Adverse Events

PtID	**PtID:** tblPtRoster.PtID
Namecode	**Namecode:** tblPtRoster.Namecode

DESCRIPTION OF EVENT

AENotifiedDt	**1. Date notified of/identified adverse event:** __ __ / __ __ __ / __ __ __ __ *dd/MMM/yyyy* ***Required; not > today***
AdvEventDs	**2. Description of Adverse Event:** **2a. Provide a description of the event:** ***Required*** _____
ParentMedCondListID	**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)* ***Required;***

AdverseEventType	***If tblMedContList.MCSOC='Eye disorders' then required***
	if tblMedCondList.MCSOC <> 'Eye disorders' then optional
	2c. If ocular event, select eye *(otherwise, leave blank)*
	     ○ Right Eye (OD) ○ Left Eye (OS)
	          if an event occurred in both eyes, complete an AE Form for each eye

AEOnsetDt	**3. Date of onset (or worsening of a pre-existing condition):** __ __ / __ __ __ / __ __ __ __ *dd/MMM/yyyy* ***Required*** ***Not > today; not < EnrollDt***
AEPrEnroll	 **4. Is the adverse event a worsening of a pre-existing condition present prior to study entry?** ○ Yes ○ No ***Required***
AENotedStdyVisExam	**5. Was the adverse event an abnormality (or worsening of an existing abnormality) identified on a study visit exam?** ○ Yes ○ No ***Required***
AEIntensity	**6. Maximum intensity (Severity)** ○ Mild ○ Moderate ○ Severe ***Required*** **Use ExpansionContainerCrf with a title of "Maximum Intensity Definitions"**

AERelStdyTrt	**7. Is there a reasonable possibility that the event was caused by a study treatment/study device?**
	○ Yes ○ No *Required*
	if 7=Yes then 7a required
	if 7= No then 7a must be null
	Use ExpansionContainerCrf with a title of "Relationship to Study Treatment Definition"
AERelStdyTrtDs	*7a. If <u>Yes</u>, which study treatment/device* _____ ☐ Uncertain (*Mark uncertain <u>only</u> when a study involves more than 1 treatment or device and you cannot determine which one caused the event.*)
AERelStdyTrtUncertain	*If 'Uncertain' is checked then treatment/device must be null.*
	If 'Uncertain' is not checked then date treatment/device be entered.

AERelStdyProc	**8. Is there a reasonable possibility that the event was caused by a study procedure (** *i.e., a diagnostic procedure and not a study treatment)***?**
	○ Yes ○ No *Required*
	if 8=Yes then 8a required
AERelStdyProcDs	*if 8=No then 8a must be null*
	Use ExpansionContainerCrf with a title of "Relationship to Study Treatment Definition"
	8a. If <u>Yes</u>, which study procedure _____

AEEffectTrt	**9. Effect on study treatment/device** *Required*
	○ No change ○ Discontinued temporarily ○ Discontinued permanently

	10. Does the event meet criteria for a serious adverse event
	○ Yes ○ No *Required*
	if 10=Yes then Additional Information for Serious Adverse Event questions 1-5 are required.
AESerious	*If 10=No then Additional Information for Serious Adverse Event questions 1-5 must be null*
	Use ExpansionContainerCrf with a title of "Adverse Event Definitions"
	If <u>Yes</u>, complete the Additional Information for Serious Adverse Event section below

TREATMENT OF ADVERSE EVENT

	1. Did patient receive treatment for the Adverse Event?
AETrt	○ Yes ○ No *Required*
	If 1=Yes then 1a, 1b, 1c required
	if 1=No then 1a(i,ii), 1b, 1c must be null
	If <u>Yes</u>, complete the following:
AESurg	**1a. Surgery/procedure:** ○ Yes ○ No
	if 1a=Yes then i and ii required
	if 1a=No, then i and ii must be null
	If <u>Yes</u>, complete the following:
AESurgDs	**i. Type of surgery/procedure** _____
AESurgDt	**ii. Date of surgery/procedure:** __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*
	Date of surgery/procedure must be <= today and > enrollment date

Adverse Events

AEMeds

1b. Medication: ○ Yes ○ No
if 1b=Yes then medications required
if 1b=No then medications must be null

AEMedsList

If Yes, list medications here and complete a Concomitant Medication Form for each medication

_____ *Max Size: 250*

AEOthTrt

1c. Other: ○ Yes ○ No

AEOthTrtCmts

if 1c=Yes, then detail required
if 1c=No, then detail must be null

If _Yes_, detail_____ *Max Size: 250*

OUTCOME

AEOutcome

1. Outcome: *Required*
if 1=Complete Recovery/Recovered with Sequelae, then 1a(i)required
if 1 <> Complete Recovery/Recovered with Sequelae, then 1a(i) must be null
if 1=Fatal, then 1b(i, ii) required
if 1=Fatal, then AESerious (Description of Event)=Yes
if 1=Fatal, then AEDeath must be checked
if 1 <> Fatal then 1b(i, ii) must be null

○ Ongoing (further improvement or worsening possible) ○ Ongoing, medically stable (further change not expected) ○ Complete Recovery ○ Recovered with Sequelae ○ Fatal

1a. If _Complete Recovery_ or _Recovered with Sequelae_, complete the following:

AEResDt

i. Date of recovery (with or without sequelae): __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*
Date of recovery must be <= today and >= date of onset

AEDeathCause

1b. If _Fatal_, complete the following:

i. Cause of death: _____

AEDeathDt

ii. Date of death ___/ ___/___
Date of death must be <= today and >= date of onset

ADDITIONAL INFORMATION FOR SERIOUS ADVERSE EVENT

AEDeath
AEConAnomaly
AELifeThreat
AEHosp
AEDisability
AEOther

1. Criteria defining event as serious adverse event: *(check all that apply)*
Required if meets criteria for serious adverse event (Description of Event section, Q 10)
If 'Death' then Outcome (prev section) must be 'Fatal'

☐ Death
☐ Congenital Anomaly
☐ Life Threatening
☐ Hospitalization -- initial or prolonged
☐ Significant Disability or Incapacity

AEOtherDs

☐ Other _____
If Other checked then description required

Weight **WeightMeas** **WeightNotAvail**	**2. Weight:** _____ ○ **lbs** ○ **kgs** ☐ **Not available** *If Not available checked, Weight must be null* *If Not available not checked, Weight is required* *If weight is not null then weight measure is required*
AERelLabData **AERelLabDataDs**	**3. Relevant tests/laboratory data (including dates)?** ○ Yes ○ No *if 3=Yes, list tests/lab data required* *if 3=No then tests/lab must be null* Use ExpansionContainerCrf with a title of "Relevant Lab Data Definitions" **If _Yes_, list:** _____ _____
AEOthRelHx **AEOthRelHxDs**	**4. Other relevant history, including preexisting medical conditions** (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)**?** ○ Yes ○ No *if 4=Yes, then detail history required* *if 4=No, then detail history must be null* **If _Yes_, detail:** _____ _____
AEMedProd **AEMedProdDs**	**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 patient was using at the time of the event. DO NOT include products used to treat the event.)* ○ Yes ○ No *if 5=Yes, then explain is required* *if 5=No, then explain must be null* **If _Yes_, please explain:** _____ _____

COMMENTS FormCmts