

ANNUAL MEETING

2015 Spring Group Meeting Convenes May 13-16

The **Alliance for the Clinical Trials in Oncology** will convene its 2015 Spring Group Meeting in Chicago, IL, May 13-16. Scientists, clinical research professionals, patient advocates and others interested in the latest developments in cancer research are expected to attend the four-day meeting at the Loews Chicago O'Hare Hotel. Meeting attendees will select from nearly 70 disease, modality, administrative and special sessions to attend led by distinguished oncology researchers and clinical trials specialists from across the country. This meeting will showcase novel and innovative cancer control, prevention, and treatment trials that are conducted by investigators through a multidisciplinary academic and community research network, which is part of the NCI National Clinical Trials Network and Community Oncology Research Program.

Meeting Highlights

Plenary Session | Friday, May 15 | 10 am-12 pm

Monica M. Bertagnolli, MD, Group Chair of the Alliance, will provide opening remarks and an introduction of the speakers for this session. | **Peter J. O'Dwyer, MD**, Director of the Developmental Therapeutics Program at the Abramson Cancer Center, will discuss the NCI MATCH trial—an umbrella protocol for multiple, single-arm phase II trials that will recruit patients with all types of cancer whose tumors no longer respond to standard therapy, and then select a targeted drug based on the specific genetic abnormalities of the patient's tumor. | **Electra D. Paskett, PhD**, Deputy Director of the Alliance Cancer Control Program (CCP), will present awards for two new initiatives from the CCP that will facilitate ongoing training and assist young investigators in establishing competitive research profiles early in their careers. | **John C. Byrd, MD**, D. Warren Brown Chair of Leukemia Research at Ohio State University Wexner Medical Center, is the 2015 Charles G. Moertel Lecture Award recipient. He will present a lecture on therapeutic agents active in chronic lymphocytic leukemia and related leukemia and lymphoma. | **Clifford Y. Ko, MD**, Director of the Division of Research and Optimal Patient Care at the American College of Surgeons (ACS) and the Robert and Kelly Day Chair of Surgical Outcomes and Professor in the Department of Surgery at the University of California at Los Angeles, will discuss his research in studying quality of care, quality of life and outcomes in cancer surgery with a lecture titled "Surgical Quality Management and Outcomes in Oncologic Care."

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Clinical Research Professionals (CRP) Information Session

Thursday, May 14 | 1 pm-5 pm

The CRP Information Session will provide updates on ongoing changes within the National Clinical Trials Network (NCTN) and the NCI Community Oncology Research Program (NCORP). Speakers include: **Trini Ajazi, MM**, Alliance Administrative Staff (Alliance updates); **Jenny Darcy**, Alliance Statistics and Data Center (Data submission in iMedidata Rave); **Martha Herring**, CTSU/Westat (CTSU/OPEN updates); **Laura Covington, MS**, NCI CIRB (Quality practices in research, and the NCI CIRB Initiative); **Michael Morris, MD**, Memorial Sloan Kettering Cancer Center (PCWG2 Response Criteria); **Debra Herzan, RN, OCN, CCRP**, **Joshua Lachewitz** and **Kurombi Wade-Oliver**, Alliance Clinical Trials Audit Staff (Pearls of Wisdom); and **Wendy Stock, MD**, University of Chicago (CALGB 10403 - An Intergroup Phase II Clinical Trial for Adolescents and Young Adults with Untreated Acute Lymphoblastic Leukemia (ALL)).

Oncology Nursing Education Session

Friday, May 15 | 8 am-10 am

The ONC Education Session will focus on two important topics: “Ethical Challenges in Palliative Care” presented by **Janet R. Ely, MSN, AOCNP, FNP**, University of Vermont Medical Center, and “Genomics and Informed Consent: Protecting Patient Interests While Facilitating Flexible Use Patient Genomic Data in the Future” by **Julie Lynch, PhD, RN, MSN, MBA**, Veterans Health Administration and RTI International.

American College of Surgeons Clinical Research Program (ACS CRP) Special Presentation Session

Friday, May 15 | 12 pm-1:30 pm

The Alliance American College of Surgeons Clinical Research Program (ACS CRP) Special Session will focus on surgical quality management and outcomes in oncologic care. Program Director **Kelly K. Hunt, MD** will present an update on recent program initiatives, including the publication of Operative Standards for Cancer Surgery. Session speakers include: **Daniel P. McKellar, MD**, Chair of the ACS Commission on Cancer (“Improving Cancer Care through the Commission on Cancer (CoC)”); **David J. Winchester, MD**, Surgical Oncologist at Northshore University HealthSystem (“Using the National Cancer

Data Base for Benchmarking and Quality Improvement”); **George J. Chang, MD** and **Caprice C. Greenberg, MD, MPH** - Co-Chairs of the Alliance ACS Cancer Care Delivery Research Committee; **Deborah Schrag, MD**, Chief of the Division of Population Sciences in Medical Oncology at Dana-Farber Cancer Institute; and **Ethan Basch, MD, MSc**, Co-Chair of the Alliance Health Outcomes Committee (“The CoC and the ACS CRP/Alliance: A Unique Partnership for Cancer Care Delivery Research”).

