

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

September 21, 2021 8:25AM

AT3SC002: System Screening (SCR) [frmSYSSCR]

System Screening [frmSYSSCR]

1.* ✓	Date of birth [Date of birth]	[dtmBRTH] (DD/MM/YYYY) Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (1930-2023)
2.* ✓	Sex at birth [Sex at birth]	[lstSXBRTH] [A:M] <input type="radio"/> Male
3.	Dummy initials [hidden] [Dummy initials]	[txtINIT_SS] <input type="text" value="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 I tem RefName	Data Variable RefName
clSXBRTH	String		Male	M	cltmSXBRTH_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 <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2023)
2.* ✓	Subject ID (3-digits) [Short Subject ID]	[txtSHORTID] <input type="text" value="A3"/>
3.*	Site and Subject ID [hidden] [Site and Subject ID]	[txtSUBJID] <input type="text" value="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

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 <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1930-2023)	
2.* ✓	Subject signed informed consent on [Date of informed consent]	[dtmIFC] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)	
3.*	Age (calculated) <i>[read-only]</i> [Age]	[numAGE] <input type="text"/> N3 (years)	
4.* ✓	Sex at birth [Sex at birth]	[IstSXBIRTH] [A:M] <input type="radio"/> Male	
5.* ✓	Race [Race]	<div><div>[IstRC] [A:REPORTED] <input type="radio"/> [IstRACE] Reported, please specify: [A:WHITE] <input type="checkbox"/> White [A:BLACK] <input type="checkbox"/> Black or African-American [A:ASIAN] <input type="checkbox"/> Asian [A:INDIAN] <input type="checkbox"/> American Indian or Alaska Native [A:HAWAIIAN] <input type="checkbox"/> Native Hawaiian or other Pacific Islander [A:OTHER] <input type="checkbox"/> [txtRACEOTH] Other, please specify: <input type="text"/> A60</div><div>[A:NOT REPORTED] <input type="radio"/> Not Available/Not Reported</div></div>	
6.* ✓	Ethnicity [Ethnicity]	[IstETHNICITY] [A:HISPANIC OR LATINO] <input type="radio"/> Hispanic or Latino [A:NOT HISPANIC OR LATINO] <input type="radio"/> Not Hispanic or Latino [A:NA] <input type="radio"/> Not Available/Not Reported	
7.* ✓	Part in parent study? [Part parent study]	[IstPART] [A:PART B] <input type="radio"/> Part B [A:PART C] <input type="radio"/> Part C [A:PART D] <input type="radio"/> Part D	
8.* ✓	Did the patient have an interruption between parent study and roll-over to this study? <i>More than a month between completion of parent study treatment and roll-over to this study will be considered an interruption.</i> [Subject initiates dosing]	[IstDAYS] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No	
9.* ✓	What is the subject's HIV status? [HIV status]	[IstHIV] [A:POSITIVE] <input type="radio"/> Positive [A:NEGATIVE] <input type="radio"/> 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]	[IstWBCLT] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No	
Subject Identifiers [sctSUBID]			
11.* ✓	Subject ID (3-digits) <i>[read-only]</i> [Short Subject ID]	[txtSHORTID1] <input type="text"/> A3	
12. ✓	Site and Subject ID from parent study [Parent study ID]	[txtSUBIDPS] <input type="text"/> A7	
13.*	Site and Subject ID <i>[hidden]</i> [Site and Subject ID]	[txtSUBID] <input type="text"/> A7	
14.	For office use only <i>[hidden]</i> [For office use only]	[numEMAIL1] <input type="text"/> N3	
15.	For office use only <i>[hidden]</i> [For office use only]	[numEMAIL2] <input type="text"/> N3	
16.	For office use only <i>[hidden]</i> [For office use only]	[numEMAIL3] <input type="text"/> 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: 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 - txtTRACEOTH	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 occurring 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?]*

[IstMH]

[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?]

[IstMHCATPRIOR]

[A: Y] ☐ Yes

[A: N] ☐ No

2.4.*
✓

End date
[End date]

[IstMHEND]

☐ [dtmMHEND] (DD/MM/YYYY)

[A: END DATE] End date, please specify Req/Unk / Req/Unk / Req/Unk (1930-2023)

[A: ONGOING] ☐ Ongoing

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

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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	IstMH, IstMHCATPRIOR
			No	N	citmYesNo_N	
clEND	String		End date	END DATE	citmEND_EndDate	IstMHEND
			Ongoing	ONGOING	citmEND_Ongoing	

RDE Analytics: RD_FRMMH		
Data Variable RefName	RD Column Name	Column Data Type
IstMH	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
IstMHCATPRIOR	LSTMHCATPRIOR_C	VARCHAR2
	LSTMHCATPRIOR	VARCHAR2
	LSTMHCATPRIOR_ND	VARCHAR2
IstMHEND	LSTMHEND_C	VARCHAR2
	LSTMHEND	VARCHAR2
	LSTMHEND_ND	VARCHAR2

IstMHEND - 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?]

[IstHH]

[A: Y] ☐ Yes

[A: N] ☐ No

2.*
✓

Hemophilia type
[Hemophilia type]

[IstHTYPE]

[A: A] ☐ Hemophilia A

[A: B] ☐ Hemophilia B

3.*
✓

Has biological phenotype changed from parent study?
[Phenotype changed?]

[IstBIO]

[A: Y] ☐ [IstPHENO]

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

6.
✓

Date occurred

Treatment

Severity

Location

Hospitalized

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]

[IstTRT]

[A: FACTOR VIII/IX] ☐ Treated with Factor/BPA

[A: OTHER] ☐ [txtTRTOTH]

Other treatment A60

6.3.*
✓

Severity
[Severity]

[IstSEV]

[A: MILD] ☐ Mild

[A: MODERATE] ☐ Moderate

[A: SEVERE] ☐ Severe

[A: LIFE THREATENING] ☐ Life threatening

6.4.*
✓

Location of bleed
[Location]

[IstLOC]

[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]

[IstHOSP]

[A: Y] ☐ [IstDAYSHOSP]

Yes

Days hospitalized

[A: NUMBER] ☐ [numDAYSHOSP]

Number of days hospitalized N3

[A: UNK] ☐ Unknown

[IstDAYSWORK]

Days missed work

[A: NUMBER] ☐ [numDAYSWORK]

Number of days missed work N3

[A: UNK] ☐ Unknown

[A: N] ☐ No

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file:///C:/Users/Nico_Van_Dessel/AppData/Local/Apps/2.0/8ROY8BMP.9NT/87KKKWE2.8YL/orac..47.0_7e15c60fcb5f8c5e_0006.0002_e3a46b3970a1f84d/HtmlResources/AnnotatedStudybook.html

21-Sep-21

Codelist Values Tables: Hemophilia History						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist I tem RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	IstHH, IstBIO, IstHOSP
			No	N	citmYesNo_N	
clHTYPE	String		Hemophilia A	A	clHTYPE_A	IstHTYPE
			Hemophilia B	B	clHTYPE_B	
clPHENO	String		Moderate (1-5%)	MODERATE	citmPHENO_MOD	IstPHENO
			Severe (<1%)	SEVERE	citmPHENO_SEV	
clBLTRT	String		Treated with Factor/BPA	FACTOR VIII/IX	citmBLTRT_Factor	IstTRT
			Other treatment	OTHER	citmBLTRT_Other	
clHHSEV	String		Mild	MILD	citmHHSEV_MILD	IstSEV
			Moderate	MODERATE	citmHHSEV_MODERATE	
			Severe	SEVERE	citmHHSEV_SEVERE	
			Life threatening	LIFE THREATENING	citmHHSEV_LIFETHREAT	
clBLLOC	String		Bleeding in joint	JOINT	citmBLLOC_Joint	IstLOC
			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	IstDAYSHOSP
			Unknown	UNK	citmDAYSHOSP_Unk	
clDAYSMISSED	String		Number of days missed work	NUMBER	citmDAYSMISSED_Number	IstDAYSWORK
			Unknown	UNK	citmDAYSMISSED_Unknown	

RDE Analytics: RD_FRMHHX		
Data Variable RefName	RD Column Name	Column Data Type
IstHH	LSTHH_C	VARCHAR2
	LSTHH	VARCHAR2
	LSTHH_ND	VARCHAR2
IstHTYPE	LSTHTYPE_C	VARCHAR2
	LSTHTYPE	VARCHAR2
	LSTHTYPE_ND	VARCHAR2
IstBIO	LSTBIO_C	VARCHAR2
	LSTBIO	VARCHAR2
	LSTBIO_ND	VARCHAR2
IstBIO - IstPHENO	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
IstTRT	LSTTRT_C	VARCHAR2
	LSTTRT	VARCHAR2
	LSTTRT_ND	VARCHAR2
IstTRT - txtTRTOTH	TXTTRTOTH	VARCHAR2
IstSEV	LSTSEV_C	VARCHAR2

	LSTSEV	VARCHAR2
	LSTSEV_ND	VARCHAR2
IstLOC	LSTLOC_C	VARCHAR2
	LSTLOC	VARCHAR2
	LSTLOC_ND	VARCHAR2
IstLOC - txtLOCOTH	TXTLOCOTH	VARCHAR2
IstHOSP	LSTHOSP_C	VARCHAR2
	LSTHOSP	VARCHAR2
	LSTHOSP_ND	VARCHAR2
IstHOSP - IstDAYSHOSP	LSTDAYSHOSP_C	VARCHAR2
	LSTDAYSHOSP	VARCHAR2
IstHOSP - numDAYSHOSP	NUMDAYSHOSP	NUMBER
IstHOSP - IstDAYSWORK	LSTDAYSWORK_C	VARCHAR2
	LSTDAYSWORK	VARCHAR2
IstHOSP - 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]	<div>[IstASSDT] [A: SAME DATE] <input type="radio"/> Same date as visit date [A: OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)</div>
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]	<div>[IstRESPIRAT] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [txtRESPIRAT] Abnormal, please specify <div>A200</div><div>[IstRESPIRATCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
3.* ✓	Heart/Cardiovascular [Heart/Cardiovascular]	<div>[IstCARDIOVA] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [txtCARDIOVA] Abnormal, please specify <div>A200</div><div>[IstCARDIOVACS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
4.* ✓	Dermatological/Skin [Dermatological/Skin]	<div>[IstSKIN] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [txtSKIN] Abnormal, please specify <div>A200</div><div>[IstSKINCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
5.* ✓	Gastrointestinal/Liver [Gastrointestinal/Liver]	<div>[IstGASTROIN] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [txtGASTROIN] Abnormal, please specify <div>A200</div><div>[IstGASTROINCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
6.* ✓	Musculoskeletal/Extremities [Musculoskeletal/Extremities]	<div>[IstMUSCULO] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [txtMUSCULO] Abnormal, please specify <div>A200</div><div>[IstMUSCULOCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
7. ✓	Neurologic [Neurologic]	<div>[IstNEURO_SCR] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [cmpNEURO] Abnormal, please specify [txtNEURO] <div>A200</div></div>

		<div>[IstNEUROCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div>
	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]	<div>[txtPEOTH] A200</div>
8.2* ✓	Is the abnormality clinically significant? [Other clinical significance]	<div>[IstPEOTHCS] [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div>

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 (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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clNDNormalAbnormal	String		Not done	NOT DONE	citmNDNormalAbnormal_ND	IstRESPIRAT, IstCARDIOVA, IstSKIN, IstGASTROIN, IstMUSCULO, IstNEURO_SCR
			Normal	NORMAL	citmNDNormalAbnormal_Normal	
			Abnormal	ABNORMAL	citmNDNormalAbnormal_Abnormal	
clYesNo	String		Yes	Y	citmYesNo_Y	IstRESPIRATCS, IstCARDIOVACS, IstSKINCS, IstGASTROINCS, IstMUSCULOCS, IstNEUROCS, IstPEOTHCS
			No	N	citmYesNo_N	

RDE Analytics: RD_FRMPE_SCR		
Data Variable RefName	RD Column Name	Column Data Type
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
IstRESPIRAT	LSTRESPIRAT_C	VARCHAR2
	LSTRESPIRAT	VARCHAR2
	LSTRESPIRAT_ND	VARCHAR2
IstRESPIRAT - txtRESPIRAT	TXTRESPIRAT	VARCHAR2
IstRESPIRAT - IstRESPIRATCS	LSTRESPIRATCS_C	VARCHAR2
	LSTRESPIRATCS	VARCHAR2
IstCARDIOVA	LSTCARDIOVA_C	VARCHAR2
	LSTCARDIOVA	VARCHAR2
	LSTCARDIOVA_ND	VARCHAR2
IstCARDIOVA - txtCARDIOVA	TXTCARDIOVA	VARCHAR2
IstCARDIOVA - IstCARDIOVACS	LSTCARDIOVACS_C	VARCHAR2
	LSTCARDIOVACS	VARCHAR2
IstSKIN	LSTSKIN_C	VARCHAR2
	LSTSKIN	VARCHAR2
	LSTSKIN_ND	VARCHAR2

IstSKIN - txtSKIN	TXTSKIN	VARCHAR2
IstSKIN - IstSKINCS	LSTSKINCS_C	VARCHAR2
	LSTSKINCS	VARCHAR2
IstGASTROIN	LSTGASTROIN_C	VARCHAR2
	LSTGASTROIN	VARCHAR2
	LSTGASTROIN_ND	VARCHAR2
IstGASTROIN - txtGASTROIN	TXTGASTROIN	VARCHAR2
IstGASTROIN - IstGASTROINCS	LSTGASTROINCS_C	VARCHAR2
	LSTGASTROINCS	VARCHAR2
IstMUSCULO	LSTMUSCULO_C	VARCHAR2
	LSTMUSCULO	VARCHAR2
	LSTMUSCULO_ND	VARCHAR2
IstMUSCULO - txtMUSCULO	TXTMUSCULO	VARCHAR2
IstMUSCULO - IstMUSCULOCS	LSTMUSCULOCS_C	VARCHAR2
	LSTMUSCULOCS	VARCHAR2
IstNEURO_SCR	LSTNEURO_SCR_C	VARCHAR2
	LSTNEURO_SCR	VARCHAR2
	LSTNEURO_SCR_ND	VARCHAR2
IstNEURO_SCR - txtNEURO	TXTNEURO	VARCHAR2
IstNEURO_SCR - IstNEUROCS	LSTNEUROCS_C	VARCHAR2
	LSTNEUROCS	VARCHAR2
RD_FRMPE_SCR_SCTPEOTH		
txtPEOTH	TXTPEOTH	VARCHAR2
	TXTPEOTH_ND	VARCHAR2
IstPEOTHCS	LSTPEOTHCS_C	VARCHAR2
	LSTPEOTHCS	VARCHAR2
	LSTPEOTHCS_ND	VARCHAR2

AT3SC002: Vital Signs (Screening) (VS SCR) [frmVS_SCR]

1.*
✓

Date collected
[Date performed]

[IstASSDT]
[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	IstASSDT
			Other	OTHER	citmDateOther_Other	

RDE Analytics: RD_FRMVS_SCR		
Data Variable RefName	RD Column Name	Column Data Type
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - 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

numRR1	NUMTEMP1_U	VARCHAR2
	NUMTEMP1_ND	VARCHAR2
	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]

[IstASSDT]
[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] ☐ [IstLAB]
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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clYesNo	String		Yes	Y	citmYesNo_Y	txtLAB
			No	N	citmYesNo_N	
clLAB	String		Hematology	HEMATOLOGY	citmLAB_Hematology	IstLAB
			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
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - 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

file:///C:/Users/Nico_Van_Dessel/AppData/Local/Apps/2.0/8ROY8BMP.9NT/87KKKWE2.8YL/orac..47.0_7e15c60fcb5f8c5e_0006.0002_e3a46b3970a1f84d/HtmlResources/AnnotatedStudybook.html

21-Sep-21

	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] <input type="radio"/> Same date as visit date [A: OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)
12-lead Electrocardiogram [sctECG_SCR]		
Supine after at least 10 minutes rest		
2.* ✓	Time performed [Time performed]	[dtmASS_T] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
3.* ✓	Rhythm [Rhythm]	[lstRHYTM] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
4.* ✓	Ventricular rate [Ventricular rate]	[numVR] <input type="text"/> N3 bpm ^[b]
5.* ✓	PR interval [PR]	[numPR] <input type="text"/> N3 msec ^[b]
6.* ✓	QRS duration [QRS]	[numQRS] <input type="text"/> N3 msec ^[b]
7.* ✓	QT interval [QT]	[numQT] <input type="text"/> N3 msec ^[b]
8.* ✓	QTc interval [QTc]	[numQTcF] <input type="text"/> N3 msec ^[b]
9.* ✓	Overall interpretation [Overall interpretation]	[lstOVERALLINT] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL, NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL, CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
10. ✓	If abnormal, please specify by checking all that apply [Abnormal]	[lstABN1] [A: SINUS BRADYCARDIA] <input type="checkbox"/> Sinus Bradycardia [A: SINUS TACHYCARDIA] <input type="checkbox"/> Sinus Tachycardia [A: ATRIAL TACHYCARDIA] <input type="checkbox"/> Atrial Tachycardia [A: VENTRICULAR TACHYCARDIA] <input type="checkbox"/> Ventricular Tachycardia [A: SICK SINUS SYNDROME] <input type="checkbox"/> Sick Sinus Syndrome [A: PREMATURE ATRIAL COMPLEXES] <input type="checkbox"/> Premature Atrial Complexes [A: PREMATURE VENTRICULAR COMPLEXES] <input type="checkbox"/> Premature Ventricular Complexes [A: Q AXIS LEFT AXIS DEVIATION] <input type="checkbox"/> Q Axis, Left Axis Deviation [A: LEFT ATRIAL ABNORMALITY] <input type="checkbox"/> Left Atrial Abnormality [A: LEFT VENTRICULAR HYPERTROPHY] <input type="checkbox"/> Left Ventricular Hypertrophy [A: ATRIAL FIBRILLATION] <input type="checkbox"/> Atrial Fibrillation [A: ATRIAL PACING] <input type="checkbox"/> Atrial Pacing [A: VENTRICULAR PACING] <input type="checkbox"/> Ventricular Pacing [A: ATRIAL VENTRICULAR PACING] <input type="checkbox"/> Atrial Ventricular Pacing [A: 1ST DEGREE A-V BLOCK] <input type="checkbox"/> 1st Degree A-V Block [A: 2ND DEGREE A-V BLOCK TYPE I] <input type="checkbox"/> 2nd Degree A-V Block Type I [A: 2ND DEGREE A-V BLOCK TYPE II] <input type="checkbox"/> 2nd Degree A-V Block Type II [A: 3RD DEGREE A-V BLOCK] <input type="checkbox"/> 3rd Degree A-V Block [A: LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Left Bundle Branch Block [A: INCOMPLETE LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Left Bundle Branch Block [A: LEFT ANTERIOR HEMIBLOCK] <input type="checkbox"/> Left Anterior Hemiblock [A: LEFT POSTERIOR HEMIBLOCK] <input type="checkbox"/> Left Posterior Hemiblock [A: RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Right Bundle Branch Block [A: INCOMPLETE RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Right Bundle Branch Block [A: INTRAVENTRICULAR CONDUCTION DELAY] <input type="checkbox"/> Intraventricular Conduction Delay [A: ANTEROSEPTAL INFARCT PATTERN] <input type="checkbox"/> Anteroseptal Infarct Pattern [A: ANTEROLATERAL INFARCT PATTERN] <input type="checkbox"/> Anterolateral Infarct Pattern [A: LATERAL INFARCT PATTERN] <input type="checkbox"/> Lateral Infarct Pattern [A: INFERIOR INFARCT PATTERN] <input type="checkbox"/> Inferior Infarct Pattern [A: OTHER, SPECIFY] <input type="checkbox"/> [txtABNOTH1] Other, specify <input type="text"/> 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 I tem RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	IstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	IstRHYTM
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	IstOVERALLINT
			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	IstABN1
			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
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - 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

IstABN1 - 2nd Degree A-V Block Type I	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
IstABN1 - 2nd Degree A-V Block Type II	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
IstABN1 - 3rd Degree A-V Block	*LSTABN1_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
IstABN1 - Left Bundle Branch Block	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Incomplete Left Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Left Anterior Hemiblock	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN1 - Left Posterior Hemiblock	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN1 - Right Bundle Branch Block	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Incomplete Right Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Intraventricular Conduction Delay	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN1 - Anteroseptal Infarct Pattern	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
IstABN1 - Anterolateral Infarct Pattern	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
IstABN1 - Lateral Infarct Pattern	*LSTABN1_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNLATERALINFARCTPATTERN	VARCHAR2
IstABN1 - Inferior Infarct Pattern	*LSTABN1_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
IstABN1 - Other, specify	LSTABN1_TXTABNOTH1_C	VARCHAR2
	LSTABN1_TXTABNOTH1	VARCHAR2
IstABN1 - 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]

[IstPTC]

[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]

[IstELIG]

[A: Y] ☐ Yes

[A: N] ☐ No

3.
✓

Failed criteria numbers
[Failed criteria]

[IstINEX]

[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]

[IstWAI VER]

[A: Y] ☐ [dtmWAI VER] (DD/MM/YYYY)

Yes, date granted

Req / Req / Req (2015-2023)

[A: N] ☐ No

5.

For office use only [hidden]
[For office use only]

[numEMAI L1]

6.

For office use only [hidden]
[For office use only]

[numEMAI L2]

7.

For office use only [hidden]
[For office use only]

[numEMAI L3]

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 I tem RefName	Data Variable RefName
cIPTC	String		Original	ORIGINAL	citmPTC_Original	IstPTC
			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	

file:///C:/Users/Nico_Van_Dessel/AppData/Local/Apps/2.0/8ROY8BMP.9NT/87KKKWE2.8YL/orac..47.0_7e15c60fcb5f8c5e_0006.0002_e3a46b3970a1f84d/HtmlResources/AnnotatedStudybook.html

21-Sep-21

			Amendment 9	AMENDMENT 9	citmPTC_Amendment9	
			Amendment 10	AMENDMENT 10	citmPTC_Amendment10	
clYesNo	String		Yes	Y	citmYesNo_Y	IstELIG, IstWAIVER
			No	N	citmYesNo_N	
clINEX	String		Inclusion criterion 1	INCLUSION CRITERION 1	citmINEX_IN1	IstINEX
			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
IstPTC	LSTPTC_C	VARCHAR2
	LSTPTC	VARCHAR2
	LSTPTC_ND	VARCHAR2
IstELIG	LSTELIG_C	VARCHAR2
	LSTELIG	VARCHAR2
	LSTELIG_ND	VARCHAR2
IstINEX	LSTINEX_ND	VARCHAR2
IstINEX - Inclusion criterion 1	LSTINEX_CITMINEXIN1_C	VARCHAR2
	LSTINEX_CITMINEXIN1	VARCHAR2
IstINEX - Inclusion criterion 2	LSTINEX_CITMINEXIN2_C	VARCHAR2
	LSTINEX_CITMINEXIN2	VARCHAR2
IstINEX - Inclusion criterion 3	LSTINEX_CITMINEXIN3_C	VARCHAR2
	LSTINEX_CITMINEXIN3	VARCHAR2
IstINEX - Inclusion criterion 4	LSTINEX_CITMINEXIN4_C	VARCHAR2
	LSTINEX_CITMINEXIN4	VARCHAR2
IstINEX - Inclusion criterion 5	LSTINEX_CITMINEXIN5_C	VARCHAR2
	LSTINEX_CITMINEXIN5	VARCHAR2
IstINEX - Exclusion criterion 1	LSTINEX_CITMINEXEX1_C	VARCHAR2
	LSTINEX_CITMINEXEX1	VARCHAR2
IstINEX - Exclusion criterion 2	LSTINEX_CITMINEXEX2_C	VARCHAR2
	LSTINEX_CITMINEXEX2	VARCHAR2
IstINEX - Exclusion criterion 3	LSTINEX_CITMINEXEX3_C	VARCHAR2
	LSTINEX_CITMINEXEX3	VARCHAR2
IstINEX - Exclusion criterion 4	LSTINEX_CITMINEXEX4_C	VARCHAR2
	LSTINEX_CITMINEXEX4	VARCHAR2
IstINEX - Exclusion criterion 5	LSTINEX_CITMINEXEX5_C	VARCHAR2
	LSTINEX_CITMINEXEX5	VARCHAR2
IstINEX - Exclusion criterion 6	LSTINEX_CITMINEXEX6_C	VARCHAR2
	LSTINEX_CITMINEXEX6	VARCHAR2
IstINEX - 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]

[IstCMIND]
[A:AE] ☐ AE
[A:OTHER] ☐ [txtCMINDCSP]
Other indication, please specify
A200

4.*
✓

Continuing from parent study?
[Continuing from parent study?]

[IstCONT]
[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]

[IstCMEND]
[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]
xxxxxxxxx.

8.*
✓

Unit
[Unit]

[IstDOSEU]
[A:UNIT] ☐ [IstDOSEUSP]
[cIDOSEUSP]
[A:OTHER] ☐ [txtDOSEUOTH]
Other, please specify
A50

9.*
✓

Frequency
[Frequency]

[IstFREQ]
[A:FREQUENCY] ☐ [IstFREQSP]
[cIFREQSP]
[A:OTHER] ☐ [txtFREQOTH]
Other, please specify
A50

10.*
✓

Route of administration
[Route]

[IstROUTE]
[A:ROUTE] ☐ [IstROUTESP]
[cIROUTESP]
[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	TXTRT	VARCHAR2
	TXTRT_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	LSTDSEU_C	VARCHAR2
	LSTDSEU	VARCHAR2
	LSTDSEU_ND	VARCHAR2
lstDOSEU - lstDOSEUSP	LSTDSEUSP_C	VARCHAR2
	LSTDSEUSP	VARCHAR2
lstDOSEU - txtDOSEUOTH	TXTDSEUOTH	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]	<div>[IstASSDT] [A: SAME DATE] <input type="radio"/> Same date as visit date [A: OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)</div>
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]	<div>[dtmASS_T] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock</div>
3.* ✓	Chest/Respiratory [Chest/Respiratory]	<div>[IstRESPIRAT] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstRESPIRATNEW] Abnormal, is the abnormality a new or worsened finding? [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [txtRESPIRATNEWSP] Yes, please specify <div>A200</div><div>[IstRESPIRATCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
4.* ✓	Heart/Cardiovascular [Heart/Cardiovascular]	<div>[IstCARDIOVA] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstCARDIOVANEW] Abnormal, is the abnormality a new or worsened finding? [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [txtCARDIOVANEWSP] Yes, please specify <div>A200</div><div>[IstCARDIOVACS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
5.* ✓	Dermatological/Skin [Dermatological/Skin]	<div>[IstSKIN] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstSKINNEW] Abnormal, is the abnormality a new or worsened finding? [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [txtSKINNEWSP] Yes, please specify <div>A200</div><div>[IstSKINCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
6.* ✓	Gastrointestinal/Liver [Gastrointestinal/Liver]	<div>[IstGASTROIN] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstGASTROINNEW] Abnormal, is the abnormality a new or worsened finding? [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [txtGASTROINNEWSP] Yes, please specify <div>A200</div><div>[IstGASTROINCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
7.* ✓	Musculoskeletal/Extremities [Musculoskeletal/Extremities]	<div>[IstMUSCULO] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstMUSCULONEW] Abnormal, is the abnormality a new or worsened finding? [A: N] <input type="radio"/> No</div>

		<div><div></div><div><div>[A: Y]</div><div><div></div><div>[txtMUSCULONEWSP]</div><div>Yes, please specify</div><div>A200</div></div></div><div><div></div><div>[IstMUSCULOCS]</div><div>Is the abnormality clinically significant?</div><div><div>[A: Y]</div><div><div></div><div>Yes</div></div><div><div>[A: N]</div><div><div></div><div>No</div></div></div></div></div></div>
8. ✓	Neurologic [Neurologic]	<div><div>[IstNEURO]</div><div><div>[A: NOT DONE]</div><div><div></div><div>Not done</div></div><div><div>[A: NORMAL]</div><div><div></div><div>Normal</div></div><div><div>[A: ABNORMAL]</div><div><div></div><div>[IstNEURONEW]</div><div>Abnormal, is the abnormality a new or worsened finding?</div><div><div>[A: N]</div><div><div></div><div>No</div></div><div><div>[A: Y]</div><div><div></div><div>[cmpNEURONEW]</div><div>Yes, please specify</div><div>[txtNEURONEWSP]</div><div>A200</div></div></div><div><div></div><div>[IstNEUROCS]</div><div>Is the abnormality clinically significant?</div><div><div>[A: Y]</div><div><div></div><div>Yes</div></div><div><div>[A: N]</div><div><div></div><div>No</div></div></div></div></div></div></div></div></div></div></div>
	Other abnormalities	Other clinical significance
9. ✓		
Directed Physical Examination - Predose - Other Entry [sctPEOTHPRE]		
<div>- If there are any other abnormalities, please record in the Add Entry section below</div> <div>- Please record only one abnormality per row</div>		
9.1* ✓	Other abnormalities [Other abnormalities]	<div><div>[txtPEOTH]</div><div>A200</div></div>
9.2* ✓	Is the abnormality clinically significant? [Other clinical significance]	<div><div>[IstPEOTHCS]</div><div><div>[A: Y]</div><div><div></div><div>Yes</div></div><div><div>[A: N]</div><div><div></div><div>No</div></div></div></div></div>
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]	<div><div>[dtmASS_T2] (hh:mm)</div><div>Req <div></div> : Req <div></div> 24-hour clock</div></div>
11.* ✓	Chest/Respiratory [Chest/Respiratory]	<div><div>[IstRESPIRAT2]</div><div><div>[A: NOT DONE]</div><div><div></div><div>Not done</div></div><div><div>[A: NORMAL]</div><div><div></div><div>Normal</div></div><div><div>[A: ABNORMAL]</div><div><div></div><div>[IstRESPIRATNEW2]</div><div>Abnormal, is the abnormality a new or worsened finding?</div><div><div>[A: N]</div><div><div></div><div>No</div></div><div><div>[A: Y]</div><div><div></div><div>[txtRESPIRATNEWSP2]</div><div>Yes, please specify</div><div>A200</div></div></div><div><div></div><div>[IstRESPIRATCS2]</div><div>Is the abnormality clinically significant?</div><div><div>[A: Y]</div><div><div></div><div>Yes</div></div><div><div>[A: N]</div><div><div></div><div>No</div></div></div></div></div></div></div></div></div></div></div>
12.* ✓	Heart/Cardiovascular [Heart/Cardiovascular]	<div><div>[IstCARDIOVA2]</div><div><div>[A: NOT DONE]</div><div><div></div><div>Not done</div></div><div><div>[A: NORMAL]</div><div><div></div><div>Normal</div></div><div><div>[A: ABNORMAL]</div><div><div></div><div>[IstCARDIOVANEW2]</div><div>Abnormal, is the abnormality a new or worsened finding?</div><div><div>[A: N]</div><div><div></div><div>No</div></div><div><div>[A: Y]</div><div><div></div><div>[txtCARDIOVANEWSP2]</div><div>Yes, please specify</div><div>A200</div></div></div><div><div></div><div>[IstCARDIOVACS2]</div><div>Is the abnormality clinically significant?</div><div><div>[A: Y]</div><div><div></div><div>Yes</div></div><div><div>[A: N]</div><div><div></div><div>No</div></div></div></div></div></div></div></div></div></div></div>

