

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

Study #	Study Title	Phase	Study Status (March 2005)	Anticipated Activation Date	Location of Participating Sites
7325	Dose-Dense and Dose-Intense Alternating Irinotecan/Capecitabine and Oxaliplatin/Capecitabine: Phase I in Solid Tumors and Phase II with Bevacizumab as First-Line Therapy of Advanced Colorectal Cancer	Phase 1/2	Protocol In Review	Summer 2005	Single-Institution
CALGB-80405	Chemotherapy and Biological Therapy for Patients with Untreated, Advanced Colorectal Cancer	Phase 3	Protocol In Review	May 2005	Nationwide
E2204	Phase II Trial of Adjuvant Gemcitabine + Cetuximab versus Gemcitabine + Bevacizumab Before and After Oral Capecitabine+ Radiation for Patients with Completely Resected Pancreatic Carcinoma	Randomized Phase 2	Protocol in Development	Summer 2005	Limited Regions
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	Concept Approval Pending	Fall 2005	Nationwide
E4203	Phase II Study of Treatment Selection Based Upon Tumor Thymidylate Synthase Expression in Previously Untreated Patients with Metastatic Colorectal Cancer	Randomized Phase 2	Activation Pending	April / May 2005	Limited Regions
E5202	A 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	Under Review at Central IRB	April / May 2005	Nationwide
RTOG-0522	A Phase III Trial of Concurrent Accelerated Radiation and Chemotherapy versus Concurrent Accelerated Radiation, Chemotherapy, and Cetuximab (C225) for Stage III and IV Head and Neck Carcinomas	Phase 3	Protocol in Development	Summer 2005	Nationwide
NSABP-R-04	A Phase III Clinical Trial Comparing Infusional 5-Fluorouracil (5-FU), Leucovorin, and Oxaliplatin (mFOLFOX6) Every Two Weeks with Bevacizumab to the Same Regimen without Bevacizumab for the Treatment of Patients with Resected Stages II and III Carcinoma of the Colon	Phase 3	Open study - Amendment with Oxaliplatin in Development	Summer 2005	Nationwide
S0502	A Phase II Dose Selection Trial Assessing Two Dose Levels of Bevacizumab, Combined with Imatinib, in Patients with Metastatic or Unresectable Gastrointestinal Stromal Tumors	Randomized Phase 2	Protocol in Review	Summer 2005	Limited Regions

Protocol in Review = 1st version protocol reviewed; revisions in process

Protocol in Development = Study idea approved; awaiting 1st version of protocol

Concept Approval Pending = Study design approved by CTEP; awaiting resolution on pharmaceutical company support

Activation Pending = CTEP has given final approval for protocol

Under Review at CIRB = Protocol approved by CTEP; in review by NCI's Central IRB

Open study - Amendment in Development = Active study being revised to include new study question