

Covenant Clinic Active Protocols 11/11/10

Breast Cancer					
Protocol ID	Accrued Patients	Enroll through	Protocol Title	Activation Date/ Annual Renewals	Protocol Updates
S0500		CTSU	A Randomized Phase III trial to test the strategy of changing therapy versus maintaining therapy for metastatic breast cancer patients who have elevated circulating tumor cell levels at first follow-up assessment	12/06/06 09/26/07 07/16/08 06/24/09 05/25/10	Revision #1 03/28/07 #2 07/25/07 #3 09/08/09 Kim 05/24/10 #4 06/09/10 #5 10/22/10
E5103 IRB # 07-011		CTSU	A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide followed by Paclitaxel with Bevacizumab or Placebo in Patients with Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer	01/16/08 12/15/08 11/25/09 04/28/10	Update #2 3/21/08 Adden #2 5/30/08 Update #3 08/14/08 Adden #3 and update#4 sent 7/6/09 Update #4 08/26/09 Adden #4 11/3/09 Adden #5 1/27/10 Kim 05/24/10 Adden #6 7/19/10 Adden #7 9/10/10
N063D/Big 0-06 ALTTO 08-005		CTSU	ALTTO: Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation Study: A Randomised, Multi-centre, Open-label, Phase III Study of Adjuvant Lapatinib, Trastuzumab, Their Sequence and Their Combination in Patients with HER2/ErbB2 Positive Primary Breast Cancer	05/21/08 05/20/09 04/07/10	Adden 1 7/24/08 Adden 2 11/20/08 Adden 3 and 4 05/20/09 Amend 4, adden 5/6 action letter 11/24/09 Amend 5/adden 7 3/24/10 Amend 6/adden 8 4/7/10 Kim 05/24/10 Amend7/Adden 9 06/16/10 Amend 8/adden 10 9/13/10 Carbo action letter sent 10/12/10 Follow-up action letter sent 10/27/10

NSABP B-43 08-044-CCTG CIRB		NSABP	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	12/15/2008 11/25/2009 Renew CIRB 8/11	Amend 1 4/21/10 Kim 05/24/10 Amend 2 & 3 9/29/10
CALGB 40502 08-047-CCTG CIRB		CTSU	A Randomized Phase III Trial of Weekly Paclitaxel Compared to Weekly Nanoparticle Albumin Bound (Nab)-Paclitaxel or Ixabepilone Combined with Bevacizumab as First or Second-Line Therapy for Locally Recurrent or Metastatic Breast Cancer.	12/15/08 11/25/09 09/20/10	Update #1 2/23/10 Kim 05/24/10 Update #2 06/02/10 Update #3 8/24/10
NSABP B-46-I			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	10/28/09 08/11/10	Kim 05/24/10 Amend 1, 2, &3 10/25/10

Cancer Control					
Protocol ID		Enroll through	Protocol Title	Activation Date/ Annual Renewals	Protocol Updates
C70604 Lead Group: CALGB 09-020-CCTC		CTSU	A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer	07/28/09 06/09/10	Kim 05/24/10
N08CB Lead Group: NCCTG 10-030-CCTC		CTSU	A Phase III Randomized, Placebo-Controlled, Double-Blind Study of Intravenous Calcium/Magnesium in Two Different Versions to Prevent Oxaliplatin Induced Sensory Neuropathy	07/28/10	
Connect CLL Celgene 10-020-CCTC		Celgene	The Chronic Lymphocytic Leukemia Disease Registry	05/07/10	Kim added 07/27/10

