



**Clinical Evaluation Research Unit**

First and foremost, Dr. Heyland and the REDOXS<sup>®</sup> Team would like to thank you for your patience during the REDOXS<sup>®</sup> website shutdown. We apologize for the inconvenience this caused and we would like to acknowledge everyone's attempts at trying to keep our August enrolment goal on track. The problem occurred during the re-boot of the system after a hardware upgrade. Unfortunately we missed 5 potential enrolments as a result of the website problem. On a positive note, we were able to enrol 11 patients this month.

We have worked with some of you to resolve some data inconsistencies resulting from the website issues. Please do not hesitate to contact us if you come across any problems with data you've entered. Our system is backed up regularly and as such our IT personnel will work to retrieve any missing data resulting from this incident.

**Congratulations to Kingston General Hospital for enrolling 4 patients in August.**

**Ottawa General and Sacre Coeur were close behind with 2 enrolments each. Well done!**

## 889 patients to go!

### Enrolment Update as of August 31, 2008

Sites Currently Enrolling	Total	August
Kingston General	42	4
St. Joseph's Hamilton	10	1
Ottawa General	46	2
Ottawa Civic	22	1
Vancouver General	9	1
Sacre Coeur, Montreal	30	2
Maisonneuve-Rosemont, Montreal	8	0
Royal Victoria, Montreal	8	0
Royal Alexandra	11	0
Grey Nun's, Edmonton	6	0
Victoria General	1	0
London Health Science Centre	9	2
Health Science Centre, Winnipeg	5	1
Queen Elizabeth II HCS (Halifax)	2	0
St. Paul's, Vancouver	2	2
Montreal General	7	0
L'Enfant Jesus (Quebec City)	6	4
Leige, Belgium	1	0
CHUV, Switzerland	5	2
Royal Jubilee Hospital, Victoria, BC	1	0
231 + 80 (from pilot) = 311 total		

#### SAE REPORTING - EFFECTIVE NOW!

Effective September 15, 2008 **it is required that all SAEs be reported to the Methods Centre within 24 hours of becoming aware of the event.** As outlined in the Research Coordinators conference call in June, this is a decrease in the reporting timeframe from 48 hours to 24 hours. This change helps the Methods Centre be compliant with European requirements.

Please remember that for all SAEs, you are asked to submit documentation of all concomitant medications given 48 hours before the onset of the event and all lab values relevant to the reported SAE.

#### SITE PAYMENTS

Site payments are processed quarterly. These payments are based on the number of locked or finalized patients and any completed SF36 questionnaires in the quarter.

Since, we are almost at the end of the third quarter, this is a reminder to the REDOXS<sup>®</sup> Research Coordinators to lock and/or finalize your eCRFs.

Please contact Suzanne Biro, Project Assistant, if you have any questions about your payment ([biros@kgh.kari.net](mailto:biros@kgh.kari.net) or 613 549 6666 x6686)

## ATTENTION PHARMACY

### EXTERNAL PHARMACY AUDITING COMING SOON

As you know, the Methods Centre must verify that all REDOXS<sup>®</sup> site pharmacies are compliant with the study protocol in a manner that protects the rights/well being of the patients and that the dispensing of the investigational products is accurate and complete. Many of you have inquired about pharmacy site monitoring visits. We have finalized our auditing process which will be done remotely rather than with a site visit.

An independent monitor will be contacting the REDOXS<sup>®</sup> site pharmacists/technicians very soon to arrange a mutually convenient time frame for the auditing to occur. The monitor will source verify high priority data elements on the pharmacy logs for, initially, 2 locked patients per site. The need for additional auditing at each site will be determined by the Methods Centre and will be based on the he results from the initial audit.

More details coming soon!

### Research Team at CERU

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### REMINDER:

#### DURATION OF DATA COLLECTION

All data including daily data, daily nutrition data, vasopressors and concomitant medication needs to be collected from Study day 1 and each day following until day 30 unless ICU discharge (actual) or death occurs before day 30. The exceptions are as follows:

##### Study Supplement Compliance

Collect data for duration of the study supplements (which is a maximum of 28 days from randomization).

##### Microbiology

Collect data 7 days prior to ICU admission until day 30, unless ICU discharge (actual) or death occurs before day 30.

##### Antibiotics

Collect data 7 days prior to ICU admission and data collection may extend beyond ICU discharge.

##### ICU stay < 5 days and transferred to ward

Collect all daily data from Study Day 1 and continue for 5 days in total = 120 hrs.

### CLARIFICATION

In Issue #4 (November 2007), there was an error on page 2 regarding daily data - gastric residual volumes and volumes discarded.

We originally said:

- ◆ *Hint: gastric residual volumes discarded can be equal to but can **never be less** than the total gastric residual volume (= volume measured).*

We should have said:

- ◆ *Hint: gastric residual volumes discarded can be equal to but can **never be greater** than the total gastric residual volume (= volume measured).*

We apologized if this caused any confusion

### PROTOCOL VIOLATIONS

We have started our data validation process and our initial reviews of the data highlight that protocol violations have not been consistently sent to the Methods Centre.

Please refer to the Protocol Violation section of your REDOXS Implementation Manual for further information.

### NEW ADDITIONS

The bacterium ***Aerococcus sp.*** has been added to the micro taxonomy on the eCRF.

The antibiotic **Valacyclovir** has been added to the antibiotic taxonomy on the eCRF.

## Good Questions !!

**In the collection of daily data, we are asked to indicate the worst P/F ratio. If I have both non-ventilated P/F ratios and ventilated P/F ratios, which one should I capture?**

You should capture the worst P/F ratio, regardless of whether the patient is ventilated or not. (Thanks to Sheilagh Mans for the question)

**In the collection of concomitant medications, we are asked to collect insulin units per day. Do you want me to capture all Insulin received?**

Yes, please records ANY kind of insulin i.e. sub-q, drip/IV (total). (Thanks to Ellen MacDonald for the question).