Alliance for Clinical Trials in Oncology

NEWS

Winter 2014
Volume 4, No. 2

info@alliancenctn.org

2014 NCTN TRANSITION

What Happens March 1

The National Cancer Institute (NCI) has transformed the previous NCI-sponsored Clinical Trials Cooperative Group Program that funded several separate organizations into a new consolidated and integrated program now called the NCI National Clinical Trials Network (NCTN). This new program will become effective March 1, 2014.

The overarching goal of the NCTN is to conduct definitive, randomized, late phase clinical treatment trials and advanced imaging trials across a broad range of diseases and diverse patient populations. It will comprise four adult network groups, one pediatric group and one Canadian collaborating clinical trials group that will generate trials for the network.

Sites can participate in one of three mutually exclusive ways, with the exception of some pediatric sites. Sites can be members of multiple network groups with varying types of membership but the NCTN category (or component) must remain the same across all groups.

NCTN Components	Component Tiers
1 Lead Academic Participating Sites (LAPS)	• LAPS Main Institution • LAPS Integral Component • LAPS Affiliates / Sub-Affiliates
2 CCOPs MB-CCOPs	• CCOP Component • CCOP Sub-Component
3 Adult Network Group	• Main Member • Affiliate • Sub-Affiliate
OR	
3 Pediatric Network Group	• Main Member

continued next page

Member institutions of network groups can enroll patients on all adult phase III trials, randomized phase II trials, as well as select early phase trials, irrespective of the specific Network Group that is leading the trial (also known as Lead Protocol Organization, or LPO). In addition, select trials for adolescent and young adults will be open to all member institutions or sites.

Here's what Alliance members need to know about the NCTN transition.

Transition Weekend

The NCI, Cancer Trials Support Unit (CTSU) and Alliance information systems will be transitioned to support the NCTN between **February 28** and **March 3**. During this time the rosters for the cooperative group will be transitioned to the NCTN rosters that include roster packages for Lead Academic Participating Sites (LAPS) from CTEP and Community Clinical Oncology Program (CCOP) from DCP. **Institutions will experience service interruptions for multiple CTSU applications during the transition weekend. Alliance information systems, including the Alliance member website and patient registration/randomization will not be available during the transition period.**

Membership Roster

In order to participate in adult NCTN trials as of March 3, a site must be a member of at least one of the adult NCTN Groups (Alliance, ECOG-ACRIN, NRG or SWOG). Any legacy ACOSOG, CALGB, NCCTG main member or affiliate (LAPS-aligned or non-LAPS affiliate) that did not receive approval as an Alliance member will not be rostered, as an Alliance member on March 1. Legacy members that do not continue their membership and are still following/treating patients on Alliance studies will be placed in a follow-up status in RSS, in order to allow them continued access to systems for data submission. The Alliance will provide additional instructions regarding roster management soon by broadcast e-mail and the Alliance website.

Patient Registration and Crediting

As of March 3, all patient registrations to NCTN trials must occur through OPEN. All new accruals to NCTN trials will be credited to the new NCTN Network Groups even if the studies are still identified under the Cooperative Group nomenclature (e.g., CALGB 140503). Accruals credited to the Alliance are subject to an audit by the Alliance.

Phase II and III studies that are currently available to cross-group participation will remain available for network participation. In the NCTN, any Participating Organization/Network Group can be credited with enrollments as long as a site is an active member of that Group.

Funding

NCI per case management payments for treatment/intervention, screening, QOL and bio-specimen collection, if applicable, will be made by the Network Group credited with the accrual OR the equivalent type will be paid via the NCTN LAPS grant or CCOP grant directly. Under the NCTN, upfront follow-up payments will be included in the base intervention payments for treatment trials. For trials that have additional funding from industry or other sources, payments will be distributed by the Network Group credited with the accrual to its sites. *continued next page*

Payment for some ancillary specimen submissions, QoL and other supplemental funds will require institutions to log into OPEN to document fulfillment. For non-Federal reimbursement of Alliance ancillary study requirements, receipt of specimens using BioMS will be used to determine payment eligibility. Please note that funding has changed for some ancillary specimen submissions. Updated funding sheets will be available on the CTSU and Alliance websites.

Protocol Amendments

During the course of 2014, active legacy trials will be amended to designate Alliance as the lead NCTN Group on the protocol title page.

