TASK DOCUMENTATION
RTS Global Adverse Event Form

	Click here to open/close previously entered data for viewing or editing
BM1	Null
	DESCRIPTION OF EVENT
AENotifiedDt	**1. Date notified of/identified adverse event:** Month ▼ Day ▼ Year ▼
	2. Description of Adverse Event
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)* _____
	Use reference below to view a list of adverse events by system:
	Click here to open/close the list
	Note: If the condition you are looking for is not in the list, please click here to send an email to request that it be added to the list.
AdverseEventType	**2c. If ocular event, select eye** *(otherwise, leave blank)* ○ OD(Right) ○ OS(Left) *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):** Month ▼ Day ▼ Year ▼
AEPrEnroll	**4. Is the adverse event a worsening of a pre-existing condition present prior to study entry?** ○ Yes ○ No
AENotedStdyVisExam	**5. Was the adverse event an abnormality (or worsening of an existing abnormality) identified on a study visit exam?** ○ Yes ○ No
AEIntensity	**6. Maximum intensity (severity):** ○ Mild ○ Moderate ○ Severe
	Click here to open/close Maximum Intensity Definitions
AERelStdyTrt	**7. Is there a reasonable possibility that the event was caused by a study treatment/ study device?** ○ Yes ○ No
	Click here to open/close Relationship to Study Treatment Definitions
AERelStdyTrtUncertain	☐ Uncertain – *(Mark uncertain only when a study involves more than 1 treatment or device and you cannot determine which one caused the event.)*

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AERelStdyDrugDevice	**7. What is the relationship of the event to study drug/device?** ○ Unrelated ○ Unlikely related ○ Possibly related ○ Probably related ○ Definitely related ○ Not assessable
	Click here to open/close Relationship to Study Drug/Device Definition
AERelStdyDrugDeviceUncertain	☐ Uncertain – *(Mark uncertain only when a study involves more than 1 drug or device and you cannot determine which one could be related to the event.)*
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
	Click here to open/close Relationship to Study Treatment Definitions
AEEffectTrt	**9. Effect on study treatment/device:** ○ No change ○ Discontinued temporarily ○ Discontinued permanently ○ If study treatment is medication, reduced dose ○ Reduced use frequency/schedule
AESerious	**10. Does the event meet criteria for a serious adverse event?** ○ Yes ○ No
	Click here to open/close Adverse Event Definitions
	If Yes, complete the Additional Information for Serious Adverse Event section below
BM2	Null
	TREATMENT OF ADVERSE EVENT
AETrt	**1. Did patient receive treatment for the adverse event?** ○ Yes ○ No
AESurg	**If *Yes*, complete the following:** **1a. Surgery/procedure** ○ Yes ○ No
AESurgDt	**If *Yes*, complete the following:** **Date of surgery/procedure:** Month ▼ Day ▼ Year ▼
AEMeds	**1b. Medication:** ○ Yes ○ No

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AEOthTrt	**1c. Other:** ○ Yes ○ No
BM3	Null
	OUTCOME
AEOutcome	**1. Outcome** ○ Ongoing (further improvement or worsening possible) ○ Ongoing, medically stable (further change not expected) ○ Complete Recovery ○ Recovered with Sequelae ○ Fatal
AEResDt	**1a. If *Complete Recovery* or *Recovered with Sequelae*, complete the following:** **i. Date of recovery (with or without sequelae):** Month ▼ Day ▼ Year ▼
AEDeathDt	**1b. If *Fatal*, complete the following:** **ii. Date of death:** Month ▼ Day ▼ Year ▼
BM4	Null
	ADDITIONAL INFORMATION FOR SERIOUS ADVERSE EVENT
AEDeath **AEConAnomaly** **AELifeThreat** **AEHosp** **AEDisability**	**1. Criteria defining event as serious adverse event:** *(check all that apply)* ☐ Death ☐ Congenital Anomaly ☐ Life Threatening ☐ Hospitalization – initial or prolonged ☐ Significant Disability or Incapacity
Weight **WeightMeas** **WeightNotAvail**	**2. Weight:** _____ ○ kgs ○ lbs ☐ Not available
AERelLabData	**3. Relevant tests/laboratory data (including dates)?** ○ Yes ○ No
	Click here to open/close Relevant Lab Data Definitions
AEOthRelHx	**4. Other relevant history, including preexisting medical conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):* ○ Yes ○ No

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AEMedProd	**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