

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 <i>[hidden]</i> [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] | [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 [A:NOT REPORTED] <input type="radio"/> Not Available/Not Reported |
| 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

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

| 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, |
| | | | No | N | citmYesNo_N | IstMHCATPRIOR |
| 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

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

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

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 | TXTRTOTH | 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] | [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) |
| 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] | [IstRESPIRAT] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [txtRESPIRAT] Abnormal, please specify <input type="text"/> [IstRESPIRATCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No |
| 3.* ✓ | Heart/Cardiovascular [Heart/Cardiovascular] | [IstCARDIOVA] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [txtCARDIOVA] Abnormal, please specify <input type="text"/> [IstCARDIOVACS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No |
| 4.* ✓ | Dermatological/Skin [Dermatological/Skin] | [IstSKIN] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [txtSKIN] Abnormal, please specify <input type="text"/> [IstSKINCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No |
| 5.* ✓ | Gastrointestinal/Liver [Gastrointestinal/Liver] | [IstGASTROIN] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [txtGASTROIN] Abnormal, please specify <input type="text"/> [IstGASTROINCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No |
| 6.* ✓ | Musculoskeletal/Extremities [Musculoskeletal/Extremities] | [IstMUSCULO] [A: NOT DONE] <input type="radio"/> Not done [A: NORMAL] <input type="radio"/> Normal [A: ABNORMAL] <input type="radio"/> [txtMUSCULO] Abnormal, please specify <input type="text"/> [IstMUSCULOCS] Is the abnormality clinically significant? [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No |
| 7. ✓ | Neurologic [Neurologic] | [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] <input type="text"/> |

| | | |
|---|---|---|
| | | <div>[IstNEUROCS] Is the abnormality clinically significant? <i>[A: Y]</i> <input type="radio"/> Yes <i>[A: N]</i> <input type="radio"/> No</div> |
| | Other abnormalities | Other clinical significance |
| 8. ✓ | | |
| Physical Examination Other Entry [sctPEOTH] | | |
| <div>- If there are any other abnormalities, please record in the Add Entry section below - Please record only one abnormality per row</div> | | |
| 8.1* ✓ | Other abnormalities [Other abnormalities] | <div>[txtPEOTH] A200</div> |
| 8.2* ✓ | Is the abnormality clinically significant? [Other clinical significance] | <div>[IstPEOTHCS] <i>[A: Y]</i> <input type="radio"/> Yes <i>[A: N]</i> <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.</div> | | |

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

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

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

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

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

Concomitant Medications [sctCM]

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

1.*
🔑

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

[numROW]

N3

2.*
✓
🔑

Medication
Trade or generic name
[Medication]

[txtTRT]

A200

3.*
✓

Indication
[Indication]

[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><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</div><div>Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2023)</div></div> |
| 12-lead Electrocardiogram - Predose [sctPRE] | | |
| Supine after at least 10 minutes rest | | |
| 2.* ✓ | Time performed [Time performed] | <div><div>[dtmASS_T] (hh:mm)</div><div>Req <input type="text"/> : Req <input type="text"/> 24-hour clock</div></div> |
| 3.* ✓ | Rhythm [Rhythm] | <div><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></div> |
| 4.* ✓ | Ventricular rate [Ventricular rate] | <div><div>[numVR]</div><div>N3 <input type="text"/> bpm^[b]</div></div> |
| 5.* ✓ | PR interval [PR] | <div><div>[numPR]</div><div>N3 <input type="text"/> msec^[b]</div></div> |
| 6.* ✓ | QRS duration [QRS] | <div><div>[numQRS]</div><div>N3 <input type="text"/> msec^[b]</div></div> |
| 7.* ✓ | QT interval [QT] | <div><div>[numQT]</div><div>N3 <input type="text"/> msec^[b]</div></div> |
| 8.* ✓ | QTc interval [QTc] | <div><div>[numQTcF]</div><div>N3 <input type="text"/> msec^[b]</div></div> |
| 9.* ✓ | Overall interpretation [Overall interpretation] | <div><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></div> |
| 10. ✓ | If abnormal, please specify by checking all that apply [Abnormal] | <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> |