NCI CIRB

All U.S. institutions/sites participating in NCTN trials as member of one or more Network Groups are required to use the NCI's CIRB as the IRB of record unless a waiver has been granted by the NCI. The NCI CIRB requirement will be phased in later this year and is expected to become mandatory within 18 months. A waiver process is being developed. No sites will be excluded from participation in the NCTN until this process has been fully developed and all Group members, CCOPs/MB-CCOPs, and LAPs have an opportunity to apply for CIRB membership and/or submit a waiver application.

Audit

Following the transition, all audits will be conducted as Alliance audits. These audits will be scheduled based on the earliest required audit date for the legacy group (ACOSOG, CALGB or NCCTG).

Website Access to Active Alliance Studies

Beginning March 1, all active Alliance and legacy ACOSOG, CALGB and NCCTG studies will be made available on the member side of the Alliance website at www.*allianceforclinicaltrialsinoncology.org*.

In addition, closed legacy ACOSOG, CALGB and NCCTG studies that require amendments will be moved to the member side of the Alliance website at the time those studies are updated. Once moved from the legacy website to the Alliance website, the protocols will only be available on the Alliance website or CTSU website, when applicable.

Access to the member side of the Alliance website requires a CTEP-IAM username and password. To obtain CTEP-IAM credentials, visit *https://eapps-ctep.nci.nih.gov/iam*

The Alliance will provide additional logistical information as it becomes available. Please also check the CTSU Member website under Transition News. *https://www.ctsu.org*.

Imaging and Radiation Oncology Core (IROC) Cooperative

Another important change resulting from the development of the NCI National Clinical Trials Network (NCTN) has been the creation of the Imaging and Radiation Oncology Core (IROC) Cooperative. IROC is the merger of radiation therapy (RT) and imaging quality assurance (QA) centers into a single group that will provide scientific and technical expertise in both diagnostic imaging and radiation oncology to the entire NCTN network. These changes will be effective March 1, 2014.

IROC Co-Directors are **David S. Followill, PhD** (radiation oncology), Chief, Section of Outreach Physics in the Department of Radiation Physics, Division of Radiation Oncology at the University of Texas MD Anderson Cancer Center, and **Michael V. Knopp, MD, PhD** (imaging), Director, Wright Center of Innovation in Biomedical Imaging, Division of Imaging Science at The Ohio State University. IROC is administratively organized through the American College of Radiology (ACR) Clinical Research Center in Philadelphia and has additional support centers in Houston, TX; Columbus, OH; Lincoln, RI and St Louis, MO.

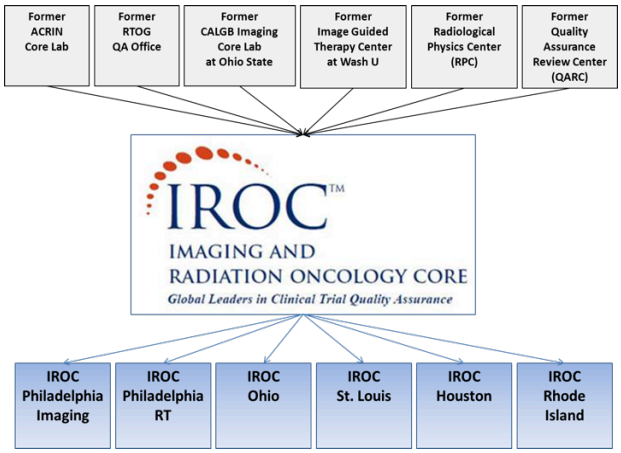


Figure 1 shows the legacy QA organizations that become IROC on March 1.

IROC will develop consistent standard operating procedures for all imaging and radiation oncology aspects of the NCTN, and will facilitate a seamless flow of imaging and RT datasets across the network. The cooperative's organizational structure will allow the delivery of a broad array of diagnostic imaging and radiation therapy QA services including other core services.

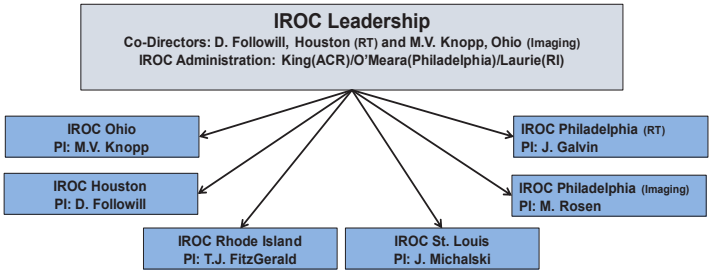


Figure 2 shows leadership for the entire IROC organization.

