

**NCI/CTEP-Sponsored Studies Selected for Inclusion in NCI-CMS Pilot Project
(Studies in Various Stages of Development)**

Study #	Study Title	Phase	Study Status (As of March 8, 2006)	Actual Date Study Opened (or Expected Date)	Location Participating Sites
C80405	Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5-FU/Leucovorin with Bevacizumab, or Cetuximab, or with the combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum	Phase 3	Study Open	Sept. 15, 2005	Nationwide
E2204	An Intergroup Randomized Phase II Study of Bevacizumab or Cetuximab in Combination with Gemcitabine and in Combination with Chemoradiation (Capecitabine and Radiation) in Patients with Completely-Resected Pancreatic Carcinoma	Randomized Phase 2	Study Open	Feb. 17, 2006	Limited Regions
E4203	Phase II Study of Treatment Selection Based Upon Tumor Thymidylate Synthase Expression in Previously Untreated Patients with Metastatic Colorectal Cancer	Randomized Phase 2	Study Open	July 14, 2005	Limited Regions
E5202	Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers	Phase 3	Study Open	August 4, 2005	Nationwide
E5204	Intergroup Randomized Phase III Study of Post-Operative Oxaliplatin, 5-Fluorouracil and Leucovorin with or without Bevacizumab in Patients with Stage II or III Rectal Cancer Receiving Pre-Operative Radiation and a 5-Fluorouracil-Based Regimen	Phase 3	Study Open	March 8, 2006	Nationwide
NSABP-R-04	A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion 5-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum	Phase 3	Study Open with Amendment #2	February 2006	Nationwide
RTOG-0522	Phase III Trial of Concurrent Accelerated Radiation & Cisplatin vs Concurrent Accelerated Radiation, Cisplatin, & Cetuximab (Followed by Surgery for Selected Patients) for Stage III & IV Head & Neck Carcinomas	Phase 3	Study Open	Nov. 22, 2005	Nationwide
S0502	Phase III Randomized Study of Imatinib, with or without Bevacizumab, in Patients with Metastatic or Unresectable Gastrointestinal Stromal Tumors	Phase 3	Protocol Under Review at Central IRB	(Mar-May 2006)	Nationwide
7325	Dose-Dense and Dose-Intense Alternating Irinotecan/Capecitabine & Oxaliplatin/Capecitabine: Phase I in Solid Tumors and Phase II with Bevacizumab as First-Line Therapy of Advanced Colorectal Cancer	Phase 1/2	Study Open	Feb. 9, 2006	Single Institution

Study open = Study open for patient enrollment.

Protocol Approved = Study has final approval & will open soon.

Protocol Under Review at Central IRB = Protocol approved; in review at NCI Central IRB.

Web page with links to the protocol summaries, eligibility and site locations: <http://www.cancer.gov/clinicaltrials/developments/NCD179N>