

Strong Attendance Numbers for First Alliance Group Meeting

More than 950 attendees gathered at the inaugural Alliance for Clinical Trials in Oncology Group Meeting in Chicago, IL, November 17-19, 2011. Attendees chose from more than 60 sessions led by renowned cancer clinical trial specialists and industry leaders. A networking event and poster session were two of the most well-attended events. Meeting attendance comprised oncologists, oncology nurses, clinical research professionals, statisticians, pharmacists, patient advocates, and others from more than 45 U.S. states, the District of Columbia and two Canadian provinces.

First Alliance Member Institutions

Congratulations to Christiana Care Health Services CCOP (PI: Stephen Grubbs, MD) and the University of Pittsburgh (PI: Rodney Landreaneau, MD) for being the first approved, post transition Alliance member institutions.

Nine other institutions have been approved, including:

- Duke University Medical Center (PI: Jeffrey Crawford, MD)
- Georgia Health Services University MB-CCOP (PI: Anand Jillella, MD)
- Harry S. Truman Veterans Administration Medical Center (PI: Shadi Haddadin, MD)
- Hematology Oncology Associates of Central New York (PI: Jeffrey Kirshner, MD)
- University of California at San Francisco (PI: Charles Ryan, MD)
- University of Missouri/Ellis Fischel Cancer Center (PI: Carl Freter, MD)
- University of Texas MD Anderson Cancer Center (PI: Kelly Hunt, MD)
- Upstate Carolina CCOP (PI: James Bearden, MD)
- Wichita CCOP (PI: Shaker Dakhil, MD)

By the Numbers

395

Number of
committee
members

31

Number of
scientific
committees

16

Number of
administrative
committees

187*

Number of
active
studies

68*

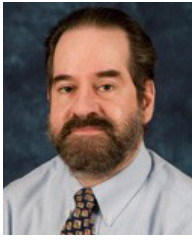
Number of
in development
studies

**as of November 2011*

Alliance Investigators Recognized by CTSU



Robert Barone, MD



Ellis Levine, MD

Six Alliance for Clinical Trials in Oncology investigators have been recognized by the National Cancer Institute (NCI) as top-enrolling individual investigators to cooperative group treatment trials through the Cancer Trials Support Unit (CTSU) in 2010.

The investigators include:

- Robert Barone, MD, at Sharp Memorial Hospital – 19 enrollments credited to ACOSOG
- Ellis Levine, MD, at Roswell Park Cancer Institute – 16 enrollments credited to CALGB
- Timothy Pluard, MD, at Washington University School of Medicine – 21 enrollments credited to CALGB
- John Reynolds, MD, at Medcenter One Health Systems – 19 enrollments credited to NCCTG
- Jacqueline Vuky, MD, at Virginia Mason CCOP – 18 enrollments; 14 credited to NCCTG
- Muhammad Salim, MD, at Allan Blair Cancer Centre – 15 enrollments; 2 credited to NCCTG



Timothy Pluard, MD



John Reynolds, MD

Participation in the NCI's cooperative group network through the CTSU is instrumental in helping cooperative group studies reach their accrual goals. Contribution to cutting edge cancer research is a vital part of answering important treatment questions.



Jacqueline Vuky, MD



Muhammad Salim, MD

Alliance ASCO 2012 Submission Policy

The 2012 American Society of Clinical Oncology (ASCO) Annual Meeting will take place June 1-5, 2012 in Chicago, IL. The deadline for submission of ASCO abstracts is February 1, 2012.

All abstract drafts from Alliance for Clinical Trials in Oncology members (including all three legacy Groups: ACOSOG, CALGB and NCCTG) must be submitted by **January 15, 2012** to the Alliance Publications Office by e-mail to pubscoord@calgb.org.

This time frame is required to ensure time for central review for content, as well as review of authorship lists. It is expected that all Alliance abstracts must follow this process. Independent submission of work related to the Alliance without this proper review is not permitted. Adherence to this guideline will assure that there is sufficient time for the review so that in turn each lead investigator will have sufficient time to submit to ASCO.

Alliance Legacy Group Treatment Trials Portfolio

The following is a list of ongoing Alliance legacy Group protocols by committee (A=Active; S=Suspended), availability to members through the NCI's Cancer Trials Support Unit (CTSU) (Y=Available; P=Pending; X=No plans to place on menu), implementation of OPEN registration system (Y=Available; P=Pending; X=No plans to put in system), and current accrual/accrual goals.

