DS--Disposition   **'DSTERM = INFORMED CONSENT OBTAINED**

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

Demographics [sctDM]

1.* ✔	Date of birth [Date of birth]	[dtmBRTH] (DD/MM/YYYY) Req ∨ / Req ∨ / Req ∨ (1930-2023)
2.* ✔	Subject signed informed consent on [Date of informed consent]	[dtmIFC] (DD/MM/YYYY) Req ∨ / Req ∨ / Req ∨ (2015-2023)
3.* ✔	Age (calculated) *[read-only]* [Age]	[numAGE] N3 (years)
4.* ✔	Sex at birth [Sex at birth]	[lstSXBRTH] *[A:M]* ◯ Male
5.* ✔	Race [Race]	[lstRC] *[A:REPORTED]* ◯ [lstRACE] Reported, please specify: *[A:WHITE]* ☐ White *[A:BLACK]* ☐ Black or African-American *[A:ASIAN]* ☐ Asian *[A:INDIAN]* ☐ American Indian or Alaska Native *[A:HAWAIIAN]* ☐ Native Hawaiian or other Pacific Islander ⸚HAWAIIAN⸚ *[A:OTHER]* ☐ [txtRACEOTH] Other, please specify: A60 *[A:NOT REPORTED]* ◯ Not Available/Not Reported
6.* ✔	Ethnicity [Ethnicity]	[lstETHNICITY] *[A:HISPANIC OR LATINO]* ◯ Hispanic or Latino *[A:NOT HISPANIC OR LATINO]* ◯ Not Hispanic or Latino *[A:NA]* ◯ Not Available/Not Reported
7.* ✔	Part in parent study? [Part parent study]	[lstPART] *[A:PART B]* ◯ Part B *[A:PART C]* ◯ Part C *[A:PART D]* ◯ Part D
8.* ✔	Did the patient have an interruption between parent study and roll-over to this study? *More than a month between completion of parent study treatment and roll-over to this study will be considered an interruption.* [Subject initiates dosing]	[lstDAYS] *[A:Y]* ◯ Yes *[A:N]* ◯ No
9.* ✔	What is the subject's HIV status? [HIV status]	[lstHIV] *[A:POSITIVE]* ◯ Positive *[A:NEGATIVE]* ◯ Negative

Will the Whole Blood Clot Formation test (ROTEM) be performed at this site? [sctDYN]

10.* ✔	Will the Whole Blood Clot Formation test (ROTEM) be performed at this site? [ROTEM available]	[lstWBCLT] *[A:Y]* ◯ Yes *[A:N]* ◯ No

Subject Identifiers [sctSUBID]

11.* ✔	Subject ID (3-digits) *[read-only]* [Short Subject ID]	[txtSHORTID1] A3
12. ✔	Site and Subject ID from parent study [Parent study ID]	[txtSUBJIDPS] A7
13.* ✔	Site and Subject ID *[hidden]* [Site and Subject ID]	[txtSUBJID] A7
14.	For office use only *[hidden]* [For office use only]	[numEMAIL1] N3
15.	For office use only *[hidden]* [For office use only]	[numEMAIL2] N3
16.	For office use only *[hidden]* [For office use only]	[numEMAIL3] N3

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

DS--Disposition
RELREC--Related Records

AT3SC002: Drug Termination (DRUG TERM) [frmDRUGTERM]

Study Drug Completion / Termination [sctDRUGTERM]

1.* ✔	Date of study drug termination [Date of study drug termination]	[dtmDRUGTERM] (DD/MM/YYYY) Req ▾ / Req ▾ / Req ▾ (2015-2023) DSTERM='COMPLETED'. If LSTDRUGCOMP_C = 'COMPLETED' then DSTERM='COMPLETED'

