Serious Adverse Event Report Form

Assigned Case #

Primary Adverse Event Term:

PAGE ___ OF ___

DATE OF THIS REPORT	PROTOCOL #	SITE #	☐ INITIAL REPORT
_____/_____/_____ (DD/MMM/YYYY)	_____	_____	☐ FOLLOW UP REPORT #
PROTOCOL TITLE:			

1. PATIENT INFORMATION

PATIENT #	PATIENT INITIALS	SEX	WEIGHT	RACE:
		☐ M ☐ F	_____ ☐ GM ☐ LB	☐ AMERICAN INDIAN OR ALASKA NATIVE ☐ ASIAN ☐ NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER ☐ BLACK OR AFRICAN AMERICAN ☐ WHITE ☐ OTHER, SPECIFY:
DATE OF BIRTH (DD/MMM/YYYY) _____/_____/_____			HEIGHT _____ ☐ CM ☐ IN	

2. SERIOUS ADVERSE EVENT (PRIMARY)

DIAGNOSTIC TERM TO DESCRIBE PRIMARY SAE

USE SIGNS AND SYMPTOMS IF DIAGNOSIS UNKNOWN.
IF MORE THAN ONE SAE TERM, PLEASE LIST ON CONTINUATION PAGE #3.

DATE OF ONSET (DD/MMM/YYYY) ___/___/___ **TIME** (24 HR) ___

DATE OF RESOLUTION (DD/MMM/YYYY) ___/___/___ **TIME** (24 HR) ___

EVENT OUTCOME

☐ RECOVERED/RESOLVED
☐ ONGOING
☐ FATAL
IF FATAL; CAUSE OF DEATH:

INTENSITY

☐ MILD
☐ MODERATE
☐ SEVERE

SERIOUS CRITERIA (CHECK ALL THAT APPLY)

☐ DEATH
DATE: ___/___/___
AUTOPSY: ☐ YES ☐ NO
DEATH CERTIFICATE: ☐ YES ☐ NO
☑ RESULTED IN PERSISTENT/SIGNIFICANT DISABILITY OR INCAPACITY
☑ MEDICALLY SIGNIFICANT
☐ LIFE –THREATENING
☐ CONGENITAL ANOMALY/BIRTH DEFECT
☐ REQUIRED OR PROLONGED HOSPITALIZATION
ADMIT DATE: ___/___/___
DISCHARGE DATE: ___/___/___

ACTION TAKEN: PATIENT

☐ NONE ☐ PROCEDURE
☐ MEDICATION ☐ OTHER
☐ DISCONTINUED STUDY
IF DISCONTINUED, WAS IT DUE TO THIS SAE?
☐ YES ☐ NO

RELATIONSHIP TO EVENT:

RELATED TO INJECTION PROCEDURE: ☐ YES ☐ NO

RELATED TO STUDY DRUG: ☐ YES ☐ NO

IF NOT RELATED, DUE TO:

☐ UNDERLYING DISEASE *(SPECIFY): _____
☐ OTHER:

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DATE OF THIS REPORT	PROTOCOL #	SITE #	INITIAL REPORT / FOLLOW UP REPORT #
___/___/___ (DD/MMM/YYYY)	.	.	☐ INITIAL REPORT ☐ FOLLOW UP REPORT # ___
PROTOCOL TITLE:			

3. STUDY DRUG

DRUG	EYE	DATE OF INITIAL STUDY DRUG ADMINISTRATION	DATE OF LATEST DOSE PRIOR TO THE EVENT	TIME OF LATEST DOSE PRIOR TO THE EVENT	TOTAL NUMBER OF DOSES GIVEN PRIOR TO ONSET OF THE EVENT
	☐OD ☐OS	___/___/___ (DAY/MONTH/YEAR)	___/___/___ (DAY/MONTH/YEAR)	___ (24 HOUR CLOCK)	
	☐OD ☐OS	___/___/___ (DAY/MONTH/YEAR)	___/___/___ (DAY/MONTH/YEAR)	___ (24 HOUR CLOCK)	

ACTION TAKEN WITH STUDY DRUG:

☐ DRUG CONTINUED
☐ DRUG WITHDRAWN DATE (DD/MMM/YYYY) ___/___/___
☐ DRUG INTERRUPTED
FROM DATE (DD/MMM/YYYY) ___/___/___
TO DATE (DD/MMM/YYYY) ___/___/___

