The REDOXS© Study

Serious Adverse Events (SAE) - Follow-up Report

No.

Complete and fax the Follow-up report to CERU at 613 548 2428 attention: Project Leader within **10 days of becoming aware of SAE.** The Project Leader and Study Coordinator to assess the need for additional details and further follow-up reporting.To be completed by the Site Investigator for **EVERY** initial SAE that was reported to CERU.

Patient Identification

Site # | Enrol. # | Initials | SAE #

Past medical history, comorbid illness and reason for admission to hospital

Admitting diagnosis to ICU and chronological events leading to the SAE

Chronological events proceeding SAE until time of this report

☐ Further details attached

Confirmation of unexpected nature of SAE (not due to progression of underlying disease

Relationship of SAE to study supplements vs. progression of underlying illness (based on timing of supplements, SAE)

Outcomes (at time of fnal report)

◯ Complete recovery/return to baseline - Date or recovery

◯ Alive with sequelae

◯ Death - death date

◯ SAE persisting

◯ Unknown/lost to follow-up

Relationship of SAE to study supplements

◯ Not related ◯ Possibly related

◯ Unlikely related ◯ Probably related

Action taken with Study supplements

◯ None (including not on study supplements)

◯ Dose reduced, interrupted or therapy delayed

◯ Study Supplments stopped permanently due to SAE

Action taken

◯ None ◯ Hospitalization

◯ Uncertain ◯ IV fluids

◯ Procedure or physical therapy ◯ Other, specify

◯ Blood or blood products

◯ Prescritption drug therapy

◯ Non-prescription drug therapy

Summary ☐ Further details attached

Signature of Site Investigator

Date

Print Form

Version: 20Feb2009

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Please use the following space to report further details concerning the SAE.

Concomitant Medications (List all concomitant medications given within 48 hours preceding the onset of the event)

Laboratory Results and Investigations (Related to the SAE) ☐ No relevant results to report

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Further Details Concerning the SAE ☐ No further details to report