| | | |
|--|--|--|
| 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  : Req  24-hour clock |
| 32.* ✓ | Rhythm [Rhythm] | <div><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></div> |
| 33.* ✓ | Ventricular rate [Ventricular rate] | <div><div>[numVR4] N3 bpm^[b]</div></div> |
| 34.* ✓ | PR interval [PR] | <div><div>[numPR4] N3 msec^[b]</div></div> |
| 35.* ✓ | QRS duration [QRS] | <div><div>[numQRS4] N3 msec^[b]</div></div> |
| 36.* ✓ | QT interval [QT] | <div><div>[numQT4] N3 msec^[b]</div></div> |
| 37.* ✓ | QTc interval [QTc] | <div><div>[numQTCF4] N3 msec^[b]</div></div> |
| 38.* ✓ | Overall interpretation [Overall interpretation] | <div><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></div> |
| 39. ✓ | If abnormal, please specify by checking all that apply [Abnormal] | <div><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</div></div><div><div>A128</div></div></div></div></div> |
| 40.* ✓ | Change from baseline (Day 1, Pre-Dose) ECG [Change from baseline] | <div><div><div>[IstCHANGE3] [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"/> [txtCHANGE3] Clinically significant worsening from baseline, specify</div></div><div><div>A128</div></div></div></div> |
| <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.</div> | | |

| 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 |
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| | *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 |

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| | 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 |

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| | *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 |

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| 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 |

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| | LSTCHANGE2_ND | VARCHAR2 |
| IstCHANGE2 - txtCHANGE2 | TXCHANGE2 | 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: 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]
[A: SLIGHT PROBLEMS]
[A: MODERATE PROBLEMS]
[A: SEVERE PROBLEMS]
[A: UNABLE]

☐

I have no problems in walking about

☐

I have slight problems in walking about

☐

I have moderate problems in walking about

☐

I have severe problems in walking about

☐

I am unable to walk about

5.*
✓

Self-Care
[Self-Care]

[IstSELF]
[A: NO PROBLEMS]
[A: SLIGHT PROBLEMS]
[A: MODERATE PROBLEMS]
[A: SEVERE PROBLEMS]
[A: UNABLE]

☐

I have no problems washing or dressing myself

☐

I have slight problems washing or dressing myself

☐

I have moderate problems washing or dressing myself

☐

I have severe problems washing or dressing myself

☐

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]
[A: SLIGHT PROBLEMS]
[A: MODERATE PROBLEMS]
[A: SEVERE PROBLEMS]
[A: UNABLE]

☐

I have no problems doing my usual activities

☐

I have slight problems doing my usual activities

☐

I have moderate problems doing my usual activities

☐

I have severe problems doing my usual activities

☐

I am unable to do my usual activities

7.*
✓

Pain/Discomfort
[Pain/Discomfort]

[IstPAIN]
[A: NO PAIN]
[A: SLIGHT PAIN]
[A: MODERATE PAIN]
[A: SEVERE PAIN]
[A: EXTREME PAIN]

☐

I have no pain or discomfort

☐

I have slight pain or discomfort

☐

I have moderate pain or discomfort

☐

I have severe pain or discomfort

☐

I have extreme pain or discomfort

8.*
✓

Anxiety/Depression
[Anxiety/Depression]

[IstANX]
[A: NOT ANXIOUS]
[A: SLIGHTLY ANXIOUS]
[A: MODERATELY ANXIOUS]
[A: SEVERELY ANXIOUS]
[A: EXTREMELY ANXIOUS]

☐

I am not anxious or depressed

☐

I am slightly anxious or depressed

☐

I am moderately anxious or depressed

☐

I am severely anxious or depressed

☐

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]

[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

[cI LANG_Q]

▼

[A: OTHER]

[txtLANGO]

Other, please specify

A100

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

In the past 4 weeks ...

4.*
✓

1. ... my swellings hurt
[Swelling]

[IstSWEL]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

5.*
✓

2. ... I had pain in my joints
[Joints pain]

[IstJOINTS]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

6.*
✓

3. ... it was painful for me to move
[Painful to move]

[IstMOVE]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

7.*
✓

4. ... I had difficulty walking as far as I wanted to
[Difficult walking]

[IstWALK]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

8.*
✓

5. ... I needed more time to get ready because of my condition
[More time needed]

[IstTIME]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

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

In the past 4 weeks ...

9.*
✓

1. ... my hemophilia was a burden for me
[Burden]

[IstBURDEN]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

10.*
✓

2. ... my hemophilia made me angry
[Angry]

[IstANGRY]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

11.*
✓

3. ... I was worried because of my hemophilia
[Worried]

[IstWORRIED]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

12.*
✓

4. ... I felt excluded
[Excluded]

[IstEXCLUDED]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

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

In the past 4 weeks ...

13.*
✓

1. ... I envied healthy people my age
[Envy]

[IstENVY]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

14.*
✓

2. ... I felt comfortable with my body
[Comfortable]

[IstCOMFORT]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

15.*
✓

3. ... hemophilia made my life more difficult
[More difficult]

[IstDIFFICULT]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

16.*
✓

4. ... I felt different from others because of my hemophilia
[Different]

[IstDIFFERENT]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

17.*
✓

5. ... I was able not to think all the time about my hemophilia
[Think about]

[IstTHINK]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

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

In the past 4 weeks ...