Clinical Research Professionals (CRP) Education Session

Friday, May 15 | 3 pm-7 pm

This CRP Education Session will cover seven in-depth presentations: 1) “ALCHEMIST (Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials/Alliance A151216 Screening Component)” by **Geoffrey Oxnard, MD**, Dana-Farber Cancer Institute; 2) “Navigating ALCHEMIST: A CRA Perspective” by **Melissa Meredith, MS, CCRP**, Washington University School of Medicine; 3) “Cheson Response Criteria” by **Bruce D. Cheson, MD**, MedStar Georgetown University Hospital; 4) “RECIST Response Criteria” by **Stephen Liu, MD**, MedStar Georgetown University Hospital; 5) “A011202 - A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy” by **Judy Boughey, MD**, Mayo Clinic; 6) “Medicare Billing” by **Lisa Pitler, MS, RN**, University of Illinois at Chicago; and 7) “Building Relationships with Investigators” by **James N. Atkins, MD**, Southeast Cancer Consortium -Upstate NCORP).





INTRODUCING ... THE ALLIANCE MEMBER SERVICES ENHANCEMENT TASK FORCE

Open Forum | Friday, May 15 | 2 pm-3 pm

The Alliance is excited to launch a new initiative to improve overall member services – the **Alliance Member Services Enhancement Task Force**. The multi-disciplinary task force is on a mission to better engage all Alliance members. With its three-fold mission, the task force seeks to determine the needs of Alliance institutional members, enhance Alliance member services accordingly, and improve overall Alliance operations. Its main goal is to assist institutional research staff in the day-to-day conduct of Alliance/National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) studies.

Working directly with Alliance members, the task force encourages participation in surveys, open forums and focus groups to help identify challenges members face on a day-to-day basis, and to help convert that information into real-time solutions that can be implemented.

Please join the task force for its **first open forum Friday, May 15, 2 pm-3 pm** in Warhol A at the Loews Chicago O'Hare Hotel. Results from a recently conducted member survey will be shared and discussed, along with next steps in this ongoing initiative. **All members are welcome.**



Alliance, NCTN Actively Work to Recruit Patients with Early-stage NSCLC for ALCHEMIST Trials

The Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials, or **ALCHEMIST**, is a group of clinical trials for patients with certain types of early-stage non-small cell lung cancer (NSCLC) that has been treated surgically.

The ALCHEMIST trials involve genetic screening of tumor specimens removed during surgery for specific gene mutations and testing of adjuvant (post-operative) treatment with drugs that target those mutations but have only been approved by the U.S. Food and Drug Administration (FDA) for use in advanced lung cancer. Patients will have already had surgery to completely remove their tumors and finished any other post-surgical chemotherapy with or without radiation therapy prescribed by their doctors before entering either of the treatment studies.

The ALCHEMIST-screening study (Alliance A151216 led by Geoffrey Oxnard, MD) will examine tumor specimens from people who have lung adenocarcinoma or other related types of lung cancer that have been surgically removed. Researchers will look for specific alterations in two genes, ALK and EGFR, that are thought to drive cancer growth and for which targeted therapies have been developed. Patients who have one of these alterations will then be referred to either of two treatment trials that are testing whether adjuvant treatment with the drugs crizotinib (Xalkori) or erlotinib (Tarceva) will prevent recurrence and improve survival.

Patients whose tumors test positive for a rearrangement of the ALK gene known as an ALK-EML4 fusion will be referred to the ALCHEMIST-ALK trial (ECOC-ACRIN E4512/ALK led by David Gerber, MD). Approximately five percent of people with adenocarcinoma or other related types of NSCLC have this genetic mutation. Patients in this phase III treatment trial will be randomly assigned to receive the drug crizotinib or a matching placebo pill for two years, or until they experience unacceptable toxicity or disease recurrence. They will then be monitored for recurrence and survival.

Patients whose tumors harbor an activating mutation in the EGFR gene will be referred to the ALCHEMIST-EGFR trial (Alliance A081105/EGFR led by Ramaswamy Govindan, MD). Mutations in EGFR are found in about

10 percent of non-small cell lung cancer cases in non-Asian people and up to 50 percent of cases in Asian patients. In this trial, patients will be randomly assigned to take the drug erlotinib or a matching placebo pill for up to two years, or until they experience unacceptable toxicity or a recurrence of their cancer. After treatment, participants will be monitored for recurrence and survival.

Patients whose tumors did not have mutations in either gene will be monitored every six months for five years on the ALCHEMIST screening study.

Researchers hope that identifying patients with early-stage lung cancer with known genetic abnormalities and treating them with drugs that target those abnormalities will help increase the number of people who can be cured of lung cancer.

