Trinity Medical Center Cancer Treatment Protocols

BREAST

BREAST – ADJUVANT	
Protocol	**Description**
NSABP B-39	*A Randomized Phase II Study of Conventional Whole Breast Irradiation (WBI) vs Partial Breast Irradiation (PBI) for Women with Stage 0, I or II Breast Cancer*
NSABP B-43	*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*
NSABP B-49	*A Phase III Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women with Node-Positive or High Risk Node-Negative, HER2-Negative Breast Cancer*
S1007	*A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER-2 Negative Breast Cancer with Recurrence Score (RS) of 25 or Less*

BREAST – ADVANCED	
Protocol	**Description**
E2108	*A Randomized Phase III Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Patients with Metastatic Breast Cancer*

GASTROINTESTINAL (GI)

GI – ADVANCED COLORECTAL	
Protocol	**Description**
E7208	*A Randomized Phase II Study of Irinotecan and Cetuximab with or without the Anti-Angiogenic Antibody, Ramucirumab, in Advanced, K-ras Wild-type Colorectal Cancer following Progression on Bevacizumab-Containing Chemotherapy* *****TEMPORARILY SUSPENDED, 6/14/12*****

GI – Advanced Colorectal, cont'd

N1048	*A Phase II/III Trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation vs Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision*

OTHER GI

Protocol	Description
CALGB 80803	*Randomized Phase II Trial of PET Scan-Directed Combined Modality Therapy in Esophageal Cancer*
RTOG 0436	*A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation for Patients with Esophageal Cancer Who are Treated without Surgery*
RTOG 1010	*A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma* *****PENDING*****
S1201	*A Randomized Phase II Pilot Study Prospectively Evaluating Treatment for Patients Based on ERCC1 (Excision Repair Cross-Complementing 1) for Advanced / Metastatic Esophageal, Gastric or Gastroesophageal Junction (GEJ) Cancer*

GENITO-URINARY (GU)

Protocol	Description
E2809	*Androgen Receptor Modulation Phase II, Randomized Study of MK-2206-Bicalutamide Combination in Patients with Rising PSA at High Risk of Progression after Primary Therapy*
RTOG 0534	*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*

GYNECOLOGIC

Protocol	Description
GOG 0238	*A Randomized Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus*

HEAD AND NECK

Protocol	Description
E1305	*A Phase III Randomized Trial of Chemotherapy with or without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer*

HEMATOLOGIC

Protocol	Description
E2903	*Phase II Trial of Pentostatin, Cyclophosphamide and Rituximab (PCR) Followed by Campath-1H for Previously-Treated Relapsed or Refractory Patients with Chronic Lymphocytic Leukemia*
S1117	*A Randomized Phase II Study of Azacitidine in Combination with Lenalidomide vs Azacitidine Alone vs Azacitidine in Combination with Vorinostat for Higher-Risk Myelodysplastic Syndromes (MDS) and Chronic Myelomonocytic Leukemia (CLL)*

LUNG

SMALL CELL LUNG

Protocol	Description
CALGB 30610	*Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer Also Receiving Cisplatin and Etoposide*

NON-SMALL CELL LUNG

Protocol	Description
CALGB 30607	*Randomized, Phase III, Double-Blind, Placebo-Controlled Trial of Sunitinib as Maintenance Therapy in Non-Progressing Patients Following an Initial Four Cycles of Platinum-Based Combination Chemotherapy in Advanced, Stage IIIB / IV Non-Small Cell Lung Cancer*
CALGB 30801	*A Randomized Phase III Double-Blind Trial Evaluating Selective COX-2 Inhibition in Cox-2 Expressing Advanced Non-Small Cell Lung Cancer*
E1505	*A Phase III Randomized Trial of Adjuvant Chemotherapy with or without Bevacizumab for Patients with Completely Resected Stage IB (≥ 4 cm) - IIIA Non-Small Cell Lung Cancer*

Non-Small Cell Lung, cont'd

E6508	*A Phase II Study of L-BLP25 and Bevacizumab in Unresectable Stage IIIA and IIIB Non-Squamous Non-Small Cell Lung Cancer after Definitive Chemoradiation*
S0819	*A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin / Paclitaxel / Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer*

MELANOMA

Protocol	Description
E1609	*A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy vs High-Dose Interferon Alfa-2b for Resected High-risk Melanoma*
E2607	*Phase II Trial of Dasatinib in Patients with Unresectable Locally Advanced or Stage IV Mucosal, Acral and Solar Melanomas*
N0879	*A Randomized Phase II Trial of Carboplatin, Paclitaxel, Bevacizumab, with or without Everolimus for Therapy of Metastatic Malignant Melanoma*

SYMPTOMS CONTROL

Protocol	Description
N08C9	*Phase III Randomized Study of Sulfasalazine vs Placebo in the Prevention of Acute Diarrhea in Patients Receiving Pelvic Radiation Therapy*
N10C1	*Vaginal DHEA for Vaginal Symptoms: A Phase III Randomized, Double-Blind, Placebo-Controlled Trial*
N10C2	*Double-Blind, Placebo-Controlled Study of Magnesium Supplements to Reduce Menopausal Hot Flashes*
NSABP P-5	*Statin Polyp Prevention Trial in Patients with Resected Colon Cancer*
S0702	*A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment*

Symptoms Control, cont'd

WFU 98110	*A Randomized Phase II Dose-Finding Study of ArginMax for Its Effect on Erectile Function and Quality of Life in Survivors of Prostate Cancer Previously Treated with Radiotherapy*
WFU 99211	*Feasibility of Delivering a Quitline Based Smoking Cessation Intervention in Cancer Patients Receiving Outpatient Treatment: A Pilot Study*

PREVENTION

Protocol	Description
CALGB 70305	*A Randomized Study to Prevent Lymphedema in Women Treated for Breast Cancer*
CALGB 70806	*Vitamin D and Breast Cancer Biomarkers* *****PENDING*****