

MTS1 Data Glossary – Tables and Fields

Study Information:

<u>Protocol</u>	<u>ProtocolDs</u>	<u>ProtocolDetailDs</u>	<u>StartDt</u>	<u>1stRecruitDt</u>	<u>RecruitEndDt</u>	<u>FinalVisitDt</u>
MTS1	Myopia Treatment Study 1	Low-Dose Atropine for Treatment of Myopia	3/1/2018	6/1/2018	3/6/2020	9/12/2022
<u># of Sites Certified</u>	<u># Sites Enrolling</u>	<u># Sites w/Randomized Pts</u>	<u># Pts Enroll</u>	<u># Pts Randomized</u>	<u>NCT ID</u>	<u>FDA IND</u>
14	13	12	200	187	NCT03334253	137441

- The case report form (CRF) for each follow up visit post-randomization (i.e. after the Run-In Follow Up visit) is the same for 6, 12, 18, 24, and 30-month visits, with the following exceptions:
 - The eyedrop questionnaire is assessed at all visits except the 30-month visit
 - Distance visual acuity is assessed at the 30-month visit only
 - Binocular near visual acuity is assessed at 6 months only
- The CRF for each phone call is the same for all phone calls at (2-weeks, 3-, 9-, 15-, and 21-months).
- The data from masked exams (cycloplegic refraction and autorefraction data) at 6, 12, 18, 24, and 30-month visits is in the clinical testing table (MTS1ClinicTesting), one row per participant PtID per Visit, which also contains cycloplegic refraction and autorefraction data from the Enrollment and Run-In Follow Up Visits prior to randomization.

Data Tables and Annotated CRF/s:

<u>Table Name</u>	<u>Short Description</u>	<u>Comments</u>	<u>Name of Annotated CRF/s</u>
MTS1AdvEvent	Adverse Event CRF	One record per PtID per adverse event reported during the study.	99MTS1AdverseEventForm
MTS1ClinicMeas	Clinical Measures CRF	One record per Visit per PtID with results of: Distance visual acuity testing (run-in FU/randomization and 30-month FU visits only or any time an ocular adverse event is reported), near visual acuity testing (run-in	02MTS1Month00RuninFURandomizationVisit 05MTS1Month06Visit 06MTS1Month12Visit 08MTS1Month18Visit 10MTS1Month24Visit 12MTS1Month30Visit

MTS1 Data Glossary – Tables and Fields

		FU/randomization and 6-month FU visits only), and binocular accommodative amplitude testing (all visits).	
MTS1ClinicTesting	Clinical Testing CRF	<p>One record per Visit per PtID with results of:</p> <p>Cycloplegic autorefraction and axial length measurement and additional biometry measures.</p> <p>Evaluated at time of enrollment; to be repeated at run-inFURandomization if >28 days from enrollment.</p>	<p>01MTS1Month00EnrollmentVisit</p> <p>02MTS1Month00RuninFURandomizationVisit</p> <p>05MTS1Month06Visit</p> <p>06MTS1Month12Visit</p> <p>08MTS1Month18Visit</p> <p>10MTS1Month24Visit</p> <p>12MTS1Month30Visit</p>
MTS1CompAssess	Compliance Assessment CRF	One record per FU Visit per PtID with assessment of study medication and spectacle compliance.	<p>05MTS1Month06Visit</p> <p>06MTS1Month12Visit</p> <p>08MTS1Month18Visit</p> <p>10MTS1Month24Visit</p> <p>12MTS1Month30Visit</p>
MTS1CompEnroll	Miscellaneous Eligibility and Complete Enrollment CRF	One record per PtID enrolled with optical correction prescribed at time of enrollment and confirmation of eligibility.	01MTS1Month00EnrollmentVisit
MTS1ConfRand	Confirm Randomization CRF	One record per PtID randomized with final confirmation of eligibility to randomize.	02MTS1Month00RuninFURandomizationVisit
MTS1DemoMedOcuHx	Demographics/Medical and Optical Correction History CRF	One record per PtID enrolled with sex, race, ethnicity, eye color, parental history with myopia, menarche status, refractive status at time of enrollment, and review of medical history / confirmation of eligibility at time of enrollment	01MTS1Month00EnrollmentVisit
MTS1DrugPackage	Drug Packages Assigned to Each Participant – Admin	One record per drug package per PtID (atropine or placebo) assigned to each participant PtID during the study.	No CRF
MTS1EyeDropQuest	Eye Drop Questionnaire CRF	One record per Visit per PtID with child assessment of their experience with eye drops since the prior visit.	<p>02MTS1Month00RuninFURandomizationVisit</p> <p>05MTS1Month06Visit</p> <p>06MTS1Month12Visit</p>

MTS1 Data Glossary – Tables and Fields

			08MTS1Month18Visit 10MTS1Month24Visit 12MTS1Month30Visit
MTS1FUCall	Phone Call CRF	One record per Visit per PtID for each phone call during the study (2-weeks, 3, 9, 15, 21, and 27-months).	03MTS1Week02Call 04MTS1Month03Call 06MTS1Month09Call 07MTS1Month15Call 09MTS1Month21Call 11MTS1Month27Call
MTS1MedHxFU	Medical History Follow-up CRF	One record per FU Visit per PtID with medical history since prior visit.	05MTS1Month06Visit 06MTS1Month12Visit 08MTS1Month18Visit 10MTS1Month24Visit 12MTS1Month30Visit
MTS1Medication	Medications CRF	One record per PtID per concomitant medication reported during the study.	99MTS1ConcomitantMedications
MTS1OptCorrHxCompAssess	Optical Correction History and Compliance Assessment CRF	One record per PtID per run-in FU visit with assessment of artificial tear eye drop compliance in run-in phase prior to randomization.	02MTS1Month00RuninFURandomizationVisit
MTS1PreExistingCondition	Pre-Exisitng Condition CRF	One record per PtID per condition pre-existing at time of enrollment prior to randomization.	00MTS1PreExistingConditionForm
MTS1PtFinalStat	Final Status CRF	One record per PtID defining patient status as dropped or completed for the study.	99MTS1FinalStatusForm
MTS1TreatRx	Treatment Prescribed CRF	One record per PtID per FU visit with treatment prescribed information.	05MTS1Month06Visit 06MTS1Month12Visit 08MTS1Month18Visit 10MTS1Month24Visit 12MTS1Month30Visit
MTS1VisitInfo	Visit Information CRF	One record per PtID per Visit with visit related information.	01MTS1Month00EnrollmentVisit 02MTS1Month00RuninFURandomizationVisit 05MTS1Month06Visit 06MTS1Month12Visit 08MTS1Month18Visit

