Enrollment Timelines
As illustrated by the chart below, the monthly enrollments for January, February and March 2010 have fallen short of those from 2009. It is imperative that we increase the rate of enrollment to meet our study timelines. In order to complete the study within the next 12 months we must enroll 38 patients a month. Given we have 34 sites screening patients, and another 2 sites anticipated to start soon, this works out to at least 1 pt/site/month. We can do this!
Interim Analysis: Next Steps

The interim analysis has been completed!
The following steps will now occur:
- It will be sent to the Data Monitoring Committee (DMC) within the next week.
- The DMC will review the data for safety and efficacy.
- The DMC will document the outcome of their review.
- The outcome of the DMC review will be communicated to all sites once it is available.

Dr. Heyland will be presenting the interim analysis results to the Canadian Critical Care Trials Group (CCCTG) at the June meeting in Prince Edward Island.

We plan to forward periodic quality reports to sites. Individualized reports will be sent to each site in early May.

A joint Steering Committee & DMC meeting will be held in May to review all safety data. Similar to previous meetings, a safety report will be sent to sites to submit to their local ethics board.

ICU Acquired Infection Adjudication

The site investigator or MD delegate is to make the determination of whether a newly acquired ICU infection exists based on antibiotic and microbiology data.

Part 1: Triggering a Suspicion of ICU Acquired Infection

We often receive questions from research coordinators asking how to answer the antibiotic and microbiology questions used to trigger a suspicion of infection.

First, the responses to the following questions require clinical inference from a physician. We strongly recommend that these questions be answered in consultation with the site investigator or MD delegate.

Next, a suspicion of ICU acquired infection can be triggered by an antibiotic or a positive culture.

**Antibiotic Triggers: only for those antibiotics started greater than 72 hrs from ICU admission**

Is this antibiotic prescribed for prophylaxis? □ YES □ NO

Is this antibiotic a substitute for an antibiotic previously ordered for an infection? □ YES □ NO

Answering ‘NO’ to both questions triggers a suspicion of infection.
An infection adjudication must be performed by the Site Inv/MD for this antibiotic.

**Microbiology Triggers: only for those cultures taken greater than 72 hrs from ICU admission**

Is this culture a manifestation of a previously diagnosed infection? □ YES □ NO

Is this a routine surveillance swab (i.e. nasal swab for MRSA or rectal swab for VRE)? □ YES □ NO

Answering ‘NO’ to both questions triggers a suspicion of infection.
An infection adjudication must be performed for this positive culture.

If a suspicion of infection has been triggered, the electronic data capture system (EDCS) generates an Infection Adjudication table pooling all relevant data for the site investigator or MD delegate to make their adjudication determination.

Refer to Part 2: Adjudicating a Suspicion of ICU Acquired Infection on the next page.
Part 2: Adjudicating a Suspicion of ICU Acquired Infection

The site investigator or MD delegate should perform an infection adjudication as follows:

For each triggered suspicion there are 3 options:

- If ‘YES’ to infection, refer to the Categories of Infection to determine whether YES - Definite, YES - Probable or YES - Possible
- If ‘NO’ to infection, refer to the Definitions to determine whether NO - Probable or NO - Possible

This suspicion has already been adjudicated

For ‘YES’ to newly acquired infection, there are 12 Categories of Infection for the site investigator to choose from. Refer to Implementation Manual Appendix 10.2.

For ‘NO’ to infection, there are two definitions for the site investigator to choose from. Refer to Implementation Manual Appendix 10.3.

For further information regarding the infection adjudication process please refer to the Implementation Manual pgs. 58-60 & Appendix 10. Contact the Project Leader if you have any questions.