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Primary Advers	se Event					PAGEOF
DATE OF THIS REPORT	Р	ROTOCOL#		SITE #		INITIAL REPORT
/						FOLLOWUR REPORT #
(DD/MMM/YYYY)	_			-		FOLLOW UP REPORT #
PROTOCOL TITLE:						
1. PATIENT INFORM	MATION					
PATIENT #	PATIENT INIT	IALS SEX	WEIGHT		RACE:	
DATE OF BIRTH (DD/MMM	M/YYYY)	F		GM	B AMERICAN INI ASIAN NATIVE HAWA	DIAN OR ALASKA NATIVE  IIAN OR OTHER PACIFIC ISLANDER  RICAN AMERICAN
/				CM	OTHER, SPEC	IFY:
2. SERIOUS ADVER	RSE EVEN	T (PRIMA	RY)			
USE SIGNS AND SYMPTOM IF MORE THAN ONE SAE TE CONTINUATION PAGE #3.	IS IF DIAGNOSI ERM, PLEASE I	S UNKNOWN.	ONGOIN FATAL IF FATAL; C.  INTENSITY MILD MODERA SEVERE	ERED/RESOLVED G AUSE OF DEATH:	DEATH DATE: / AUTOPSY: DEATH CERTIFICA  RESULTED IN PERSIS OR INCAPACITY  MEDICALLY SIGNIFIC LIFE -THREATENING CONGENITAL ANOMA	STENT/SIGNIFICANT DISABILITY  ANT  LLY/BIRTH DEFECT  DNGED HOSPITALIZATION
/ / / DD/MMR	W/YYYY)	IIME (24 HR)			NONE PROCEDUR MEDICATION OTI DISCONTINUED STUE	HER
DATE OF RESOLUTION (	DD/MMM/YYYY)	TIME (24 HR)			IF DISCONTINUED, WAS	
RELATIONSHIP TO EV		: YES	S NO			
RELATED TO STUDY DRU	JG:	YES	NO			
IF NOT RELATED, DUE UNDERLYING DISEAS OTHER:		):		-		

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Primary Advers	se Eve	nt Terr						PAG	E OF		
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DATE OF THIS REPORT		PROTOC	OL#	SITE	<b>#</b>			☐ INITIAL RE	PORT		
(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ACTION TAKEN WITH DRUG CONTINUED DRUG WITHDRAWN DRUG INTERRUPTED FROM DATE (DD/MMM/ TO DATE (DD/MMM/	DATE (DD/M		/// ///			TUDY DRUG DISCO					NA NA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		
		/									
			/								
		/	/								
		/	/								
		/	/								
		/	/								
		/	/								
		/	/								
		/	/								
		/	/								
		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.					-	//		//		Y	N
8.								/		Y	N

IF MORE SPACE IS NEEDED, PLEASE USE CONTINUATION PAGE

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Primary Adverse	Event le	rm:						PAGEOF		
DATE OF THIS REPORT	PROTO	COL#		SITE #			INITI	AL REPORT		
(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

IF MORE SPACE IS NEEDED, PLEASE USE CONTINUATION PAGE

	Serious Adverse Event Report Form										
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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.							//	Y N			
6.					<u> </u>		_//	Y N			
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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	Re	port Fo	rm			
Primary Adverse Even		•				PAGE OF
DATE OF THIS REPORT	PROTOCOL#		SITE #		INITI	AL REPORT
						OW UP BEDORT #
(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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Primary Adverse Event					PAGE	OF						
TATE OF THE REPORT												
	PROTOCO	DL#	SITE #			INITIAL RE	EPORT					
(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									

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

DATE OF THIS REPORT	PROTOCOL#	SITE #		☐ INITIAL REPORT	
/ / / (DD/MMM/YYYY)				FOLLOW UP REPO	RT#
PROTOCOL TITLE:					
4A. RELEVANT LABS AND	TESTS				_
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.									
3.									□ Y □ N
4.									
5.									$\square$ Y $\square$ N

## **7A. MANAGEMENT OF SAE**

WAS	WAS 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.								□ Y □ N					
2.													
3.								Y N					
4.								Y N					
5.								Y N					
6.								Y N					
7.								Y N					
8.								Y N					
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	Report Form							
Primary Adverse Ever	nt Term:		PAG	E OF				
DATE OF THIS REPORT	PROTOCOL#	SITE #		INITIAL	REPORT			
(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		