MTS1 Data Glossary – Tables and Fields

			10MTS1Month24Visit 12MTS1Month30Visit
MTS1PtRoster	Patient Roster - Admin	One record per PtID screened and enrolled into the study.	No CRF

MTS1 Data Glossary – Tables and Fields

MTS1AdvEvent

Description: Adverse Event Form

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient Identifier			
ParentLoginVisitID	Unique ID for the Visit			
AENotifiedDt	Date notified of/identified adverse event			
MedicalCondition	Medical Condition			
MedicalConditionMM	Medical Condition determined by the Medical Monitor			
AdverseEventType	If ocular event, select eye			OD = Right Eye, OS = Left Eye
AEOndsetDt	Date of onset (or worsening of a pre-existing condition)			
AEPrEnroll	Is the adverse event a worsening of a pre-existing condition present prior to study entry			Yes, No
AENotedStdyVisExam	Was the adverse event an abnormality (or worsening of an existing abnormality) identified on a study visit exam			Yes, No
AEIntensity	Maximum intensity (Severity)			Mild, Moderate, Severe
AERelStdyTrt	Is there a reasonable possibility that the event was caused by a study treatment/study device			Yes, No
AERelStdyTrtUncertain	Uncertain which treatment/study device caused event			1 = Checked
AERelStdyProc	Is there a reasonable possibility that the event was caused by a study procedure			Yes, No
AEEffectTrt	Effect on study treatment/device			No change, Discontinued temporarily, Discontinued permanently, Reduced dose, Reduced use frequency/schedule
AE Serious	Does the event meet criteria for a serious adverse event			Yes, No

MTS1 Data Glossary – Tables and Fields

AETrt	Did patient receive treatment for the Adverse Event			Yes, No
AE Surg	Surgery/procedure			Yes, No
AE SurgDt	Date of surgery/procedure			
AEMedsList	If yes, list medications here			
AE OthTrt	Other Treatment of Adverse Event			Yes, No
AE Outcome	Outcome			Ongoing (further improvement / worsening possible), Ongoing, medically stable, Complete Recovery, Recovered with Sequelae, Fatal
AEResDt	Date of Recovery (with or without sequelae)			
AEDeathCause	Cause of death			
AEDeathDt	Date of Death			
AEDeath	Criteria Defining Event as Serious Adverse Event: Death			1 = Checked
AE ConAnomaly	Criteria Defining Event as Serious Adverse Event: Congenital Anomaly			1 = Checked
AE LifeThreat	Criteria Defining Event as Serious Adverse Event: Life Threatening			1 = Checked
AE Hosp	Criteria Defining Event as Serious Adverse Event: Hospitalization -- initial or prolonged			1 = Checked
AE Disability	Criteria Defining Event as Serious Adverse Event: Significant Disability or Incapacity			1 = Checked
AE Other	Criteria Defining Event as Serious Adverse Event: Other			1 = Checked
Weight	Weight	0		
WeightMeas	Weight Measurement			lbs, kgs
WeightNotAvail	Weight: Not available			1 = Checked
AERelLabData	Relevant Tests/Laboratory Data			Yes, No
AE OthRelHx	Other relevant history, including preexisting medical conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)			Yes, No
AEMedProd	Concomitant medical			Yes, No

MTS1 Data Glossary – Tables and Fields

	products and therapy dates (exclude treatment of event)			
FormCmts	Form Comments			
MMAERelStdyTrt	MM Is there a reasonable possibility that the event was caused by a study treatment/study device			Yes, No, Unrelated, Unlikely related, Possibly related, Probably related, Definitely related, Not assessable
MMAESerious	MM Does the event meet criteria for a serious adverse event			Yes, No
MMUnexpected	MM Was the event unexpected			Yes, No
AERelStdyDrugDevice	What is the relationship of the event to study drug/device			Unrelated, Unlikely related, Possibly related, Probably related, Definitely related, Not assessable
AERelStdyDrugDeviceUncertain	Uncertain which study drug/device is related to event			1 = Checked
MMHospDiscRptObtained	MM Hospital Discharge Reports Obtained			Yes, No, Not Requested, No, Requested Not Obtained
AERelStdyTrtHighLvl	If Yes, to which of the following was the adverse event possibly related			Study drug (drug effect), Other study treatment, Study device (function), Administration of study drug/device, Prep for the administration of study drug, Study diagnostic procedure, More than one of the above
AERelStdyTrtWhich	If related to the study drug/device and the study has more than one study drug or device, please indicate which one or indicate uncertain if you cannot determine			
AERelStdyDrugDeviceHighLvl	If possibly, probably or definitely related, to which of the following was the adverse event			Study drug (drug effect), Other study treatment, Study device (function),