ALCHEMIST is supported by the National Cancer Institute (NCI) with leadership and coordination of the trials by the Alliance for Clinical Trials in Oncology and the ECOG-ACRIN Cancer Research Group. All NCI National Clinical Trials Network (NCTN) groups are participating in these trials.

Here are some frequently asked questions (FAQs).

Q1: Is ALCHEMIST one trial or three separate trials?

The ALCHEMIST study is made up of three separate protocols: ALCHEMIST-screening (A151216), ALCHEMIST-EGFR (A081105) and ALCHEMIST-ALK (E4512). The first is a screening study that provides EGFR and ALK genotyping while the other two are treatment trials studying adjuvant targeted therapies.

Q2: Do I need to have all three trials open before I accrue patients?

Yes, all the trials (A151216, A081105 and E4512) need to be IRB approved before patients are accrued to any of them. Sites will not be able to use the OPEN system to register patients to ALCHEMIST-screening until all three trials have been IRB approved. Refer to the materials, including the activation notice, on the CTSU website for additional guidance.

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Q3: Can I just register patients to ALCHEMIST-screening (A151216) and not consider the treatment trials, or is the intent to register patients to the screening study in order to then put the eligible patients on the treatment trials?

The intent of ALCHEMIST-screening is to screen patients for the treatment trials. Therefore, all patients registered to the screening study and found to be eligible for the treatment trials should be registered to the treatment trials.

Q4: I have a patient where we did local testing and the patient is negative for both ALK and EGFR. Is this patient eligible?

In Update #1 of ALCHEMIST-screening, issued on 3/15/15, patients are now eligible to be enrolled regardless of any local genotyping results. If positive for EGFR or ALK on the screening study, they then would be potentially eligible for the treatment trials.

Q5: Is there a timeframe I need to follow to register post-op patients to this trial?

The timeline for ALCHEMIST-screening is intended to allow sufficient time for genotyping so that patients will remain potentially eligible for the treatment trials. Patients that do not receive adjuvant therapy need to be registered to the screening study up to 75 days following surgery, those patients that are receiving adjuvant therapy are to be registered up to 165 days after surgery, and those patients receiving both adjuvant chemotherapy and radiation therapy are to be registered up to 225 days following surgery.

Q6: Can patients be receiving adjuvant therapy while being registered to ALCHEMIST?

Yes, patients can be receiving adjuvant therapy while being registered to ALCHEMIST-screening.

Q7: I don't understand the pre-registration and registration steps?

The pre-registration step was developed to allow flexibility so that patients can be consented to ALCHEMIST-screening either prior to surgery or after surgery. All patients must pre-register first. Those that have already undergone surgery will then immediately proceed to registration to the study. However, pre-operative patients will first need to complete surgery to allow a final eligibility review prior to registering to the screening study.

Q8: When do I send in the tissue to Response Genetics? When do I collect and send in the blood?

Tissue is sent to Response Genetics for genotyping after the patient is registered. Blood can be collected at any point following pre-registration up until 30 days after registration. Once collected the blood is to be shipped to the NCI BCR within one week of collection.

Q9: If my patient is locally EGFR or ALK positive, do I need to send in a block?

Patients who are locally positive for EGFR or ALK still need to send in tissue and blood. The tissue is used for confirmation of the genotype, and the tissue and blood are both used for further genomic studies.

Q10: If my patient is locally EGFR or ALK positive, do I need to wait for results on ALCHEMIST-screening before enrolling the patient onto one of the treatment trials?

Patients who are locally positive for EGFR or ALK can register to one of the treatment trials immediately after registering for ALCHEMIST-screening, without waiting for genotyping results from Response Genetics.

Q11: Are there shipping kits available for the block and blood collection?

No, there are no shipping kits available for those submissions. The instructions about how to ship the materials are in the protocol.

Q12: I have a patient with adenosquamous carcinoma. Is she eligible?

The eligibility for ALCHEMIST-screening has been updated with Update #1 to specifically allow patients with adenosquamous carcinoma, as this is a subtype of lung adenocarcinoma.

Q13: I have a patient with a second primary lung cancer. Would he be eligible?

No, a second primary lung cancer is considered a concurrent malignancy; therefore, such a patient would not be eligible for ALCHEMIST.



Prospective Surveillance for Breast Cancer-Related Lymphedema

By Pamela Ostby, PhD(c), RN, OCN
 Sinclair School of Nursing
 Jane M. Armer, PhD, RN, FAAN
 Ellis Fischel Cancer Center
 University of Missouri-Columbia

Definition and Incidence

Breast cancer-related lymphedema (BCRL) is a chronic, debilitating condition. It occurs most often in women who have undergone axillary lymph node dissection, sentinel lymph node biopsy (SLNB), mastectomy, or radiation therapy for treatment of breast cancer.¹ Trauma to the lymphatic channels inhibits the flow of lymphatic fluid and causes swelling of the soft tissues and extracellular spaces.² Breast cancer survivors are at lifetime risk for developing lymphedema (LE) with occurrence from 41 percent to 94 percent within 60 months of surgery, depending on the methods of assessment and criteria for LE.³ Determining incidence and documenting follow-up of BCRL are difficult due to a wide-range of onset from early in the post-operative period to beyond 30 years posttreatment.^{3,4} BCRL is a chronic condition with recognized treatment but currently no cure.

