Serious Adverse Event Form—Initial

Participant Trial Number: ☐☐☐ - ☐☐☐ **Participant Initials:** ☐☐ **SAE Number:** ☐☐

Site:

1. EVENT TYPE: *(please confirm 'No' or 'Yes' for each category)*

	No	Yes
1.1 Death	☐	☐
1.2 Life-threatening	☐	☐
1.3 Hospitalisation or prolongation of existing hospitalisation	☐	☐
1.4 Persistent or significant disability/incapacity	☐	☐
1.5 Congenital anomaly/birth defect	☐	☐
1.6 Requires medical intervention to prevent one of the above, or it is otherwise medically significant *(please specify below)*	☐	☐

2. EVENT DETAILS:

2.1 Date event deemed serious: d d - m m m - y y y y

2.2 Date site aware of this event: d d - m m m - y y y y

2.3 Adverse events: *(Please refer to Page 3 of this form for guidance on completion of this section)*

System Organ Class (SOC)	Adverse event (CTCAE term V5.0) *(Exactly as stated in the CTCAE document)*	CTCAE Grade:

2. EVENT DETAILS CONTINUED:

2.4 Details of Event:

Please include all **relevant** details of the event, any tests performed and associated results:

_____ *(Please continue on SAE Continuation Sheet (pg.5) as necessary)*

Please add details of any **relevant** medical history, concomitant medication and associated dates of administration:

_____ *(Please continue on SAE Continuation Sheet (pg. 5) as necessary)*

NOT APPROVED

3. CAUSALITY:

3.1 Was the event related to administration of the study procedures?

☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated

3.2 Has the participant withdrawn from participation in the intervention due to this SAE? **No** ☐ **Yes** ☐

4. OUTCOME OF EVENT: *(please select one only)*

1. Resolved—no sequelae ☐ → **Date of resolution:** d d – m o n – y y y y

2. Resolved— with sequelae ☐ → **Details of sequelae:** _____ **Date of resolution:** d d – m o n – y y y y

3. Unresolved ☐ → Please complete the SAE Follow-up Form as appropriate

4. Death ☐ → Please complete Notification of Death form

5. Unresolved at time of death/withdrawal ☐ → Please complete Death Notification Form/Withdrawal Form as appropriate

(Please note: your name must be on the trial delegation log with responsibility code 12)

Practitioner assessing causality (print name): _____

Signature: _____ **Date signed:** d d – m o n – y y y y

(Please note: your name must be on the trial delegation log with responsibility code 11)

Form completed by (print name): _____

Signature: _____ **Date signed:** d d – m o n – y y y y

Completion Guidelines for Serious Adverse Event Form—Initial

Form dates	Use format: 0 6 - J U N - 1 9 5 6
Date deemed Serious	This is the date when an adverse event is considered to be serious i.e. date the AE fitted one of the event types in box 1.
Date site became aware of the event	Date the investigator team at site first became aware of this event—this may be different from the date the event was deemed to be serious. **N.B. GCP requires that investigators report all SAEs to the trial sponsor 'immediately' or at least within 24 hours of their first knowledge of the event**

NOTES FOR GRADING OVERALL SEVERITY & TOXICITY

NCI Common Toxicity Criteria for Adverse Events (V5.0)

Symptoms in section 2.3 of this SAE form should be described in accordance with the NCI Common Toxicity Criteria for Adverse Events (V5.0) (NCI CTCAE). The NCI CTCAE (V5.0) can be found here https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf
Symptoms should be recorded using the numbers linked to the System Organ Class (as listed below), the adverse event term within that class (as listed in CTCAE (V5.0),

System Organ Class (SOC)					
1.	Blood and lymphatic system disorders	10.	Immune System Disorders	19.	Psychiatric disorders
2.	Cardiac disorders	11.	Infections and infestations	20.	Renal and urinary disorders
3.	Congenital, familial and genetic disorders	12.	Injury, poisoning and procedural complications	21.	Reproductive system and breast disorders
4.	Ear and labyrinth disorders	13.	Investigations	22.	Respiratory, thoracic and mediastinal disorders
5.	Endocrine disorders	14.	Metabolism and nutrition disorders	23.	Skin and subcutaneous tissue disorders
6.	Eye disorders	15.	Musculoskeletal and connective tissue disorders	24.	Social circumstances
7.	Gastrointestinal disorders	16.	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	25.	Surgical and medical procedures
8.	General disorders and administration site conditions	17.	Nervous system disorders	26.	Vascular disorders
9.	Hepatobiliary disorders	18.	Pregnancy, puerperium and perinatal conditions		

If the SAE Continuation page is required, it must be signed and dated by both the person who has responsibility for completing the SAE Form and the Clinical member of staff responsible for assessing causality; the signatures must appear on your Site Signature and Delegation Log.

Completion Guidelines for Serious Adverse Event Form—Initial

Was the event related to administration of the study procedures?	

Unrelated:	There is no evidence of any causal relationship
Unlikely:	There is little evidence to suggest a causal relationship (e.g. because the event did not occur within a reasonable time after administration of the trial treatment). There is another reasonable explanation of the event (e.g. the patient's clinical condition, other concomitant medications).
Possibly:	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial treatment). However, the influence of other factors may have contributed to the event (e.g. the patient's clinical condition, other concomitant medications).
Probably:	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely:	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.

If an SAE Continuation Form is required, it must be signed and dated by both the person who has responsibility for completing the SAE Form and the Clinical member of staff responsible for assessing causality; the signatures must appear on your Site Signature and Delegation Log.

SAE Continuation Sheet

(Please use this sheet to continue answering question 2 - Event Details)

2.4 Details of Event:

Please include all **relevant** details of the event, any tests performed and associated results:

Practitioner assessing causality (print name): _____

(Please note: your name must be on the trial delegation log with responsibility code 12)

Signature: _____ **Date signed:**

d d - m o n - y y y y

Form completed by (print name): _____

(Please note: your name must be on the trial delegation log with responsibility code 11)

Signature: _____ **Date signed:**

d d - m o n - y y y y