



The *REDOXS*[®] Study
REducing DEaths due to OXidative STress

A randomized trial of glutamine and antioxidant supplementation in critically ill patients

Serious Adverse Events

This study is registered at Clinicaltrials.gov.
Identification number NCT00133978

Definition of a Serious Adverse Event

A **Serious Adverse Event (SAE)** is defined as any untoward medical occurrence that at any dose:

- Results in death.
- Is life-threatening (refers to an event in which the study participant was, in the opinion of the qualified investigator (QI), at risk of death from the event if medical intervention had not occurred. NOTE: This does not include an event that hypothetically had it occurred in a more serious form, might have caused death).
- Requires in patient hospitalization or prolongation of existing hospitalization.
- Results in persistent or significant disability/incapacity (i.e. a substantial disruption in an individual's ability to conduct normal life functions).
- Is a congenital anomaly or birth defect.
- Other medically important condition (Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious events when, based on medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above).

Adverse Events

Adverse events are any untoward medical occurrences in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. Given the high acuity of diseases and morbidity related to critical illness, for the REDOXS[®] Study, adverse events are NOT to be reported to CERU.

Unexpected Serious Adverse Event (SAE)

For the purposes of the REDOXS[®] Study, given the population of critically ill patients with organ dysfunction, an unexpected SAE is defined as an event that is serious, i.e. fits the above definition, and is NOT expected due to the progression of the underlying disease or co-morbid illnesses.

All unexpected and serious adverse events MUST be reported to Clinical Evaluation Research Unit (CERU) within 24 hrs of becoming aware of the event, regardless of the relationship of the study supplements to the event.

Expected Serious Adverse Event

Expected SAEs, including deaths, which are serious adverse events but are expected due to the progression of the underlying disease or co-morbid illnesses are NOT to be reported to CERU.

What should be reported to the Clinical Evaluation Research Unit (CERU)?

All serious (according to definition above) and unexpected adverse events MUST be reported to CERU, regardless of whether they are felt to be related to the study supplements (in the opinion of the Site Investigator) or not.

Examples of serious and unexpected SAEs:

A 30 yr. patient admitted with a drug overdose develops a ST segment elevation and a myocardial infarction. This is **unexpected** and should be reported to CERU within **24 hrs** of becoming aware of this event.

vs.

A 65 yr old patient with a history of coronary artery disease that presents with septic shock develops positive troponin levels and ECG changes. This is **expected** and does not need to be reported to CERU.

What about unexpected death?

All serious events that result in unexpected death **MUST** be reported to CERU within **24 hrs** of becoming aware of the event. For example: a patient with sepsis is improving and getting better but then dies unexpectedly the next morning. This is a serious adverse event (results in death) and was unexpected and is to be reported immediately.

Examples of serious and expected SAEs:

For example, a mechanically ventilated patient develops pneumonia. This is a serious adverse event but since pneumonia is expected, this does not need to be reported.

NOTE: As a guideline, events that are captured in the Case Report Forms (CRFs) such as phlebitis, ICU acquired infections, dialysis, organ failures, etc are considered to be expected events and hence do not need to be captured as SAEs.

What about expected death?

For example, a patient with fulminant sepsis is not improving, now has multi-organ system failure. Family has agreed to withdraw treatment and patient dies. This is a serious adverse event but death was expected due to the progression of the underlying disease (sepsis). Do not need to report to CERU.

As with any study there may be other risks or side effects that we do not know about with administration of these study supplements. The Site Investigator must adhere closely to the ICH-GCP Guidelines, however when in doubt he/she can contact the Project Leader for the study.

Unblinding

As established by the Sponsor and the Steering Committee, the investigational products used in the REDOXS study[®] are nutrients that are not associated with known risks and there are no antidotes to the nutrients.

In the event of a serious adverse event, the treatment of the patient in the REDOXS[®] Study is **not** dependent on the knowledge of the study treatment code. It has been established by the Sponsor and the Data Monitoring Committee (DMC) for the REDOXS[®] study that Code breaking (or unblinding) procedures will **only** be requested by the DMC.

