

Serious Adverse Event Report Form	Assigned Case #
Primary Adverse Event Term:	PAGE OF

DATE OF THIS REPORT ____/____/____ (DD/MMM/YYYY)	PROTOCOL # _____	SITE # _____	<input type="checkbox"/> INITIAL REPORT <input type="checkbox"/> FOLLOW UP REPORT # <input type="text"/>
PROTOCOL TITLE:			

1. PATIENT INFORMATION

PATIENT # <input type="text"/>	PATIENT INITIALS .	SEX <input type="checkbox"/> M <input type="checkbox"/> F	WEIGHT _____ <input type="checkbox"/> GM <input type="checkbox"/> LB	RACE: <input type="checkbox"/> AMERICAN INDIAN OR ALASKA NATIVE <input type="checkbox"/> ASIAN <input type="checkbox"/> NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER <input type="checkbox"/> BLACK OR AFRICAN AMERICAN <input type="checkbox"/> WHITE <input type="checkbox"/> OTHER, SPECIFY: <input type="text"/>
DATE OF BIRTH (DD/MMM/YYYY) ____/____/____		HEIGHT _____ <input type="checkbox"/> CM <input type="checkbox"/> IN		

2. SERIOUS ADVERSE EVENT (PRIMARY)

DIAGNOSTIC TERM TO DESCRIBE PRIMARY SAE <div style="border: 1px solid black; height: 40px; width: 100%;"></div> <p>USE SIGNS AND SYMPTOMS IF DIAGNOSIS UNKNOWN. IF MORE THAN ONE SAE TERM, PLEASE LIST ON CONTINUATION PAGE #3.</p>		EVENT OUTCOME <input type="checkbox"/> RECOVERED/RESOLVED <input type="checkbox"/> ONGOING <input type="checkbox"/> FATAL IF FATAL; CAUSE OF DEATH: _____ INTENSITY <input type="checkbox"/> MILD <input type="checkbox"/> MODERATE <input type="checkbox"/> SEVERE	SERIOUS CRITERIA (CHECK ALL THAT APPLY) <input type="checkbox"/> DEATH DATE: ____/____/____ AUTOPSY: <input type="checkbox"/> YES <input type="checkbox"/> NO DEATH CERTIFICATE: <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> RESULTED IN PERSISTENT/SIGNIFICANT DISABILITY OR INCAPACITY <input checked="" type="checkbox"/> MEDICALLY SIGNIFICANT <input type="checkbox"/> LIFE-THREATENING <input type="checkbox"/> CONGENITAL ANOMALY/BIRTH DEFECT <input type="checkbox"/> REQUIRED OR PROLONGED HOSPITALIZATION ADMIT DATE: ____/____/____ DISCHARGE DATE: ____/____/____
DATE OF ONSET (DD/MMM/YYYY) ____/____/____	TIME (24 HR) <input type="text"/>	ACTION TAKEN: PATIENT <input type="checkbox"/> NONE <input type="checkbox"/> PROCEDURE <input type="checkbox"/> MEDICATION <input type="checkbox"/> OTHER <input type="text"/> <input type="checkbox"/> DISCONTINUED STUDY IF DISCONTINUED, WAS IT DUE TO THIS SAE? <input type="checkbox"/> YES <input type="checkbox"/> NO	
DATE OF RESOLUTION (DD/MMM/YYYY) ____/____/____		TIME (24 HR) <input type="text"/>	
RELATIONSHIP TO EVENT: RELATED TO INJECTION PROCEDURE: <input type="checkbox"/> YES <input type="checkbox"/> NO RELATED TO STUDY DRUG: <input type="checkbox"/> YES <input type="checkbox"/> NO IF NOT RELATED, DUE TO: <input type="checkbox"/> UNDERLYING DISEASE *(SPECIFY): _____ <input type="checkbox"/> OTHER: <input type="text"/>			

<h2 style="margin: 0;">Serious Adverse Event Report Form</h2>	Assigned Case # <div style="border: 1px solid black; height: 20px; width: 100%; margin-top: 5px;"></div>
Primary Adverse Event Term:	PAGE <div style="border: 1px solid black; width: 20px; height: 15px; display: inline-block;"></div> OF <div style="border: 1px solid black; width: 20px; height: 15px; display: inline-block;"></div>

