The REDOXS© Circular

September 2008 Issue # 14

Clinical Evaluation Research Unit

The *REDOXS*© Study
REducing Deaths due to OXidative Stress

September was a slow month with only 13 enrolments and as such we were well below our target.

Very soon we will welcome 5 German ICUs to the study. Additionally, 5 ICUs from the United States will hopefully be on board by the end of 2008.This will take us to a grand total of 35 sites, and is expected to help with enrolment.

Recording the timing of organ failures

For the REDOXS© Study we ask that when screening a potential patient against the inclusion criteria that you go back to the onset of organ failure to ensure the organ failures are related to their acute illness. As such these organ failures may occur for example, on the ward, in the ER or in the OR.

In order to help facilitate the Source Verification process, it is suggested that when you collect the times and dates of the organ failures that you write down the location of the information in the medical chart on your REDOXS worksheets. This may also be useful for other pieces of data recorded on the worksheets.

Pharmacy

SHELF LIFE EXTENTSION

Fresenius-Kabi has notified us that the REDOXS© enteral products are being given extended expiration dates.

All site pharmacies will receive information about the shelf life extension in an upcoming email.

Stay Tuned!

Correction

In last month's newsletter, the August enrolment tally for some sites was calculated incorrectly. Please see the Enrolment table below for both August and September

876 patients to go!

Enrolment Update

Sites Currently Enrolling	Total (as of Sept 30/08)	August	September
Kingston General	42	4	0
St. Joseph's Hamilton	11	1	1
Ottawa General	49	2	3
Ottawa Civic	23	1	1
Vancouver General	9	1	0
Sacre Coeur, Montreal	31	2	1
Maisonneuve-Rosemont, Montreal	9	0	1
Royal Victoria, Montreal	8	0	0
Royal Alexandra	12	0	1
Grey Nun's, Edmonton	6	0	0
Victoria General	1	0	0
London Health Science Centre	9	0	0
Health Science Centre, Winnipeg	6	0	1
Queen Elizabeth II HCS (Halifax)	3	0	1
St. Paul's, Vancouver	2	0	0
Montreal General	7	0	0
L'Enfant Jesus (Quebec City)	8	0	2
Leige, Belgium	1	0	0
CHUV, Switzerland	5	0	0
Royal Jubilee Hospital, Victoria, BC	2	0	1
244 + 80 (from pilot) = 324 total (as of September 30, 2008)			

REDOXS© Study Contact Information
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Some findings.....

We appreciate your efforts to lock and finalize REDOXS© eCRF in a timely fashion because it allows us to begin preliminary analysis of the data. Some interesting preliminary findings are listed below.

- At the recent European Society of Enteral and Parenteral Nutrition Conference, we presented a poster highlighting that 97% and 99% of study participants received enteral and parenteral study supplements respectively. However, approximately 78% of patients who received enteral supplements had protocol violations, that is the patient received < 80% of prescribed volumes). The adoption of strategies to improve the delivery of enteral study supplements such as motility agents and small bowel feedings were used in only 51.9% and 28% of patients with protocol violations.
- In a recent abstract submission to the American Society for Parenteral and Enteral Nutrition we found that 85% of patients in enrolled in the REDOXS© Study received enteral nutrition but 98.5% of these patients received <80% of the prescribed calories on at least one day. Of these patients, 55% had high gastric residual volumes and only 78% and 41% of these patients were given motility agents or had small bowel feeds respectively.

Conclusions: Please help us optimize delivery of enteral study supplements and enteral nutrition by using motility agents and small bowel feedings.

Primary Diagnosis

In the electronic case report form you are asked to identify the Primary ICU Diagnosis. This is the diagnosis that resulted in the patient's admission to ICU. If the diagnosis cannot be found in the eCRF taxonomy, look in the relevant category and select the "other" option and type in the diagnosis in the text box provided.

The following conditions should not be entered as the Primary ICU Diagnosis.

- Hypotension
- Respiratory Failure
- Renal Disease
- Coronary angiogram-stenting

We ask that the Site Investigator and Research Coordinator identify the underlying cause of the condition as the Primary ICU Diagnosis.

