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PARAMEDIC3
Medication Route in Cardiac Arrest

Serious Adverse Event Form—Follow-up

Participant Trial Number: ☐☐☐ - ☐☐☐☐☐ **SAE reference number** (*for trial office use only):* ☐

Please report immediately on the PARAMEDIC3 trial database or email wctuqa@warwick.ac.uk

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:

1. Have there been any additional or worsening adverse event symptoms since the initial report was submitted?

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

Please complete part 2 below with any new or updated information.

2. Location of further event: **On scene** ☐
En-route to hospital ☐
In hospital ☐

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

_____
_____
_____
_____
_____
_____

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3. CAUSALITY:

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

☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated

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 Has the participant withdrawn from participation in the intervention due to this SAE: **No** ☐ **Yes** ☐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 **Time of resolution:** ☐☐ : ☐☐ *24 hour clock*

2. Resolved— with sequelae ☐ → **Details of sequelae:** _____ Date of resolution: d d – m o n – y y y y **Time of resolution:** ☐☐ : ☐☐ *24 hour clock*

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

4. Death ☐

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

Clinician assessing causality (print name): _____ *(Please note: your name must be on the trial delegation log with responsibility code F)*

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 G)*

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

TRIAL OFFICE USE:

Received:	*Initial:*	*Checked:*	*Initial:*

Completion Guidelines for CRF PARAMEDIC3 Serious Adverse Event Form—Follow-up report

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.

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.