

NCCTG DMC Report 11/25/03

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):

* Recommendation: The committee reviewed the second interim analysis of cardiac toxicity, and voted 6-0 to continue the study per protocol. The adverse event data were 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)

* Recommendation: The DMC voted 6-0 to recommend that the trial be closed to accrual due to the slow accrual. The adverse event data were reviewed and no issues were found.