

AT3SC002: Demographic Data and Informed Consent Recording (DM) [frmDM]		
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]	[txtSUBJDPS] <input type="text"/> A7
13.*	Site and Subject ID <i>[hidden]</i> [Site and Subject ID]	[txtSUBJID] <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					

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]  
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

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]

[IstCOMPDISC]  
[A: COMPLETED]

[dtmCOMP] (DD/MM/YYYY)

Completed, date of study completion | Req ▾ / | Req ▾ / | Req ▾ (2015-2023)

[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

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]

[txtDISCPHYSDC]

Physician Decision, please specify

A200

[A: PROTOCOL VIOLATION]

[txtDISCPV]

Protocol Violation, please specify

A200

[A: STUDY TERMINATED]

Study Terminated by Sponsor

[A: SUBJECT WITHDREW CONSENT]

Subject Withdrew Consent

[A: OTHER]

[txtDISCOTH]

Other, please specify

A200

[A: AT]

More than 1 AT measurement <15%

[A: EMERGENCY]

Temporary discontinuation due to a regional or national emergency

2.\*  
✓

Will the subject roll-over to the next OLE study?  
[Will the subject roll-over to the next OLE study?]

[IstROLLOVER]  
[A: Y] ☐ Yes  
[A: N] ☐ No

3.

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

[numEMAIL1]  
N3

4.

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

[numEMAIL2]  
N3

5.

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

[numEMAIL3]  
N3

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

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