MTS1 Data Glossary – Tables and Fields

	possibly/probably/definitely related			Administration of study drug/device, Prep for the administration of study drug, Study diagnostic procedure, More than one of the above
AERelStdyDrugDeviceWhich	If related to the study drug/device and the study has more than one study drug or device, please indicate which one or indicate uncertain if you cannot determine			
MMAERelStdyTrtHighLvl	MM To which of the following was the adverse event possibly related			Study drug (drug effect), Other study treatment, Study device (function), Administration of study drug/device, Prep for the administration of study drug, Study diagnostic procedure, More than one of the above
MMInitialCmtsDt	MM Date Initial Comments entered			
AEMedEvent	Criteria Defining Event as Serious Adverse Event: Significant Medical Event			1 = Checked
AENCILevel	Level of Severity (based on National Cancer Institute)			Grade 1, Grade 2, Grade 3, Grade 4, Grade 5

MTS1 Data Glossary – Tables and Fields

MTS1ClinicMeas

Description: MTS1 Clinical Measures form

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient Identifier			
ParentLoginVisitID	Unique ID for the Visit			
DistVANotDoneReas	Distance Visual Acuity Not Done			
ETDRSVisAcuOD	Right Eye score			0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100
ETDRSVisAcuOS	Left Eye score			0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100
BinNrVANotDone	Near Visual Acuity Not Done			1 = Checked
BinNrVAOU	Binocular Near VA			20/12, 20/16, 20/20, 20/25, 20/32, 20/40, 20/50, 20/63, 20/80, 20/100, 20/125, 20/160, 20/200, 20/250, 20/320,

MTS1 Data Glossary – Tables and Fields

				20/400, 20/500, 20/640, 20/800
BinAccAmpNotDone	Binocular Accommodative Amplitue Not Done			1 = Checked
NrPtAcc	Near point of accommodation (cm)	0.5	60	
Visit	Visit			

MTS1 Data Glossary – Tables and Fields

MTS1ClinicTesting

Description: MTS1 Clinical Testing

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient ID			
ParentLoginVisitID	Unique ID for the Visit			
Visit	Visit			
AutoRefNotDone	Autorefration Not Done			1 = Checked
AutoRef1SphOD	Autorefration right eye sphere measurement 1			
AutoRef1CylOD	Autorefration right eye cylinder measurement 1			
AutoRef1AxisOD	Autorefration right eye axis measurement 1			180, 179, 178, 177, 176, 175, 174, 173, 172, 171, 170, 169, 168, 167, 166, 165, 164, 163, 162, 161, 160, 159, 158, 157, 156, 155, 154, 153, 152, 151, 150, 149, 148, 147, 146, 145, 144, 143, 142, 141, 140, 139, 138, 137, 136, 135, 134, 133, 132, 131, 130, 129, 128, 127, 126, 125, 124, 123, 122, 121, 120, 119, 118, 117, 116, 115, 114, 113, 112, 111, 110, 109, 108, 107, 106, 105, 104, 103, 102, 101, 100, 99, 98, 97, 96, 95, 94, 93, 92, 91, 90, 89, 88, 87, 86, 85, 84, 83, 82, 81, 80, 79, 78, 77, 76, 75, 74, 73, 72, 71, 70, 69, 68, 67, 66, 65, 64, 63, 62, 61, 60, 59, 58, 57, 56, 55, 54, 53, 52, 51, 50, 49, 48, 47, 46, 45, 44, 43, 42, 41, 40, 39, 38, 37, 36, 35, 34, 33, 32, 31, 30, 29, 28, 27, 26, 25, 24, 23, 22, 21, 20, 19, 18, 17, 16, 15, 14, 13, 12, 11, 10, 9, 8, 7, 6, 5, 4, 3, 2, 1

MTS1 Data Glossary – Tables and Fields

AutoRef1SphOS	Autorefraction left eye sphere measurement 1			
AutoRef1CylOS	Autorefraction left eye cylinder measurement 1			
AutoRef1AxisOS	Autorefraction left eye axis measurement 1			180, 179, 178, 177, 176, 175, 174, 173, 172, 171, 170, 169, 168, 167, 166, 165, 164, 163, 162, 161, 160, 159, 158, 157, 156, 155, 154, 153, 152, 151, 150, 149, 148, 147, 146, 145, 144, 143, 142, 141, 140, 139, 138, 137, 136, 135, 134, 133, 132, 131, 130, 129, 128, 127, 126, 125, 124, 123, 122, 121, 120, 119, 118, 117, 116, 115, 114, 113, 112, 111, 110, 109, 108, 107, 106, 105, 104, 103, 102, 101, 100, 99, 98, 97, 96, 95, 94, 93, 92, 91, 90, , 89, 88, 87, 86, 85, 84, 83, 82, 81, 80, 79, 78, 77, 76, 75, 74, 73, 72, 71, 70, 69, 68, 67, 66, 65, 64, 63, 62, 61, 60, 59, 58, 57, 56, 55, 54, 53, 52, 51, 50, 49, 48, 47, 46, 45, 44, 43, 42, 41, 40, 39, 38, 37, 36, 35, 34, 33, 32, 31, 30, 29, 28, 27, 26, 25, 24, 23, 22, 21, 20, 19, 18, 17, 16, 15, 14, 13, 12, 11, 10, 9, 8, 7, 6, 5, 4, 3, 2, 1
AutoRef2SphOD	Autorefraction right eye sphere measurement 2			
AutoRef2CylOD	Autorefraction right eye cylinder measurement 2			
AutoRef2AxisOD	Autorefraction right eye axis measurement 2			180, 179, 178, 177, 176, 175, 174, 173, 172, 171, 170, 169, 168, 167, 166, 165, 164, 163, 162, 161, 160, 159, 158, 157, 156, 155, 154, 153,

