUMBER
lstDRUGCOMP - txtDISCPHYSDEC	TXTDISCPHYSDEC	VARCHAR2
lstDRUGCOMP - txtDISCPV	TXTDISCPV	VARCHAR2
lstDRUGCOMP - txtDISCOTH	TXTDISCOTH	VARCHAR2
lstCOMMERC	LSTCOMMERC_C	VARCHAR2
	LSTCOMMERC	VARCHAR2
	LSTCOMMERC_ND	VARCHAR2
numEMAIL1	NUMEMAIL1	NUMBER
	NUMEMAIL1_ND	VARCHAR2
numEMAIL2	NUMEMAIL2	NUMBER
	NUMEMAIL2_ND	VARCHAR2
numEMAIL3	NUMEMAIL3	NUMBER
	NUMEMAIL3_ND	VARCHAR2

DS--Disposition

AT3SC002: Trial Termination (TERM) [frmTERM]

Trial Completion / Discontinuation [sctTERM]

1.* ✔	Please specify if the subject completed the entire course of the trial as specified in the protocol or if the subject discontinued from the trial early [Completed/Discontinued]	**[lstCOMPDISC]** *[A:COMPLETED]* **[dtmCOMP] (DD/MM/YYYY)** DSTERM=COMPLETE Completed, date of study completion Req / Req / Req (2015-2023) *[A:DISCONTINUED]* **[dtmDISC] (DD/MM/YYYY)** DSTERM=DISCONTINUE Discontinued, date of study discontinuation Req / Req / Req (2015-2023) **[lstDISCRS]** Discontinued - please specify the primary reason for early termination *[A:ADVERSE EVENT]* **[cmpAE]** Adverse Event DSTERM=AVSER EVENT Please specify AE#(s) - as recorded on AE form **[numAESEQ1] [numAESEQ2] [numAESEQ3] [numAESEQ4] [numAESEQ5] [numAESEQ6]** N3 N3 N3 N3 N3 N3 *[A:DEATH]* Death DSTERM=DEATH *[A:LOST TO FOLLOW-UP]* Lost to follow-up *[A:NON-COMPLIANT]* Non-Compliance with Study Drug *[A:PHYSICIAN DECISION]* **[txtDISCPHYSDEC]** Physician Decision, please specify A200 *[A:PROTOCOL VIOLATION]* **[txtDISCPV]** Protocol Violation, please specify A200 *[A:STUDY TERMINATED]* Study Terminated by Sponsor *[A:SUBJECT WITHDREW CONSENT]* Subject Withdrew Consent *[A:OTHER]* **[txtDISCOTH]** Other, please specify A200 *[A:AT]* More than 1 AT measurement <15% *[A:EMERGENCY]* Temporary discontinuation due to a regional or national emergency
2.* ✔	Will the subject roll-over to the next OLE study? [Will the subject roll-over to the next OLE study?]	**[lstROLLOVER]** *[A:Y]* Yes *[A:N]* No
3.	For office use only *[hidden]* [For office use only]	**[numEMAIL1]** N3
4.	For office use only *[hidden]* [For office use only]	**[numEMAIL2]** N3
5.	For office use only *[hidden]* [For office use only]	**[numEMAIL3]** N3

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: Trial Termination

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clCompDisc	String		Completed	COMPLETED	citmCompDisc_Comp	lstCOMPDISC
			Discontinued	DISCONTINUED	citmCompDisc_Disc	
clDISCRS	String		Adverse Event	ADVERSE EVENT	citmDISCRS_AE	lstDISCRS
			Death	DEATH	citmDISCRS_Death	
			Lost to follow-up	LOST TO FOLLOW-UP	citmDISCRS_LostFU	
			Non-Compliance with Study Drug	NON-COMPLIANT	citmDISCRS_NonCompliant	
			Physician Decision	PHYSICIAN DECISION	citmDISCRS_PhysDec	
			Protocol Violation	PROTOCOL VIOLATION	citmDISCRS_PV	
			Study Terminated by Sponsor	STUDY TERMINATED	citmDISCRS_StudyTerm	
			Subject Withdrew Consent	SUBJECT WITHDREW CONSENT	citmDISCRS_WDConsent	
			Other	OTHER	citmDISCRS_Other	
			More than 1 AT measurement <15%	AT	citmDISCRS_AT	
			Temporary discontinuation due to a regional or national emergency	EMERGENCY	citmDISCRS_EMERGENCY	
clYesNo	String		Yes	Y	citmYesNo_Y	lstROLLOVER

