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DATE OF THIS REPORT	PROTOCOL#	SIT	TE #		INITIAL REPORT
					T SOLLOW UP DEPORT #
(DD/MMM/YYYY)		_			FOLLOW UP REPORT #
PROTOCOL TITLE:					
1. PATIENT INFORMAT	ION				
PATIENT # PATI	ENT INITIALS SEX	WEIGHT		RACE:	
	м		GM LB	AMERICAN IND	IAN OR ALASKA NATIVE IAN OR OTHER PACIFIC ISLANDER
DATE OF BIRTH (DD/MMM/YY	HEIGHT BLACK OR AFRICAN WHITE			ICAN AMERICAN	
		CM IN OTHER, SPECIFY:			FY:
2. SERIOUS ADVERSE	EVENT (PRIMARY)			
USE SIGNS AND SYMPTOMS IF IF MORE THAN ONE SAE TERM, CONTINUATION PAGE #3.	EVENT OUTCOME RECOVERED/RESOLVED ONGOING FATAL IF FATAL; CAUSE OF DEATH: INTENSITY MILD MODERATE SEVERE ACT N		OR INCAPACITY MEDICALLY SIGNIFICA LIFE -THREATENING CONGENITAL ANOMAI	/ YES NO TE: YES NO TENT/SIGNIFICANT DISABILITY	
DATE OF ONSET (DD/MMM/YYYY			ACTION TAKEN: PATIENT NONE PROCEDURE MEDICATION OTHER DISCONTINUED STUDY		
/ / /	(27111)			IF DISCONTINUED, WAS I	T DUE TO THIS SAE?
RELATIONSHIP TO EVENT RELATED TO INJECTION PROC RELATED TO STUDY DRUG:		NO NO			
IF NOT RELATED, DUE TO UNDERLYING DISEASE *(S					

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(DD/MMM/YYYY)				·		FOLLOW UP REPORT #						
PROTOCOL TITLE:												
3. STUDY DRUG	•								-			
DRUG	EYE		DATE OF INITIA DRUG ADMINIS			OF LATEST DOSE OR TO THE EVENT		LATEST DOSE TO THE EVENT	TOTAL NUMBER OF DOSES GIVEN PRIOR TO ONSET OF THE EVENT			
		os	/ (DAY/MONTH	/	(DA	/ / / / AY/MONTH/YEAR)	(24)	HOUR CLOCK)				
OD OS /					/ / / / AY/MONTH/YEAR)	(24 HOUR CLOCK)						
ACTION TAKEN WITH			(DAT/MOINT)	I LAIN								
DRUG WITHDRAWN DRUG INTERRUPTED FROM DATE (DD/MMM/ TO DATE (DD/MMM/	/YYY)	//				TUDY DRUG DISCO						
1. RELEVANT LAI			D/MMM/YYYY)		RESULT V	v/units		NORMAL	RANGE			
		/_										
		/_	/									
		/_										
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		/_										
		/_	/									
		/_										
		/_	/									
		/										
		/_	MODE CDACE IS	NEEDED	DIEACE	LICE CONTINUATIO	L DACE					
5. RELEVENT ME	DICAL HI			S NEEDED, I	PLEASE	USE CONTINUATIO	NPAGE					
-						START DAT (DD/MMM/YY		STOP DA' (DD/MMM/Y	CONTINUING /			
1.								//	Y N			
2. 3.						/ /		/ /	Y N			
4.						/ /		/ /	YN			
5.						//		//	YN			
6. 7.						/ /		/ /	Y N			
8.												