Breast Committee

Group	Protocol Number	Study Title	Phase	Status	CTSU	OPEN	Current Accrual	Accrual Goal	Projected Closure
ACOSOG	Z1031	A randomized phase III trial comparing 16 to 18 weeks of neoadjuvant exemestane (25 mg daily), letrozole (2.5 mg), or anastrozole (1 mg) in postmenopausal women with clinical stage II and III estrogen receptor positive breast cancer (limited access trial)	III	S	Y	Y	622	610	1/2012
ACOSOG	Z1072	A phase II trial exploring the success of cryoablation therapy in the treatment of invasive breast carcinoma (limited access)	II	A	X	Y	65	99	
ACOSOG	Z1071	A phase II study evaluating the role of sentinel lymph node surgery and axillary lymph node dissection following preoperative chemotherapy in women with node positive breast cancer (T0-4, N1-2, M0) at initial diagnosis	II	S	Y	X	756	660	
CALGB	40601	Rand neoadj taxol+ trastuz and/or lapat HER2+ br ca	III	A	Y	P	245	400	
CALGB	40603	Taxol +/- carbo --> ddAC +/- bev in HER2 neg br ca	II	S	Y	X	355	362	
NCCTG	N0733	Phase II trial of capecitabine and lapatinib with or without IMC-A12 in patients with HER2 positive breast cancer previously treated with trastuzumab and an anthracycline and/or a taxane	II	A	Y	Y	53	154	
NCCTG	N0937	Phase II trial of brostallicin and cisplatin in patients with metastatic triple negative breast cancer	II	A	P	P	21	46	
NCCTG	N093B	Phase I/II study of panobinostat (LBH589) and letrozole in patients with triple negative metastatic breast cancer	I/II	S	P	P	12	48	
NCCTG	N1031	Randomized phase II study of two doses of pixantrone in patients with metastatic breast cancer	II	S	X	X	47	56	

Cancer Control Program

Group	Protocol Number	Study Title	Phase	Status	CTSU	OPEN	Current Accrual	Accrual Goal	Projected Closure
CALGB	70305	Prevention of lymphedema in women treated for br ca	II	A	Y	X	636	780	1/2013
CALGB	70604	Standard vs. longer interval zoledronic acid in metastatic ca	III	A	Y	X	1421	1758	5/2012
CALGB	70806	Vitamin D and breast cancer markers	II	A	P	P	65	99	
CALGB	70807	Diet change for active surveillance prostate cancer patients	III	A	Y	X	44	464	
NCCTG	N0932	Assessment of patient satisfaction with participation in phase II/III NCCTG clinical trials	II/III	A	X	X	496	NA	
NCCTG	N07C4	A randomized phase II trial evaluating two non-pharmacologic interventions in cancer survivors for the treatment of sleep-wake disturbances	II	A	P	P	40	168	
NCCTG	N08C1	Paclitaxel-associated acute pain syndrome natural history study		A	X	X	295	360	
NCCTG	N08C9	Phase III, randomized study of sulfasalazine versus placebo in the prevention of acute diarrhea in patients receiving pelvic radiation therapy	III	A	X	X	6	140	
NCCTG	N08CB	A phase III Randomized, placebo-controlled, double-blind study of intravenous calcium/magnesium in two different versions to prevent oxaliplatin-induced sensory neurotoxicity	III	A	Y	P	215	354	
NCCTG	N09C6	A phase III, randomized double-blind study of doxepin rinse versus placebo in the treatment of acute oral mucositis pain in patients receiving radiotherapy with or without chemotherapy	III	A	P	P	71	198	
NCCTG	N10C1	Vaginal DHEA for vaginal dryness: A phase III randomized, double blind, placebo-controlled study	III	A	P	P	20	456	
NCCTG	N10C2	Phase III double-blind, placebo-controlled study of magnesium supplements to reduce menopausal hot flashes	III	A	P	P	0	288	