DATE OF THIS REPORT <div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px 0;"></div> (DD/MMM/YYYY)	PROTOCOL # <div style="border: 1px solid black; height: 20px; width: 100%; margin-top: 5px;"></div>	SITE # <div style="border: 1px solid black; height: 20px; width: 100%; margin-top: 5px;"></div>	<input type="checkbox"/> INITIAL REPORT <input type="checkbox"/> FOLLOW UP REPORT # <div style="border: 1px solid black; width: 40px; height: 15px; display: inline-block;"></div>
PROTOCOL TITLE:		<div style="border: 1px solid black; height: 60px; width: 100%; margin-top: 5px;"></div>	

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
<div style="border: 1px solid black; width: 100%; height: 100%;"></div>	<input type="checkbox"/> OD <input type="checkbox"/> OS	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px 0;"></div> (DAY/MONTH/YEAR)	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px 0;"></div> (DAY/MONTH/YEAR)	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px 0;"></div> (24 HOUR CLOCK)	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px 0;"></div>
<div style="border: 1px solid black; width: 100%; height: 100%;"></div>	<input type="checkbox"/> OD <input type="checkbox"/> OS	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px 0;"></div> (DAY/MONTH/YEAR)	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px 0;"></div> (DAY/MONTH/YEAR)	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px 0;"></div> (24 HOUR CLOCK)	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px 0;"></div>

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
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		
	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>		

IF MORE SPACE IS NEEDED, PLEASE USE CONTINUATION PAGE

5. RELEVANT MEDICAL HISTORY

	START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	CONTINUING?
1. <div style="border: 1px solid black; height: 15px; width: 100%;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<input type="checkbox"/> Y <input type="checkbox"/> N
2. <div style="border: 1px solid black; height: 15px; width: 100%;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<input type="checkbox"/> Y <input type="checkbox"/> N
3. <div style="border: 1px solid black; height: 15px; width: 100%;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<input type="checkbox"/> Y <input type="checkbox"/> N
4. <div style="border: 1px solid black; height: 15px; width: 100%;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<input type="checkbox"/> Y <input type="checkbox"/> N
5. <div style="border: 1px solid black; height: 15px; width: 100%;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<input type="checkbox"/> Y <input type="checkbox"/> N
6. <div style="border: 1px solid black; height: 15px; width: 100%;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<input type="checkbox"/> Y <input type="checkbox"/> N
7. <div style="border: 1px solid black; height: 15px; width: 100%;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<input type="checkbox"/> Y <input type="checkbox"/> N
8. <div style="border: 1px solid black; height: 15px; width: 100%;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<div style="border: 1px solid black; width: 60px; height: 20px;"></div>	<input type="checkbox"/> Y <input type="checkbox"/> N

IF MORE SPACE IS NEEDED, PLEASE USE CONTINUATION PAGE

Serious Adverse Event Report Form		Assigned Case # <div></div>
Primary Adverse Event Term: <div></div>		PAGE <div></div> OF <div></div>

DATE OF THIS REPORT <div></div> (DD/MMM/YYYY)	PROTOCOL # <div></div>	SITE # <div></div>	<input type="checkbox"/> INITIAL REPORT <input type="checkbox"/> FOLLOW UP REPORT # <div></div>
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.							<input type="checkbox"/>	<input type="checkbox"/> Y	<input type="checkbox"/> N
2.							<input type="checkbox"/>	<input type="checkbox"/> Y	<input type="checkbox"/> N
3.							<input type="checkbox"/>	<input type="checkbox"/> Y	<input type="checkbox"/> N
4.							<input type="checkbox"/>	<input type="checkbox"/> Y	<input type="checkbox"/> N
5.							<input type="checkbox"/>	<input type="checkbox"/> Y	<input type="checkbox"/> N
6.							<input type="checkbox"/>	<input type="checkbox"/> Y	<input type="checkbox"/> N
7.							<input type="checkbox"/>	<input type="checkbox"/> Y	<input type="checkbox"/> N
8.							<input type="checkbox"/>	<input type="checkbox"/> Y	<input type="checkbox"/> N

IF MORE SPACE IS NEEDED, PLEASE USE CONTINUATION PAGE

<h2 style="margin: 0;">Serious Adverse Event Report Form</h2>	Assigned Case # <div style="border: 1px solid black; height: 20px; width: 100%;"></div>
Primary Adverse Event Term: <div style="border: 1px solid black; width: 600px; height: 20px;"></div>	PAGE <div style="border: 1px solid black; width: 20px; height: 15px;"></div> OF <div style="border: 1px solid black; width: 20px; height: 15px;"></div>