Symptoms

Symptoms of lymphedema including heaviness, swelling, numbness, pain, and decreased function are often accompanied by psychosocial sequelae, as well.^{5,6,7} Three levels of objective LE criteria include: Grade I, pitting of the skin with the application of pressure and reversible edema with elevation; Grade II, edema which is firmer and no longer exhibits pitting under pressure; and Grade III, worsening swelling and severe thickening of the skin, often with the development of skin folds.⁸ Once diagnosed, daily management of symptoms is critical to reduce progression. BCRL prevalence will continue to rise, despite less invasive surgical methods and the use of SLNB, due to the lifetime risk of lymphedema development and longer years of survivorship. Cancer survivors are living longer with increased comorbidities limiting mobility, which further increase the risk for BCRL development.⁹

Treatment

There are evidence-based treatment protocols for BCRL, but they are not universally applied. Complete (or complex or combined) decongestive therapy (CDT) is considered the international 'gold standard' for LE treatment.^{2, 10} With the goal of therapy to move lymphatic fluid to an area where it can drain and reduce swelling, patients receive a combination of components that make up the CDT regimen which may include: manual lymphatic drainage (MLD); compression bandaging of the extremity and compression garments; exercises; and meticulous skin care.² There is a lack of rigorously-conducted, comparative research LE studies which impedes the development and standardization of evidence-based assessment and treatment for hundreds of thousands of cancer survivors. Currently, there are three clinical trials in progress administered by NCI-funded national oncology clinical trial groups, including LE assessment: (1) CALGB (Alliance) 70305, a randomized education/exercise intervention study to reduce risk of BCRL; (2) Alliance A011202, a randomized phase III trial comparing axillary lymph node dissection to axillary radiation in breast cancer patients (cT1-3N1) who have positive sentinel lymph node disease after neoadjuvant chemotherapy; and (3) NCI R01 Gynecological Oncology Group 0244, which aims to prospectively estimate the incidence of lower extremity LE in patients undergoing radical surgery with a concurrent lymphadenectomy for a gynecologic malignancy. Clinical trials relevant to surgical management of axillary node detection and disease, such as ACOSOG Z0011 (Alliance), a randomized trial of axillary node dissection in women with clinical breast cancer (T1-1, N0, M0) who have a positive sentinel node;¹¹ and ACOSOG Z1071 (Alliance), 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 diagnosis¹² are research studies that may have practice-changing implications in reducing lymphedema incidence.

Prospective Surveillance of BCRL

In addition to clinical studies relevant to LE treatment, there is a great deal of interest in prospective surveillance

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of BCRL, which suggests a multidisciplinary approach to secondary prevention with women diagnosed with breast cancer.¹³ A complete prospective BCRL surveillance program includes pre-operative history and physical exam, including bilateral baseline circumferential arm measurements. Baseline pre-operative measurement with no surgical swelling is valuable as a comparator to post-operative measurements when assessment for LE may be complicated by post-op swelling.¹³⁻¹⁴ Pre- and post-operative limb circumferences at regular intervals, such as quarterly for 12 months, semi-annually for 1 to 3 years, and then annually, thereafter, have potential to identify BCRL at a subclinical level, when there is a better chance for preventing progression to a chronic state.¹³⁻¹⁴ After a historical examination of models of care, Gerber et al. introduced the Prospective Surveillance Model (PSM), an integration of a functional assessment of physical impairments as part of survivorship care for patients with cancer.¹⁵ A prospective BCRL surveillance study underway at Ellis Fischel Cancer Center (an Alliance institution) aims to evaluate if earlier detection of BCRL with the use of self-report symptom questionnaires and interval circumferences increases early referral to LE treatment and improves QOL and functional outcomes. In relation to costs, while direct and indirect prospective surveillance model cost data are lacking, an examination of direct provider fees and durable medical equipment costs suggests that prospective BCRL surveillance may decrease direct treatment costs.¹⁶ According to the 2013 Institute of Medicine (IOM) report, a rapid transition from a fee-for-service to a new payment model should occur with a demonstrated increase in quality and affordability.¹⁷ As costs for cancer care are projected to increase to \$173 billion with a 45 percent increase in cancer cases by 2020, a prospective surveillance model may be key in planning survivorship plans of care.¹⁷

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Super Things for Cancer Research: Alliance Community Oncology Committee

By Robert J. Behrens, MD
Medical Oncology and Hematology Associates
Chair, Alliance Community Oncology Committee

Most people select green when getting ready for St. Patrick's Day. For me this year, it had to be blue. One of my most outgoing patients, Nancy, had given me a pair of superman socks even with a red cape on the back of the socks. She has been living with stage IV rectal cancer for more than four years and was starting cycle 1 day 1 on a trial later that day. The socks would have been a better fit for her than me, but I knew she'd smile at the sight of them.