13.* ✓	Dermatological/Skin [Dermatological/Skin]	<div>[IstSKIN2] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstSKINNEW2] Abnormal, is the abnormality a new or worsened finding? [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [txtSKINNEWSP2] Yes, please specify <div>A200</div><div>[IstSKINCS2] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
14.* ✓	Gastrointestinal/Liver [Gastrointestinal/Liver]	<div>[IstGASTROI N2] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstGASTROI NNEW2] Abnormal, is the abnormality a new or worsened finding? [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [txtGASTROI NNEWSP2] Yes, please specify <div>A200</div><div>[IstGASTROI NCS2] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
15.* ✓	Musculoskeletal/Extremities [Musculoskeletal/Extremities]	<div>[IstMUSCULO2] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstMUSCULONEW2] Abnormal, is the abnormality a new or worsened finding? [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [txtMUSCULONEWSP2] Yes, please specify <div>A200</div><div>[IstMUSCULOCS2] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
16. ✓	Neurologic [Neurologic]	<div>[IstNEURO2] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstNEURONEW2] Abnormal, is the abnormality a new or worsened finding? [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [cmpNEURONEW2] Yes, please specify [txtNEURONEWSP2] <div>A200</div><div>[IstNEUROCS2] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
	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]	<div>[txtPEOTH2] <div>A200</div></div>
17.2* ✓	Is the abnormality clinically significant? [Other clinical significance]	<div>[IstPEOTHCS2] [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div>

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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clINDNormalAbnormal	String		Not done	NOT DONE	citmNDNormalAbnormal_ND	IstRESPIRAT, IstCARDIOVA, IstSKIN, IstGASTROIN, IstMUSCULO, IstNEURO, IstRESPIRAT2, IstCARDIOVA2, IstSKIN2, IstGASTROIN2, IstMUSCULO2, IstNEURO2
			Normal	NORMAL	citmNDNormalAbnormal_Normal	
			Abnormal	ABNORMAL	citmNDNormalAbnormal_Abnormal	
clNoYes	String		No	N	citmNoYes_N	IstRESPIRATNEW, IstCARDIOVANEW, IstSKINNEW, IstGASTROINNEW, IstMUSCULONEW, IstNEURONEW, IstRESPIRATNEW2, IstCARDIOVANEW2, IstSKINNEW2, IstGASTROINNEW2, IstMUSCULONEW2, IstNEURONEW2
			Yes	Y	citmNoYes_Y	
clYesNo	String		Yes	Y	citmYesNo_Y	IstRESPIRATCS, IstCARDIOVACS, IstSKINCS, IstGASTROINCS, IstMUSCULOCS, IstNEUROCS, IstPEOTHCS, IstRESPIRATCS2, IstCARDIOVACS2, IstSKINCS2, IstGASTROINCS2, IstMUSCULOCS2, IstNEUROCS2, IstPEOTHCS2
			No	N	citmYesNo_N	

RDE Analytics: RD_FRMPE_D1		
Data Variable RefName	RD Column Name	Column Data Type
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
IstRESPIRAT	LSTRESPIRAT_C	VARCHAR2
	LSTRESPIRAT	VARCHAR2
	LSTRESPIRAT_ND	VARCHAR2
IstRESPIRAT - IstRESPIRATNEW	LSTRESPIRATNEW_C	VARCHAR2
	LSTRESPIRATNEW	VARCHAR2
IstRESPIRAT - txtRESPIRATNEWSP	TXTRESPIRATNEWSP	VARCHAR2
IstRESPIRAT - IstRESPIRATCS	LSTRESPIRATCS_C	VARCHAR2
	LSTRESPIRATCS	VARCHAR2
IstCARDIOVA	LSTCARDIOVA_C	VARCHAR2
	LSTCARDIOVA	VARCHAR2

	LSTCARDIOVA_ND	VARCHAR2
IstCARDIOVA - IstCARDIOVANEW	LSTCARDIOVANEW_C	VARCHAR2
	LSTCARDIOVANEW	VARCHAR2
IstCARDIOVA - txtCARDIOVANEWSP	TXTCARDIOVANEWSP	VARCHAR2
IstCARDIOVA - IstCARDIOVACS	LSTCARDIOVACS_C	VARCHAR2
	LSTCARDIOVACS	VARCHAR2
IstSKIN	LSTSKIN_C	VARCHAR2
	LSTSKIN	VARCHAR2
	LSTSKIN_ND	VARCHAR2
IstSKIN - IstSKINNEW	LSTSKINNEW_C	VARCHAR2
	LSTSKINNEW	VARCHAR2
IstSKIN - txtSKINNEWSP	TXTSKINNEWSP	VARCHAR2
IstSKIN - IstSKINCS	LSTSKINCS_C	VARCHAR2
	LSTSKINCS	VARCHAR2
IstGASTROIN	LSTGASTROIN_C	VARCHAR2
	LSTGASTROIN	VARCHAR2
	LSTGASTROIN_ND	VARCHAR2
IstGASTROIN - IstGASTROINNEW	LSTGASTROINNEW_C	VARCHAR2
	LSTGASTROINNEW	VARCHAR2
IstGASTROIN - txtGASTROINNEWSP	TXTGASTROINNEWSP	VARCHAR2
IstGASTROIN - IstGASTROINCS	LSTGASTROINCS_C	VARCHAR2
	LSTGASTROINCS	VARCHAR2
IstMUSCULO	LSTMUSCULO_C	VARCHAR2
	LSTMUSCULO	VARCHAR2
	LSTMUSCULO_ND	VARCHAR2
IstMUSCULO - IstMUSCULONEW	LSTMUSCULONEW_C	VARCHAR2
	LSTMUSCULONEW	VARCHAR2
IstMUSCULO - txtMUSCULONEWSP	TXTMUSCULONEWSP	VARCHAR2
IstMUSCULO - IstMUSCULOCS	LSTMUSCULOCS_C	VARCHAR2
	LSTMUSCULOCS	VARCHAR2
IstNEURO	LSTNEURO_C	VARCHAR2
	LSTNEURO	VARCHAR2
	LSTNEURO_ND	VARCHAR2
IstNEURO - IstNEURONEW	LSTNEURONEW_C	VARCHAR2
	LSTNEURONEW	VARCHAR2
IstNEURO - txtNEURONEWSP	TXTNEURONEWSP	VARCHAR2
IstNEURO - IstNEUROCS	LSTNEUROCS_C	VARCHAR2
	LSTNEUROCS	VARCHAR2
dtmASS_T2	DTMASS_T2	DATE
	DTMASS_T2_TMS	VARCHAR2
	DTMASS_T2_ND	VARCHAR2
IstRESPIRAT2	LSTRESPIRAT2_C	VARCHAR2
	LSTRESPIRAT2	VARCHAR2
	LSTRESPIRAT2_ND	VARCHAR2
IstRESPIRAT2 - IstRESPIRATNEW2	LSTRESPIRATNEW2_C	VARCHAR2
	LSTRESPIRATNEW2	VARCHAR2
IstRESPIRAT2 - txtRESPIRATNEWSP2	TXTRESPIRATNEWSP2	VARCHAR2
IstRESPIRAT2 - IstRESPIRATCS2	LSTRESPIRATCS2_C	VARCHAR2
	LSTRESPIRATCS2	VARCHAR2
IstCARDIOVA2	LSTCARDIOVA2_C	VARCHAR2
	LSTCARDIOVA2	VARCHAR2
	LSTCARDIOVA2_ND	VARCHAR2
IstCARDIOVA2 - IstCARDIOVANEW2	LSTCARDIOVANEW2_C	VARCHAR2

	LSTCARDIOVANEW2	VARCHAR2
IstCARDIOVA2 - txtCARDIOVANEWSP2	TXTCARDIOVANEWSP2	VARCHAR2
IstCARDIOVA2 - IstCARDIOVACS2	LSTCARDIOVACS2_C	VARCHAR2
	LSTCARDIOVACS2	VARCHAR2
IstSKIN2	LSTSKIN2_C	VARCHAR2
	LSTSKIN2	VARCHAR2
	LSTSKIN2_ND	VARCHAR2
IstSKIN2 - IstSKINNEW2	LSTSKINNEW2_C	VARCHAR2
	LSTSKINNEW2	VARCHAR2
IstSKIN2 - txtSKINNEWSP2	TXTSKINNEWSP2	VARCHAR2
IstSKIN2 - IstSKINCS2	LSTSKINCS2_C	VARCHAR2
	LSTSKINCS2	VARCHAR2
IstGASTROIN2	LSTGASTROIN2_C	VARCHAR2
	LSTGASTROIN2	VARCHAR2
	LSTGASTROIN2_ND	VARCHAR2
IstGASTROIN2 - IstGASTROINNEW2	LSTGASTROINNEW2_C	VARCHAR2
	LSTGASTROINNEW2	VARCHAR2
IstGASTROIN2 - txtGASTROINNEWSP2	TXTGASTROINNEWSP2	VARCHAR2
IstGASTROIN2 - IstGASTROINCS2	LSTGASTROINCS2_C	VARCHAR2
	LSTGASTROINCS2	VARCHAR2
IstMUSCULO2	LSTMUSCULO2_C	VARCHAR2
	LSTMUSCULO2	VARCHAR2
	LSTMUSCULO2_ND	VARCHAR2
IstMUSCULO2 - IstMUSCULONEW2	LSTMUSCULONEW2_C	VARCHAR2
	LSTMUSCULONEW2	VARCHAR2
IstMUSCULO2 - txtMUSCULONEWSP2	TXTMUSCULONEWSP2	VARCHAR2
IstMUSCULO2 - IstMUSCULOCS2	LSTMUSCULOCS2_C	VARCHAR2
	LSTMUSCULOCS2	VARCHAR2
IstNEURO2	LSTNEURO2_C	VARCHAR2
	LSTNEURO2	VARCHAR2
	LSTNEURO2_ND	VARCHAR2
IstNEURO2 - IstNEURONEW2	LSTNEURONEW2_C	VARCHAR2
	LSTNEURONEW2	VARCHAR2
IstNEURO2 - txtNEURONEWSP2	TXTNEURONEWSP2	VARCHAR2
IstNEURO2 - IstNEUROCS2	LSTNEUROCS2_C	VARCHAR2
	LSTNEUROCS2	VARCHAR2
RD_FRMPE_D1_SCTPEOTHPRE		
txtPEOTH	TXTPEOTH	VARCHAR2
	TXTPEOTH_ND	VARCHAR2
IstPEOTHCS	LSTPEOTHCS_C	VARCHAR2
	LSTPEOTHCS	VARCHAR2
	LSTPEOTHCS_ND	VARCHAR2
RD_FRMPE_D1_SCTPEOTH6H		
txtPEOTH2	TXTPEOTH2	VARCHAR2
	TXTPEOTH2_ND	VARCHAR2
IstPEOTHCS2	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

[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]	<div>[IstASSDT] [A: SAME DATE] <input type="radio"/> Same date as visit date [A: OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)</div>
12-lead Electrocardiogram - Predose [sctPRE]		
Supine after at least 10 minutes rest		
2.* ✓	Time performed [Time performed]	<div>[dtmASS_T] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock</div>
3.* ✓	Rhythm [Rhythm]	<div>[IstRHYTM] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant</div>
4.* ✓	Ventricular rate [Ventricular rate]	<div>[numVR] N3 <input type="text"/> bpm^[b]</div>
5.* ✓	PR interval [PR]	<div>[numPR] N3 <input type="text"/> msec^[b]</div>
6.* ✓	QRS duration [QRS]	<div>[numQRS] N3 <input type="text"/> msec^[b]</div>
7.* ✓	QT interval [QT]	<div>[numQT] N3 <input type="text"/> msec^[b]</div>
8.* ✓	QTc interval [QTc]	<div>[numQTcF] N3 <input type="text"/> msec^[b]</div>
9.* ✓	Overall interpretation [Overall interpretation]	<div>[IstOVERALLINT] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL, NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL, CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant</div>
10. ✓	If abnormal, please specify by checking all that apply [Abnormal]	<div><div><div>[IstABN1] [A: SINUS BRADYCARDIA] [A: SINUS TACHYCARDIA] [A: ATRIAL TACHYCARDIA] [A: VENTRICULAR TACHYCARDIA] [A: SICK SINUS SYNDROME] [A: PREMATURE ATRIAL COMPLEXES] [A: PREMATURE VENTRICULAR COMPLEXES] [A: Q AXIS LEFT AXIS DEVIATION] [A: LEFT ATRIAL ABNORMALITY] [A: LEFT VENTRICULAR HYPERTROPHY] [A: ATRIAL FIBRILLATION] [A: ATRIAL PACING] [A: VENTRICULAR PACING] [A: ATRIAL VENTRICULAR PACING] [A: 1ST DEGREE A-V BLOCK] [A: 2ND DEGREE A-V BLOCK TYPE I] [A: 2ND DEGREE A-V BLOCK TYPE II] [A: 3RD DEGREE A-V BLOCK] [A: LEFT BUNDLE BRANCH BLOCK] [A: INCOMPLETE LEFT BUNDLE BRANCH BLOCK] [A: LEFT ANTERIOR HEMIBLOCK] [A: LEFT POSTERIOR HEMIBLOCK] [A: RIGHT BUNDLE BRANCH BLOCK] [A: INCOMPLETE RIGHT BUNDLE BRANCH BLOCK] [A: INTRAVENTRICULAR CONDUCTION DELAY] [A: ANTEROSEPTAL INFARCT PATTERN] [A: ANTEROLATERAL INFARCT PATTERN] [A: LATERAL INFARCT PATTERN] [A: INFERIOR INFARCT PATTERN] [A: OTHER, SPECIFY]</div><div><input type="checkbox"/> Sinus Bradycardia <input type="checkbox"/> Sinus Tachycardia <input type="checkbox"/> Atrial Tachycardia <input type="checkbox"/> Ventricular Tachycardia <input type="checkbox"/> Sick Sinus Syndrome <input type="checkbox"/> Premature Atrial Complexes <input type="checkbox"/> Premature Ventricular Complexes <input type="checkbox"/> Q Axis, Left Axis Deviation <input type="checkbox"/> Left Atrial Abnormality <input type="checkbox"/> Left Ventricular Hypertrophy <input type="checkbox"/> Atrial Fibrillation <input type="checkbox"/> Atrial Pacing <input type="checkbox"/> Ventricular Pacing <input type="checkbox"/> Atrial Ventricular Pacing <input type="checkbox"/> 1st Degree A-V Block <input type="checkbox"/> 2nd Degree A-V Block Type I <input type="checkbox"/> 2nd Degree A-V Block Type II <input type="checkbox"/> 3rd Degree A-V Block <input type="checkbox"/> Left Bundle Branch Block <input type="checkbox"/> Incomplete Left Bundle Branch Block <input type="checkbox"/> Left Anterior Hemiblock <input type="checkbox"/> Left Posterior Hemiblock <input type="checkbox"/> Right Bundle Branch Block <input type="checkbox"/> Incomplete Right Bundle Branch Block <input type="checkbox"/> Intraventricular Conduction Delay <input type="checkbox"/> Anteroseptal Infarct Pattern <input type="checkbox"/> Anterolateral Infarct Pattern <input type="checkbox"/> Lateral Infarct Pattern <input type="checkbox"/> Inferior Infarct Pattern <input type="checkbox"/> [txtABNOTH1] Other, specify <div>A128</div></div></div></div>

12-lead Electrocardiogram - 30 Minutes Postdose [sct30M]		
11.* ✓	Time performed [Time performed]	[dtmASS_T2] (hh:mm) Req <input type="button" value="v"/> : Req <input type="button" value="v"/> 24-hour clock
12.* ✓	Rhythm [Rhythm]	[IstRHYTM2] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A:ABNORMAL CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
13.* ✓	Ventricular rate [Ventricular rate]	[numVR2] <input type="text" value="N3"/> bpm ^[b]
14.* ✓	PR interval [PR]	[numPR2] <input type="text" value="N3"/> msec ^[b]
15.* ✓	QRS duration [QRS]	[numQRS2] <input type="text" value="N3"/> msec ^[b]
16.* ✓	QT interval [QT]	[numQT2] <input type="text" value="N3"/> msec ^[b]
17.* ✓	QTc interval [QTc]	[numQTcF2] <input type="text" value="N3"/> msec ^[b]
18.* ✓	Overall interpretation [Overall interpretation]	[IstOVERALLINT2] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL, NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A:ABNORMAL, CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
19.* ✓	If abnormal, please specify by checking all that apply [Abnormal]	[IstABN2] [A:SINUS BRADYCARDIA] <input type="checkbox"/> Sinus Bradycardia [A:SINUS TACHYCARDIA] <input type="checkbox"/> Sinus Tachycardia [A:ATRIAL TACHYCARDIA] <input type="checkbox"/> Atrial Tachycardia [A:VENTRICULAR TACHYCARDIA] <input type="checkbox"/> Ventricular Tachycardia [A:SICK SINUS SYNDROME] <input type="checkbox"/> Sick Sinus Syndrome [A:PREMATURE ATRIAL COMPLEXES] <input type="checkbox"/> Premature Atrial Complexes [A:PREMATURE VENTRICULAR COMPLEXES] <input type="checkbox"/> Premature Ventricular Complexes [A:Q AXIS LEFT AXIS DEVIATION] <input type="checkbox"/> Q Axis, Left Axis Deviation [A:LEFT ATRIAL ABNORMALITY] <input type="checkbox"/> Left Atrial Abnormality [A:LEFT VENTRICULAR HYPERTROPHY] <input type="checkbox"/> Left Ventricular Hypertrophy [A:ATRIAL FIBRILLATION] <input type="checkbox"/> Atrial Fibrillation [A:ATRIAL PACING] <input type="checkbox"/> Atrial Pacing [A:VENTRICULAR PACING] <input type="checkbox"/> Ventricular Pacing [A:ATRIAL VENTRICULAR PACING] <input type="checkbox"/> Atrial Ventricular Pacing [A:1ST DEGREE A-V BLOCK] <input type="checkbox"/> 1st Degree A-V Block [A:2ND DEGREE A-V BLOCK TYPE I] <input type="checkbox"/> 2nd Degree A-V Block Type I [A:2ND DEGREE A-V BLOCK TYPE II] <input type="checkbox"/> 2nd Degree A-V Block Type II [A:3RD DEGREE A-V BLOCK] <input type="checkbox"/> 3rd Degree A-V Block [A:LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Left Bundle Branch Block [A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Left Bundle Branch Block [A:LEFT ANTERIOR HEMIBLOCK] <input type="checkbox"/> Left Anterior Hemiblock [A:LEFT POSTERIOR HEMIBLOCK] <input type="checkbox"/> Left Posterior Hemiblock [A:RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Right Bundle Branch Block [A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Right Bundle Branch Block [A:INTRAVENTRICULAR CONDUCTION DELAY] <input type="checkbox"/> Intraventricular Conduction Delay [A:ANTEROSEPTAL INFARCT PATTERN] <input type="checkbox"/> Anteroseptal Infarct Pattern [A:ANTEROLATERAL INFARCT PATTERN] <input type="checkbox"/> Anterolateral Infarct Pattern [A:LATERAL INFARCT PATTERN] <input type="checkbox"/> Lateral Infarct Pattern [A:INFERIOR INFARCT PATTERN] <input type="checkbox"/> Inferior Infarct Pattern [A:OTHER, SPECIFY] <input type="checkbox"/> [txtABNOTH2] Other, specify <div><div>A128</div></div>
20.* ✓	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	[IstCHANGE1] [A:NO SIGNIFICANT WORSENING FROM BASELINE] <input type="radio"/> No significant worsening from baseline [A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE] <input type="radio"/> [txtCHANGE1] Clinically significant worsening from baseline, specify <div><div>A128</div></div>
12-lead Electrocardiogram - 2 Hours Postdose [sct2H]		

21.* ✓	Time performed [Time performed]	[dtmASS_T3] (hh:mm) Req <input type="button" value="v"/> : Req <input type="button" value="v"/> 24-hour clock
22.* ✓	Rhythm [Rhythm]	[IstRHYTM3] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
23.* ✓	Ventricular rate [Ventricular rate]	[numVR3] N3 <input type="text"/> bpm ^[b]
24.* ✓	PR interval [PR]	[numPR3] N3 <input type="text"/> msec ^[b]
25.* ✓	QRS duration [QRS]	[numQRS3] N3 <input type="text"/> msec ^[b]
26.* ✓	QT interval [QT]	[numQT3] N3 <input type="text"/> msec ^[b]
27.* ✓	QTc interval [QTc]	[numQTCF3] N3 <input type="text"/> msec ^[b]
28.* ✓	Overall interpretation [Overall interpretation]	[IstOVERALLINT3] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL, NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL, CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
29.* ✓	If abnormal, please specify by checking all that apply [Abnormal]	[IstABN3] [A: SINUS BRADYCARDIA] <input type="checkbox"/> Sinus Bradycardia [A: SINUS TACHYCARDIA] <input type="checkbox"/> Sinus Tachycardia [A: ATRIAL TACHYCARDIA] <input type="checkbox"/> Atrial Tachycardia [A: VENTRICULAR TACHYCARDIA] <input type="checkbox"/> Ventricular Tachycardia [A: SICK SINUS SYNDROME] <input type="checkbox"/> Sick Sinus Syndrome [A: PREMATURE ATRIAL COMPLEXES] <input type="checkbox"/> Premature Atrial Complexes [A: PREMATURE VENTRICULAR COMPLEXES] <input type="checkbox"/> Premature Ventricular Complexes [A: Q AXIS LEFT AXIS DEVIATION] <input type="checkbox"/> Q Axis, Left Axis Deviation [A: LEFT ATRIAL ABNORMALITY] <input type="checkbox"/> Left Atrial Abnormality [A: LEFT VENTRICULAR HYPERTROPHY] <input type="checkbox"/> Left Ventricular Hypertrophy [A: ATRIAL FIBRILLATION] <input type="checkbox"/> Atrial Fibrillation [A: ATRIAL PACING] <input type="checkbox"/> Atrial Pacing [A: VENTRICULAR PACING] <input type="checkbox"/> Ventricular Pacing [A: ATRIAL VENTRICULAR PACING] <input type="checkbox"/> Atrial Ventricular Pacing [A: 1ST DEGREE A-V BLOCK] <input type="checkbox"/> 1st Degree A-V Block [A: 2ND DEGREE A-V BLOCK TYPE I] <input type="checkbox"/> 2nd Degree A-V Block Type I [A: 2ND DEGREE A-V BLOCK TYPE II] <input type="checkbox"/> 2nd Degree A-V Block Type II [A: 3RD DEGREE A-V BLOCK] <input type="checkbox"/> 3rd Degree A-V Block [A: LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Left Bundle Branch Block [A: INCOMPLETE LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Left Bundle Branch Block [A: LEFT ANTERIOR HEMIBLOCK] <input type="checkbox"/> Left Anterior Hemiblock [A: LEFT POSTERIOR HEMIBLOCK] <input type="checkbox"/> Left Posterior Hemiblock [A: RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Right Bundle Branch Block [A: INCOMPLETE RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Right Bundle Branch Block [A: INTRAVENTRICULAR CONDUCTION DELAY] <input type="checkbox"/> Intraventricular Conduction Delay [A: ANTEROSEPTAL INFARCT PATTERN] <input type="checkbox"/> Anteroseptal Infarct Pattern [A: ANTEROLATERAL INFARCT PATTERN] <input type="checkbox"/> Anterolateral Infarct Pattern [A: LATERAL INFARCT PATTERN] <input type="checkbox"/> Lateral Infarct Pattern [A: INFERIOR INFARCT PATTERN] <input type="checkbox"/> Inferior Infarct Pattern [A: OTHER, SPECIFY] <input type="checkbox"/> [txtABNOTH3] Other, specify <div>A128</div>
30.* ✓	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	[IstCHANGE2] [A: NO SIGNIFICANT WORSENING FROM BASELINE] <input type="radio"/> No significant worsening from baseline [A: CLINICALLY SIGNIFICANT WORSENING FROM BASELINE] <input type="radio"/> [txtCHANGE2] Clinically significant worsening from baseline, specify <div>A128</div>
12-lead Electrocardiogram - 4 Hours Postdose [sct4H]		
31.*	Time performed	[dtmASS_T4] (hh:mm)

✓	[Time performed]	Req <div></div> : Req <div></div> 24-hour clock
32.* ✓	Rhythm [Rhythm]	<div>[IstRHYTM4]</div> <div>[A:NORMAL]</div> <div><div></div>Normal</div> <div>[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]</div> <div><div></div>Abnormal, Not Clinically Significant</div> <div>[A:ABNORMAL CLINICALLY SIGNIFICANT]</div> <div><div></div>Abnormal, Clinically Significant</div>
33.* ✓	Ventricular rate [Ventricular rate]	<div>[numVR4]</div> <div>N3</div> bpm ^[b]
34.* ✓	PR interval [PR]	<div>[numPR4]</div> <div>N3</div> msec ^[b]
35.* ✓	QRS duration [QRS]	<div>[numQRS4]</div> <div>N3</div> msec ^[b]
36.* ✓	QT interval [QT]	<div>[numQT4]</div> <div>N3</div> msec ^[b]
37.* ✓	QTc interval [QTc]	<div>[numQTCF4]</div> <div>N3</div> msec ^[b]
38.* ✓	Overall interpretation [Overall interpretation]	<div>[IstOVERALLINT4]</div> <div>[A:NORMAL]</div> <div><div></div>Normal</div> <div>[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]</div> <div><div></div>Abnormal, Not Clinically Significant</div> <div>[A:ABNORMAL, CLINICALLY SIGNIFICANT]</div> <div><div></div>Abnormal, Clinically Significant</div>
39. ✓	If abnormal, please specify by checking all that apply [Abnormal]	<div>[IstABN4]</div> <div>[A:SINUS BRADYCARDIA]</div> <div><div></div>Sinus Bradycardia</div> <div>[A:SINUS TACHYCARDIA]</div> <div><div></div>Sinus Tachycardia</div> <div>[A:ATRIAL TACHYCARDIA]</div> <div><div></div>Atrial Tachycardia</div> <div>[A:VENTRICULAR TACHYCARDIA]</div> <div><div></div>Ventricular Tachycardia</div> <div>[A:SICK SINUS SYNDROME]</div> <div><div></div>Sick Sinus Syndrome</div> <div>[A:PREMATURE ATRIAL COMPLEXES]</div> <div><div></div>Premature Atrial Complexes</div> <div>[A:PREMATURE VENTRICULAR COMPLEXES]</div> <div><div></div>Premature Ventricular Complexes</div> <div>[A:Q AXIS LEFT AXIS DEVIATION]</div> <div><div></div>Q Axis, Left Axis Deviation</div> <div>[A:LEFT ATRIAL ABNORMALITY]</div> <div><div></div>Left Atrial Abnormality</div> <div>[A:LEFT VENTRICULAR HYPERTROPHY]</div> <div><div></div>Left Ventricular Hypertrophy</div> <div>[A:ATRIAL FIBRILLATION]</div> <div><div></div>Atrial Fibrillation</div> <div>[A:ATRIAL PACING]</div> <div><div></div>Atrial Pacing</div> <div>[A:VENTRICULAR PACING]</div> <div><div></div>Ventricular Pacing</div> <div>[A:ATRIAL VENTRICULAR PACING]</div> <div><div></div>Atrial Ventricular Pacing</div> <div>[A:1ST DEGREE A-V BLOCK]</div> <div><div></div>1st Degree A-V Block</div> <div>[A:2ND DEGREE A-V BLOCK TYPE I]</div> <div><div></div>2nd Degree A-V Block Type I</div> <div>[A:2ND DEGREE A-V BLOCK TYPE II]</div> <div><div></div>2nd Degree A-V Block Type II</div> <div>[A:3RD DEGREE A-V BLOCK]</div> <div><div></div>3rd Degree A-V Block</div> <div>[A:LEFT BUNDLE BRANCH BLOCK]</div> <div><div></div>Left Bundle Branch Block</div> <div>[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]</div> <div><div></div>Incomplete Left Bundle Branch Block</div> <div>[A:LEFT ANTERIOR HEMIBLOCK]</div> <div><div></div>Left Anterior Hemiblock</div> <div>[A:LEFT POSTERIOR HEMIBLOCK]</div> <div><div></div>Left Posterior Hemiblock</div> <div>[A:RIGHT BUNDLE BRANCH BLOCK]</div> <div><div></div>Right Bundle Branch Block</div> <div>[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]</div> <div><div></div>Incomplete Right Bundle Branch Block</div> <div>[A:INTRAVENTRICULAR CONDUCTION DELAY]</div> <div><div></div>Intraventricular Conduction Delay</div> <div>[A:ANTEROSEPTAL INFARCT PATTERN]</div> <div><div></div>Anteroseptal Infarct Pattern</div> <div>[A:ANTEROLATERAL INFARCT PATTERN]</div> <div><div></div>Anterolateral Infarct Pattern</div> <div>[A:LATERAL INFARCT PATTERN]</div> <div><div></div>Lateral Infarct Pattern</div> <div>[A:INFERIOR INFARCT PATTERN]</div> <div><div></div>Inferior Infarct Pattern</div> <div>[A:OTHER, SPECIFY]</div> <div><div></div>[txtABNOTH4]</div> <div>Other, specify</div> <div>A128</div>
40.* ✓	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	<div>[IstCHANGE3]</div> <div>[A:NO SIGNIFICANT WORSENING FROM BASELINE]</div> <div><div></div>No significant worsening from baseline</div> <div>[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]</div> <div><div></div>[txtCHANGE3]</div> <div>Clinically significant worsening from baseline, specify</div> <div>A128</div>
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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	IstRHYTM, IstRHYTM2, IstRHYTM3, IstRHYTM4
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	IstOVERALLINT, IstOVERALLINT2, IstOVERALLINT3, IstOVERALLINT4
			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	IstABN1, IstABN2, IstABN3, IstABN4
			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	IstCHANGE1
			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	IstCHANGE2
			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	IstCHANGE3
			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
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - 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
IstOVERALLINT2	LSTOVERALLINT2_C	VARCHAR2
	LSTOVERALLINT2	VARCHAR2
	LSTOVERALLINT2_ND	VARCHAR2
IstABN2	LSTABN2_ND	VARCHAR2
IstABN2 - Sinus Bradycardia	*LSTABN2_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNSINUSBRADYCARDIA	VARCHAR2
IstABN2 - Sinus Tachycardia	*LSTABN2_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNSINUSTACHYCARDIA	VARCHAR2
IstABN2 - Atrial Tachycardia	*LSTABN2_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNATRIALTACHYCARDIA	VARCHAR2
IstABN2 - Ventricular Tachycardia	*LSTABN2_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN2_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
IstABN2 - Sick Sinus Syndrome	*LSTABN2_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN2_CITMABNSICKSINUSSYNDROME	VARCHAR2
IstABN2 - Premature Atrial Complexes	*LSTABN2_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN2_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
IstABN2 - Premature Ventricular Complexes	*LSTABN2_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN2_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
IstABN2 - Q Axis, Left Axis Deviation	*LSTABN2_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN2_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
IstABN2 - Left Atrial Abnormality	*LSTABN2_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN2_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
IstABN2 - Left Ventricular Hypertrophy	*LSTABN2_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN2_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
IstABN2 - Atrial Fibrillation	*LSTABN2_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN2_CITMABNATRIALFIBRILLATION	VARCHAR2
IstABN2 - Atrial Pacing	*LSTABN2_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN2_CITMABNATRIALPACING	VARCHAR2
IstABN2 - Ventricular Pacing	*LSTABN2_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN2_CITMABNVENTRICULARPACING	VARCHAR2
IstABN2 - Atrial Ventricular Pacing	*LSTABN2_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN2_CITMABNATRIALVENTRICULARPACING	VARCHAR2
IstABN2 - 1st Degree A-V Block	*LSTABN2_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN2_CITMABN1STDEGREEAVBLOCK	VARCHAR2
IstABN2 - 2nd Degree A-V Block Type I	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
IstABN2 - 2nd Degree A-V Block Type II	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN2_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
IstABN2 - 3rd Degree A-V Block	*LSTABN2_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN2_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
IstABN2 - Left Bundle Branch Block	*LSTABN2_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN2 - Incomplete Left Bundle Branch Block	*LSTABN2_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN2 - Left Anterior Hemiblock	*LSTABN2_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN2 - Left Posterior Hemiblock	*LSTABN2_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN2 - Right Bundle Branch Block	*LSTABN2_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN2 - Incomplete Right Bundle Branch Block	*LSTABN2_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2

