Form number: 13

# Serious Adverse Event Form—Initial

sepsis adapt
Biomarker-guided antibiotic duration for sepsis

**Participant Trial Number:** ☐☐☐☐ **Participant Initials:** ☐☐ **Age at Onset:** ☐☐☐

**Randomising Site:**

***Please email immediately to the ADAPT-Sepsis Coordinating Centre at adaptsepsistrial@warwick.ac.uk***

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

| | No | Yes |
|---|---|---|
| **1.** Death | ☐ | ☐ |
| **2.** Life-threatening | ☐ | ☐ |
| **3.** Hospitalisation or prolongation of existing hospitalisation | ☐ | ☐ |
| **4.** Persistent or significant disability/incapacity | ☐ | ☐ |
| **5.** Congenital anomaly/birth defect | ☐ | ☐ |
| **6.** Other reason *(please specify below)* | ☐ | ☐ |

**B. EVENT DETAILS:**

**1. Date event deemed serious:** d d – m o n – y y y y

**2. Date site aware of this event:** d d – m o n – y y y y

**3. Details of Event:**

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

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

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

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

**C. SEVERITY ASSESSMENT:**

☐ Mild—Does not interfere with patient's usual functioning

☐ Moderate—Interferes to some extent with patient's usual functioning

☐ Severe—Interferes significantly with patient's usual functioning

☐ Fatal/Life threatening— Causes death or risk of death, organ damage or disability

**D. CAUSALITY:**

**In the opinion of the reporting clinician...**

**1.** Was the event related to the trial intervention?

*(Causality should be assessed and initialled by clinician)*

☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated

☐ *Clinicians initials*

*Please continue to Section E.*

*Please skip section E and continue to Section F*

**E. EXPECTEDNESS:**

**1. Was the event?** Expected: ☐ Unexpected: ☐

**F. 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

*(Please note: your name must be on the trial delegation log)*

**Reporting Clinician (print name):** _____

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

**Form completed by (print name):** _____

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

## SAE EVALUATION FORM *(for Trial Office use only)*

**Date adverse event information was passed to CI:** d d - m o n - y y y y

**Were further investigations requested by CI?** No ☐ Yes ☐ → **Date further investigations carried out:** d d - m o n - y y y y

**Details of investigations:**

**Date findings of further investigations passed to CI:** d d - m o n - y y y y

Is the event related to the intervention? → No ☐

Yes ☐

Is it Unexpected? → No ☐

Yes ☐

Date report sent to MREC/MHRA/sponsor (within 15 days of sponsor first aware of event): d d - m o n - y y y y

**Chief Investigators signature:** _____ **Date:** d d - m o n - y y y y

## Completion Guidelines for CRF 13 Serious Adverse Event Form

| | |
|---|---|
| Date of Birth: | Please use the following formats for dates: 06/Jun/1956. |
| 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 to become categorised as a SAE |
| Date site became aware of the event | Please enter the 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 |

**In the opinion of the reporting clinician...was the event related to the trial intervention?**

| | |
|---|---|
| **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. |

**The SAE Continuation Sheet must be signed and dated by both the person who has responsibility for completing the SAE Form and the Clinician responsible for SAE attribution; the signatures must appear on your Site Signature and Delegation Log.**