In the event that the research site is concerned about the well being of the research participant, they are instructed to stop the study supplements and contact the Project Leader.

Time Frames for SAEs reporting by Sites to CERU

Time Frames for sites to CERU

This reporting is done in **2 phases**:

1. The **Serious Adverse Events Initial Report** *must* be completed and faxed to CERU **within 24 hrs** of becoming aware of each event.
2. The **Serious Adverse Events Follow-up Report** *must* be completed and faxed to CERU **within 10 days** from becoming aware of the event. The Project Leader will collaborate with the Study Coordinator to assess the need for additional details and further follow-up reporting.

Both forms must be completed by the Site Investigator/delegate, or the Study Coordinator in consultation with the Site Investigator/delegate.

Refer to SAE Reporting by sites Algorithm on next page

SAE Reporting by sites to the Clinical Evaluation Research Unit (CERU)

**Serious if:*

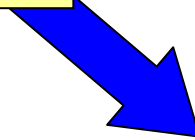
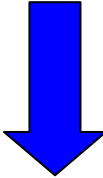
- *Results in death*
- *Is life threatening*
- *Requires or prolongs in-patient hospitalization*
- *Results in persistent or significant disability/incapacity*
- *May require medical or surgical intervention to prevent one of the other outcomes to defining serious*

To be reported, the event needs to be both **Serious* and Unexpected****

Study Coordinator (SC) or Site Investigator (SI) identifies SAE

** *Unexpected if:*

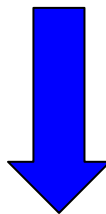
not expected due to the progression of the underlying disease or co-morbid illnesses.



SC faxes the SAE **initial** report to the Project Leader **within 24 hours** of becoming aware of the event (# 613 548 2428) **plus**

- **concomitant medications**
(given within the 48 hours preceding the SAE)
- **lab values**
(related to the SAE)

SC reports SAE to local Ethics Board as per required timelines



SC faxes the SAE **follow-up** report to the Project Leader **within 10 days** from becoming aware of the event (fax # 613 548 2428).

The Project Leader will collaborate with the Study Coordinator to assess the need for additional details and further follow-up reporting.

Initial SAE Report

All Serious Adverse Events that are unexpected must be reported to CERU **within 24 hrs** of becoming aware of the event by filling out the **Serious Adverse Events Initial Report (see next page)**.

The initial report can be downloaded off the REDOXS website under the Welcome, Home Page (Site Status Page) or can be downloaded off www.criticalcarenutrition webpage (Click REDOXS® Study, Resources, Study Procedures Manual).

This form must be completed by the Site Investigator/delegate in consultation with the Study Coordinator and requires the signature of the Site Investigator.

Only include those SAEs that occur during the study period. This includes the timeframe from the time of randomization to the end of the study period (actual ICU discharge, death or Study Day 30). For a SAE that occurred during the study period and is still not resolved by the end of the study period, refer to section on SAE follow up.

All known data elements on the form must be completed within 24 hrs of discovery of the event. It may be that certain aspects of the form may change (for example, the resolution date may not be known at the time of reporting) and this should be made clear in the narrative form that will follow at a later date.

The following fields of the Initial form must be completed:

- Patient identification
 - Your REDOXS® **site number**
 - REDOXS® **enrolment number**
 - Patient's **initials**
 - **DOB** (date format dd/mmm/yyyy)
 - Gender, select **male** or **female**
 - **Height** (cm)
 - **Weight** (kg)
- **Name of Site Investigator**
- **Name of person reporting the SAE**
- **SAE #:** Record the sequential SAE # for the patient; i.e. for the first SAE for the patient, enter 01. For the second SAE for the patient, enter 02.
- **Serious Adverse Event Reported (only one per form):**
Record the event that you are reporting (must be serious and unexpected).

Do NOT record death (outcome) as a SAE but the underlying cause of death.

Do not record respiratory failure as a SAE but what was felt to cause the respiratory failure i.e. sepsis.