18.*
✓

1. ... I had to avoid sports that I like because of my hemophilia
[Avoid sports]

[IstAVOID]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

[A: NOT APPLICABLE]

Not applicable

19.*
✓

2. ... I had to avoid sports like football
[Avoid football]

[IstFOOTBALL]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

[A: NOT APPLICABLE]

Not applicable

20.*
✓

3. ... I played sports just as much as others
[As others]

[IstPLAYED]
[A: NEVER]

Never

[A: RARELY]

Rarely

[A: SOMETIMES]

Sometimes

[A: OFTEN]

Often

[A: ALL THE TIME]

All the time

[A: NOT APPLICABLE]

Not applicable

4. ... I didn't have the freedom to travel where I wanted

[IstFREEDOM]

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

| | | |
|---|---|---|
| 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 |
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| | 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 |
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| | 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 |
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| | LSTHEALTHY_ND | VARCHAR2 |
| IstJEOPARD | LSTJEOPARD_C | VARCHAR2 |
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| | LSTEARLY | VARCHAR2 |
| | LSTEARLY_ND | VARCHAR2 |
| IstBLEEDING | LSTBLEEDING_C | VARCHAR2 |
| | LSTBLEEDING | VARCHAR2 |
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| IstCONTROL | LSTCONTROL_C | VARCHAR2 |
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| | 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 |
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| | 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 |
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| IstNOCARE | LSTNOCARE_C | VARCHAR2 |
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| | 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 | HEMECARE | 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 <i>(for internal use only)</i> [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] <input type="radio"/> [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] <input type="radio"/> Ongoing at the end of trial [A:UNKNOWN] <input type="radio"/> Unknown | | | | | | | |
| 5.* ✓ | Severity [Severity] | | | | | | [IstAEINT] [A:MILD] <input type="radio"/> Mild [A:MODERATE] <input type="radio"/> Moderate [A:SEVERE] <input type="radio"/> Severe | | | | | | | |
| 6.* ✓ | Relationship to ALN-AT3SC? [Relationship to ALN-AT3SC] | | | | | | [IstAEREL] [A:NOT RELATED] <input type="radio"/> Not related [A:UNLIKELY RELATED] <input type="radio"/> Unlikely related [A:POSSIBLY RELATED] <input type="radio"/> Possibly related [A:DEFINITELY RELATED] <input type="radio"/> 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] <input type="radio"/> Vial [A:PFS] <input type="radio"/> PFS [A:UNKNOWN] <input type="radio"/> Unknown | | | | | | | |
| 8.* ✓ | Action taken with ALN-AT3SC? [Action taken] | | | | | | [IstACT] [A:DOSE NOT CHANGED] <input type="radio"/> Dose not changed [A:DRUG WITHDRAWN] <input type="radio"/> Drug withdrawn [A:DOSE REDUCED] <input type="radio"/> Dose reduced [A:DRUG INTERRUPTED] <input type="radio"/> Drug interrupted [A:NOT APPLICABLE] <input type="radio"/> Not applicable [A:UNKNOWN] <input type="radio"/> Unknown | | | | | | | |
| 9.* ✓ | Concomitant therapy taken for this AE? [Medication taken] | | | | | | [IstAETRT] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No | | | | | | | |
| 10.* ✓ | Outcome [Outcome] | | | | | | [IstAEOUT] [A:RECOVERED/RESOLVED] <input type="radio"/> Recovered / Resolved [A:RECOVERED/RESOLVED WITH SEQUELAE] <input type="radio"/> Recovered / Resolved with sequelae [A:RECOVERING/RESOLVING] <input type="radio"/> Recovering / Resolving [A:NOT RECOVERED/NOT RESOLVED] <input type="radio"/> Not recovered / Not resolved [A:FATAL] <input type="radio"/> Fatal [A:UNKNOWN] <input type="radio"/> Unknown | | | | | | | |
| 11.* ✓ | Was this event an injection site reaction? [Was this event an injection site reaction?] | | | | | | [IstAEINJ] [A:Y] <input type="radio"/> [IstSYMPREYN] Yes, was the reaction measurable? [A:Y] <input type="radio"/> [numSYMPRE] Yes, size of reaction (mm): N3 [A:N] <input type="radio"/> No [A:N] <input type="radio"/> No | | | | | | | |
| 12. ✓ | Is this event an adverse event of Clinical Interest? [Event of Clinical Interest?] | | | | | | [IstAECI] [A:Y] <input type="radio"/> [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 | IstAEEND |
| | | | Ongoing at the end of trial | ONGOING | citmAEEND_Ongoing | |
| | | | Unknown | UNKNOWN | citmAEEND_Unknown | |
| clAEINT | String | | Mild | MILD | citmAEINT_MILD | IstAEINT |
| | | | Moderate | MODERATE | citmAEINT_MODERATE | |
| | | | Severe | SEVERE | citmAEINT_SEVERE | |
| clAEREL | String | | Not related | NOT RELATED | citmAEREL_NotRelated | IstAEREL |
| | | | Unlikely related | UNLIKELY RELATED | citmAEREL_UnlikelyRelated | |
| | | | Possibly related | POSSIBLY RELATED | citmAEREL_PossiblyRelated | |
| | | | Definitely related | DEFINITELY RELATED | citmAEREL_DefinitelyRelated | |
| clAEREL2 | String | | Vial | VIAL | citmAEREL2_VIAL | IstAEREL2 |
| | | | PFS | PFS | citmAEREL2_PFS | |
| | | | Unknown | UNKNOWN | citmAEREL2_UNKNOWN | |
| clAETRT | String | | Dose not changed | DOSE NOT CHANGED | citmAETRT_DoseNotChanged | IstACT |
| | | | 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 | IstAETRT, IstAEINJ, IstSYMPREYN, IstAECI, IstAESI, IstAESER, IstDEATH, IstTHREAT, IstHOSPI, IstDIS, IstCONG, IstMIE |
| | | | No | N | citmYesNo_N | |
| clAEOUT | String | | Recovered / Resolved | RECOVERED/RESOLVED | citmAEOUT_RecRes | IstAEOUT |
| | | | 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 | IstAECIS |
| | | | 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 | IstTHROMBO, IstTHROMBO2 |
| | | | Suspected thrombosis | SUSPECTED | citmTHROMBO_SUSPECTED | |
| clAESIS | String | | Severe or serious ISRs, please complete the Supplemental Adverse Event of Special Interest form | ISR | citmAESIS_ISR | IstAESIS |
| | | | ALT or AST elevations >3× ULN. Please create an Unscheduled Visit and complete the 'Hepatic Assessments in Patients who Experience LFT Elevations' form | LFT | citmAESIS_LFT | |
| | | | Thrombosis | THROMBO | citmAESIS_THROMBO | |
| | | | Systemic injection associated reactions (IARs), defined as hypersensitivity reactions which are related or possibly related to IMP | IAR | citmAESIS_IAR | |
| | | | Cholecystitis | CHOLEC | citmAESIS_CHOLEC | |
| | | | | | | |

