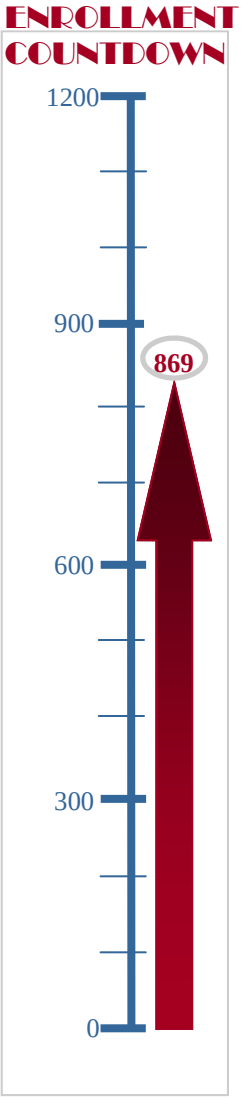
THE REDOXS© CIRCULAR

Data current to 30-Aug-2010

Site #	Institution	Aug	Cumulative
1	Kingston General	1	78
2	St. Joseph Healthcare	-	56
3	Ottawa General	9	157
4	Ottawa Civic	3	56
5	Vancouver General	-	20
6	Sacre-Coeur	2	71
7	Maisonneuve-Rosemont	-	15
8	Royal Victoria	-	14
9	Royal Alexandra	-	24
11	Grey Nun's	-	15
13	Victoria General	2	8
14	London HSC	-	17
16	Capital Health, QEII	-	17
19	Montreal General	2	21
20	L'Enfant Jesus	-	26
21	Liege, Belgium	-	8
22	CHUV, Switzerland	-	11
23	Royal Jubilee	-	9
25	Mount Sinai	1	37
26	U of Colorado	1	20

Site #	Institution	Aug	Cumulative
27	Miami Valley, Ohio	2	12
28	Fletcher Allen, Vermont	-	10
30	U of Louisville	-	18
31	U of Texas	-	9
32	University Hospital	1	8
33	Laval	-	10
34	Emory University	-	-
35	Kiel, Germany	-	3
37	Greifswald, Germany	-	8
38	Hamburg-Altona, Germany	-	4
39	Jewish Hospital	-	3
40	Atlanticare	-	3
41	Hershey Medical Center	-	1
42	Intermountain Healthcare	2	2
43	Mayo Clinic, Arizona	-	-
*number patients from closed sites			18
number patients enrolled in pilot			80
TOTALS		**26**	**869**



26 patients were enrolled in August, a fine showing for summer vacation season!

Congratulations to Dr. White and his team at Intermountain Healthcare in Utah for enrolling their first 2 REDOXS© patients!

Welcome to the REDOXS© Team Tracey Bentall! Fantastic job enrolling your first patient at UH London.

Thanks to the teams at Kingston General, Ottawa General, Ottawa Civic, Sacre-Coeur, Victoria General, Montreal General, Mount Sinai, University of Colorado and Miami Valley for enrolling patients in August.

We look forward to seeing our recruitment increase in the Fall as sites begin to resume regular activity.

Remember our monthly recruitment goal is 1 patient/site = 35 patients/month

Next Interim Analysis

We are now 31 patients away from the 2nd interim analysis milestone of 900 patients. More news to follow in this regard very soon.

STUDY CHAIR
Daren Heyland
dkh2@queensu.ca

PROJECT LEADERS
Janet Overvelde
overvelj@kgh.kari.net
Rupinder Dhaliwal
dhaliwar@kgh.kari.net

DATA MANAGEMENT
Jennifer Korol
korolj@kgh.kari.net
Shawna Froese
froeses@kgh.kari.net

PROJECT ASSISTANTS
Maureen Dansereau
danserem@kgh.kari.net
Susan Campbell
campbes3@kgh.kari.net

Duration of the Administration of Study Supplements

Per study procedures the REDOXS© Study Supplements should be administered from within 2 hours of randomization until the first of the following occurs: ICU discharge, death or the end of 28th day (from randomization).

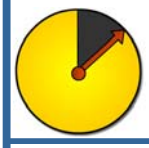
The exception to the above timeline is patients with an ICU stay < 5 days. In instances where a REDOXS© patient is discharged from the ICU and transferred elsewhere in the hospital < 5 days from ICU admission, the following should occur:

- **Parenteral** supplements should continue until the end of study day 5 or for 120 hours, whichever is longer.
- **Enteral** supplements should continue until the end of study day 5 or for 120 hours, whichever is longer, if the feeding tube is in place. If the feeding tube in no longer clinically indicated, then enteral supplement administration is considered complete from the time the feeding tube is removed.

CT Sub Study: Please forward any available CT Scans to the University of Waterloo as soon as possible.

Lab Sub Study Sites: Please contact The Project Leader if you required any laboratory supplies or if you have any questions concerning lab procedures.

3rd Quarter Payments



Please note the 3rd quarter ends Sept 30th, site payments will be processed the following week. Please ensure you send in your Investigator Confirmation Forms.

Recording HIV/AIDS Drugs in the EDCS

If an HIV/AIDS drug does not appear on the existing antibiotic taxonomy in the EDCS, record the drug name in the comments field.

Protocol Violations: What is the data telling us?

A recent review of Protocol Violation data has revealed that for a great number of REDOXS© patients, the enteral study supplements are being held primarily for two reasons:

- Procedures/OR
- Due to high gastric residual volumes (GRV)

In instances where the supplements are being held for procedures, it is important that the site ensures the study supplement rate is doubled to make up for any losses during the study day. If you have any questions regarding how to adjust the rate please contact the Project Leader.

As per the Enteral Feeding Protocol found in the Administration of Study Supplements Manual, GRVs are defined as "high" when they are greater than 250 mL. When a patient experiences high GRVs the site should exercise the following strategies:

1) Hold enteral feeds
2) Administer motility agents
3) Switch to small bowel feeding

} **DO NOT STOP STUDY SUPPLEMENTS**

Refer to the Administration of Study Supplements Manual for details concerning mitigating and managing interruptions to the REDOXS© study supplements.

Antibiotic Data

Q: I have a patient who received antibiotics at home, but within 7 days of ICU admission. Do I need to collect this antibiotic data?

A: We are not asking you to collect data for other hospital stays that may have occurred shortly before the current stay or for antibiotics use at home. We only want you to record antibiotics administered within the required timelines from the current hospital stay.

Q: If an antibiotic is ongoing at ICU discharge, how should this be recorded in the EDC system?

A: If the antibiotic is started in ICU and continues after ICU discharge, you will need to follow the patient to get this data.