



# Serious Adverse Event Form—Initial

SAE Reference no.  
For trial office use only

TNO:

Age at onset:

Site:

**Please email immediately to the RECOVERY-RS Coordinating Centre to:  
WCTUQA@warwick.ac.uk & RECOVERY-RS@warwick.ac.uk**

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

	No	Yes
1. Death .....	<input type="checkbox"/>	<input type="checkbox"/>
2. Life-threatening .....	<input type="checkbox"/>	<input type="checkbox"/>
3. Hospitalisation or prolongation of existing hospitalisation .....	<input type="checkbox"/>	<input type="checkbox"/>
4. Persistent or significant disability/incapacity .....	<input type="checkbox"/>	<input type="checkbox"/>
5. Congenital anomaly/birth defect .....	<input type="checkbox"/>	<input type="checkbox"/>
6. Requires medical intervention to prevent one of the above, or it is otherwise medically significant <i>(please specify below)</i> .....	<input type="checkbox"/>	<input type="checkbox"/>

**B. EVENT DETAILS:**

1. Date event deemed serious:   -    -

2. Date site aware of this event:   -    -

3. Time event deemed serious: 24 hour clock   :

**C. EVENT DETAILS CONTINUED:**

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

*(Please continue on SAE Continuation Form as necessary)*

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

*(Please continue on SAE Continuation Form as necessary)*

**D. CAUSALITY:**

1. Was the event related to administration of the trial procedures?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Definitely	Probably	Possibly	Unlikely	Unrelated

2. Has the participant withdrawn from participation in the intervention due to this SAE:

No	Yes
<input type="checkbox"/>	<input type="checkbox"/>

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

1. Resolved—no sequelae

Date of resolution:   -    -

Time of resolution:   :    
24 hour clock

2. Resolved— with sequelae

Details of sequelae:

Date of resolution:   -    -

3. Unresolved

Please complete the SAE Follow-up Form as appropriate

Time of resolution:   :    
24 hour clock

4. Death

5. Unresolved at time of death/withdrawal

Please complete Withdrawal Form if appropriate

Clinician assessing causality (print name): \_\_\_\_\_

*(Please note: you must have read appropriate training slides and signed online training form)*

Signature: \_\_\_\_\_

Date signed:   -    -

Form completed by (print name): \_\_\_\_\_

Signature: \_\_\_\_\_

Date signed:   -    -

**Completion Guidelines Serious Adverse Event Form**

Form dates:

Use format: 

0	6	-	J	U	N	-	1	9	5	6
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Date and time deemed Serious

This is the date and time 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**

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.