Standard Serious Adverse Event Form for Study Conducting in Phase 1 Clinical Trial Centre

Protocol Code (CRE#)	No of Subject(s) Recruited:	Reported to HA AIRS? ☐ Yes ☐ No	Type of report ☐ Initial ☐ Follow-up (case not completed) ☐ Follow-up (case completed)	Date of Report day / month / year
Date of Last Dose Prior to SAE Event: day / month / year		Total No. of SAE(s) in Study: (incl. this SAE)	Total No. of SAE(s) for this Subject: (incl. this SAE)	Study Drug Start Date: day / month / year

Patient Identification

Patient No.	Patient Initials			Date of Birth			Sex	Date of Enrolment		
	first	mid	last	day	month	year	☐ Male ☐ Female	day	month	year

Serious Adverse Event

SAE Start Event			SAE Stop Date		
day	month	year	day	month	year

Tick all appropriate to serious adverse event
- ☐ patient died, date of death: day month year
  - Autopsy:
    - ☐ Yes
    - ☐ Planned
    - ☐ No
- ☐ life threatening
- ☐ required inpatient hospitalization or prolongation of existing hospitalization
- ☐ persistent or significant disability/incapacity
- ☐ congenital anomaly/birth defect
- ☐ other (specify):_______________________

Description of SAE (use extra paper if necessary; enclose a discharge summary if any)

1. Diagnosis/Syndrome:_______________________
2. Full description of SAE

Outcome of Event to Date

- ☐ complete recovery
- ☐ recovery with sequelae
- ☐ present at time of this report
- ☐ unknown
- ☐ died

If the patient died, cause of death ___________________

Causal relationship between death and study drug/treatment:
- ☐ associated
- ☐ possible associated
- not associated –give alternative explanation: ______________________

Study Drug Information

Study Drug	Formulation, Strength & Route	Therapy Dates [day/month/year]	from			to		
Starting Dose & Frequency	Current Dose & Frequency	Indication						

Causal relationship between study drug and event
- ☐ definite associated
- ☐ probable associated
- ☐ possible associated
- ☐ unlikely associated
- ☐ not associated -give alternative explanation:
- ☐ unknown

Action taken with study drug / treatment as a result of the SAE
- ☐ None
- ☐ Dosage adjusted
- ☐ Temporarily interrupted
- ☐ Permanently discontinued

Withdrawn from study as a result of the SAE
- ☐ Yes
- ☐ No

Concomitant Drug/Treatment and Relevant Medical History

Relevant medical history [e.g. previous diagnoses, surgery, allergies, pregnancy with date of last period (day/month/year); use extra paper if necessary]

Serious Adverse Event Report for Study Conducting Phase 1 Clinical Trial Centre

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Concomitant Drug/Treatment (exclude those used to treat the SAE, use extra paper if necessary)

Drug/Treatment	Dose, Frequency & Route Used (if applicable)	Indication	Therapy Dates [day/month/year]						Causal Relationship to Event
			from			to			
									☐ associated ☐ possible associated ☐ not associated
									☐ associated ☐ possible associated ☐ not associated
									☐ associated ☐ possible associated ☐ not associated
									☐ associated ☐ possible associated ☐ not associated

Investigator

Name: ________________________ Signature:___________________ Tel: ______________________ Fax: ___________________