| | | | | | | |
|--|--|--|----------------|--------|------------------|--|
| | | | Cholelithiasis | CHOLEL | citmAESIS_CHOLEL | |
|--|--|--|----------------|--------|------------------|--|

| RDE Analytics: RD_FRMAE | | |
|-------------------------|----------------|------------------|
| Data Variable RefName | RD Column Name | Column Data Type |
| numROW | NUMROW | NUMBER |
| | NUMROW_ND | VARCHAR2 |
| txtAE | TXTAE | VARCHAR2 |
| | TXTAE_ND | VARCHAR2 |
| dtmSTART | DTMSTART | DATE |
| | DTMSTART_DTS | VARCHAR2 |
| | DTMSTART_DTR | VARCHAR2 |
| | DTMSTART_ND | VARCHAR2 |
| lstAEEND | LSTAEEND_C | VARCHAR2 |
| | LSTAEEND | VARCHAR2 |
| | LSTAEEND_ND | VARCHAR2 |
| lstAEEND - dtmEND | DTMEND | DATE |
| | DTMEND_DTS | VARCHAR2 |
| | DTMEND_DTR | VARCHAR2 |
| lstAEINT | LSTAEINT_C | VARCHAR2 |
| | LSTAEINT | VARCHAR2 |
| | LSTAEINT_ND | VARCHAR2 |
| lstAEREL | LSTAEREL_C | VARCHAR2 |
| | LSTAEREL | VARCHAR2 |
| | LSTAEREL_ND | VARCHAR2 |
| lstAEREL2 | LSTAEREL2_C | VARCHAR2 |
| | LSTAEREL2 | VARCHAR2 |
| | LSTAEREL2_ND | VARCHAR2 |
| lstACT | LSTACT_C | VARCHAR2 |
| | LSTACT | VARCHAR2 |
| | LSTACT_ND | VARCHAR2 |
| lstAETRT | LSTAETRT_C | VARCHAR2 |
| | LSTAETRT | VARCHAR2 |
| | LSTAETRT_ND | VARCHAR2 |
| lstAEOUT | LSTAEOUT_C | VARCHAR2 |
| | LSTAEOUT | VARCHAR2 |
| | LSTAEOUT_ND | VARCHAR2 |
| lstAEINJ | LSTAEINJ_C | VARCHAR2 |
| | LSTAEINJ | VARCHAR2 |
| | LSTAEINJ_ND | VARCHAR2 |
| lstAEINJ - lstSYMPREYN | 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] | [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) |
| Please examine all body parts / organs and body systems and select the appropriate response: [sctPE] | | |
| If it is a new, clinically significant finding started after first dose of study drug, please also record it on the AE form | | |
| 2.* ✓ | Time performed [Time performed] | [dtmASS_T] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock |
| 3.* ✓ | Chest/Respiratory [Chest/Respiratory] | [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 |
| 4.* ✓ | Heart/Cardiovascular [Heart/Cardiovascular] | [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 |
| 5.* ✓ | Dermatological/Skin [Dermatological/Skin] | [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 |
| 6.* ✓ | Gastrointestinal/Liver [Gastrointestinal/Liver] | [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 |
| 7.* ✓ | Musculoskeletal/Extremities [Musculoskeletal/Extremities] | [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]