DATE OF THIS REPORT <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div> (DD/MMM/YYYY)	PROTOCOL # <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div>	SITE # <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div>	<input type="checkbox"/> INITIAL REPORT <input type="checkbox"/> FOLLOW UP REPORT # <div style="border: 1px solid black; width: 50px; height: 15px;"></div>
PROTOCOL TITLE: <div style="border: 1px solid black; height: 60px; width: 100%;"></div>			

2A. ADDITIONAL SERIOUS ADVERSE EVENT

DIAGNOSTIC TERM TO DESCRIBE PRIMARY SAE <div style="border: 1px solid black; height: 60px; width: 100%;"></div> <small>USE SIGNS AND SYMPTOMS IF DIAGNOSIS UNKNOWN. IF MORE THAN ONE SAE TERM, PLEASE LIST ON CONTINUATION PAGE #3.</small>	EVENT OUTCOME <input type="checkbox"/> RESOLVED <input type="checkbox"/> ONGOING <input type="checkbox"/> FATAL IF FATAL; CAUSE OF DEATH: <div style="border: 1px solid black; height: 30px; width: 100%;"></div> INTENSITY <input type="checkbox"/> MILD <input type="checkbox"/> MODERATE <input type="checkbox"/> SEVERE	SERIOUS CRITERIA (CHECK ALL THAT APPLY) <input type="checkbox"/> DEATH <input type="checkbox"/> RESULTED IN PERSISTENT/SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> MEDICALLY SIGNIFICANT <input type="checkbox"/> LIFE –THREATENING <input type="checkbox"/> CONGENITAL ANOMALY/BIRTH DEFECT <input type="checkbox"/> REQUIRED OR PROLONGED HOSPITALIZATION
DATE OF ONSET (DD/MMM/YYYY) <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div>	TIME (24 HR) <div style="border: 1px solid black; width: 50px; height: 20px; margin: 5px 0;"></div>	ACTION TAKEN: PATIENT <input type="checkbox"/> NONE <input type="checkbox"/> PROCEDURE <input type="checkbox"/> MEDICATION <input type="checkbox"/> OTHER <div style="border: 1px solid black; width: 100px; height: 15px;"></div> <input type="checkbox"/> DISCONTINUED STUDY IF DISCONTINUED, WAS IT DUE TO THIS SAE? <input type="checkbox"/> YES <input type="checkbox"/> NO
DATE OF RESOLUTION (DD/MMM/YYYY) <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div>	TIME (24 HR) <div style="border: 1px solid black; width: 50px; height: 20px; margin: 5px 0;"></div>	
RELATIONSHIP TO EVENT: RELATED TO INJECTION: <input type="checkbox"/> YES <input type="checkbox"/> NO RELATED TO STUDY DRUG: <input type="checkbox"/> YES <input type="checkbox"/> NO		IF NOT RELATED, DUE TO: <input type="checkbox"/> UNDERLYING DISEASE: <div style="border: 1px solid black; width: 100px; height: 15px;"></div> <input type="checkbox"/> OTHER: <div style="border: 1px solid black; width: 100px; height: 15px;"></div> *COMPLETE ADDITIONAL SUSPECT MEDICATION SECTION