IF STUDY DRUG DISCONTINUED, DID EVENT ABATE? ☐ YES ☐ NO ☐ NA
IF STUDY DRUG RESTARTED, DID EVENT REOCCUR? ☐ YES ☐ NO ☐ NA

4. RELEVANT LABS AND DIAGNOSTIC TESTS

TEST	DATE(DD/MMM/YYYY)	RESULT W/UNITS	NORMAL RANGE
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		

IF MORE SPACE IS NEEDED, PLEASE USE CONTINUATION PAGE

5. RELEVENT MEDICAL HISTORY

	START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	CONTINUING?
1.	___/___/___	___/___/___	☐ Y ☐ N
2.	___/___/___	___/___/___	☐ Y ☐ N
3.	___/___/___	___/___/___	☐ Y ☐ N
4.	___/___/___	___/___/___	☐ Y ☐ N
5.	___/___/___	___/___/___	☐ Y ☐ N
6.	___/___/___	___/___/___	☐ Y ☐ N
7.	___/___/___	___/___/___	☐ Y ☐ N
8.	___/___/___	___/___/___	☐ Y ☐ N

IF MORE SPACE IS NEEDED, PLEASE USE CONTINUATION PAGE

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___/___/___ (DD/MMM/YYYY)	_____		☐ FOLLOW UP REPORT #
PROTOCOL TITLE:			

6. RELEVENT CONCOMITANT MEDICATIONS – DO NOT INCLUDE ANY SUSPECT OR TREATMENT MEDICATIONS

	MEDICATION *(DO NOT LIST DRUGS USED TO TREAT EVENT)*	INDICATION	DOSE	DOSE UNIT	ROUTE	FREQ	START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	CONTINUING?
1.							___/___/___	___/___/___	☐ Y ☐ N
2.							___/___/___	___/___/___	☐ Y ☐ N
3.							___/___/___	___/___/___	☐ Y ☐ N
4.							___/___/___	___/___/___	☐ Y ☐ N
5.							___/___/___	___/___/___	☐ Y ☐ N
6.							___/___/___	___/___/___	☐ Y ☐ N
7.							___/___/___	___/___/___	☐ Y ☐ N
8.							___/___/___	___/___/___	☐ Y ☐ N

IF MORE SPACE IS NEEDED, PLEASE USE CONTINUATION PAGE

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DATE OF THIS REPORT ___/___/___ (DD/MMM/YYYY)	PROTOCOL #	SITE #	☐ INITIAL REPORT ☐ FOLLOW UP REPORT #
PROTOCOL TITLE:			

7. MANAGEMENT OF SAE

WAS AN INTERVENTION DONE TO TREAT THE SAE? ☐ YES ☐ NO ☐ UNK

	TREATMENT INTERVENTION	ROUTE OF ADMIN.	UNIT DOSE	FREQ	TOTAL DAILY DOSE	START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	CONTINUING?
1.						/ /	/ /	☐ Y ☐ N
2.						/ /	/ /	☐ Y ☐ N
3.						/ /	/ /	☐ Y ☐ N
4.						/ /	/ /	☐ Y ☐ N
5.						/ /	/ /	☐ Y ☐ N
6.						/ /	/ /	☐ Y ☐ N
7.						/ /	/ /	☐ Y ☐ N
8.						/ /	/ /	☐ Y ☐ N

IF MORE SPACE IS NEEDED, PLEASE USE CONTINUATION PAGE

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PROTOCOL TITLE:			

8. EVENT NARRATIVE

PLEASE DESCRIBE THE DEVELOPMENT OF THE ADVERSE EVENT, TREATMENTS TO THE EVENT, EVENT OUTCOME, AND RATIONAL FOR CAUSALITY ASSESSMENT

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DATE OF THIS REPORT ___/___/___ (DD/MMM/YYYY)	**PROTOCOL #**	**SITE #**	☐ **INITIAL REPORT** ☐ **FOLLOW UP REPORT #**
PROTOCOL TITLE:			

2A. ADDIOTIONAL SERIOUS ADVERSE EVENT

DIAGNOSTIC TERM TO DESCRIBE PRIMARY SAE

USE SIGNS AND SYMPTOMS IF DIAGNOSIS UNKNOWN.
IF MORE THAN ONE SAE TERM, PLEASE LIST ON CONTINUATION PAGE #3.