☐ 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

[A: OTHER] [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]</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_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 |

| | | |
|---|--|---|
| 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> |

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| 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>[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 A128</div> |
| 21.* | Change from baseline (Day 1, Pre-Dose) ECG | <div>[IstCHANGE1]</div> |

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| <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> |

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| | | <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> |

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| | | <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 | |
|--|--|--|--|--|---|--|

| RDE Analytics: RD_FRMECG_M12M24 | | |
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| 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 |

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| | *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 |

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| | *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 |

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| | 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 |

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|---|---|----------|
| | *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_EN0H6H] (DD/MM/YYYY hh:mm)
Req / Req / Req (2015-2023)
Req : Req 24-hour clock

3.*
✓

Total volume urine collected
[Total volume urine collected]

[numPKUR_V0H6H]
xxxxx. mL

6h - 12h urine collection interval [sctPKUR_6H12H]

4.*
✓

End date and time
[End date and time]

[dPKUR_EN6H12H] (DD/MM/YYYY hh:mm)
Req / Req / Req (2015-2023)
Req : Req 24-hour clock

5.*
✓

Total volume urine collected
[Total volume urine collected]

[numPKUR_V6H12H]
xxxxx. mL

12h - 24h urine collection interval [sctPKUR_12H24H]

6.*
✓

End date and time
[End date and time]

[dPKUR_EN12H24H] (DD/MM/YYYY hh:mm)
Req / Req / Req (2015-2023)
Req : Req 24-hour clock

7.*
✓

Total volume urine collected
[Total volume urine collected]

[numPKUR_V12H24H]
xxxxx. mL

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

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

| | | |
|---|--|---|
| AT3SC002: 12-lead ECG (ECG) [frmECG_PRE] | | |
| Assessment Date [sctASSDT] | | |
| 1.* ✓ | Date collected [Date performed] | [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] 50mg QM [A: 50 Q2M] [IstDOSING] 50mg Q2M [A: DOSING] Dosing [A: NO DOSING] No Dosing [A: 80 QM] 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] Yes [A: N] No</div> |
| 3.* ✓ | Choose the current visit [Choose the current visit] | <div>[IstCURVIS] [cIVISIT] ▼</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><div><div>[IstNOTCHANGED] Dose level not changed, please specify reason [A: SAME DOSE] Participant eligible to continue on original dosing [A: CRITERIA NOT MET] [IstCRITNOTMET] Protocol dose change criteria not met [A: NOT A PROTOCOL-SPECIFIED VISIT FOR POTENTIAL DOSE CHANGE] Not a protocol-specified visit for potential dose change [A: WITHOUT AT GREATER THAN 35 OR LESS THAN 15] Without two previous predose AT levels from central lab testing > 35% or < 15% at a protocol-specified visit for potential dose change</div><div>[A: AT GREATER THAN 35] [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] Participant previously had more than 1 AT level < 15% at the 50mg QM or 80mg QM dose level and is not eligible to re-escalate to the same dose level [A: OTHER] [txtAT35O] Other, please specify A200</div></div><div><div>[A: AT LESS THAN 15] [txtAT15O] Two previous predose AT levels from central lab testing < 15%, please specify reason A200</div><div>[A: OTHER] [txtNOTCHOTH] Other, please specify A200</div></div></div><div><div>[A: DOSE LEVEL ESCALATED]</div><div>[IstESCAL] Dose level escalated, please specify reason [A: AT LEVELS GREATER THAN 35] Two previous predose AT levels from central lab testing > 35% [A: OTHER] [txtESCALO] Other, please specify A200</div></div><div><div>[A: DOSE LEVEL DE-ESCALATED]</div><div>[txtDEESCALO] Dose level de-escalated, please specify reason A200</div></div><div><div>[A: TREATMENT DISCONTINUED]</div><div>[IstDISCONT] Treatment discontinued, please specify reason [A: AT LEVELS LESS THAN 15] Two previous predose AT levels from central lab testing < 15% [A: OTHER] [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 | |
| | | | | | | |