2B. ADDITIONAL SERIOUS ADVERSE EVENT

DIAGNOSTIC TERM TO DESCRIBE PRIMARY SAE <div style="border: 1px solid black; height: 60px; width: 100%;"></div> <small>USE SIGNS AND SYMPTOMS IF DIAGNOSIS UNKNOWN. IF MORE THAN ONE SAE TERM, PLEASE LIST ON CONTINUATION PAGE #3.</small>	EVENT OUTCOME <input type="checkbox"/> RECOVERED/RESOLVED <input type="checkbox"/> ONGOING <input type="checkbox"/> FATAL IF FATAL; CAUSE OF DEATH: <div style="border: 1px solid black; height: 30px; width: 100%;"></div> INTENSITY <input type="checkbox"/> MILD <input type="checkbox"/> MODERATE <input type="checkbox"/> SEVERE	SERIOUS CRITERIA (CHECK ALL THAT APPLY) <input type="checkbox"/> DEATH <input type="checkbox"/> RESULTED IN PERSISTENT/SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> MEDICALLY SIGNIFICANT <input type="checkbox"/> LIFE –THREATENING <input type="checkbox"/> CONGENITAL ANOMALY/BIRTH DEFECT <input type="checkbox"/> REQUIRED OR PROLONGED HOSPITALIZATION
DATE OF ONSET (DD/MMM/YYYY) <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div>	TIME (24 HR) <div style="border: 1px solid black; width: 50px; height: 20px; margin: 5px 0;"></div>	ACTION TAKEN: PATIENT <input type="checkbox"/> NONE <input type="checkbox"/> PROCEDURE <input type="checkbox"/> MEDICATION <input type="checkbox"/> OTHER <div style="border: 1px solid black; width: 100px; height: 15px;"></div> <input type="checkbox"/> DISCONTINUED STUDY IF DISCONTINUED, WAS IT DUE TO THIS SAE? <input type="checkbox"/> YES <input type="checkbox"/> NO
DATE OF RESOLUTION (DD/MMM/YYYY) <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div>	TIME (24 HR) <div style="border: 1px solid black; width: 50px; height: 20px; margin: 5px 0;"></div>	
RELATIONSHIP TO EVENT: RELATED TO INJECTION: <input type="checkbox"/> YES <input type="checkbox"/> NO RELATED TO STUDY DRUG: <input type="checkbox"/> YES <input type="checkbox"/> NO		IF NOT RELATED, DUE TO: <input type="checkbox"/> UNDERLYING DISEASE: <div style="border: 1px solid black; width: 100px; height: 15px;"></div> <input type="checkbox"/> OTHER: <div style="border: 1px solid black; width: 100px; height: 15px;"></div> *COMPLETE ADDITIONAL SUSPECT MEDICATION SECTION

Serious Adverse Event Report Form	Assigned Case # <div style="border: 1px solid black; height: 20px; width: 100%;"></div>
Primary Adverse Event Term:	PAGE <div style="border: 1px solid black; width: 20px; display: inline-block;"></div> OF <div style="border: 1px solid black; width: 20px; display: inline-block;"></div>

DATE OF THIS REPORT <div style="border: 1px solid black; width: 100px; height: 20px; display: inline-block;"></div> (DD/MMM/YYYY)	PROTOCOL # <div style="border: 1px solid black; width: 100px; height: 20px; display: inline-block;"></div>	SITE # <div style="border: 1px solid black; width: 100px; height: 20px; display: inline-block;"></div>	<input type="checkbox"/> INITIAL REPORT <input type="checkbox"/> FOLLOW UP REPORT # <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
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: <input type="checkbox"/> DRUG CONTINUED <input type="checkbox"/> DRUG WITHDRAWN DATE(DD/MMM/YYYY) <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> <input type="checkbox"/> DRUG INTERRUPTED FROM DATE (DD/MMM/YYYY) <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> TO DATE (DD/MMM/YYYY) <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>			IF SUSPECT DRUG DISCONTINUED OR REDUCED, DID EVENT ABATE? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA IF SUSPECT DRUG RESTARTED OR INCREASED, DID EVENT REOCCUR? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> 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: <input type="checkbox"/> DRUG CONTINUED <input type="checkbox"/> DRUG WITHDRAWN DATE(DD/MMM/YYYY) <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> <input type="checkbox"/> DRUG INTERRUPTED FROM DATE (DD/MMM/YYYY) <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> TO DATE (DD/MMM/YYYY) <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>			IF SUSPECT DRUG DISCONTINUED OR REDUCED, DID EVENT ABATE? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA IF SUSPECT DRUG RESTARTED OR INCREASED, DID EVENT REOCCUR? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> 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: <input type="checkbox"/> DRUG CONTINUED <input type="checkbox"/> DRUG WITHDRAWN DATE(DD/MMM/YYYY) <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> <input type="checkbox"/> DRUG INTERRUPTED FROM DATE (DD/MMM/YYYY) <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> TO DATE (DD/MMM/YYYY) <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>			IF SUSPECT DRUG DISCONTINUED OR REDUCED, DID EVENT ABATE? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA IF SUSPECT DRUG RESTARTED OR INCREASED, DID EVENT REOCCUR? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> 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: <input type="checkbox"/> DRUG CONTINUED <input type="checkbox"/> DRUG WITHDRAWN DATE(DD/MMM/YYYY) <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> <input type="checkbox"/> DRUG INTERRUPTED FROM DATE (DD/MMM/YYYY) <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> TO DATE (DD/MMM/YYYY) <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>			IF SUSPECT DRUG DISCONTINUED OR REDUCED, DID EVENT ABATE? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA IF SUSPECT DRUG RESTARTED OR INCREASED, DID EVENT REOCCUR? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA			