	*LSTABN2_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN2 - Intraventricular Conduction Delay	*LSTABN2_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN2_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN2 - Anteroseptal Infarct Pattern	*LSTABN2_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
IstABN2 - Anterolateral Infarct Pattern	*LSTABN2_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
IstABN2 - Lateral Infarct Pattern	*LSTABN2_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNLATERALINFARCTPATTERN	VARCHAR2
IstABN2 - Inferior Infarct Pattern	*LSTABN2_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
IstABN2 - Other, specify	LSTABN2_TXTABNOTH2_C	VARCHAR2
	LSTABN2_TXTABNOTH2	VARCHAR2
IstABN2 - txtABNOTH2	TXTABNOTH2	VARCHAR2
IstCHANGE1	LSTCHANGE1_C	VARCHAR2
	LSTCHANGE1	VARCHAR2
	LSTCHANGE1_ND	VARCHAR2
IstCHANGE1 - txtCHANGE1	TXTCHANGE1	VARCHAR2
dtmASS_T3	DTMASS_T3	DATE
	DTMASS_T3_TMS	VARCHAR2
	DTMASS_T3_ND	VARCHAR2
IstRHYTM3	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
IstOVERALLINT3	LSTOVERALLINT3_C	VARCHAR2
	LSTOVERALLINT3	VARCHAR2
	LSTOVERALLINT3_ND	VARCHAR2
IstABN3	LSTABN3_ND	VARCHAR2
IstABN3 - Sinus Bradycardia	*LSTABN3_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNSINUSBRADYCARDIA	VARCHAR2
IstABN3 - Sinus Tachycardia	*LSTABN3_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNSINUSTACHYCARDIA	VARCHAR2
IstABN3 - Atrial Tachycardia	*LSTABN3_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNATRIALTACHYCARDIA	VARCHAR2
IstABN3 - Ventricular Tachycardia	*LSTABN3_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
IstABN3 - Sick Sinus Syndrome	*LSTABN3_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN3_CITMABNSICKSINUSSYNDROME	VARCHAR2

IstABN3 - Premature Atrial Complexes	*LSTABN3_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN3_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
IstABN3 - Premature Ventricular Complexes	*LSTABN3_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN3_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
IstABN3 - Q Axis, Left Axis Deviation	*LSTABN3_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN3_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
IstABN3 - Left Atrial Abnormality	*LSTABN3_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN3_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
IstABN3 - Left Ventricular Hypertrophy	*LSTABN3_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN3_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
IstABN3 - Atrial Fibrillation	*LSTABN3_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN3_CITMABNATRIALFIBRILLATION	VARCHAR2
IstABN3 - Atrial Pacing	*LSTABN3_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN3_CITMABNATRIALPACING	VARCHAR2
IstABN3 - Ventricular Pacing	*LSTABN3_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN3_CITMABNVENTRICULARPACING	VARCHAR2
IstABN3 - Atrial Ventricular Pacing	*LSTABN3_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN3_CITMABNATRIALVENTRICULARPACING	VARCHAR2
IstABN3 - 1st Degree A-V Block	*LSTABN3_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN3_CITMABN1STDEGREEAVBLOCK	VARCHAR2
IstABN3 - 2nd Degree A-V Block Type I	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
IstABN3 - 2nd Degree A-V Block Type II	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
IstABN3 - 3rd Degree A-V Block	*LSTABN3_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN3_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
IstABN3 - Left Bundle Branch Block	*LSTABN3_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN3 - Incomplete Left Bundle Branch Block	*LSTABN3_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN3 - Left Anterior Hemiblock	*LSTABN3_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN3 - Left Posterior Hemiblock	*LSTABN3_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN3 - Right Bundle Branch Block	*LSTABN3_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN3 - Incomplete Right Bundle Branch Block	*LSTABN3_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN3 - Intraventricular Conduction Delay	*LSTABN3_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN3_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN3 - Anteroseptal Infarct Pattern	*LSTABN3_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN3_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
IstABN3 - Anterolateral Infarct Pattern	*LSTABN3_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN3_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
IstABN3 - Lateral Infarct Pattern	*LSTABN3_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN3_CITMABNLATERALINFARCTPATTERN	VARCHAR2
IstABN3 - Inferior Infarct Pattern	*LSTABN3_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN3_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
IstABN3 - Other, specify	LSTABN3_TXTABNOTH3_C	VARCHAR2
	LSTABN3_TXTABNOTH3	VARCHAR2
IstABN3 - txtABNOTH3	TXTABNOTH3	VARCHAR2
IstCHANGE2	LSTCHANGE2_C	VARCHAR2
	LSTCHANGE2	VARCHAR2

	LSTCHANGE2_ND	VARCHAR2
lstCHANGE2 - txtCHANGE2	TXCHANGE2	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

IstABN4 - Atrial Ventricular Pacing	*LSTABN4_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN4_CITMABNATRIALVENTRICULARPACING	VARCHAR2
IstABN4 - 1st Degree A-V Block	*LSTABN4_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN4_CITMABN1STDEGREEAVBLOCK	VARCHAR2
IstABN4 - 2nd Degree A-V Block Type I	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
IstABN4 - 2nd Degree A-V Block Type II	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
IstABN4 - 3rd Degree A-V Block	*LSTABN4_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN4_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
IstABN4 - Left Bundle Branch Block	*LSTABN4_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN4 - Incomplete Left Bundle Branch Block	*LSTABN4_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN4 - Left Anterior Hemiblock	*LSTABN4_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN4 - Left Posterior Hemiblock	*LSTABN4_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN4 - Right Bundle Branch Block	*LSTABN4_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN4 - Incomplete Right Bundle Branch Block	*LSTABN4_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN4 - Intraventricular Conduction Delay	*LSTABN4_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN4_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN4 - Anteroseptal Infarct Pattern	*LSTABN4_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
IstABN4 - Anterolateral Infarct Pattern	*LSTABN4_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
IstABN4 - Lateral Infarct Pattern	*LSTABN4_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNLATERALINFARCTPATTERN	VARCHAR2
IstABN4 - Inferior Infarct Pattern	*LSTABN4_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
IstABN4 - Other, specify	LSTABN4_TXTABNOTH4_C	VARCHAR2
	LSTABN4_TXTABNOTH4	VARCHAR2
IstABN4 - txtABNOTH4	TXTABNOTH4	VARCHAR2
IstCHANGE3	LSTCHANGE3_C	VARCHAR2
	LSTCHANGE3	VARCHAR2
	LSTCHANGE3_ND	VARCHAR2
IstCHANGE3 - 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]

[IstASSDT]
[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	IstASSDT
			Other	OTHER	citmDateOther_Other	

RDE Analytics: RD_FRMWBCLT		
Data Variable RefName	RD Column Name	Column Data Type
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - 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]

[IstASSDT]
[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]

[IstSAMPLE_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]

[IstSAMPLE_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]

[IstSAMPLE_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]

[IstSAMPLE_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]

[IstSAMPLE_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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clActTimeNotCol	String		Actual Time	ACTUAL TIME	citmActTimeNotCol_ActTime	IstSAMPLE_PRE, IstSAMPLE_30MIN, IstSAMPLE_2H, IstSAMPLE_4H, IstSAMPLE_8H
			Not collected	NOT COLLECTED	citmActTimeNotCol_NotCol	

RDE Analytics: RD_FRMPKBLD		
Data Variable RefName	RD Column Name	Column Data Type
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
IstSAMPLE_PRE	LSTSAMPLE_PRE_C	VARCHAR2
	LSTSAMPLE_PRE	VARCHAR2
	LSTSAMPLE_PRE_ND	VARCHAR2
IstSAMPLE_PRE - dtmSAMPLE_T_PRE	DTMSAMPLE_T_PRE	DATE
	DTMSAMPLE_T_PRE_TMS	VARCHAR2
IstSAMPLE_30MIN	LSTSAMPLE_30MIN_C	VARCHAR2
	LSTSAMPLE_30MIN	VARCHAR2
	LSTSAMPLE_30MIN_ND	VARCHAR2
IstSAMPLE_30MIN - dtmSAMPLE_T_30MIN	DTMSAMPLE_T_30MIN	DATE
	DTMSAMPLE_T_30MIN_TMS	VARCHAR2

IstSAMPLE_2H	LSTSAMPLE_2H_C	VARCHAR2
	LSTSAMPLE_2H	VARCHAR2
	LSTSAMPLE_2H_ND	VARCHAR2
IstSAMPLE_2H - dtmSAMPLE_T_2H	DTMSAMPLE_T_2H	DATE
	DTMSAMPLE_T_2H_TMS	VARCHAR2
IstSAMPLE_4H	LSTSAMPLE_4H_C	VARCHAR2
	LSTSAMPLE_4H	VARCHAR2
	LSTSAMPLE_4H_ND	VARCHAR2
IstSAMPLE_4H - dtmSAMPLE_T_4H	DTMSAMPLE_T_4H	DATE
	DTMSAMPLE_T_4H_TMS	VARCHAR2
IstSAMPLE_8H	LSTSAMPLE_8H_C	VARCHAR2
	LSTSAMPLE_8H	VARCHAR2
	LSTSAMPLE_8H_ND	VARCHAR2
IstSAMPLE_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]

[IstASSDT]
[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]

[IstLANG]
[A: LANGUAGE] ☐ [IstLANG_Q]
Language | [clLANG_Q]
[A: OTHER] ☐ [txtLANGO]
Other, please specify
A100

EQ-5D [sctEQ5D]

4.*
✓

Mobility
[Mobility]

[IstMOB]
[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]

[IstSELF]
[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]

[IstUSACT]
[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]

[IstPAIN]
[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]

[IstANX]
[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 I tem RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	IstASSDT
			Other	OTHER	citmDateOther_Other	
clLANG	String		Language of the questionnaire	LANGUAGE	citmLANG_LANGUAGE	IstLANG
			Other, please specify	OTHER	citmLANG_OTHER	
clLANG_Q	String		Bulgarian	BULGARIAN	citmLANG_BUL	IstLANG_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	IstMOB
			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	IstSELF
			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	IstUSACT
			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	IstPAIN
			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	IstANX
			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
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
IstLANG	LSTLANG_C	VARCHAR2
	LSTLANG	VARCHAR2
	LSTLANG_ND	VARCHAR2
IstLANG - IstLANG_Q	LSTLANG_Q_C	VARCHAR2
	LSTLANG_Q	VARCHAR2
IstLANG - txtLANGO	TXTLANGO	VARCHAR2
IstMOB	LSTMOB_C	VARCHAR2
	LSTMOB	VARCHAR2
	LSTMOB_ND	VARCHAR2
IstSELF	LSTSELF_C	VARCHAR2
	LSTSELF	VARCHAR2
	LSTSELF_ND	VARCHAR2
IstUSACT	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]	<div>[IstASSDT] [A: SAME DATE] <input type="radio"/> Same date as visit date [A: OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)</div>
2.* ✓	Time performed [Time performed]	<div>[dtmASS_T] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock</div>
3.* ✓	Language of the questionnaire [Language of the questionnaire]	<div>[IstLANG] [A: LANGUAGE] <input type="radio"/> [IstLANG_Q] Language [cILANG_Q] <input type="text"/> [A: OTHER] <input type="radio"/> [txtLANGO] Other, please specify <input type="text" value="A100"/></div>

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]	<div>[IstSWEL] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>
5.* ✓	2. ... I had pain in my joints [Joints pain]	<div>[IstJOINTS] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>
6.* ✓	3. ... it was painful for me to move [Painful to move]	<div>[IstMOVE] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>
7.* ✓	4. ... I had difficulty walking as far as I wanted to [Difficult walking]	<div>[IstWALK] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>
8.* ✓	5. ... I needed more time to get ready because of my condition [More time needed]	<div>[IstTIME] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>

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]	<div>[IstBURDEN] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>
10.* ✓	2. ... my hemophilia made me angry [Angry]	<div>[IstANGRY] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>
11.* ✓	3. ... I was worried because of my hemophilia [Worried]	<div>[IstWORRIED] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>
12.* ✓	4. ... I felt excluded [Excluded]	<div>[IstEXCLUDED] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>

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

In the past 4 weeks ...

13.* ✓	1. ... I envied healthy people my age [Envy]	<div>[IstENVY] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>
14.* ✓	2. ... I felt comfortable with my body [Comfortable]	<div>[IstCOMFORT] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>
15.* ✓	3. ... hemophilia made my life more difficult [More difficult]	<div>[IstDIFFICULT] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>
16.* ✓	4. ... I felt different from others because of my hemophilia [Different]	<div>[IstDIFFERENT] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>
17.* ✓	5. ... I was able not to think all the time about my hemophilia [Think about]	<div>[IstTHINK] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time</div>

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]	<div>[IstAVOID] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time [A: NOT APPLICABLE] <input type="radio"/> Not applicable</div>
19.* ✓	2. ... I had to avoid sports like football [Avoid football]	<div>[IstFOOTBALL] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time [A: NOT APPLICABLE] <input type="radio"/> Not applicable</div>
20.* ✓	3. ... I played sports just as much as others [As others]	<div>[IstPLAYED] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time [A: NOT APPLICABLE] <input type="radio"/> Not applicable</div>
	4. ... I didn't have the freedom to travel where I wanted	<div>[IstFREEDOM]</div>

21.* ✓	[Travel]	<div>[A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time [A:NOT APPLICABLE] <input type="radio"/> Not applicable</div>
22.* ✓	5. ... it was necessary for me to plan everything in advance [Plan in advance]	<div>[IstADVANCE] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time [A:NOT APPLICABLE] <input type="radio"/> Not applicable</div>
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]	<div>[IstWORK] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time [A:NOT APPLICABLE] <input type="radio"/> Not applicable</div>
24.* ✓	2. ... I was able to work/study like healthy colleagues [Healthy]	<div>[IstHEALTHY] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time [A:NOT APPLICABLE] <input type="radio"/> Not applicable</div>
25.* ✓	3. ... my everyday work/school activities were jeopardized by my hemophilia [Jeopardized]	<div>[IstJEOPARD] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time [A:NOT APPLICABLE] <input type="radio"/> Not applicable</div>
26.* ✓	4. ... I found it difficult to pay attention at work/school because I was in pain [Attention]	<div>[IstATTENTION] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time [A:NOT APPLICABLE] <input type="radio"/> Not applicable</div>
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]	<div>[IstEARLY] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
28.* ✓	2. ... I was able to tell whether or not I was bleeding [Bleeding]	<div>[IstBLEEDING] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
29.* ✓	3. ... I was able to control my bleeds [Control bleeds]	<div>[IstCONTROL] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
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]	<div>[IstDEPENDENT] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
31.* ✓	2. ... I was dependent on physicians for the treatment of my hemophilia [Dependent on physicians]	<div>[IstTREATMENT] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
32.* ✓	3. ... I was annoyed about the amount of time spent having the injections [Annoyed]	<div>[IstANNOYED] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
33.* ✓	4. ... I felt the injections interrupted my daily activities [Daily activities interrupted]	<div>[IstINTERRUPTED] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
34.* ✓	5. ... I was afraid of complications [Afraid]	<div>[IstAFRAID] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
35.* ✓	6. ... I had problems with how my treatment was administered [Problems with administration]	<div>[IstPROBLEMS] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
36.* ✓	7. ... I was afraid that in case of emergency, other doctors wouldn't know how to treat hemophilia [Emergency]	<div>[IstTREAT] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
37.* ✓	8. ... I was satisfied with the hemophilia center [Satisfied]	<div>[IstSATISFIED] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
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]	<div>[IstTHINKING] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
39.* ✓	2. ... I have been expecting that things will get better in the future [Better in future]	<div>[IstBETTER] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
40.* ✓	3. ... I have been worrying that my condition is worsening [Worsening condition]	<div>[IstWORSENING] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
41.* ✓	4. ... my life plans have been influenced by my hemophilia [Life plans]	<div>[IstLIFE] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
42.* ✓	5. ... I have been afraid that I will need a wheelchair [Wheelchair]	<div>[IstWHEELCHAIR] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time</div>
9. The next questions are about hemophilia and your FAMILY PLANNING [sctFAMILY]		
Recently ...		
43.* ✓	1. ... I have had difficulties having children [Difficult having children]	<div>[IstCHILDREN] [A:NEVER] <input type="radio"/> Never [A:RARELY] <input type="radio"/> Rarely [A:SOMETIMES] <input type="radio"/> Sometimes [A:OFTEN] <input type="radio"/> Often [A:ALL THE TIME] <input type="radio"/> All the time [A:NOT APPLICABLE] <input type="radio"/> Not applicable</div>
	2. ... I have been afraid that I cannot have children	

44.* ✓	[Afraid cannot have children]	[IstAFRAIDCHILD] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time [A: NOT APPLICABLE] <input type="radio"/> 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]	[IstNOCARE] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time [A: NOT APPLICABLE] <input type="radio"/> Not applicable
46.* ✓	4. ... I worry about not being able to raise a family [Worry]	[IstWORRY] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time [A: NOT APPLICABLE] <input type="radio"/> 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]	[IstDATE] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time
48.* ✓	2. ... I have been insecure in my intimate relationships because of my hemophilia [Insecure]	[IstINSECURE] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> All the time
49.* ✓	3. ... I haven't been able to have a normal relationship because of my hemophilia [No normal relationship]	[IstNOREL] [A: NEVER] <input type="radio"/> Never [A: RARELY] <input type="radio"/> Rarely [A: SOMETIMES] <input type="radio"/> Sometimes [A: OFTEN] <input type="radio"/> Often [A: ALL THE TIME] <input type="radio"/> 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 I tem RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	IstASSDT
			Other	OTHER	citmDateOther_Other	
clLANG	String		Language of the questionnaire	LANGUAGE	citmLANG_LANGUAGE	IstLANG
			Other, please specify	OTHER	citmLANG_OTHER	
clLANG_Q	String		Bulgarian	BULGARIAN	citmLANG_BUL	IstLANG_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	IstSWEL, IstJOINTS, IstMOVE, IstWALK, IstTIME, IstBURDEN, IstANGRY, IstWORRIED, IstEXCLUDED, IstENVY, IstCOMFORT, IstDIFFICULT, IstDIFFERENT, IstTHINK, IstEARLY, IstBLEEDING, IstCONTROL, IstDEPENDENT, IstTREATMENT, IstANNOYED,
			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	IstAVOID, IstFOOTBALL, IstPLAYED, IstFREEDOM, IstADVANCE, IstWORK, IstHEALTHY,
			Rarely	RARELY	citmHAEM2_Rarely	
			Sometimes	SOMETIMES	citmHAEM2_Sometimes	

			Often	OFTEN	citmHAEM2_Often	IstJEOPARD, IstATTENTION, IstCHILDREN, IstAFRAIDCHILD, IstNOCARE, IstWORRY
			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
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
IstLANG	LSTLANG_C	VARCHAR2
	LSTLANG	VARCHAR2
	LSTLANG_ND	VARCHAR2
IstLANG - IstLANG_Q	LSTLANG_Q_C	VARCHAR2
	LSTLANG_Q	VARCHAR2
IstLANG - txtLANGO	TXTLANGO	VARCHAR2
IstSWEL	LSTSWEL_C	VARCHAR2
	LSTSWEL	VARCHAR2
	LSTSWEL_ND	VARCHAR2
IstJOINTS	LSTJOINTS_C	VARCHAR2
	LSTJOINTS	VARCHAR2
	LSTJOINTS_ND	VARCHAR2
IstMOVE	LSTMOVE_C	VARCHAR2
	LSTMOVE	VARCHAR2
	LSTMOVE_ND	VARCHAR2
IstWALK	LSTWALK_C	VARCHAR2
	LSTWALK	VARCHAR2
	LSTWALK_ND	VARCHAR2
IstTIME	LSTTIME_C	VARCHAR2
	LSTTIME	VARCHAR2
	LSTTIME_ND	VARCHAR2
IstBURDEN	LSTBURDEN_C	VARCHAR2
	LSTBURDEN	VARCHAR2
	LSTBURDEN_ND	VARCHAR2
IstANGRY	LSTANGRY_C	VARCHAR2
	LSTANGRY	VARCHAR2
	LSTANGRY_ND	VARCHAR2
IstWORRIED	LSTWORRIED_C	VARCHAR2
	LSTWORRIED	VARCHAR2
	LSTWORRIED_ND	VARCHAR2
IstEXCLUDED	LSTEXCLUDED_C	VARCHAR2
	LSTEXCLUDED	VARCHAR2
	LSTEXCLUDED_ND	VARCHAR2
IstENVY	LSTENVY_C	VARCHAR2
	LSTENVY	VARCHAR2
	LSTENVY_ND	VARCHAR2
IstCOMFORT	LSTCOMFORT_C	VARCHAR2
	LSTCOMFORT	VARCHAR2

	LSTCOMFORT_ND	VARCHAR2
IstDIFFICULT	LSTDIFFICULT_C	VARCHAR2
	LSTDIFFICULT	VARCHAR2
	LSTDIFFICULT_ND	VARCHAR2
IstDIFFERENT	LSTDIFFERENT_C	VARCHAR2
	LSTDIFFERENT	VARCHAR2
	LSTDIFFERENT_ND	VARCHAR2
IstTHINK	LSTTHINK_C	VARCHAR2
	LSTTHINK	VARCHAR2
	LSTTHINK_ND	VARCHAR2
IstAVOID	LSTAVOID_C	VARCHAR2
	LSTAVOID	VARCHAR2
	LSTAVOID_ND	VARCHAR2
IstFOOTBALL	LSTFOOTBALL_C	VARCHAR2
	LSTFOOTBALL	VARCHAR2
	LSTFOOTBALL_ND	VARCHAR2
IstPLAYED	LSTPLAYED_C	VARCHAR2
	LSTPLAYED	VARCHAR2
	LSTPLAYED_ND	VARCHAR2
IstFREEDOM	LSTFREEDOM_C	VARCHAR2
	LSTFREEDOM	VARCHAR2
	LSTFREEDOM_ND	VARCHAR2
IstADVANCE	LSTADVANCE_C	VARCHAR2
	LSTADVANCE	VARCHAR2
	LSTADVANCE_ND	VARCHAR2
IstWORK	LSTWORK_C	VARCHAR2
	LSTWORK	VARCHAR2
	LSTWORK_ND	VARCHAR2
IstHEALTHY	LSTHEALTHY_C	VARCHAR2
	LSTHEALTHY	VARCHAR2
	LSTHEALTHY_ND	VARCHAR2
IstJEOPARD	LSTJEOPARD_C	VARCHAR2
	LSTJEOPARD	VARCHAR2
	LSTJEOPARD_ND	VARCHAR2
IstATTENTION	LSTATTENTION_C	VARCHAR2
	LSTATTENTION	VARCHAR2
	LSTATTENTION_ND	VARCHAR2
IstEARLY	LSTEARLY_C	VARCHAR2
	LSTEARLY	VARCHAR2
	LSTEARLY_ND	VARCHAR2
IstBLEEDING	LSTBLEEDING_C	VARCHAR2
	LSTBLEEDING	VARCHAR2
	LSTBLEEDING_ND	VARCHAR2
IstCONTROL	LSTCONTROL_C	VARCHAR2
	LSTCONTROL	VARCHAR2
	LSTCONTROL_ND	VARCHAR2
IstDEPENDENT	LSTDEPENDENT_C	VARCHAR2
	LSTDEPENDENT	VARCHAR2
	LSTDEPENDENT_ND	VARCHAR2
IstTREATMENT	LSTTREATMENT_C	VARCHAR2
	LSTTREATMENT	VARCHAR2
	LSTTREATMENT_ND	VARCHAR2
IstANNOYED	LSTANNOYED_C	VARCHAR2

	LSTANNOYED	VARCHAR2
	LSTANNOYED_ND	VARCHAR2
IstINTERRUPTED	LSTINTERRUPTED_C	VARCHAR2
	LSTINTERRUPTED	VARCHAR2
	LSTINTERRUPTED_ND	VARCHAR2
IstAFRAID	LSTAFRAID_C	VARCHAR2
	LSTAFRAID	VARCHAR2
	LSTAFRAID_ND	VARCHAR2
IstPROBLEMS	LSTPROBLEMS_C	VARCHAR2
	LSTPROBLEMS	VARCHAR2
	LSTPROBLEMS_ND	VARCHAR2
IstTREAT	LSTTREAT_C	VARCHAR2
	LSTTREAT	VARCHAR2
	LSTTREAT_ND	VARCHAR2
IstSATISFIED	LSTSATISFIED_C	VARCHAR2
	LSTSATISFIED	VARCHAR2
	LSTSATISFIED_ND	VARCHAR2
IstTHINKING	LSTTHINKING_C	VARCHAR2
	LSTTHINKING	VARCHAR2
	LSTTHINKING_ND	VARCHAR2
IstBETTER	LSTBETTER_C	VARCHAR2
	LSTBETTER	VARCHAR2
	LSTBETTER_ND	VARCHAR2
IstWORSENING	LSTWORSENING_C	VARCHAR2
	LSTWORSENING	VARCHAR2
	LSTWORSENING_ND	VARCHAR2
IstLIFE	LSTLIFE_C	VARCHAR2
	LSTLIFE	VARCHAR2
	LSTLIFE_ND	VARCHAR2
IstWHEELCHAIR	LSTWHEELCHAIR_C	VARCHAR2
	LSTWHEELCHAIR	VARCHAR2
	LSTWHEELCHAIR_ND	VARCHAR2
IstCHILDREN	LSTCHILDREN_C	VARCHAR2
	LSTCHILDREN	VARCHAR2
	LSTCHILDREN_ND	VARCHAR2
IstAFRAIDCHILD	LSTAFRAIDCHILD_C	VARCHAR2
	LSTAFRAIDCHILD	VARCHAR2
	LSTAFRAIDCHILD_ND	VARCHAR2
IstNOCARE	LSTNOCARE_C	VARCHAR2
	LSTNOCARE	VARCHAR2
	LSTNOCARE_ND	VARCHAR2
IstWORRY	LSTWORRY_C	VARCHAR2
	LSTWORRY	VARCHAR2
	LSTWORRY_ND	VARCHAR2
IstDATE	LSTDATE_C	VARCHAR2
	LSTDATE	VARCHAR2
	LSTDATE_ND	VARCHAR2
IstINSECURE	LSTINSECURE_C	VARCHAR2
	LSTINSECURE	VARCHAR2
	LSTINSECURE_ND	VARCHAR2
IstNOREL	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?]	<div>[IstLABLFT]</div> <div>[A:CENTRAL] <input type="checkbox"/> Central lab</div> <div>[A:LOCAL] <input type="checkbox"/> Local lab</div> <div>[A:NOT APPLICABLE] <input type="checkbox"/> 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)</div>
2.* ✓	Date collected [Date performed]	<div>[IstASSDT]</div> <div>[A:SAME DATE] <input type="radio"/> Same date as visit date</div> <div>[A:OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)</div>
3.* ✓	Time performed [Time performed]	<div>[dtmASS_T] (hh:mm)</div> <div>Req <input type="text"/> : Req <input type="text"/> 24-hour clock</div>
4.* ✓	Was this conducted in the clinic or during a home visit? [Administration at clinic or home?]	<div>[IstADMHC]</div> <div>[A:CLINIC] <input type="radio"/> Clinic - administered by a healthcare professional</div> <div>[A:HOME] <input type="radio"/> Home - administered by a healthcare professional</div> <div>[A:HOMEPAT] <input type="radio"/> Home - administered by patient</div> <div>[A:HOMECARE] <input type="radio"/> Home - administered by caregiver</div> <div>[A:CLINICPAT] <input type="radio"/> Clinic - administered by patient</div> <div>[A:CLINICCARE] <input type="radio"/> Clinic - administered by caregiver</div>
5. ✓	Planned dose (weight based) [Planned dose (weight based)]	<div>[numADM]</div> <div><input type="text"/> x.xxx mg/kg</div>
6. ✓	Fixed dose [Fixed dose]	<div>[numADM2]</div> <div><input type="text"/> xxxx. mg</div>
7.* ✓	Type of dispensed kit [Type of dispensed kit]	<div>[IstKITTYPE]</div> <div>[A:VIAL] <input type="radio"/> Vial</div> <div>[A:PFS] <input type="radio"/> Pre-filled syringe (PFS)</div> <div>[A:NOT APPLICABLE] <input type="radio"/> Not applicable</div>
8.* ✓	Total volume administered at this visit [Volume administered]	<div>[numVOLADM]</div> <div><input type="text"/> xxxx. mL</div>
9.* ✓	Was the full dose successfully administered? [Dose administered?]	<div>[IstDOSEADM]</div> <div>[A:Y] <input type="radio"/> Yes</div> <div>[A:N] <input type="radio"/> [txtDOSEADMNO] No, provide the reason for partial dose <input type="text"/> A128</div>
10.* ✓	Injection site location [Injection site]	<div>[IstINJSITE]</div> <div>[A:RIGHT UPPER QUADRANT] <input type="radio"/> Right upper quadrant</div> <div>[A:LEFT UPPER QUADRANT] <input type="radio"/> Left upper quadrant</div> <div>[A:RIGHT LOWER QUADRANT] <input type="radio"/> Right lower quadrant</div> <div>[A:LEFT LOWER QUADRANT] <input type="radio"/> Left lower quadrant</div> <div>[A:RIGHT UPPER ARM HIGH] <input type="radio"/> Right upper arm high</div> <div>[A:LEFT UPPER ARM HIGH] <input type="radio"/> Left upper arm high</div> <div>[A:RIGHT UPPER ARM LOW] <input type="radio"/> Right upper arm low</div> <div>[A:LEFT UPPER ARM LOW] <input type="radio"/> Left upper arm low</div> <div>[A:RIGHT UPPER THIGH] <input type="radio"/> Right upper thigh</div> <div>[A:LEFT UPPER THIGH] <input type="radio"/> Left upper thigh</div> <div>[A:RIGHT LOWER THIGH] <input type="radio"/> Right lower thigh</div> <div>[A:LEFT LOWER THIGH] <input type="radio"/> Left lower thigh</div> <div>[A:OTHER] <input type="radio"/> [txtINJSITEOTH] Other site location <input type="text"/> A128</div>
11.* ✓	Was a 29 gauge needle used? [Was a 29 gauge needle used?]	<div>[IstNEEDLE]</div> <div>[A:Y] <input type="radio"/> Yes</div> <div>[A:N] <input type="radio"/> No</div>
12.* ✓	Was the Dose Injection associated with an Adverse Event? [Injection linked with AE?]	<div>[txtISRAE]</div> <div>[A:Y] <input type="radio"/> [cmpAE] Yes Please specify AE#(s) - as recorded on AE form [numAESEQ1] [numAESEQ2] [numAESEQ3] [numAESEQ4] [numAESEQ5] [numAESEQ6] <input type="text"/> N3 <input type="text"/> N3 <input type="text"/> N3 <input type="text"/> N3 <input type="text"/> N3 <input type="text"/> N3</div> <div>[A:N] <input type="radio"/> No</div>
13.	For office use only [hidden]	<div>[numEMAIL1]</div> <div><input type="text"/></div>

	[For office use only]	<div>N3</div>
14.	For office use only <i>[hidden]</i> [For office use only]	<div>[numEMAIL2]</div> <div>N3</div>
15.	For office use only <i>[hidden]</i> [For office use only]	<div>[numEMAIL3]</div> <div>N3</div>
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 I tem RefName	Data Variable RefName
clLABLFT	String		Central lab	CENTRAL	citmLABLFT_CENTRAL	IstLABLFT
			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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clADMHC	String		Clinic - administered by a healthcare professional	CLINIC	citmADMHC_CLINIC	IstADMHC
			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	IstKITTYPE
			Pre-filled syringe (PFS)	PFS	citmKITTYPE_PFS	
			Not applicable	NOT APPLICABLE	citmKITTYPE_NOTAPPLICABLE	
clYesNo	String		Yes	Y	citmYesNo_Y	IstDOSEADM, IstNEEDLE, txtISRAE
			No	N	citmYesNo_N	
clINJSITE	String		Right upper quadrant	RIGHT UPPER QUADRANT	citmINJSITE_RUQ	IstINJSITE
			Left upper quadrant	LIGHT UPPER QUADRANT	citmINJSITE_LUQ	
			Right lower quadrant	RIGHT LOWER QUADRANT	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
IstLABLFT	LSTLABLFT_ND	VARCHAR2
IstLABLFT - Central lab	*LSTLABLFT_CITMLABLFTCENTRAL_C	VARCHAR2
	*LSTLABLFT_CITMLABLFTCENTRAL	VARCHAR2
IstLABLFT - Local lab	LSTLABLFT_CITMLABLFTLOCAL_C	VARCHAR2
	LSTLABLFT_CITMLABLFTLOCAL	VARCHAR2
IstLABLFT - 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
IstASSDT	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	LSTDSEADM_C	VARCHAR2
	LSTDSEADM	VARCHAR2
	LSTDSEADM_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: 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]

[IstAEEND]
[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]

[IstAEINT]
[A:MILD] ☐ Mild
[A:MODERATE] ☐ Moderate
[A:SEVERE] ☐ Severe

6.*
✔

Relationship to ALN-AT3SC?
[Relationship to ALN-AT3SC]

[IstAEREL]
[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]

[IstAEREL2]
[A:VIAL] ☐ Vial
[A:PFS] ☐ PFS
[A:UNKNOWN] ☐ Unknown

8.*
✔

Action taken with ALN-AT3SC?
[Action taken]

[IstACT]
[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]

[IstAETRT]
[A:Y] ☐ Yes
[A:N] ☐ No

10.*
✔

Outcome
[Outcome]

[IstAEOUT]
[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?]


