Alliance for Clinical Trials in Oncology

NEWS

Winter 2014
Volume 4, No. 1

info@alliancenctn.org

LEADERSHIP MESSAGE

Beginning on March 1, 2014, the Alliance for Clinical Trials in Oncology will operate under its first National Cancer Institute (NCI) U10 funding awards, completing the process of merging ACOSOG, CALGB, and NCCTG into a single National Clinical Trials Network (NCTN) Group. In this new NCI-funded system, we join colleagues in the Children's Oncology Group, ECOG-ACRIN, NRG Oncology and SWOG in designing and executing practice-changing clinical trials that include approximately 20,000 cancer patients each year.

Over the past two years, Alliance scientific and administrative committees have expanded our combined scientific and operational excellence through many new collaborations. The tremendous effort by these outstanding researchers is the reason for our exceptional success in obtaining peer-reviewed funding for the Group. Alliance institutional leaders have also worked hard to maintain robust study accrual. We are proud that 137 institutions have formally joined the Alliance as Main Members. Of these, 73 represent community programs and 64 are academic institutions.

Congratulations and thanks to all of the outstanding researchers who worked so hard to achieve these important goals.

Thank you for being a member of the Alliance!

Happy New Year,

Monica M. Bertagnolli, MD

Monica M. Bertagnolli, MD
Group Chair

Alliance Awards Double Membership Accrual Points

The Alliance for Clinical Trials in Oncology announces that double accrual points towards meeting Alliance annual membership accrual requirements* will be granted for every enrollment to the following trials:

1. **CALGB 30610** Phase III comparison of thoracic radiotherapy regimens in patients with limited small cell lung cancer also receiving cisplatin and etoposide
2. **CALGB 40903** Phase II study neoadjuvant letrozole for postmenopausal women with estrogen receptor positive ductal carcinoma in situ (DCIS)
3. **NCCTG N1048** A phase II/III trial of neoadjuvant FOLFOX with selective use of combination XRT in locally advanced rectal cancer
4. **Alliance A51101** A randomized phase II trial of myeloablative versus non-myeloablative consolidation chemotherapy for newly diagnosed primary CNS B-cell lymphoma

*Institutions will not receive a corresponding increase in per-case payments. This is effective as of December 12, 2013.

Questions:

Contact Karen Chuang, Alliance Senior Project Manager, by e-mail at kchuang@uchicago.edu.

Alliance Forms New Task Force to Enhance Study Accrual

Accrual has always been a high priority for the Alliance, as trials utilize a tremendous amount of resources and studies need to be timely in order to be scientifically and clinically relevant. In the current days of diminishing resources and increased scrutiny, the need to address accrual proactively has become acute. In April 2013, the Alliance formed a task force to focus on accrual. Its mission is to optimize study accrual across the portfolio. Its methods are twofold: first, the task force monitors, assesses and anticipates accrual issues using data-driven tools, and then develops effective interventions for accrual issues. The task force's membership has representation from multiple areas of the Alliance, including executive officers, patient advocates, statisticians, communications, community oncology, cancer control and Alliance staff.

For prospective studies (i.e., Alliance concepts), the task force has developed an accrual assessment sheet to analyze key areas that may be predictive of poor accrual. High-risk concepts are flagged for development of an accrual plan by the study team, which is reviewed by the task force. This technique is currently being piloted, and will be assessed on its predictive power after one year.

For ongoing studies, a subgroup does an in-depth review of the accrual of all studies in the Alliance portfolio on a regular basis, and puts studies into "zones" of accrual performance. Danger zone studies are reviewed and three studies are selected every two to three months for an analysis. The analytic technique used is a FMEA, or failure mode effects analysis. This technique studies a problem by breaking it down into multiple components, and further dividing the components (which are the "failure modes") into subset areas. Then each of these areas is graded for severity and probability, and a hazard score is developed. High hazard score items are selected for development of an action plan. The task force utilizes this technique for accrual with the failure modes being: patient level, physician/site level, regulatory/systems, protocol/operations, ethics, and other. The action plan items are put together into an accrual enhancement plan, which is then carried out through a work assignment grid. Example items from an accrual enhancement plan are patient brochures, CRP/PI talking points, advocacy outreach, and double accrual membership points. This process takes place as a collaborative effort between the study team, committee, and the accrual task force.

