


# The REDOXs® Circular

## Enrolment as of Sept 30, 2009


### Canada

Site #	Institution 	Sept	Cumulative
1	Kingston General Hospital	2	65
2	St. Joseph's Healthcare	2	38
3	Ottawa General	4	103
4	Ottawa Civic	2	40
5	Vancouver General	-	19
6	Sacre-Coeur, Montreal	-	56
7	Maisonneuve-Rosemont	-	13
8	*Royal Victoria, Montreal	-	8
9	Royal Alexandra, Edmonton	1	18
11	Grey Nun's, Edmonton	1	14
13	Victoria General	1	5
14	London HSC	1	12
15	HSC Winnipeg	-	8
16	Queen Elizabeth II, Halifax	1	10
17	†Sunnybrook, Toronto	-	2
18	†St. Paul's, Vancouver	-	6
19	Montreal General	-	10
20	Enfant-Jesus, Quebec City	-	19
23	Royal Jubilee, Victoria	-	6
25	Mount Sinai, Toronto	2	20
29	St. Boniface, Winnipeg	-	-
32	University Hospital, London	-	3








\* site on hold due to staffing issues

† Screening activities have been stopped, site closing out

### United States

Site #	Institution 	Sept	Cumulative
26	University of Colorado	1	13
27	Miami Valley, Ohio	1	4
28	Fletcher Allen, Vermont	1	6
30	University of Louisville	-	8
31	University of Texas	1	1

### Europe

Site #	Institution 	Sept	Cumulative
21	Liege, Belgium	-	3
22	CHUV, Switzerland 	-	9
24	UZ Brussels, Belgium 	-	2
35	University Medical Center SH, Kiel 	1	2
36	University Medical Center SH, Lübeck 	-	-
37	EMA University, Greifswald 	3	4
38	Asklepios Klinik Hamburg-Altona 	1	2

#### Enrolment Totals:

‡Includes 80 from pilot

#### Monthly Cumulative‡

<b>Aug 2009</b>	21	583
<b>Sept 2009</b>	26	609

Congratulations to the team at St. Joseph's Healthcare for winning the Smokin' 600 Challenge!

Well done team at the University of Texas for enrolling your first REDOXs® patient!

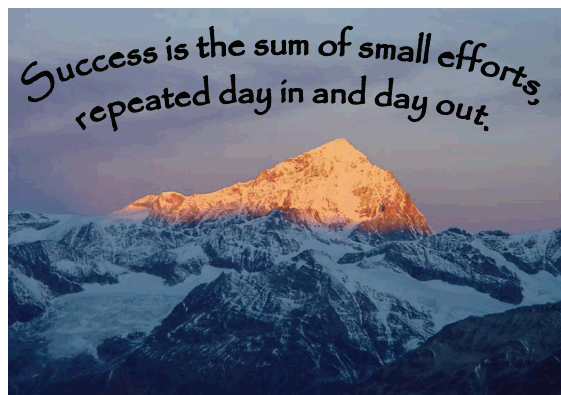
Remember our target is 2 pts/site/month.

## 600th Patient Enrolled

We have reached, the halfway point of the study with the enrolment of the 600th patient in September!

Congratulations REDOXS® Colleagues on your achievement, it has been a challenging climb, you have now reached the summit!

On behalf of Dr. Heyland, thanks to each of you for your contributions to the REDOXS® Study.



## Interim Analysis is on the Horizon...

As we have mentioned in previous Circulars, the enrolment of the 600th patient means an interim analysis will be conducted soon. Please continue to complete your data collection and entry. Thanks for your efforts!

Current # enrolled = **609**

Current # locked charts = **513**

We require 600 locked charts for the interim analysis.

## Serious Adverse Event Reporting: A Few Reminders

For an adverse event to be reported to the Methods Centre is must be **serious and unexpected**.

### Defining Serious

Any untoward medical occurrence that at any dose:

- ◆ Results in death
- ◆ Is life-threatening
- ◆ Requires in patient hospitalization or prolongation of existing hospitalization
- ◆ Results in persistent or significant disability/incapacity
- ◆ Is a congenital anomaly or birth defect
- ◆ Other medically important condition

### Defining Unexpected

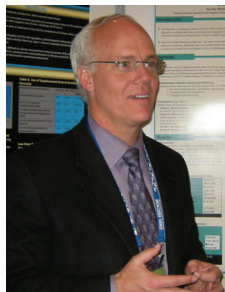
For the purposes of the REDOXS® Study, given the population of critically ill patients with organ dysfunction, an unexpected SAE is defined as an event that is serious and is **NOT expected due to the progression of the underlying disease or co-morbid illnesses.**

Please note: Deaths related to the progression of underlying illness are NOT considered unexpected & do NOT need to be reported.

All unexpected SAEs **must be** reported to the Methods Centre **within 24 hours** of becoming aware of the event. Always contact the Project Leader if you have questions regarding whether an event should be reported.

## Meet the Methods Centre

Have you ever wondered what the voice on the other end of the phone looks like? Here is your REDOXS® Project Team.



**Dr. Daren Heyland**  
Study Chair



**Rupinder Dhaliwal**  
Project Leader



**Janet Overvelde**  
Project Leader



**Jennifer Korol**  
Data Manager



**Shawna Froese**  
Data Assistant



**Suzanne Biro**  
Project Assistant



**Xuran Jiang**  
Data Analyst



### We want to acknowledge you!

We will be starting a new feature in our REDOXS® Circular, "The Faces of REDOXS®". We want to acknowledge the great people that make the REDOXS® Study a success by featuring a photo and a few words about your site. Janet will be requesting site team photos over the coming months.