Form number: 14

Serious Adverse Event Form—Follow-up

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. 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 B. of Initial Report)

B. FURTHER DETAILS OF EVENT:

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

_____
_____
_____
_____
_____
_____
_____ *(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 question E

Please skip question E and continue to question 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: _____ d d - m o n - y y y y

Completion Guidelines for CRF 14 Serious Adverse Event Form—Follow-up report

Date of Birth: Please use the following formats for dates: 06/Jun/1956.

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

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 participant'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 participant'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.