The task force has follow-up from the completion of its first accrual enhancement plan. Alliance A091103 (Phase II Study of Angiopoietin-1 and 2 Peptibody AMG386 for the Treatment of Angiosarcoma) was targeted by the National Cancer Institute (NCI) for a corrective action plan because of low accrual. The task force analyzed the study and determined that accrual was suffering due to three main reasons: the study is in a rare tumor population and patient awareness was an issue, and awareness of the study within the Alliance was low. The plan focused on patient advocacy/community outreach, with requests for publicity to multiple organizations. It also focused on assessing sites that had opened the trial and had or had not accrued patients, and

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Alliance Trial Seeks to Influence Future Treatment for Patients with Rectal Cancer

NCCTG N1048 (PROSPECT) A Phase II/III Trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation Versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision

The current North American standard of care for curative intent treatment for locally advanced (stage II and III) rectal cancer is trimodality therapy using chemotherapy and pelvic radiation prior to surgery. Pelvic radiation is a key component of rectal cancer treatment because it decreases the local recurrence rate; however, some patients experience long-term adverse effects from radiation. Advances in chemotherapy and surgical technique may enable radiation to be omitted for rectal cancer patients who respond well to induction chemotherapy with the FOLFOX regimen.

N1048, also referred to as PROSPECT (Preoperative Radiation Or Selective Preoperative radiation and Evaluation before Chemotherapy and TME), is a randomized phase II/III trial of the selective use of radiation therapy in intermediate risk clinical stage II-III rectal cancer.

In this study, Alliance investigators will learn whether radiation can be used selectively rather than consistently for treatment of locally advanced rectal cancer. All patients will undergo surgery. Investigators hypothesize that if patients respond to neoadjuvant chemotherapy (FOLFOX for six cycles), then it will be safe to omit pelvic radiation without compromising outcomes. It is anticipated that this strategy will minimize toxicity without compromising cure rates. The study is not designed to eliminate radiation, but rather to see if it can be used strategically for those patients who do not respond to neoadjuvant FOLFOX instead of reflexively for all patients.

N1048 (PROSPECT) is a two-arm study with one to one randomization. The control arm of the study includes standard chemoradiation for rectal cancer. The choice of capecitabine or 5FU for sensitization is up to the treating physician. The intervention arm includes six cycles of neoadjuvant FOLFOX followed by restaging. Patients with clinical response to induction FOLFOX proceed directly to surgery. Those patients with no response (non-responders) will undergo chemoradiation first. In this manner, the intervention arm is a dynamic strategy that includes radiation for tumors that do not respond to FOLFOX.

Patients will be randomized to either neoadjuvant combined modality therapy with 5FU/capecitabine and synchronous radiation or to pre-operative FOLFOX with selective use of radiation depending on response to neoadjuvant chemotherapy (FOLFOX). The phase II component will focus on safety and early evidence of inferiority of the intervention group compared to the standard of care group based on the pelvic R0 resection rate and time to local recurrence. The phase III component will evaluate clinical outcomes of both groups relative to co-primary endpoints of disease-free survival and time to local recurrence.

This study has the potential to personalize rectal cancer therapy and increase the number of available approaches to treatment. It includes quality of life assessments, patient-reported assessments of treatment toxicity, along with biological, immunologic and pharmacogenomic correlative studies.