MTS1 Data Glossary – Tables and Fields

				152, 151, 150, 149, 148, 147, 146, 145, 144, 143, 142, 141, 140, 139, 138, 137, 136, 135, 134, 133, 132, 131, 130, 129, 128, 127, 126, 125, 124, 123, 122, 121, 120, 119, 118, 117, 116, 115, 114, 113, 112, 111, 110, 109, 108, 107, 106, 105, 104, 103, 102, 101, 100, 99, 98, 97, 96, 95, 94, 93, 92, 91, 90, 89, 88, 87, 86, 85, 84, 83, 82, 81, 80, 79, 78, 77, 76, 75, 74, 73, 72, 71, 70, 69, 68, 67, 66, 65, 64, 63, 62, 61, 60, 59, 58, 57, 56, 55, 54, 53, 52, 51, 50, 49, 48, 47, 46, 45, 44, 43, 42, 41, 40, 39, 38, 37, 36, 35, 34, 33, 32, 31, 30, 29, 28, 27, 26, 25, 24, 23, 22, 21, 20, 19, 18, 17, 16, 15, 14, 13, 12, 11, 10, 9, 8, 7, 6, 5, 4, 3, 2, 1
AutoRef2SphOS	Autorefraction left eye sphere measurement 2			
AutoRef2CylOS	Autorefraction left eye cylinder measurement 2			
AutoRef2AxisOS	Autorefraction left eye axis measurement 2			180, 179, 178, 177, 176, 175, 174, 173, 172, 171, 170, 169, 168, 167, 166, 165, 164, 163, 162, 161, 160, 159, 158, 157, 156, 155, 154, 153, 152, 151, 150, 149, 148, 147, 146, 145, 144, 143, 142, 141, 140, 139, 138, 137, 136, 135, 134, 133, 132, 131, 130, 129, 128, 127, 126, 125, 124, 123, 122, 121, 120, 119, 118, 117, 116, 115, 114, 113, 112, 111, 110, 109,

MTS1 Data Glossary – Tables and Fields

				108, 107, 106, 105, 104, 103, 102, 101, 100, 99, 98, 97, 96, 95, 94, 93, 92, 91, 90, , 89, 88, 87, 86, 85, 84, 83, 82, 81, 80, 79, 78, 77, 76, 75, 74, 73, 72, 71, 70, 69, 68, 67, 66, 65, 64, 63, 62, 61, 60, 59, 58, 57, 56, 55, 54, 53, 52, 51, 50, 49, 48, 47, 46, 45, 44, 43, 42, 41, 40, 39, 38, 37, 36, 35, 34, 33, 32, 31, 30, 29, 28, 27, 26, 25, 24, 23, 22, 21, 20, 19, 18, 17, 16, 15, 14, 13, 12, 11, 10, 9, 8, 7, 6, 5, 4, 3, 2, 1
AutoRef3SphOD	Autorefraction right eye sphere measurement 3			
AutoRef3CylOD	Autorefraction right eye cylinder measurement 3			
AutoRef3AxisOD	Autorefraction right eye axis measurement 3			180, 179, 178, 177, 176, 175, 174, 173, 172, 171, 170, 169, 168, 167, 166, 165, 164, 163, 162, 161, 160, 159, 158, 157, 156, 155, 154, 153, 152, 151, 150, 149, 148, 147, 146, 145, 144, 143, 142, 141, 140, 139, 138, 137, 136, 135, 134, 133, 132, 131, 130, 129, 128, 127, 126, 125, 124, 123, 122, 121, 120, 119, 118, 117, 116, 115, 114, 113, 112, 111, 110, 109, 108, 107, 106, 105, 104, 103, 102, 101, 100, 99, 98, 97, 96, 95, 94, 93, 92, 91, 90, , 89, 88, 87, 86, 85, 84, 83, 82, 81, 80, 79, 78, 77, 76, 75, 74, 73, 72, 71, 70, 69, 68, 67, 66, 65, 64, 63, 62, 61, 60, 59, 58, 57, 56, 55, 54, 53, 52, 51, 50, 49,

MTS1 Data Glossary – Tables and Fields

				48, 47, 46, 45, 44, 43, 42, 41, 40, 39, 38, 37, 36, 35, 34, 33, 32, 31, 30, 29, 28, 27, 26, 25, 24, 23, 22, 21, 20, 19, 18, 17, 16, 15, 14, 13, 12, 11, 10, 9, 8, 7, 6, 5, 4, 3, 2, 1
AutoRef3SphOS	Autorefration left eye sphere measurement 3			
AutoRef3CylOS	Autorefration left eye cylinder measurement 3			
AutoRef3AxisOS	Autorefration left eye axis measurement 3			180, 179, 178, 177, 176, 175, 174, 173, 172, 171, 170, 169, 168, 167, 166, 165, 164, 163, 162, 161, 160, 159, 158, 157, 156, 155, 154, 153, 152, 151, 150, 149, 148, 147, 146, 145, 144, 143, 142, 141, 140, 139, 138, 137, 136, 135, 134, 133, 132, 131, 130, 129, 128, 127, 126, 125, 124, 123, 122, 121, 120, 119, 118, 117, 116, 115, 114, 113, 112, 111, 110, 109, 108, 107, 106, 105, 104, 103, 102, 101, 100, 99, 98, 97, 96, 95, 94, 93, 92, 91, 90, , 89, 88, 87, 86, 85, 84, 83, 82, 81, 80, 79, 78, 77, 76, 75, 74, 73, 72, 71, 70, 69, 68, 67, 66, 65, 64, 63, 62, 61, 60, 59, 58, 57, 56, 55, 54, 53, 52, 51, 50, 49, 48, 47, 46, 45, 44, 43, 42, 41, 40, 39, 38, 37, 36, 35, 34, 33, 32, 31, 30, 29, 28, 27, 26, 25, 24, 23, 22, 21, 20, 19, 18, 17, 16, 15, 14, 13, 12, 11, 10, 9, 8, 7, 6, 5, 4, 3, 2, 1
AxialLenNotDone	Axial Length and Additional Biometry Not Done			1 = Checked
AxialLen1OD	Right eye axial length	15.00	30.00	