Nancy is a great example of the importance of community oncology. She has benefitted from prior research proving efficacy for several new drugs for cancer. Without patients volunteering years ago to try then experimental drugs such as bevacizumab, cetuximab, or regorafenib; she likely would not have lived with her metastatic cancer for four years. Our research team (from local to nationwide) also enables her to try experimental drugs that she hopes will give her even more time. Nancy also gets to play 'Superman' by volunteering to advance oncologic science. This is the true purpose of community oncology – bringing cutting edge cancer science to the real world and bringing the real world to cutting edge cancer science.

The Alliance Community Oncology Committee has seen several, large challenges the past few years. Some of the challenges have been cooperative group restructuring, transition from Community Clinical Oncology Program (CCOP) to NCI Community Oncology Research Program (N-CORP), shrinking budgets, high regulatory burdens, and trying to understand CCDR (Cancer Care Delivery Research). Our committee tries to foster communication and cooperation between Alliance leadership, scientific committees, NCI, and other cancer researchers. NCI representatives have been frequent guest lecturers at our meetings to work with Alliance community members. This interaction hopefully builds more fruitful research opportunities across our nation. Our committee also assists to pair motivated community oncologists with scientific committee leaders to partner on current Alliance protocols. The objective of this partnership is to tailor scientific trials to address pertinent problems and ensure feasibility in a variety of practice settings. Our committee also tries to 'cheerlead' to increase accrual throughout the entire Alliance network.

CCDR is coming soon. Our committee members are providing input with the Alliance protocols in development. There is a breast cancer CCDR concept aimed at improving the coordination of post-treatment surveillance between medical oncologists, radiation oncologists, surgeons, etc. Hopefully, this study yields a long-term goal of forming an evidence-based, risk-stratified approach to breast cancer follow-up that accounts for patients' risk of recurrence and treatment side effects as well as the preferences of patients and providers. Other CCDR trial plans include colorectal and lung cancer surveillance.

We are living and working in an era of tremendous change. This comes with some headaches, but also opportunities to make things better. Hopefully with everyone's combined efforts, we can do super things with cancer research.

Alliance Board of Directors Elects Three New Members

The Alliance for Clinical Trials in Oncology welcomes three new members to the Alliance Board of Directors:



Grossman

Steven R. Grossman, MD, PhD

Dr. Grossman is the Alliance Principal Investigator, Deputy Director and Dianne Nunnally Hoppes Endowed Chair in Cancer Research at VCU Massey Cancer Center. He is an internationally recognized expert in gastrointestinal cancers, and currently holds a National Institutes of Health grant to support his research examining the role of tumor suppressor proteins in cancer. Building on this research, he is developing a potentially new way of treating pancreatic cancer.



Libutti

Steven K. Libutti, MD

Dr. Libutti is the Alliance Principal Investigator at Montefiore Medical Center and Associate Director for Clinical Services of the Albert Einstein Cancer Center. He is an internationally recognized expert in endocrine surgery and provides surgical consultation and treatment for patients with disorders of the thyroid, parathyroid, adrenal glands, and for endocrine tumors arising in the pancreas. Currently, he is studying tumor neovascular formation and the interaction between tumor cells, endothelial cells and the components of the tumor microenvironment including fibroblasts and cancer stem cells.



Reding

Douglas J. Reding, MD, MPH

Dr. Reding is the Alliance Principal Investigator at Wisconsin NCI Community Oncology Research Program and Oncology Research Director at Marshfield Clinic. He specializes in treating numerous cancer- and blood-related conditions, including leukemia, lymphoma, melanoma, myeloma, sarcoma, solid organ tumors and hematological tumors. His areas of interest include therapy for breast cancer and hematologic malignancies, early detection and cancer screening, evaluation of environmental exposures and the subsequent development of malignancy with a special interest in agricultural and rural populations, and evaluation of environmental exposure and the associated genetic abnormalities that result with subsequent development of cancer.

Alliance Statistics and Data Center Moves Forward with Data Management Consolidation

Last fall, the Alliance Statistics and Data Center (SDC) announced the consolidation of all Alliance data management activities, which are being moved to the Mayo Clinic. This move was based on National Cancer Institute (NCI) budget constraints and conducted after careful consideration to standardize and consolidate process, and reduce overall operational costs. This consolidation is specific to Alliance data management activities, which includes services such as eligibility review, data query, on-going data review, case-evaluations, overdue materials monitoring, and addressing site questions. It does not impact staffing levels or locations for other SDC functions such as statistics or bioinformatics, which will remain in a distributed model.

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Over the past year, more than 70 studies have been physically transferred from Duke to the Mayo Clinic, and studies are continuing to be moved with a completion date by the end of August 2015. A continuously updated list of transferred studies is available on the Alliance website.