N1048 (PROSPECT) is currently available on the CTSU menu (www.ctsu.org) to all Alliance members and most other cooperative groups. The Study Chairs are Deborah Schrag, MD MPH, Dana-Farber Cancer Institute, e-mail: deb_schrag@dfci.harvard.edu; Robert McWilliams, MD, Mayo Clinic, e-mail: mcwilliams.robert@mayo.edu; and Alessandro Fichera, MD, University of Washington, e-mail: afichera@uw.edu.

Alliance Researchers Explore Ways to Set New Treatment Standard in Lung Cancer

CALGB 30610/RTOG 0538 Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer Also Receiving Cisplatin and Etoposide

Jeffrey Bogart, MD, of State University of New York Upstate Medical University and lead investigator on CALGB 30610/RTOG 0538, wants to establish a better standard treatment option for patients with limited-stage small cell lung cancer – defined as cancer limited to the lung, and regional lymph nodes. Currently, the standard treatment is chemotherapy in combination with modest total doses of radiation therapy.

"What we've found from past scientific studies is that it matters how the radiation is given to the chest," said Dr. Bogart. "A trial that was started more than 20 years ago (INT 0096) looked at giving radiation therapy twice a day to the chest compared to giving it once a day – both with a fairly low total dose of radiation (45 Gy). Patients who received the twice-daily regimen finished quicker – in three weeks versus five weeks. There was a better cure rate and better survival for these patients (five-year survival was 26 percent with twice daily radiation and 16 percent with once-a-day radiation). On the other hand, there were more side effects with this regimen, particularly with difficulty in swallowing (esophagitis) and dehydration. However, once-a-day treatment really caught on and became routine in this country, partly because of concerns about the side effects of twice daily treatment and partly because it could sometimes be difficult to administer two treatments a day – either the clinic could not do it or it was difficult for the patient to come in."

Meanwhile, other radiation regimens have been considered and studied. For example, legacy group CALGB had quite a long history (dating back to the 1980s) of investigating high-dose once-a-day radiation therapy in phase I and II trials where doses were up to 70 Gy, which was more than a 50 percent increase in radiation dosage.

Although combining both intensive chemotherapy and radiation is never a simple treatment, study results looked promising and it appeared that radiation was fairly well tolerated, according to Dr. Bogart. This is particularly the case with CALGB 39808 (Topotecan/Paclitaxel Induction Followed by Consolidation Chemoradiotherapy for Limited Stage Small Cell Lung Cancer: A Phase II Study), which has had the longest follow-up and good long-term survival for those patients. However, only a small percentage of patients where the cancer came back – in the chest where the radiation was targeted.

In CALGB 30610/RTOG 0538, an intergroup study led by the Alliance (CALGB) and the NRG Oncology (RTOG), in collaboration with ECOG-ACRIN (ECOG) and SWOG, investigators will determine whether administering thoracic radiotherapy, 70 Gy (2 Gy once daily over seven weeks) will improve median and two-year survival compared with 45 Gy (1.5 Gy twice daily over three weeks) in patients with limited-stage small cell lung cancer.

"Two questions present themselves," said Dr. Bogart. "Does the cumulative dose of radiation matter? Does it matter how many times a day you give the radiation? The thought is, if the patients on the high-dose arm do best then we have a new standard of care that people are comfortable with. If the low-dose arm is best, this is more evidence that we should be doing this twice a day, and I think people will be more convinced."

This trial is unique in other ways. It started with three arms, but the experimental arm (a concomitant boost regimen of 61.20) was eliminated based on the acute side effect profile. Dr. Bogart stated that in the case of limited-stage small cell lung cancer, it is very important how toxic the treatment is. "We're really looking at whether giving the higher dose of radiation will be beneficial," he said. "We're looking for a regimen that has the best efficacy, but we hope, the least toxicity as well."