MTS1 Data Glossary – Tables and Fields

	measurement 1			
AxialLen1OS	Left eye axial length measurement 1	15.00	30.00	
MeanCorneaRad1OD	Right eye mean corneal radius measurement 1	7.00	10.00	
MeanCorneaRad1OS	Left eye mean corneal radius measurement 1	7.00	10.00	
AntChamDepth1OD	Right eye anterior chamber depth measurement 1	3.00	5.00	
AntChamDepth1OS	Left eye anterior chamber depth measurement 1	3.00	5.00	
LensThick1OD	Right eye lens thickness measurement 1	2.50	5.00	
LensThick1OS	Left eye lens thickness measurement 1	2.50	5.00	
LensThick1NA	Lens thickness not available measurement 1			1 = Checked
AxialLen2OD	Right eye axial length measurement 2	15.00	30.00	
AxialLen2OS	Left eye axial length measurement 2	15.00	30.00	
MeanCorneaRad2OD	Right eye mean corneal radius measurement 2	7.00	10.00	
MeanCorneaRad2OS	Left eye mean corneal radius measurement 2	7.00	10.00	
AntChamDepth2OD	Right eye anterior chamber depth measurement 2	3.00	5.00	
AntChamDepth2OS	Left eye anterior chamber depth measurement 2	3.00	5.00	
LensThick2OD	Right eye lens thickness measurement 2	3.00	5.00	
LensThick2OS	Left eye lens thickness measurement 2	3.00	5.00	
LensThick2NA	Lens thickness not available measurement 2			1 = Checked
AxialLen3OD	Right eye axial length measurement 3	15.00	30.00	
AxialLen3OS	Left eye axial length measurement 3	15.00	30.00	
MeanCorneaRad3OD	Right eye mean corneal radius measurement 3	7.00	10.00	
MeanCorneaRad3OS	Left eye mean corneal radius measurement 3	7.00	10.00	
AntChamDepth3OD	Right eye anterior chamber depth measurement 3	3.00	5.00	
AntChamDepth3OS	Left eye anterior chamber depth measurement 3	3.00	5.00	
LensThick3OD	Right eye lens thickness measurement 3	3.00	5.00	
LensThick3OS	Left eye lens thickness measurement 3	3.00	5.00	

MTS1 Data Glossary – Tables and Fields

LensThick3NA	Lens thickness not available measurement 3			1 = Checked
Unblind	Was ANY masked examiner able to identify the patient's treatment group at any time			Yes, No, Not Applicable
AutoRefInstrID	Instrument Identifier (autorefraction)			
AxialLenInstrID	Instrument Identifier (biometry)			
TestingDone	Testing: Not Done, Right eye only, Left eye only, or Both eyes			Not Done, Right eye only, Left eye only, Both eyes
FlatCorneaRad1OD	Right eye flat corneal radius measurement 1	33.75	52.00	
FlatCorneaRad1OS	Left eye flat corneal radius measurement 1	33.75	52.00	
AR_RecdDt	Date Autorefraction printout received at Jaeb Center			
AR_ProcessDt	Date Autorefraction printout processed at Jaeb Center			

MTS1 Data Glossary – Tables and Fields

MTS1CompAssess

Description: MTS1 Compliance Assessment form

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient ID			
ParentLoginVisitID	Unique ID for the Visit			
ParentLoginID	RecID from tblLogin			
Visit	Visit			
AmpulesReturned	Were remaining ampules of study medication brought to the visit			
AmpulesRemain	Number of remaining ampules of study medication	0	210	
CalendarReturned	Was the participant's compliance calendar brought to the visit			
MTS1MedCompl	Assessment of compliance with study medication based on review of calendar and interview with parent and/or child			Poor (<25%), Fair (26% to 50%), Good (51% to 75%), Excellent (76% to 100%), N/A (30-month Visit)
MTS1SpecCompl	Assessment of spectacle (or contact lens) wear compliance since last visit (after interview with parent and/or child)			Poor (<25% of waking hours), Fair (26% to 50% of waking hours), Good (51% to 75% of waking hours), Excellent (76% to 100% of waking hours)

MTS1 Data Glossary – Tables and Fields

MTS1CompEnroll

Description: MTS1 Miscellaneous Eligibility and Complete Enrollment

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient ID			
ParentLoginVisitID	Unique ID for the Visit			
ParentLoginID	RecID from tblLogin			
OptCorrRx	Optical correction prescribed			Change in optical correction, Continuing in current optical correction
SpecCritMet	Do spectacles (and/or contact lenses) meet study criteria based on a standard refractions (with or without cycloplegia)			Yes, No
EligCriteria	Verify all of the following			1 = Checked
PtContactComp	Participant Contact Information Form has been completed			1 = Checked

MTS1 Data Glossary – Tables and Fields

MTS1ConfRand

Description: Confirm Randomization

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient ID			
ParentLoginVisitID	Unique ID for the Visit			
ParentLoginID	RecID from tblLogin			
RandCriteria	Randomization Criteria			1 = Checked
AddlArtTears	Were an additional 30 ampules of Artificial Tears given to subject during Run-In?			Yes, No