Carston

Alliance SDC Leadership Transitions

Michael Carston, MS, has been named Director of Information Systems. He is replacing Lori Smith, who has transferred to another area within the Mayo Clinic. Mr. Carston has more than 16 years of IT experience, including extensive experience with Alliance IT systems. He will bring a wealth of knowledge to the SDC leadership team.



Kiefer

The Alliance SDC is implementing a streamlined administrative structure, including the alignment of the Data Management and Systems Management units into a new Data Coordination Unit with **Beth Kiefer** serving as the Director. **Debbie Sawyer**, former Director of the Data Management, will be a senior advisor to the group as the SDC works through the data management consolidation.



Sawyer

The Alliance SDC would like to recognize Ms. Sawyer for her many contributions to the Cancer and Leukemia Group (CALGB) and Alliance for more than 20 years. She was the Director of Data Operations for CALGB from 1994-2011 and has been the Director of Data Management for the Alliance SDC since 2011. Her contributions to CALGB and Alliance have been profound and lasting. She has represented the Alliance on multiple national committees and task forces, managed a high-volume data operation, and always maintained data quality and member service as highest priority. The SDC thanks Ms. Sawyer for her leadership, commitment and extensive contributions to the Alliance.

Meet New Staff

Alliance Foundation Trials, LLC (AFT)



Gollerkeri



Gaskin



Pucillo



DuFrane



White

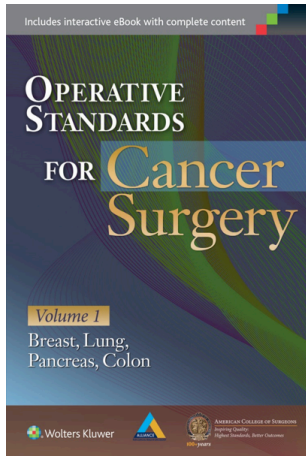


Rogers

Alliance Foundation Trials, LLC (AFT) is a not-for-profit corporation that allows Alliance researchers and institutions to lead and participate in cancer clinical trials supported by organizations outside of the NCI. Current AFT studies are funded by a number of pharmaceutical company sponsors and the Patient-Centered Outcomes Research Institute (PCORI). The Alliance welcomes new AFT administrative staff.

- Drew Gollerkeri**, Controller | e-mail: dgollerkeri@alliancefoundationtrials.org | phone 617-732-7898
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New Cancer Surgery Manual Available from Alliance ACS Clinical Research Program



The Alliance American College of Surgeons Clinical Research Program will publish, in conjunction with Wolters Kluwer, the first comprehensive, evidence-based examination of cancer surgery techniques that are critical to achieve optimal outcomes in a cancer operation in June. *Operative Standards for Cancer Surgery* is a unique manual that focuses on best practices for breast, colon, lung and pancreatic surgery, describing the surgical procedures that occur between skin incision and skin closure that directly affect cancer outcomes. The effort to develop a manual that details the critical elements of cancer surgery was first envisioned by **Heidi Nelson, MD, FACS** (former ACS CRP Director and Principal Investigator), and the resulting textbook has been the main focus of the activities of the ACS CRP Cancer Care Standards Development Committee, previously chaired by **Kelly K. Hunt, MD, FACS** for three years. Dr. Hunt is now Director of ACS CRP.

Operative Standards provides concrete recommendations based on the strongest available evidence on the proper conduct of operations and detailed information on the oncologic principles, avoidable pitfalls, and the quality of the evidence on which these recommendations are based. Since randomized trials have not addressed all of the components of operations within each disease site, this manual draws on the experience and consensus opinion of the experts writing the individual chapters. Identifying the lack of evidence on certain topics has been an unintended consequence of writing *Operative Standards*, and has galvanized the authors to establish standards where none currently exist. More than 120 surgeons participated in this first edition, which is perhaps the best resource currently available on the proper conduct of an operation for cancer of the breast, colon, lung, and pancreas.

Anticipating continued evolution in surgical oncology, these initial four disease site sections will be updated every two to three years. Planning is already underway for the second edition of the manual and will include procedures in melanoma, gastric cancer, esophageal cancer, rectal cancer and thyroid cancer.

Operative Standards for Cancer Surgery is available at [http://www.lww.com Product/9781451194753](http://www.lww.com/Product/9781451194753). Purchasers of the print edition will also receive the bundled interactive eBook edition, offering tablet, smartphone or online access.

Alliance Abstracts | ASCO Annual Meeting

The American Society of Clinical Oncology (ASCO) is the world's leading professional organization representing physicians who treat people with cancer. Its annual meeting, held May 29–June 2 in Chicago, is considered the premier educational and scientific event in the oncology community. The Alliance for Clinical Trials in Oncology will present approximately 30 abstracts at this year's 51st Annual ASCO Meeting. Alliance abstracts will include the following diseases and modalities: gastrointestinal (GI), neuro-oncology, breast, experimental therapeutics, lymphoma, health outcomes, symptom intervention and transplant. Alliance researchers will present these abstracts in multiple forums from oral abstract sessions to poster discussions and from general poster sessions to plenary, and publication only.