Refer to the study protocol (CALGB 30610), 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 Jeffrey Bogart, MD, State University of New York Upstate Medical University, e-mail: bogartj@upstate.edu. The Alliance Study Co-Chair is Gregory Masters, MD, Helen F. Graham Cancer Center, Medical Oncology Hematology Consultants, e-mail: gmasters@cbg.org. The NRG Oncology (RTOG Radiation Oncology) Study Chair is Rotsuko Komaki. MD, MD Anderson Cancer Center, e-mail: rkomaki@mdanderson.org.

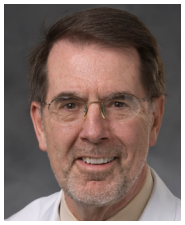
A Closer Look at Who's Who in the Alliance

This article is the last in a four-part, monthly series to feature an overview of all Alliance committees, along with short biographies of leaders within each area of the Alliance. This month's series introduces chairs of the Alliance administrative committees.

Habermann

Hurd

Bearden



Crawford

***Who's Who* Alliance Administrative Committees**

Audit Committee

Co-Chair **Thomas M. Habermann, MD**, Professor of Medicine at Mayo Clinic. With a focus on finding improvements in the diagnosis and treatment of hematologic diseases, Dr. Habermann is known as a world-class expert in the field of lymphoma. His primary interests are clinical research with an emphasis in lymphoma.

Co-Chair **David D. Hurd, MD**, Professor and Director, Blood and Marrow Transplant Program at the Wake Forest University School of Medicine. Dr. Hurd specializes in acute and chronic leukemia, Hodgkin's disease, lymphomas, multiple myeloma, non-Hodgkin's lymphoma, clinical trials, bone marrow and stem cell transplantation. He is a past recipient of the National Cancer Institute's Joan K. Mauer Memorial Award for excellence in clinical trial audits and quality assurance.

The Alliance Audit Committee is comprised of volunteer physicians and clinical research professionals from Alliance member institutions who conduct on-site institutional audits at regular intervals to review primary records for compliance with federal regulations, Alliance policy and protocol requirements. The committee submits a report of audit results to the Group Chair and the Institutional Performance Evaluation Committee (IPEC).

Conflict of Interest (COI) Committee

Co-Chair **James D. Bearden, III, MD**, Director of the Bearden-Josey Center for Breast Health; Managing Physician at Gibbs Cancer Center and Vice President of Clinical Research at the Spartanburg Regional Healthcare System. Dr. Bearden, honored for extraordinary service in the fight against colon cancer, has the distinction of being the first board-certified oncologist in the state of South Carolina. He was instrumental in helping the Gibbs Cancer Center become one of only 10 community hospitals in the country to participate in the National Cancer Institute's Community Cancer Centers Program.

Co-Chair **Jeffrey Crawford, MD**, Chief, Division of Medical Oncology and Professor of Medicine at the Duke University Medical Center. Dr. Crawford focuses on lung cancer (small-cell and non-small-cell), chemotherapy and hematopoietic growth factors. His research has led to U.S. Food and Drug Administration approval of trials such as one of filgrastim to reduce the morbidity of chemotherapy-related neutropenia and another of vinorelbine in treatment of patients with advanced non-small cell carcinoma of lung cancer.

The Alliance Conflict of Interest (COI) Committee confidentially reviews COI disclosure forms and, if necessary, additional information submitted by all Alliance leaders. Based on its review, the committee makes recommendations at least annually to the Executive Committee concerning potential conflicts of interest or possible violations of the Alliance policy related to conflict of interest reporting. The Executive Committee determines whether a conflict of interest or violation of policy exists and forwards its recommendation

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Alliance Administrative Committees

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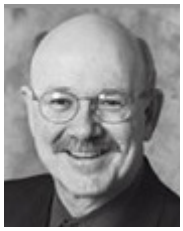
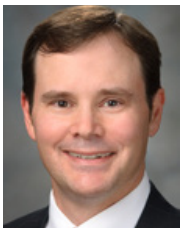


Morton

for action to the Alliance Group Chair or to the Group Vice Chair if the Group Chair is the subject of the report.

