

NCCTG's Data Monitoring Committee Report rcvd 11/4/04

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 DMC, upon consideration of all data, recommended unanimously the study continue per protocol. The adverse event data were reviewed and no issues were identified.

#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): Issue: Consider the request to release data to the study team and terminate DMC monitoring.

- *Action:* The DMC voted unanimously to release the data to the study team and terminate DMC monitoring, subject to the condition that the data not be reported prior to ASCO submission and that the data be updated at a date as close as is feasible to the submission. The adverse event data were reviewed and no issues were identified.