GI Committee

Group	Protocol Number	Study Title	Phase	Status	CTSU	OPEN	Current Accrual	Accrual Goal	Projected Closure
ACOSOG	Z5041	A phase II study of preoperative gemcitabine and erlotinib plus pancreatic resection and postoperative gemcitabine and erlotinib for patients with operable pancreatic adenocarcinoma	II	A	X	Y	95	105	1/2012
ACOSOG	Z6051	A phase III prospective randomized trial comparing laparoscopic-assisted resection versus open resection for rectal cancer	III	A	Y	Y	346	480	
ACOSOG	Z6091	Pilot / phase III randomized trial comparing standard systemic therapy to cytoreduction + hyperthermic intraperitoneal mitomycin + standard systemic therapy in patients with limited peritoneal dissemination of colon adenocarcinoma	III	A	Y	Y	1	340	
CALGB	80405	FOLFOX/FOLFIRI + bv, + C225, or + bv/C225 for mets colon ca	III	A	Y	X	2231	2234	02/2012
CALGB	80701	Rand ph II ever +/- bev in adv or met panc net (NCCTG endorsed)	II	A	Y	P	58	138	
CALGB	80702	Ph III 6 vs 12 txs of FOLFOX +/- celecoxib for st III col ca	III	A	Y	P	382	2500	
CALGB	80802	Ph III rand soraf+dox vs soraf in adv HCC	III	A	Y	P	72	480	
CALGB	80803	PET scan-directed combined modality therapy in esophageal cancer	II	A	P	P	0	204	
NCCTG	N0543	A phase II trial of pharmacogenetic-based dosing of irinotecan, oxaliplatin, and capecitabine as first-line therapy for advanced small bowel adenocarcinoma	II	A	P	P	28	36	
NCCTG	N0849	Randomized phase II trial of extended neoadjuvant therapy for locally advanced adenocarcinoma of the esophagus, gastroesophageal junction, or gastric cardia	II	A	P	P	35	96	
NCCTG	N0949	Randomized phase III trial of mFOLFOX7 or XELOX plus bevacizumab versus 5-fluorouracil/leucovorin or capecitabine plus bevacizumab as first-line treatment in elderly patients with metastatic colorectal cancer	III	A	Y	Y	7	380	

GU Committee

Group	Protocol Number	Study Title	Phase	Status	CTSU	OPEN	Current Accrual	Accrual Goal	Projected Closure
CALGB	90202	Early vs delayed zoledronic acid to prevent SREs in PCa	III	A	Y	P	621	680	8/2012
CALGB	90203	Neoadj docetaxel/ADT + RP vs RP alone in high-risk localized PCa	III	A	Y	P	381	750	8/2016
CALGB	90601	Gemcitabine, cisplatin, +/- bevacizumab in pts with advanced TCC	III	A	Y	P	159	500	
CALGB	90802	Everolimus +/- bevacizumab for adv RCC pts failing TKIs	III	A	Y	P	24	700	

Leukemia Committee

Group	Protocol Number	Study Title	Phase	Status	CTSU	OPEN	Current Accrual	Accrual Goal	Projected Closure
CALGB	10403	ALL: Phase II study for adolescents and young adults with ALL	II	A	X	X	226	300	02/2013
CALGB	10404	CLL: Phase II study of four flu/antibody comb in prev untrtd CLL	II	A	X	X	322	405	10/2012
CALGB	10701	ALL: Dasatinib as primary therapy for Ph+ ALL	II	A	P	P	2	66	
CALGB	10801	AML: Ph II study of dasat/dnr/cytarabine + ara-c/dasat + dasat	II	A	P	P	13	59	
CALGB	11001	AML: Ph II study of sorafenib + chemotherapy in FLT+ pts >= 60 years	II	A	P	P	3	49	
CALGB	11002	AML: Rnd ph II study of decitabine-based ind in pts age >= 60	II	A	P	P	0	172	

Lymphoma Committee

Group	Protocol Number	Study Title	Phase	Status	CTSU	OPEN	Current Accrual	Accrual Goal	Projected Closure
CALGB	50303	NHL: R-CHOP vs EPOCH-R in DLBCL	III	A	Y	P	411	478	11/2012
CALGB	50604	Ph II response-adapted chemo based on PET for st I & II HL	II	A	P	P	50	149	
CALGB	50801	Ph II response-adapted tx based on PET for bulky st I & II HL	II	A	P	P	10	123	
CALGB	50901	Ph II of ofatum in unt'd follicular NHL	II	A	P	Y	0	100	
CALGB	50904	Rand ph II of ofatum/benda vs ofatum/bort/benda in unt'd FL	II	A	P	P	5	130	