MTS1 Data Glossary – Tables and Fields

MTS1DemoMedOcuHx

Description: MTS1 Demographics/Medical and Optical Correction History

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient ID			
ParentLoginVisitID	Unique ID for the Visit			
ParentLoginID	RecID from tblLogin			
Sex	Sex of the participant			
Ethnicity	Do you consider yourself Hispanic/Latino or not Hispanic/Latino			Hispanic or Latino, Not Hispanic or Latino, Unknown/not reported
Race	Which of the following racial designations best describes you (race)			
RaceDs	If more than one race, please specify			
EyeColor	Eye Color			Brown, Not brown
MotherMyop	Does the biological mother have myopia			Yes, No, Unknown
FatherMyop	Does the biological father have myopia			Yes, No, Unknown
EligCriteria	All of the following must be true for the participant to be eligible			1 = Checked
CurrSpecs	Does participant currently wear single-vision spectacles			Yes, No
CurrContacts	Does participant currently wear single-vision soft contact lenses (with or without spectacles)			Yes, No
RefCorrMeetCrit	Does current refractive correction meet protocol criteria			Yes, No
MenarcheStatus	Menarche status			Post-menarche, Pre-menarche, Male
PregnancyStatus	Pregnancy test			Negative, Positive, Not done
CurrWearRefCorr	Does participant currently wear refractive correction (single-vision spectacles or contact lenses)?			Yes, No
RefCorrCompl	If Yes, has compliance with refractive correction been more than 75% of all waking hours based upon investigator judgement after discussion with parent?			Yes, No

MTS1 Data Glossary – Tables and Fields

MedRecsPriorEnr	Are there medical records for the participant prior to enrollment that can be reviewed to help support eligibility?			Yes medical records, No medical records
ENoAll	Participant has no known atropine allergy			
ENoAbn	Participant has no abnormality of the cornea, lens, central retina, iris, or ciliary body			
ENoAtr	No atropine, pirenzepine, or other anti-muscarinic agent			
ENoAPrior	No Ortho-K, rigid gas permeable, or other contact lenses being used to reduce myopia progression			
ENoLenses	No bifocals, progressive-addition lenses, or multi-focal contact lenses			
ENoAmb	No amblyopia			
ENoNys	No nystagmus			
ENoStrab	No manifest strabismus			
ENoSurg	No prior eyelid, strabismus, intraocular, or refractive surgery			

MTS1 Data Glossary – Tables and Fields

MTS1DrugPackage

Description: One row per drug package assigned to each participant during the study.

Data Source: One row per package number with treatment group for each package randomly assigned prior to the study. Package numbers were assigned randomly to each participant (PtID) by the study website during the study. Two packages randomly assigned to each participant depending upon treatment group at each FU visit at randomization, 6, 12, and 18-months post-randomization. Additional packages could be randomly assigned in between visits if needed.

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient ID assigned to package			Note: only drug packages assigned to a PtID are included in the table.
PackageNum	MTS1 Drug Package Number			M0001 to M9999
MTS1DrugType	MTS1 Drug Type (Atropine or Placebo)			Atropine, Placebo
DrugAssignVisit	Visit when package assigned to patient			
DrugAssignExtra	Package assigned between visits			Yes, No
LotNum	Lot number from manufacturer			
ParentInventoryItemsID	RecID from tblITAInventoryItems			
RcvdDt	Date drugs received from manufacturer			
ManufacDt	Manufacture date of drugs			
VerificationCode	Verification Code on drug label and used in Inventory Tracking			
AssignDt	Date of clinical site's drug assignment submission			

MTS1 Data Glossary – Tables and Fields

MTS1EyeDropQuest

Description: MTS1 Eye Drop Questionnaire Form

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient ID			
ParentLoginVisitID	Unique ID for the Visit			
ParentLoginID	RecID from tblLogin			
Visit	Visit			
HateEyedrops	Do you hate eye drops			
DropsHurtEyes	Do your eye drops hurt your eyes			
HardTimeSeeing	Do you have a hard time seeing			
TroubleReading	Do you have trouble reading up close			
BrightLightOutside	Does bright light make it hard to do things outside			
BotherByLook	Are you bothered by how your eye drops make your eyes look			
BotherHurt	Does it bother you because your eye drops hurt your eyes			
BotherHardSee	Does it bother you because you have a hard time seeing			
BotherTroubleRead	Does it bother you because you have trouble reading up close			
BotherLightOutside	Does it bother you because bright light makes it hard to do things outside			

MTS1 Data Glossary – Tables and Fields

MTS1FUCall

Description: MTS1 Phone Call Form

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient ID			
ParentLoginVisitID	Unique ID for the Visit			
Visit	Visit			
CallNotDone	Call not done			1 = Checked
CallDt	Date of phone call			
MTS1PersSpokenWith	Person spoken with			Mother, Father, Other
TakingMed	Has the participant been taking the prescribed study medication			
SideEffects	Has the participant experienced any side effects or other adverse effects since the last visit			Yes, No
CalendarCompliance	Has the participant been marking on their calendar the days they have taken prescribed study medication and worn their optical correction?			

MTS1 Data Glossary – Tables and Fields

MTS1MedHxFU

Description: MTS1 Medical History follow-up form

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient ID			
ParentLoginVisitID	Unique ID for the Visit			
Visit	Visit			
AESinceLast	Have there been any adverse ocular events since the last visit			Yes, No
AE1Hr	Have there been any adverse systemic events within 1 hour of study medication since the last visit			Yes, No
SeriousAE	Have there been any serious adverse events since the last visit			Yes, No
MyopiaTx	Is the participant undergoing any treatment for myopia besides study drops			Yes, No
MenarcheStatus	Menarche status			Post-menarche, Pre-menarche, Male
PregnancyStatusFU	Pregnancy test			Negative, Positive, Not done