Constitution and Bylaws Committee

Chair **Roscoe F. Morton, MD**, Clinical Assistant Professor at the University of Iowa College of Medicine-Des Moines and Partner at Medical Oncology and Hematology Associates of Iowa. Dr. Morton's research focuses on colon and rectal cancer, breast cancer, lung cancer and melanoma.

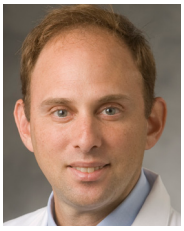


Brown

The Alliance Constitution and Bylaws Committee is responsible for reviewing the constitution and bylaws and making recommendations to the Board of Directors for changes as they deem necessary for the proper oversight and efficient operation of the Alliance.

Data and Safety Monitoring Board (DSMB)

Chair **Paul D. Brown, MD**, Professor, Department of Radiation Oncology at the University of Texas MD Anderson Cancer Center in Houston, TX. Dr. Brown specializes in treatment of all central nervous system tumors, both primary and metastatic brain and spinal cord cancers. As Chair, he works closely with the Alliance Group Statistician to conduct DSMB business.



Peppercorn

The primary goals of the Alliance Data and Safety Monitoring Board (DSMB) are to monitor all National Cancer Institute Cancer Therapy Evaluation Program (NCI-CTEP) sponsored phase III and randomized phase II trials, and select DCP-sponsored trials. The DSMB reviews interim analyses of outcome and toxicity data that are prepared by each study statistician, and makes recommendations to the Group Chair concerning whether the study needs to be continued, changed or terminated. In addition, the DSMB reviews and approves major modifications to studies that are proposed by the study team. All DSMB recommendations for study closure or study design changes are forwarded to the NCI for review and approval. In addition, the DSMB authorizes release of study data results.

Levine

Ethics Committee

Chair **Jeffrey Peppercorn, MD, MPH**, Associate Professor of Medicine, Division of Medical Oncology and Associate, Trent Center for Bioethics and Humanities at the Duke University Medical Center. Dr. Peppercorn's interests include breast cancer (early stage and advanced), medical ethics and health care policy. His research focuses on issues of bioethics and health policy in oncology, and he is involved in development of novel therapeutics for breast cancer and efforts to improve care and outcomes among breast cancer survivors.

The Alliance Ethics Committee provides in depth review and commentary concerning important issues facing Alliance researchers. These reviews are used by the Group Chair and Board of Directors to adjust Alliance polices when changing circumstances warrant this.

Institutional Performance Evaluation Committee (IPEC)

Chair **Ellis G. Levine, MD**, Professor of Oncology, Department of Medicine at the Roswell Park Cancer Institute and Associate Professor of Medicine, School of Medicine and Biomedical Sciences at the State University of New York at Buffalo. Dr. Levine is an expert in the areas of bladder, breast, prostate and testicular cancers. His research interests include novel therapies for breast and urothelial cancer.

Alliance Administrative Committees

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Nikcevich

The Alliance Institutional Performance Evaluation Committee (IPEC) is responsible for semi-annual reviews of the performance of Alliance institutional members, using a quality evaluation mechanism that includes summary reports of established metrics. The committee has revised policies from the three legacy groups to develop new metrics for institutional evaluation, as well as an Alliance institutional probation policy. The committee submits its findings to the Group Chair and the Membership Committee for use in recommending performance-based changes in institutional membership status to the Board of Directors.

Finnes

Membership Committee

Chair **Daniel A. Nikcevich, MD**, President and Chief Medical Officer of Essentia Health (East Region) and Principal Investigator of the Duluth Community Clinical Oncology Program (CCOP). Dr. Nikcevich's clinical and scientific interests include the care and management of patients with hematologic malignancies, breast cancer, sarcoma, renal cell carcinoma, and melanoma.