Research Team at CERU

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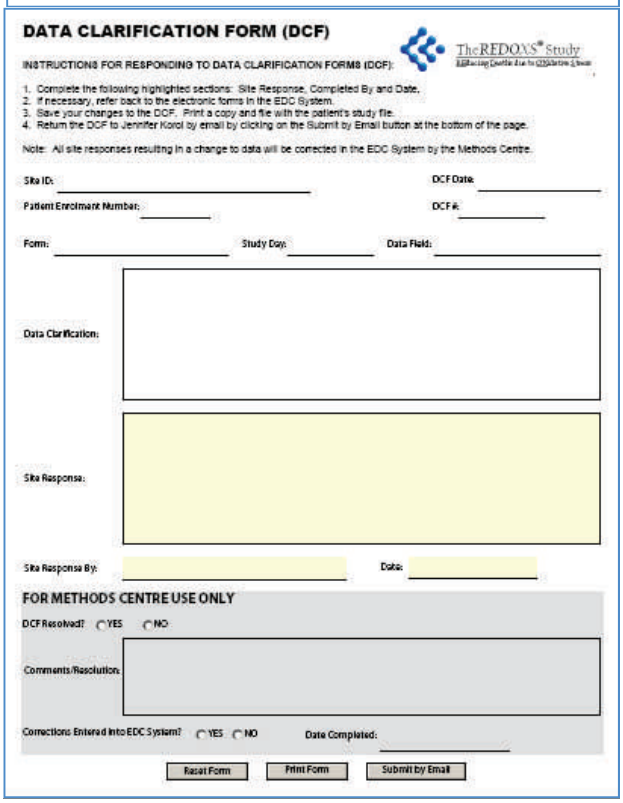
Data Query Process and the Data Clarification Form (DCF)

We mentioned in the July 2008 REDOXS© Circular that we implemented a process to address data inconsistencies with participating sites. Moving forward, we will ask for formal clarification of data via email. Attached to the email will be a Data Clarification Form (see below). The Research Coordinator will be asked to respond to the data query, complete and email the form back to the Methods Centre. Accompanying this month's newsletter are the instructions for emailing the completed form.

Some sites will be familiar with this data query process already. As we continue to examine more of the data as the study progresses, please be prepared to respond to these queries in a timely manner.



DATA CLARIFICATION FORM (DCF)

The REDOXS© Study

INSTRUCTIONS FOR RESPONDING TO DATA CLARIFICATION FORMS (DCF):

1. Complete the following highlighted sections: Site Response, Completed By and Date.
2. If necessary, refer back to the electronic forms in the EDC System.
3. Save your changes to the DCF. Print a copy and file with the patient's study file.
4. Return the DCF to Jennifer Korol by email by clicking on the Submit by Email button at the bottom of the page.

Note: All site responses resulting in a change to data will be corrected in the EDC System by the Methods Centre.

Site ID: _____ DCF Date: _____

Patient Enrolment Number: _____ DCF #: _____

Form: _____ Study Day: _____ Data Field: _____

Data Clarification:

Site Response:

Site Response By: _____ Date: _____

FOR METHODS CENTRE USE ONLY

DCF Resolved? ○ YES ○ NO

Comments/Resolution:

Corrections Entered into EDC System? ○ YES ○ NO Date Completed: _____

Reset Form | Print Form | Submit by Email

Elevated Urea in Patients with Renal Disease

If your site REDOXS© team has concerns about elevated urea levels in patients with renal disease, please refer to the guidelines in the Administration of Study Supplement Manual , Appendix II Algorithm for Elevated Urea in patients with Renal Disease. (pg 12-14)

Good Questions !!

I have a REDOXS© patient who does not want to answer one of the questions of the SF36 questionnaire. Can I leave it blank in the eCRF?
Yes, a question can be left blank on the SF36 in the eCRF. However, please make sure you write a note in the comment field on the 3 or 6 Month Information Page about which questions were not answered. This will prevent us from querying you about this missing piece of data.

I have a potential REDOXS© patient with 2 organ failures but in addition the patient has chronic renal failure. Does this renal failure meet the inclusion criterion?
If the patient has chronic renal failure requiring dialysis, this renal failure cannot be used to meet the renal failure inclusion criterion. In this case two other organ failures must be present for the patient to be eligible. (Thanks to Betty Jean Ashley for the question)