			No	N	citmYesNo_N	

RDE Analytics: RD_FRMTERM		
Data Variable RefName	**RD Column Name**	**Column Data Type**
lstCOMPDISC	LSTCOMPDISC_C	VARCHAR2
	LSTCOMPDISC	VARCHAR2
	LSTCOMPDISC_ND	VARCHAR2
lstCOMPDISC - dtmCOMP	DTMCOMP	DATE
	DTMCOMP_DTS	VARCHAR2
lstCOMPDISC - dtmDISC	DTMDISC	DATE
	DTMDISC_DTS	VARCHAR2
lstCOMPDISC - lstDISCRS	LSTDISCRS_C	VARCHAR2
	LSTDISCRS	VARCHAR2
lstCOMPDISC - numAESEQ1	NUMAESEQ1	NUMBER
lstCOMPDISC - numAESEQ2	NUMAESEQ2	NUMBER
lstCOMPDISC - numAESEQ3	NUMAESEQ3	NUMBER
lstCOMPDISC - numAESEQ4	NUMAESEQ4	NUMBER
lstCOMPDISC - numAESEQ5	NUMAESEQ5	NUMBER
lstCOMPDISC - numAESEQ6	NUMAESEQ6	NUMBER
lstCOMPDISC - txtDISCPHYSDEC	TXTDISCPHYSDEC	VARCHAR2
lstCOMPDISC - txtDISCPV	TXTDISCPV	VARCHAR2
lstCOMPDISC - txtDISCOTH	TXTDISCOTH	VARCHAR2
lstROLLOVER	LSTROLLOVER_C	VARCHAR2
	LSTROLLOVER	VARCHAR2
	LSTROLLOVER_ND	VARCHAR2
numEMAIL1	NUMEMAIL1	NUMBER
	NUMEMAIL1_ND	VARCHAR2
numEMAIL2	NUMEMAIL2	NUMBER
	NUMEMAIL2_ND	VARCHAR2
numEMAIL3	NUMEMAIL3	NUMBER
	NUMEMAIL3_ND	VARCHAR2

AT3SC002: Trial Completion (COMP) [frmCOMP]

Trial Completion [sctCOMP]

1.* ✔	Did the subject experience any Adverse Events during the study? *If yes, please ensure that all Adverse Events are recorded on the Adverse Events form* [Any Adverse Events]	**[lstAE]** *[A:Y]* ◯ Yes *[A:N]* ◯ No
2.* ✔	Did the subject take any concomitant medication at screening and/or during the study? *If yes, please ensure that all medications are recorded on the Concomitant medications form* [Any concomitant medication]	**[lstCM]** *[A:Y]* ◯ Yes *[A:N]* ◯ No
3.* ✔	Was there a protocol amendment implemented for this subject during the trial? *If yes, please complete the Protocol Amendment & Informed Consent form* [Any protocol amendment?]	**[lstIFC_AMEND]** *[A:Y]* ◯ Yes *[A:N]* ◯ No
Signatures [sctSIGN]		
4.* ✔	Is the CRF complete? *If yes, please wait for confirmation that there are no outstanding queries/issues before signing-off the casebook.* [CRF complete]	**[lstCOMP]** *[A:Y]* ◯ Yes *[A:N]* ◯ No

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: Trial Completion

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	lstAE, lstCM, lstIFC_AMEND, lstCOMP
			No	N	citmYesNo_N	

