

The REDOXs© Circular

As of November 30, 2009

Canada

Site #	Institution	Nov	Cumulative
1	Kingston General Hospital	-	67
2	St. Joseph's Healthcare	-	43
3	Ottawa General	3	112
4	Ottawa Civic	1	42
5	Vancouver General	-	19
6	Sacre-Coeur, Montreal	-	59
7	Maisonneuve-Rosemont	2	15
8	Royal Victoria, Montreal	1	10
9	Royal Alexandra, Edmonton	1	19
11	Grey Nun's, Edmonton	-	14
13	Victoria General	-	6
14	London HSC	-	12
15	HSC Winnipeg	-	8
16	Queen Elizabeth II, Halifax	-	11
19	Montreal General	3	13
20	Enfant-Jesus, Quebec City	3	23
23	Royal Jubilee, Victoria	-	7
25	Mount Sinai, Toronto	4	27
29	St. Boniface, Winnipeg	-	-
32	University Hospital, London	1	6
33	Laval, Quebec City	1	2
17	†Sunnybrook, Toronto	-	2
18	†St. Paul's, Vancouver	-	6

† Screening activities have been stopped, site closing out

United States

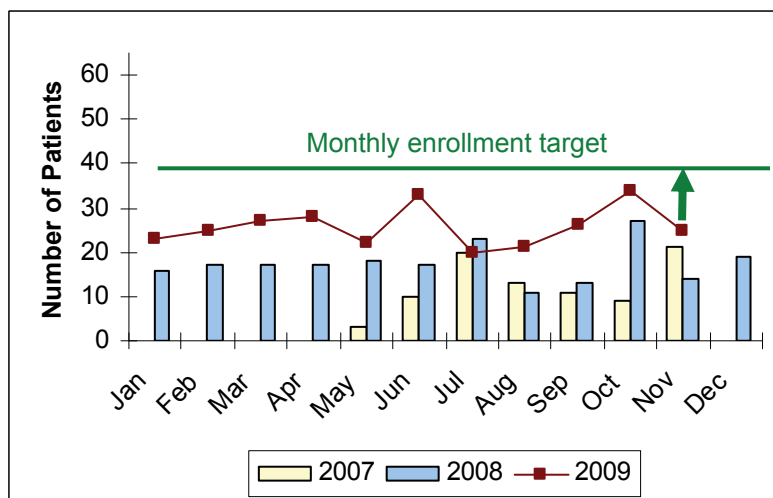
Site #	Institution	Nov	Cumulative
26	University of Colorado	1	16
27	Miami Valley, Ohio	-	4
28	Fletcher Allen, Vermont	1	7
30	University of Louisville	-	9
31	University of Texas	1	2

Europe

Site #	Institution	Nov	Cumulative
21	Liege, Belgium	1	6
22	CHUV, Switzerland	1	10
24	UZ Brussels, Belgium	-	2
35	Kiel	-	2
36	Lübeck	-	-
37	Greifswald	-	5
38	Hamburg-Altona	-	2

Cumulative Enrollment: 668
 (includes 80 patients from pilot)

Patients enrolled in November: 25



Congratulations to Cheryl Ethier at Mt Sinai for enrolling 4 patients into the study this month! Thanks to all who enrolled patients.

31 actively recruiting sites = 62 patients per month (2 pts/site/month)

We are aiming for 40 pts/month.

We appreciate your continued commitment towards REDOXs©.



Pharmacy Audits

The external Pharmacy Auditor is nearing the end of first round of Pharmacy Audits. Site Pharmacies should prepare for the request for data log submission for the next round in the New Year.

We are pleased to announce that there have been very few data discrepancies reported to date. In general, REDOXS© records have been clear and the management of Investigational Product has been well documented. Centres have been very good at documenting unused, wasted, and product returned to the pharmacy.

A few reminders to share with Pharmacy staff are as follows:

- ◆ For corrections, errors and adjustments, please remember that a single line through the incorrect entry or data element followed by the date (noticed/changed) and an initial must follow
- ◆ Data values and data entry are required for all fields. The use of ditto marks (" ") for repetitive entry has led to some incorrect data collection (e.g. more vials of a particular Lot # of Selenium dispensed than available in inventory).

Site Staffing Changes — Please ensure you inform the Project Leaders of any staffing changes at your site. Remember to update your Delegation of Authority Logs and forward a copy to the methods centre.

CERU Holiday Office Closure—Please note the CERU offices will be closed between Christmas and New Year (Dec 24th @ 1200 hrs until January 4th). During this time please call (613) 484-3830 for URGENT study related matters.



Pharmacy Reminder—Site Pharmacies are reminded to ensure they have adequate inventory for any potential enrolments over the holiday period. Given the CERU holiday office closure, orders will not be able to be filled from Dec 24th—Jan 4th. Call Suzanne Biro at (613) 549-6666 x6686.

Principal Investigator Commentary: The Use of Oxepa in REDOXS© Patients

We have recently received queries from site dietitians regarding the use of Oxepa in REDOXS© patients. Oxepa should NOT be used in patients enrolled in the REDOXS© study (see pg. 9 of the Administration of Study Supplements Manual).

Dr. Heyland has provided the following commentary regarding this topic:

“Notwithstanding the fact that Oxepa is recommended by the Canadian Critical Care Guidelines for patient with Acute Lung Injury/ARDS, we prohibit its use in the REDOXS© study because it contains supplemental antioxidants. This has not been a big problem because the overall use of Oxepa in ICUs worldwide has been low. However, there have been some occasions where clinicians or dietitians have insisted that a REDOXS© study patient receive Oxepa. It could be made aware to them that there are 2 ARDSnet studies that were presented at the American Thoracic Society Meeting this year that suggested that Oxepa ingredients, particularly fish oils are associated with no clinical benefit and perhaps increased harm. Until these studies are published, we will not be changing our Canadian guidelines but it may deter insistent clinicians from using the product in study patients. If in the end, they continue to insist, please note that the use of Oxepa is a protocol violation, a note to file will need to be created and to forwarded to the Project Leader.”

Contact the Project Leaders for any additional questions regarding the use of Oxepa.



The Faces of REDOXS©

**St. Joseph’s Healthcare Hamilton
Hamilton, Ontario, Canada**

Pictured to the left is Dr. Deborah Cook’s team at St. Joseph’s Healthcare Hamilton.

The team at St. Joseph’s has been part of the REDOXS© study since the pilot phase in 2005. This site has recruited 42 patients to date and is one of our top 5 enrolling sites!

Left to right— Dr. Deborah Cook, France Clarke, Ellen McDonald and Andrea Tkaczyk

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