- **Date SAE reported**
- **Date became aware of SAE**
- **Seriousness of the SAE:** (select all that apply: patient died, life threatening, requires or prolongs hospitalization, results in persistent or significant

disability/incapacity; may required medical or surgical intervention to prevent one of the other outcomes).

- **Outcomes:** Select the most appropriate at the time of the initial report: complete recovery/return to baselines (include date of recovery), alive with sequelae, death (include date of death), SAE persisting, unknown/lost to follow up
- Record the date and time for the following:
 - **Onset of SAE**
 - **ICU admission**
 - **Start of study supplements**
 - **Stop of study supplements**
 - **Resolution of SAE**
- **Action taken:** Select all that apply from the following – none, uncertain, procedure or physical therapy, blood of blood products, prescription drug therapy, non-prescription drug therapy, hospitalization, IV fluids, other.
- **Action take with Study Supplements:** none (including not on study supplements), dose reduced, interrupted or therapy delayed (include date/time), study supplements stopped permanently due to SAE (include date/time).
- **Relationship of SAE to the study supplements:** The determination of the relationship of the event to the supplements is to be done by the Site Investigator/delegate in collaboration with the Study Coordinator. To assist the Investigator in making this assessment, the following definitions have been provided:
 - **Not related:** A serious adverse event that is clearly due to extraneous causes (disease, environment, etc.) and does not meet the criteria for drug relationship listed under “Possibly” or “Probably”.
 - **Unlikely related:** A serious adverse event that is more likely due to other causes than study nutrients.
 - **Possibly related:** Suggests that the association of this SAE with the study drug is unknown and the event is not reasonably supported by other conditions.
 - **Probably related:** Suggests that a reasonable temporal sequence of this SAE with study drug administration exists and the association of the event with the study drug seems likely.

Once SAE form completed fax to CERU at # **613-548-2428**

Attention: Project Leader REDOXS[®]

See the following page for an example of a completed Initial Report.

Example of a completed Initial SAE Report

The REDOXs[®] Study
Serious Adverse Events (SAE) - Initial Report
1

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 d/c or death, whatever comes first)

Patient Information

Site number Initials Male Height (cm)

Enrolment # DOB Female Weight (kg)

Name of Site Investigator

Person Reporting SAE

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

	Date (dd/mm/yyyy)	Time (hh:mm)
Onset of SAE	<input type="text" value="28-Jul-2007"/>	<input type="text" value="12:50"/>
ICU admission	<input type="text" value="27-Jul-2007"/>	<input type="text" value="02:00"/>
Start of study supplements	<input type="text" value="28-Jul-2007"/>	<input type="text" value="07:00"/>
Stop of study supplements	<input type="text" value="28-Jul-2007"/>	<input type="text" value="13:00"/>

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 Possibly related

Unlikely related Probably related

Signature of Site Investigator

Date

Complete Follow up report within required timelines

Follow-up SAE Report

The **Serious Adverse Events Follow-up Report** must be completed and faxed to CERU within this time frame:

- within 10 days from becoming aware of the event.

In the event that the event has not resolved, explained or stabilized, the Project Leader will collaborate with the Study Coordinator for additional details and further follow-up reporting.

The follow-up report can be downloaded off the REDOXS website under the Welcome, Home Page (Site Status Page) or can be downloaded off www.criticalcarenutrition webpage (Click REDOXS® Study, Resources, Study Procedures Manual).

This form **must be completed by the Site Investigator/designate** by reviewing the Serious Adverse Events Report (Initial) and the patient's medical chart. To make this process easier, it is strongly recommended that this be done as close to the event as possible.

Since the information in the Follow-up Report will be reviewed by the Data Monitoring Committee, it **must** include details on the patients admitting diagnosis, co-morbidities, a chronological complete narration of the events leading to the SAE, the nature of the SAE, action taken with the study supplements, the outcome and the relationship to the study supplements.

