

NCCTG DMC Report 4/22/03

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:

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

* Action: After discussion, the committee agreed unanimously (3-0, with Dr. Goldberg abstaining) to release the trial data to the study team. The adverse event data were reviewed and no issues were found.

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* #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

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

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

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