[IstAEINJ]
[A:Y] ☐ [IstSYMPREYN]
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?]

[IstAECI]
[A:Y] ☐ [IstAECIS]

		<div>Yes, please specify: [A: ISR] <input type="radio"/> Severe or serious ISRs, please complete the Supplemental Adverse Event of Clinical Interest form [A: LFT] <input type="radio"/> 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] <input type="radio"/> [IstTHROMBO] 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] <input type="radio"/> Confirmed thrombosis [A: SUSPECTED] <input type="radio"/> Suspected thrombosis [A: N] <input type="radio"/> No</div>
13.* ✓	Is this event an adverse event of Special Interest? If <u>Yes</u> , 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?]	<div>[IstAESI] [A: Y] <input type="radio"/> [IstAESIS] Yes, please specify [A: ISR] <input type="radio"/> Severe or serious ISRs, please complete the Supplemental Adverse Event of Special Interest form [A: LFT] <input type="radio"/> 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] <input type="radio"/> [IstTHROMBO2] 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] <input type="radio"/> Confirmed thrombosis [A: SUSPECTED] <input type="radio"/> Suspected thrombosis [A: IAR] <input type="radio"/> Systemic injection associated reactions (IARs), defined as hypersensitivity reactions which are related or possibly related to IMP [A: CHOLEC] <input type="radio"/> Cholecystitis [A: CHOLEL] <input type="radio"/> Cholelithiasis [A: N] <input type="radio"/> No</div>
Serious AE [sctAESER]		
14.* ✓	Is the AE serious? If <u>Yes</u> , 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]	<div>[IstAESER] [A: Y] <input type="radio"/> [IstDEATH] Yes Results in death? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No [IstTHREAT] Is life-threatening? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No [IstHOSPI] Requires in-patient hospitalization or prolongation of existing hospitalization? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No [IstDIS] Results in persistent or significant disability or incapacity? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No [IstCONG] Is a congenital abnormality or birth defect? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No [IstMIE] Is an important medical event? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No [A: N] <input type="radio"/> No</div>
15.	SAE reference number [hidden] [SAE reference number]	<div>[txtSAEREFNO] A50</div>
16.	For office use only [hidden] [For office use only]	<div>[numEMAIL1] N3</div>
17.	For office use only [hidden] [For office use only]	<div>[numEMAIL2] N3</div>
18.	For office use only [hidden] [For office use only]	<div>[numEMAIL3] N3</div>
19.	For office use only [hidden] [For office use only]	<div>[numEMAIL4] N3</div>
<div>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.</div>		

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	
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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	LTSYMPREYN_C	VARCHAR2
	LTSYMPREYN	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
IstAESI - IstTHROMBO2	LSTTHROMBO2_C	VARCHAR2
	LSTTHROMBO2	VARCHAR2
IstAESER	LSTAESER_C	VARCHAR2
	LSTAESER	VARCHAR2
	LSTAESER_ND	VARCHAR2
IstAESER - IstDEATH	LSTDEATH_C	VARCHAR2
	LSTDEATH	VARCHAR2
IstAESER - IstTHREAT	LSTTHREAT_C	VARCHAR2
	LSTTHREAT	VARCHAR2
IstAESER - IstHOSPI	LSTHOSPI_C	VARCHAR2
	LSTHOSPI	VARCHAR2
IstAESER - IstDIS	LSTDIS_C	VARCHAR2
	LSTDIS	VARCHAR2
IstAESER - IstCONG	LSTCONG_C	VARCHAR2
	LSTCONG	VARCHAR2
IstAESER - IstMIE	LSTMIE_C	VARCHAR2
	LSTMIE	VARCHAR2
txtSAEREFNO	TX TSAEREFNO	VARCHAR2
	TX TSAEREFNO_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]

[IstSYMP]
[A: ERYTHEMA]
[A: INDURATION]
[A: PRURITUS]
[A: OEDEMA]
[A: PHLEBITIS]
[A: PALLOR AND PIGMENT CHANGE]
[A: LIPODYSTROPHY]
[A: ULCERATION]
[A: PAIN]
[A: TENDERNESS]
[A: OTHER]

☐ Erythema
☐ Induration
☐ Pruritus
☐ Oedema
☐ Phlebitis
☐ Pallor and pigment change
☐ Lipodystrophy
☐ Ulceration
☐ Pain
☐ Tenderness
☐ 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 I tem RefName	Data Variable RefName
clSYMP	String		Erythema	ERYTHEMA	citmSYMP_Erythema	IstSYMP
			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_CITMSYMPPALORANDPIGMENTCHANGE_C	VARCHAR2
	*LSTSYMP_CITMSYMPPALORANDPIGMENTCHANGE	VARCHAR2
lstSYMP - Lipodystrophy	*LSTSYMP_CITSYMPLIPODYSTROPHY_C	VARCHAR2
	*LSTSYMP_CITSYMPLIPODYSTROPHY	VARCHAR2
lstSYMP - Ulceration	*LSTSYMP_CITSYMPULCERATION_C	VARCHAR2
	*LSTSYMP_CITSYMPULCERATION	VARCHAR2
lstSYMP - Pain	LSTSYMP_CITSYMPPAIN_C	VARCHAR2
	LSTSYMP_CITSYMPPAIN	VARCHAR2
lstSYMP - Tenderness	*LSTSYMP_CITSYMPTENDERNESS_C	VARCHAR2
	*LSTSYMP_CITSYMPTENDERNESS	VARCHAR2
lstSYMP - Other	LSTSYMP_CITSYMPOTHER_C	VARCHAR2
	LSTSYMP_CITSYMPOTHER	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]

[IstISR]
[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]

[IstAECIFUYN]
[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]

[IstAECIFU]
[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	IstISR
			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	IstAECIFUYN
			No	N	citmYesNo_N	
clAECIFU	String		Photograph	PHOTO	citmAECIFU_PHOTO	IstAECIFU
			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]

[IstISR]

[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]

[IstAESIFUYN]

[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]

[IstAESIFU]

[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	IstISR
			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	IstAESIFUYN
			No	N	citmYesNo_N	
clAECIFU	String		Photograph	PHOTO	citmAECIFU_PHOTO	IstAESIFU
			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	Preparation 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

[Preparation 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]

[1stBLDDUREN]

[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]

[1stBLDMED]

[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	1stBLDDUREN
			Ongoing at the end of trial	ONGOING	citmCMEND_Ongoing	
clBLDMED	String		mcg of rFVIIa	µg	citmBLDMED_RFVIIA	1stBLDMED
			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]	[IstASSDT] [A: SAME DATE] <input type="radio"/> Same date as visit date [A: OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)
12-lead Electrocardiogram [sctECG24H]		
Supine after at least 10 minutes rest		
2.* ✓	Time performed [Time performed]	[dtmASS_T] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
3.* ✓	Rhythm [Rhythm]	[IstRHYTM] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
4.* ✓	Ventricular rate [Ventricular rate]	[numVR] <input type="text"/> N3 bpm ^[b]
5.* ✓	PR interval [PR]	[numPR] <input type="text"/> N3 msec ^[b]
6.* ✓	QRS duration [QRS]	[numQRS] <input type="text"/> N3 msec ^[b]
7.* ✓	QT interval [QT]	[numQT] <input type="text"/> N3 msec ^[b]
8.* ✓	QTc interval [QTc]	[numQTcF] <input type="text"/> N3 msec ^[b]
9.* ✓	Overall interpretation [Overall interpretation]	[IstOVERALLINT] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL, NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL, CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
10. ✓	If abnormal, please specify by checking all that apply [Abnormal]	[IstABN1] [A: SINUS BRADYCARDIA] <input type="checkbox"/> Sinus Bradycardia [A: SINUS TACHYCARDIA] <input type="checkbox"/> Sinus Tachycardia [A: ATRIAL TACHYCARDIA] <input type="checkbox"/> Atrial Tachycardia [A: VENTRICULAR TACHYCARDIA] <input type="checkbox"/> Ventricular Tachycardia [A: SICK SINUS SYNDROME] <input type="checkbox"/> Sick Sinus Syndrome [A: PREMATURE ATRIAL COMPLEXES] <input type="checkbox"/> Premature Atrial Complexes [A: PREMATURE VENTRICULAR COMPLEXES] <input type="checkbox"/> Premature Ventricular Complexes [A: Q AXIS LEFT AXIS DEVIATION] <input type="checkbox"/> Q Axis, Left Axis Deviation [A: LEFT ATRIAL ABNORMALITY] <input type="checkbox"/> Left Atrial Abnormality [A: LEFT VENTRICULAR HYPERTROPHY] <input type="checkbox"/> Left Ventricular Hypertrophy [A: ATRIAL FIBRILLATION] <input type="checkbox"/> Atrial Fibrillation [A: ATRIAL PACING] <input type="checkbox"/> Atrial Pacing [A: VENTRICULAR PACING] <input type="checkbox"/> Ventricular Pacing [A: ATRIAL VENTRICULAR PACING] <input type="checkbox"/> Atrial Ventricular Pacing [A: 1ST DEGREE A-V BLOCK] <input type="checkbox"/> 1st Degree A-V Block [A: 2ND DEGREE A-V BLOCK TYPE I] <input type="checkbox"/> 2nd Degree A-V Block Type I [A: 2ND DEGREE A-V BLOCK TYPE II] <input type="checkbox"/> 2nd Degree A-V Block Type II [A: 3RD DEGREE A-V BLOCK] <input type="checkbox"/> 3rd Degree A-V Block [A: LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Left Bundle Branch Block [A: INCOMPLETE LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Left Bundle Branch Block [A: LEFT ANTERIOR HEMIBLOCK] <input type="checkbox"/> Left Anterior Hemiblock [A: LEFT POSTERIOR HEMIBLOCK] <input type="checkbox"/> Left Posterior Hemiblock [A: RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Right Bundle Branch Block [A: INCOMPLETE RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Right Bundle Branch Block [A: INTRAVENTRICULAR CONDUCTION DELAY] <input type="checkbox"/> Intraventricular Conduction Delay [A: ANTEROSEPTAL INFARCT PATTERN] <input type="checkbox"/> Anteroseptal Infarct Pattern [A: ANTEROLATERAL INFARCT PATTERN] <input type="checkbox"/> Anterolateral Infarct Pattern [A: LATERAL INFARCT PATTERN] <input type="checkbox"/> Lateral Infarct Pattern [A: INFERIOR INFARCT PATTERN] <input type="checkbox"/> Inferior Infarct Pattern [A: OTHER, SPECIFY] <input type="checkbox"/> [txtABNOTH1] Other, specify <div>A128</div>

11.*
✓

Change from baseline (Day 1, Pre-Dose) ECG
[Change from baseline]

[IstCHANGE1]
[A:NO SIGNIFICANT WORSENING FROM BASELINE]
[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]

No 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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	IstRHYTM
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	IstOVERALLINT
			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	IstABN1
			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	IstCHANGE1
			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

IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
IstRHYTM	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
IstOVERALLINT	LSTOVERALLINT_C	VARCHAR2
	LSTOVERALLINT	VARCHAR2
	LSTOVERALLINT_ND	VARCHAR2
IstABN1	LSTABN1_ND	VARCHAR2
IstABN1 - Sinus Bradycardia	*LSTABN1_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSBRADYCARDIA	VARCHAR2
IstABN1 - Sinus Tachycardia	*LSTABN1_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSTACHYCARDIA	VARCHAR2
IstABN1 - Atrial Tachycardia	*LSTABN1_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNATRIALTACHYCARDIA	VARCHAR2
IstABN1 - Ventricular Tachycardia	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
IstABN1 - Sick Sinus Syndrome	*LSTABN1_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN1_CITMABNSICKSINUSSYNDROME	VARCHAR2
IstABN1 - Premature Atrial Complexes	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
IstABN1 - Premature Ventricular Complexes	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
IstABN1 - Q Axis, Left Axis Deviation	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
IstABN1 - Left Atrial Abnormality	*LSTABN1_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
IstABN1 - Left Ventricular Hypertrophy	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
IstABN1 - Atrial Fibrillation	*LSTABN1_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN1_CITMABNATRIALFIBRILLATION	VARCHAR2
IstABN1 - Atrial Pacing	*LSTABN1_CITMABNATRIALPACING_C	VARCHAR2

	*LSTABN1_CITMABNATRIALPACING	VARCHAR2
IstABN1 - Ventricular Pacing	*LSTABN1_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARPACING	VARCHAR2
IstABN1 - Atrial Ventricular Pacing	*LSTABN1_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALVENTRICULARPACING	VARCHAR2
IstABN1 - 1st Degree A-V Block	*LSTABN1_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN1STDEGREEAVBLOCK	VARCHAR2
IstABN1 - 2nd Degree A-V Block Type I	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
IstABN1 - 2nd Degree A-V Block Type II	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
IstABN1 - 3rd Degree A-V Block	*LSTABN1_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
IstABN1 - Left Bundle Branch Block	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Incomplete Left Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Left Anterior Hemiblock	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN1 - Left Posterior Hemiblock	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN1 - Right Bundle Branch Block	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Incomplete Right Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Intraventricular Conduction Delay	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN1 - Anteroseptal Infarct Pattern	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
IstABN1 - Anterolateral Infarct Pattern	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
IstABN1 - Lateral Infarct Pattern	*LSTABN1_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNLATERALINFARCTPATTERN	VARCHAR2
IstABN1 - Inferior Infarct Pattern	*LSTABN1_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
IstABN1 - Other, specify	LSTABN1_TXTABNOTH1_C	VARCHAR2
	LSTABN1_TXTABNOTH1	VARCHAR2
IstABN1 - txtABNOTH1	TXTABNOTH1	VARCHAR2
IstCHANGE1	LSTCHANGE1_C	VARCHAR2
	LSTCHANGE1	VARCHAR2
	LSTCHANGE1_ND	VARCHAR2
IstCHANGE1 - 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]

[IstASSDT]
[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]

[IstSAMPLE_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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clActTimeNotCol	String		Actual Time	ACTUAL TIME	citmActTimeNotCol_ActTime	IstSAMPLE_24H
			Not collected	NOT COLLECTED	citmActTimeNotCol_NotCol	

RDE Analytics: RD_FRMPKBLD24H		
Data Variable RefName	RD Column Name	Column Data Type
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
IstSAMPLE_24H	LSTSAMPLE_24H_C	VARCHAR2
	LSTSAMPLE_24H	VARCHAR2
	LSTSAMPLE_24H_ND	VARCHAR2
IstSAMPLE_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]	<div>[IstASSDT] [A: SAME DATE] <input type="radio"/> Same date as visit date [A: OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)</div>
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]	<div>[dtmASS_T] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock</div>
3.* ✓	Chest/Respiratory [Chest/Respiratory]	<div>[IstRESPIRAT] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstRESPIRATNEW] Abnormal, is the abnormality a new or worsened finding? [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [txtRESPIRATNEWSP] Yes, please specify <input type="text"/> [IstRESPIRATCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div>
4.* ✓	Heart/Cardiovascular [Heart/Cardiovascular]	<div>[IstCARDIOVA] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstCARDIOVANEW] Abnormal, is the abnormality a new or worsened finding? [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [txtCARDIOVANEWSP] Yes, please specify <input type="text"/> [IstCARDIOVACS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div>
5.* ✓	Dermatological/Skin [Dermatological/Skin]	<div>[IstSKIN] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstSKINNEW] Abnormal, is the abnormality a new or worsened finding? [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [txtSKINNEWSP] Yes, please specify <input type="text"/> [IstSKINCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div>
6.* ✓	Gastrointestinal/Liver [Gastrointestinal/Liver]	<div>[IstGASTROIN] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstGASTROINNEW] Abnormal, is the abnormality a new or worsened finding? [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [txtGASTROINNEWSP] Yes, please specify <input type="text"/> [IstGASTROINCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div>
7.* ✓	Musculoskeletal/Extremities [Musculoskeletal/Extremities]	<div>[IstMUSCULO] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [IstMUSCULONEW]</div>

Abnormal, is the abnormality a new or worsened finding?

[A: N]

☐ No

[A: Y]

☐ [txtMUSCULONEWSP]

Yes, please specify

A200

[IstMUSCULOCS]

Is the abnormality clinically significant?

[A: Y]

☐ Yes

[A: N]

☐ No

8.*
✓

Neurologic

[Neurologic]

[IstNEURO3]

[A: NOT DONE]

☐ Not done

[A: NORMAL]

☐ Normal

[A: ABNORMAL]

☐ [IstNEURONEW]

Abnormal, is the abnormality a new or worsened finding?

[A: N]

☐ No

[A: Y]

☐ [cmpNEURONEW]

Yes, please specify

[txtNEURONEWSP]

A200

[IstNEUROCS]

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]

[IstPEOTHCS]

[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 I tem RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	IstASSDT
			Other	OTHER	citmDateOther_Other	
clNDNormalAbnormal	String		Not done	NOT DONE	citmNDNormalAbnormal_ND	IstRESPIRAT, IstCARDIOVA, IstSKIN, IstGASTROIN, IstMUSCULO, IstNEURO3
			Normal	NORMAL	citmNDNormalAbnormal_Normal	
			Abnormal	ABNORMAL	citmNDNormalAbnormal_Abnormal	
clNoYes	String		No	N	citmNoYes_N	IstRESPIRATNEW, IstCARDIOVANEW, IstSKINNEW, IstGASTROINNEW, IstMUSCULONEW, IstNEURONEW
			Yes	Y	citmNoYes_Y	
clYesNo	String		Yes	Y	citmYesNo_Y	IstRESPIRATCS, IstCARDIOVACS, IstSKINCS, IstGASTROINCS, IstMUSCULOCS, IstNEUROCS, IstPEOTHCS
			No	N	citmYesNo_N	

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

IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
IstRESPIRAT	LSTRESPIRAT_C	VARCHAR2
	LSTRESPIRAT	VARCHAR2
	LSTRESPIRAT_ND	VARCHAR2
IstRESPIRAT - IstRESPIRATNEW	LSTRESPIRATNEW_C	VARCHAR2
	LSTRESPIRATNEW	VARCHAR2
IstRESPIRAT - txtRESPIRATNEWSP	TXTRESPIRATNEWSP	VARCHAR2
IstRESPIRAT - IstRESPIRATCS	LSTRESPIRATCS_C	VARCHAR2
	LSTRESPIRATCS	VARCHAR2
IstCARDIOVA	LSTCARDIOVA_C	VARCHAR2
	LSTCARDIOVA	VARCHAR2
	LSTCARDIOVA_ND	VARCHAR2
IstCARDIOVA - IstCARDIOVANEW	LSTCARDIOVANEW_C	VARCHAR2
	LSTCARDIOVANEW	VARCHAR2
IstCARDIOVA - txtCARDIOVANEWSP	TXTCARDIOVANEWSP	VARCHAR2
IstCARDIOVA - IstCARDIOVACS	LSTCARDIOVACS_C	VARCHAR2
	LSTCARDIOVACS	VARCHAR2
IstSKIN	LSTSKIN_C	VARCHAR2
	LSTSKIN	VARCHAR2
	LSTSKIN_ND	VARCHAR2
IstSKIN - IstSKINNEW	LSTSKINNEW_C	VARCHAR2
	LSTSKINNEW	VARCHAR2
IstSKIN - txtSKINNEWSP	TXTSKINNEWSP	VARCHAR2
IstSKIN - IstSKINCS	LSTSKINCS_C	VARCHAR2
	LSTSKINCS	VARCHAR2
IstGASTROIN	LSTGASTROIN_C	VARCHAR2
	LSTGASTROIN	VARCHAR2
	LSTGASTROIN_ND	VARCHAR2
IstGASTROIN - IstGASTROINNEW	LSTGASTROINNEW_C	VARCHAR2
	LSTGASTROINNEW	VARCHAR2
IstGASTROIN - txtGASTROINNEWSP	TXTGASTROINNEWSP	VARCHAR2
IstGASTROIN - IstGASTROINCS	LSTGASTROINCS_C	VARCHAR2
	LSTGASTROINCS	VARCHAR2
IstMUSCULO	LSTMUSCULO_C	VARCHAR2
	LSTMUSCULO	VARCHAR2
	LSTMUSCULO_ND	VARCHAR2
IstMUSCULO - IstMUSCULONEW	LSTMUSCULONEW_C	VARCHAR2
	LSTMUSCULONEW	VARCHAR2
IstMUSCULO - txtMUSCULONEWSP	TXTMUSCULONEWSP	VARCHAR2
IstMUSCULO - IstMUSCULOCS	LSTMUSCULOCS_C	VARCHAR2
	LSTMUSCULOCS	VARCHAR2
IstNEURO3	LSTNEURO3_C	VARCHAR2
	LSTNEURO3	VARCHAR2
	LSTNEURO3_ND	VARCHAR2
IstNEURO3 - IstNEURONEW	LSTNEURONEW_C	VARCHAR2
	LSTNEURONEW	VARCHAR2

IstNEURO3 - txtNEURONEWSP	TXTNEURONEWSP	VARCHAR2
IstNEURO3 - IstNEUROCS	LSTNEUROCS_C	VARCHAR2
	LSTNEUROCS	VARCHAR2
RD_FRMPE_SCTPEOTH		
txtPEOTH	TXTPEOTH	VARCHAR2
	TXTPEOTH_ND	VARCHAR2
IstPEOTHCS	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]

[IstASSDT]
[A: SAME DATE]

Same date as visit date

[dtmASS] (DD/MM/YYYY)
Other date, please specify

Req / Req / Req (2015-2023)

Weight [sctANTMEAS]

2.*
✓

Weight
[Weight]

[numWEI GHT]
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	IstASSDT
			Other	OTHER	citmDateOther_Other	

RDE Analytics: RD_FRMVS		
Data Variable RefName	RD Column Name	Column Data Type
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - 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]

[IstASSDT]
[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] ☐ [IstLAB2]
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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clYesNo	String		Yes	Y	citmYesNo_Y	txtLAB
			No	N	citmYesNo_N	
clLAB2	String		Hematology	HEMATOLOGY	citmLAB2_Hematology	IstLAB2
			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
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - 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

file:///C:/Users/Nico_Van_Dessel/AppData/Local/Apps/2.0/8ROY8BMP.9NT/87KKKWE2.8YL/orac..47.0_7e15c60fcb5f8c5e_0006.0002_e3a46b3970a1f84d/HtmlResources/AnnotatedStudybook.html

21-Sep-21

	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?]	<div>[IstLABLFT] [A:CENTRAL] <input type="checkbox"/> Central lab [A:LOCAL] <input type="checkbox"/> Local lab [A:NOT APPLICABLE] <input type="checkbox"/> 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)</div>
2.* ✓	Date collected [Date performed]	<div>[IstASSDT] [A:SAME DATE] <input type="radio"/> Same date as visit date [A:OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)</div>
3.* ✓	Time performed [Time performed]	<div>[dtmASS_T] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock</div>
4.* ✓	Was this conducted in the clinic or during a home visit? [Administration at clinic or home?]	<div>[IstADMHC] [A:CLINIC] <input type="radio"/> Clinic - administered by a healthcare professional [A:HOME] <input type="radio"/> Home - administered by a healthcare professional [A:HOMEPAT] <input type="radio"/> Home - administered by patient [A:HOMECARE] <input type="radio"/> Home - administered by caregiver [A:CLINICPAT] <input type="radio"/> Clinic - administered by patient [A:CLINICCARE] <input type="radio"/> Clinic - administered by caregiver</div>
5. ✓	Planned dose (weight based) [Planned dose (weight based)]	<div>[numADM] <input type="text"/> x.xxx mg/kg</div>
6. ✓	Fixed dose [Fixed dose]	<div>[numADM2] <input type="text"/> xxxx. mg</div>
7.* ✓	Type of dispensed kit [Type of dispensed kit]	<div>[IstKITTYPE] [A:VIAL] <input type="radio"/> Vial [A:PFS] <input type="radio"/> Pre-filled syringe (PFS) [A:NOT APPLICABLE] <input type="radio"/> Not applicable</div>
8.* ✓	Total volume administered at this visit [Volume administered]	<div>[numVOLADM] <input type="text"/> xxxx. mL</div>
9.* ✓	Was the full dose successfully administered? [Dose administered?]	<div>[IstDOSEADM] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> [txtDOSEADMNO] No, provide the reason for partial dose <input type="text"/> A128</div>
10.* ✓	Injection site location [Injection site]	<div>[IstINJSITE] [A:RIGHT UPPER QUADRANT] <input type="radio"/> Right upper quadrant [A:LEFT UPPER QUADRANT] <input type="radio"/> Left upper quadrant [A:RIGHT LOWER QUADRANT] <input type="radio"/> Right lower quadrant [A:LEFT LOWER QUADRANT] <input type="radio"/> Left lower quadrant [A:RIGHT UPPER ARM HIGH] <input type="radio"/> Right upper arm high [A:LEFT UPPER ARM HIGH] <input type="radio"/> Left upper arm high [A:RIGHT UPPER ARM LOW] <input type="radio"/> Right upper arm low [A:LEFT UPPER ARM LOW] <input type="radio"/> Left upper arm low [A:RIGHT UPPER THIGH] <input type="radio"/> Right upper thigh [A:LEFT UPPER THIGH] <input type="radio"/> Left upper thigh [A:RIGHT LOWER THIGH] <input type="radio"/> Right lower thigh [A:LEFT LOWER THIGH] <input type="radio"/> Left lower thigh [A:OTHER] <input type="radio"/> [txtINJSITEOTH] Other site location <input type="text"/> A128</div>
11.* ✓	Was a 29 gauge needle used? [Was a 29 gauge needle used?]	<div>[IstNEEDLE] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No</div>
12.* ✓	Was the Dose Injection associated with an Adverse Event? [Injection linked with AE?]	<div>[txtISRAE] [A:Y] <input type="radio"/> [cmpAE] Yes Please specify AE#(s) - as recorded on AE form [numAESEQ1] [numAESEQ2] [numAESEQ3] [numAESEQ4] [numAESEQ5] [numAESEQ6] <input type="text"/> N3 <input type="text"/> N3 <input type="text"/> N3 <input type="text"/> N3 <input type="text"/> N3 <input type="text"/> N3 [A:N] <input type="radio"/> No</div>
13.	For office use only [hidden]	<div>[numEMAIL1]</div>

	[For office use only]	<div>N3</div>
14.	For office use only <i>[hidden]</i> [For office use only]	<div>[numEMAIL2]</div> <div>N3</div>
15.	For office use only <i>[hidden]</i> [For office use only]	<div>[numEMAIL3]</div> <div>N3</div>
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 I tem RefName	Data Variable RefName
clLABLFT	String		Central lab	CENTRAL	citmLABLFT_CENTRAL	IstLABLFT
			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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clADMHC	String		Clinic - administered by a healthcare professional	CLINIC	citmADMHC_CLINIC	IstADMHC
			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	IstKITTYPE
			Pre-filled syringe (PFS)	PFS	citmKITTYPE_PFS	
			Not applicable	NOT APPLICABLE	citmKITTYPE_NOTAPPLICABLE	
clYesNo	String		Yes	Y	citmYesNo_Y	IstDOSEADM, IstNEEDLE, txtISRAE
			No	N	citmYesNo_N	
clINJSITE	String		Right upper quadrant	RIGHT UPPER QUADRANT	citmINJSITE_RUQ	IstINJSITE
			Left upper quadrant	LIGHT UPPER QUADRANT	citmINJSITE_LUQ	
			Right lower quadrant	RIGHT LOWER QUADRANT	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
IstLABLFT	LSTLABLFT_ND	VARCHAR2
IstLABLFT - Central lab	*LSTLABLFT_CITMLABLFTCENTRAL_C	VARCHAR2
	*LSTLABLFT_CITMLABLFTCENTRAL	VARCHAR2
IstLABLFT - Local lab	LSTLABLFT_CITMLABLFTLOCAL_C	VARCHAR2
	LSTLABLFT_CITMLABLFTLOCAL	VARCHAR2
IstLABLFT - 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
IstASSDT	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	LSTDSEADM_C	VARCHAR2
	LSTDSEADM	VARCHAR2
	LSTDSEADM_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?]