The following additional documentation is required and is to be attached to the follow-up report:

- Medication the patient received in the 48 hours before the onset of the SAE
- Laboratory results related to the SAE must also be provided.
 - Examples: if the event is cardiac arrest, provide cardiac enzymes; if the event is cholestasis/pancreatitis, provide liver function tests & amylases. For further clarification about which lab tests are relevant, the Study Coordinator is encouraged to ask the Site Investigator.
 -

All data fields in the follow-up form must be completed:

- **Patient identification: Site #, Initials, enrolment # and SAE #** can be copied from in initial reporting form.
- **Patient medical history, comorbid illness and reason for admission to hospital:** provide a detailed narrative of this information.
- **Admitting diagnosis to ICU and chronological events leading to the SAE:** provide a detailed narrative of this information
- **Confirmation of Unexpected nature of the SAE:** record the pertinent clinical features that, in the opinion of the Site Investigator, made him/her think that the event was unexpected.
- **Relationship of the SAE to the study supplements vs. progression of underlying disease:** If the event is considered to be related to the study supplement, record the pertinent clinical features that, in the opinion of the Site Investigator, made him/her think that the event was related to the study supplements vs. the progression of underlying disease. Refer to the definitions of

degree of relationship to the study supplements (not related, unlikely related, possibly related, probably related).

- **Outcomes:** Select the most appropriate at the time of the FOLLOW-UP report: complete recovery/return to baselines (include date of recovery), alive with sequelae, death (include date of death), SAE persisting, unknown/lost to followup
- **Action taken:** Select all actions taken from the onset of SAE; including those that occurred between the initial report and the follow-up report) – none, uncertain, procedure or physical therapy, blood of blood products, prescription drug therapy, non-prescription drug therapy, hospitalization, IV fluids, other.
- **Action take with Study Supplements:** none (including not on study supplements), dose reduced, interrupted or therapy delayed (include date/time), study supplements stopped permanently due to SAE (include date/time).
- **Relationship of SAE to the study supplements:** The determination of the relationship of the event to the supplements is to be done by the Site Investigator/delegate in collaboration with the Study Coordinator. To assist the Investigator in making this assessment, the following definitions have been provided:
 - **Not related:** A serious adverse event that is clearly due to extraneous causes (disease, environment, etc.) and does not meet the criteria for drug relationship listed under “Possibly” or “Probably”.
 - **Unlikely related:** A serious adverse event that is more likely due to other causes than study nutrients.
 - **Possibly related:** Suggests that the association of this SAE with the study drug is unknown and the event is not reasonably supported by other conditions.
 - **Probably related:** Suggests that a reasonable temporal sequence of this SAE with study drug administration exists and the association of the event with the study drug seems likely.

The completed-**Follow-up Report must** be signed by the Site Investigator and **copies of the relevant medication and lab documentation must be** faxed to CERU at:

613-548-2428

Attention: Project Leader, REDOXS®

See the following page for an example of a completed Follow-up Report.

SAE Follow up

Any subject who experiences a serious adverse event during the study period, should be followed by the Study Coordinator until the event:

- (1) resolves
- (2) an outcome is reached, or
- (3) the event is otherwise explained or stabilized.

The Project Leader will follow up with the Study Coordinator at the site to obtain documentation regarding the status of the subject. This information will be forwarded to the Data Monitoring Committee.

If follow-up information reveals that the event no longer meets the serious, unexpected, or drug related criteria, this information will be provided to Health Canada/other Regulatory authorities, the Data Monitoring Committee, Steering Committee & Fresenius-Kabi.