IROC's infrastructure will be built on a uniform platform. The informatics infrastructure will function at an enterprise level for all protocol activity, from patient entry to data management. IROC's efforts have the potential to substantially advance the use of imaging and radiation therapy within clinical trials and thereby help to further achieve the transformative goals of the NCTN.

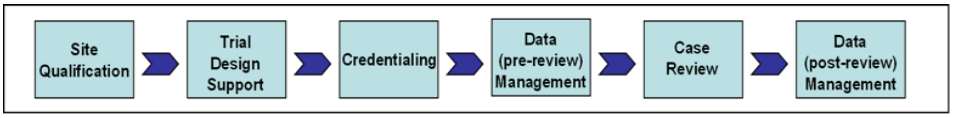


Figure 3 shows array of diagnostic imaging and radiation therapy QA services.

IROC will launch a new website in the coming months that will provide updated information about its services.

Content submission by Fran Laurie, Director of Operations
Imaging and Radiation Oncology Core Group – Rhode Island QA Center – IROC RI

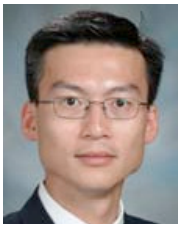
Symmans

Translational Research Director Named

W. Fraser Symmans, MD, has been selected to serve as the Director of the Alliance Translational Research Program. In this role, he will oversee the activities of all scientific and administrative committees devoted to designing and executing the highest quality translational science by the Alliance and by the NCTN as a whole.

Dr. Symmans is Professor and Director of Research Operations in the Department of Pathology at The University of Texas MD Anderson Cancer Center. His clinical diagnostic practice is in Breast Surgical Pathology and Cytopathology. An expert in breast cancer translational research, he co-developed a method to increase the prognostic information from pathologic assessment of response from neoadjuvant chemotherapy. He also adapted genomic technologies to clinical needle biopsies of breast cancer in order to use gene expression profiling to identify important genes for response to chemotherapy and, independently, to endocrine therapy; to validate gene expression tests with clinical potential; and to establish their performance in the context of clinical testing. In this capacity, he directs a CLIA-compliant pharmacogenomics laboratory to support clinical trials.

Dr. Symmans has served as principal investigator for numerous National Institutes of Health (NIH) and United States Department of Defense (DOD) funded awards to develop and validate predictive and prognostic biomarkers, including identifying estrogen reporter genes to predict response to endocrine therapy, validating transcriptional profile data to predict response to adjuvant paclitaxel therapy and integrating pathologic findings with clinical-radiologic tumor measurements to quantify response to neoadjuvant chemotherapy. He is also an active member within multicenter research collaborations, is a Susan G. Komen Scholar, and participates within the National Clinical Institute"s (NCI) North American Breast Group (NABG) and the Breast International Group (BIG) where he co-chairs the Residual Disease Working Group and is a member of the Biomarkers Working Group and the Breast Oncology Local Regional (BOLD) Task Force. Dr. Symmans currently serves as the Chair of the Pathology and Biomarkers Committees for the iSPY 2 Clinical Trial Investigators, and is a member of the Clinical Working Group for Microarray Quality Control Study (MAQC-II), for the U.S. Food and Drug Administration (FDA). Within the Alliance, Dr. Symmans has served as a member of the Breast Committee and the Clinical Trials Concept Review Committee.



Chang

Greenberg

New ACS CRP Cancer Care Delivery Research Committee

The Alliance/American College of Surgeons Clinical Research Program (ACS CRP) Cancer Care Delivery Research (CCDR) Committee has been developed to consolidate and promote the CCDR activities within the Alliance. It has evolved from a merger of the ACS CRP Research Committee and the Comparative Effectiveness Research working group of the Health Outcomes Committee to complement the extensive health services research portfolio of the Alliance through its various committees within the Cancer Control Program.