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|--------------|--------|--|-------------------------|-------------------------|-----------------------------|---------------|
| | | | 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 |

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|--|--|-------------|--|-----|-----------------|
| | | | | 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] <input type="radio"/> No significant worsening from baseline [A:CLINICALLY SIGNIFICANT WORSENING FROM BASELINE] <input type="radio"/> [txtCHANGE1] Clinically significant worsening from baseline, specify A128</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 <input type="text"/> : Req <input type="text"/> 24-hour clock</div> |
| 23.* ✓ | Rhythm [Rhythm] | <div>[IstRHYTM4] [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> |
| 24.* ✓ | Ventricular rate [Ventricular rate] | <div>[numVR4] <input type="text"/> N3 bpm^[b]</div> |
| 25.* ✓ | PR interval [PR] | <div>[numPR4] <input type="text"/> N3 msec^[b]</div> |
| 26.* ✓ | QRS duration [QRS] | <div>[numQRS4] <input type="text"/> N3 msec^[b]</div> |
| 27.* ✓ | QT interval [QT] | <div>[numQT4] <input type="text"/> N3 msec^[b]</div> |
| 28.* ✓ | QTc interval [QTc] | <div>[numQTcF4] <input type="text"/> N3 msec^[b]</div> |
| 29.* ✓ | Overall interpretation [Overall interpretation] | <div>[IstOVERALLINT4] [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> |
| 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><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"/> [txtABNOTH4] Other, specify A128</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 |

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| | *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.*
✓

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)]

[IstADDVIS]

[A: Y] ☐ Yes

[A: N] ☐ No

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

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

| Codelist Values Tables: Additional Visits | | | | | | |
|---|--------------------|--------|-------|------|------------------------|-----------------------|
| Codelist RefName | Codelist Data Type | Subset | Label | Code | Codelist I tem 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_UNS] | | |
| 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_UNS] | | |
| 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>Which Protocol Amendment Version is effective for this subject for this AT Follow-Up Visit? [Protocol Amendment Version effective?]</div> <div>[IstPROTATFU] [A:PROTAM5] <input type="radio"/> Protocol Amendment 5 (or lower) [A:PROTAM6] <input type="radio"/> Protocol Amendment 6 (or higher)</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 Item 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 |
| | | |

| | | |
|--|-----------------------|----------|
| | 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 | | | |
|---------|---------------|--|--|--|

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






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


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

| | | | | |
|---------|---------------|--|--|--|
| 3. ✓ | Date and Time | | | |
|---------|---------------|--|--|--|

Unscheduled Telephone Calls Entry [sctTELUNS]

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

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

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

| Keys (navigation)/Uniqueness: Telephone Calls | | |
|---|------------|---------|
| Item | Unique | Order # |
| sctTELSCHED (Repeating section) | | |
| 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 / 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 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]

[lstTESTS_LFT]

[A:ALT]

Alanine Transaminase

[A:AST]

Aspartate Aminotransferase

[A:ALP]

Alkaline Phosphatase

[A:GGT]

Gamma Glutamyl Transferase

[A:TBIL]

Total bilirubin

[A:DBIL]

Direct bilirubin

4.2.*
✓

Value
[Value]

[txtVALUE_LFT]

A100

4.3.*
✓

Unit
[Unit]

[lstUNIT_LFT]

[A:UNIT]

Units

[lstUNITS_LFT]

[A:OTHER]

Other

[txtUNITO_LFT]

A50

4.4.*
✓

Interpretation
[Interpretation]

[lstCSLAB_LFT]

[A:NORMAL]

Normal

[A:ABNORMAL NCS]

Abnormal, not clinically significant

[A:ABNORMAL CS]

[txtINTP_LFT]

Abnormal, clinically significant, please specify

A50

4.5.*
✓

Normal Range

[cmpNR_LFT]

[txtNRLL_LFT]

Normal range - lower limit

A40

[txtNRUL_LFT]

Normal range - upper limit

A40

[txtNRTB_LFT]

Normal range - text based

A40

| | Type of sample | Lab test | Value | Unit | Interpretation | Normal Range |
|---------|----------------|----------|-------|------|----------------|--------------|
| 5. ✓ | | | | | | |

