

ACTIVE PROTOCOL LIST

Updated 6/2/2010

Study #	Protocol Title
	BRAIN
R0614 (Kristina)	A Randomized, Phase III, Double-Blind Placebo-Controlled Trial of Memantine for Prevention of Cognitive Dysfunction in Patients Receiving Whole-Brain Radiotherapy
	BREAST
	BREAST – ADJUVANT
PACCT-1 (Jennifer)	Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: The TAILORx Trial
NSABP-B39 (Jim)	A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II
E5103 (Jennifer)	A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide followed by Paclitaxel with Bevacizumab or Placebo with Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer
NSABP-B44 (Jim)	A Multicenter Phase III Randomized Trial of Adjuvant Therapy for Patients with Her2-Positive Node-Positive or High Risk Node-Negative Breast Cancer Comparing Chemotherapy Plus Trastuzumab with Chemotherapy Plus Trastuzumab Plus Bevacizumab
NSABP-B46 (Jim)	A Phase III Clinical Trial Comparing the Combination of TC Plus Bevacizumab to TC Alone and to TAC for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer
	BREAST-DCIS
NSABP-B43 (Jim)	A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma in Situ Resected by Lumpectomy
	BREAST-NEOADJUVANT
NSABP-B40 (Jim)	A Randomized Phase III Trial of Neoadjuvant Therapy in Patients with Palpable and Operable Breast Cancer Evaluating the Effect on Pathologic Complete Response {pCR} of Adding Capecitabine or Gemcitabine to Docetaxel when Administered Before AC with or without Bevacizumab and Correlative Science Studies Attempting to Identify Predictors of High Likelihood for pCR with Each of the Regimens
NSABP-B41 (Jim)	A Randomized Phase III Trial of Neoadjuvant Therapy for Patients with Palpable and Operable HER2-Positive Breast Cancer Comparing the Combination of Trastuzumab Plus Lapatinib to Trastuzumab and to Lapatinib Administered with Weekly Paclitaxel Following AC Accompanied by Correlative Science Studies to Identify Predictors of Pathologic Complete Response
	BREAST—METASTATIC
CALGB 40502 (Jennifer)	A Randomized Phase III Trial of Weekly Paclitaxel Compared to Weekly Nanoparticle Albumin Bound Nab-Paclitaxel or Ixabepilone Combined with Bevacizumab as First-Line Therapy for Locally Recurrent or Metastatic Breast Cancer ** Her + or Her -**

CALGB 40302 (Jennifer)	Endocrine Therapy With or Without Inhibition of EGF and HER2 Growth Factor Receptors: A Randomized, Double-Blind, Placebo-Controlled Phase III Trial of Fulvestrant With or Without Lapatinib (GW572016) For Postmenopausal Women with Hormone Receptor Positive Advanced Breast Cancer
CALGB 40503 (Jennifer)	Endocrine Therapy in Combination with anti-VEGF Therapy: A Randomized, Double-Blind, Placebo-Controlled Phase III Trial of Endocrine Therapy Alone or Endocrine Therapy Plus Bevacizumab (NSC 704865; IND 7921) For Women with Hormone Receptor-Positive Advanced Breast Cancer
	<u>GASTROINTESTINAL</u>
	ANAL CANAL
E3205 (Jim)	Phase II Trial of Cetuximab Plus Cisplatin, 5-Fluorouracil and Radiation in Immunocompetent Patients with Anal Carcinoma
	ADJUVANT RECTAL
NSABP R-04 (Jim)	A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion of 5-FU with or without Oxaliplatin in the Treatment of Patients with Operable Cancer of the Rectum
	ADJUVANT COLON
E5202 (Jim)	A Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin vs. 5-FU, Leucovorin, Oxaliplatin, and Bevacizumab for Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers
	METASTATIC COLORECTAL
CC0904 (Kristina)	A Randomized, Multicenter, Phase 2 Study to Compare the Efficacy of Panitumumab in Combination With mFOLFOX6 to the Efficacy of Bevacizumab in Combination with mFOLFOX6 in Patients With Previously Untreated, KRAS Wild-Type, Unresectable, Metastatic Colorectal Cancer
CC1001 (Jim)	Phase I/II Study of KRN330 plus Irinotecan after First-Line or Adjuvant FOLFOX/ CapOx Failure in Patients with Metastatic Colorectal Cancer
	GASTRIC/GASTROESOPHAGEAL
	None currently available
	PANCREAS
	None currently available
	<u>GENITOURINARY</u>
	PROSTATE
E3805 (Jim)	ChemoHormonal Therapy versus Androgen Ablation Randomized Trial for Extensive Disease in Prostate Cancer (CHAARTED)
CTSU90203 (CALGB) (Jim)	A Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior To Radical Prostatectomy Versus Immediate Radical Prostatectomy In Patients With High-Risk, Clinically Localized Prostate Cancer
RTOG 0534 (Kristina)	A Phase III Trial Of Short Term Androgen Deprivation With Pelvic Lymph Node Or Prostate Bed Only Radiotherapy (SPPORT) In Prostate Cancer Patients With A Rising PSA After Radical Prostatectomy