MTS1 Data Glossary – Tables and Fields

MTS1Medication

Description: Medications Form

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Subject ID			
ParentLoginVisitID	Unique ID for the Visit			
ParentLoginID	RecID from tblLogin			
MedDose	Dose per administration			
MedUnit	Dose per administration unit			aerosol, ampules, capsules, cream, dl, elixir, g, gal, gtt-drops, IU, kg, L, lbs, M, mcg, meq, mg, mL, Ointment, pills, pt, puff, ounces, qt, tablet, tbs, tsp, ul, units, vials
MedDoseUnk	Dose per administration is unknown			1 = Checked
MedRoute	Route			PO, SC, Topical - ocular, Gtt, Intravitreal, IV, IM, Oral Inhalation, Topical - skin, Nasal, Other, Topical, ID, PR, Vaginal, Transurethral, Sublingual, Peribulbar, Intra-articular, Retrobulbar, Transdermal, Subconjunctival, Subtenons, Intrauterine, Epidural, Gastrostomy tube, Intracavernous
MedLocSide	If treatment is for eye or ear, which was treated with medication			Right, Left, Both
MedFreqType	Frequency			Fixed Regimen, As Needed, One Time Treatment
MedFreqNum	Frequency number			1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33,

MTS1 Data Glossary – Tables and Fields

				34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50
MedFreqPer	Frequency period			Day, Week, Month, Year
MedFreqUnk	Medication frequency is unknown			1 = Checked
MedFreqAsNeededDs	If frequency is 'as needed', approximate frequency			> 1 per day, 1 per day, 1 per week, 2 - 6 per week, 1 per month, 2 - 3 per month, 1 per year, 2 - 5 per year, 6 - 11 per year
MedInd	Indication			Prior to enrollment, New, Prevention
ParentLoginIDMedCondition	Medical Condition			
AdvEvent1	Adverse Event 1			
MedStartTrtCat	Start date of treatment category			On treatment at time of enrollment, Treatment started after enrollment
MedStartDt	If treatment started after enrollment/randomization , Medication Start Date			
MedStartDtApprox	Medication Start Date is approximate			1 = Checked
MedStopDt	Medication Stop Date			
MedStopDtApprox	Medication Stop Date is approximate			1 = Checked
MedOngoing	Medication is ongoing			1 = Checked
MedStartPreEnrRange	If on treatment at time of enrollment, Medication Start Range			<=30 days, >30 days to < 3 months, 3 months to < 6 months, 6 months to < 1 year, 1 year to < 5 years, 5 years to < 10 years, >=10 years, Unknown
MedStartMonth	If treatment started after enrollment, Medication Start Month			1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
MedStartYear	If treatment started after enrollment, Medication Start Year			
MedStopMonth	Medication stop Month			1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
MedStopYear	Medication stop Year			
MedStopDtUnk	Medication stop date unknown			1 = Checked
PreExist1	PreExisting Condition 1			

MTS1 Data Glossary – Tables and Fields

MedStartDtUnk	Medication start date unknown			1 = Checked
MedCondNotReqd	Condition not required to be reported on medical condition form			1 = Checked
PreExistCondNotReqd	Condition not required to be reported on pre-existing condition form			1 = Checked
DrugName				
AdvEventNotReqd	Condition not required to be reported on adverse event form			1 = Checked
ParentLoginIDMedCondition2	Medical Condition			
PreExist2	PreExisting Condition 2			
AdvEvent2	Adverse Event 2			
MedRouteOthDs	Route: If Other, describe			

MTS1 Data Glossary – Tables and Fields

MTS1OptCorrHxCompAssess

Description: Optical Correction History and Compliance Assessment Form

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient ID			
ParentLoginVisitID	Unique ID for the Visit			
ParentLoginID	RecID from tblLogin			
Visit	Visit			
CurrCorrMetCrit	Current correction meets eligibility criteria			Yes, No
AmpulAtVisit	Remaining ampules of study medication brought to the visit			Yes, No
AmpulRemain	Remaining number of ampules	0	60	
CalAtVisit	Compliance calendar brought to the visit			Yes, No
DaysDropsUsed	Days drops used	0	42	
AbleToInstill	Able to instill drops			Yes, No

MTS1 Data Glossary – Tables and Fields

MTS1PreExistingCondition

Description: Pre-exisitng Condition Form

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Subject ID			
ParentLoginVisitID	Unique ID for the Visit			
ParentLogInID	RecID from tblLogIn			
MedicalCondition	Medical Condition			
PreExistDuration	Approximate duration prior to enrollment			<=30d, >1m-<3m, 3m-<6m, 6m-<12m, 1yr-<5yr, 5yr-<10yr, 10yr-<20yr, >=20yr
PreExistMedCurr	If the medical condition has been treated with medication, is the medication currently being taken			Yes, No
MedCondStatus	Medical condition status			Ongoing (further improvement / worsening possible), Ongoing, medically stable, Complete Recovery, Recovered with Sequelae
MedCondResDt	Recovery Date			
MedCondResDtApprox	Recovery date of medical condition is approximate			1 = Checked
MedCondDs	Description entered when a generic medical condition is selected (e.g. Allergy NOS or Drug Allergy)			
PreExistCondEye	If ocular condition, select eye			OD = Right Eye, OS = Left Eye

MTS1 Data Glossary – Tables and Fields

MTS1PtFinalStat

Description: Final Status Form

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Participant ID			
ParentLoginVisitID	Unique ID for the Visit			
ParentLoginID	RecID from tblLogin			
PtFinalStatusReason	Reason participant's participation in the Study has ended			ID obtained in error, Participant does not meet screening eligibility, Lost to follow up, Requests to withdraw not in writing, Requests to withdraw in writing, Site withdraws participant, Death, Participant has completed the study
PtWithdrawAE	Reason for participant/parent withdrawal: Adverse event			1 = Checked
PtWithdrawChgDr	Reason for participant/parent withdrawal: Changed doctor			1 = Checked
PtWithdrawNoStdyTrt	Reason for participant/parent withdrawal: Does not want study treatment			1 = Checked
PtWithdrawFin	Reason for participant/parent withdrawal: Finances			1 = Checked
PtWithdrawChgIns	Reason for participant/parent withdrawal: Changed insurance			1 = Checked
PtWithdrawMoved	Reason for participant/parent withdrawal: Moved			1 = Checked
PtWithdrawOthTrtReq	Reason for participant/parent withdrawal: Other treatment requested			1 = Checked
PtWithdrawPoorHealth	Reason for participant/parent withdrawal: Poor health			1 = Checked
PtWithdrawPoorOut	Reason for participant/parent withdrawal: Poor outcome			1 = Checked
PtWithdrawSched	Reason for			1 = Checked