Alliance Cancer Control Program Awards

The Alliance NCORP Research Base, which is supported by the NCI Division of Cancer Prevention (DCP) and administrated through the Alliance Cancer Control Program (CCP), supports Alliance researchers and junior investigators and their work through two annual funding awards: Alliance Cancer Control Program Pilot Project Award and Alliance Cancer Control Program Junior Faculty Award.

The **CCP Pilot Project Award** will provide funds to support CCP projects within the areas of cancer prevention, risk assessment, screening, symptom intervention, surveillance, health outcomes research, or specific population groups, including minority and underserved, elderly, or adolescent and young adult populations. These pilot projects are to generate preliminary data that will lead to Alliance protocols. Applicants and their respective institutions must be Alliance members and must be a member of an Alliance CCP committee. Awardees must attend at least one Alliance Group meeting to present the results of their research. Applications should be in the form of a three- to five-page concept to conduct a CCP pilot clinical trial.

The **CCP Junior Faculty Award** will provide funds to support training and research initiatives for junior faculty and post-doctoral fellows in the CCP. These awards are to facilitate ongoing training and assist junior faculty and post-docs in establishing a competitive research profile early in their career. Junior faculty may have either an instructor or assistant professor position within their institution and must be within five years of their first faculty appointment, and post-doctoral fellows must maintain their fellowship for the entire one-year award period. Each applicant must work with a mentor throughout that time, allocating protected time to engage in training activities and conduct a research project in the field of cancer prevention and control, such as areas including cancer prevention, risk assessment, screening, symptom intervention, surveillance, health outcomes research, or specific population groups, including minority and underserved, elderly, or adolescent and young adult populations. Upon successful re-application, awards may be renewed for one additional year. Applicants, their mentors, and their respective institutions must be Alliance members, and either the applicant or the mentor must be a member of a relevant Alliance CCP committee. Applicants who are not current a member of an Alliance CCP committee are highly encouraged to become a member of the appropriate committee relevant to their

proposal, if funded. Awardees must attend at least one Alliance Group meeting to present the results of their research.

How to Apply. To apply for each award, submit applications to Electra D. Paskett, PhD by e-mail at electra.paskett@osumc.edu no later than June 1 (5 pm ET). Approved projects will be funded with an anticipated budget start date of August 1. Requested funds must be expended within one year from the date of award. For additional questions, contact Dr. Paskett by e-mail (above) or by phone (614) 293-7713.

Alliance Scholar Award

The Alliance for Clinical Trials in Oncology Foundation invites applications for the 2016 Alliance Scholar Awards. Applications must be submitted by midnight CST June 15.

Alliance Scholar Award recipients will receive a two-year, non-renewable cancer research grant of \$40,000 direct costs per year, plus 10 percent indirect costs each year for two years. Successful applicants will be announced at the 2015 Alliance Fall Group Meeting, held in Chicago November 4-8. Funding will begin approximately January 1, 2016.

This award is exclusively for oncology junior faculty at Alliance institutions within five years of training (rank below Associate Professor). 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. Potential applicants must work with the relevant Alliance Scientific Committee Chair prior to submission of application to ensure endorsement of the relevant Alliance Scientific Committee and include a letter of support from the relevant Alliance Scientific Committee Chair with application materials. Projects supported by other non-institutional funds are not eligible.

How to Apply. All applicants should use the on-line application center to apply for the Alliance Scholar Award. The center can be found on the Alliance website under *Support Research (Awards/Scholar Award)*. A CTEP-IAM username and password are needed to access the site. If you do not have a CTEP-IAM username and password, information on how to obtain one can be found at the bottom of the log-in screen on the Alliance website. For additional questions, contact Zoe Rogers by e-mail at zrogers@alliancefoundationtrials.org.



Green

Mark R. Green, MD, an internationally renowned expert in lung cancer research and treatment, died February 23. He was 70. Dr. Green served as Medical Director of Network for Medical Communication and Research and Clinical Professor of Medicine at The Medical University of South Carolina (MUSC).

Dr. Green joined the Cancer and Leukemia Group B (CALGB) in 1979, and served the Group in many leadership roles. He was a member of the Lymphoma Committee from 1979-1997, and served as Chair of the Respiratory Committee from 1979-2004. He was the Vice Chair of CALGB from 1995-2003. Finally, he was the Chair of the CALGB and then Alliance DSMB from 1995-2011. He had a profound influence on the practice of oncology, with particular contributions to improving the lives of patients with lung cancer. Dr. Green is recognized for his early investigations of induction chemotherapy and treatment of lung cancer as a systemic disease. These investigations led to the identification of induction chemotherapy followed by radiation as superior to radiotherapy alone for patients with locoregionally advanced unresectable non-small cell lung cancer. Under his leadership, the CALGB investigated the role of adjuvant chemotherapy for stage 1B non-small cell lung cancer, the timing of concurrent radiotherapy for limited stage small cell lung cancer and the role of new drugs, including taxanes, gemcitabine and topotecan. A lung cancer tissue bank was established to facilitate translational research. Dr. Green authored more than 300 scientific publications and co-authored *The Comprehensive Textbook of Thoracic Oncology*.