Gastrointestinal Cancer

Protocol ID		Enroll through	Protocol Title	Activation Date/ Annual Renewals	Protocol Updates
C80405 Lead Group: CALGB 076		CTSU	A Phase III Trial of Irinotecan / 5-FU / Leucovorin or Oxaliplatin / 5-FU / Leucovorin with Bevacizumab, or Cetuximab (C225), or with the Combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or	9/28/05 7/19/06 05/30/07 03/26/08 3/18/09 2/23/10	Updates #1 5/31/06 #2 10/18/06 #3 9/26/07 #4 3/26/08 #5 10/27/08 #6 11/3/09 Kim 05/24/10 #7 06/23/10 #8 07/16/10 #9 and #10 9/13/10
NSABP P-5 Lead Group: NSABP 10-028		NSABP	Statin Polyp Prevention Trial in Patients with Resected Colon Cancer	06/25/10	Amend #1 08/09/10 Updated IB 9/17/10
CALGB 80702 CIRB 10-031		CTSU	A Phase III Trial of 6 versus 12 Treatments of Adjuvant FOLFOX plus Celecoxib or Placebo for Patients with Resected Stage III Colon Cancer	08/11/10 renew 3/3/11	
PAVES Amgen 20080259 10-016		Amgen	A Phase 3, Randomized, Double-blind, Placebo-controlled Study of Pegfilgrastim Administered to Subjects With Newly Diagnosed, Locally advanced or Metastatic Colorectal Cancer Treated With Bevacizumab and Either 5-fluorouracil, Oxaliplatin, Leucovorin (FOLFOX) or 5-fluorouracil, Irinotecan, Leucovorin (FOLFIRI).	08/16/10	

Genitourinary Cancer

Protocol ID	Accrued Patients	Enroll through	Protocol Title	Activation Date/ Annual Renewals	Protocol Updates
CALGB-90202 Lead Group: CALGB IRB #009		CTSU	A Randomized, Double-Blind, Placebo-Controlled Phase III Study of Early versus Standard Zoledronic Acid to Prevent Skeletal Related Events in Men with Prostate Cancer Metastatic to Bone	03/10/04 01/12/05 11/30/05 10/18/06 07/25/07 05/21/08 07/22/09 06/23/10	Updates #1 01/12/05 #2 06/01/05 #3 09/28/05 #4 03/29/06 #5 01/31/07 #6 05/30/07 #7 12/21/07 Kim 05/24/10 #8 11/01/10

Lung Cancer

Protocol ID	Accrued Patients	Enroll through	Protocol Title	Activation Date/ Annual Renewals	Protocol Updates
E5508 ECOG CIRB 10-037 CCTC		CTSU	Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed or Both Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Stage Non-Squamous Non-Small cell Lung Cancer	9/3/10 09/08/10	Carbo action letter 10/07/10 Follow up action letter 10/27/10

ECOG E1505 IRB #07-005		CTSU	A Phase III Randomized Trial Of Adjuvant Chemotherapy With Or Without Bevacizumab For Patients With Completely Resected Stage IB (> Or = 4cm) -IIIA Non-Small Cell Lung Cancer (NSCLC)	NEW 09/26/07 08/14/08 07/08/09 06/10/10	Adden #5 6/9/08 Adden 6&7 5/18/09 Kim 05/24/10 Addend 8 08/11/10 Update 3. addemd 9 9/10/10
-------------------------------	--	------	--	---	--

Melanoma

Protocol ID	Accrued Patients	Enroll through	Protocol Title	Activation Date/ Annual Renewals	Protocol Updates

Myeloma

Protocol ID	Accrued Patients	Enroll through	Protocol Title	Activation Date/ Annual Renewals	Protocol Updates
E1A06 08-007		CTSU	An Intergroup Phase III Randomized Controlled Trial Comparing Melphalan, Prednisone and Thalidomide (MPT) Versus Melphalan, Prednisone and Lenalidomide (Revlimid(tm)) (MPR) in Newly Diagnosed Multiple Myeloma Patients Who Are Not Candidates for High-Dose Therapy	05/21/08 05/20/09 04/28/10	Adden 1 11/24/08 Adden 2&3 10/16/09 Adden 4 1/27/10 Adden 5 4/28/10 Kim 05/26/10 Adden 6 7/21/10 Addend 7 9/29/10
09-058-CCTC		online	Connect MM: The Multiple Myeloma Disease Registry	12/17/09 10/19/10	Kim 05/26/10 Revision to PRO's 06/17/10