MTS1 Data Glossary – Tables and Fields

	participant/parent withdrawal: Scheduling/availability issues			
PtWithdrawTravDiff	Reason for participant/parent withdrawal: Travel difficulty			1 = Checked
PtWithdrawVisLen	Reason for participant/parent withdrawal: Visit too lengthy			1 = Checked
PtWithdrawUnk	Reason for participant/parent withdrawal: Unknown			1 = Checked
PtWithdrawOth	Reason for participant/parent withdrawal: Other			1 = Checked
WithdrawDt	Date of Withdrawal			
WithdrawReasCmts	Withdrawal Reason Comments			
DeathDt	Date of Death			
DeathDs	Cause of death			
NoOngoingAE	Affirm that there are no ongoing adverse events			1 = Checked
PreRandPtFinalStatReas	Reason participant's participation in the Study has ended (Pre-rand reason)			ID obtained in error, Participant does not meet screening eligibility, Lost to follow up prior to randomization, Requests to withdraw not in writing, Requests to withdraw in writing, Site withdraws participant, Death
PostRandPtFinalStatReas	Reason participant's participation in the Study has ended (Post-rand reason)			Requests to withdraw not in writing, Requests to withdraw in writing, Lost to follow up, Site withdraws participant, Death
PtFinalStatReas	Reason participant's participation in the Study has ended			ID obtained in error, Participant does not meet screening eligibility, Requests to withdraw not in writing, Requests to withdraw in writing, Lost to follow up, Site withdraws participant, Death

MTS1 Data Glossary – Tables and Fields

MTS1TreatRx

Description: Treatment Prescribed Form

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient ID			
ParentLoginVisitID	Unique ID for the Visit			
ParentLoginID	RecID in tblLogin			
Visit	Visit			
MTS1CorrRx	Refractive correction prescription			Change in optical correction is required, Continuing in current optical correction, N/A (Virtual Visit)
SpecsMetCrit	Do spectacles (and/or contact lenses) meet study criteria based on a standard refraction (with or without cycloplegia			
ContMed	Is study medication being continued at the protocol-specified dose			Yes, No
ContMedDs	If no, what is changing and why			
MTSTreatRx	Is any treatment for myopia besides study drops being prescribed			Yes, No
MTSTreatRxDs	If yes, what is being prescribed and why			
ContMed_YN_NA	Is study medication being continued at the protocol-specified dose at the 6-month, 12-month, and 18-month visits			Yes, No, Not Applicable
StopMed	Is study medication being discontinued at the 24-month visit			Yes, No, Not Applicable
StopMedDs	If no, what is changing and why			

MTS1 Data Glossary – Tables and Fields

MTS1VisitInfo

Description: Visit Information Form

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Patient Identifier			
ParentLoginVisitID	Unique ID for the Visit			
ParentLogInID	RecID from tblLogIn			
Visit	Visit			
VisitDt	Visit Date			
OutOfWin	Visit was completed out of window			1 = Checked
OutOfWinReason	Reason visit was completed out of window			COVID-19 pandemic, Bad weather, Travel difficulty, Financial issue, Poor health, Personal issue, Work issue, Subject on vacation, Visits too lengthy, Investigator away, Clinic appointment not available, Site forgot to schedule, Difficulty contacting subject, Poor outcome, Good outcome, Adverse event, Unknown, Other
VisitMiss	Visit was missed			1 = Checked
VisitMissReason	Reason visit was missed			COVID-19 pandemic, Bad weather, Travel difficulty, Financial issue, Poor health, Personal issue, Work issue, Subject on vacation, Visits too lengthy, Investigator away, Clinic appointment not available, Site forgot to schedule, Difficulty contacting subject, Poor outcome, Good outcome, Adverse event, Unknown, Other
VisitVirtual	Visit was completed virtually			1 = Checked

MTS1 Data Glossary – Tables and Fields

	(e.g., by phone or Internet)			
--	------------------------------	--	--	--

MTS1 Data Glossary – Tables and Fields

MTS1PtRoster

Description: Patient Roster

Data Source: Case Report Form

Field_Name	Description	Min	Max	Possible_Values
RecID	Unique record ID in table			
PtID	Unique Patient Identifier			
SiteID	Site Identifier			
Protocol	Protocol from tblProtocol			
ParentStratumID	RecID from tblStratum			
EnrollDt	Date of enrollment			
RandDt	Date of randomization			
VisitSchedStartDt	Date Visit Schedule starts from			
PtStatus	Patient Status			Active, Completed, Dropped, Pending
PtStatusChgDt	Date status last changed			
StudyEye	Study Eye			OD, OS, OU
TrtGroup	Treatment group randomization assignment			Atropine or Placebo
AgeAsofEnrollDt	Age at Enrollment			Age in years else if >=90, "90 or older"
AgeAsofRandDt				
Eligible	Patient eligible			Yes, No
SitePtNum	Incremental number for Patient at a site			
MTS1PtStatus	MTS1 patient status			PreEnrolled, Enrolled, DroppedPreRand, Randomized, DroppedPostRand, CompRCT, DropPreEnrolled