The Alliance Membership Committee reviews institutional applications for membership, and makes recommendation regarding these proposals to the Board of Directors. The committee also receives regular reports regarding the efficiency and performance of member institutions from the Institutional Performance Evaluation Committee (IPEC) and from other appropriate sources, and makes recommendations concerning membership status to the Group Chair and Board of Directors.

Perez

Pharmacy Committee

Chair **Heidi D. Finnes, PharmD, BCOP**, Assistant Professor of Pharmacy, College of Medicine, Mayo Clinic, and Pharmacy Coordinator, Hematology/Oncology Disease Management, Mayo Clinic Cancer Center. Dr. Finnes participates in cancer center research and practice through the review and creation of clinical trial and non–study order sets. She also coordinates outpatient oncology pharmacy educational experiences and provides education on chemotherapy and targeted therapy to pharmacists, nurses, allied health providers and physicians locally and nationally.

The Alliance Pharmacy Committee is a resource for research pharmacists at all Alliance member institutions, providing education and support that ensures maximal safety and adherence to Alliance treatment protocols. Dr. Finnes leads committee members in a review of all Alliance protocols for accuracy, clarity, and consistency of drug distribution, dosing, and administration information, and development supportive educational materials for new agents. The committee works closely with the Oncology Nursing Committee in its educational activities.

Publications Committee

Chair **Edith A. Perez, MD**, Deputy Director at the Mayo Clinic Cancer Center and Serene M. and Frances C. Durling Professor of Medicine, Division of Hematology/Oncology at the Mayo Clinic. Dr. Perez is actively involved in clinical trials that explore the use of targeted therapeutic agents for the treatment and prevention of breast cancer. She leads studies to evaluate the role of genetic biomarkers in the development, aggressiveness and therapeutic efficacy of therapies for breast cancer.

In addition to serving as the Group Vice Chair for the Alliance, Dr. Perez leads the Publications Committee in reviewing existing policies and best practices concerning

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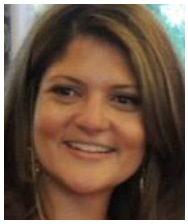
Introducing New Alliance Staff, Appointments


Killinger

Patrick (Pat) J. F. Killinger, MA, recently joined the Alliance as Operation Manager for the Mayo Clinic Cancer Center Clinical Research Office. Mr. Killinger is responsible for managing and coordinating regulatory, roster and audit activities that occur at Mayo with the Alliance Chicago Office and the Office of the Group Chair in Boston, MA. He brings to the Alliance more than 14 years of experience in business and research operations management, including an extensive background in work flow, process development and improvement planning for academic and professional research centers and health care services. At Mayo, Mr. Killinger oversees daily operations of the Cancer Clinical Research Office and manages staff who develop and coordinate clinical trial activities for government and pharmaceutical studies.


Lewandowski

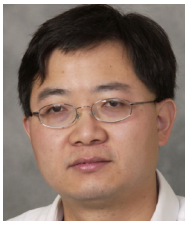
Alison Lewandowski joined the Alliance as the Meetings and Operations Coordinator in the Office of the Group Chair. Ms. Lewandowski was previously at Archetype Consulting where she worked in marketing, operations and communications. Her experience includes positions in events, finance and with the Boston Convention and Visitors Bureau. She graduated from Johnson & Wales University magna cum laude with a degree in Sport/Entertainment and Event Management.


Oberg

Ann L. Oberg, PhD, is now Director of Bioinformatics in the Alliance Statistics and Data Center (SDC). The Bioinformatics unit enables the efficient experimental design, processing, handling, and analysis of high-dimensional data from Alliance studies within a sound statistical framework. Dr. Oberg is on the Translational Research Program Executive Committee, and will coordinate statistical review of the protocols. She will also facilitate access to statistical resources for Alliance translational protocol development and execution. She has extensive statistical consulting experience in both clinical and basic science research and is co-investigator on several NIH funded grants. Dr. Oberg is also Director of the Statistical Core for both the Mayo Clinic Ovarian and Pancreas SPORE grants.


