

Complete and fax the INITIAL report to CERU at 613 548 2428 attention: Project Leader within **24 hours** of becoming aware of the event.
 Complete one form for **EVERY** adverse event that is Serious and Unexpected. Report only those SAEs that occur from the time of randomization to the end of the study period (30 days from admission to ICU or until ICU discharge or death, whatever comes first)

Patient Information

Site number Initials Male Height (cm) Name of Site Investigator SAE #

Enrolment # DOB Female Weight (kg) Person Reporting SAE

Record the sequential SAE # for the patient i.e. for 1st SAE for this patient, write 01; For 2nd SAE for this patient, write 02.

Serious Adverse Event Reported (only one per form)

Date SAE reported

Date became aware of SAE

Seriousness (select all that apply)

- Patient died --> please document date in Outcomes
- Life threatening
- Requires or prolongs hospitalization
- Results in persistent or significant disability/incapacity
- May require medical or surgical intervention to prevent one of other outcomes.

Outcomes (at the time of initial report) - select only one

- Complete recovery/return to baseline - Date of recovery
- Alive with sequelae
- Death - death date
- SAE persisting
- Unknown/lost to follow-up

Action taken (select all that apply)

- None
- Uncertain
- Procedure or physical therapy
- Blood or blood products
- Prescription drug therapy
- Non-prescription drug therapy
- Hospitalization
- IV fluids
- Other

Action taken with Study supplements

(select only one)

- None (including not on study supplements)
- Dose reduced, interrupted or therapy delayed
- Study Supplements stopped permanently due to SAE

Relationship of SAE to Study Supplements

- Not related
- Unlikely related
- Possibly related
- Probably related

	Date (dd/mmm/yyyy)	Time(hh:mm)
Onset of SAE	<input type="text"/>	<input type="text"/>
ICU admission	<input type="text"/>	<input type="text"/>
Start of study supplements	<input type="text"/>	<input type="text"/>
Stop of study supplements	<input type="text"/>	<input type="text"/>

Signature of Site Investigator

Date