SERIOUS ADVERSE EVENT DATA COLLECTION FORM FOR INVESTIGATIONAL PRODUCTS

SITE Nº: **PROJECT CODE (Sponsor)**	**PATIENT Nº:**	**REPORT TYPE:** ☐ **INITIAL** ☐ **FOLLOW UP**	**RANDOMIZATION**:
SPONSOR ID:	CASE ID:	DYNAMIC RECEIVED DATE:	

I. ADVERSE EVENT INFORMATION

1a.COUNTRY	2. BIRTH DATE			2a. AGE (YRS, MTHS,DAYS)	3. GENDER	3a. WEIGHT	3b. HEIGHT	3.c RACE
	Day (dd)	Month (mmm)	Year (yyyy)		☐ **MALE** ☐ **FEMALE**	Kg	cm	☐ **WHITE** ☐ **BLACK** ☐ **ASIAN** ☐ **OTHER** If Other-specify

7. SERIOUS ADVERSE EVENT DESCRIPTION (signs and characteristics, severity, dates and outcome of hospitalization etc. If non-serious events are included in this text, please add (NS) after the event form)).

EVENT:

4-6.ONSET DATE OF THE SAE

Day (dd)	Month (mmm)	Year (yyyy)

8. SERIOUS CRITERIA

☐ DEATH
☐ LIFE -THREATENING
☐ HOSPITALIZATION/PROLONGED IN-PATIENT HOSPITALIZATION
☐ PERMANENT OR SIGNIFICANT DISABILITY
☐ CONGENITAL ANOMALY/BIRTH DEFECT
☐ MEDICALLY SIGNIFICANT

9. OUTCOME

	dd	mmm	yyyy
☐ FATAL/Date of death			
☐ RESOLVED			
☐ RESOLVED WITH SEQUELAE			

☐ IMPROVED
☐ PERSISTING
☐ WORSENED
☐ UNKNOWN

10.POSSIBLE CAUSES OF THE EVENT (Check off all that apply)

☐ PRE-EXISTING/UNDERLYING DISEASE-SPECIFY _____

☐ STUDY TREATMENT-SPECIFY THE DRUG(S) RELATED TO THE EVENT _____

☐ OTHER TREATMENT (CONCOMITANT OR PREVIOUS)-SPECIFY _____

☐ PROTOCOL-RELATED PROCEDURE _____

☐ OTHER (Specify) _____

II. STUDY DRUGS INFORMATION

Information of additional study drugs (s) can be completed on the Additional Study Drugs Information Form

Additional form provided? ☐ Yes ⟶ No. of extra pages _____ ☐ No

11. STUDY DRUG (drug and brand name) (1)	12. DOSE (Units)	12a FREQUENCY	12b. ROUTE	13. STUDY DISEASE	14. RELATED	15. START DATE			15a LAST DATE PRIOR TO SAE		
					☐ YES ☐ NO	dd	mmm	yyyy	dd	mmm	yyyy

16. WAS DRUG REGIMEN ALTERED IN RESPONSE TO THE EVENT?

☐ YES, ☐ NO ☐ NA

☐ Reduced-specify (date and new dose-go to 1)

☐ Temporarily interrupted (go to 2 or 3)

☐ Permanently Discontinued (go to 4)

DATES WHEN DRUG REGIMEN ALTERED

	dd	mmm	yyyy
1. Reduced			
2. Stopped			
3. Restarted			
4. Discontinued			

DETAILS OF NEW DOSE

New Dose	Units	Frequency

17. DID REACTION ABATE AFTER STOPPING DRUG?

☐ YES ☐ NO ☐ NA

18. DID THE EVENT REAPPEAR AFTER REINTRODUCTION?

☐ YES ☐ NO ☐ NA

III. CONCOMITANT MEDICATIONS (Record drugs being taken at the time of the event) AND RELEVANT HISTORY

Information of additional Concomitant Medication and Relevant History can be completed on the Additional Concomitant Medication and Relevant HistoryForm

Additional form provided? ☐ Yes ⟶ No. of extra pages _____ ☐ No

19. CONCOMITANT MEDICATIONS (drug and brand name)	**19e. INDICATION FOR USE**	**19a. DAILY DOSE (units)**	**19b. ROUTE**	**19c. ONSET DATE**			**19d. STOPPED DATE**			**19f. Ongoing**
				dd	mmm	yyyy	dd	mmm	yyyy	
1. ☐										☐
2. ☐										☐
3. ☐										☐
4. ☐										☐
5. ☐										☐

20. . RELEVANT INFORMATION FROM THE MEDICAL HISTORY (e.g Diagnostics, allergies, pregnancy, past medication, relevant previous disease...)	**20.a START DATE**			**20.b STOP DATE**			**20.c Ongoing**
	dd	**mmm**	**yyyy**	**dd**	**mmm**	**yyyy**	
1. ☐							☐
2. ☐							☐
3. ☐							☐
4. ☐							☐
5. ☐							☐

21. ANY RELEVANT LABORATORY/DIAGNOSTIC TEST(S) PROCEDURE (S) ? (Including laboratory values preceding the event)

Information of additional laboratory/diagnostic test can be completed on the Additional Laboratory/Diagnostic Test Form

Additional form provided? ☐ Yes ⟶ No. of extra pages _____ ☐ No

Name of test	Result (units)	Normal Range	Date of test		
			dd	mmm	yyyy
1.					
2.					
3.					
4.					
5.					
6.					

22. ANY TREATMENT(S) FOR SAE?

Information of additional treatment/procedure (s) for SAE can be completed on the Additional treatment/procedure (s) for SAE Form

Additional form provided? ☐ Yes ⟶ No. of extra pages _____ ☐ No

Name of treatment/procedure	Total daily dose/unit	Start date			End date			Ongoing
		dd	mmm	yyyy	dd	mmm	yyyy	
1.								☐
2.								☐
3.								☐
4.								☐
5.								☐
6.								☐

IV. INVESTIGATOR INFORMATION

23. NAME AND ADDRESS OF THE INVESTIGATOR	
REPORT PREPARED BY:	DATE (Dd/mmm/yyyy):
INVESTIGATOR/DESIGNEE SIGNATURE:	DATE (Dd/mmm/yyyy):