RDE Analytics: RD_FRMCOMP

Data Variable RefName	RD Column Name	Column Data Type
lstAE	LSTAE_C	VARCHAR2
	LSTAE	VARCHAR2
	LSTAE_ND	VARCHAR2
lstCM	LSTCM_C	VARCHAR2
	LSTCM	VARCHAR2
	LSTCM_ND	VARCHAR2
lstIFC_AMEND	LSTIFC_AMEND_C	VARCHAR2
	LSTIFC_AMEND	VARCHAR2
	LSTIFC_AMEND_ND	VARCHAR2
lstCOMP	LSTCOMP_C	VARCHAR2
	LSTCOMP	VARCHAR2
	LSTCOMP_ND	VARCHAR2

AT3SC002: Protocol Amendment & Informed Consent (PROT IFC) - Repeating Form [frmPROT_ICF]

#	Row No	Amendment version in effect	Date of updated informed consent	Fitusiran restart date after dosing hold
1				

Protocol Amendment & Informed Consent [sctPROT_IFC]

1.* 🔑	Row No ***(for internal use only)*** *[read-only]* [Row No]	**[numROW]** N3
2.* ✔ 🔑	Amendment version in effect [Amendment version in effect]	**[lstAMPTC]** *[A:AMENDMENT 1]* ◯ Amendment 1 *[A:AMENDMENT 2]* ◯ Amendment 2 *[A:AMENDMENT 3]* ◯ Amendment 3 *[A:AMENDMENT 4]* ◯ Amendment 4 *[A:AMENDMENT 5]* ◯ Amendment 5 *[A:AMENDMENT 6]* ◯ Amendment 6 *[A:AMENDMENT 7]* ◯ Amendment 7 *[A:AMENDMENT 8]* ◯ Amendment 8 *[A:AMENDMENT 9]* ◯ Amendment 9 *[A:AMENDMENT 10]* ◯ Amendment 10
3.* ✔	Subject signed updated informed consent on [Date of updated informed consent]	**[dtmIFC_AMEND] (DD/MM/YYYY)** Req / Req / Req (2015-2023)
4. ✔	Fitusiran restart date after dosing hold [Fitusiran restart date after dosing hold]	**[dRES] (DD/MM/YYYY)** Req / Req / Req (2015-2023)

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

Keys (navigation) / Uniqueness: Protocol Amendment & Informed Consent

Item	Unique	Order #
frmPROT_ICF (Repeating form)		
sctPROT_IFC		
numROW	None	1
lstAMPTC	None	2

Codelist Values Tables: Protocol Amendment & Informed Consent

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clAMPTC	String		Amendment 1	AMENDMENT 1	citmAMPTC_Amendment1	lstAMPTC
			Amendment 2	AMENDMENT 2	citmAMPTC_Amendment2	
			Amendment 3	AMENDMENT 3	citmAMPTC_Amendment3	
			Amendment 4	AMENDMENT 4	citmAMPTC_Amendment4	
			Amendment 5	AMENDMENT 5	citmAMPTC_Amendment5	
			Amendment 6	AMENDMENT 6	citmAMPTC_Amendment6	
			Amendment 7	AMENDMENT 7	citmAMPTC_Amendment7	
			Amendment 8	AMENDMENT 8	citmAMPTC_Amendment8	
			Amendment 9	AMENDMENT 9	citmAMPTC_Amendment9	
			Amendment 10	AMENDMENT 10	citmAMPTC_Amendment10	

RDE Analytics: RD_FRMPROT_ICF

Data Variable RefName	RD Column Name	Column Data Type
numROW	NUMROW	NUMBER
	NUMROW_ND	VARCHAR2
lstAMPTC	LSTAMPTC_C	VARCHAR2
	LSTAMPTC	VARCHAR2
	LSTAMPTC_ND	VARCHAR2
dtmIFC_AMEND	DTMIFC_AMEND	DATE
	DTMIFC_AMEND_DTS	VARCHAR2
	DTMIFC_AMEND_ND	VARCHAR2
dRES	DRES	DATE

	DRES_DTS	VARCHAR2
	DRES_ND	VARCHAR2

AT3SC002: eDiary - Query handling (eDiary) - Repeating Form [frmDIARY_QUERY]						
#	Row No	Type of Bleed Event	Date of bleed	Time of bleed	Event Identifier	Query topic
1						

