

NCCTG DMC Toxicity Report from October 8, 2002

The National Cancer Institute has requested that each cooperative group Data Monitoring Committee (DMC) provide DMC recommendations to institutional review boards. For intergroup studies coordinated by NCCTG, the Operations Office of each participating group will receive a report of the NCCTG DMC's recommendations. The cooperative group will be responsible for making the information available to its member institutions. Below is SWOG's report:

#N9831 (Adjuvant AC + Paclitaxel +/- Trastuzumab in HER-2 Overexpressing Node-Positive Breast Cancer):

* Action: The committee reviewed a request from Dr. Perez to release ejection fraction data on the first 1000 patients who have completed 3 months of AC, and to release ejection fraction data from 9 and 18 month follow-up on arm A patients. The committee voted 4-0 to release the ejection fraction data for the first 3 months for all arms, but to deny the request to release data from the 9 and 18 month exams on arm A. The committee reviewed and approved 4-0 a request to release the data from the sErbB1 and sErbB2 substudy to the study team, with the stipulation that no outcome data be released. The committee reviewed and approved 4-0 the study team's revised analysis plan to deal with the temporary suspension of arm C. The adverse event data was reviewed and no issues were noted.

#93-46-53 (Laparoscopic-Assisted Colectomy vs. Open Colectomy for Colon Cancer):

* Action: After discussion, review of the letter from Dr. Nelson, review of the recent Lancet publication, and review of an interim analysis presented, the committee voted 3-0 (with Dr. Goldberg excused due to conflict) to continue per protocol with final analysis planned for 2005. The adverse event data was reviewed and no issues were found.

#N9841 (A Randomized Phase III Equivalence Trial of Irinotecan (CPT-11) vs Oxaliplatin (OXAL)/ 5-Fluorouracil (5-FU)/Leucovorin (CF) in Patients with Advanced Colorectal Carcinoma Previously Treated with 5-FU):

* The DMC voted unanimously (6-0) to accept the report without discussion. No toxicity problems were found.