Example of a completed Follow-up SAE Report

The REDOXS [®] Study		Serious Adverse Events (SAE) - Follow-up Report		No. <input style="width: 50px;" type="text" value="1"/>
<p>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.</p>				
Patient Identification	<input type="text" value="01"/>	<input type="text" value="12"/>	<input type="text" value="CL"/>	<input type="text" value="01"/>
<p>Chronological events preceding SAE until time of this report</p> <div style="border: 1px solid black; padding: 5px; min-height: 100px;"> <p>Patient returned from OR 27/07/07. Cardiac arrest, pacer wires non functioning, no capture; no cardiac output</p> </div>		<p>Past medical history, comorbid illness and reason for admission to hospital</p> <div style="border: 1px solid black; padding: 5px; min-height: 100px;"> <p>DMII, COPD, hiatus hernia</p> </div>		<p>Admitting diagnosis to ICU and chronological events leading to the SAE</p> <div style="border: 1px solid black; padding: 5px; min-height: 100px;"> <p>CABG X2 July 27, 2007; on IABP, pressor support. Cardiac arrest; resuscitation attempts unsuccessful</p> </div>
<p>Outcomes (at time of final report)</p> <p><input type="radio"/> Complete recovery/return to baseline - Date or recovery <input style="width: 50px;" type="text"/></p> <p><input type="radio"/> Alive with sequelae</p> <p><input checked="" type="radio"/> Death - death date <input style="width: 50px;" type="text" value="28-Jul-2007"/></p> <p><input type="radio"/> SAE persisting</p> <p><input type="radio"/> Unknown/lost to follow-up</p>		<p>Confirmation of unexpected nature of SAE (not due to progression of underlying disease)</p> <div style="border: 1px solid black; padding: 5px; min-height: 100px;"> <p>Pt was improving overall. Less inotizopie/vasopressor requirements. Onset of asystole/cardiac arrest was unexpected</p> </div>		<p>Relationship of SAE to study supplements vs. progression of underlying illness (based on timing of supplements, SAE)</p> <div style="border: 1px solid black; padding: 5px; min-height: 100px;"> <p>No relationship</p> </div>
<p>Action taken</p> <p><input type="radio"/> None</p> <p><input type="radio"/> Uncertain</p> <p><input checked="" type="radio"/> Procedure or physical therapy</p> <p><input type="radio"/> Blood or blood products</p> <p><input checked="" type="radio"/> Prescription drug therapy</p> <p><input type="radio"/> Non-prescription drug therapy</p> <p><input type="radio"/> Hospitalization</p> <p><input checked="" type="radio"/> IV fluids</p> <p><input type="radio"/> Other, specify <input style="width: 100px;" type="text"/></p>		<p>Relationship of SAE to study supplements</p> <p><input checked="" type="radio"/> Not related</p> <p><input type="radio"/> Unlikely related</p> <p><input type="radio"/> Possibly related</p> <p><input type="radio"/> Probably related</p>		<p>Action taken with Study supplements</p> <p><input type="radio"/> None (including not on study supplements)</p> <p><input type="radio"/> Dose reduced, interrupted or therapy delayed <input style="width: 50px;" type="text"/> <input style="width: 50px;" type="text"/></p> <p><input checked="" type="radio"/> Study Supplements stopped permanently due to SAE <input style="width: 50px;" type="text" value="28-Jul-2007"/> <input style="width: 50px;" type="text" value="11:00"/></p>
<p>Signature of Site Investigator <input style="width: 200px;" type="text"/></p>		<p>Date <input style="width: 100px;" type="text" value="31-Jul-2007"/></p>		<p>Summary</p> <div style="border: 1px solid black; padding: 5px; min-height: 100px;"> <p>Patient suffered a terminal cardiac arrest following salvage cardiac bypass grafting.</p> </div>
				<p>Print Form</p>

Time Frames for SAEs reporting by CERU to Health Canada and other Regulatory Bodies