RTOG 0815 (Kristina)	A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy With or Without Short-Term Androgen Deprivation Therapy for Patients With Intermediate-Risk Prostate Cancer
	RENAL CELL
E2805 (Jim)	A Randomized, Double-Blind Phase III Trial of Adjuvant Sunitinib versus Sorafenib versus Placebo in Patients with Resected Renal Cell Carcinoma .
E2804 (Jim)	The BeST Trial: A Randomized Phase II Study of VEGF, RAF kinase, and mTOR Combination Targeted Therapy (CTT) with Bevacizumab, Sorafenib and Temezirolimus in Advanced Renal Cell Carcinoma
	GYNECOLOGIC
	OVARIAN/FALLOPIAN TUBE/PRIMARY PERITONEAL
G212 (Jennifer)	A Randomized Phase III Trial of Maintenance Chemotherapy Comparing 12 Monthly Cycles of Single Agent Paclitaxel or XYOTAX TM (CT-2103) (IND# 70177), Versus No Treatment Until Documented Relapse in Women With Advanced Ovarian or Primary Peritoneal Cancer Who Achieve a Complete Clinical Response to Primary Platinum/Taxane Chemotherapy
G252 (Jennifer)	A Phase III Clinical Trial of Bevacizumab with IV Versus IP Chemotherapy in Ovarian, Fallopian Tube, and Primary Peritoneal Carcinoma : NCI-Supplied Agent: Bevacizumab (NSC#704865, IND#7921)
CC0902 (Jennifer)	A Randomized, Double-Blind, Placebo-Controlled, Phase III Study to Assess the Efficacy and Safety of Weekly Farletuzumab (MORAb-003) in Combination with Carboplatin and Taxane in Subjects with Platinum-sensitive Ovarian Cancer in First Relapse
G0126T (Jennifer)	A Phase II Trial of Belinostat and Carboplatin in the Treatment of patients with Recurrent or Persistent Platinum-Resistant Ovarian, Fallopian Tube, or primary Peritoneal Cancer
	ENDOMETRIAL/UTERINE
G249 (Jennifer)	A Phase III Trial of Pelvic Radiation Therapy versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High Risk, Early Stage Endometrial Carcinoma
G258 (Jennifer)	A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed By Carboplatin and Paclitaxel vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma
G261 (Jennifer)	A Randomized Phase III Trial of Paclitaxel Plus Carboplatin versus Ifosfamide Plus Paclitaxel in Chemotherapy-Naïve Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus
G0086P (Jennifer)	A Three Arm Randomized Phase II study of Paclitaxel/Carboplatin/Bevacizumab (NSC #704865, IND #7921), Paclitaxel/Carboplatin/Temezirolimus (NSC #683864, IND 61010) and Ixabepilone (NSC #710428, IND #59699)/Carboplatin/Bevacizumab as initial Therapy for patients with Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer
	VULVA/VAGINA/GERM CELL/STROMAL
	None currently available
	CERVICAL
G240	A Randomized Phase III Trial of Cisplatin Plus Paclitaxel With and Without NCI

