DS--Disposition 'DSTERM = INFORMED CONSENT OBTAINED

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

INFORMED CONSENT OBTAINED

Demographics [sctDM]

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

Key: [*] = Item is required [✔] = Source verification required
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' *[A:DISCONTINUED]* **[lstDISCRS]** DISTERM=DISCONTINUED Discontinued - please specify the primary reason for early termination *[A:ADVERSE EVENT]* **[cmpAE]** DSTERM= AVDER DISTERM=ADVERSE 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 DISTERM=DEATH *[A:LOST TO FOLLOW-UP]* Lost to follow-up DSTERM=FOLLOW-UP DISTERM=LOST TO FOLLOW-UP *[A:NON-COMPLIANT]* Non-Compliance with Study Drug DISTERM=NON-COMPLIANT *[A:PHYSICIAN DECISION]* **[txtDISCPHYSDEC]** DISTERM=PHYSICIAN DECISION Physician Decision, please specify DSTERM= TXTDISCPHYSDEC A200 *[A:PROTOCOL VIOLATION]* **[txtDISCPV]** DISTERM=PROTOCOL VIOLATION Protocol Violation, please specify A200 *[A:STUDY TERMINATED]* Study Terminated by Sponsor DISTERM=STUDY TERMINATED *[A:SUBJECT WITHDREW CONSENT]* Subject Withdrew Consent DISTERM=SUBJECT WITHDREW CONSENT *[A:OTHER]* **[txtDISCOTH]** DISTERM=OTHER Other, please specify A200 *[A:AT]* More than 1 AT measurement < DISTERM=AT *[A:EMERGENCY]* Temporary discontinuation due to a regi DISTERM=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