George J. Chang, MD, MS, of the MD Anderson Cancer Center, and **Caprice C. Greenberg MD, MPH**, of the University of Wisconsin School of Medicine and Public Health, serve as committee co-chairs. ACS CCDR is comprised of a multidisciplinary membership, and current committee members have expertise in comparative effectiveness research, health services research, health disparities, administrative database linking, psychometrics, health

continued last page

Growth Biomarker Strategy in Neoadjuvant Setting May Predict Long-term Outcome for Patients with ER+ Breast Cancer

Alliance A011106 Alternate Approaches for Clinical Stage II or III Estrogen Receptor Positive Breast Cancer Neoadjuvant Treatment (ALTERNATE) in postmenopausal women

Estrogen receptor positive (ER+) breast cancer in postmenopausal women is a major public health problem. In the U.S., 1 in 8 women will be diagnosed with breast cancer in their life time.[1] More than 232,000 new cancer cases and nearly 39,520 deaths are expected to be attributed to breast cancer each year.[2] Among all breast cancer cases, more than 75 percent occur in postmenopausal women, in whom 80 percent of the cases are ER+.[3] Since the majority of breast cancer cases are diagnosed at an early stage (I-III), relapse of early stage disease accounts for the majority of breast cancer deaths.[1] Although ER+ breast cancer tends to recur later in the course of disease than ER- breast cancer, the cumulative rate of recurrence over time is similar for both disease groups.[4-5] Therefore, recurrence of ER+ breast cancer in postmenopausal women is a major contributor of breast cancer mortality.

Adjuvant therapy following curative surgery has significantly improved breast cancer outcome. In the case of ER+ breast cancer, systemic chemotherapy followed by endocrine treatment with tamoxifen has been shown to half the breast cancer mortality rate.[6] The recent introduction of aromatase inhibitors (AIs) in early stage breast cancer has further reduced the recurrence rate, however a significant number of patients recur despite the current standard treatment. At a median follow-up of 120 months in patients enrolled in the Arimidex, Tamoxifen, Alone or in Combination (ATAC) trial, recurrence was observed in 19.7 percent and 24.0 percent of patients treated with five years of adjuvant anastrozole and tamoxifen, respectively, with a persistent risk of relapse over time observed in both treatment arms, indicating a need to improve the current standard therapy.[7] However, the evaluation of new agents in the adjuvant setting has traditionally required large number of patients and years of follow up to demonstrate the effectiveness in reducing cancer relapse and/or mortality. The development of surrogate endpoints for disease free survival (DFS) and overall survival (OS) is needed for efficient drug screening and to expedite the drug development process.

The goal of Alliance A011106 is to develop a Ki67-based (growth) biomarker strategy in the neoadjuvant setting to predict long-term outcome of patients with ER+ breast cancer. Alliance researchers intend to validate the achievement of the Modified Preoperative Endocrine Prognostic Index (PEPI) score of 0, post neoadjuvant endocrine therapy as a surrogate marker of success for DFS.[8] Based on promising data in the metastatic setting, researchers will also compare fulvestrant alone, fulvestrant in combination with anastrozole and anastrozole alone in regards to the rate of modified PEPI 0 to provide rationale for future adjuvant studies of fulvestrant in ER+ early stage breast cancer. In this trial, endocrine resistant tumors are identified early by Ki67 assessment on the four-week tumor (required) and then the 12-week (optional) biopsies. Patients with tumor levels of Ki67 greater than 10 percent at these time points will be switched to neoadjuvant weekly paclitaxel, or other standard taxane and/or anthracycline or CMF (cyclophosphamide, methotrexate and fluorouracil) regimens to assess the rate of complete pathologic response (pCR) to chemotherapy as a secondary endpoint.

By providing validated surrogate endpoints for endocrine therapy agents and the response data (pCR rate) to standard chemotherapy for the resistant population, results from this study are expected to provide the foundation for future novel therapeutics development for early stage ER+ breast cancer.

Refer to the study protocol (Alliance A011106), which can be found on the CTSU menu (ctsu.org) for complete information on the trial design, treatment plan and patient eligibility. The Alliance Study Chair is Cynthia Ma, MD, PhD, Washington University School of Medicine, e-mail: cma@dom.wustl.edu.

Sources

1. Howlader, N., et al., SEER Cancer Statistics Review, 1975-2008, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2008/, based on November 2010 SEER data submission, posted to the SEER web site, 2011. 2011.
2. DeSantis, C., et al., Breast cancer statistics, 2011. CA: A Cancer Journal for Clinicians, 2011. 61(6): p. 409-18.

continued page 10

Alliance Presents Novel Data at American Society of Hematology Annual Meeting

The Alliance for Clinical Trials in Oncology presented an impressive array of novel data from many of its hematology studies during the 55th American Society of Hematology (ASH) Annual Meeting and Exposition held in New Orleans, LA. Many of these data will help change the delivery of hematologic cancer care or help elucidate the underlying cause and effect relationships seen in this field.

Here is a summary of the Alliance trials.