DATE OF ONSET (DD/MMM/YYYY) ___/___/___ **TIME** (24 HR)

DATE OF RESOLUTION (DD/MMM/YYYY) ___/___/___ **TIME** (24 HR)

EVENT OUTCOME

☐ RESOLVED
☐ ONGOING
☐ FATAL
IF FATAL; CAUSE OF DEATH:

INTENSITY

☐ MILD
☐ MODERATE
☐ SEVERE

SERIOUS CRITERIA (CHECK ALL THAT APPLY)

☐ DEATH
☐ RESULTED IN PERSISTENT/SIGNIFICANT DISABILITY OR INCAPACITY
☐ MEDICALLY SIGNIFICANT
☐ LIFE –THREATENING
☐ CONGENITAL ANOMALY/BIRTH DEFECT
☐ REQUIRED OR PROLONGED HOSPITALIZATION

ACTION TAKEN: PATIENT

☐ NONE ☐ PROCEDURE
☐ MEDICATION ☐ OTHER:
☐ DISCONTINUED STUDY
IF DISCONTINUED, WAS IT DUE TO THIS SAE?
☐ YES ☐ NO

RELATIONSHIP TO EVENT:

RELATED TO INJECTION: ☐ YES ☐ NO
RELATED TO STUDY DRUG: ☐ YES ☐ NO

IF NOT RELATED, DUE TO:

☐ UNDERLYING DISEASE:
☐ OTHER:

***COMPLETE ADDITIONAL SUSPECT MEDICATION SECTION**

2B. ADDIOTIONAL SERIOUS ADVERSE EVENT

DIAGNOSTIC TERM TO DESCRIBE PRIMARY SAE

USE SIGNS AND SYMPTOMS IF DIAGNOSIS UNKNOWN.
IF MORE THAN ONE SAE TERM, PLEASE LIST ON CONTINUATION PAGE #3.

DATE OF ONSET (DD/MMM/YYYY) ___/___/___ **TIME** (24 HR)

DATE OF RESOLUTION (DD/MMM/YYYY) ___/___/___ **TIME** (24 HR)

EVENT OUTCOME

☐ RECOVERED/RESOLVED
☐ ONGOING
☐ FATAL
IF FATAL; CAUSE OF DEATH:

INTENSITY

☐ MILD
☐ MODERATE
☐ SEVERE

SERIOUS CRITERIA (CHECK ALL THAT APPLY)

☐ DEATH
☐ RESULTED IN PERSISTENT/SIGNIFICANT DISABILITY OR INCAPACITY
☐ MEDICALLY SIGNIFICANT
☐ LIFE –THREATENING
☐ CONGENITAL ANOMALY/BIRTH DEFECT
☐ REQUIRED OR PROLONGED HOSPITALIZATION

ACTION TAKEN: PATIENT

☐ NONE ☐ PROCEDURE
☐ MEDICATION ☐ OTHER:
☐ DISCONTINUED STUDY
IF DISCONTINUED, WAS IT DUE TO THIS SAE?
☐ YES ☐ NO

RELATIONSHIP TO EVENT:

RELATED TO INJECTION: ☐ YES ☐ NO
RELATED TO STUDY DRUG: ☐ YES ☐ NO

IF NOT RELATED, DUE TO:

☐ UNDERLYING DISEASE:
☐ OTHER:

***COMPLETE ADDITIONAL SUSPECT MEDICATION SECTION**

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____/____/____			
PROTOCOL TITLE:			

3A. CO-SUSPECT MEDICATION(S)

CO-SUSPECT DRUG	START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	DOSE	ROUTE	FREQ	INDICATION

ACTION TAKEN WITH CO-SUSPECT DRUG:
- ☐ DRUG CONTINUED
- ☐ DRUG WITHDRAWN DATE(DD/MMM/YYYY) ____/____/____
- ☐ DRUG INTERRUPTED
  - FROM DATE (DD/MMM/YYYY) ____/____/____
  - TO DATE (DD/MMM/YYYY) ____/____/____

IF SUSPECT DRUG DISCONTINUED OR REDUCED, DID EVENT ABATE?
☐ YES ☐ NO ☐ NA

IF SUSPECT DRUG RESTARTED OR INCREASED, DID EVENT REOCCUR?
☐ YES ☐ NO ☐ NA

3B. CO-SUSPECT MEDICATION(S)

CO-SUSPECT DRUG	START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	DOSE	ROUTE	FREQ	INDICATION

ACTION TAKEN WITH CO-SUSPECT DRUG:
- ☐ DRUG CONTINUED
- ☐ DRUG WITHDRAWN DATE(DD/MMM/YYYY) ____/____/____
- ☐ DRUG INTERRUPTED
  - FROM DATE (DD/MMM/YYYY) ____/____/____
  - TO DATE (DD/MMM/YYYY) ____/____/____