[IstTEL]
[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 I tem RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	IstTEL
			No	N	citmYesNo_N	

RDE Analytics: RD_FRMTEL		
Data Variable RefName	RD Column Name	Column Data Type
IstTEL	LSTTEL_C	VARCHAR2
	LSTTEL	VARCHAR2
	LSTTEL_ND	VARCHAR2
IstTEL - dtTEL	DTTEL	DATE
	DTTEL_DTS	VARCHAR2
	DTTEL_DTR	VARCHAR2

file:///C:/Users/Nico_Van_Dessel/AppData/Local/Apps/2.0/8ROY8BMP.9NT/87KKKWE2.8YL/orac..47.0_7e15c60fcb5f8c5e_0006.0002_e3a46b3970a1f84d/HtmlResources/AnnotatedStudybook.html

21-Sep-21

AT3SC002: 12-lead ECG (ECG M12M24) [frmECG_M12M24]		
Assessment Date [sctECGDT]		
1.* ✓	Date collected [Date performed]	[IstASSDT] [A: SAME DATE] <input type="radio"/> Same date as visit date [A: OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (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 <input type="text"/> : Req <input type="text"/> 24-hour clock
3.* ✓	Rhythm [Rhythm]	[IstRHYTM] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
4.* ✓	Ventricular rate [Ventricular rate]	[numVR] <input type="text"/> N3 bpm ^[b]
5.* ✓	PR interval [PR]	[numPR] <input type="text"/> N3 msec ^[b]
6.* ✓	QRS duration [QRS]	[numQRS] <input type="text"/> N3 msec ^[b]
7.* ✓	QT interval [QT]	[numQT] <input type="text"/> N3 msec ^[b]
8.* ✓	QTc interval [QTc]	[numQTcF] <input type="text"/> N3 msec ^[b]
9.* ✓	Overall interpretation [Overall interpretation]	[IstOVERALLINT] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL, NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL, CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
10. ✓	If abnormal, please specify by checking all that apply [Abnormal]	[IstABN1] [A: SINUS BRADYCARDIA] <input type="checkbox"/> Sinus Bradycardia [A: SINUS TACHYCARDIA] <input type="checkbox"/> Sinus Tachycardia [A: ATRIAL TACHYCARDIA] <input type="checkbox"/> Atrial Tachycardia [A: VENTRICULAR TACHYCARDIA] <input type="checkbox"/> Ventricular Tachycardia [A: SICK SINUS SYNDROME] <input type="checkbox"/> Sick Sinus Syndrome [A: PREMATURE ATRIAL COMPLEXES] <input type="checkbox"/> Premature Atrial Complexes [A: PREMATURE VENTRICULAR COMPLEXES] <input type="checkbox"/> Premature Ventricular Complexes [A: Q AXIS LEFT AXIS DEVIATION] <input type="checkbox"/> Q Axis, Left Axis Deviation [A: LEFT ATRIAL ABNORMALITY] <input type="checkbox"/> Left Atrial Abnormality [A: LEFT VENTRICULAR HYPERTROPHY] <input type="checkbox"/> Left Ventricular Hypertrophy [A: ATRIAL FIBRILLATION] <input type="checkbox"/> Atrial Fibrillation [A: ATRIAL PACING] <input type="checkbox"/> Atrial Pacing [A: VENTRICULAR PACING] <input type="checkbox"/> Ventricular Pacing [A: ATRIAL VENTRICULAR PACING] <input type="checkbox"/> Atrial Ventricular Pacing [A: 1ST DEGREE A-V BLOCK] <input type="checkbox"/> 1st Degree A-V Block [A: 2ND DEGREE A-V BLOCK TYPE I] <input type="checkbox"/> 2nd Degree A-V Block Type I [A: 2ND DEGREE A-V BLOCK TYPE II] <input type="checkbox"/> 2nd Degree A-V Block Type II [A: 3RD DEGREE A-V BLOCK] <input type="checkbox"/> 3rd Degree A-V Block [A: LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Left Bundle Branch Block [A: INCOMPLETE LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Left Bundle Branch Block [A: LEFT ANTERIOR HEMIBLOCK] <input type="checkbox"/> Left Anterior Hemiblock [A: LEFT POSTERIOR HEMIBLOCK] <input type="checkbox"/> Left Posterior Hemiblock [A: RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Right Bundle Branch Block [A: INCOMPLETE RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Right Bundle Branch Block [A: INTRAVENTRICULAR CONDUCTION DELAY] <input type="checkbox"/> Intraventricular Conduction Delay [A: ANTEROSEPTAL INFARCT PATTERN] <input type="checkbox"/> Anteroseptal Infarct Pattern [A: ANTEROLATERAL INFARCT PATTERN] <input type="checkbox"/> Anterolateral Infarct Pattern [A: LATERAL INFARCT PATTERN] <input type="checkbox"/> Lateral Infarct Pattern [A: INFERIOR INFARCT PATTERN] <input type="checkbox"/> Inferior Infarct Pattern [A: OTHER, SPECIFY] <input type="checkbox"/> [txtABNOTH1] Other, specify <div>A128</div>

11.* ✓	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	<div>[IstCHANGE4] [A:NO SIGNIFICANT WORSENING FROM BASELINE] <input type="radio"/> No significant worsening from baseline [A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE] <input type="radio"/> [txtCHANGE4] Clinically significant worsening from baseline, specify A128</div>
12-lead Electrocardiogram - 30 Minutes Postdose [sct30M]		
12.* ✓	Time performed [Time performed]	<div>[dtmASS_T2] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock</div>
13.* ✓	Rhythm [Rhythm]	<div>[IstRHYTM2] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A:ABNORMAL CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant</div>
14.* ✓	Ventricular rate [Ventricular rate]	<div>[numVR2] <input type="text"/> bpm^[b]</div>
15.* ✓	PR interval [PR]	<div>[numPR2] <input type="text"/> msec^[b]</div>
16.* ✓	QRS duration [QRS]	<div>[numQRS2] <input type="text"/> msec^[b]</div>
17.* ✓	QT interval [QT]	<div>[numQT2] <input type="text"/> msec^[b]</div>
18.* ✓	QTc interval [QTc]	<div>[numQTcF2] <input type="text"/> msec^[b]</div>
19.* ✓	Overall interpretation [Overall interpretation]	<div>[IstOVERALLINT2] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL, NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A:ABNORMAL, CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant</div>
20. ✓	If abnormal, please specify by checking all that apply [Abnormal]	<div><div><div>[IstABN2] [A:SINUS BRADYCARDIA] [A:SINUS TACHYCARDIA] [A:ATRIAL TACHYCARDIA] [A:VENTRICULAR TACHYCARDIA] [A:SICK SINUS SYNDROME] [A:PREMATURE ATRIAL COMPLEXES] [A:PREMATURE VENTRICULAR COMPLEXES] [A:Q AXIS LEFT AXIS DEVIATION] [A:LEFT ATRIAL ABNORMALITY] [A:LEFT VENTRICULAR HYPERTROPHY] [A:ATRIAL FIBRILLATION] [A:ATRIAL PACING] [A:VENTRICULAR PACING] [A:ATRIAL VENTRICULAR PACING] [A:1ST DEGREE A-V BLOCK] [A:2ND DEGREE A-V BLOCK TYPE I] [A:2ND DEGREE A-V BLOCK TYPE II] [A:3RD DEGREE A-V BLOCK] [A:LEFT BUNDLE BRANCH BLOCK] [A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK] [A:LEFT ANTERIOR HEMIBLOCK] [A:LEFT POSTERIOR HEMIBLOCK] [A:RIGHT BUNDLE BRANCH BLOCK] [A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK] [A:INTRAVENTRICULAR CONDUCTION DELAY] [A:ANTEROSEPTAL INFARCT PATTERN] [A:ANTEROLATERAL INFARCT PATTERN] [A:LATERAL INFARCT PATTERN] [A:INFERIOR INFARCT PATTERN] [A:OTHER, SPECIFY]</div><div><input type="checkbox"/> Sinus Bradycardia <input type="checkbox"/> Sinus Tachycardia <input type="checkbox"/> Atrial Tachycardia <input type="checkbox"/> Ventricular Tachycardia <input type="checkbox"/> Sick Sinus Syndrome <input type="checkbox"/> Premature Atrial Complexes <input type="checkbox"/> Premature Ventricular Complexes <input type="checkbox"/> Q Axis, Left Axis Deviation <input type="checkbox"/> Left Atrial Abnormality <input type="checkbox"/> Left Ventricular Hypertrophy <input type="checkbox"/> Atrial Fibrillation <input type="checkbox"/> Atrial Pacing <input type="checkbox"/> Ventricular Pacing <input type="checkbox"/> Atrial Ventricular Pacing <input type="checkbox"/> 1st Degree A-V Block <input type="checkbox"/> 2nd Degree A-V Block Type I <input type="checkbox"/> 2nd Degree A-V Block Type II <input type="checkbox"/> 3rd Degree A-V Block <input type="checkbox"/> Left Bundle Branch Block <input type="checkbox"/> Incomplete Left Bundle Branch Block <input type="checkbox"/> Left Anterior Hemiblock <input type="checkbox"/> Left Posterior Hemiblock <input type="checkbox"/> Right Bundle Branch Block <input type="checkbox"/> Incomplete Right Bundle Branch Block <input type="checkbox"/> Intraventricular Conduction Delay <input type="checkbox"/> Anteroseptal Infarct Pattern <input type="checkbox"/> Anterolateral Infarct Pattern <input type="checkbox"/> Lateral Infarct Pattern <input type="checkbox"/> Inferior Infarct Pattern <input type="checkbox"/> [txtABNOTH2] Other, specify A128</div></div></div>
21.*	Change from baseline (Day 1, Pre-Dose) ECG	<div>[IstCHANGE1]</div>

<div>✓</div>	[Change from baseline]	<div>[A:NO SIGNIFICANT WORSENING FROM BASELINE]</div> <div>[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]</div> <div><div>No significant worsening from baseline</div><div><div>[txtCHANGE1]</div><div>Clinically significant worsening from baseline, specify</div><div>A128</div></div></div>
12-lead Electrocardiogram - 2 Hours Postdose [sct2H]		
<div>22.*</div> <div>✓</div>	Time performed [Time performed]	<div>[dtmASS_T3] (hh:mm)</div> <div>Req <div>▼</div> : Req <div>▼</div> 24-hour clock</div>
<div>23.*</div> <div>✓</div>	Rhythm [Rhythm]	<div>[IstRHYTM3]</div> <div>[A:NORMAL]</div> <div><div>Normal</div><div>Abnormal, Not Clinically Significant</div><div>Abnormal, Clinically Significant</div></div> <div>[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]</div> <div>[A:ABNORMAL CLINICALLY SIGNIFICANT]</div>
<div>24.*</div> <div>✓</div>	Ventricular rate [Ventricular rate]	<div>[numVR3]</div> <div>N3</div> bpm ^[b]
<div>25.*</div> <div>✓</div>	PR interval [PR]	<div>[numPR3]</div> <div>N3</div> msec ^[b]
<div>26.*</div> <div>✓</div>	QRS duration [QRS]	<div>[numQRS3]</div> <div>N3</div> msec ^[b]
<div>27.*</div> <div>✓</div>	QT interval [QT]	<div>[numQT3]</div> <div>N3</div> msec ^[b]
<div>28.*</div> <div>✓</div>	QTc interval [QTc]	<div>[numQTcF3]</div> <div>N3</div> msec ^[b]
<div>29.*</div> <div>✓</div>	Overall interpretation [Overall interpretation]	<div>[IstOVERALLINT3]</div> <div>[A:NORMAL]</div> <div><div>Normal</div><div>Abnormal, Not Clinically Significant</div><div>Abnormal, Clinically Significant</div></div> <div>[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]</div> <div>[A:ABNORMAL, CLINICALLY SIGNIFICANT]</div>
<div>30.*</div> <div>✓</div>	If abnormal, please specify by checking all that apply [Abnormal]	<div>[IstABN3]</div> <div>[A:SINUS BRADYCARDIA]</div> <div>[A:SINUS TACHYCARDIA]</div> <div>[A:ATRIAL TACHYCARDIA]</div> <div>[A:VENTRICULAR TACHYCARDIA]</div> <div>[A:SICK SINUS SYNDROME]</div> <div>[A:PREMATURE ATRIAL COMPLEXES]</div> <div>[A:PREMATURE VENTRICULAR COMPLEXES]</div> <div>[A:Q AXIS LEFT AXIS DEVIATION]</div> <div>[A:LEFT ATRIAL ABNORMALITY]</div> <div>[A:LEFT VENTRICULAR HYPERTROPHY]</div> <div>[A:ATRIAL FIBRILLATION]</div> <div>[A:ATRIAL PACING]</div> <div>[A:VENTRICULAR PACING]</div> <div>[A:ATRIAL VENTRICULAR PACING]</div> <div>[A:1ST DEGREE A-V BLOCK]</div> <div>[A:2ND DEGREE A-V BLOCK TYPE I]</div> <div>[A:2ND DEGREE A-V BLOCK TYPE II]</div> <div>[A:3RD DEGREE A-V BLOCK]</div> <div>[A:LEFT BUNDLE BRANCH BLOCK]</div> <div>[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]</div> <div>[A:LEFT ANTERIOR HEMIBLOCK]</div> <div>[A:LEFT POSTERIOR HEMIBLOCK]</div> <div>[A:RIGHT BUNDLE BRANCH BLOCK]</div> <div>[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]</div> <div>[A:INTRAVENTRICULAR CONDUCTION DELAY]</div> <div>[A:ANTEROSEPTAL INFARCT PATTERN]</div> <div>[A:ANTEROLATERAL INFARCT PATTERN]</div> <div>[A:LATERAL INFARCT PATTERN]</div> <div>[A:INFERIOR INFARCT PATTERN]</div> <div>[A:OTHER, SPECIFY]</div> <div><div><div>Sinus Bradycardia</div><div>Sinus Tachycardia</div><div>Atrial Tachycardia</div><div>Ventricular Tachycardia</div><div>Sick Sinus Syndrome</div><div>Premature Atrial Complexes</div><div>Premature Ventricular Complexes</div><div>Q Axis, Left Axis Deviation</div><div>Left Atrial Abnormality</div><div>Left Ventricular Hypertrophy</div><div>Atrial Fibrillation</div><div>Atrial Pacing</div><div>Ventricular Pacing</div><div>Atrial Ventricular Pacing</div><div>1st Degree A-V Block</div><div>2nd Degree A-V Block Type I</div><div>2nd Degree A-V Block Type II</div><div>3rd Degree A-V Block</div><div>Left Bundle Branch Block</div><div>Incomplete Left Bundle Branch Block</div><div>Left Anterior Hemiblock</div><div>Left Posterior Hemiblock</div><div>Right Bundle Branch Block</div><div>Incomplete Right Bundle Branch Block</div><div>Intraventricular Conduction Delay</div><div>Anteroseptal Infarct Pattern</div><div>Anterolateral Infarct Pattern</div><div>Lateral Infarct Pattern</div><div>Inferior Infarct Pattern</div><div>[txtABNOTH3]</div><div>Other, specify</div><div>A128</div></div></div>
<div>31.*</div> <div>✓</div>	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	<div>[IstCHANGE2]</div> <div>[A:NO SIGNIFICANT WORSENING FROM BASELINE]</div> <div><div>No significant worsening from baseline</div></div>

		<div><div>[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]</div><div><div><div></div></div><div>[txtCHANGE2]</div></div><div>Clinically significant worsening from baseline, specify</div><div>A128</div></div>
12-lead Electrocardiogram - 4 Hours Postdose [sct4H]		
32.* ✓	Time performed [Time performed]	<div><div>[dtmASS_T4] (hh:mm)</div><div>Req <div></div> : Req <div></div> 24-hour clock</div></div>
33.* ✓	Rhythm [Rhythm]	<div><div>[IstRHYTM4]</div><div><div>[A:NORMAL]</div><div><div></div></div>Normal</div><div><div>[A:ABNORMAL NOT CLINICALLY SIGNIFICANT]</div><div><div></div></div>Abnormal, Not Clinically Significant</div><div><div>[A:ABNORMAL CLINICALLY SIGNIFICANT]</div><div><div></div></div>Abnormal, Clinically Significant</div></div>
34.* ✓	Ventricular rate [Ventricular rate]	<div><div>[numVR4]</div><div>N3 bpm^[b]</div></div>
35.* ✓	PR interval [PR]	<div><div>[numPR4]</div><div>N3 msec^[b]</div></div>
36.* ✓	QRS duration [QRS]	<div><div>[numQRS4]</div><div>N3 msec^[b]</div></div>
37.* ✓	QT interval [QT]	<div><div>[numQT4]</div><div>N3 msec^[b]</div></div>
38.* ✓	QTc interval [QTc]	<div><div>[numQTCF4]</div><div>N3 msec^[b]</div></div>
39.* ✓	Overall interpretation [Overall interpretation]	<div><div>[IstOVERALLINT4]</div><div><div>[A:NORMAL]</div><div><div></div></div>Normal</div><div><div>[A:ABNORMAL, NOT CLINICALLY SIGNIFICANT]</div><div><div></div></div>Abnormal, Not Clinically Significant</div><div><div>[A:ABNORMAL, CLINICALLY SIGNIFICANT]</div><div><div></div></div>Abnormal, Clinically Significant</div></div>
40. ✓	If abnormal, please specify by checking all that apply [Abnormal]	<div><div>[IstABN4]</div><div><div>[A:SINUS BRADYCARDIA]</div><div><div></div></div>Sinus Bradycardia</div><div><div>[A:SINUS TACHYCARDIA]</div><div><div></div></div>Sinus Tachycardia</div><div><div>[A:ATRIAL TACHYCARDIA]</div><div><div></div></div>Atrial Tachycardia</div><div><div>[A:VENTRICULAR TACHYCARDIA]</div><div><div></div></div>Ventricular Tachycardia</div><div><div>[A:SICK SINUS SYNDROME]</div><div><div></div></div>Sick Sinus Syndrome</div><div><div>[A:PREMATURE ATRIAL COMPLEXES]</div><div><div></div></div>Premature Atrial Complexes</div><div><div>[A:PREMATURE VENTRICULAR COMPLEXES]</div><div><div></div></div>Premature Ventricular Complexes</div><div><div>[A:Q AXIS LEFT AXIS DEVIATION]</div><div><div></div></div>Q Axis, Left Axis Deviation</div><div><div>[A:LEFT ATRIAL ABNORMALITY]</div><div><div></div></div>Left Atrial Abnormality</div><div><div>[A:LEFT VENTRICULAR HYPERTROPHY]</div><div><div></div></div>Left Ventricular Hypertrophy</div><div><div>[A:ATRIAL FIBRILLATION]</div><div><div></div></div>Atrial Fibrillation</div><div><div>[A:ATRIAL PACING]</div><div><div></div></div>Atrial Pacing</div><div><div>[A:VENTRICULAR PACING]</div><div><div></div></div>Ventricular Pacing</div><div><div>[A:ATRIAL VENTRICULAR PACING]</div><div><div></div></div>Atrial Ventricular Pacing</div><div><div>[A:1ST DEGREE A-V BLOCK]</div><div><div></div></div>1st Degree A-V Block</div><div><div>[A:2ND DEGREE A-V BLOCK TYPE I]</div><div><div></div></div>2nd Degree A-V Block Type I</div><div><div>[A:2ND DEGREE A-V BLOCK TYPE II]</div><div><div></div></div>2nd Degree A-V Block Type II</div><div><div>[A:3RD DEGREE A-V BLOCK]</div><div><div></div></div>3rd Degree A-V Block</div><div><div>[A:LEFT BUNDLE BRANCH BLOCK]</div><div><div></div></div>Left Bundle Branch Block</div><div><div>[A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK]</div><div><div></div></div>Incomplete Left Bundle Branch Block</div><div><div>[A:LEFT ANTERIOR HEMIBLOCK]</div><div><div></div></div>Left Anterior Hemiblock</div><div><div>[A:LEFT POSTERIOR HEMIBLOCK]</div><div><div></div></div>Left Posterior Hemiblock</div><div><div>[A:RIGHT BUNDLE BRANCH BLOCK]</div><div><div></div></div>Right Bundle Branch Block</div><div><div>[A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK]</div><div><div></div></div>Incomplete Right Bundle Branch Block</div><div><div>[A:INTRAVENTRICULAR CONDUCTION DELAY]</div><div><div></div></div>Intraventricular Conduction Delay</div><div><div>[A:ANTEROSEPTAL INFARCT PATTERN]</div><div><div></div></div>Anteroseptal Infarct Pattern</div><div><div>[A:ANTEROLATERAL INFARCT PATTERN]</div><div><div></div></div>Anterolateral Infarct Pattern</div><div><div>[A:LATERAL INFARCT PATTERN]</div><div><div></div></div>Lateral Infarct Pattern</div><div><div>[A:INFERIOR INFARCT PATTERN]</div><div><div></div></div>Inferior Infarct Pattern</div><div><div>[A:OTHER, SPECIFY]</div><div><div></div></div>[txtABNOTH4]</div><div>Other, specify</div><div>A128</div></div>

		<div>Clinically significant worsening from baseline, specify</div> <div>A128</div>
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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	IstRHYTM, IstRHYTM2, IstRHYTM3, IstRHYTM4
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	IstOVERALLINT, IstOVERALLINT2, IstOVERALLINT3, IstOVERALLINT4
			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	IstABN1, IstABN2, IstABN3, IstABN4
			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	IstCHANGE4
			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	IstCHANGE1
			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	IstCHANGE2
			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	IstCHANGE3

			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE_1_1	
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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
IstABN1 - Atrial Fibrillation	*LSTABN1_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN1_CITMABNATRIALFIBRILLATION	VARCHAR2
IstABN1 - Atrial Pacing	*LSTABN1_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALPACING	VARCHAR2
IstABN1 - Ventricular Pacing	*LSTABN1_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARPACING	VARCHAR2
IstABN1 - Atrial Ventricular Pacing	*LSTABN1_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALVENTRICULARPACING	VARCHAR2
IstABN1 - 1st Degree A-V Block	*LSTABN1_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN1STDEGREEAVBLOCK	VARCHAR2
IstABN1 - 2nd Degree A-V Block Type I	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
IstABN1 - 2nd Degree A-V Block Type II	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
IstABN1 - 3rd Degree A-V Block	*LSTABN1_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
IstABN1 - Left Bundle Branch Block	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Incomplete Left Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Left Anterior Hemiblock	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN1 - Left Posterior Hemiblock	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN1 - Right Bundle Branch Block	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Incomplete Right Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Intraventricular Conduction Delay	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN1 - Anteroseptal Infarct Pattern	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
IstABN1 - Anterolateral Infarct Pattern	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
IstABN1 - Lateral Infarct Pattern	*LSTABN1_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNLATERALINFARCTPATTERN	VARCHAR2
IstABN1 - Inferior Infarct Pattern	*LSTABN1_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
IstABN1 - Other, specify	LSTABN1_TXTABNOTH1_C	VARCHAR2
	LSTABN1_TXTABNOTH1	VARCHAR2
IstABN1 - txtABNOTH1	TXTABNOTH1	VARCHAR2
IstCHANGE4	LSTCHANGE4_C	VARCHAR2
	LSTCHANGE4	VARCHAR2
	LSTCHANGE4_ND	VARCHAR2
IstCHANGE4 - txtCHANGE4	TXTCHANGE4	VARCHAR2
dtmASS_T2	DTMASS_T2	DATE
	DTMASS_T2_TMS	VARCHAR2
	DTMASS_T2_ND	VARCHAR2
IstRHYTM2	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
IstABN2 - Left Bundle Branch Block	*LSTABN2_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN2 - Incomplete Left Bundle Branch Block	*LSTABN2_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN2 - Left Anterior Hemiblock	*LSTABN2_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN2 - Left Posterior Hemiblock	*LSTABN2_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN2 - Right Bundle Branch Block	*LSTABN2_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN2 - Incomplete Right Bundle Branch Block	*LSTABN2_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN2 - Intraventricular Conduction Delay	*LSTABN2_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN2_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN2 - Anteroseptal Infarct Pattern	*LSTABN2_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
IstABN2 - Anterolateral Infarct Pattern	*LSTABN2_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
IstABN2 - Lateral Infarct Pattern	*LSTABN2_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNLATERALINFARCTPATTERN	VARCHAR2
IstABN2 - Inferior Infarct Pattern	*LSTABN2_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
IstABN2 - Other, specify	LSTABN2_TXTABNOTH2_C	VARCHAR2
	LSTABN2_TXTABNOTH2	VARCHAR2
IstABN2 - txtABNOTH2	TXTABNOTH2	VARCHAR2
IstCHANGE1	LSTCHANGE1_C	VARCHAR2
	LSTCHANGE1	VARCHAR2
	LSTCHANGE1_ND	VARCHAR2
IstCHANGE1 - txtCHANGE1	TXTCHANGE1	VARCHAR2
dtmASS_T3	DTMASS_T3	DATE
	DTMASS_T3_TMS	VARCHAR2
	DTMASS_T3_ND	VARCHAR2
IstRHYTM3	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
IstOVERALLINT3	LSTOVERALLINT3_C	VARCHAR2
	LSTOVERALLINT3	VARCHAR2

	LSTOVERALLINT3_ND	VARCHAR2
IstABN3	LSTABN3_ND	VARCHAR2
IstABN3 - Sinus Bradycardia	*LSTABN3_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNSINUSBRADYCARDIA	VARCHAR2
IstABN3 - Sinus Tachycardia	*LSTABN3_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNSINUSTACHYCARDIA	VARCHAR2
IstABN3 - Atrial Tachycardia	*LSTABN3_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNATRIALTACHYCARDIA	VARCHAR2
IstABN3 - Ventricular Tachycardia	*LSTABN3_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN3_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
IstABN3 - Sick Sinus Syndrome	*LSTABN3_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN3_CITMABNSICKSINUSSYNDROME	VARCHAR2
IstABN3 - Premature Atrial Complexes	*LSTABN3_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN3_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
IstABN3 - Premature Ventricular Complexes	*LSTABN3_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN3_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
IstABN3 - Q Axis, Left Axis Deviation	*LSTABN3_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN3_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
IstABN3 - Left Atrial Abnormality	*LSTABN3_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN3_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
IstABN3 - Left Ventricular Hypertrophy	*LSTABN3_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN3_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
IstABN3 - Atrial Fibrillation	*LSTABN3_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN3_CITMABNATRIALFIBRILLATION	VARCHAR2
IstABN3 - Atrial Pacing	*LSTABN3_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN3_CITMABNATRIALPACING	VARCHAR2
IstABN3 - Ventricular Pacing	*LSTABN3_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN3_CITMABNVENTRICULARPACING	VARCHAR2
IstABN3 - Atrial Ventricular Pacing	*LSTABN3_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN3_CITMABNATRIALVENTRICULARPACING	VARCHAR2
IstABN3 - 1st Degree A-V Block	*LSTABN3_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN3_CITMABN1STDEGREEAVBLOCK	VARCHAR2
IstABN3 - 2nd Degree A-V Block Type I	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
IstABN3 - 2nd Degree A-V Block Type II	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN3_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
IstABN3 - 3rd Degree A-V Block	*LSTABN3_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN3_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
IstABN3 - Left Bundle Branch Block	*LSTABN3_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN3 - Incomplete Left Bundle Branch Block	*LSTABN3_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN3 - Left Anterior Hemiblock	*LSTABN3_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN3 - Left Posterior Hemiblock	*LSTABN3_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN3 - Right Bundle Branch Block	*LSTABN3_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN3 - Incomplete Right Bundle Branch Block	*LSTABN3_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN3_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN3 - Intraventricular Conduction Delay	*LSTABN3_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN3_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN3 - 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

IstABN4 - Q Axis, Left Axis Deviation	*LSTABN4_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN4_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
IstABN4 - Left Atrial Abnormality	*LSTABN4_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN4_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
IstABN4 - Left Ventricular Hypertrophy	*LSTABN4_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN4_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
IstABN4 - Atrial Fibrillation	*LSTABN4_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN4_CITMABNATRIALFIBRILLATION	VARCHAR2
IstABN4 - Atrial Pacing	*LSTABN4_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN4_CITMABNATRIALPACING	VARCHAR2
IstABN4 - Ventricular Pacing	*LSTABN4_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN4_CITMABNVENTRICULARPACING	VARCHAR2
IstABN4 - Atrial Ventricular Pacing	*LSTABN4_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN4_CITMABNATRIALVENTRICULARPACING	VARCHAR2
IstABN4 - 1st Degree A-V Block	*LSTABN4_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN4_CITMABN1STDEGREEAVBLOCK	VARCHAR2
IstABN4 - 2nd Degree A-V Block Type I	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
IstABN4 - 2nd Degree A-V Block Type II	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
IstABN4 - 3rd Degree A-V Block	*LSTABN4_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN4_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
IstABN4 - Left Bundle Branch Block	*LSTABN4_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN4 - Incomplete Left Bundle Branch Block	*LSTABN4_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN4 - Left Anterior Hemiblock	*LSTABN4_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN4 - Left Posterior Hemiblock	*LSTABN4_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN4 - Right Bundle Branch Block	*LSTABN4_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN4 - Incomplete Right Bundle Branch Block	*LSTABN4_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN4 - Intraventricular Conduction Delay	*LSTABN4_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN4_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN4 - Anteroseptal Infarct Pattern	*LSTABN4_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
IstABN4 - Anterolateral Infarct Pattern	*LSTABN4_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
IstABN4 - Lateral Infarct Pattern	*LSTABN4_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNLATERALINFARCTPATTERN	VARCHAR2
IstABN4 - Inferior Infarct Pattern	*LSTABN4_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
IstABN4 - Other, specify	LSTABN4_TXTABNOTH4_C	VARCHAR2
	LSTABN4_TXTABNOTH4	VARCHAR2
IstABN4 - txtABNOTH4	TXTABNOTH4	VARCHAR2
IstCHANGE3	LSTCHANGE3_C	VARCHAR2
	LSTCHANGE3	VARCHAR2
	LSTCHANGE3_ND	VARCHAR2
IstCHANGE3 - 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?]	[IstPKSUB] [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Codelist Values Tables: PK Subset Question						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist I tem RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	IstPKSUB
			No	N	citmYesNo_N	

RDE Analytics: RD_FRMPKQUEST		
Data Variable RefName	RD Column Name	Column Data Type
IstPKSUB	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_ENOH6H] (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_VOH6H]
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_ENOH6H	DPKUR_ENOH6H	DATE
	DPKUR_ENOH6H_DTS	VARCHAR2
	DPKUR_ENOH6H_ND	VARCHAR2
numPKUR_VOH6H	NUMPKUR_VOH6H	FLOAT
	NUMPKUR_VOH6H_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]	[IstASSDT] [A: SAME DATE] <input type="radio"/> Same date as visit date [A: OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)
12-lead Electrocardiogram - Predose [sctECG_UNUS]		
Supine after at least 10 minutes rest		
2.* ✓	Time performed [Time performed]	[dtmASS_T] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
3.* ✓	Rhythm [Rhythm]	[IstRHYTM] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
4.* ✓	Ventricular rate [Ventricular rate]	[numVR] <input type="text"/> N3 bpm ^[b]
5.* ✓	PR interval [PR]	[numPR] <input type="text"/> N3 msec ^[b]
6.* ✓	QRS duration [QRS]	[numQRS] <input type="text"/> N3 msec ^[b]
7.* ✓	QT interval [QT]	[numQT] <input type="text"/> N3 msec ^[b]
8.* ✓	QTc interval [QTc]	[numQTcF] <input type="text"/> N3 msec ^[b]
9.* ✓	Overall interpretation [Overall interpretation]	[IstOVERALLINT] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL, NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL, CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
10. ✓	If abnormal, please specify by checking all that apply [Abnormal]	[IstABN1] [A: SINUS BRADYCARDIA] <input type="checkbox"/> Sinus Bradycardia [A: SINUS TACHYCARDIA] <input type="checkbox"/> Sinus Tachycardia [A: ATRIAL TACHYCARDIA] <input type="checkbox"/> Atrial Tachycardia [A: VENTRICULAR TACHYCARDIA] <input type="checkbox"/> Ventricular Tachycardia [A: SICK SINUS SYNDROME] <input type="checkbox"/> Sick Sinus Syndrome [A: PREMATURE ATRIAL COMPLEXES] <input type="checkbox"/> Premature Atrial Complexes [A: PREMATURE VENTRICULAR COMPLEXES] <input type="checkbox"/> Premature Ventricular Complexes [A: Q AXIS LEFT AXIS DEVIATION] <input type="checkbox"/> Q Axis, Left Axis Deviation [A: LEFT ATRIAL ABNORMALITY] <input type="checkbox"/> Left Atrial Abnormality [A: LEFT VENTRICULAR HYPERTROPHY] <input type="checkbox"/> Left Ventricular Hypertrophy [A: ATRIAL FIBRILLATION] <input type="checkbox"/> Atrial Fibrillation [A: ATRIAL PACING] <input type="checkbox"/> Atrial Pacing [A: VENTRICULAR PACING] <input type="checkbox"/> Ventricular Pacing [A: ATRIAL VENTRICULAR PACING] <input type="checkbox"/> Atrial Ventricular Pacing [A: 1ST DEGREE A-V BLOCK] <input type="checkbox"/> 1st Degree A-V Block [A: 2ND DEGREE A-V BLOCK TYPE I] <input type="checkbox"/> 2nd Degree A-V Block Type I [A: 2ND DEGREE A-V BLOCK TYPE II] <input type="checkbox"/> 2nd Degree A-V Block Type II [A: 3RD DEGREE A-V BLOCK] <input type="checkbox"/> 3rd Degree A-V Block [A: LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Left Bundle Branch Block [A: INCOMPLETE LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Left Bundle Branch Block [A: LEFT ANTERIOR HEMIBLOCK] <input type="checkbox"/> Left Anterior Hemiblock [A: LEFT POSTERIOR HEMIBLOCK] <input type="checkbox"/> Left Posterior Hemiblock [A: RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Right Bundle Branch Block [A: INCOMPLETE RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Right Bundle Branch Block [A: INTRAVENTRICULAR CONDUCTION DELAY] <input type="checkbox"/> Intraventricular Conduction Delay [A: ANTEROSEPTAL INFARCT PATTERN] <input type="checkbox"/> Anteroseptal Infarct Pattern [A: ANTEROLATERAL INFARCT PATTERN] <input type="checkbox"/> Anterolateral Infarct Pattern [A: LATERAL INFARCT PATTERN] <input type="checkbox"/> Lateral Infarct Pattern [A: INFERIOR INFARCT PATTERN] <input type="checkbox"/> Inferior Infarct Pattern [A: OTHER, SPECIFY] <input type="checkbox"/> [txtABNOTH1] Other, specify <div>A128</div>

