MTS1 : Myopia Treatment Study 1
Adverse Event Form

Patient ID: M01-004-2299

SECTION: ADVERSE EVENT **(AdverseEvent_a_05)**

BM1: tblMTS1AdvEvent.dbo.ColumnName_Property_Not_Set_In_Template

DESCRIPTION OF EVENT

1. Date notified of/identified adverse event: tblMTS1AdvEvent.dbo.AENotifiedDt
26 Sep 2022

2. Description of Adverse Event

Note: This event description will be included on reports to FDA, DSMB, etc. and should NOT contain names or any PHI.

2a. Provide a description of the event: tblMTS1AdvEvent.dbo.AdvEventDs
EYE IRRITATION

2b. Enter keyword to see list of codes and select the most appropriate code: *(if you cannot find the event, use reference below to view a list of adverse events by system)* tblMTS1AdvEvent.dbo.ParentMedCondListID
Conjunctivitis (Eye disorders)

Use reference below to view a list of adverse events by system:

2c. If ocular event, select eye: tblMTS1AdvEvent.dbo.AdverseEventType
(otherwise, leave blank) OS(Left)
if an event occurred in both eyes, complete an AE Form for each eye

3. Date of onset (or worsening of a pre-existing condition): tblMTS1AdvEvent.dbo.AEOnsetDt
26 Sep 2022

4. Is the adverse event a worsening of a pre-existing condition present prior to study entry? tblMTS1AdvEvent.dbo.AEPrEnroll
No

5. Was the adverse event an abnormality (or worsening of an existing abnormality) identified on a study visit exam? tblMTS1AdvEvent.dbo.AENotedStdyVisExam
No

6. Maximum Severity (intensity): tblMTS1AdvEvent.dbo.AEIntensity
Moderate

7. Is there a reasonable possibility that the event was related to study drug, study device, other type of study intervention (e.g., laser, surgical procedure), or a study procedure? tblMTS1AdvEvent.dbo.AERelStdyTrt
Yes

7a. If *Yes*, to which of the following source(s) was the adverse event possibly related? tblMTS1AdvEvent.dbo.AERelStdyTrtHighLvl
Study drug (drug effect) or biological product

NOTE: If there is more than one possible source for the selection in 7a above (i.e. 'Study drug' is selected and the study has more than one study drug) OR 'More than one of the above' is selected, please complete 7b.

7b. Please specify/list each source that the adverse event was possibly related to. If cannot determine between two or more different sources, indicate uncertain. tblMTS1AdvEvent.dbo.AERelStdyTrtHighLvlDs

8. Effect on study drug/treatment/device: tblMTS1AdvEvent.dbo.AEEffectTrt
No change

8a. If the study has *more than one study drug, treatment or device*, which one(s) changed frequency: tblMTS1AdvEvent.dbo.AEEffectTrtDs

9. Does the event meet criteria for a serious adverse event? tblMTS1AdvEvent.dbo.AESerious
No
If Yes, complete the Additional Information for Serious Adverse Event section below

BM2: tblMTS1AdvEvent.dbo.ColumnName_Property_Not_Set_In_Template

TREATMENT OF ADVERSE EVENT

1. Did participant receive treatment for the adverse event? tblMTS1AdvEvent.dbo.AETrt
No

If *Yes*, complete the following:

1a. Surgery/procedure: tblMTS1AdvEvent.dbo.AESurg

If *Yes*, complete the following:

Type of surgery/procedure: tblMTS1AdvEvent.dbo.AESurgDs

Date of surgery/procedure: tblMTS1AdvEvent.dbo.AESurgDt

1b. Medication: tblMTS1AdvEvent.dbo.AEMeds

If *Yes*, list medications here and complete a Concomitant Medication Form for each medication: tblMTS1AdvEvent.dbo.AEMedsList

1c. Other: tblMTS1AdvEvent.dbo.AEOthTrt

If *Yes*, detail: tblMTS1AdvEvent.dbo.AEOthTrtCmts

BM3: tblMTS1AdvEvent.dbo.ColumnName_Property_Not_Set_In_Template

OUTCOME

1. Outcome: tblMTS1AdvEvent.dbo.AEOutcome
Ongoing (medically stable, e.g., chronic condition where no further change expected)

1a. If *Complete Recovery* or *Recovered/Resolved with Sequelae*, complete the following:

i. Date of recovery (with or without sequelae): tblMTS1AdvEvent.dbo.AEResDt

1b. If *Fatal*, complete the following:

i. Cause of death: tblMTS1AdvEvent.dbo.AEDeathCause

ii. Date of death: tblMTS1AdvEvent.dbo.AEDeathDt

BM4: tblMTS1AdvEvent.dbo.ColumnName_Property_Not_Set_In_Template

ADDITIONAL INFORMATION FOR SERIOUS ADVERSE EVENT

1. Criteria defining event as serious adverse event: *(check all that apply)*

tblMTS1AdvEvent.dbo.AEDeath ☐	Results in Death
tblMTS1AdvEvent.dbo.AELifeThreat ☐	Is Life Threatening (a non-life-threatening event which, had it been more severe, might have become life-threatening, is not necessarily considered a serious adverse event)
tblMTS1AdvEvent.dbo.AEHosp ☐	Requires inpatient hospitalization or prolongation of existing hospitalization
tblMTS1AdvEvent.dbo.AEDisability ☐	Results in Significant Disability/Incapacity or substantial disruption of the ability to conduct normal life functions
tblMTS1AdvEvent.dbo.AEConAnomaly ☐	Results in a Congenital Anomaly or Birth Defect
tblMTS1AdvEvent.dbo.AEMedEvent ☐	An important medical event that may not have resulted in one of the listed outcomes but jeopardized the participant in such a way that medical or surgical intervention may be required to prevent one of the listed outcomes and is serious based upon appropriate medical judgment by either investigator or Sponsor
tblMTS1AdvEvent.dbo.AEOther ☐	Other tblMTS1AdvEvent.dbo.AEOtherDs

2. Weight: tblMTS1AdvEvent.dbo.Weight tblMTS1AdvEvent.dbo.WeightMeas tblMTS1AdvEvent.dbo.WeightNotAvail ☐ Not available

3. Relevant tests/laboratory data (including dates)? tblMTS1AdvEvent.dbo.AERelLabData

If *Yes*, list: tblMTS1AdvEvent.dbo.AERelLabDataDs

4. Other relevant history, including preexisting medical conditions*(e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)*: tblMTS1AdvEvent.dbo.AEOthRelHx

If *Yes*, detail: tblMTS1AdvEvent.dbo.AEOthRelHxDs

5. Concomitant medical products and therapy dates (exclude treatment of event)? *(List and provide therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that a participant was using at the time of the event. DO NOT include products used to treat the event.)* tblMTS1AdvEvent.dbo.AEMedProd

If *Yes*, please explain: tblMTS1AdvEvent.dbo.AEMedProdDs

BM5: tblMTS1AdvEvent.dbo.ColumnName_Property_Not_Set_In_Template

COMMENTS

tblMTS1AdvEvent.dbo.FormCmts