CALGB-8461, CALGB-9665, CALGB-20202

Differential clinical impact of gene mutations and their combinations in primary cytogenetically normal acute myeloid leukemia (CN-AML). Maharry K, Mrózek K, Becker H, Metzeler KH, Mendler JH, Whitman SP, Eisfeld A-K, Schwind S, Wu Y-Z, Nicolet D, Kolitz JE, Baer MR, Powell BL, Bucci D, Caligiuri MA, Carroll AJ, Volinia S, Stone RM, Marcucci G, Bloomfield CD. Blood 122(21), Abstract 2540, 2013

This evaluation helps to define a particularly complex clinical question regarding the prognoses of patients with acute myeloid leukemia who have normal cytogenetics at clinical presentation. Specifically, 12 gene mutations were evaluated in 364 patients and then correlated with mutational frequency and age. The findings reveal that CEBPA and NPM1 mutations define a favorable prognosis when present as a single marker and the IDH2 mutation usually proceeds to a poor outcome. Interestingly the patterns of NPM1+DNMT3A and NPM1+IDH2 mutations may actually define a favorable prognostic profile which would require corroboration in larger patient cohorts.

CALGB-9621, CALGB-9710, CALGB-10503, CALGB-19808

Obesity is an adverse prognostic factor for overall and disease-free survival in adult acute promyelocytic leukemia but not in acute myeloid leukemia: a pooled analysis from four Alliance prospective studies. Castillo JJ, Mulkey F, Geyer S, Kolitz JE, Blum W, Powell BL, Larson RA, Stone RM. Blood 122(21), Abstract 832, 2013

Obesity has been shown to correlate with adverse outcomes for many disease states but this has not been evaluated in a systematic fashion for AML. This evaluation relies on data from CALGB-9621, CALGB-9710, CALGB-10503 and CALGB-19808 to show that for AML in general, there is NO correlation with obesity and outcome, but in the subset who have acute promyelocytic leukemia, obesity at presentation confers a statistically significant, independent adverse prognosis. The authors further question whether current "non-chemo" approaches for traditionally good risk patients (WBC<10,000/uL at diagnosis) reflect the same findings.

CALGB 10403

Frontline-treatment of acute lymphoblastic leukemia (ALL) in older adolescents and young adults (AYA) using a pediatric regimen is feasible: Toxicity results of the prospective US intergroup trial C10403 (Alliance). Advani AS, Sanford B, Luger S, Devidas M, Larsen EC, Liedtke M, Voorhees PM, Foster MC, Claxton DF, Geyer S, Parker E, Coffan K, Carroll WL, Winick NJ, Coutre SE, Tallman MS, Appelbaum FR, Erba HP, Stone RM, Hunger SP, Larson RA, Stock W. Blood 122(21), Abstract 3903, 2013

Children with ALL traditionally have better outcomes than adults with ALL. Why? One postulate is that children are treated with more aggressive treatment regimens than older adolescents or young adults. This study seeks to answer this question by treating older adolescents and young adults with a pediatric ALL regimen and then compare toxicities and outcomes to a parallel (COG 0232) study performed in children. While the clinical outcomes of this intergroup study are still being evaluated on the 318 enrolled patients, the toxicity results are surprising. Overall mortality during induction was low (2 percent) with increased hyperglycemia, hyperbilirubinemia, pancreatitis, thrombosis and febrile neutropenia compared to the younger patients. In addition, increased incidence of neuropathy, osteonecrosis and mucositis was seen in patients age 20 or older. Based on these findings, the overall toxicities were manageable with a complete treatment related mortality of three percent suggesting that the regimen was feasible in this patient population.

CALGB-10403, CALGB-59909

Comparison of deep sequencing and allele-specific oligonucleotide PCR methods for MRD quantitation in acute lymphoblastic leukemia and mantle cell lymphoma: CALGB 10403 and CALGB 59909 (Alliance). Malnassy

continued next page

G, Geyer S, Fulton N, Koval G, Niedzwiecki D, Carlton V, Weng L, Kaplan LD, Marcucci G, Damon LE, Larson RA, Stone RM, Cheson BD, Faham M, Stock W. Blood 122(21), Abstract 2547, 2013

The assessment of minimal residual disease (MRD)is key to prognosticating and monitoring of patients with many cancer types especially for those with ALL and mantle cell lymphoma. Traditionally, allele specific oligonucleotide (ASO)-PCR would be used but the downside is the need to make patient specific primers which can be time consuming and expensive. This study compared sequencing-based MRD analysis with the traditional ASO-PCR analysis and found similar results with less expense of time and effort. Sequencing-based MRD analysis will likely supplant the ASO-PCR based work.