11.*
✓

Change from baseline (Day 1, Pre-Dose) ECG
[Change from baseline]

[IstCHANGE1]
[A:NO SIGNIFICANT WORSENING FROM BASELINE]
[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]

No 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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	IstRHYTM
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	IstOVERALLINT
			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	IstABN1
			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	IstCHANGE1
			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

IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
IstRHYTM	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
IstOVERALLINT	LSTOVERALLINT_C	VARCHAR2
	LSTOVERALLINT	VARCHAR2
	LSTOVERALLINT_ND	VARCHAR2
IstABN1	LSTABN1_ND	VARCHAR2
IstABN1 - Sinus Bradycardia	*LSTABN1_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSBRADYCARDIA	VARCHAR2
IstABN1 - Sinus Tachycardia	*LSTABN1_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSTACHYCARDIA	VARCHAR2
IstABN1 - Atrial Tachycardia	*LSTABN1_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNATRIALTACHYCARDIA	VARCHAR2
IstABN1 - Ventricular Tachycardia	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
IstABN1 - Sick Sinus Syndrome	*LSTABN1_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN1_CITMABNSICKSINUSSYNDROME	VARCHAR2
IstABN1 - Premature Atrial Complexes	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
IstABN1 - Premature Ventricular Complexes	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
IstABN1 - Q Axis, Left Axis Deviation	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
IstABN1 - Left Atrial Abnormality	*LSTABN1_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
IstABN1 - Left Ventricular Hypertrophy	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
IstABN1 - Atrial Fibrillation	*LSTABN1_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN1_CITMABNATRIALFIBRILLATION	VARCHAR2
IstABN1 - Atrial Pacing	*LSTABN1_CITMABNATRIALPACING_C	VARCHAR2

	*LSTABN1_CITMABNATRIALPACING	VARCHAR2
IstABN1 - Ventricular Pacing	*LSTABN1_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARPACING	VARCHAR2
IstABN1 - Atrial Ventricular Pacing	*LSTABN1_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALVENTRICULARPACING	VARCHAR2
IstABN1 - 1st Degree A-V Block	*LSTABN1_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN1STDEGREEAVBLOCK	VARCHAR2
IstABN1 - 2nd Degree A-V Block Type I	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
IstABN1 - 2nd Degree A-V Block Type II	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
IstABN1 - 3rd Degree A-V Block	*LSTABN1_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
IstABN1 - Left Bundle Branch Block	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Incomplete Left Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Left Anterior Hemiblock	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN1 - Left Posterior Hemiblock	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN1 - Right Bundle Branch Block	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Incomplete Right Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Intraventricular Conduction Delay	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN1 - Anteroseptal Infarct Pattern	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
IstABN1 - Anterolateral Infarct Pattern	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
IstABN1 - Lateral Infarct Pattern	*LSTABN1_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNLATERALINFARCTPATTERN	VARCHAR2
IstABN1 - Inferior Infarct Pattern	*LSTABN1_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
IstABN1 - Other, specify	LSTABN1_TXTABNOTH1_C	VARCHAR2
	LSTABN1_TXTABNOTH1	VARCHAR2
IstABN1 - txtABNOTH1	TXTABNOTH1	VARCHAR2
IstCHANGE1	LSTCHANGE1_C	VARCHAR2
	LSTCHANGE1	VARCHAR2
	LSTCHANGE1_ND	VARCHAR2
IstCHANGE1 - 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]	<div>[IstVIS] [A: 50 QM] <input type="radio"/> 50mg QM [A: 50 Q2M] <input type="radio"/> [IstDOSING] 50mg Q2M [A: DOSING] <input type="radio"/> Dosing [A: NO DOSING] <input type="radio"/> No Dosing [A: 80 QM] <input type="radio"/> 80mg QM</div>
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?]	<div>[IstLAB6M] [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div>
3.* ✓	Choose the current visit [Choose the current visit]	<div>[IstCURVIS] [cIVISIT] <input type="button" value="v"/></div>
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?]	<div><div>[IstDOSECHANGE] [A: DOSE LEVEL NOT CHANGED]</div><div><input type="radio"/> [IstNOTCHANGED] Dose level not changed, please specify reason [A: SAME DOSE] <input type="radio"/> Participant eligible to continue on original dosing [A: CRITERIA NOT MET] <input type="radio"/> [IstCRITNOTMET] Protocol dose change criteria not met [A: NOT A PROTOCOL-SPECIFIED VISIT FOR POTENTIAL DOSE CHANGE] <input type="radio"/> Not a protocol-specified visit for potential dose change [A: WITHOUT AT GREATER THAN 35 OR LESS THAN 15] <input type="radio"/> 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] <input type="radio"/> [IstAT35] 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] <input type="radio"/> 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] <input type="radio"/> [txtAT35O] Other, please specify A200</div><div><input type="radio"/> [txtAT15O] Two previous predose AT levels from central lab testing < 15%, please specify reason A200</div><div><input type="radio"/> [txtNOTCHOTH] Other, please specify A200</div><div><div>[A: DOSE LEVEL ESCALATED]</div><div><input type="radio"/> [IstESCAL] Dose level escalated, please specify reason [A: AT LEVELS GREATER THAN 35] <input type="radio"/> Two previous predose AT levels from central lab testing > 35% [A: OTHER] <input type="radio"/> [txtESCALO] Other, please specify A200</div></div><div><div>[A: DOSE LEVEL DE-ESCALATED]</div><div><input type="radio"/> [txtDEESCALO] Dose level de-escalated, please specify reason A200</div></div><div><div>[A: TREATMENT DISCONTINUED]</div><div><input type="radio"/> [IstDISCONT] Treatment discontinued, please specify reason [A: AT LEVELS LESS THAN 15] <input type="radio"/> Two previous predose AT levels from central lab testing < 15% [A: OTHER] <input type="radio"/> [txtDISCONT] Other, please specify A200</div></div></div>

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

cINOTCHANGED	String		Participant eligible to continue on original dosing	SAME DOSE	citmNOTCHANGED_SAMEDOSE	IstNOTCHANGED
			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	
cCRITNOTMET	String		Not a protocol-specified visit for potential dose change	NOT A PROTOCOL-SPECIFIED VISIT FOR POTENTIAL DOSE CHANGE	citmCRITNOTMET_VISIT	IstCRITNOTMET
			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	
cAT35	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	IstAT35
			Other	OTHER	citmAT35_OTHER	
cESCAL	String		Two previous predose AT levels from central lab testing > 35%	AT LEVELS GREATER THAN 35	citmESCAL_AT	IstESCAL
			OTHER	OTHER	citmESCAL_OTHER	
cDISCONT	String		Two previous predose AT levels from central lab testing < 15%	AT LEVELS LESS THAN 15	citmDISCONT_AT	IstDISCONT
			Other	OTHER	citmDISCONT_OTHER	
cVISITAT	String		PR Day 1	PRD1	citmVISITAT_PRD1	IstVISITAT1, IstVISITAT2, IstVISITAT3
			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
IstVIS	LSTVIS_C	VARCHAR2
	LSTVIS	VARCHAR2
	LSTVIS_ND	VARCHAR2
IstVIS - IstDOSING	LSTDOSING_C	VARCHAR2
	LSTDOSING	VARCHAR2
IstLAB6M	LSTLAB6M_C	VARCHAR2
	LSTLAB6M	VARCHAR2
	LSTLAB6M_ND	VARCHAR2
IstCURVIS	LSTCURVIS_C	VARCHAR2
	LSTCURVIS	VARCHAR2
	LSTCURVIS_ND	VARCHAR2
IstDOSECHANGE	LSTDSECHANGE_C	VARCHAR2
	LSTDSECHANGE	VARCHAR2
	LSTDSECHANGE_ND	VARCHAR2
IstDOSECHANGE - IstNOTCHANGED	LSTNOTCHANGED_C	VARCHAR2
	LSTNOTCHANGED	VARCHAR2
IstDOSECHANGE - IstCRITNOTMET	LSTCRITNOTMET_C	VARCHAR2
	LSTCRITNOTMET	VARCHAR2

IstDOSECHANGE - IstAT35	LSTAT35_C	VARCHAR2
	LSTAT35	VARCHAR2
IstDOSECHANGE - txtAT350	TXTAT350	VARCHAR2
IstDOSECHANGE - txtAT150	TXTAT150	VARCHAR2
IstDOSECHANGE - txtNOTCHOTH	TXTNOTCHOTH	VARCHAR2
IstDOSECHANGE - IstESCAL	LSTESCAL_C	VARCHAR2
	LSTESCAL	VARCHAR2
IstDOSECHANGE - txtESCALO	TXTESCALO	VARCHAR2
IstDOSECHANGE - txtDEESCALO	TXTDEESCALO	VARCHAR2
IstDOSECHANGE - IstDISCONT	LSTDISCONT_C	VARCHAR2
	LSTDISCONT	VARCHAR2
IstDOSECHANGE - txtDISCONTO	TXTDISCONTO	VARCHAR2
cmpAT1	CMPAT1_ND	VARCHAR2
cmpAT1 - IstVISITAT1	LSTVISITAT1_C	VARCHAR2
	LSTVISITAT1	VARCHAR2
cmpAT1 - dAT1	DAT1	DATE
	DAT1_DTS	VARCHAR2
cmpAT1 - numAT1	NUMAT1	FLOAT
	NUMAT1_U	VARCHAR2
cmpAT2	CMPAT2_ND	VARCHAR2
cmpAT2 - IstVISITAT2	LSTVISITAT2_C	VARCHAR2
	LSTVISITAT2	VARCHAR2
cmpAT2 - dAT2	DAT2	DATE
	DAT2_DTS	VARCHAR2
cmpAT2 - numAT2	NUMAT2	FLOAT
	NUMAT2_U	VARCHAR2
cmpAT3	CMPAT3_ND	VARCHAR2
cmpAT3 - IstVISITAT3	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]	[IstASSDT] [A: SAME DATE] <input type="radio"/> Same date as visit date [A: OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (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 <input type="text"/> : Req <input type="text"/> 24-hour clock
3.* ✓	Rhythm [Rhythm]	[IstRHYTM] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
4.* ✓	Ventricular rate [Ventricular rate]	[numVR] <input type="text"/> N3 bpm ^[b]
5.* ✓	PR interval [PR]	[numPR] <input type="text"/> N3 msec ^[b]
6.* ✓	QRS duration [QRS]	[numQRS] <input type="text"/> N3 msec ^[b]
7.* ✓	QT interval [QT]	[numQT] <input type="text"/> N3 msec ^[b]
8.* ✓	QTc interval [QTc]	[numQTcF] <input type="text"/> N3 msec ^[b]
9.* ✓	Overall interpretation [Overall interpretation]	[IstOVERALLINT] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL, NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL, CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
10. ✓	If abnormal, please specify by checking all that apply [Abnormal]	[IstABN1] [A: SINUS BRADYCARDIA] <input type="checkbox"/> Sinus Bradycardia [A: SINUS TACHYCARDIA] <input type="checkbox"/> Sinus Tachycardia [A: ATRIAL TACHYCARDIA] <input type="checkbox"/> Atrial Tachycardia [A: VENTRICULAR TACHYCARDIA] <input type="checkbox"/> Ventricular Tachycardia [A: SICK SINUS SYNDROME] <input type="checkbox"/> Sick Sinus Syndrome [A: PREMATURE ATRIAL COMPLEXES] <input type="checkbox"/> Premature Atrial Complexes [A: PREMATURE VENTRICULAR COMPLEXES] <input type="checkbox"/> Premature Ventricular Complexes [A: Q AXIS LEFT AXIS DEVIATION] <input type="checkbox"/> Q Axis, Left Axis Deviation [A: LEFT ATRIAL ABNORMALITY] <input type="checkbox"/> Left Atrial Abnormality [A: LEFT VENTRICULAR HYPERTROPHY] <input type="checkbox"/> Left Ventricular Hypertrophy [A: ATRIAL FIBRILLATION] <input type="checkbox"/> Atrial Fibrillation [A: ATRIAL PACING] <input type="checkbox"/> Atrial Pacing [A: VENTRICULAR PACING] <input type="checkbox"/> Ventricular Pacing [A: ATRIAL VENTRICULAR PACING] <input type="checkbox"/> Atrial Ventricular Pacing [A: 1ST DEGREE A-V BLOCK] <input type="checkbox"/> 1st Degree A-V Block [A: 2ND DEGREE A-V BLOCK TYPE I] <input type="checkbox"/> 2nd Degree A-V Block Type I [A: 2ND DEGREE A-V BLOCK TYPE II] <input type="checkbox"/> 2nd Degree A-V Block Type II [A: 3RD DEGREE A-V BLOCK] <input type="checkbox"/> 3rd Degree A-V Block [A: LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Left Bundle Branch Block [A: INCOMPLETE LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Left Bundle Branch Block [A: LEFT ANTERIOR HEMIBLOCK] <input type="checkbox"/> Left Anterior Hemiblock [A: LEFT POSTERIOR HEMIBLOCK] <input type="checkbox"/> Left Posterior Hemiblock [A: RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Right Bundle Branch Block [A: INCOMPLETE RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Right Bundle Branch Block [A: INTRAVENTRICULAR CONDUCTION DELAY] <input type="checkbox"/> Intraventricular Conduction Delay [A: ANTEROSEPTAL INFARCT PATTERN] <input type="checkbox"/> Anteroseptal Infarct Pattern [A: ANTEROLATERAL INFARCT PATTERN] <input type="checkbox"/> Anterolateral Infarct Pattern [A: LATERAL INFARCT PATTERN] <input type="checkbox"/> Lateral Infarct Pattern [A: INFERIOR INFARCT PATTERN] <input type="checkbox"/> Inferior Infarct Pattern [A: OTHER, SPECIFY] <input type="checkbox"/> [txtABNOTH1] Other, specify <div>A128</div>

11.* ✓	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	<div>[IstCHANGE4] [A:NO SIGNIFICANT WORSENING FROM BASELINE] <input type="radio"/> No significant worsening from baseline [A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE] <input type="radio"/> [txtCHANGE4] Clinically significant worsening from baseline, specify A128</div>
12-lead Electrocardiogram - 30 Minutes Postdose [sct30M]		
This section should only be completed for subjects under Amendment 8		
12.* ✓	Time performed [Time performed]	<div>[dtmASS_T2] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock</div>
13.* ✓	Rhythm [Rhythm]	<div>[IstRHYTM2] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A:ABNORMAL CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant</div>
14.* ✓	Ventricular rate [Ventricular rate]	<div>[numVR2] <input type="text"/> N3 bpm^[b]</div>
15.* ✓	PR interval [PR]	<div>[numPR2] <input type="text"/> N3 msec^[b]</div>
16.* ✓	QRS duration [QRS]	<div>[numQRS2] <input type="text"/> N3 msec^[b]</div>
17.* ✓	QT interval [QT]	<div>[numQT2] <input type="text"/> N3 msec^[b]</div>
18.* ✓	QTc interval [QTc]	<div>[numQTcF2] <input type="text"/> N3 msec^[b]</div>
19.* ✓	Overall interpretation [Overall interpretation]	<div>[IstOVERALLINT2] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL, NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A:ABNORMAL, CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant</div>
20. ✓	If abnormal, please specify by checking all that apply [Abnormal]	<div><div><div>[IstABN2] [A:SINUS BRADYCARDIA] [A:SINUS TACHYCARDIA] [A:ATRIAL TACHYCARDIA] [A:VENTRICULAR TACHYCARDIA] [A:SICK SINUS SYNDROME] [A:PREMATURE ATRIAL COMPLEXES] [A:PREMATURE VENTRICULAR COMPLEXES] [A:Q AXIS LEFT AXIS DEVIATION] [A:LEFT ATRIAL ABNORMALITY] [A:LEFT VENTRICULAR HYPERTROPHY] [A:ATRIAL FIBRILLATION] [A:ATRIAL PACING] [A:VENTRICULAR PACING] [A:ATRIAL VENTRICULAR PACING] [A:1ST DEGREE A-V BLOCK] [A:2ND DEGREE A-V BLOCK TYPE I] [A:2ND DEGREE A-V BLOCK TYPE II] [A:3RD DEGREE A-V BLOCK] [A:LEFT BUNDLE BRANCH BLOCK] [A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK] [A:LEFT ANTERIOR HEMIBLOCK] [A:LEFT POSTERIOR HEMIBLOCK] [A:RIGHT BUNDLE BRANCH BLOCK] [A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK] [A:INTRAVENTRICULAR CONDUCTION DELAY] [A:ANTEROSEPTAL INFARCT PATTERN] [A:ANTEROLATERAL INFARCT PATTERN] [A:LATERAL INFARCT PATTERN] [A:INFERIOR INFARCT PATTERN] [A:OTHER, SPECIFY]</div><div><input type="checkbox"/> Sinus Bradycardia <input type="checkbox"/> Sinus Tachycardia <input type="checkbox"/> Atrial Tachycardia <input type="checkbox"/> Ventricular Tachycardia <input type="checkbox"/> Sick Sinus Syndrome <input type="checkbox"/> Premature Atrial Complexes <input type="checkbox"/> Premature Ventricular Complexes <input type="checkbox"/> Q Axis, Left Axis Deviation <input type="checkbox"/> Left Atrial Abnormality <input type="checkbox"/> Left Ventricular Hypertrophy <input type="checkbox"/> Atrial Fibrillation <input type="checkbox"/> Atrial Pacing <input type="checkbox"/> Ventricular Pacing <input type="checkbox"/> Atrial Ventricular Pacing <input type="checkbox"/> 1st Degree A-V Block <input type="checkbox"/> 2nd Degree A-V Block Type I <input type="checkbox"/> 2nd Degree A-V Block Type II <input type="checkbox"/> 3rd Degree A-V Block <input type="checkbox"/> Left Bundle Branch Block <input type="checkbox"/> Incomplete Left Bundle Branch Block <input type="checkbox"/> Left Anterior Hemiblock <input type="checkbox"/> Left Posterior Hemiblock <input type="checkbox"/> Right Bundle Branch Block <input type="checkbox"/> Incomplete Right Bundle Branch Block <input type="checkbox"/> Intraventricular Conduction Delay <input type="checkbox"/> Anteroseptal Infarct Pattern <input type="checkbox"/> Anterolateral Infarct Pattern <input type="checkbox"/> Lateral Infarct Pattern <input type="checkbox"/> Inferior Infarct Pattern <input type="checkbox"/> [txtABNOTH2] Other, specify A128</div></div></div>

21.* ✓	Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline]	<div>[IstCHANGE1] [A:NO SIGNIFICANT WORSENING FROM BASELINE] [A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]</div> <div><div><input type="radio"/> No significant worsening from baseline</div><div><input type="radio"/> [txtCHANGE1] Clinically significant worsening from baseline, specify A128</div></div>
12-lead Electrocardiogram - 4 Hours Postdose [sct4H]		
This section should only be completed for subjects under Amendment 8		
22.* ✓	Time performed [Time performed]	<div>[dtmASS_T4] (hh:mm) Req <div></div> : Req <div></div> 24-hour clock</div>
23.* ✓	Rhythm [Rhythm]	<div>[IstRHYTM4] [A:NORMAL] [A:ABNORMAL NOT CLINICALLY SIGNIFICANT] [A:ABNORMAL CLINICALLY SIGNIFICANT]</div> <div><div><input type="radio"/> Normal</div><div><input type="radio"/> Abnormal, Not Clinically Significant</div><div><input type="radio"/> Abnormal, Clinically Significant</div></div>
24.* ✓	Ventricular rate [Ventricular rate]	<div>[numVR4] N3 bpm^[b]</div>
25.* ✓	PR interval [PR]	<div>[numPR4] N3 msec^[b]</div>
26.* ✓	QRS duration [QRS]	<div>[numQRS4] N3 msec^[b]</div>
27.* ✓	QT interval [QT]	<div>[numQT4] N3 msec^[b]</div>
28.* ✓	QTc interval [QTc]	<div>[numQTcF4] N3 msec^[b]</div>
29.* ✓	Overall interpretation [Overall interpretation]	<div>[IstOVERALLINT4] [A:NORMAL] [A:ABNORMAL, NOT CLINICALLY SIGNIFICANT] [A:ABNORMAL, CLINICALLY SIGNIFICANT]</div> <div><div><input type="radio"/> Normal</div><div><input type="radio"/> Abnormal, Not Clinically Significant</div><div><input type="radio"/> Abnormal, Clinically Significant</div></div>
30. ✓	If abnormal, please specify by checking all that apply [Abnormal]	<div><div><div>[IstABN4] [A:SINUS BRADYCARDIA] [A:SINUS TACHYCARDIA] [A:ATRIAL TACHYCARDIA] [A:VENTRICULAR TACHYCARDIA] [A:SICK SINUS SYNDROME] [A:PREMATURE ATRIAL COMPLEXES] [A:PREMATURE VENTRICULAR COMPLEXES] [A:Q AXIS LEFT AXIS DEVIATION] [A:LEFT ATRIAL ABNORMALITY] [A:LEFT VENTRICULAR HYPERTROPHY] [A:ATRIAL FIBRILLATION] [A:ATRIAL PACING] [A:VENTRICULAR PACING] [A:ATRIAL VENTRICULAR PACING] [A:1ST DEGREE A-V BLOCK] [A:2ND DEGREE A-V BLOCK TYPE I] [A:2ND DEGREE A-V BLOCK TYPE II] [A:3RD DEGREE A-V BLOCK] [A:LEFT BUNDLE BRANCH BLOCK] [A:INCOMPLETE LEFT BUNDLE BRANCH BLOCK] [A:LEFT ANTERIOR HEMIBLOCK] [A:LEFT POSTERIOR HEMIBLOCK] [A:RIGHT BUNDLE BRANCH BLOCK] [A:INCOMPLETE RIGHT BUNDLE BRANCH BLOCK] [A:INTRAVENTRICULAR CONDUCTION DELAY] [A:ANTEROSEPTAL INFARCT PATTERN] [A:ANTEROLATERAL INFARCT PATTERN] [A:LATERAL INFARCT PATTERN] [A:INFERIOR INFARCT PATTERN] [A:OTHER, SPECIFY]</div><div><div><input type="checkbox"/> Sinus Bradycardia</div><div><input type="checkbox"/> Sinus Tachycardia</div><div><input type="checkbox"/> Atrial Tachycardia</div><div><input type="checkbox"/> Ventricular Tachycardia</div><div><input type="checkbox"/> Sick Sinus Syndrome</div><div><input type="checkbox"/> Premature Atrial Complexes</div><div><input type="checkbox"/> Premature Ventricular Complexes</div><div><input type="checkbox"/> Q Axis, Left Axis Deviation</div><div><input type="checkbox"/> Left Atrial Abnormality</div><div><input type="checkbox"/> Left Ventricular Hypertrophy</div><div><input type="checkbox"/> Atrial Fibrillation</div><div><input type="checkbox"/> Atrial Pacing</div><div><input type="checkbox"/> Ventricular Pacing</div><div><input type="checkbox"/> Atrial Ventricular Pacing</div><div><input type="checkbox"/> 1st Degree A-V Block</div><div><input type="checkbox"/> 2nd Degree A-V Block Type I</div><div><input type="checkbox"/> 2nd Degree A-V Block Type II</div><div><input type="checkbox"/> 3rd Degree A-V Block</div><div><input type="checkbox"/> Left Bundle Branch Block</div><div><input type="checkbox"/> Incomplete Left Bundle Branch Block</div><div><input type="checkbox"/> Left Anterior Hemiblock</div><div><input type="checkbox"/> Left Posterior Hemiblock</div><div><input type="checkbox"/> Right Bundle Branch Block</div><div><input type="checkbox"/> Incomplete Right Bundle Branch Block</div><div><input type="checkbox"/> Intraventricular Conduction Delay</div><div><input type="checkbox"/> Anteroseptal Infarct Pattern</div><div><input type="checkbox"/> Anterolateral Infarct Pattern</div><div><input type="checkbox"/> Lateral Infarct Pattern</div><div><input type="checkbox"/> Inferior Infarct Pattern</div><div><input type="checkbox"/> [txtABNOTH4] Other, specify A128</div></div></div></div>

31.*
✓

Change from baseline (Day 1, Pre-Dose) ECG
[Change from baseline]

[IstCHANGE3]
[A:NO SIGNIFICANT WORSENING FROM BASELINE]
[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]

No 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 I tem RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	IstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	IstRHYTM, IstRHYTM2, IstRHYTM4
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	IstOVERALLINT, IstOVERALLINT2, IstOVERALLINT4
			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	IstABN1, IstABN2, IstABN4
			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	IstCHANGE4
			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	IstCHANGE1
			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	IstCHANGE3

			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
IstABN1 - Atrial Fibrillation	*LSTABN1_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN1_CITMABNATRIALFIBRILLATION	VARCHAR2
IstABN1 - Atrial Pacing	*LSTABN1_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALPACING	VARCHAR2
IstABN1 - Ventricular Pacing	*LSTABN1_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARPACING	VARCHAR2
IstABN1 - Atrial Ventricular Pacing	*LSTABN1_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALVENTRICULARPACING	VARCHAR2
IstABN1 - 1st Degree A-V Block	*LSTABN1_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN1STDEGREEAVBLOCK	VARCHAR2
IstABN1 - 2nd Degree A-V Block Type I	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
IstABN1 - 2nd Degree A-V Block Type II	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
IstABN1 - 3rd Degree A-V Block	*LSTABN1_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
IstABN1 - Left Bundle Branch Block	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Incomplete Left Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Left Anterior Hemiblock	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN1 - Left Posterior Hemiblock	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN1 - Right Bundle Branch Block	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Incomplete Right Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Intraventricular Conduction Delay	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN1 - Anteroseptal Infarct Pattern	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
IstABN1 - Anterolateral Infarct Pattern	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
IstABN1 - Lateral Infarct Pattern	*LSTABN1_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNLATERALINFARCTPATTERN	VARCHAR2
IstABN1 - Inferior Infarct Pattern	*LSTABN1_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
IstABN1 - Other, specify	LSTABN1_TXTABNOTH1_C	VARCHAR2
	LSTABN1_TXTABNOTH1	VARCHAR2
IstABN1 - txtABNOTH1	TXTABNOTH1	VARCHAR2
IstCHANGE4	LSTCHANGE4_C	VARCHAR2
	LSTCHANGE4	VARCHAR2
	LSTCHANGE4_ND	VARCHAR2
IstCHANGE4 - txtCHANGE4	TXTCHANGE4	VARCHAR2
dtmASS_T2	DTMASS_T2	DATE
	DTMASS_T2_TMS	VARCHAR2
	DTMASS_T2_ND	VARCHAR2
IstRHYTM2	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
IstABN2 - Left Bundle Branch Block	*LSTABN2_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN2 - Incomplete Left Bundle Branch Block	*LSTABN2_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN2 - Left Anterior Hemiblock	*LSTABN2_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN2 - Left Posterior Hemiblock	*LSTABN2_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN2 - Right Bundle Branch Block	*LSTABN2_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN2 - Incomplete Right Bundle Branch Block	*LSTABN2_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN2_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN2 - Intraventricular Conduction Delay	*LSTABN2_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN2_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN2 - Anteroseptal Infarct Pattern	*LSTABN2_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
IstABN2 - Anterolateral Infarct Pattern	*LSTABN2_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
IstABN2 - Lateral Infarct Pattern	*LSTABN2_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNLATERALINFARCTPATTERN	VARCHAR2
IstABN2 - Inferior Infarct Pattern	*LSTABN2_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN2_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
IstABN2 - Other, specify	LSTABN2_TXTABNOTH2_C	VARCHAR2
	LSTABN2_TXTABNOTH2	VARCHAR2
IstABN2 - txtABNOTH2	TXTABNOTH2	VARCHAR2
IstCHANGE1	LSTCHANGE1_C	VARCHAR2
	LSTCHANGE1	VARCHAR2
	LSTCHANGE1_ND	VARCHAR2
IstCHANGE1 - txtCHANGE1	TXTCHANGE1	VARCHAR2
dtmASS_T4	DTMASS_T4	DATE
	DTMASS_T4_TMS	VARCHAR2
	DTMASS_T4_ND	VARCHAR2
IstRHYTM4	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
IstOVERALLINT4	LSTOVERALLINT4_C	VARCHAR2
	LSTOVERALLINT4	VARCHAR2

	LSTOVERALLINT4_ND	VARCHAR2
IstABN4	LSTABN4_ND	VARCHAR2
IstABN4 - Sinus Bradycardia	*LSTABN4_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNSINUSBRADYCARDIA	VARCHAR2
IstABN4 - Sinus Tachycardia	*LSTABN4_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNSINUSTACHYCARDIA	VARCHAR2
IstABN4 - Atrial Tachycardia	*LSTABN4_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNATRIALTACHYCARDIA	VARCHAR2
IstABN4 - Ventricular Tachycardia	*LSTABN4_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN4_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
IstABN4 - Sick Sinus Syndrome	*LSTABN4_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN4_CITMABNSICKSINUSSYNDROME	VARCHAR2
IstABN4 - Premature Atrial Complexes	*LSTABN4_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN4_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
IstABN4 - Premature Ventricular Complexes	*LSTABN4_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN4_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
IstABN4 - Q Axis, Left Axis Deviation	*LSTABN4_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN4_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
IstABN4 - Left Atrial Abnormality	*LSTABN4_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN4_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
IstABN4 - Left Ventricular Hypertrophy	*LSTABN4_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN4_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
IstABN4 - Atrial Fibrillation	*LSTABN4_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN4_CITMABNATRIALFIBRILLATION	VARCHAR2
IstABN4 - Atrial Pacing	*LSTABN4_CITMABNATRIALPACING_C	VARCHAR2
	*LSTABN4_CITMABNATRIALPACING	VARCHAR2
IstABN4 - Ventricular Pacing	*LSTABN4_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN4_CITMABNVENTRICULARPACING	VARCHAR2
IstABN4 - Atrial Ventricular Pacing	*LSTABN4_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN4_CITMABNATRIALVENTRICULARPACING	VARCHAR2
IstABN4 - 1st Degree A-V Block	*LSTABN4_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN4_CITMABN1STDEGREEAVBLOCK	VARCHAR2
IstABN4 - 2nd Degree A-V Block Type I	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
IstABN4 - 2nd Degree A-V Block Type II	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN4_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
IstABN4 - 3rd Degree A-V Block	*LSTABN4_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN4_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
IstABN4 - Left Bundle Branch Block	*LSTABN4_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN4 - Incomplete Left Bundle Branch Block	*LSTABN4_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN4 - Left Anterior Hemiblock	*LSTABN4_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN4 - Left Posterior Hemiblock	*LSTABN4_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN4 - Right Bundle Branch Block	*LSTABN4_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN4 - Incomplete Right Bundle Branch Block	*LSTABN4_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN4_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN4 - Intraventricular Conduction Delay	*LSTABN4_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN4_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN4 - Anteroseptal Infarct Pattern	*LSTABN4_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2