IF MORE SPACE IS NEEDED, PLEASE USE CONTINUATION PAGE

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Primary Adverse	Event le	rm:						PAGE OF		<u> </u>
DATE OF THIS REPORT	PROTO	COL#		SITE #			INITI	AL REPORT		
(DD/MMM/YYYY)		FOLLOW UP REPORT #								
PROTOCOL TITLE: 6. RELEVENT CONCO	OMITANT M	EDIC ATION	le DOI	NOT INCL	LIDE AN	V SUSPECT OF	TDEAT	MENT MEDICAT	IONS	
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)	CONTIN	UING?
1.						//		//	ΟΥ	N
2.									Y	N
3.									Y	N
4. <u> </u>									Y	N N
6.		1						/ /	Y	N
7.									Y	N
8.									Y	N

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DATE OF THIS REPORT	PROTO	COL#		SITE #		☐ INIT	AL REPORT				
(DD/MMM/YYYY)						FOL	LOW UP REPORT	#			
PROTOCOL TITLE: 7. MANAGEMENT OF S WAS AN INTERVENTION DO		THE SA	E? YES	NO UNK							
TREATMENT INTERVENTION	ROUTE OF ADMIN.	UNIT DOSE	FREQ	TOTAL DAILY DOSE	START DATE (DD/MMM/YYYY)		STOP DATE D/MMM/YYYY)	CONTINUING?			
1.							//	Y N			
2.					//		//	YN			
3.					//			Y N			
4.							//	YN			
5.					//		//	YN			
6.					//		//	YN			
7.							//	Y N			
8.					///		//				

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DATE OF THIS REPORT	PROTOCOL#	SITE #	INIT	AL REPORT
(DD/MMM/YYYY)			FOL	LOW UP REPORT #
PROTOCOL TITLE:				
8. EVENT NARRATIVE	MENT OF THE ADVEDSE EVENT	TREATMENTS TO THE EVENT, EVENT OUT	COME AND D	ATIONAL FOR CALISALITY
ASSESSMENT	MENT OF THE ADVERSE EVENT,	TREATMENTS TO THE EVENT, EVENT OUT	COME, AND K	ATIONAL FOR CAUSALITY

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DATE OF THIS REPORT	PROTOCOL#		SITE #		INITI	AL REPORT		
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(DD/MMM/YYYY)					L FULI	LOW UP REPORT #		
PROTOCOL TITLE:								
2A. ADDIOTIONAL SERIOUS	ADVERSE	EVENT						
DIAGNOSTIC TERM TO DESCRIBE PR	IMARY SAE	RESOLVED ONGOING FATAL IF FATAL; CAU	1	OR INCAPACITY MEDICALLY SIGN LIFE -THREATEN CONGENITAL AN	PERSISTEN NIFICANT NING OMALY/BIR	NT/SIGNIFICANT DISABILITY		
USE SIGNS AND SYMPTOMS IF DIAGNOS IF MORE THAN ONE SAE TERM, PLEASE CONTINUATION PAGE #3.	INTENSITY MILD MODERATE		10710117117111					
DATE OF RESOLUTION (DD/MMM/YYYY) DATE OF RESOLUTION (DD/MMM/YYYY) TIME (24 HR)		SEVERE		ACTION TAKEN: F NONE PROCE MEDICATION DISCONTINUED: IF DISCONTINUED, V YES NO	EDURE OTHER STUDY	TO THIS SAE?		
RELATIONSHIP TO EVENT: RELATED TO INJECTION: RELATED TO STUDY DRUG: YE				IF NOT RELATED, UNDERLYING DIS OTHER: *COMPLETE ADDITIO	SEASE:	CT MEDICATION SECTION		
2B. ADDIOTIONAL SERIOUS		EVENT						
DIAGNOSTIC TERM TO DESCRIBE PR	IMARY SAE	ONGOING FATAL	ED/RESOLVED SE OF DEATH:	OR INCAPACITY MEDICALLY SIGN LIFE —THREATE CONGENITAL AN	ERSISTENTA NIFICANT NING OMALY/BIR	SIGNIFICANT DISABILITY		
USE SIGNS AND SYMPTOMS IF DIAGNOSIS UNKNOWN. IF MORE THAN ONE SAE TERM, PLEASE LIST ON CONTINUATION PAGE #3.		INTENSITY MILD MODERATE	Ē	ACTION TAKEN:	PATIENT			
				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: RELATED TO STUDY DRUG: YE				IF NOT RELATED, UNDERLYING DIS OTHER: *COMPLETE ADDITIO	SEASE:	CT MEDICATION SECTION		

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	PROTOCO)L#	SITE #			INITIAL RE	EPORT				
(DD/MMM/YYYY)						FOLLOW	UP REPORT #				
PROTOCOL TITLE:											
3A. CO-SUSPECT MEDICATI	ON(S)										
CO-SUSPECT DRUG		START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	DOSE	ROUTE	FREQ	INDICATION				
ACTION TAKEN WITH CO-SUSPEC DRUG CONTINUED		:		UG DISCONTINUE IO NA	D OR REDUC	ED, DID EVEN	NT ABATE?				
DRUG WITHDRAWN DATE(DD/MMM/ DRUG INTERRUPTED FROM DATE (DD/MMM/YYYY) TO DATE (DD/MMM/YYYY)	/	IF SUSPECT DRUG RESTARTED OR INCREASED, DID EVENT REOCCUR? YES NO NA									
3B. CO-SUSPECT MEDICATI	B. 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-SUSPEC DRUG CONTINUED DRUG WITHDRAWN DATE(DD/MMM/ 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 MEDICATI	ON(S)										
CO-SUSPECT DRUG		START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	DOSE	ROUTE	FREQ	INDICATION				
ACTION TAKEN WITH CO-SUSPEC DRUG CONTINUED DRUG WITHDRAWN DATE(DD/MMM/		:	YES N	UG DISCONTINUE			_				
FROM DATE (DD/MMM/YYYY) TO DATE (DD/MMM/YYYY)	/	V		UG RESTARTED C	JR INCREASE	:D, DID EVEN	REOCCUR!				
3D. CO-SUSPECT MEDICATI	ON(S)		,				·				
CO-SUSPECT DRUG		START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	DOSE	ROUTE	FREQ	INDICATION				
ACTION TAKEN WITH CO-SUSPEC DRUG CONTINUED DRUG WITHDRAWN DATE(DD/MMM/ DRUG INTERRUPTED		:	YES N	UG DISCONTINUE IO NA UG RESTARTED C							
FROM DATE (DD/MMM/YYYY) TO DATE (DD/MMM/YYYY)			YES N	IO NA							

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DATE OF THIS REPORT	PROTOCOL#	SITE #		INITIAL REPORT			
(DD/MMM/YYYY)				FOLLOW UP REPOR	(1 π		
PROTOCOL TITLE:							
4A. RELEVANT LABS AND	IESIS						
TEST	DATE(DD/MMM/YYYY)	RESULT W/UNITS	NORM	AL RANGE			

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

	IOT LIST DRUGS USED REAT EVENT	INDICATION	DOSE	DOSE UNIT	ROUTE	FREQ	START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	CONTINUING?
1.									□ Y □ N
2.									YN
3.									
4.									YN
5.									□ Y □ N

7A. MANAGEMENT OF SAE

WAS	VAS AN INTERVENTION DONE TO TREAT THE SAE? YES NO UNK												
TREATMENT INTERVENTION		ROUTE OF UNIT ADMIN. DOSE FREQ		TOTAL DAILY DOSE	START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	CONTINUING?						
1.													
2.								Y N					
3.								Y N					
4.								Y N					
5.								YN					
6.								Y N					
7.								Y N					
8.								Y N					
			IF MORE	E SPACE IS N	NEEDED, PLEASE US	SE CONTINUATION PAGE		<u>.</u>					

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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 s Adverse Event Report Form is inconsistent with the infor	is complete and accurate										
REPORTER SIGNATURE	TITLE	PRINTED NAME	DA	ATE	PHC	ONE					
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	DA	ATE	PHC	DNE					