1.*	Row No ***(for internal use only)*** *[read-only]* [Row No]	**[numROW]** N3
2.	Type of Bleed Event *[read-only]* [Type of Bleed Event]	**[lstQ1_Query]** *[A:BLEED]* ○ Bleed *[A:PRE-BLEED]* ○ Pre-Bleed
3.	What date did the bleed occur? *[read-only]* [Date of bleed]	**[dtmQ2_Query] (DD/MM/YYYY)** Req / Req / Req (2015-2023)
4.	What time did the bleed occur? *[read-only]* [Time of bleed]	**[dtmQ2tm_Query] (hh:mm)** Req : Req *24-hour clock*
5.	Event Identifier *[read-only]* [Event Identifier]	**[txtEID]** A20
6.	Query topic *[read-only]* [Query topic]	**[txtQ3_Query]** A200

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

Keys (navigation) / Uniqueness: eDiary - Query handling		
Item	**Unique**	**Order #**
frmDIARY_QUERY (Repeating form)		
sctINFOQUERY		
numROW	None	1

Codelist Values Tables: eDiary - Query handling						
Codelist RefName	**Codelist Data Type**	**Subset**	**Label**	**Code**	**Codelist Item RefName**	**Data Variable RefName**
clQ2	String		Bleed	BLEED	citmQ2_Bleed	lstQ1_Query
			Pre-Bleed	PRE-BLEED	citmQ2_Prebleed	

RDE Analytics: RD_FRMDIARY_QUERY		
Data Variable RefName	**RD Column Name**	**Column Data Type**
numROW	NUMROW	NUMBER
	NUMROW_ND	VARCHAR2
lstQ1_Query	LSTQ1_QUERY_C	VARCHAR2
	LSTQ1_QUERY	VARCHAR2
	LSTQ1_QUERY_ND	VARCHAR2
dtmQ2_Query	DTMQ2_QUERY	DATE
	DTMQ2_QUERY_DTS	VARCHAR2
	DTMQ2_QUERY_ND	VARCHAR2
dtmQ2tm_Query	DTMQ2TM_QUERY	DATE
	DTMQ2TM_QUERY_TMS	VARCHAR2
	DTMQ2TM_QUERY_ND	VARCHAR2
txtEID	TXTEID	VARCHAR2
	TXTEID_ND	VARCHAR2
txtQ3_Query	TXTQ3_QUERY	VARCHAR2
	TXTQ3_QUERY_ND	VARCHAR2

AT3SC002: Patient Diary (bleeding events/factor use) (DIARY) - Repeating Form [frmDIARY]

#	Row No	Language of the questionnaire	Bleed, Pre-bleed or perioperative bleed	Date and time of bleed	Causality	What was the severity of the bleed?	Location of bleed or symptoms	Factor or Bypassing Agent product taken	Product Administration Details
1									

1.* Row No ***(for internal use only)*** *[read-only]*
[Row No]

[numROW]
N3

2.* Language of the questionnaire
[Language of the questionnaire]

[lstLANG]
[A:LANGUAGE] Language **[lstLANG_Q]** **[clLANG_Q]**
[A:OTHER] **[txtLANGO]** Other, please specify
A100

3.* Identify what type of event occurred. The event can be a bleed, pre-bleed or perioperative bleed only.
[Bleed, Pre-bleed or perioperative bleed]

[lstQ1]
[A:BLEED] Bleed
[A:PRE-BLEED SYMPTOMS ONLY] Pre-bleed symptoms only (please only tick if a bleed did not later occur)
[A:PREEMPTIVE TREATMENT] Preemptive treatment
[A:PERIOPERATIVE] Perioperative

4. What date and time did the bleed occur?
[Date and time of bleed]

[dtmQ2] (DD/MM/YYYY hh:mm)
Req / Req / Req (2015-2023)
Req : Req *24-hour clock*

5. Causality (Investigator's assessment)
[Causality]

[lstCAUS]
[A:DENTAL] Dental/Surgical Procedure
[A:SPONTANEOUS] Spontaneous
[A:TRAUMATIC] Traumatic
[A:OTHER] **[txtCAUSO]** Other, specify
A128
[A:UNKNOWN] Unknown