	*LSTABN4_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
IstABN4 - Anterolateral Infarct Pattern	*LSTABN4_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
IstABN4 - Lateral Infarct Pattern	*LSTABN4_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNLATERALINFARCTPATTERN	VARCHAR2
IstABN4 - Inferior Infarct Pattern	*LSTABN4_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN4_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
IstABN4 - Other, specify	LSTABN4_TXTABNOTH4_C	VARCHAR2
	LSTABN4_TXTABNOTH4	VARCHAR2
IstABN4 - txtABNOTH4	TXTABNOTH4	VARCHAR2
IstCHANGE3	LSTCHANGE3_C	VARCHAR2
	LSTCHANGE3	VARCHAR2
	LSTCHANGE3_ND	VARCHAR2
IstCHANGE3 - 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.* ✓	<div><div>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)]</div><div>[IstADDVIS] [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div></div>
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

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	IstADDVIS
			No	N	citmYesNo_N	

RDE Analytics: RD_FRMADDVIS		
Data Variable RefName	RD Column Name	Column Data Type
IstADDVIS	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]

[IstEOSQUEST]

[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	IstEOSQUEST
			Early Termination	EARLY TERMINATION	citmEOSQUEST_ET	

RDE Analytics: RD_FRMEOSQUEST		
Data Variable RefName	RD Column Name	Column Data Type
IstEOSQUEST	LSTEOSQUEST_C	VARCHAR2
	LSTEOSQUEST	VARCHAR2
	LSTEOSQUEST_ND	VARCHAR2

AT3SC002: 12-lead ECG (Unscheduled) (ECG UNS) [frmECG_UNUS]		
1.* ✓	Date collected [Date performed]	[IstASSDT] [A: SAME DATE] <input type="radio"/> Same date as visit date [A: OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)
12-lead Electrocardiogram [sctECG_UNUS]		
Supine after at least 10 minutes rest		
2.* ✓	Time performed [Time performed]	[dtmASS_T] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
3.* ✓	Rhythm [Rhythm]	[IstRHYTM] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
4.* ✓	Ventricular rate [Ventricular rate]	[numVR] <input type="text"/> N3 bpm ^[b]
5.* ✓	PR interval [PR]	[numPR] <input type="text"/> N3 msec ^[b]
6.* ✓	QRS duration [QRS]	[numQRS] <input type="text"/> N3 msec ^[b]
7.* ✓	QT interval [QT]	[numQT] <input type="text"/> N3 msec ^[b]
8.* ✓	QTc interval [QTc]	[numQTcF] <input type="text"/> N3 msec ^[b]
9.* ✓	Overall interpretation [Overall interpretation]	[IstOVERALLINT] [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL, NOT CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Not Clinically Significant [A: ABNORMAL, CLINICALLY SIGNIFICANT] <input type="radio"/> Abnormal, Clinically Significant
10. ✓	If abnormal, please specify by checking all that apply [Abnormal]	[IstABN1] [A: SINUS BRADYCARDIA] <input type="checkbox"/> Sinus Bradycardia [A: SINUS TACHYCARDIA] <input type="checkbox"/> Sinus Tachycardia [A: ATRIAL TACHYCARDIA] <input type="checkbox"/> Atrial Tachycardia [A: VENTRICULAR TACHYCARDIA] <input type="checkbox"/> Ventricular Tachycardia [A: SICK SINUS SYNDROME] <input type="checkbox"/> Sick Sinus Syndrome [A: PREMATURE ATRIAL COMPLEXES] <input type="checkbox"/> Premature Atrial Complexes [A: PREMATURE VENTRICULAR COMPLEXES] <input type="checkbox"/> Premature Ventricular Complexes [A: Q AXIS LEFT AXIS DEVIATION] <input type="checkbox"/> Q Axis, Left Axis Deviation [A: LEFT ATRIAL ABNORMALITY] <input type="checkbox"/> Left Atrial Abnormality [A: LEFT VENTRICULAR HYPERTROPHY] <input type="checkbox"/> Left Ventricular Hypertrophy [A: ATRIAL FIBRILLATION] <input type="checkbox"/> Atrial Fibrillation [A: ATRIAL PACING] <input type="checkbox"/> Atrial Pacing [A: VENTRICULAR PACING] <input type="checkbox"/> Ventricular Pacing [A: ATRIAL VENTRICULAR PACING] <input type="checkbox"/> Atrial Ventricular Pacing [A: 1ST DEGREE A-V BLOCK] <input type="checkbox"/> 1st Degree A-V Block [A: 2ND DEGREE A-V BLOCK TYPE I] <input type="checkbox"/> 2nd Degree A-V Block Type I [A: 2ND DEGREE A-V BLOCK TYPE II] <input type="checkbox"/> 2nd Degree A-V Block Type II [A: 3RD DEGREE A-V BLOCK] <input type="checkbox"/> 3rd Degree A-V Block [A: LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Left Bundle Branch Block [A: INCOMPLETE LEFT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Left Bundle Branch Block [A: LEFT ANTERIOR HEMIBLOCK] <input type="checkbox"/> Left Anterior Hemiblock [A: LEFT POSTERIOR HEMIBLOCK] <input type="checkbox"/> Left Posterior Hemiblock [A: RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Right Bundle Branch Block [A: INCOMPLETE RIGHT BUNDLE BRANCH BLOCK] <input type="checkbox"/> Incomplete Right Bundle Branch Block [A: INTRAVENTRICULAR CONDUCTION DELAY] <input type="checkbox"/> Intraventricular Conduction Delay [A: ANTEROSEPTAL INFARCT PATTERN] <input type="checkbox"/> Anteroseptal Infarct Pattern [A: ANTEROLATERAL INFARCT PATTERN] <input type="checkbox"/> Anterolateral Infarct Pattern [A: LATERAL INFARCT PATTERN] <input type="checkbox"/> Lateral Infarct Pattern [A: INFERIOR INFARCT PATTERN] <input type="checkbox"/> Inferior Infarct Pattern [A: OTHER, SPECIFY] <input type="checkbox"/> [txtABNOTH1] Other, specify <div>A128</div>

11.*
✓

Change from baseline (Day 1, Pre-Dose) ECG
[Change from baseline]

[IstCHANGE1]
[A:NO SIGNIFICANT WORSENING FROM BASELINE]
[A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE]

No 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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clRhythm	String		Normal	NORMAL	citmRhythm_NORMAL	IstRHYTM
			Abnormal, Not Clinically Significant	ABNORMAL NOT CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALNCS	
			Abnormal, Clinically Significant	ABNORMAL CLINICALLY SIGNIFICANT	citmRhythm_ABNORMALCS	
clOVERALLINT	String		Normal	NORMAL	citmOVERALLINT_Normal	IstOVERALLINT
			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	IstABN1
			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	IstCHANGE1
			Clinically significant worsening from baseline, please explain	CLINICALLY SIGNIFICANT WORSENING FROM BASELINE	citmCHANGE_CLINICALLYSIGNIFICANTWORSENINGFROMBASELINE	

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

IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
IstRHYTM	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
IstOVERALLINT	LSTOVERALLINT_C	VARCHAR2
	LSTOVERALLINT	VARCHAR2
	LSTOVERALLINT_ND	VARCHAR2
IstABN1	LSTABN1_ND	VARCHAR2
IstABN1 - Sinus Bradycardia	*LSTABN1_CITMABNSINUSBRADYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSBRADYCARDIA	VARCHAR2
IstABN1 - Sinus Tachycardia	*LSTABN1_CITMABNSINUSTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNSINUSTACHYCARDIA	VARCHAR2
IstABN1 - Atrial Tachycardia	*LSTABN1_CITMABNATRIALTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNATRIALTACHYCARDIA	VARCHAR2
IstABN1 - Ventricular Tachycardia	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARTACHYCARDIA	VARCHAR2
IstABN1 - Sick Sinus Syndrome	*LSTABN1_CITMABNSICKSINUSSYNDROME_C	VARCHAR2
	*LSTABN1_CITMABNSICKSINUSSYNDROME	VARCHAR2
IstABN1 - Premature Atrial Complexes	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREATRIALCOMPLEXES	VARCHAR2
IstABN1 - Premature Ventricular Complexes	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES_C	VARCHAR2
	*LSTABN1_CITMABNPREMATUREVENTRICULARCOMPLEXES	VARCHAR2
IstABN1 - Q Axis, Left Axis Deviation	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION_C	VARCHAR2
	*LSTABN1_CITMABNQAXISLEFTAXISDEVIATION	VARCHAR2
IstABN1 - Left Atrial Abnormality	*LSTABN1_CITMABNLEFTATRIALABNORMALITY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTATRIALABNORMALITY	VARCHAR2
IstABN1 - Left Ventricular Hypertrophy	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY_C	VARCHAR2
	*LSTABN1_CITMABNLEFTVENTRICULARHYPERTROPHY	VARCHAR2
IstABN1 - Atrial Fibrillation	*LSTABN1_CITMABNATRIALFIBRILLATION_C	VARCHAR2
	*LSTABN1_CITMABNATRIALFIBRILLATION	VARCHAR2
IstABN1 - Atrial Pacing	*LSTABN1_CITMABNATRIALPACING_C	VARCHAR2

	*LSTABN1_CITMABNATRIALPACING	VARCHAR2
IstABN1 - Ventricular Pacing	*LSTABN1_CITMABNVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNVENTRICULARPACING	VARCHAR2
IstABN1 - Atrial Ventricular Pacing	*LSTABN1_CITMABNATRIALVENTRICULARPACING_C	VARCHAR2
	*LSTABN1_CITMABNATRIALVENTRICULARPACING	VARCHAR2
IstABN1 - 1st Degree A-V Block	*LSTABN1_CITMABN1STDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN1STDEGREEAVBLOCK	VARCHAR2
IstABN1 - 2nd Degree A-V Block Type I	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEI	VARCHAR2
IstABN1 - 2nd Degree A-V Block Type II	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII_C	VARCHAR2
	*LSTABN1_CITMABN2NDDEGREEAVBLOCKTYPEII	VARCHAR2
IstABN1 - 3rd Degree A-V Block	*LSTABN1_CITMABN3RDDEGREEAVBLOCK_C	VARCHAR2
	*LSTABN1_CITMABN3RDDEGREEAVBLOCK	VARCHAR2
IstABN1 - Left Bundle Branch Block	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Incomplete Left Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETELEFTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Left Anterior Hemiblock	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTANTERIORHEMIBLOCK	VARCHAR2
IstABN1 - Left Posterior Hemiblock	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNLEFTPOSTERIORHEMIBLOCK	VARCHAR2
IstABN1 - Right Bundle Branch Block	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNRIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Incomplete Right Bundle Branch Block	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK_C	VARCHAR2
	*LSTABN1_CITMABNINCOMPLETERIGHTBUNDLEBRANCHBLOCK	VARCHAR2
IstABN1 - Intraventricular Conduction Delay	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY_C	VARCHAR2
	*LSTABN1_CITMABNINTRAVENTRICULARCONDUCTIONDELAY	VARCHAR2
IstABN1 - Anteroseptal Infarct Pattern	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROSEPTALINFARCTPATTERN	VARCHAR2
IstABN1 - Anterolateral Infarct Pattern	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNANTEROLATERALINFARCTPATTERN	VARCHAR2
IstABN1 - Lateral Infarct Pattern	*LSTABN1_CITMABNLATERALINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNLATERALINFARCTPATTERN	VARCHAR2
IstABN1 - Inferior Infarct Pattern	*LSTABN1_CITMABNINFERIORINFARCTPATTERN_C	VARCHAR2
	*LSTABN1_CITMABNINFERIORINFARCTPATTERN	VARCHAR2
IstABN1 - Other, specify	LSTABN1_TXTABNOTH1_C	VARCHAR2
	LSTABN1_TXTABNOTH1	VARCHAR2
IstABN1 - txtABNOTH1	TXTABNOTH1	VARCHAR2
IstCHANGE1	LSTCHANGE1_C	VARCHAR2
	LSTCHANGE1	VARCHAR2
	LSTCHANGE1_ND	VARCHAR2
IstCHANGE1 - 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_UNUS]

1.*
✓

Date and time of visit
[Date and time of visit]

[dtmVISIT_DT_UNUS] (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?]

[IstVISDELETED]
[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	cltmYes_Y	IstVISDELETED

RDE Analytics: RD_FRMDOV_REP		
Data Variable RefName	RD Column Name	Column Data Type
dtmVISIT_DT_UNUS	DTMVISIT_DT_UNUS	DATE
	DTMVISIT_DT_UNUS_DTS	VARCHAR2
	DTMVISIT_DT_UNUS_DTR	VARCHAR2
	DTMVISIT_DT_UNUS_ND	VARCHAR2
IstVISDELETED	LSTVISDELETED_ND	VARCHAR2
IstVISDELETED - 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.* ✓	<div><div>Which Protocol Amendment Version is effective for this subject for this AT Follow-Up Visit? [Protocol Amendment Version effective?]</div><div><div>[IstPROTATFU]</div><div><div>[A:PROTAM5]</div><div><input type="radio"/> Protocol Amendment 5 (or lower)</div></div><div><div>[A:PROTAM6]</div><div><input type="radio"/> Protocol Amendment 6 (or higher)</div></div></div></div>
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

Codelist Values Tables: Protocol Version for AT Follow-Up Visit						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist I tem RefName	Data Variable RefName
clPROTATFU	String		Protocol Amendment 5 (or lower)	PROTAM5	citmPROTATFU_PROTAM5	IstPROTATFU
			Protocol Amendment 6 (or higher)	PROTAM6	citmPROTATFU_PROTAM6	

RDE Analytics: RD_FRMPROTATFU			
Data Variable RefName	RD Column Name	Column Data Type	
IstPROTATFU	LSTPROTATFU_C	VARCHAR2	
	LSTPROTATFU	VARCHAR2	
	LSTPROTATFU_ND	VARCHAR2	

AT3SC002: Vital Signs (VS EXW) [frmVS_EXW]

Assessment Date [sctASSDT]

1.*
✓

Date collected
[Date performed]

[IstASSDT]
[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	IstASSDT
			Other	OTHER	citmDateOther_Other	

RDE Analytics: RD_FRMVS_EXW		
Data Variable RefName	RD Column Name	Column Data Type
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - 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]

[IstASSDT]
[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?]

[IstPDMARK]
[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 I tem RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	IstASSDT
			Other	OTHER	citmDateOther_Other	
clPDMARK	String		Yes	Y	citmPDMARK_Y	IstPDMARK
			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
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
IstPDMARK	LSTPDMARK_C	VARCHAR2
	LSTPDMARK	VARCHAR2
	LSTPDMARK_ND	VARCHAR2

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

Date of Unscheduled Visit [sctDOV_UNNS]

1.*
✓

Date and time of visit
[Date and time of visit]

[dtmVISIT_DT_UNNS] (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?]

[IstVISDELETED]
[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	cltmYes_Y	IstVISDELETED

RDE Analytics: RD_FRMDOV_SURG		
Data Variable RefName	RD Column Name	Column Data Type
dtmVISIT_DT_UNNS	DTMVISIT_DT_UNNS	DATE
	DTMVISIT_DT_UNNS_DTS	VARCHAR2
	DTMVISIT_DT_UNNS_DTR	VARCHAR2
	DTMVISIT_DT_UNNS_ND	VARCHAR2
IstVISDELETED	LSTVISDELETED_ND	VARCHAR2
IstVISDELETED - 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]

[IstSURGLOC]
[A:STUDY CENTER] ☐ Study center
[A:OTHER LOCATION/SITE] ☐ Other location/site

2.
✓

Date performed
[Date performed]

[IstASSDT_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	IstSURGLOC
			Other location/site	OTHER LOCATION/SITE	citmSURGLOC_OTHER	
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	IstASSDT_POP
			Other	OTHER	citmDateOther_Other	

RDE Analytics: RD_FRMLAB_POP		
Data Variable RefName	RD Column Name	Column Data Type
IstSURGLOC	LSTSURGLOC_C	VARCHAR2
	LSTSURGLOC	VARCHAR2
	LSTSURGLOC_ND	VARCHAR2
IstASSDT_POP	LSTASSDT_POP_C	VARCHAR2
	LSTASSDT_POP	VARCHAR2
	LSTASSDT_POP_ND	VARCHAR2
IstASSDT_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]

[IstDOSEU]
[A: UNIT] Unit specification [IstDOSEUSP]
[ciDOSEUSP]

[A: OTHER] [txtDOSEUOTH]
Other, please specify
A50

7.*
✔

Frequency
[Frequency]

[IstFREQ]
[A: FREQUENCY] Frequency specification [IstFREQSP]
[ciFREQSP]

[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	IstDOSEU
			Other	OTHER	citmUnitOther_Other	
clDOSEUSP	String		mg	MG	citmDOSEUSP_MG	IstDOSEUSP
			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	IstFREQ
			Other	OTHER	citmFrequencyOther_Other	
clFREQSP	String		q.d. - once daily	QD	citmFREQSP_QD	IstFREQSP
			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
IstDOSEU	LSTDUSEU_C	VARCHAR2
	LSTDUSEU	VARCHAR2
	LSTDUSEU_ND	VARCHAR2
IstDOSEU - IstDOSEUSP	LSTDUSEUSP_C	VARCHAR2
	LSTDUSEUSP	VARCHAR2
IstDOSEU - txtDOSEUOTH	TXTDUSEUOTH	VARCHAR2
IstFREQ	LSTFREQ_C	VARCHAR2
	LSTFREQ	VARCHAR2
	LSTFREQ_ND	VARCHAR2
IstFREQ - IstFREQSP	LSTFREQSP_C	VARCHAR2
	LSTFREQSP	VARCHAR2
IstFREQ - 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?]

[IstTRANSF]
[A: Y] [IstTRANSTP]
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]

[IstSURG]
[A: ELEC] Elective surgery
[A: EMERGE] Emergency surgery

7.*
✓

Minor/Major surgery
[Minor/Major surgery]

[IstSURGMM]
[A: MINOR] Minor surgery
[A: MAJOR] Major surgery

8.*
✓

Treatment paused
[Treatment paused]

[IstTPAU]
[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	IstTRANSF, IstTPAU
			No	N	citmYesNo_N	
clTRANSTP	String		Red blood cell (RBCs)	RBC	citmTRANSP_RBC	IstTRANSTP
			Platelets	PL	citmTRANSP_PL	
			Fresh frozen plasma (FFP)	FFP	citmTRANSP_FFP	
			Cryoprecipitate	CRYO	citmTRANSP_CRYO	
clSURG	String		Elective surgery	ELEC	citmSURG_ELEC	IstSURG
			Emergency surgery	EMERGE	citmSURG_EMERG	
clSURGMM	String		Minor surgery	MINOR	citmSURGMM_MINOR	IstSURGMM
			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]

[IstLAB_BPA]

[A: Y] ☐ [cmpLAB_BPA]

Yes

[IstLAB_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

[IstLAB_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

[IstLAB_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	IstLAB_BPA
			No	N	citmYesNo_N	
clActTimeNotCol	String		Actual Time	ACTUAL TIME	citmActTimeNotCol_ActTime	IstLAB_PRE, IstLAB_10M, IstLAB_60M
			Not collected	NOT COLLECTED	citmActTimeNotCol_NotCol	

RDE Analytics: RD_FRMLAB_BPA		
Data Variable RefName	RD Column Name	Column Data Type
IstLAB_BPA	LSTLAB_BPA_C	VARCHAR2
	LSTLAB_BPA	VARCHAR2
	LSTLAB_BPA_ND	VARCHAR2
IstLAB_BPA - IstLAB_PRE	LSTLAB_PRE_C	VARCHAR2
	LSTLAB_PRE	VARCHAR2
IstLAB_BPA - tLAB_PRE	TLAB_PRE	DATE
	TLAB_PRE_TMS	VARCHAR2
IstLAB_BPA - tINTAKE	TINTAKE	DATE
	TINTAKE_TMS	VARCHAR2
IstLAB_BPA - IstLAB_10M	LSTLAB_10M_C	VARCHAR2
	LSTLAB_10M	VARCHAR2
IstLAB_BPA - tLAB_10M	TLAB_10M	DATE
	TLAB_10M_TMS	VARCHAR2
IstLAB_BPA - IstLAB_60M	LSTLAB_60M_C	VARCHAR2
	LSTLAB_60M	VARCHAR2
IstLAB_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]

[IstASSDT]
[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?]

[IstTRANSFU_SV]
[A: N]

☐ No

[A: Y]

☐ [IstTRANSTPP]
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?]

[IstHERS]
[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 I tem RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	IstASSDT
			Other	OTHER	citmDateOther_Other	
clNoYes	String		No	N	citmNoYes_N	IstTRANSFU_SV
			Yes	Y	citmNoYes_Y	
clTRANSTP	String		Red blood cell (RBCs)	RBC	citmTRANSP_RBC	IstTRANSTPP
			Platelets	PL	citmTRANSP_PL	
			Fresh frozen plasma (FFP)	FFP	citmTRANSP_FFP	
			Cryoprecipitate	CRYO	citmTRANSP_CRYO	
clHERS	String		Excellent	EXC	citmHERS_EXC	IstHERS
			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
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - 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
IstTRANSFU_SV	LSTTRANSFU_SV_C	VARCHAR2
	LSTTRANSFU_SV	VARCHAR2
	LSTTRANSFU_SV_ND	VARCHAR2
IstTRANSFU_SV - Red blood cell (RBCs)	LSTTRANSTPP_NUMRBC_C	VARCHAR2
	LSTTRANSTPP_NUMRBC	VARCHAR2
IstTRANSFU_SV - numRBC	NUMRBC	NUMBER
IstTRANSFU_SV - Platelets	LSTTRANSTPP_NUMPL_C	VARCHAR2
	LSTTRANSTPP_NUMPL	VARCHAR2
IstTRANSFU_SV - numPL	NUMPL	NUMBER
IstTRANSFU_SV - Fresh frozen plasma (FFP)	LSTTRANSTPP_NUMFFP_C	VARCHAR2
	LSTTRANSTPP_NUMFFP	VARCHAR2
IstTRANSFU_SV - numFFP	NUMFFP	NUMBER
IstTRANSFU_SV - Cryoprecipitate	LSTTRANSTPP_NUMCRYO_C	VARCHAR2
	LSTTRANSTPP_NUMCRYO	VARCHAR2
IstTRANSFU_SV - numCRYO	NUMCRYO	NUMBER
IstHERS	LSTHERS_C	VARCHAR2
	LSTHERS	VARCHAR2
	LSTHERS_ND	VARCHAR2

AT3SC002: Perioperative Questionnaire (POPQ) [frmPOPQ]

Assessment date and time [sctPOPQDT]

1.*
✓

Date collected
[Date performed]

[IstASSDT]
[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?]

[IstTRANSFU]
[A: N]

☐ No

[A: Y]

☐ [IstTRANSTPP]
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?]

[IstHERS_PO]
[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 I tem RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	IstASSDT
			Other	OTHER	citmDateOther_Other	
clNoYes	String		No	N	citmNoYes_N	IstTRANSFU
			Yes	Y	citmNoYes_Y	
clTRANSTP	String		Red blood cell (RBCs)	RBC	citmTRANSP_RBC	IstTRANSTPP
			Platelets	PL	citmTRANSP_PL	
			Fresh frozen plasma (FFP)	FFP	citmTRANSP_FFP	
			Cryoprecipitate	CRYO	citmTRANSP_CRYO	
clHERS	String		Excellent	EXC	citmHERS_EXC	IstHERS_PO
			Good	GOOD	citmHERS_GOOD	
			Moderate	MOD	citmHERS_MOD	
			None	NONE	citmHERS_NONE	

RDE Analytics: RD_FRMPOPOQ		
Data Variable RefName	RD Column Name	Column Data Type
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
dtmASS_T	DTMASS_T	DATE
	DTMASS_T_TMS	VARCHAR2
	DTMASS_T_ND	VARCHAR2
IstTRANSFU	LSTTRANSFU_C	VARCHAR2
	LSTTRANSFU	VARCHAR2

file:///C:/Users/Nico_Van_Dessel/AppData/Local/Apps/2.0/8ROY8BMP.9NT/87KKKWE2.8YL/orac..47.0_7e15c60fcb5f8c5e_0006.0002_e3a46b3970a1f84d/HtmlResources/AnnotatedStudybook.html

21-Sep-21

	LSTTRANSFU_ND	VARCHAR2
IstTRANSFU - Red blood cell (RBCs)	LSTTRANSTPP_NUMRBC_C	VARCHAR2
	LSTTRANSTPP_NUMRBC	VARCHAR2
IstTRANSFU - numRBC	NUMRBC	NUMBER
IstTRANSFU - Platelets	LSTTRANSTPP_NUMPL_C	VARCHAR2
	LSTTRANSTPP_NUMPL	VARCHAR2
IstTRANSFU - numPL	NUMPL	NUMBER
IstTRANSFU - Fresh frozen plasma (FFP)	LSTTRANSTPP_NUMFFP_C	VARCHAR2
	LSTTRANSTPP_NUMFFP	VARCHAR2
IstTRANSFU - numFFP	NUMFFP	NUMBER
IstTRANSFU - Cryoprecipitate	LSTTRANSTPP_NUMCRYO_C	VARCHAR2
	LSTTRANSTPP_NUMCRYO	VARCHAR2
IstTRANSFU - numCRYO	NUMCRYO	NUMBER
IstHERS_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?]

[IstCOVCOMP]

[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

[IstTHROM]

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	IstCOVCOMP
			No, please complete Postoperative visit 3	N	citmCOVCOMP_N	
clTHROMDT	String		Date	DATE	citmTHROMDT_DATE	IstTHROM
			Not Applicable	NAP	citmTHROMDT_NAP	

RDE Analytics: RD_FRMCOMP_POPV2		
Data Variable RefName	RD Column Name	Column Data Type
IstCOVCOMP	LSTCOVCOMP_C	VARCHAR2
	LSTCOVCOMP	VARCHAR2
	LSTCOVCOMP_ND	VARCHAR2
IstCOVCOMP - dtSTART	DTSTART	DATE
	DTSTART_DTS	VARCHAR2
	DTSTART_DTR	VARCHAR2
IstCOVCOMP - dtEND	DTEND	DATE
	DTEND_DTS	VARCHAR2
	DTEND_DTR	VARCHAR2
IstCOVCOMP - IstTHROM	LSTTHROM_C	VARCHAR2
	LSTTHROM	VARCHAR2
IstCOVCOMP - dTHROM	DTHROM	DATE
	DTHROM_DTS	VARCHAR2
IstCOVCOMP - 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]

[IstASSDT]
[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?]

[IstHERS_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]

[IstTHROM]
[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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clHERS	String		Excellent	EXC	citmHERS_EXC	IstHERS_PO
			Good	GOOD	citmHERS_GOOD	
			Moderate	MOD	citmHERS_MOD	
			None	NONE	citmHERS_NONE	
clTHROMDT	String		Date	DATE	citmTHROMDT_DATE	IstTHROM
			Not Applicable	NAP	citmTHROMDT_NAP	

RDE Analytics: RD_FRMCOMP_POP		
Data Variable RefName	RD Column Name	Column Data Type
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
IstHERS_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]	[IstTELSCHED] [cIteLSCHED] 		
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]	[IstDOSE] [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]	[IstACTVIS] [cIACVIS] 		

2. ✓	Date and Time			
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Telephone call(s) 2 weeks after scheduled AT Follow-up visit(s) Entry [sctTELAFU]






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		
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3. ✓	Date and Time			
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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		
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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)		
IstTELSCHED	Individual	1

Codelist Values Tables: Telephone Calls						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist I tem RefName	Data Variable RefName
cIteLSCHED	String		2 Weeks post Month 1 visit	M1	citmTELSCHED_M1	IstTELSCHED
			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?]	[IstBLEEDYN] [A: Y] <input type="radio"/> [IstTREATYN] Yes, Did the symptoms require treatment with Factor VIII, Factor IX, aPCC, rFVIIa, or Antifibrinolytics? [A: Y] <input type="radio"/> [IstTREATBEF] Yes, Was treatment for these symptoms started before this phone call? [A: Y] <input type="radio"/> [IstTREATNUM] Yes, this treatment was: [cITREATNUM] ▾ [A: N] <input type="radio"/> No [A: N] <input type="radio"/> No [A: N] <input type="radio"/> No

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

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	IstBLEEDYN, IstTREATYN, IstTREATBEF
			No	N	citmYesNo_N	
clTREATNUM	String		The First Treatment	FIRST TREATMENT	citmTREATNUM_FIRST	IstTREATNUM
			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
IstBLEEDYN	LSTBLEEDYN_C	VARCHAR2
	LSTBLEEDYN	VARCHAR2
	LSTBLEEDYN_ND	VARCHAR2
IstBLEEDYN - IstTREATYN	LSTTREATYN_C	VARCHAR2
	LSTTREATYN	VARCHAR2
IstBLEEDYN - IstTREATBEF	LSTTREATBEF_C	VARCHAR2
	LSTTREATBEF	VARCHAR2
IstBLEEDYN - IstTREATNUM	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]

[IstASSDT]
[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]

[IstLAB_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]

[IstLAB_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]

[IstLAB_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	IstASSDT
			Other	OTHER	citmDateOther_Other	
clActTimeNotCol	String		Actual Time	ACTUAL TIME	citmActTimeNotCol_ActTime	IstLAB_PRE, IstLAB_10M, IstLAB_60M
			Not collected	NOT COLLECTED	citmActTimeNotCol_NotCol	

RDE Analytics: RD_FRMLAB_BLEED		
Data Variable RefName	RD Column Name	Column Data Type
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
txtREFNO	TXTREFNO	VARCHAR2
	TXTREFNO_ND	VARCHAR2
IstLAB_PRE	LSTLAB_PRE_C	VARCHAR2
	LSTLAB_PRE	VARCHAR2
	LSTLAB_PRE_ND	VARCHAR2
IstLAB_PRE - tLAB_PRE	TLAB_PRE	DATE

file:///C:/Users/Nico_Van_Dessel/AppData/Local/Apps/2.0/8ROY8BMP.9NT/87KKKWE2.8YL/orac..47.0_7e15c60fcb5f8c5e_0006.0002_e3a46b3970a1f84d/HtmlResources/AnnotatedStudybook.html

21-Sep-21

	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?]

[IstIMAG]

[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]

[IstIMAGSP]

[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?]

