Serious Adverse Event Form—Follow-up

REGAIN ID: ☐☐☐ – ☐☐☐ **Participant Initials:** ☐☐ **SAE Number:** ☐☐

Site:

1. THIS REPORT RELATES TO THE ADVERSE EVENT DEEMED SERIOUS ON: d d – m o n – y y y y

(Date must match to that stated in Section 2 of Initial Report)

2. FURTHER DETAILS OF EVENT:

2.1 Have there been any additional serious adverse event symptoms or worsening in grade of the event symptoms reported on the initial report?

Yes ☐ **No** ☐ → *Please continue to next page.*

Please complete part 2.2 below with any new or updated information.

2.2 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:**

Please include all relevant further details of the event, any additional tests performed, updated results and treatment:

_____

_____

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

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3.2 Has the participant withdrawn from participation in the intervention due to this SAE: **No** ☐ **Yes** ☐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

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

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

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

4.4 Death ☐ → Please complete Notification of Death Form

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

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

Completion Guidelines for Serious Adverse Event Form—Follow-Up

Form dates: Use format: 0 6 - J U N - 1 9 5 6

Further details of event: Please add any additional **relevant** information that has come to light since the initial report

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 participants'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 participants'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.

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) and 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 an SAE Continuation Sheet 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 - Further Details of Event)

2. Further details of event:

Please include all relevant further details of the event, any additional tests performed, updated results and treatment:

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