He received his medical degree from Harvard University and trained at Harvard's Beth Israel Hospital, the National Cancer Institute and Stanford University. In 1976, he joined the University of California San Diego, where he held the Edwin and Evelyn Tisch Chair in Cancer Research, established in his honor, and served as director of the UCSD Cancer Center. In 1986, he led the center to NCI designation for the first time. Dr. Green joined MUSC in 1996 as the Director of the Hollings Cancer Center and the Mary M. Gilbreth Professor of Oncology. He served as director until 2000, and retired from the full-time faculty as a Professor Emeritus in 2004.



Parsa

Andrew Parsa, MD, an internationally renowned neurosurgeon specializing in complex tumors of the brain and spine, died April 13. He was 48. Dr. Parsa was Chief of Neurological Surgery and the Michael J. Marchese Professor and Chair of the Department of Neurological Surgery at Northwestern University Feinberg School of Medicine.

Dr. Parsa was a key member of the Alliance NeuroOncology Committee. In addition to being a talented neurosurgeon expert in the management of skull-based tumors, his laboratory helped to develop novel immunotherapies for glioblastoma. He was the Principal Investigator of an ongoing Alliance NCTN

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trial (A071101) testing a new vaccine for prevention of post surgical tumor recurrence – one the largest randomized brain tumor vaccine trial ever to be funded by the National Cancer Institute. His research on brain tumor immunology provided landmark insights, including the identification of a novel link between oncogenesis and immune-resistance in brain tumors.

He received his medical and graduate degrees at Downstate Medical Center, where he initiated one of the first vaccine studies for brain tumor patients. He finished his neurosurgical training at Columbia University and spent 10 years at the University of California San Francisco (UCSF) in positions of professor, vice chair, and Reza and Georgianna Khatib Endowed Chair in Skull Base Tumor Surgery, prior to moving to Northwestern University.



Wetzler

Meir Wetzler, MD, a prominent hematologic oncologist, died February 24. He was 60. Dr. Wetzler served as Chief of the Leukemia Section and Professor of Medicine in the Department of Medicine at Roswell Park Cancer Institute.

Dr. Wetzler joined CALGB in 1994, and served as Study Chair for many successful CALGB leukemia protocols. He served on the Leukemia and Leukemia Correlative Science Committees since 2000. He was also a member of the CALGB Executive Committee and Board of Directors from 2008-2011. His research focused on three areas: the role of the breakpoint cluster region (BCR) gene in chronic and acute leukemia, the involvement of cytokines and their signal transduction in leukemogenesis, and the development of immunotherapy for leukemia.

Dr. Wetzler was prominent in his field and served on the National Comprehensive Cancer Network's Chronic Myelogenous Leukemia (CML) Treatment Committee, helping set the standard of care for CML patients. At Roswell Park, Wetzler chaired the Pharmacy and Therapeutics Committee and co-chaired the Ambulatory Services Executive Committee. He also oversaw the leukemia tissue biorepository and managed a research laboratory, in addition to carrying a full clinical load. He authored more than 100 scholarly articles.

He received his medical degree from Hebrew University's Hadassah Medical School in Jerusalem and completed a residency in internal medicine at Kaplan Hospital in Rehovot. He joined Roswell Park in 1994 following two fellowships in clinical immunology/biologic therapy and medical oncology, respectively, at The University of Texas MD Anderson Cancer Center.



Alliance Helps Kilimanjaro Climb for Cancer Clinical Trials Campaign Raise Funds

The Kilimanjaro Climb for Cancer Clinical Trials campaign, sponsored by the Southwest Oncology Group's (SWOG) Hope Foundation, raised \$110,000 to support cancer research and contributed a portion of this effort to the Alliance for Clinical Trials in Oncology Foundation.

This past February, SWOG Cancer Research Chair Charles D. Blanke, MD, successfully scaled Mount Kilimanjaro in Tanzania to raise awareness of the importance of clinical trials in developing better treatments for cancer patients and to help more patients enroll to studies. The effort was also completed to raise money to help offset dwindling federal funding of cancer clinical trials. As a result, the Alliance through its foundation received more than \$5,400. The Alliance provided marketing support, helping to spread the word about the campaign through its website and other social media vehicles.

Upcoming Meeting Dates

2015
Spring Group Meeting
May 13-16

Fall Group Meeting
November 4-8

2016
Fall Group Meeting
November 2-5

2017
Fall Group Meeting
November 1-4

All meetings are open to all Alliance members and will be held at Loews Chicago O'Hare Hotel, 5300 N. River Road, Rosemont, IL 60018

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