CALGB-10801

Adding the KIT inhibitor dasatinib (DAS) to standard induction and consolidation therapy for newly diagnosed patients (pts) with core binding factor (CBF) acute myeloid leukemia (AML): Initial results of the CALGB 10801 (Alliance) study. Geyer S, Zhao J, Caroll AJ, Bucci D, Vij R, Blum W, Pardee T, Wetzler M, Stock W, Bloomfield CD, Larson RA, Stone RM. Blood 122(21), Abstract 357, 2013

KIT activation occurs in 25 percent of favorable prognosis (core binding factor—CBF) AML (t(8;21) and inv (16)) which can lead to treatment failure. The oral tyrosine kinase inhibitor dasatinib (DAS) can function as an inhibitor of KIT as well. This study shows that rapid screening of AML patients for CBF and treatment with DAS in conjunction with chemotherapy is feasible in not only younger patients but in older patients as well. Initial clinical outcomes appear to be at least as good as with standard chemotherapy while ongoing evaluation of this treatment cohort continues.

CALGB-11001

Initial results of a phase II trial of sorafenib plus standard induction in older adults with mutant FLT3 acute myeloid leukemia (AML) (Alliance trial C11001). Uy GL, Sanford B, Marcucci G, Zhao W, Geyer S, Klepin HD, Powell BL, Baer MR, Stock W, Stone RM, Larson RA. Blood 122(21), Abstract 2653, 2013

Sorafenib has single agent, anti-FLT3 activity in the AML setting. This study utilizes sorafenib in an older AML population with mutated FLT3 in conjunction with standard induction chemotherapy. In this study, the feasibility of rapid FLT3 mutation evaluation along with combination drug evaluation is being performed. The turn around time of 48 hours for FLT3 mutation evaluation was met in over 99% of the patients on this trial. FLT3 mutations were identified in 17.6 percent (81/459) of the patients screened for this study. To date 52 patients have enrolled. Responses and toxicities were similar to expected and no unexpected sorafenib toxicities were noted. Evaluation is ongoing.

NCCTG-N1087

The AKT inhibitor MK2206 in combination with rituximab and bendamustine is tolerable and active in relapsed or refractory chronic lymphocytic leukemia: Results from a phase 1 study (NCCTG N1087, Alliance). Ding W, Shanafelt TD, Zent CS, Leis JF, LaPlant BR, Call TG, Hanson CA, Erlichman C, Habermann TM, Reeder C, Nikcevich D, Bowen D, Conte MJ, Boysen J, Secreto C, Lesnick C, Tschumper RC, Jelinek DF, Kay NE . Blood 122(21), Abstract 2882, 2013

MK2206 is an inhibitor of AKT activation downstream of the B-cell receptor (BCR) signaling pathway. BCR signaling is critical for CLL B cells in their bi-directional interactions with bone marrow stroma. This phase I study evaluated the combination of MK2206 along with rituximab and bendamustine in patients with relapsed or refractory B CLL. Though this represents a small cohort of patients, the results are promising with an 89 percent ORR and 22 percent CR rate with good overall patient tolerance. The regimen compares favorably to BR alone in this setting.

CALGB-50403

Minimal residual disease (MRD) status following induction chemo-immunotherapy predicts progression-free survival in mantle cell lymphoma (MCL): CALGB 50403 (Alliance). Fulton N, Jeffrey J, Kaplan LD, Koval G, Malnassy G, Jung S-H, Devine S, Shea TC, Leonard JP, Cheson BD, Stock W. Blood 122(21), Abstract 3002, 2013

This study looks at mantle cell lymphoma (MCL) patients enrolled in CALGB-50403 who underwent treatment with maintenance vs consolidation bortezomib therapy following aggressive chemo-immunotherapy and autologous stem cell transplant for adults l60 years old or younger with previously untreated disease. Eradication of minimal residual disease (MRD) has been found to be an important biomarker for progression free survival (PFS) in MCL. Forty-nine out of the initial 151 patients enrolled in the study had evaluable samples from three time points and were evaluated for MRD using standard primer sets if IGH/BCL-1 gene rearrangements. None of the patients who achieved MRD status at the completion of chemo-immunotherapy (n=15) had progressed while 10/32 patients with any level of MRD did progress.