[IstACTBLD]

[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 I tem RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	IstIMAG
			No	N	citmYesNo_N	
clIMAGSP	String		Ultrasound	ULTRASOUND	citmIMAGSP_ULTRASOUND	IstIMAGSP
			CT Imaging	CT SCAN	citmIMAGSP_CT	
			MRI Imaging	MRI	citmIMAGSP_MRI	
			Other	OTHER	itmIMAGSP_OTHER	
clACTBLD	String		Yes	Y	citmACTBLD_Y	IstACTBLD
			No	N	citmACTBLD_N	
			Indeterminate	INDETERMINATE	citmACTBLD_INDET	

RDE Analytics: RD_FRMIMAG		
Data Variable RefName	RD Column Name	Column Data Type
IstIMAG	LSTIMAG_C	VARCHAR2
	LSTIMAG	VARCHAR2
	LSTIMAG_ND	VARCHAR2
numEMAIL1	NUMEMAIL1	NUMBER
	NUMEMAIL1_ND	VARCHAR2
numEMAIL2	NUMEMAIL2	NUMBER
	NUMEMAIL2_ND	VARCHAR2
RD_FRMIMAG_SCTIMAG		
IstIMAGSP	LSTIMAGSP_C	VARCHAR2
	LSTIMAGSP	VARCHAR2
	LSTIMAGSP_ND	VARCHAR2

IstIMAGSP - txtIMAGOTH	TXTIMAGOTH	VARCHAR2
dIMAG	DIMAG	DATE
	DIMAG_DTS	VARCHAR2
	DIMAG_ND	VARCHAR2
IstACTBLD	LSTACTBLD_C	VARCHAR2
	LSTACTBLD	VARCHAR2
	LSTACTBLD_ND	VARCHAR2

AT3SC002: Date of Unscheduled Visit (DOV UNS) [frmDOV_UNUS]		
Date of Unscheduled Visit [sctDOV_UNUS]		
1.* ✓	Date and time of visit [Date and time of visit]	[dtmVISIT_DT_UNUS] (DD/MM/YYYY hh:mm) Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2023) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock
2.	Should this visit be marked as deleted? [hidden] [Should this visit be marked as deleted?]	[IstVISDELETED] [A: Y] <input type="checkbox"/> Yes
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

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	cltmYes_Y	IstVISDELETED

RDE Analytics: RD_FRMDOV_UNUS		
Data Variable RefName	RD Column Name	Column Data Type
dtmVISIT_DT_UNUS	DTMVISIT_DT_UNUS	DATE
	DTMVISIT_DT_UNUS_DTS	VARCHAR2
	DTMVISIT_DT_UNUS_DTR	VARCHAR2
	DTMVISIT_DT_UNUS_ND	VARCHAR2
IstVISDELETED	LSTVISDELETED_ND	VARCHAR2
IstVISDELETED - Yes	LSTVISDELETED_CITMYESY_C	VARCHAR2
	LSTVISDELETED_CITMYESY	VARCHAR2

AT3SC002: Unscheduled Assessments (ASS UNS) [frmASS_UNUS]

Unscheduled Assessments [sctASS_UNUS]

1 *

✓

Check the assessments to be completed at this unscheduled visit
[Performed assessments during visit]

[IstASS_UNUS]

[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
cIASS_UNUS	String		Imaging	IMAG	citmASS_UNUS_IMAG	IstASS_UNUS
			Central Laboratory Assessments	LAB	citmASS_UNUS_LAB	
			12-lead Electrocardiogram	ECG	citmASS_UNUS_ECG	
			EQ-5D Questionnaire	EQ5D	citmASS_UNUS_EQ5D	
			HAEM-A-QOL Questionnaire	HAEMAQOL	citmASS_UNUS_HAEMAQOL	
			Directed Physical Examination	DIRECTED PE	citmASS_UNUS_PE	
			Plasma PK Sampling	PKBLD	citmASS_UNUS_PKBLD	
			Vital Signs	VITAL SIGNS	citmASS_UNUS_VS	
			Whole Blood Clot Formation (ROTEM)	WHOLE BLOOD CLOT	citmASS_UNUS_WBCLT	
			Local Laboratory Assessments	LOCLAB	citmASS_UNUS_LOCLAB	
			Hepatic Assessments in Patients who Experience LFT Elevations	HEPATIC	citmASS_UNUS_HEPATIC	
			FibroTest/FibroScan	FIBRO	citmASS_UNUS_FIBRO	

RDE Analytics: RD_FRMASS_UNUS		
Data Variable RefName	RD Column Name	Column Data Type
IstASS_UNUS	LSTASS_UNUS_ND	VARCHAR2
IstASS_UNUS - Imaging	LSTASS_UNUS_CITMASSUNSIMAG_C	VARCHAR2
	LSTASS_UNUS_CITMASSUNSIMAG	VARCHAR2
IstASS_UNUS - Central Laboratory Assessments	LSTASS_UNUS_CITMASSUNSLAB_C	VARCHAR2
	LSTASS_UNUS_CITMASSUNSLAB	VARCHAR2
IstASS_UNUS - 12-lead Electrocardiogram	LSTASS_UNUS_CITMASSUNSECG_C	VARCHAR2
	LSTASS_UNUS_CITMASSUNSECG	VARCHAR2
IstASS_UNUS - EQ-5D Questionnaire	LSTASS_UNUS_CITMASSUNSEQ5D_C	VARCHAR2
	LSTASS_UNUS_CITMASSUNSEQ5D	VARCHAR2
IstASS_UNUS - HAEM-A-QOL Questionnaire	*LSTASS_UNUS_CITMASSUNSHAEMAQOL_C	VARCHAR2
	*LSTASS_UNUS_CITMASSUNSHAEMAQOL	VARCHAR2
IstASS_UNUS - Directed Physical Examination	LSTASS_UNUS_CITMASSUNSPE_C	VARCHAR2
	LSTASS_UNUS_CITMASSUNSPE	VARCHAR2
IstASS_UNUS - Plasma PK Sampling	*LSTASS_UNUS_CITMASSUNSPKBLD_C	VARCHAR2
	*LSTASS_UNUS_CITMASSUNSPKBLD	VARCHAR2
IstASS_UNUS - Vital Signs	LSTASS_UNUS_CITMASSUNSVS_C	VARCHAR2
	LSTASS_UNUS_CITMASSUNSVS	VARCHAR2
IstASS_UNUS - Whole Blood Clot Formation (ROTEM)	*LSTASS_UNUS_CITMASSUNSWBCLT_C	VARCHAR2
	*LSTASS_UNUS_CITMASSUNSWBCLT	VARCHAR2
IstASS_UNUS - Local Laboratory Assessments	*LSTASS_UNUS_CITMASSUNSLOCLAB_C	VARCHAR2

	*LSTASS_UNSCITMASSUNSLOCLAB	VARCHAR2
IstASS_UNSHepatic Assessments in Patients who Experience LFT Elevations	*LSTASS_UNSCITMASSUNSHEPATIC_C	VARCHAR2
	*LSTASS_UNSCITMASSUNSHEPATIC	VARCHAR2
IstASS_UNSFibroTest/FibroScan	*LSTASS_UNSCITMASSUNSFIBRO_C	VARCHAR2
	*LSTASS_UNSCITMASSUNSFIBRO	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different.		

AT3SC002: Imaging (IMAG) [frmIMAG_UNUS]

Imaging [sctIMAG_UNUS]

1.*
✓

Date of imaging
[Date of imaging]

[IstASSDT_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]

[IstIMAG_UNUS]
[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	IstASSDT_IMAG
			Other	OTHER	citmDateOther_Other	
clIMAGSP	String		Ultrasound	ULTRASOUND	citmIMAGSP_ULTRASOUND	IstIMAG_UNUS
			CT Imaging	CT SCAN	citmIMAGSP_CT	
			MRI Imaging	MRI	citmIMAGSP_MRI	
			Other	OTHER	itmIMAGSP_OTHER	

RDE Analytics: RD_FRMIMAG_UNUS		
Data Variable RefName	RD Column Name	Column Data Type
IstASSDT_IMAG	LSTASSDT_IMAG_C	VARCHAR2
	LSTASSDT_IMAG	VARCHAR2
	LSTASSDT_IMAG_ND	VARCHAR2
IstASSDT_IMAG - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
IstIMAG_UNUS	LSTIMAG_UNUS_ND	VARCHAR2
IstIMAG_UNUS - Ultrasound	*LSTIMAG_UNUS_CITMIMAGSPULTRASOUND_C	VARCHAR2
	*LSTIMAG_UNUS_CITMIMAGSPULTRASOUND	VARCHAR2
IstIMAG_UNUS - CT Imaging	LSTIMAG_UNUS_CITMIMAGSPCT_C	VARCHAR2
	LSTIMAG_UNUS_CITMIMAGSPCT	VARCHAR2
IstIMAG_UNUS - MRI Imaging	LSTIMAG_UNUS_CITMIMAGSPMRI_C	VARCHAR2
	LSTIMAG_UNUS_CITMIMAGSPMRI	VARCHAR2
IstIMAG_UNUS - Other	LSTIMAG_UNUS_TXTIMAGOTH_C	VARCHAR2
	LSTIMAG_UNUS_TXTIMAGOTH	VARCHAR2
IstIMAG_UNUS - 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_UNUS]		
Actual Time of Plasma PK Sampling [sctPKBLD_UNUS]		
1.* ✓	Actual time [Actual time]	[dtmSAMPLE_T_UNUS] (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_UNUS		
Data Variable RefName	RD Column Name	Column Data Type
dtmSAMPLE_T_UNUS	DTMSAMPLE_T_UNUS	DATE
	DTMSAMPLE_T_UNUS_TMS	VARCHAR2
	DTMSAMPLE_T_UNUS_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]

[IstTESTS_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]

[IstUNIT_LFT]

[A:UNIT]

[IstUNITS_LFT]

Units | [cIUNIT]

▼

[A:OTHER] [txtUNITO_LFT]

Other

A50

4.4.*
✓

Interpretation
[Interpretation]

[IstCSLAB_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_UNNS]

5.1.*
✓

Type of sample
[Type of sample]

[IstTYPE]

[A:BLOOD] Blood (blood, serum, plasma)

[A:URINE] Urine

5.2.*
✓

Lab test
[Lab test]

[IstTEST]

[A:TEST]

[IstTESTS]

Tests | [cITESTS_UNNS]

▼

[A:OTHER] [txtTESTO]

Other, please specify

A50

5.3.*
✓

Value
[Value]

[txtVALUE]

		A100
5.4* ✓	Unit [Unit]	<div><div>[IstUNIT] [A:UNIT]</div><div><div><input type="radio"/> [IstUNITS] Units [cIUNIT]</div><div><input type="radio"/> [txtUNITO] Other, please specify</div></div><div>A50</div></div>
5.5* ✓	Interpretation [Interpretation]	<div><div>[IstCSLAB] [A:NORMAL]</div><div><div><input type="radio"/> Normal</div><div><input type="radio"/> Abnormal, not clinically significant</div><div><input type="radio"/> [txtIINTP] Abnormal, clinically significant, please specify</div></div><div>A50</div></div>
5.6* ✓	Normal Range [Normal Range]	<div><div>[cmpNR] [txtNRLL] Normal range - lower limit</div><div>A40</div><div><div>[txtNRUL] Normal range - upper limit</div><div>A40</div><div><div>[txtNRTB] Normal range - text based</div><div>A40</div></div></div></div>

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)		
IstTESTS_LFT	Group	1

Codelist Values Tables: Local Laboratory Assessments						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cTESTSLFT_UN	String		Alanine Transaminase	ALT	citmTESTS_ALT	IstTESTS_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	IstUNIT_LFT, IstUNIT
			Other	OTHER	citmUnitOther_Other	
clUNIT	String		%	%	citmUNIT_PER	IstUNITS_LFT, IstUNITS
			/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	
cCSLAB	String		Normal	NORMAL	citmCSLAB_NORM	IstCSLAB_LFT, IstCSLAB
			Abnormal, not clinically significant	ABNORMAL NCS	citmCSLAB_ABNCS	
			Abnormal, clinically significant	ABNORMAL CS	citmCSLAB_ABCS	
cTYPE	String		Blood (blood, serum, plasma)	BLOOD	citmTYPE_BLOOD	IstTYPE
			Urine	URINE	citmTYPE_URINE	
cTEST	String		Test	TEST	citmTEST_TEST	IstTEST
			Other	OTHER	citmTEST_OTHER	
cTESTS_UN	String		Hepatitis A virus antibody (IgG)	HEP A IGG	citmTESTS_HEPAIGG	IstTESTS
			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_UN		
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]	[IstASSDT] [A: SAME DATE] <input type="radio"/> Same date as visit date [A: OTHER] <input type="radio"/> [dtmASS] (DD/MM/YYYY) Other date, please specify Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2023)
3.* ✓	Kit ID number [Kit ID number]	[txtREFNO] A11
Imaging [sctLFTIMAGE]		
4.* ✓	Date imaging performed [Date imaging performed]	[IstASSDTIM] [A: SAME DATE] <input type="radio"/> Same date as visit date [A: OTHER] <input type="radio"/> [dtmASSIM] (DD/MM/YYYY) Other date, please specify Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2023)
5.* ✓	Type of imaging [Type of imaging]	[IstIMAGE] [A: ULTRASOUND] <input type="radio"/> Ultrasound with Doppler flow [A: CT] <input type="radio"/> CT [A: MRI] <input type="radio"/> MRI
6.* ✓	Result [Result]	[txtI IMAGE] 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]	[IstLFTCM] [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No
8.* ✓	Other potentially hepatotoxic agents including any work-related exposures? [Hepatotoxic agents]	[IstAGENTS] [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> 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]	[IstALCOHOL] [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [IstALCWEEK] Yes Taking the past month into account, please indicate maximum alcohol consumption per week [A: BEER] <input type="radio"/> [numBEER] Beer (units/week): xxx. [A: WINE] <input type="radio"/> [numWINE] Wine (units/week): xxx. [A: DISTILLED SPIRITS] <input type="radio"/> [numDISTIL] Distilled spirits (units/week): xxx. [IstALCDAY] Taking the past month into account, please indicate maximum alcohol consumption per day [A: BEER] <input type="radio"/> [numBEERDAY] Beer (units/day): xxx. [A: WINE] <input type="radio"/> [numWINEDAY] Wine (units/day): xxx. [A: DISTILLED SPIRITS] <input type="radio"/> [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]	[IstALCOHOL2] [A: N] <input type="radio"/> No [A: Y] <input type="radio"/> [IstALCWEEK2] Yes Taking the past month into account, please indicate maximum alcohol consumption per week [A: BEER] <input type="checkbox"/> [numBEER2] Beer (units/week): xxx. [A: WINE] <input type="checkbox"/> [numWINE2] Wine (units/week): xxx. [A: DISTILLED SPIRITS] <input type="checkbox"/> [numDISTIL2] Distilled spirits (units/week): xxx. [IstALCDAY2] Taking the past month into account, please indicate maximum alcohol consumption per day

		<div><div>[A: BEER]</div><div>[A: WINE]</div><div>[A: DISTILLED SPIRITS]</div></div> <div><div><input type="checkbox"/></div><div>[numBEERDAY2] Beer (units/day): <input type="text" value="xxx."/></div><div><input type="checkbox"/></div><div>[numWINEDAY2] Wine (units/day): <input type="text" value="xxx."/></div><div><input type="checkbox"/></div><div>[numDISTILDAY2] Distilled spirits (units/day): <input type="text" value="xxx."/></div></div>
11.* ✓	Recent travel to areas where hepatitis A or E is endemic? [Travel]	<div>[IstTRAVEL] [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No</div>
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 I tem RefName	Data Variable RefName
clDateOther	String		Same date as visit date	SAME DATE	citmDateOther_Date	IstASSDT, IstASSDTIM
			Other	OTHER	citmDateOther_Other	
clIMAGE	String		Ultrasound with Doppler flow	ULTRASOUND	citmtIMAGE_ULTRASOUND	IstIMAGE
			CT	CT	citmtIMAGE_CT	
			MRI	MRI	citmtIMAGE_MRI	
clYesNo	String		Yes	Y	citmYesNo_Y	IstLFTCM, IstAGENTS, IstTRAVEL
			No	N	citmYesNo_N	
clNoYes	String		No	N	citmNoYes_N	IstALCOHOL, IstALCOHOL2
			Yes	Y	citmNoYes_Y	
clALCTYP	String		Beer	BEER	citmALCTYP_BEER	IstALCWEEK, IstALCDAY, IstALCWEEK2, IstALCDAY2
			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
IstASSDT	LSTASSDT_C	VARCHAR2
	LSTASSDT	VARCHAR2
	LSTASSDT_ND	VARCHAR2
IstASSDT - dtmASS	DTMASS	DATE
	DTMASS_DTS	VARCHAR2
txtREFNO	TXTREFNO	VARCHAR2
	TXTREFNO_ND	VARCHAR2
IstASSDTIM	LSTASSDTIM_C	VARCHAR2
	LSTASSDTIM	VARCHAR2
	LSTASSDTIM_ND	VARCHAR2
IstASSDTIM - dtmASSIM	DTMASSIM	DATE
	DTMASSIM_DTS	VARCHAR2
IstIMAGE	LSTIMAGE_C	VARCHAR2
	LSTIMAGE	VARCHAR2
	LSTIMAGE_ND	VARCHAR2
txtIMAGE	TXTIMAGE	VARCHAR2
	TXTIMAGE_ND	VARCHAR2
IstLFTCM	LSTLFTCM_C	VARCHAR2
	LSTLFTCM	VARCHAR2
	LSTLFTCM_ND	VARCHAR2
IstAGENTS	LSTAGENTS_C	VARCHAR2
	LSTAGENTS	VARCHAR2
	LSTAGENTS_ND	VARCHAR2

IstALCOHOL	LSTALCOHOL_C	VARCHAR2
	LSTALCOHOL	VARCHAR2
	LSTALCOHOL_ND	VARCHAR2
IstALCOHOL - IstALCWEEK	LSTALCWEEK_C	VARCHAR2
	LSTALCWEEK	VARCHAR2
IstALCOHOL - numBEER	NUMBEER	FLOAT
IstALCOHOL - numWINE	NUMWINE	FLOAT
IstALCOHOL - numDISTIL	NUMDISTIL	FLOAT
IstALCOHOL - IstALCDAY	LSTALCDAY_C	VARCHAR2
	LSTALCDAY	VARCHAR2
IstALCOHOL - numBEERDAY	NUMBEERDAY	FLOAT
IstALCOHOL - numWINEDAY	NUMWINEDAY	FLOAT
IstALCOHOL - numDISTILDAY	NUMDISTILDAY	FLOAT
IstALCOHOL2	LSTALCOHOL2_C	VARCHAR2
	LSTALCOHOL2	VARCHAR2
	LSTALCOHOL2_ND	VARCHAR2
IstALCOHOL2 - Beer	LSTALCWEEK2_NUMBEER2_C	VARCHAR2
	LSTALCWEEK2_NUMBEER2	VARCHAR2
IstALCOHOL2 - numBEER2	NUMBEER2	FLOAT
IstALCOHOL2 - Wine	LSTALCWEEK2_NUMWINE2_C	VARCHAR2
	LSTALCWEEK2_NUMWINE2	VARCHAR2
IstALCOHOL2 - numWINE2	NUMWINE2	FLOAT
IstALCOHOL2 - Distilled spirits	LSTALCWEEK2_NUMDISTIL2_C	VARCHAR2
	LSTALCWEEK2_NUMDISTIL2	VARCHAR2
IstALCOHOL2 - numDISTIL2	NUMDISTIL2	FLOAT
IstALCOHOL2 - Beer	LSTALCDAY2_NUMBEERDAY2_C	VARCHAR2
	LSTALCDAY2_NUMBEERDAY2	VARCHAR2
IstALCOHOL2 - numBEERDAY2	NUMBEERDAY2	FLOAT
IstALCOHOL2 - Wine	LSTALCDAY2_NUMWINEDAY2_C	VARCHAR2
	LSTALCDAY2_NUMWINEDAY2	VARCHAR2
IstALCOHOL2 - numWINEDAY2	NUMWINEDAY2	FLOAT
IstALCOHOL2 - Distilled spirits	LSTALCDAY2_NUMDISTILDAY2_C	VARCHAR2
	LSTALCDAY2_NUMDISTILDAY2	VARCHAR2
IstALCOHOL2 - numDISTILDAY2	NUMDISTILDAY2	FLOAT
IstTRAVEL	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]

[IstFIBT]
[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	IstFIBT
			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
IstFIBT	LSTFIBT_C	VARCHAR2
	LSTFIBT	VARCHAR2
	LSTFIBT_ND	VARCHAR2

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)

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]

[IstDRUGCOMP]
[A: COMPLETED]

Completed

[A: DISCONTINUED]

[IstDISCRS]

Discontinued - please specify the primary reason for early termination
[A: ADVERSE EVENT]

[A: DEATH]

[A: LOST TO FOLLOW-UP]

[A: NON-COMPLIANT]

[A: PHYSICIAN DECISION]

[A: PROTOCOL VIOLATION]

[A: STUDY TERMINATED]

[A: SUBJECT WITHDREW CONSENT]

[A: OTHER]

[A: AT]

[A: EMERGENCY]

[cmpAE]

Adverse Event
Please specify AE#(s) - as recorded on AE form
[numAESEQ1] [numAESEQ2] [numAESEQ3] [numAESEQ4] [numAESEQ5] [numAESEQ6]
N3 N3 N3 N3 N3 N3

Death

DEATH

Lost to follow-up

LOST TO FOLLOW-UP

Non-Compliance with Study Drug

NON-COMPLIANT

[txtDISCPHYSDEC]

Physician Decision, please specify
A200

[txtDISCPV]

Protocol Violation, please specify
A200

Study Terminated by Sponsor

STUDY TERMINATED

Subject Withdrew Consent

SUBJECT WITHDREW CONSENT

[txtDISCOTH]

Other, please specify
A200

More than 1 AT measurement <15%

AT

Temporary discontinuation due to a regional or national emergency

EMERGENCY

3.*
✓

Will the patient continue to use commercially available fitusiran?
[Will the patient continue to use commercially available fitusiran?]

[IstCOMMERC]
[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	IstDRUGCOMP
			Discontinued	DISCONTINUED	citmCompDisc_Disc	
clDISCRS	String		Adverse Event	ADVERSE EVENT	citmDISCRS_AE	IstDISCRS
			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	IstCOMMERC

		No	N	citmYesNo_N	
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RDE Analytics: RD_FRMDRUGTERM		
Data Variable RefName	RD Column Name	Column Data Type
dtmDRUGTERM	DTMDRUGTERM	DATE
	DTMDRUGTERM_DTS	VARCHAR2
	DTMDRUGTERM_ND	VARCHAR2
lstDRUGCOMP	LSTDUGCOMP_C	VARCHAR2
	LSTDUGCOMP	VARCHAR2
	LSTDUGCOMP_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

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]

[IstCOMPDISC]
[A: COMPLETED]

[dtmCOMP] (DD/MM/YYYY)
Completed, date of study completion

Req / Req / Req (2015-2023)

[A: DISCONTINUED]

[dtmDISC] (DD/MM/YYYY)
Discontinued, date of study discontinuation

Req / Req / Req (2015-2023)

[IstDISCRS]
Discontinued - please specify the primary reason for early termination
[A: ADVERSE EVENT]

[cmpAE]
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]

Death

[A: LOST TO FOLLOW-UP]

Lost to follow-up

[A: NON-COMPLIANT]

Non-Compliance with Study Drug

[A: PHYSICIAN DECISION]

[txtDISCPHYSEDEC]
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?]

[IstROLLOVER]
[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	IstCOMPDISC
			Discontinued	DISCONTINUED	citmCompDisc_Disc	
clDISCRS	String		Adverse Event	ADVERSE EVENT	citmDISCRS_AE	IstDISCRS
			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	IstROLLOVER

file:///C:/Users/Nico_Van_Dessel/AppData/Local/Apps/2.0/8ROY8BMP.9NT/87KKKWE2.8YL/orac..47.0_7e15c60fcb5f8c5e_0006.0002_e3a46b3970a1f84d/HtmlResources/AnnotatedStudybook.html

21-Sep-21

		No	N	citmYesNo_N	
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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]

[IstAE]

[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]

[IstCM]

[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?]

[IstIFC_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]

[IstCOMP]

[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 I tem RefName	Data Variable RefName
clYesNo	String		Yes	Y	citmYesNo_Y	IstAE, IstCM, IstIFC_AMEND, IstCOMP
			No	N	citmYesNo_N	


RDE Analytics: RD_FRMCOMP		
Data Variable RefName	RD Column Name	Column Data Type
IstAE	LSTAE_C	VARCHAR2
	LSTAE	VARCHAR2
	LSTAE_ND	VARCHAR2
IstCM	LSTCM_C	VARCHAR2
	LSTCM	VARCHAR2
	LSTCM_ND	VARCHAR2
IstIFC_AMEND	LSTIFC_AMEND_C	VARCHAR2
	LSTIFC_AMEND	VARCHAR2
	LSTIFC_AMEND_ND	VARCHAR2
IstCOMP	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_ICF]

1.* 	Row No <i>(for internal use only)</i> [read-only] [Row No]	[numROW] <input type="text" value="N3"/>		
2.*  	Amendment version in effect [Amendment version in effect]	[IstAMPTC] [A:AMENDMENT 1] <input type="radio"/> Amendment 1 [A:AMENDMENT 2] <input type="radio"/> Amendment 2 [A:AMENDMENT 3] <input type="radio"/> Amendment 3 [A:AMENDMENT 4] <input type="radio"/> Amendment 4 [A:AMENDMENT 5] <input type="radio"/> Amendment 5 [A:AMENDMENT 6] <input type="radio"/> Amendment 6 [A:AMENDMENT 7] <input type="radio"/> Amendment 7 [A:AMENDMENT 8] <input type="radio"/> Amendment 8 [A:AMENDMENT 9] <input type="radio"/> Amendment 9 [A:AMENDMENT 10] <input type="radio"/> Amendment 10		
3.* 	Subject signed updated informed consent on [Date of updated informed consent]	[dtmIFC_AMEND] (DD/MM/YYYY) Req <input type="text" value=""/> <input type="text" value=""/> / Req <input type="text" value=""/> <input type="text" value=""/> / Req <input type="text" value=""/> <input type="text" value=""/> (2015-2023)		
4. 	Fitusiran restart date after dosing hold [Fitusiran restart date after dosing hold]	[dRES] (DD/MM/YYYY) Req <input type="text" value=""/> <input type="text" value=""/> / Req <input type="text" value=""/> <input type="text" value=""/> / Req <input type="text" value=""/> <input type="text" value=""/> (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_ICF		
numROW	None	1
IstAMPTC	None	2

Codelist Values Tables: Protocol Amendment & Informed Consent						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist I tem RefName	Data Variable RefName
clAMPTC	String		Amendment 1	AMENDMENT 1	citmAMPTC_Amendment1	IstAMPTC
			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
IstAMPTC	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 <i>(for internal use only)</i> <i>[read-only]</i> [Row No]	[numROW] N3				
2.	Type of Bleed Event <i>[read-only]</i> [Type of Bleed Event]	[lstQ1_Query] <i>[A: BLEED]</i> <input type="radio"/> Bleed <i>[A: PRE-BLEED]</i> <input type="radio"/> Pre-Bleed				
3.	What date did the bleed occur? <i>[read-only]</i> [Date of bleed]	[dtmQ2_Query] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)				
4.	What time did the bleed occur? <i>[read-only]</i> [Time of bleed]	[dtmQ2tm_Query] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock				
5.	Event Identifier <i>[read-only]</i> [Event Identifier]	[txtEID] A20				
6.	Query topic <i>[read-only]</i> [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 <i>(for internal use only)</i> [read-only] [Row No]			[numROW] N3					
2.*	Language of the questionnaire [Language of the questionnaire]			[IstLANG] [A: LANGUAGE] <input type="radio"/> Language [IstLANG_Q] [clLANG_Q] <input type="button" value="v"/> [A: OTHER] <input type="radio"/> [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]			[IstQ1] [A: BLEED] <input type="radio"/> Bleed [A: PRE-BLEED SYMPTOMS ONLY] <input type="radio"/> Pre-bleed symptoms only (please only tick if a bleed did not later occur) [A: PREEMPTIVE TREATMENT] <input type="radio"/> Preemptive treatment [A: PERIOPERATIVE] <input type="radio"/> Perioperative					
4.	What date and time did the bleed occur? [Date and time of bleed]			[dtmQ2] (DD/MM/YYYY hh:mm) Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2023) Req <input type="button" value="v"/> : Req <input type="button" value="v"/> 24-hour clock					
5.	Causality (Investigator's assessment) [Causality]			[IstCAUS] [A: DENTAL] <input type="radio"/> Dental/Surgical Procedure [A: SPONTANEOUS] <input type="radio"/> Spontaneous [A: TRAUMATIC] <input type="radio"/> Traumatic [A: OTHER] <input type="radio"/> [txtCAUSO] Other, specify A128 [A: UNKNOWN] <input type="radio"/> Unknown					
6.	What was the severity of the bleed? (Investigator's assessment) [What was the severity of the bleed?]			[IstBLDSEV] [A: MILD] <input type="radio"/> Mild [A: MODERATE] <input type="radio"/> Moderate [A: SEVERE] <input type="radio"/> Severe					
7.	Where was the bleed or pre-bleed symptoms? [Location of bleed or symptoms]			[IstQ3] [A: SKIN/MUCOSA] <input type="radio"/> Skin/Mucosa [A: JOINT] <input type="radio"/> Joint [A: MUSCLE] <input type="radio"/> Muscle [A: INTERNAL] <input type="radio"/> Internal [A: OPERATIVE] <input type="radio"/> Operative Site					
8.	Did you use Factor or Bypassing Agent product? <i>If Yes, please complete a record below for each injection.</i> [Factor or Bypassing Agent product taken]			[IstQ4] [A: Y] <input type="radio"/> [IstQ6] Yes How much product did you need to treat the bleed? [A: OPTION 1] <input type="radio"/> I needed more product than normal to control bleeding [A: OPTION 2] <input type="radio"/> I needed the same amount of product as normal to control bleeding [A: OPTION 3] <input type="radio"/> I needed less product than normal to control bleeding [IstQ7] How did the bleed respond to treatment? [A: OPTION 1] <input type="radio"/> Responded worse than prior bleeds in this location [A: OPTION 2] <input type="radio"/> Responded similarly to prior bleeds in this location [A: OPTION 3] <input type="radio"/> Responded better than prior bleeds in this location [A: OPTION 4] <input type="radio"/> I haven't bled in this location / not sure how bleed responded [A: N] <input type="radio"/> No					
	Order	Injection date and time				Name of product		Total dose	Unit
9.									
Product Administration Details Entry [sctQ5]									
9.1	Order of injection [Order]			[IstORDER] [A: FIRST] <input type="radio"/> First injection [A: FOLLOWUP1] <input type="radio"/> Follow-up 1 injection [A: FOLLOWUP2] <input type="radio"/> Follow-up 2 injection [A: FOLLOWUP NUMBER] <input type="radio"/> [numQ5FUX] Follow-up number N2					

9.2	Date and time of the injection [Injection date and time]	[dtmQ5] (DD/MM/YYYY hh:mm) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023) Req <input type="text"/> : Req <input type="text"/> 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] <input type="radio"/> IU [A: U] <input type="radio"/> U [A: µg] <input type="radio"/> 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_UN	evtUNS.frmDOV_UN.sctDOV_UN.dtmVISIT_DT_UN evtBLEED.frmDOV_REP.sctDOV_UN.dtmVISIT_DT_UN evtATFU.frmDOV_REP.sctDOV_UN.dtmVISIT_DT_UN evtPOP_V3.frmDOV_SURG.sctDOV_UN.dtmVISIT_DT_UN evtPOP_SCR.frmDOV_SURG.sctDOV_UN.dtmVISIT_DT_UN evtPOP_SV.frmDOV_SURG.sctDOV_UN.dtmVISIT_DT_UN evtPOP_V1.frmDOV_SURG.sctDOV_UN.dtmVISIT_DT_UN evtPOP_V2.frmDOV_SURG.sctDOV_UN.dtmVISIT_DT_UN
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 cITELSCHEd 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.