6. What was the severity of the bleed? (Investigator's assessment)
[What was the severity of the bleed?]

[lstBLDSEV]
[A:MILD] Mild
[A:MODERATE] Moderate
[A:SEVERE] Severe

7. Where was the bleed or pre-bleed symptoms?
[Location of bleed or symptoms]

[lstQ3]
[A:SKIN/MUCOSA] Skin/Mucosa
[A:JOINT] Joint
[A:MUSCLE] Muscle
[A:INTERNAL] Internal
[A:OPERATIVE] Operative Site

8. Did you use Factor or Bypassing Agent product?
If Yes, please complete a record below for each injection.
[Factor or Bypassing Agent product taken]

[lstQ4]
[A:Y] **[lstQ6]** Yes
How much product did you need to treat the bleed?
[A:OPTION 1] I needed more product than normal to control bleeding
[A:OPTION 2] I needed the same amount of product as normal to control bleeding
[A:OPTION 3] I needed less product than normal to control bleeding
[lstQ7]
How did the bleed respond to treatment?
[A:OPTION 1] Responded worse than prior bleeds in this location
[A:OPTION 2] Responded similarly to prior bleeds in this location
[A:OPTION 3] Responded better than prior bleeds in this location
[A:OPTION 4] I haven't bled in this location / not sure how bleed responded
[A:N] No

	Order	Injection date and time	Name of product	Total dose	Unit
9.					

Product Administration Details Entry [sctQ5]

9.1 Order of injection
[Order]

[lstORDER]
[A:FIRST] First injection
[A:FOLLOWUP1] Follow-up 1 injection
[A:FOLLOWUP2] Follow-up 2 injection
[A:FOLLOWUP NUMBER] **[numQ5FUX]** Follow-up number N2

9.2 ✔	Date and time of the injection [Injection date and time]	**[dtmQ5] (DD/MM/YYYY hh:mm)** Req / Req / Req (2015-2023) Req : Req *24-hour clock*
9.3 ✔	Name of product [Name of product]	**[txtQ5]** A30
9.4 ✔	Total dose [Total dose]	**[numQ5]** N10
9.5 ✔	Unit [Unit]	**[lstQ5]** *[A:IU]* IU *[A:U]* U *[A:µg]* µg

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

Keys (navigation)/Uniqueness: Patient Diary (bleeding events/factor use)

Item	Unique	Order #
frmDIARY (Repeating form)		
sctINFO		
numROW	Group	1

Codelist Values Tables: Patient Diary (bleeding events/factor use)

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clLANG	String		Language of the questionnaire	LANGUAGE	citmLANG_LANGUAGE	lstLANG
			Other, please specify	OTHER	citmLANG_OTHER	
clLANG_Q	String		Bulgarian	BULGARIAN	citmLANG_BUL	lstLANG_Q
			English (for UK)	ENGLISHUK	citmLANG_ENG_UK	
			English (for US)	ENGLISHUS	citmLANG_ENG_US	
			French (for Switzerland)	FRENCHCH	citmLANG_FRA_CH	
			German (for Switzerland)	GERMANCH	citmLANG_GER_CH	
			Russian	RUSSIAN	citm_LANG_RUS	
clQ1	String		Bleed	BLEED	citmQ1_Bleed	lstQ1
			Pre-bleed symptoms only (please only tick if a bleed did not later occur)	PRE-BLEED SYMPTOMS ONLY	citmQ1_Prebleedsymptomsonly	
			Preemptive treatment	PREEMPTIVE TREATMENT	citmQ1_Preemptivetreatment	
			Perioperative	PERIOPERATIVE	citmQ1_Perioperative	
clCAUS	String		Dental/Surgical Procedure	DENTAL	citmCAUS_DentalSurgicalProcedure	lstCAUS
			Spontaneous	SPONTANEOUS	citmCAUS_Spontaneous	
			Traumatic	TRAUMATIC	citmCAUS_Traumatic	
			Other	OTHER	citmCAUS_Other	
			Unknown	UNKNOWN	citmCAUS_Unknown	
clAEINT	String		Mild	MILD	citmAEINT_MILD	lstBLDSEV
			Moderate	MODERATE	citmAEINT_MODERATE	
			Severe	SEVERE	citmAEINT_SEVERE	
clQ3	String		Skin/Mucosa	SKIN/MUCOSA	citmQ3_SkinMucosa	lstQ3
			Joint	JOINT	citmQ3_Joint	
			Muscle	MUSCLE	citmQ3_Muscle	
			Internal	INTERNAL	citmQ3_Internal	
			Operative Site	OPERATIVE	citmQ3_OperativeSite	
clYesNo	String		Yes	Y	citmYesNo_Y	lstQ4
			No	N	citmYesNo_N	
clQ6	String		I needed more product than normal to control bleeding	OPTION 1	citmQ6_Option1	lstQ6
			I needed the same amount of product as normal to control bleeding	OPTION 2	citmQ6_Option2	
			I needed less product than normal to control bleeding	OPTION 3	citmQ6_Option3	
clQ7	String		Responded worse than prior bleeds in this location	OPTION 1	citmQ7_Option1	lstQ7
			Responded similarly to prior bleeds in this location	OPTION 2	citmQ7_Option2	

