



NECSteps Data Safety Monitoring Board Report to Site Principal Investigators

April 2, 2004

Study Toward Evidence-based Pediatric Surgery

The NECSteps Data Safety Monitoring Board met via teleconference on March 17, 2004 from 12 noon – 1 pm EST. In attendance were members Richard Olshen, PhD, Brad Efron, PhD, Marilyn Butler, MD, Art D'Harlingue, MD; Study PI Larry Moss, MD, and Lead Study Coordinator Bonnie Lang Silverman, PhD. Jeffrey Gould, MD, MPH was absent.

The Board reviewed and discussed the statistical report assembled by the Lead Site. These are the Board's conclusions.

1. The randomization strategy appears successful, with an almost equal number of infants randomized into each group. The Board found no concern over the randomization schema of the trial and expects the groups to become more equal as additional patients are enrolled.
2. The observed birth weight distribution is consistent with the known pattern of this disease, with the sample more heavily weighted towards babies weighing < 1000 gms. Clinical members of the Board believe the birth weight distribution of the trial population will represent the overall population with NEC.
3. The overall mortality (without regard to treatment group), is compatible with most recently reported mortality in these infants.
4. The Board therefore recommended continuation of the trial based on the observed mortality difference between groups not reaching the difference defined in the protocol as justification for early cessation of the trial. All members agreed that continuation of the NECSteps Trial did not present a risk to patients.
5. The Board expected a likelihood that the trial would produce clinically relevant findings and strongly recommended that the Trial accrue the full 130 subjects during the next 12 months