(Jennifer)	supplied Bevacizumab vs. the Non-Platinum Doublet, Topotecan Plus Paclitaxel, With and Without NCI-Supplied Bevacizumab , in Stage IVB, Recurrent or Persistent Carcinoma of the Cervix
R0724 (Jennifer)	A Phase III Randomized Study of Concurrent Chemotherapy and Pelvic Radiation Therapy With or Without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy
	<u>HEMATOLOGIC</u>
	LYMPHOMA
S0816 (Kristina)	A Phase II Trial of Response-Adapted Therapy of Stage III-IV Hodgkin Lymphoma Using Early Interim FDG-PET Imaging
	CLL
E2903 (Kristina)	Phase II Trial of Pentostatin, Cyclophosphamide and Rituximab (PCR) Followed By Campath-1H For Previously Treated Relapsed or Refractory Patients with Chronic Lymphocytic Leukemia
	MULTIPLE MYELOMA
S0777 (Kristina)	A Randomized Phase III Trial of CC-5013 (Lenalidomide, NSC-703813) and Low Dose Dexamethasone (LLD) Versus Bortezomib (PS-341, NSC-681239), Lenalidomide and Low Dose Dexamethasone (BLLD) for Induction , in Patients with Previously Untreated Multiple Myeloma without an Intent for Immediate Autologous Stem Cell Transplant
	MDS/BONE MARROW FAILURE SYNDROMES
	None currently available
	<u>HEAD AND NECK/ ESOPHAGEAL</u>
E1305 (Erin)	A Phase III Randomized Trial of Chemotherapy with or without Bevacizumab In Patients with Recurrent Or Metastatic Head and Neck Cancer
R0436 (Erin)	Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation for Patients With Esophageal Cancer Who Are Treated Without Surgery
R0619 (Erin)	A Randomized Phase II Trial of Chemoradiotherapy versus Chemoradiotherapy and Vandetanib for patients with High-Risk Postoperative Advanced Squamous Cell Carcinoma of the Head and Neck
	<u>LUNG</u>
	NON-SMALL CELL
E1505 (Kristina)	A Phase III Randomized Trial of Adjuvant Chemotherapy with or without Bevacizumab For Patients with Completely Resected Stage IB (≥ 4cm)-IIIA Non-Small Cell Lung Cancer (NSCLC)
E4508 (Kristina)	Three-Arm Randomized Phase II Study of Carboplatin and Paclitaxel in Combination with Cetuximab, IMC-A12 or Both for Advanced Non-Small Cell Lung Cancer Patients Who Will Not Receive Bevacizumab-based Therapy
CC0711 (Kristina)	A Double-Blind, Randomized, Placebo-Controlled Phase III Study to Assess the Efficacy of recMAGE-A3+AS15 Antigen-Specific Cancer Immunotherapeutic as Adjuvant Therapy in Patients with Resectable MAGE-A3-Positive Non-Small Cell Lung Cancer [MAGE-A3]
CALGB30506	A Randomized Phase III Trial of Adjuvant Therapy in Early Stage Non-Small Cell

(Kristina)	Lung Cancer Evaluating the Potential Utility of a Genomic Prognostic Model to Identify Patients as Candidates for Adjuvant Chemotherapy
CALGB140503 (Kristina)	A Phase III Randomized Trial of Lobectomy versus Sublobar Resection for Small (≤ 2 cm) Peripheral Non-Small Cell Lung Cancer
R0617 (Kristina)	A Randomized Phase III Comparison of Standard- Dose (60 Gy) Versus Highdose (74 Gy) Conformal Radiotherapy With Concurrent and Consolidation Carboplatin/Paclitaxel +/- Cetuximab (IND #103444) in Patients With Stage IIIA/IIIB Non-Small Cell Lung Cancer
	SMALL CELL
E1508 (Kristina)	A Randomized Phase II Study of Cisplatin and Etoposide in Combination with Either Hedgehog Inhibitor GD-0449 or IGF-IR MoAB IMC-A12 for Patients with Extensive Stage Small Cell Lung Cancer
	MELANOMA
E1697 (Kristina)	Phase III Randomized Study of Four Weeks High Dose IFN-$\alpha 2\beta$ in Stage T2bN0, T3a-b, T4a-bN0, and T1-4, N1a,2a,3 (microscopic) Melanoma
E2607 (Kristina)	A Phase II Trial of Dasatinib in Patients with Unresectable Locally Advanced or Stage IV Mucosal, Acral, and Solar Melanomas
	SPINAL METASTASIS
R0631 (Kristina)	A Phase II/III Study of Image-Guided Radiosurgery/SBRT for patients with Localized Spine Metastasis