			Responded better than prior bleeds in this location	OPTION 3	citmQ7_Option3	
			I haven't bled in this location / not sure how bleed responded	OPTION 4	citmQ7_Option4	
clORDER	String		First injection	FIRST	citmORDER_FirstInjection	lstORDER
			Follow-up 1 injection	FOLLOWUP1	citmORDER_FU1Injection	
			Follow-up 2 injection	FOLLOWUP2	citmORDER_FU2Injection	
			Follow-up number	FOLLOWUP NUMBER	citmORDER_FUXInjection	
clQ5	String		IU	IU	citmQ5_IU	lstQ5
			U	U	citmQ5_U	
			µg	µg	citmQ5_g	

RDE Analytics: RD_FRMDIARY		
Data Variable RefName	**RD Column Name**	**Column Data Type**
numROW	NUMROW	NUMBER
	NUMROW_ND	VARCHAR2
lstLANG	LSTLANG_C	VARCHAR2
	LSTLANG	VARCHAR2
	LSTLANG_ND	VARCHAR2
lstLANG - lstLANG_Q	LSTLANG_Q_C	VARCHAR2
	LSTLANG_Q	VARCHAR2
lstLANG - txtLANGO	TXTLANGO	VARCHAR2
lstQ1	LSTQ1_C	VARCHAR2
	LSTQ1	VARCHAR2
	LSTQ1_ND	VARCHAR2
dtmQ2	DTMQ2	DATE
	DTMQ2_DTS	VARCHAR2
	DTMQ2_ND	VARCHAR2
lstCAUS	LSTCAUS_C	VARCHAR2
	LSTCAUS	VARCHAR2
	LSTCAUS_ND	VARCHAR2
lstCAUS - txtCAUSO	TXTCAUSO	VARCHAR2
lstBLDSEV	LSTBLDSEV_C	VARCHAR2
	LSTBLDSEV	VARCHAR2
	LSTBLDSEV_ND	VARCHAR2
lstQ3	LSTQ3_C	VARCHAR2
	LSTQ3	VARCHAR2
	LSTQ3_ND	VARCHAR2
lstQ4	LSTQ4_C	VARCHAR2
	LSTQ4	VARCHAR2
	LSTQ4_ND	VARCHAR2
lstQ4 - lstQ6	LSTQ6_C	VARCHAR2
	LSTQ6	VARCHAR2
lstQ4 - lstQ7	LSTQ7_C	VARCHAR2
	LSTQ7	VARCHAR2
RD_FRMDIARY_SCTQ5		
lstORDER	LSTORDER_C	VARCHAR2
	LSTORDER	VARCHAR2
	LSTORDER_ND	VARCHAR2
lstORDER - numQ5FUX	NUMQ5FUX	NUMBER
dtmQ5	DTMQ5	DATE
	DTMQ5_DTS	VARCHAR2
	DTMQ5_ND	VARCHAR2
txtQ5	TXTQ5	VARCHAR2
	TXTQ5_ND	VARCHAR2