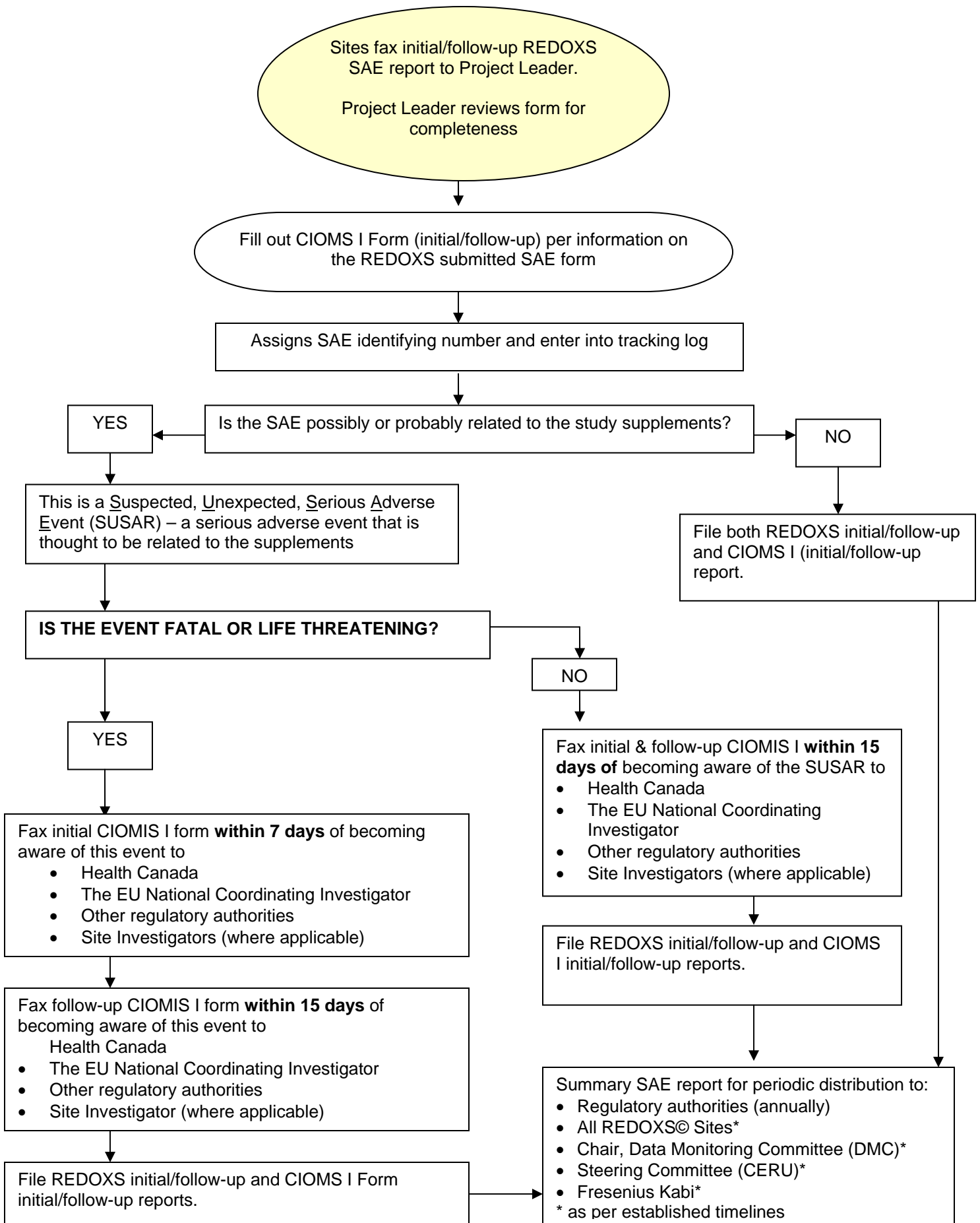
The Project Leader will report, using the CIOMIS form:

1. All serious and unexpected adverse events that are considered to be **related** to the study supplements to Health Canada and other Regulatory authorities within the time frames specified ⁽¹⁾:
 - fatal or life-threatening SAEs:
 - immediately where possible and in any event within 7 days of becoming aware of the event
 - a follow-up report no later than 15 days from becoming aware of the event
 - non fatal/life threatening SAEs:
 - no later than 15 days from becoming aware of the event
2. A summary of all SAEs (related and unrelated), including a SAE Tracking Form will be forwarded to the Chair of the Data Monitoring Committee (DMC), Steering Committee (CERU), all participating sites, Regulatory authorities and Fresenius Kabi as per established time frames-

Each REDOXS[®] site must provide proof to the CERU that the summary SAE report was sent to the local REB. This can be a copy of the local REB's acknowledgement of receipt or a copy of the cover letter sent by site to the local REB.