Alliance Members on the Move

Schwartz

Gary Schwartz, MD, has been named Chief of the Division of Hematology/Oncology in the Department of Medicine at New York-Presbyterian/Columbia University Medical Center, and Associate Director for Research at the Herbert Irving Comprehensive Cancer Center. At the center, Dr. Schwartz will lead the expansion of clinical research and patient care, with a focus on building a comprehensive team of physicians and scientists to conduct research on the full spectrum of cancers and to bring the resulting advances to patients. He will also continue his research on improving ways to treat melanoma, sarcoma, and cancers of the gastrointestinal tract, his areas of expertise and clinical specialty. He serves as Co-Chair of the Experimental Therapeutics Committee for the Alliance.

Warren

Kimberlie J. Warren, PhD, recently joined the Alliance Patient Advocate Committee. Dr. Warren is a charter member and current chair of a local, grassroots, breast cancer advocacy and education group, African American Women In Touch. She has also filled roles as speaker, poster presenter, and webinar-based facilitator at various cancer-related events. She helped to develop content on personalized medicine that is posted on the Cancer Information and Support Network website. Dr. Warren is also an active Advocate in Science for Susan G. Komen.

Lymphoma Research Foundation RFP: Two-Year Adolescent/Young Adult Group Correlative Studies Grant

The Lymphoma Research Foundation (LRF) seeks proposals for correlative clinical/translational studies in adolescent/ young adult (AYA) lymphomas. Applications to this initiative must be an adjunct to a major NCI cooperative group research project in lymphoma relating to work in the clinical setting or involving primary lymphoma patient samples. The application deadline is March 5, 2014.

Innovative research by definition may uncover new questions and new areas requiring investigation. Basic funding often does not allow for additional, correlative studies to explore these areas. Adolescent/young adult patients with lymphoma are an understudied population that would particularly benefit from adjunct studies. The intention of the current request for proposals is to fund adjunct studies to complement and synergize with ongoing lymphoma clinical trials within the NCI Cancer Cooperative Groups. The applications should clearly focus on lymphoma research and have a high degree of relevance to research questions pertinent to adolescent and young adult lymphomas.

Applications may be for a time frame of up to two years duration for a budget of no more than $50,000 per year ($100K in total over two years). LRF allows 25 percent overhead, smaller overhead amounts are preferred. Up to three projects will be funded based on the recommendations of the grant review meeting and funding availability.

Applicants are encouraged to design proposals that will complement existing, ongoing clinical trials/recently completed within the NCI Cancer Cooperative Groups. Possible projects include correlative studies to ongoing trials (including translational laboratory or imaging studies), utilization of patient samples for specialized analyses, quality of life and survivorship issues, and Phase I or II clinical trials of novel therapeutic approaches.

For more information. Contact Whitney Steen, Research Communication and Projects Coordinator, by e-mail at wsteen@lymphoma.org or by phone at (646) 465-9120. Also, visit the LRF website at www.lymphoma.org for additional information.

ANNOUNCEMENTS

Oncology Nursing Committee Seeks A-ONC Education Coordinator

The Alliance Oncology Nursing Committee is seeking an A-ONC Education Coordinator. The responsibilities of this position include but are not limited to: mandatory attendance at all Alliance group meetings; collaboration with the other A-ONC education coordinators to develop continuing education programs for the Alliance group meetings and assist with obtaining CEU certification; participation in regular conference calls to discuss A-ONC business and future initiatives; and assisting with other educational opportunities throughout the year (i.e., webinars).

Minimum requirements for position include: registered nurse; master's degree or higher with a strong interest in developing nursing education pertinent to oncology research; employment at an Alliance institution; demonstrated commitment to the Alliance; excellent writing and organizational skills; minimum of one year of experience working with research protocols within the cooperative group setting; and main employer will allow time to fulfill position responsibilities (documented via letter or e-mail). Anticipated time commitment is four hours per month and two to four days away with each Alliance meeting (two times per year). Funding to Alliance meetings must be by the main member site.

Those interested in the Education Coordinator position should submit a CV/resume and a one-page letter of interest by March 1, 2014 to Lisa Kottschade RN, MSN, CNP, by e-mail at Kottschade.lisa@mayo.edu or by mail to Lisa Kottschade RN, MSN, CNP, 200 First Street SW, Rochester, MN 55905. Decisions regarding the A-ONC Education Coordinator will be made by March 15, 2014.