2.* ✔	Please specify if the patient completed the entire course of ALN-AT3SC treatment as specified in the protocol or if the patient discontinued ALN-AT3SC early
	[Please specify if the patient completed the entire course of ALN-AT3SC treatment]
		[lstDRUGCOMP]
		[A:COMPLETED] ○ Completed DSTERM='COMPLETED' AACSS
		[A:DISCONTINUED] ○ [lstDISCRS]
		   Discontinued - please specify the primary reason for early termination
		   [A:ADVERSE EVENT] ○ [cmpAE] DSTERM= AVDERSE EVENT
		      Adverse Event
		      Please specify AE#(s) - as recorded on AE form
		      [numAESEQ1] [numAESEQ2] [numAESEQ3] [numAESEQ4] [numAESEQ5] [numAESEQ6]
		      N3 N3 N3 N3 N3 N3
		   [A:DEATH] ○ Death DSTERM= DEATH
		   [A:LOST TO FOLLOW-UP] ○ Lost to follow-up DSTERM=FOLLUW-UP
		   [A:NON-COMPLIANT] ○ Non-Compliance with Study Drug
		   [A:PHYSICIAN DECISION] ○ [txtDISCPHYSDEC]
		      Physician Decision, please specify DSTERM= TXTDISCPHYSDEC
		      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 EMERGENCY

3.* ✔	Will the patient continue to use commercially available fitusiran? [Will the patient continue to use commercially available fitusiran?]	[lstCOMMERC] [A:Y] ○ Yes [A:N] ○ No
4.	For office use only [hidden] [For office use only]	[numEMAIL1] N3
5.	For office use only [hidden] [For office use only]	[numEMAIL2] N3
6.	For office use only [hidden] [For office use only]	[numEMAIL3] N3

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

Codelist Values Tables: Drug Termination

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

DS--Disposition

AT3SC002: Trial Termination (TERM) [frmTERM]

Trial Completion / Discontinuation [sctTERM]

1.* ✔	Please specify if the subject completed the entire course of the trial as specified in the protocol or if the subject discontinued from the trial early
	[Completed/Discontinued]
		[lstCOMPDISC]
		[A: COMPLETED] ◯ **[dtmCOMP]** (DD/MM/YYYY) **DSTERM=COMPLETE**
		     Completed, date of study completion `Req▾` / `Req▾` / `Req▾` (2015-2023)
		[A: DISCONTINUED] ◯ **[dtmDISC]** (DD/MM/YYYY) **DSTERM=DISCONTINUE**
		     Discontinued, date of study discontinuation `Req▾` / `Req▾` / `Req▾` (2015-2023)
		[lstDISCRS]
		     Discontinued - please specify the primary reason for early termination
		   [A: ADVERSE EVENT] ◯ **[cmpAE]**
		     Adverse Event **DSTERM=AVSER EVENT**
		     Please specify AE#(s) - as recorded on AE form
		     [numAESEQ1] [numAESEQ2] [numAESEQ3] [numAESEQ4] [numAESEQ5] [numAESEQ6]
		     `N3` `N3` `N3` `N3` `N3` `N3`
		   [A: DEATH] ◯ Death **DSTERM=DEATH**
		   [A: LOST TO FOLLOW-UP] ◯ Lost to follow-up
		   [A: NON-COMPLIANT] ◯ Non-Compliance with Study Drug
		   [A: PHYSICIAN DECISION] ◯ **[txtDISCPHYSDEC]**
		     Physician Decision, please specify
		     `A200`
		   [A: PROTOCOL VIOLATION] ◯ **[txtDISCPV]**
		     Protocol Violation, please specify
		     `A200`
		   [A: STUDY TERMINATED] ◯ Study Terminated by Sponsor
		   [A: SUBJECT WITHDREW CONSENT] ◯ Subject Withdrew Consent
		   [A: OTHER] ◯ **[txtDISCOTH]**
		     Other, please specify
		     `A200`
		   [A: AT] ◯ More than 1 AT measurement <15%
		   [A: EMERGENCY] ◯ Temporary discontinuation due to a regional or national emergency

2.* ✔	Will the subject roll-over to the next OLE study? [Will the subject roll-over to the next OLE study?]	**[lstROLLOVER]** *[A: Y]* ◯ Yes *[A: N]* ◯ No
3.	For office use only *[hidden]* [For office use only]	**[numEMAIL1]** `N3`
4.	For office use only *[hidden]* [For office use only]	**[numEMAIL2]** `N3`
5.	For office use only *[hidden]* [For office use only]	**[numEMAIL3]** `N3`

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

Codelist Values Tables: Trial Termination

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