Serious Adverse Event Report Form	Assigned Case # <div style="border: 1px solid black; height: 20px; width: 100%;"></div>
Primary Adverse Event Term: <div style="border: 1px solid black; width: 300px; height: 20px;"></div>	PAGE <div style="border: 1px solid black; width: 20px; height: 15px;"></div> OF <div style="border: 1px solid black; width: 20px; height: 15px;"></div>

DATE OF THIS REPORT <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div> <small>(DD/MMM/YYYY)</small>	PROTOCOL # <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div>	SITE # <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div>	<input type="checkbox"/> INITIAL REPORT <input type="checkbox"/> FOLLOW UP REPORT # <div style="border: 1px solid black; width: 40px; height: 15px;"></div>
PROTOCOL TITLE: <div style="border: 1px solid black; width: 650px; height: 50px; margin-top: 5px;"></div>			

4A. RELEVANT LABS AND TESTS

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

6A. RELEVANT 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.								<input type="checkbox"/> Y <input type="checkbox"/> N
2.								<input type="checkbox"/> Y <input type="checkbox"/> N
3.								<input type="checkbox"/> Y <input type="checkbox"/> N
4.								<input type="checkbox"/> Y <input type="checkbox"/> N
5.								<input type="checkbox"/> Y <input type="checkbox"/> 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.					/ /	/ /	<input type="checkbox"/> Y <input type="checkbox"/> N
2.					/ /	/ /	<input type="checkbox"/> Y <input type="checkbox"/> N
3.					/ /	/ /	<input type="checkbox"/> Y <input type="checkbox"/> N
4.					/ /	/ /	<input type="checkbox"/> Y <input type="checkbox"/> N
5.					/ /	/ /	<input type="checkbox"/> Y <input type="checkbox"/> N
6.					/ /	/ /	<input type="checkbox"/> Y <input type="checkbox"/> N
7.					/ /	/ /	<input type="checkbox"/> Y <input type="checkbox"/> N
8.					/ /	/ /	<input type="checkbox"/> Y <input type="checkbox"/> N

IF MORE SPACE IS NEEDED, PLEASE USE CONTINUATION PAGE

Serious Adverse Event Report Form		Assigned Case # <div style="border: 1px solid black; height: 20px; width: 100%;"></div>
Primary Adverse Event Term: <div style="border: 1px solid black; width: 300px; height: 20px;"></div>		PAGE <div style="border: 1px solid black; width: 20px; height: 15px;"></div> OF <div style="border: 1px solid black; width: 20px; height: 15px;"></div>

DATE OF THIS REPORT <div style="border: 1px solid black; width: 40px; height: 15px;"></div> / <div style="border: 1px solid black; width: 40px; height: 15px;"></div> / <div style="border: 1px solid black; width: 40px; height: 15px;"></div> (DD/MMM/YYYY)	PROTOCOL # <div style="border: 1px solid black; width: 100%; height: 20px;"></div>	SITE # <div style="border: 1px solid black; width: 100%; height: 20px;"></div>	<input type="checkbox"/> INITIAL REPORT <input type="checkbox"/> FOLLOW UP REPORT # <div style="border: 1px solid black; width: 40px; height: 15px;"></div>
PROTOCOL TITLE: <div style="border: 1px solid black; height: 50px;"></div>			

THIS SECTION MUST BE COMPLETED IF THIS IS THE LAST PAGE	Is this the last page <input type="checkbox"/> Y <input type="checkbox"/> N	Number of Pages in this Report _____
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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
<div style="border: 1px solid black; height: 40px;"></div>	<div style="border: 1px solid black; height: 40px;"></div>	<div style="border: 1px solid black; height: 40px;"></div>	<div style="border: 1px solid black; height: 40px;"></div>	<div style="border: 1px solid black; height: 40px;"></div>

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
<div style="border: 1px solid black; height: 80px;"></div>	<div style="border: 1px solid black; height: 80px;"></div>	<div style="border: 1px solid black; height: 80px;"></div>	<div style="border: 1px solid black; height: 80px;"></div>	<div style="border: 1px solid black; height: 80px;"></div>