Refer to SAE Reporting Algorithm by CERU and the CIOMIS form template on the following pages.

SAE Reporting by Clinical Evaluation Research Unit (CERU)



CIOMIS Form Template

SUSPECT ADVERSE REACTION REPORT (CIOMS)				Reported on behalf of the Principal Investigator by: Clinical Evaluation Research Unit Kingston General Hospital 76 Stuart Street, Angada 4, Kingston, ON K7L 2V8					
SAE #									
I EVENT DESCRIPTION									
1. PATIENT INITIALS	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE YRS	3. SEX	4-6 reaction onset		8-12 CHECK ALL APPROPRIATE TO EVENT:
		day	month	year			day	month	
DESCRIBE EVENT: Study Title: The REDOXs® Study: A randomized trial of Glutamine and antioxidant supplementation in critically ill patients. Patient <randomization number> / <initials>, a/an <age>-year-old <race> <sex> admitted to the ICU on <date> with history of <condition(s)>. Patient presented with <diagnosis/symptoms>. The relevant past medical history includes: <med history>. Past surgeries include: <surg history>. Allergies include: <list here>. The patient was enrolled in the REDOXs® Study and began to receive blinded study treatment both enterally and parenterally (Antioxidant; Glutamine; Antioxidant and Glutamine; or Placebo) on <date> at <time> hours. The study supplements were continued until <date> at <time> hours for a total of <number of hours/minutes>. The SAE was identified as <event>. The onset of the event was <date> @ <time>. <Describe the event and the chronological events preceding this event>. This SAE was unexpected and was not related to the progression of the underlying disease. Investigations included <tests, investigations>. Treatment included: <interventions>, <medications to treat SAE>, <discharge medications>. Concurrent medications include (i.e. medications patient received in the 48 hrs before onset of SAE): <Vasopressor Drug Infusions, IV Drug Infusions, Daily Medications, PRN Medications>. The study medication <action taken with study drug> for <#> days during hospitalization. The event <resolution, provide date>. The patient <patient status in trial> the study. The Primary Investigator determined that the Event was <not related, unlikely related, possibly related or probably related> to the study medication and due to <event causality>.								<input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENCE OF SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> MEDICALLY SIGNIFICANT	
13. RELEVANT TESTS/LABORATORY DATA Laboratory investigations revealed <investigations>									
II DRUG INFORMATION									
14. IDENTIFIED DRUG(S) Blinded: Antioxidant; Glutamine; Antioxidant and Glutamine; or Placebo						20. DID EVENT ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A			
15. DAILY DOSE Enteral 480 ml/day Parenteral 240 ml/day			16. ROUTE OF ADMINISTRATION I.V. Infusion and/or feeding tube			21. DID EVENT REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A			
17. INDICATION(S) FOR USE Organ failures									
18. THERAPY DATES (From/To) <<start date - stop date>>			19. THERAPY DURATION <<number of days received supplements>>						
III CONCOMITANT DRUGS AND HISTORY									
22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (exclude those used to treat the adverse event)									
<Drug Name>	<Dose>	<Route>	<Onset Date>	<End Date>	<Indication>				

CIOMIS Form Template

23. OTHER RELEVANT HISTORY <i><Past Medical History & Known Allergies></i>		
IV. MANUFACTURER		
24a NAME & ADDRESS OF MANUFACTURER Fersenius Kabi Deutschland GmbH Kabi Strategic Business Center Medical Scientific Affairs – Nutrition Therapy D – 61346 Bad Homburg		Company Remarks: <<Comments for Health Canada>>
Study No.: The REDOXs® Study Patient No.:	24b MFR CONTROL NO. <<SAE case #>>	
24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL	
DATE OF THIS REPORT:	25a REPORT TYPE: <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP <input type="checkbox"/> FINAL	
SAE reported by:	<name>	<title>
Causality assessment by:	<name>	<title>
Sponsor assessment (circle one)	Agree Disagree Comments:	