LEGEND

Current Status
A=Active
S=Suspended

CTSU Status
Y=Available
P=Pending
X=No plans to place on menu

OPEN Registration System Status
Y=Available
P=Pending
X=No plans to put in system

Neuro-Oncology Committee

Group	Protocol Number	Study Title	Phase	Status	CTSU	OPEN	Current Accrual	Accrual Goal	Projected Closure
NCCTG	N0572	A phase I/II trial of sorafenib and CCI-779 in patients with recurrent glioblastoma	I/II	A	P	P	95	144	
NCCTG	N0574	A phase III randomized trial of the role of whole brain radiation therapy in addition to radiosurgery in the management of patients with one to three cerebral metastases	III	A	Y	P	101	138	08/2014
NCCTG	N0577	Phase III intergroup study of radiotherapy versus temozolomide alone versus radiotherapy with concomitant and adjuvant temozolomide for patients with 1p/19q codeleted anaplastic glioma	III	A	Y	P	32	488	
NCCTG	N0872	Phase I/randomized phase II double blind study of either dasatinib or placebo combined with bevacizumab in recurrent glioblastoma	I/II	A	P	P	18	158	
NCCTG	N0874	Phase I/II study of vorinostat (suberoylanilide hydroxamic acid [SAHA]), temozolomide, and radiation therapy in patients with newly diagnosed glioblastoma	I/II	A	Y	Y	15	132	
NCCTG	N0877	Phase I/randomized phase II trial of either dasatinib or placebo combined with standard chemo-radiotherapy for newly diagnosed glioblastoma multiforme (GBM)	I/II	A	P	P	21	177	
NCCTG	N107C	A phase III trial of post-surgical stereotactic radiosurgery compared with whole brain radiotherapy (WBRT) for resected metastatic brain disease	III	A	Y	Y	1	192	
NCCTG	N057K	Phase I/II evaluation of everolimus (RAD001), radiation and temozolomide (TMZ) followed by adjuvant temozolomide and everolimus in newly diagnosed glioblastoma	I/II	S	X	X	121	138	

Respiratory Committee

Group	Protocol Number	Study Title	Phase	Status	CTSU	OPEN	Current Accrual	Accrual Goal	Projected Closure
ACOSOG	Z4099	A randomized phase III study of sublobar resection (+/- brachytherapy) versus stereotactic body radiation therapy in high risk patients with stage I non-small cell lung cancer (NSCLC)	III	A	Y	Y	1	420	
CALGB	30607	Sunitinib as maint following chemo in stage IIIB/IV NSCLC	III	A	Y	P	158	244	9/2013
CALGB	30610	Comparison of XRT regimens in LSCLC	III	A	Y	P	202	710	
CALGB	30801	Evaluating COX-2 inhibition in COX-2 exprsng NSCLC	III	A	Y	P	85	297	
CALGB	30901	Pem vs obs for 2nd line meso	II	A	Y	X	3	96	
CALGB	140503	Lobectomy vs limited resection for < 2cm NSCLC tumors	II	A	Y	P	65	99	
NCCTG	N0923	A randomized double-blinded phase II study of NTX-010, a replication-competent picornavirus, after standard platinum-containing cytoreductive induction chemotherapy in patients with extensive stage small cell lung cancer	II	A	Y	P	26	99	

Transplant Committee

Group	Protocol Number	Study Title	Phase	Status	CTSU	OPEN	Current Accrual	Accrual Goal	Projected Closure
CALGB	100103	Non-myeloablative allo transplant for older pts w/ AML CR1	II	A	X	X	131	136	02/2012
CALGB	100601	Reduced intensity allo HCT for pts w/ relapsed hem mal or MDS	II	A	P	P	6	88	
CALGB	100701	Reduced Allo SCT for high-risk CLL	II	A	P	P	23	78	
CALGB	100801	5-Azacitidine + RIT for myelodysplasia and older pts w/AML	II	A	P	P	15	64	

LEGEND

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SEASON'S GREETINGS!



ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY