

Alliance Membership

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ALLIANCE MEMBERSHIP AT A GLANCE

Clinical Trials Access

- Scientific expertise from a wide variety of academic and community practice settings
- New investigational agents that are not part of conventional chemotherapies
- Translational research, including imaging, leukemia and solid tumor correlative sciences, and pharmacogenomics and population pharmacology
- Cancer control research, including cancer in the elderly, community oncology, comparative effectiveness research, health disparities, health outcomes, prevention and symptom intervention

ALLIANCE INSTITUTIONS*

Allan Blair Cancer Centre
Atlanta Regional CCOP
Avera Cancer Institute
Bay Area Cancer Institute (CCOP)
Baylor University Medical Center
Cancer Research for the Ozarks (CCOP)
Carolinas Medical Center
Cedar Rapids Oncology Project (CCOP)
Central Baptist Hospital
Christiana Care CCOP
Dayton CCOP
Doctors Hospital of Laredo
Duke University Medical Center
Eastern Maine Medical Center
Edwards Comprehensive Cancer Center
Geisinger Medical Center (CCOP)
Georgia Health Sciences MB CCOP
Grand Rapids CCOP
Greenville CCOP
Gunderson Lutheran Health System CCOP
Hackensack University Medical Center
Harry S. Truman VA
Heartland Cancer Research CCOP
Hematology Oncology Associates
of Central New York (HOACNY)
Huntsman Cancer Institute/University of Utah
Iowa Oncology Research Association CCOP
Lakeland Regional Cancer Center
Legacy Good Samaritan Medical Center
London Regional Cancer Center

Main Line Health CCOP
MD Anderson
Mehary Medical College MBCCOP
Metro-Minnesota CCOP
Michigan Cancer Research Consortium CCOP
Missouri Valley Cancer Care
Montana Cancer Consortium CCOP
Morton Plant Mease Health Care
New Hampshire Oncology-Hematology PA
Northeast Georgia Medical Center
Sanford Bismarck Medical Center
Sanford Research USD (CCOP)
Sharp Memorial Hospital
Southeast Cancer Control Consortium (CCOP)
SUNY Upstate Medical University
Tufts Medical Center
University of Arkansas
University of California San Francisco
University of Kentucky
University of Maryland
University of Missouri
University of North Carolina
University of Pittsburgh
Upstate Carolina CCOP
Wake Forest University Health Sciences
Western Pennsylvania Hospital
West Virginia University
Wichita CCOP

**as of December 1, 2012*

are welcome to apply for membership. Successful applicants will meet all membership requirements, including accrual, data quality and timeliness, adherence to Alliance policies and procedures, and participation in Alliance scientific activities.

Questions: Learn more about Alliance membership today, contact Marcia Kelly, Membership and Administrative Manager, by e-mail marciak@uchicago.edu or phone 773-834-7676.

Alliance ASCO 2013 Submission Policy

The 2013 American Society of Clinical Oncology (ASCO) Annual Meeting will take place May 31-June 4, 2013 in Chicago, IL. The deadline for submission of ASCO abstracts is February 5, 2013.

All draft abstracts from Alliance for Clinical Trials in Oncology (including all three legacy groups: ACOSOG, CALGB and NCCTG) must be submitted by Tuesday, January 22, 2013 to the Alliance by e-mail to pubscoord@calgb.org. This deadline is firm, and is required to ensure time for central review of content, as well as review of author lists. Adherence to this guideline will assure sufficient time for the each lead investigator to submit to ASCO. All Alliance abstracts must follow this process. Independent submission of work related to the Alliance without this proper review is not permitted.

For accepted abstracts, please send the publications coordinator (pubscoord@calgb.org) the acceptance notification and final accepted abstract within one (1) week after notification of acceptance from ASCO.

An Alliance abstract should contain the following information:

Study number(s)

- For an Alliance study X, the study number should appear in the title as “Alliance X”
- For a legacy study, the study number should appear in the title as “[Legacy Group Name] X (Alliance)” (e.g., “CALGB 40101 (Alliance)”)
- If multiple studies are involved and the title cannot accommodate all of the numbers, the study numbers must appear in the text of the abstract.

Authors

- The Alliance statistician must appear in the list of authors, usually as second author
- The list of authors should reflect study participation, including patient accrual and scientific input

Affiliation and grant support

- Provide institutional affiliation and grant/foundation support for each author

Corresponding author

- Provide the name and contact information of the corresponding author

2013 ASCO Annual Meeting: Abstract Schedule

Author deadline to submit abstract to Alliance for review	January 22, 2013
ASCO abstract submission deadline	February 5, 2013 / 11:59 pm EST
Author deadline to send accepted abstract to Alliance	One week after notification of acceptance from ASCO
ASCO meeting dates	May 31-June 4, 2013

Questions: For more information about the Alliance abstract submission process, contact the publications coordinator (pubscoord@calgb.org).

Alliance Forms New Research Committee



Deborah Schrag



Stephen Edge



George Chang



Caprice Greenberg



Barbara Pockaj



David Winchester

The Alliance for Clinical Trials in Oncology announces the formation of the new Cancer Care Delivery Research Committee of the American College of Surgeons Clinical Research Program (ACS CRP). This new committee represents the reformulation of the Comparative Effectiveness Research Committee (formerly part of the Cancer Control Program and led by **Deborah Schrag, MD**) and the Research Development Committee (formerly of ACS CRP and led by **Stephen Edge, MD**). **George Chang, MD**, and **Caprice Greenberg, MD**, will lead the new committee.



Heidi Nelson

Dr. Edge will assume the role of vice chair of the committee with a role to help foster collaboration between the Commission on Cancer and the Alliance. **Barbara Pockaj, MD**, former committee vice chair will also continue on the committee and develop projects related to breast cancer outcomes. Special thanks are extended to **David Winchester, MD**, **Heidi Nelson, MD**, and Drs. Edge and Schrag for their help in transitioning this important program into its next phase.



Alliance Members on the Move



Federico Innocenti

Federico Innocenti, MD, PhD, has been selected as the 2013 recipient of the Leon I. Goldberg Young Investigator Award from the American Society for Clinical Pharmacology and Therapeutics. The Goldberg award honors young scientists for accomplishments in the field of clinical pharmacology achieved early in their careers. Dr. Innocenti is associate director for oncology research in the University of North Carolina at Chapel Hill (UNC) Institute for Pharmacogenomics and Individualized Therapy, an associate professor in UNC Division of Pharmacotherapy and Experimental Therapeutics, and vice chair of the Alliance GI Committee.

NCI Revises Clinical Trials Audit Guidelines

Effective January 1, 2013, the National Cancer Institute's Clinical Trials Monitoring Branch (CTMB) will institute guidelines revised in October 2012 for auditing of clinical trials for cooperative groups, community clinical oncology program research bases, and the Cancer Trials Support Unit (CTSU). Complete guidelines, along with other support materials, can be found on the NCI website: http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring_coop_ccop_ctsu.htm

The Alliance Audit Committee has reviewed the guidelines and summarized the following key points for Alliance members.

Choosing Patient Lists for Audit

When choosing audit patient lists, a minimum number of cases equivalent to 10% of patients accrued since the last audit will be reviewed. Ten percent of patient cases accrued must be selected from each participating institution (Main Member, Affiliate, CCOP, each individual CCOP component and Special Member). For selection purposes, the 10% of chosen cases must be rounded up. For example, if 12 patient cases are eligible for selection, at least two cases will be audited. For selection of patient cases, the following apply where appropriate: 1) 10% of Group/CCOP cases, 2) 10% of Group/CCOP "endorsed" cases, 3) 10% of "non- endorsed" cases credited to the Group or CCOP, and 4) 10% accrual from Division of Cancer Prevention (DCP)/Cancer Control cases through the CTSU mechanism.

Institutional Review Board (IRB) / Informed Consent Content (ICC)

1. Protocol amendments should be approved, or disapproved, within 90 days of the posting dates.
2. Even if a "Request for Rapid Amendment (RRA)" resulting from an Action Letter indicating temporary suspension of accrual allows expedited review, a Major deficiency will be assigned if the approval (or disapproval) is greater than 90 days.
3. Protocol updates which are only editorial or administrative in nature (typographical errors, rephrasing or reformatting, changes in contact information) are exempt from the 90 day requirement.
4. Any site that uses CIRB as its IRB of record should have a copy of its CIRB Facilitated Review Form for each applicable study available for auditors. The new guidelines require that each site (even the affiliates that use their main member's IRB) maintain all CIRB approvals either hard copy or downloaded in a database. Auditors will not need to assure each and every approval are present, but are required to assure these files are maintained on site.
5. A random sample of at least 10% of external safety reports reportable per Office for Human Research Protections (OHRP) policy regarding unanticipated problems should be reviewed for each protocol selected for an audit. (See Appendix 6 of CTMB guidelines.) Sites should have a copy of the relevant policy available for review at audit time.

Drug Accountability

The revised guidelines clarify several of the compliant and non-compliant items, but most importantly, added a new category for review. The "Authorized Prescriptions" category is used to assure procedures are in place so that pharmacy staff ensure persons prescribing the DCTD-agent are investigators registered with PMB and/or prescriptions are co-signed by a registered investigator. Auditors are required to assure there is a procedure in place. Auditors will discuss local procedures with the investigational pharmacist or pharmacy director.

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NCI Clinical Trials Audit Guidelines

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It is highly recommended each site provide its pharmacy staff with a copy of the revised section 5.3 of the guidelines.

Responding to Audits

Site Corrective Action Plans (CAPs) are now called Corrective and Preventative Action (CAPA) plans to assure all plans provide preventative measures for past deficiencies.

Looking Ahead

The Pharmaceutical Management Branch (PMB) has announced the development of a new Drug Accountability Record Form (DARF) specifically for oral agents, called the DARF (Oral). It is expected the new form will be approved early 2013 and will become effective spring 2013. The current drug accountability form will still be referred to as the DARF and will continue to be used for injectable agents. Only oral agents will be tracked on the new DARF (Oral). The new form will be oriented horizontally (landscape) with columns to account for patient returns. For more information about the PMB, please click on the following link to review the November 2012 Inside PMB newsletter: http://ctep.cancer.gov/branches/pmb/inside_pmb/nov2012.pdf

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Alliance Releases Annual Manuscripts Book

The Alliance Publications Committee, in collaboration with the Office of the Group Chair, proudly announced the release of the 2012 Alliance Published Manuscripts book at the 2012 Fall Alliance Committee Meetings held November 15-17 at the Intercontinental Chicago O'Hare in Chicago, IL. The book featured original manuscripts published by the three legacy groups between September 1, 2011 and August 30, 2012. While the book had a limited release, it marked the beginning of an annual tradition to recognize and honor the work of Alliance researchers. More than 70 published manuscripts were cited in the book, along with the manuscripts deemed most significant in the past year by the Alliance review panel. For more information on the selection process, visit the Alliance website (AllianceforClinicalTrialsinOncology.org).

Alliance Conflict of Interest Policy

The Alliance Board of Directors approved the Alliance Conflict of Interest (COI) Policy at the 2012 Alliance Group Meeting, and it is currently in effect. The COI policy is designed to monitor possible financial conflicts of interest of Alliance study investigators and group leaders involved in the development, conduct, analysis and reporting of Alliance clinical trials. The policy helps to protect the integrity of study data through a management plan that includes independent data review when study chairs have financial interests related to a study.

Alliance study chairs, study co-chairs, committee chairs and vice chairs, Data and Safety Monitoring Board (DSMB) members, Study Concept Review Committee (SCRC) members, main member principal investigators, group leaders and Alliance staff are required to disclose all financial arrangements greater than \$5,000 annually that are related to Alliance research studies.

The Alliance has established a formal COI collection and review process. The Alliance Chicago Office staff requests completion of COI forms at least annually. Prior to concept submission, proposed study chairs/co-chairs are required to submit a COI disclosure form. The staff forwards any forms documenting potential conflicts of interest to the COI Committee. A COI Committee member reviews the disclosures and if necessary contacts the individual for additional information. The COI Committee forwards any conflict of interest disclosures of concern, along with their recommendations to the Group Chair and Executive Committee. The Alliance Executive Committee sends its recommendations to the Group Chair for action. Failure to submit COI forms or to comply with COI management plans by individuals subject to the COI policy may result in suspension of Alliance membership privileges including study or committee chairpersonship. Updated COI forms must be submitted within 30 days of a change in financial arrangements. Study specific COI forms must be submitted until study results are published.

Alliance institutions are required to implement Financial Conflict of Interest (FCOI) policies in compliance with federal regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought (42 CFR Part 50 Subpart F). The institutional policy is separate from the Alliance COI policy for investigators and group leaders.

For a copy of the full policy, visit the Alliance website (member side) or click the following link: <https://www.allianceforclinicaltrialsinoncology.org/main/member/standard.xhtml?path=%2F-Member%2FGovernance>.

Questions: Contact Trini Ajazi, Chief Administrative Officer, by e-mail tajazi@uchicago.edu or phone 773-702-8672 for more information about the Alliance Conflict of Interest Policy.

Alliance Launches New BioSpecimen Management System

The Alliance will activate its new biospecimen management system (BioMS) on January 8, 2013. BioMS is a web-based tool that must be used at enrolling sites to log, ship and track biospecimens collected from Alliance clinical trial participants. This includes biospecimens collected from both newly enrolled participants as well as participants previously enrolled on any new Alliance trial, or legacy CALGB, NCCTG or ACOSOG trial involving biospecimen submission.

Although new Alliance protocol documents will refer to BioMS and the BioMS website, it is not possible to immediately amend all existing trial protocols. All clinical research staff at Alliance sites should be made aware that all actively accruing Alliance, ACOSOG, NCCTG and CALGB protocols will utilize BioMS for logging biospecimens, starting January 8, 2013.

Sites previously using the CALGB Specimen Tracking System (STS) for logging and shipping biospecimens must also begin using BioMS in January. The STS system will be retired and users will be redirected to the BioMS website for logging specimens related to CALGB legacy studies. The BioMS has a similar look to STS, but has a number of performance and usability enhancements based on extensive user feedback.

Logging biospecimens in BioMS is a prerequisite for shipping to any Alliance biorepository or assay lab associated with an Alliance trial. Sites that ship specimens without first logging them in BioMS will be contacted by the Alliance repository or assay lab staff, which may result in a delay in specimen processing.

Clinical research staff may access BioMS using most standard web browsers at the web address that will be provided soon. Access to BioMS will require a valid IAM (CTSUS) username and password and users will be able to view and enter data only on those biospecimens collected from participants registered at the clinical site with which they are associated. In the meantime, training materials, user manuals, and FAQs are available on the BioMS help site, now available at this temporary location: <https://cbmiapps.wustl.edu/confluence/display/BP/BioSpecimen+Management+System+-+BioMS>.

Foundation Announces New Alliance Scholar Award for Junior Faculty

The Alliance for Clinical Trials in Oncology Foundation announces a new award format for its investigator awards for 2013, The Alliance Scholar Award. The award is a two-year, non-renewable cancer research grant exclusively for oncology junior faculty at Alliance institutions. Applicants must be within five years of training and ranked below Associate Professor. The award pays up to \$40,000 in direct costs per year for two years. The Foundation's policy provides for Alliance institutions to include up to 10 percent of indirect costs in the budget.

General guidelines for Alliance Scholar applicants:

- Applicants must have completed training in an oncology clinical specialty (e.g., medical, surgical, radiation, gynecologic, etc.).
- Proposals must be nominated by an Alliance Scientific Committee Chair and be closely tied to the research agenda of the Alliance. In order to ensure endorsement of the relevant Alliance Scientific Committee, potential applicants must work with the respective committee chair prior to submission of application to obtain a letter of support for inclusion with application materials.
- Projects supported by other non-institutional funds are not eligible.

The deadline to submit applications for the award is by midnight (Central Standard Time) April 15, 2013. Successful applicants will be announced at the 2013 Alliance Group Meeting, held in Chicago, IL, November 7-9, 2013. Funding will begin approximately January 1, 2014.

The award's formal Request for Proposals (RFP), with a link to a new online submission portal, will be available soon. In the meantime, visit the Foundation page on the Alliance website (AllianceforClinicalTrialsinOncology.org) for more information about the Alliance Scholar Award.

Alliance Trials Portfolio

The following is a list of ongoing Alliance 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), listed on the CTSU menu (A=Alliance Section; C=CALGB Section; N=NCCTG Section), and implementation of OPEN registration system (Y=Available; P=Pending; X=No plans to put in system) as of December 1, 2012.

Breast Committee

Updated 12/01/12

Protocol Number	Study Title	Phase	Status	CTSU	OPEN
ACOSOG Z1072	A phase II trial exploring the success of cryoablation therapy in the treatment of invasive breast carcinoma (limited access trial)	II	A	X	Y
ACOSOG Z11102	Impact of breast conservation surgery on surgical outcomes and cosmesis in patients with multiple ipsilateral breast cancers (MIBC)		A	Y (A)	Y
Alliance 8129	Phase I/II trial of IMC-A12 in combination with temsirolimus in patients with metastatic breast cancer	I/II	A	Y (A)	Y
CALGB 40903	Phase II study neoadjuvant letrozole for postmenopausal women with estrogen receptor positive ductal carcinoma in situ (DCIS)	II	A	Y (A)	Y
NCCTG N093B	Phase I/II study of panobinostat (LBH589) and letrozole in patients with triple negative metastatic breast cancer	I/II	A	Y (A)	Y

LEGEND

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

Alliance Trials Portfolio continued

GI Committee

Updated 12/01/12

Protocol Number	Study Title	Phase	Status	CTSU	OPEN
ACOSOG Z5041	Laparoscopic-assisted resection or open resection in treating patients with stage IIA, stage IIIA, or stage IIIB rectal cancer	III	A	Y (Z)	Y
ACOSOG Z6051	A phase III prospective randomized trial comparing laparoscopic-assisted resection versus open resection for rectal cancer	II/III	A	N	Y
CALGB 80702	A phase III trial of 6 versus 12 treatments of adjuvant FOLFOX plus celecoxib or placebo for patients with resected stage III colon cancer	III	A	Y (C)	Y
CALGB 80802	Phase III randomized study of sorafenib plus doxorubicin versus sorafenib in patients with advanced hepatocellular carcinoma (HCC)	III	A	Y (C)	Y
CALGB 80803	Randomized phase II trial of PET scan-directed combined modality therapy in esophageal cancer	II	A	Y (C)	Y
NCCTG N0543	A phase II trial of pharmacogenetic-based dosing in irinotecan, oxaliplatin, and capecitabine as first-line therapy for advanced small bowel adenocarcinoma	II	A	X	X
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 (N)	Y
NCCTG N1048	A phase II/III trial of neoadjuvant FOLFOX with selective use of combination XRT in locally advanced rectal cancer	II/III	A	Y (N)	Y

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Alliance Trials Portfolio continued

GU Committee

Updated 12/01/12

Protocol Number	Study Title	Phase	Status	CTSU	OPEN
CALGB 90203	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	III	A	Y (C)	Y
CALGB 90601	A randomized double-blinded phase III study comparing gemcitabine, cisplatin, and bevacizumab to gemcitabine, cisplatin, and placebo in patients with advanced transitional cell carcinoma	III	A	Y (C)	Y
CALGB 90802	Randomized phase III trial comparing everolimus versus everolimus plus bevacizumab for advanced renal cell carcinoma progressing after treatment with tyrosine kinase inhibitors	III	A	Y (C)	Y

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Alliance Trials Portfolio continued

Leukemia Committee

Updated 12/01/12

Protocol Number	Study Title	Phase	Status	CTSU	OPEN
CALGB 10701	A phase II study of dasatinib (Sprycel) (IND #73969, NSC #732517) as primary therapy followed by transplantation for adults = 50 years with newly diagnosed Ph+ acute lymphoblastic leukemia	II	A	Y (C)	P
CALGB 10801	A phase II study of induction (daunorubicin/ cytarabine) and consolidation (high-dose cytarabine) chemotherapy plus dasatinib (NSC #732517, IND #73969) and continuation therapy with dasatinib alone in newly diagnosed patients with core binding factor acute myeloid leukemia (AML)	II	A	P	P
CALGB 11001	A phase II study incorporating sorafenib (IND 69896, NSC 724772) into the therapy of patients ≥ 60 years of age with FLT3 mutated acute myeloid leukemia	II	A	P	P
CALGB 11002	A randomized phase II trial of decitabine-based induction strategies for patients ≥ 60 years old with acute myeloid leukemia (AML)	II	A	P	P
NCCTG N1087	Phase I/II study of the combination of bendamustine, rituximab and MK-2206 in the treatment of relapsed chronic lymphocytic leukemia and small lymphocytic lymphoma	I/II	S	X	Y

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Alliance Trials Portfolio continued

Lymphoma Committee

Updated 12/01/12

Protocol Number	Study Title	Phase	Status	CTSU	OPEN
CALGB 50303	A phase III randomized study of R-CHOP v. dose-adjusted EPOCH-R with molecular profiling in untreated de novo diffuse large B-cell lymphomas	III	A	Y (C)	P
CALGB 50604	Phase II trial of response-adapted chemotherapy based on positron emission tomography for non-bulky stage I and II Hodgkin lymphoma	II	A	Y (C)	Y
CALGB 50801	Phase II trial of response-adapted therapy based on positron emission tomography (PET) for bulky stage I and stage II classical Hodgkin lymphoma (HL)	II	A	P	Y
CALGB 50901	A phase II trial of ofatumumab (CALGB IND# 112390) in previously untreated follicular non-Hodgkin's lymphoma (NHL)	II	A	P	Y
CALGB 50904	A randomized phase II trial of ofatumumab and bendamustine vs. ofatumumab, bortezomib and bendamustine in patients with untreated follicular lymphoma	II	A	Y (A)	Y
CALGB 51101	A randomized phase II trial of myeloablative versus non-myeloablative consolidation chemotherapy for newly diagnosed primary CNS B-cell lymphoma	II	A	Y (C)	Y
NCCTG N1088	A pilot/feasibility phase I study of bendamustine, rituximab and lenalidomide in patients with refractory/relapsed indolent NHL (NCCTG only)	I	A	X	X

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Alliance Trials Portfolio continued

Neuro-Oncology Committee

Updated 12/01/12

Protocol Number	Study Title	Phase	Status	CTSU	OPEN
NCCTG N0572	A phase I/II trial of sorafenib and CCI-779 in patients with recurrent glioblastoma	I/II	A	X	X
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	S	Y (N)	X
NCCTG N0872	Phase I/randomized phase II double blind study of either dasatinib or placebo combined with bevacizumab in recurrent glioblastoma	I/II	A	Y (A)	Y
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	Y (A)	Y
NCCTG N107C	A phase III trial of post-surgical stereotactic radiosurgery compared with whole brain radiotherapy (WBRT for resected metastatic brain disease)	I	A	Y (N)	Y

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Alliance Trials Portfolio continued

Respiratory Committee

Updated 12/01/12

Protocol Number	Study Title	Phase	Status	CTSU	OPEN
ACOSOG Z4099	A randomized phase III study of sublobar resection (+/- brachytherapy) versus stereotactic body radiation therapy in high risk patients with <u>stage I non-small cell lung cancer (NSCLC)</u>	III	A	Y (Z)	Y
CALGB 30607	Randomized, phase III, 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	III	A	Y (C)	Y
CALGB 30610	Phase III comparison of thoracic radiotherapy regimens in patients with limited small cell lung cancer also receiving cisplatin and etoposide	III	A	Y (C)	P
CALGB 30801	A randomized phase III double blind trial evaluating selective COX-2 inhibition in COX-2 expressing advanced non-small cell lung cancer	III	A	Y (C)	Y
CALGB 30901	Randomized phase II study of maintenance pemetrexed versus observation for patients with malignant pleural mesothelioma without <u>progression after first-line chemotherapy</u>	II	A	Y (C)	Y
CALGB 31102	Phase I study of accelerated hypofractionated radiation therapy with concomitant chemotherapy for unresectable stage III non-small cell lung cancer (limited access)	I	A	Y (A)	Y
CALGB 140503	A phase III randomized trial of lobectomy versus sublobar resection for small (<=2 cm) peripheral non-small cell lung cancer	III	A	Y (C)	Y
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 <u>extensive stage small cell lung</u>	II	A	Y (N)	P

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Alliance Trials Portfolio continued

Transplant Committee

Updated 12/01/12

Protocol Number	Study Title	Phase	Status	CTSU	OPEN
CALGB 100701	Phase II study of reduced-intensity allogeneic stem cell transplant for high-risk chronic lymphocytic leukemia (CLL)	II	A	P	P
CALGB 100801	Phase II study of the addition of azacitidine (IND #87574, NSC #102816) to reduced-intensity conditioning allogeneic transplantation for myelodysplasia (MDS) and older patients with AML	II	A	P	P

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Alliance Trials Portfolio continued

Cancer Control Program

Updated 12/01/12

Protocol Number	Study Title	Phase	Status	CTSU	OPEN
Alliance A211201	Change in mammographic density with metformin use: A companion study to NCIC study MA.32	-	A	Y (A)	Y
Alliance 221102	Randomized Double-Blind Placebo Controlled Study of Subcutaneous Testosterone in the Adjuvant Treatment of Postmenopausal Women with Aromatase Inhibitor Induced Arthralgias	-	A	Y (A)	P
CALGB 70305	A randomized study to prevent lymphedema in women treated for breast cancer (limited access)	II	A	Y (C)	X
CALGB 70806	Vitamin D and breast cancer biomarkers	II	A	Y (C)	Y
CALGB 70807	The Men's Eating and Living (MEAL) study: A randomized trial of diet to alter disease progression in prostate cancer patients on active surveillance	III	A	Y (C)	Y
NCCTG N0392	Assessment of patient satisfaction with participation in phase II/III NCCTG clinical trials	II/III	A	X	X
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
NCCTG N08C9	Phase III, randomized study of sulfasalazine versus placebo in the prevention of acute diarrhea in patients receiving pelvic radiation therapy	III	A	Y (A)	Y
NCCTG N10C1	Vaginal DHEA for vaginal symptoms: A phase III randomized, double-blind, placebo-controlled study	III	A	P	X
NCCTG N10C2	Phase III double-blind, placebo-controlled study of magnesium supplements to reduce menopausal hot flashes	III	A	X	X
NCCTG GLNE010	Validation and comparison of biomarkers for the early detection of colorectal adenocarcinoma	-	A	Y (A)	X

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Alliance Trials Portfolio continued

Experimental Therapeutics Committee

Updated 12/01/12

Protocol Number	Study Title	Phase	Status	CTSU	OPEN
Alliance A091101	TPF Induction Chemotherapy and Veliparib: A Phase 1/Randomized Phase 2 Study in Patients with Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck	I/II	A	Y (A)	Y
Alliance A091102	Phase II study of MLN8237 in advanced/metastatic sarcoma	II	S	Y (A)	Y
Alliance A091103	Phase II study of the angiopoietin-1 and -2 peptibody AMG 386 for the treatment of angiosarcoma	II	A	Y (A)	Y
Alliance A091104	A phase II study of MK-2206 in patients with progressive, recurrent/metastatic adenoid cystic carcinoma	II	A	Y (A)	Y
NCCTG N0871	A phase II study of carboplatin (CBDCA), paclitaxel (TAXOL), and everolimus (RAD001) in previously untreated patients with measurable disease with cancer of unknown primary (CUP)	II	A	X	X
NCCTG N0879	A randomized phase II trial of carboplatin, paclitaxel, bevacizumab, with or without everolimus for therapy of metastatic malignant melanoma	II	A	X	X
NCCTG N1085	A phase I/feasibility study of everolimus (RAD001) plus R-CHOP for new untreated diffuse large B-cell lymphoma (DLBCL)	I	A	X	X

LEGEND

Current Status: A = Active; S = Suspended

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

(A) = Alliance Section **(C)** = CALGB Section **(N)** = NCCTG Section **(Z)** = ACOSOG Section

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

Upcoming Alliance Meetings / 2013 & 2014

2013 Committee Meetings

Open to Alliance committee members only

March 14-17, 2013

InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018

**Breast Committee will meet on Sunday, March 17*

***Draft schedule available on Alliance website.*

2013 Group Meeting

Open to Alliance members

November 7-9, 2013

InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018

*For meeting and travel inquiries,
contact Katherine Faherty:
e-mail: kefaherty@partners.org
phone: 617-525-3022*

2014 Committee Meetings

Open to Alliance committee members only

May 8-10, 2014*

InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018

**date changed from March 27-29, 2014*

*For more information on the Alliance
and updates to meeting information,
visit AllianceforClinicalTrialsinOncology.org*

2014 Group Meeting

Open to Alliance members

November 6-8, 2014

InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018