IF SUSPECT DRUG DISCONTINUED OR REDUCED, DID EVENT ABATE?
☐ YES ☐ NO ☐ NA

IF SUSPECT DRUG RESTARTED OR INCREASED, DID EVENT REOCCUR?
☐ YES ☐ NO ☐ NA

3C. CO-SUSPECT MEDICATION(S)

CO-SUSPECT DRUG	START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	DOSE	ROUTE	FREQ	INDICATION

ACTION TAKEN WITH CO-SUSPECT DRUG:
- ☐ DRUG CONTINUED
- ☐ DRUG WITHDRAWN DATE(DD/MMM/YYYY) ____/____/____
- ☐ DRUG INTERRUPTED
  - FROM DATE (DD/MMM/YYYY) ____/____/____
  - TO DATE (DD/MMM/YYYY) ____/____/____

IF SUSPECT DRUG DISCONTINUED OR REDUCED, DID EVENT ABATE?
☐ YES ☐ NO ☐ NA

IF SUSPECT DRUG RESTARTED OR INCREASED, DID EVENT REOCCUR?
☐ YES ☐ NO ☐ NA

3D. CO-SUSPECT MEDICATION(S)

CO-SUSPECT DRUG	START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	DOSE	ROUTE	FREQ	INDICATION

ACTION TAKEN WITH CO-SUSPECT DRUG:
- ☐ DRUG CONTINUED
- ☐ DRUG WITHDRAWN DATE(DD/MMM/YYYY) ____/____/____
- ☐ DRUG INTERRUPTED
  - FROM DATE (DD/MMM/YYYY) ____/____/____
  - TO DATE (DD/MMM/YYYY) ____/____/____

IF SUSPECT DRUG DISCONTINUED OR REDUCED, DID EVENT ABATE?
☐ YES ☐ NO ☐ NA

IF SUSPECT DRUG RESTARTED OR INCREASED, DID EVENT REOCCUR?
☐ YES ☐ NO ☐ NA

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___/___/___ (DD/MMM/YYYY)			
PROTOCOL TITLE:			

4A. RELEVANT LABS AND TESTS

TEST	DATE(DD/MMM/YYYY)	RESULT W/UNITS	NORMAL RANGE

6A. RELAVENT CONCOMITANT MEDICATIONS –DO NOT INCLUDE ANY SUSPECT OR TREATMENT MEDICATIONS

	DO NOT LIST DRUGS USED TO TREAT EVENT	INDICATION	DOSE	DOSE UNIT	ROUTE	FREQ	START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	CONTINUING?
1.									☐ Y ☐ N
2.									☐ Y ☐ N
3.									☐ Y ☐ N
4.									☐ Y ☐ N
5.									☐ Y ☐ N

7A. MANAGEMENT OF SAE

WAS AN INTERVENTION DONE TO TREAT THE SAE? ☐ YES ☐ NO ☐ UNK

	TREATMENT INTERVENTION	ROUTE OF ADMIN.	UNIT DOSE	FREQ	TOTAL DAILY DOSE	START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	CONTINUING?
1.						___/___/___	___/___/___	☐ Y ☐ N
2.						___/___/___	___/___/___	☐ Y ☐ N
3.						___/___/___	___/___/___	☐ Y ☐ N
4.						___/___/___	___/___/___	☐ Y ☐ N
5.						___/___/___	___/___/___	☐ Y ☐ N
6.						___/___/___	___/___/___	☐ Y ☐ N
7.						___/___/___	___/___/___	☐ Y ☐ N
8.						___/___/___	___/___/___	☐ Y ☐ N

IF MORE SPACE IS NEEDED, PLEASE USE CONTINUATION PAGE

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DATE OF THIS REPORT	PROTOCOL #	SITE #	☐ INITIAL REPORT
___/___/___ (DD/MMM/YYYY)			☐ FOLLOW UP REPORT #
PROTOCOL TITLE:			

THIS SECTION MUST BE COMPLETED IF THIS IS THE LAST PAGE	Is this the last page ☐ Y ☐ N	Number of Pages in this Report ____

Reporter Certification: By signing below, I hereby certify that (1) the information contained in this Serious Adverse Event Report Form is complete and accurate in all respects and (2) I am not aware of any information that is inconsistent with the information contained herein.

REPORTER SIGNATURE	TITLE	PRINTED NAME	DATE	PHONE

Investigator Certification: By signing below, I hereby certify that (1) I have reviewed the information contained in this Serious Adverse Event Report Form, (2) such information is complete and accurate in all respects and (3) I am not aware of any information that is inconsistent with the information contained herein.

INVESTIGATOR SIGNATURE	TITLE	PRINTED NAME	DATE	PHONE