Local Laboratory Tests Entry [sctTEST_UNNS]

5.1.*
✓

Type of sample
[Type of sample]

[lstTYPE]

[A:BLOOD]

Blood (blood, serum, plasma)

[A:URINE]

Urine

5.2.*
✓

Lab test
[Lab test]

[lstTEST]

[A:TEST]

[lstTESTS]

Tests

[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> |
| <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.</div> | | |

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 | |
| cICSLAB | String | | Normal | NORMAL | citmCSLAB_NORM | IstCSLAB_LFT, IstCSLAB |
| | | | Abnormal, not clinically significant | ABNORMAL NCS | citmCSLAB_ABNCS | |
| | | | Abnormal, clinically significant | ABNORMAL CS | citmCSLAB_ABCS | |
| cITYPE | String | | Blood (blood, serum, plasma) | BLOOD | citmTYPE_BLOOD | IstTYPE |
| | | | Urine | URINE | citmTYPE_URINE | |
| cITEST | String | | Test | TEST | citmTEST_TEST | IstTEST |
| | | | Other | OTHER | citmTEST_OTHER | |
| cITESTS_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]</div><div>Beer (units/day):</div><div>xxx.</div></div> <div><div><input type="checkbox"/></div><div>[numWINEDAY2]</div><div>Wine (units/day):</div><div>xxx.</div></div> <div><div><input type="checkbox"/></div><div>[numDISTILDAY2]</div><div>Distilled spirits (units/day):</div><div>xxx.</div></div> |
| 11.* ✓ | Recent travel to areas where hepatitis A or E is endemic? [Travel] | <div>[IstTRAVEL]</div> <div>[A: Y] <input type="radio"/> Yes</div> <div>[A: N] <input type="radio"/> No</div> | |
| <div>Key: [*] = Item is required [✓] = Source verification required</div> <div>Note: Source verification critical settings made in InForm will override any settings made in Central Designer.</div> | | | |

| 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 I tem 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]

[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]

[txtDISCPHYSDEC]

Physician Decision, please specify

A200

[A: PROTOCOL VIOLATION]

[txtDISCPV]

Protocol Violation, please specify

A200

[A: STUDY TERMINATED]

Study Terminated by Sponsor

[A: SUBJECT WITHDREW CONSENT]

Subject Withdrew Consent

[A: OTHER]

[txtDISCOTH]

Other, please specify

A200

[A: AT]

More than 1 AT measurement < 15%

[A: EMERGENCY]

Temporary discontinuation due to a regional or national emergency

DISTERM=COMPLETED

DISTERM=DISCONTINUED

DISTERM=ADVERSE EVENT

DISTERM=DEATH

DISTERM=LOST TO FOLLOW-UP

DISTERM=NON-COMPLIANT

DISTERM=PHYSICIAN DECISION

DISTERM=PROTOCOL VIOLATION

DISTERM=STUDY TERMINATED

DISTERM=SUBJECT WITHDREW CONSENT

DISTERM=OTHER

DISTERM=AT

DISTERM=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 |

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 | |
|--|--|----|---|-------------|--|

| 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]
[A: LOST TO FOLLOW-UP]
[A: NON-COMPLIANT]
[A: PHYSICIAN DECISION]

Death

Lost to follow-up

Non-Compliance with Study Drug

[txtDISCPHYSEDEC]
Physician Decision, please specify

A200

[A: PROTOCOL VIOLATION]

[txtDISCPV]
Protocol Violation, please specify

A200

[A: STUDY TERMINATED]
[A: SUBJECT WITHDREW CONSENT]
[A: OTHER]

Study Terminated by Sponsor

Subject Withdrew Consent

[txtDISCOTH]
Other, please specify

A200

[A: AT]
[A: EMERGENCY]

More than 1 AT measurement <15%

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 | |
|--|--|----|---|-------------|--|

