	S	erious	Advers	se Event		Assigned Case #		
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Primary Adve	rse Event		•			PAGE OF		
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DATE OF THIS REPOR	T Pi	ROTOCOL#		SITE #		INITIAL REPORT		
<u>//</u>	_					FOLLOW UP REPORT #		
(DD/MMM/YYYY)	) -			-		- TOLLOW OF NET ONLY		
PROTOCOL TITLE:								
1. PATIENT INFO	RMATION							
PATIENT#	PATIENT INITI	ALS SEX	WEIGHT		RACE:			
			ı —	GM LI	AMERICAN IND	DIAN OR ALASKA NATIVE		
	'				ASIAN NATIVE HAWA	IIAN OR OTHER PACIFIC ISLANDER		
DATE OF BIRTH (DD/M	IMM/YYYY)		HEIGHT			RICAN AMERICAN		
1 1				CM	WHITE OTHER, SPEC	IFY:		
2. SERIOUS ADVI		F (DDIMAE						
			EVENT OU	TCOME	SERIOUS CRITERIA (	CHECK ALL THAT APPLY)		
USE SIGNS AND SYMPTOMS IF DIAGNOSIS UNKNOWN. IF MORE THAN ONE SAE TERM, PLEASE LIST ON CONTINUATION PAGE #3.			ONGOIN FATAL	AUSE OF DEATH: .	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: / /			
DATE OF ONSET (DD/N	MMM/YYYY)	TIME (24 HR)			ACTION TAKEN: PATI NONE PROCEDUR MEDICATION OTH			
DATE OF RESOLUTION	N (DD/MMM/YYYY)	TIME (24 HR)			IF DISCONTINUED, WAS YES NO			
RELATIONSHIP TO			□ vic					
RELATED TO INJECTION	ON PROCEDURE:	YES	NO					
RELATED TO STUDY D	RUG:	YES	NO					
IF NOT RELATED, D UNDERLYING DISE OTHER:		:		-				

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(DD/MMM/YYYY)								FOLLOW	IP REPOR	г#	
PROTOCOL TITLE:											
3. STUDY DRUG											
DRUG		ΥE	DATE OF INITI			OF LATEST DOSE OR TO THE EVENT		LATEST DOSE	DOSES G		OR TO
DRUG	OD	os	(DAY/MONTH	//YEAR)	(DA	/ / / / AY/MONTH/YEAR)	(24	HOUR CLOCK)	UNSET	OF THE EV	ZENI
	OD	OS	/ (DAY/MONTH			/ / / / AY/MONTH/YEAR)	(24	HOUR CLOCK)			
ACTION TAKEN WITH DRUG CONTINUED DRUG WITHDRAWN DRUG INTERRUPTED FROM DATE (DD/MMM/ TO DATE (DD/MMM/	DATE (DD/M		/// ///			TUDY DRUG DISCO					NA NA
4. RELEVANT LA	BS AND						T				
TEST		DATE(D	D/MMM/YYYY)		RESULT V	V/UNITS		NORMAL	RANGE		
		/									
			/								
		/	/								
		/	/								
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		/	/								
		/	/								
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		/	/								
		II.	F MORE SPACE IS	S NEEDED, I	PLEASE	USE CONTINUATIO	N PAGE				
5. RELEVENT ME	DICAL	HISTOF	RY								
						START DA (DD/MMM/Y		STOP DA (DD/MMM/Y		CONTINU	JING?
1.	_	_								Y	N
2.								//		Y	N
3. 4.										Y	N N
5.										Y	N
6.										Y	N
7.				<u>-</u>	-	//		//		Y	N
8.								/		Y	N

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Primary Adverse	Event le	rm:						PAGEOF		
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(DD/MMM/YYYY)							FOL	LOW UP REPORT #		
PROTOCOL TITLE:  6. RELEVENT CONCO	OMITANT M			NOT INC.	LIDE AN	V SUSPECT on a	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 N
5.									Y	N
6.		1						/ /	Y	N
7.									Y	N
8.								//	Y	N

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DATE OF THIS REPORT	PROTO	COL#		SITE #		□ IN	ITIAL REPORT	
(DD/MMM/YYYY)						FC	LLOW UP REPORT	#
PROTOCOL TITLE:  7. MANAGEMENT OF S WAS AN INTERVENTION DO		T THE SA	<b>E?</b> YES	NO UNK				
TREATMENT INTERVENTION	ROUTE OF ADMIN.	UNIT DOSE	FREQ	TOTAL DAILY DOSE	START DATE (DD/MMM/YYY		STOP DATE DD/MMM/YYYY)	CONTINUING?
1.							//	Y N
2.								
3.							//	Y N
4.							_//	YN
5.							//	YN
6.					<u> </u>		_//	YN
7.							//	Y N
8.					//			YN

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Primary Adverse Eve	nt lerm:			PAGE OF
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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						LOW UP PEROPT #	
(DD/MMM/YYYY)					FOLI	OW UP REPORT #	
PROTOCOL TITLE:							
2A. ADDIOTIONAL SERIOUS	ADVERSE	EVENT					
DIAGNOSTIC TERM TO DESCRIBE PR	IMARY SAE	RESOLVED ONGOING FATAL IF FATAL; CAU	)	OR INCAPACITY MEDICALLY SIGN LIFE -THREATEN CONGENITAL AN	PERSISTEN IIFICANT IING OMALY/BIR	IT/SIGNIFICANT DISABILITY	
USE SIGNS AND SYMPTOMS IF DIAGNOS IF MORE THAN ONE SAE TERM, PLEASE CONTINUATION PAGE #3.	INTENSITY  MILD MODERATE		ACTION TAKEN: PATIENT				
DATE OF ONSET (DD/MMM/YYYY)  / / /  DATE OF RESOLUTION (DD/MMM/YYYY)	TIME (24 HR)  TIME (24 HR)	SEVERE		NONE PROCE MEDICATION DISCONTINUED S IF DISCONTINUED, V YES NO	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	ADVERSE	EVENT					
DIAGNOSTIC TERM TO DESCRIBE PR	IMARY SAE	ONGOING FATAL	ED/RESOLVED SE OF DEATH:	OR INCAPACITY MEDICALLY SIGN LIFE –THREATEI CONGENITAL AN	ERSISTENT/ IIFICANT NING OMALY/BIR	SIGNIFICANT DISABILITY	
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)		INTENSITY  MILD  MODERATE	≣	ACTION TAKEN: F	PATIENT		
DATE OF ONSET (DD/MMM/YYYY)  TIME (24 HR)  DATE OF RESOLUTION (DD/MMM/YYYY)  TIME (24 HR)		SEVERE		NONE PROCE MEDICATION DISCONTINUED S IF DISCONTINUED, V YES NO	DURE OTHER STUDY	TO THIS SAE?	
RELATIONSHIP TO EVENT: RELATED TO INJECTION: YE RELATED TO STUDY DRUG: YE				IF NOT RELATED, UNDERLYING DIS OTHER:	SEASE:	CT MEDICATION SECTION	

Seri	ous	Adverse E	vent		Assi	Assigned Case #						
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(DD/MMM/YYYY)						FOLLOW	UP REPORT #					
PROTOCOL TITLE:												
A. 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-SUSPECTORUS DRUG CONTINUED		:		JG DISCONTINUE O 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)	YYYY)	// V V	IF SUSPECT DRUG RESTARTED OR INCREASED, DID EVENT REOCCUR?  YES NO NA									
BB. 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)					<u> </u>						
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)			YES N	JG DISCONTINUE O NA  JG RESTARTED C O NA			_					
3D. CO-SUSPECT MEDICATION	ON(S)	<u>/</u>										
CO-SUSPECT DRUG	OII(O)	START DATE (DD/MMM/YYYY)	STOP DATE (DD/MMM/YYYY)	DOSE	ROUTE	FREQ	INDICATION					
		(BB/WINGER 1 1 1 1 )	(DD/WWW.FITT.)									
ACTION TAKEN WITH CO-SUSPEC  DRUG CONTINUED  DRUG WITHDRAWN DATE(DD/MMM/ DRUG INTERRUPTED		:	YES N	JG DISCONTINUE O NA  JG RESTARTED C			_					
FROM DATE (DD/MMM/YYYY) TO DATE (DD/MMM/YYYY)	_/	<u>/</u>	IF SUSPECT DRUG RESTARTED OR INCREASED, DID EVENT REOCCUR?  YES NO NA									

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(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 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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(DD/MMM/YYYY)				FOLLO	W UP REPO	RT#		
PROTOCOL TITLE:								
THIS SECTION MUST BE COMPLETED IF PAGE	THIS IS THE LAST IS this	s the last page 🗆 Y 🗆 N	Number of	f Pages in t	his Report	t		
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: Ethis Serious Adverse Event I not aware of any information	Report Form, (2) such inf	ormation is complete and a	ccurate i					
INVESTIGATOR SIGNATURE	TITLE	PRINTED NAME	DA	ATE	PHC	DNE		