REDOXS© Bulletin   Study Days

The Issue

It has come to our attention there is some confusion arising from the definition of Study days for the REDOXS© study and the date that the computer assigns to these study days. This may be a problem for those sites that follow a flow sheet **other than midnight to midnight** and are collecting data for this period.

Clarification

Study day 1:

- Is **always** from the day of ICU admission until the end of your site's flow sheet.
- May **not** be the same day that the patient is randomized and may **not** be the same day that the supplements get started.
- The actual # hours will vary from site to site and patient to patient according to the time of admission and hence the amount of data available on study day 1 will vary considerably.

Study Day 2 (and onwards):

- Is the next 24 hours period according to your flow sheet

Solution

If your flow sheet runs from **any other time except midnight to midnight,** please review the example below to see if you are collecting data accurately.

Example:
Flow sheet 0700-0700 (this is actually considered to be 07:00 to 06:59).

ICU admission 16th August 00:45 hr Randomization date: 16th August 14:00 hrs

Study day	Date assigned by computer	Should represents period from			
		Date	Time	Date	Time
1	16th August	Aug 16th	00:45	to	Aug 16th	06:59
2	17th August	Aug 16th	07:00	to	Aug 17th	06:59
3	18th August	Aug 17th	07:00	to	Aug 18th	06:59
4	19th August	Aug 18th	07:00	to	Aug 19th	06:59
5	20th August	Aug 19th	07:00	to	Aug 20th	06:59

What to do:

1. Please review the entered data to see if it represents the correct periods. If not, please notify us immediately and correct the data asap.
2. Indicate on your worksheets clearly the period that study day 1, 2,3, etc should represent.
3. Please place a **NOTE TO FILE** in your regulatory binder illustrating what time periods study day 1, 2 etc represent.

If you would prefer, please call Jennifer Korol, database manager at 613-548-6051 to help guide you through this process.

October 15th 2007