| 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? <i>If <u>yes</u>, please ensure that all Adverse Events are recorded on the Adverse Events form</i> [Any Adverse Events] | [IstAE] [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No |
| 2.* ✓ Did the subject take any concomitant medication at screening and/or during the study? <i>If <u>yes</u>, please ensure that all medications are recorded on the Concomitant medications form</i> [Any concomitant medication] | [IstCM] [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No |
| 3.* ✓ Was there a protocol amendment implemented for this subject during the trial? <i>If <u>yes</u>, please complete the Protocol Amendment & Informed Consent form</i> [Any protocol amendment?] | [IstIFC_AMEND] [A: Y] <input type="radio"/> Yes [A: N] <input type="radio"/> No |
| Signatures [sctSIGN] | |
| 4.* ✓ Is the CRF complete? <i>If <u>yes</u>, please wait for confirmation that there are no outstanding queries/issues before signing-off the casebook.</i> [CRF complete] | [IstCOMP] [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: 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> <small>[read-only]</small> | | | [numROW] N3 | | | | | |
| 2.* | Language of the questionnaire <small>[Language of the questionnaire]</small> | [IstLANG] <small>[A:LANGUAGE]</small> <input type="radio"/> Language <small>[IstLANG_Q]</small> <small>[A:OTHER]</small> <input type="radio"/> <small>[txtLANGO]</small> Other, please specify A100 | | | | | | | |
| 3.* | Identify what type of event occurred. The event can be a bleed, pre-bleed or perioperative bleed only. <small>[Bleed, Pre-bleed or perioperative bleed]</small> | [IstQ1] <small>[A:BLEED]</small> <input type="radio"/> Bleed <small>[A:PRE-BLEED SYMPTOMS ONLY]</small> <input type="radio"/> Pre-bleed symptoms only (please only tick if a bleed did not later occur) <small>[A:PREEMPTIVE TREATMENT]</small> <input type="radio"/> Preemptive treatment <small>[A:PERIOPERATIVE]</small> <input type="radio"/> Perioperative | | | | | | | |
| 4. | What date and time did the bleed occur? <small>[Date and time of bleed]</small> | [dtmQ2] (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 | | | | | | | |
| 5. | Causality (Investigator's assessment) <small>[Causality]</small> | [IstCAUS] <small>[A:DENTAL]</small> <input type="radio"/> Dental/Surgical Procedure <small>[A:SPONTANEOUS]</small> <input type="radio"/> Spontaneous <small>[A:TRAUMATIC]</small> <input type="radio"/> Traumatic <small>[A:OTHER]</small> <input type="radio"/> <small>[txtCAUSO]</small> Other, specify A128 <small>[A:UNKNOWN]</small> <input type="radio"/> Unknown | | | | | | | |
| 6. | What was the severity of the bleed? (Investigator's assessment) <small>[What was the severity of the bleed?]</small> | [IstBLDSEV] <small>[A:MILD]</small> <input type="radio"/> Mild <small>[A:MODERATE]</small> <input type="radio"/> Moderate <small>[A:SEVERE]</small> <input type="radio"/> Severe | | | | | | | |
| 7. | Where was the bleed or pre-bleed symptoms? <small>[Location of bleed or symptoms]</small> | [IstQ3] <small>[A:SKIN/MUCOSA]</small> <input type="radio"/> Skin/Mucosa <small>[A:JOINT]</small> <input type="radio"/> Joint <small>[A:MUSCLE]</small> <input type="radio"/> Muscle <small>[A:INTERNAL]</small> <input type="radio"/> Internal <small>[A:OPERATIVE]</small> <input type="radio"/> Operative Site | | | | | | | |
| 8. | Did you use Factor or Bypassing Agent product? <small>If Yes, please complete a record below for each injection.</small> <small>[Factor or Bypassing Agent product taken]</small> | [IstQ4] <small>[A:Y]</small> <input type="radio"/> <small>[IstQ6]</small> Yes How much product did you need to treat the bleed? <small>[A:OPTION 1]</small> <input type="radio"/> I needed more product than normal to control bleeding <small>[A:OPTION 2]</small> <input type="radio"/> I needed the same amount of product as normal to control bleeding <small>[A:OPTION 3]</small> <input type="radio"/> I needed less product than normal to control bleeding <small>[IstQ7]</small> How did the bleed respond to treatment? <small>[A:OPTION 1]</small> <input type="radio"/> Responded worse than prior bleeds in this location <small>[A:OPTION 2]</small> <input type="radio"/> Responded similarly to prior bleeds in this location <small>[A:OPTION 3]</small> <input type="radio"/> Responded better than prior bleeds in this location <small>[A:OPTION 4]</small> <input type="radio"/> I haven't bled in this location / not sure how bleed responded <small>[A:N]</small> <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 <small>[Order]</small> | [IstORDER] <small>[A:FIRST]</small> <input type="radio"/> First injection <small>[A:FOLLOWUP1]</small> <input type="radio"/> Follow-up 1 injection <small>[A:FOLLOWUP2]</small> <input type="radio"/> Follow-up 2 injection <small>[A:FOLLOWUP NUMBER]</small> <input type="radio"/> <small>[numQ5FUX]</small> 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] <input type="text" value="A30"/> |
| 9.4 ✓ | Total dose [Total dose] | [numQ5] <input type="text" value="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. | | |

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

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|--|
| 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.* |

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