numQ5	NUMQ5	NUMBER
	NUMQ5_ND	VARCHAR2
lstQ5	LSTQ5_C	VARCHAR2
	LSTQ5	VARCHAR2
	LSTQ5_ND	VARCHAR2

InForm Special Properties For Study Design: AT3SC002			
InForm Special Property	**Property Type**	**Data Object RefName**	**Data Object Path RefName**
Screening	Visit	evtSYSSCR	evtSYSSCR
Enrollment	Visit	evtSYSENR	evtSYSENR
Screening	Form	frmSYSSCR	evtSYSSCR.frmSYSSCR
Enrollment	Form	frmSYSENR	evtSYSENR.frmSYSENR
Patient Identification	Form	frmDM	evtSCR.frmDM
Study Completion	Form	Unassigned	Unassigned
Reg Docs	Form	Unassigned	Unassigned
Visit Report	Form	Unassigned	Unassigned
Initials (Screening)	Item	txtINIT_SS	evtSYSSCR.frmSYSSCR.txtINIT_SS
DOB (Screening)	Item	dtmBRTH	evtSCR.frmDM.sctDM.dtmBRTH evtSYSSCR.frmSYSSCR.dtmBRTH
Screening date (Screening)	Item	Unassigned	Unassigned
Patient No. (Enrollment)	Item	txtSUBJID	evtSCR.frmDM.sctSUBID.txtSUBJID evtSYSENR.frmSYSENR.txtSUBJID
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	dtmVISIT_DT_UNS	evtUNS.frmDOV_UNS.sctDOV_UNS.dtmVISIT_DT_UNS evtBLEED.frmDOV_REP.sctDOV_UNS.dtmVISIT_DT_UNS evtATFU.frmDOV_REP.sctDOV_UNS.dtmVISIT_DT_UNS evtPOP_V3.frmDOV_SURG.sctDOV_UNS.dtmVISIT_DT_UNS evtPOP_SCR.frmDOV_SURG.sctDOV_UNS.dtmVISIT_DT_UNS evtPOP_SV.frmDOV_SURG.sctDOV_UNS.dtmVISIT_DT_UNS evtPOP_V1.frmDOV_SURG.sctDOV_UNS.dtmVISIT_DT_UNS evtPOP_V2.frmDOV_SURG.sctDOV_UNS.dtmVISIT_DT_UNS
Randomization field (Randomization)	Item	Unassigned	Unassigned

Personal/Protected Health Information Table: AT3SC002		
Item RefName	**Section RefName**	**Form RefName**
No items have been defined as "Personal/Protected Health Information".		
Please note: emails sent from the trial server by the InForm application are not encrypted. If you are subject to HIPAA requirements, you should identify and block all Personal/Protected Health Information items that may be included in email notifications.		

Unit Conversions For Study Design: AT3SC002
No unit conversion data.

Review States for Study: AT3SC002
No Review States have been defined.

In-place Revisions Summary Table: AT3SC002					
Deployment Instance: PROD					
Data Object RefName	**Type**	**Actual Change Path**	**Description**	**Study Version**	**Path**
sctTELSCHED	Section	frmTEL2.sctTELSCHED	Codelists clTELSCHED and clACVIS will be updated according to MSU plan 08	AT3SC002 10.0.1 LTE14762 0.0.2 LTE14762 11.0.0 LTE14762 11.2.36 LTE14762 12.5.30	frmTEL2.sctTELSCHED.* frmTEL2.sctTELSCHED.* frmTEL2.sctTELSCHED.* frmTEL2.sctTELSCHED.* frmTEL2.sctTELSCHED.*
sctVISPUR	Section	frmVISPUR.sctVISPUR	Codelists clVISIT and clVISITAT will be updated according to MSU plan 08	LTE14762 12.5.30	frmVISPUR.sctVISPUR.*

Custom Events for Study Design: AT3SC002
No custom events have been defined.