Journal Invites Clinical Trials Results Contributions

Two years ago, The Oncologist created the Clinical Trial Results (CTR) section of its publication. The journal has published the results of a growing number of studies on a diverse range of topics, covering gastric, pancreatic, breast, and lung cancers, and representing a number of outcomes. Now nearing 20 published trials, this has been an active section for the journal.

The Oncologist has optimized the section for phase I and phase II trials that inform researchers of adverse events, pharmacokinetics, and trial design. The format promises rapid publication and results that are fully indexed and citable by PubMed. Part of the journal's vision is that the adverse event data will become part of a searchable database that will allow independent analyses to be performed.

The CTR section has two parts: a brief author summary containing four sections: background, methods, results and conclusion (followed by a brief discussion), and the data set. They invite researchers to have their trial results considered for publication as a CTR. To learn more about this initiative, visit the journal's website at http://clinicaltrialresults.theoncologist.com/visiting/results Publications@AllianceNCTN.org.

Spotlight on Trials

continued from page 6

3. Anderson, W.F., et al., Estrogen receptor breast cancer phenotypes in the Surveillance, Epidemiology, and End Results database. Breast Cancer Res Treat, 2002. 76(1): p. 27-36.
4. Demicheli, R., et al., Recurrence and mortality according to estrogen receptor status for breast cancer patients undergoing conservative surgery. Ipsilateral breast tumour recurrence dynamics provides clues for tumour biology within the residual breast. BMC Cancer, 2010. 10: p. 656.
5. Demicheli, R., et al., Recurrence and mortality dynamics for breast cancer patients undergoing mastectomy according to estrogen receptor status: different mortality but similar recurrence. Cancer Sci, 2010. 101(3): p. 826-30.
6. Early Breast Cancer Trialists' Collaborative, G., Relevance of breast cancer hormone receptors and other factors to the efficacy of adjuvant tamoxifen: patient-level meta-analysis of randomised trials. The Lancet, 2011. 378(9793): p. 771-784.
7. Cuzick, J., et al., Effect of anastrozole and tamoxifen as adjuvant treatment for early-stage breast cancer: 10-year analysis of the ATAC trial. The Lancet Oncology, 2010. 11(12): p. 1135-1141.
8. Ellis, M.J., et al., Outcome prediction for estrogen receptor-positive breast cancer based on postneoadjuvant endocrine therapy tumor characteristics. J Natl Cancer Inst, 2008. 100(19): p. 1380-8.

ACS CRP Cancer Care Delivery Research

continued from page 5

informatics, systems engineering, patient engagement, health economics, and dissemination and implementation.

Since its formation, the committee's main goals have been to identify research priorities, develop initial studies and obtain external funding. To date, four protocols have been approved, including three projects funded by the Patient Centered Outcomes Research Institute (PCORI) to study post-treatment surveillance for breast, colorectal and lung cancers. The committee will focus on three key scientific priority areas: 1) comparative effectiveness and patient-centered outcomes research; 2) cancer economics; and 3) systems redesign and organizational change. In addition, overlying these priorities will be activities in stakeholder engagement and dissemination and implementation of new findings to ensure integration of the new evidence into practice.

Supporting these scientific priorities, the committee and ACS CRP leadership have been working to develop a unique partnership with the Commission on Cancer (CoC) and its network of nearly 1,500 accredited cancer programs. This partnership facilitates CCDR activities that will utilize the National Cancer Data Base (NCDB) that captures cancer incidence and treatment information for more than 70 percent of newly diagnosed cancer cases in the U.S. Partnership with the CoC and the NCDB will help develop the capacity to 1) examine current practice patterns and healthcare utilization in real-world settings; 2) perform dissemination and implementation and prospective cancer care delivery research to assess changes in cancer practice based upon clinical trial results and newly established practices; and 3) ultimately conduct new cluster randomized and pragmatic clinical trials.

The committee meets twice yearly face-to-face at Alliance meetings and is instituting monthly conference calls. Administratively, the committee is housed within the ACS CRP but it works in close collaboration with the Health Outcomes Committee and is utilizing the liaison approach to connect to other committees across the Alliance for collaborative research opportunities.

2014 Meeting Dates

Spring Group Meeting
May 7-10

&

Fall Group Meeting
November 5-8

Both meetings are open to all Alliance members and will be held at the InterContinental Chicago O'Hare
5300 N. River Road, Rosemont, IL

For meeting and travel inquiries,
contact Alison Lewandowski
e-mail: alewandowski@partners.org
phone: 617-525-3022

For more information on the Alliance and updates about meetings, visit **AllianceforClinicalTrialsinOncology.org**