Smith

Scott E. Smith, MD, PhD, joined the Alliance as an Executive Officer in the Central Protocol Operations Office. Dr. Smith is responsible for the oversight, development and conduct of the Alliance's clinical trials for leukemia, lymphoma, myeloma and stem cell transplantation. His specialties include leukemia, non-Hodgkin lymphoma, refractory lymphoma, relapsed lymphoma and bone marrow disorders. Dr. Smith is also an Associate Professor of Hematology and Oncology at Loyola University Medical Center.


Wang

Xiaofei Wang, PhD, is now Associate Director for Statistics in the Alliance Statistics and Data Center (SDC). All activities within the Alliance SDC based on statistical principles fall under the overall responsibility of the Statistics unit. Dr. Wang partners with Dr. Karla Ballman, the Statistics unit's director, for overall unit planning and direction; manages unit activities within a respective site; and represents the unit within Alliance leadership in the absence of the director. His statistical method research interests include design and analysis of clinical trials, statistical methods for diagnostic medicine, biomarker discovery and validation and health outcomes research. Dr. Wang is also an Associate Professor of Biostatistics in the Department of Biostatistics & Bioinformatics at Duke University School of Medicine.

2014 Alliance Meeting Abstract Submissions

Abstract submission deadlines for the following meetings are approaching. **All draft abstracts** from Alliance for Clinical Trials in Oncology (including all three legacy groups: ACOSOG, CALGB and NCCTG) **must be submitted by the dates indicated below to the Alliance by e-mail to Publications@AllianceNCTN.org.**

February 3	56th Annual Meeting of the American Society for Therapeutic Radiation and Oncology (ASTRO) *(September 14-17, San Francisco, California)*
February 14	19th Congress of the European Hematology Association (EHA) *(June 12-15, Milan, Italy)*

These deadlines are firm, and 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 these symposiums and conferences. *All Alliance abstracts must follow this process. Independent submission of work related to the Alliance without this proper review is not appropriate.*

Abstract Requirements

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

- Provide institutional affiliation for each author

Corresponding author

- Provide the name and contact information of the corresponding author

Accepted Abstracts

Send the publications coordinator the acceptance Send the publications coordinator the acceptance notification and final accepted abstract within one week after hearing from meeting or association.

Questions: If you have questions about the abstract review process, contact the publications coordinator at Publications@AllianceNCTN.org.

CTEP-AERS Training Available Now

Training for the Cancer Therapy Evaluation Program Adverse Event Reporting System (CTEP-AERS) is now available. CTEP-AERS is the NCI's new web-based system for submitting expedited reports for serious and/or unexpected events. It is the CTEP version of the Cancer Adverse Event Reporting System (caAERS) integrated into the CTEP Enterprise System.

Standing WebEx training sessions are held on Mondays, Wednesdays and Fridays for one hour and 15 minutes, continuing throughout this summer. Registration is limited to 30 registrants.

Sign-up instructions are on the CTEP-AERS page of the CTEP website: http://ctep.cancer.gov/protocolDevelopment/electronic_applications/adverse_events.htm). Follow the instructions below to register for a session. If you are already registered and wish to change sessions, follow the cancellation instructions at the bottom of the registration e-mail you received prior to attempting a new registration.

To register for CTEP-AERS Trainings

- Click this link: http://tinyurl.com/AERS-Registration
- Click "Show All Meetings" in the middle of the page.
- All meeting times are in Eastern Standard Time. Click the time zone (far right side of the page - currently set to New York Time) to change time zones.
- Click "Register" next to the training session group you would like to attend:
  - CTEP-AERS Training Sessions are Mondays at 3pm, Wednesdays at 2pm and Fridays at 10am EST)
  - CTEP-AERS Tuesday/Thursday Trainings are on Tuesdays and Thursdays at various times.

The next available meeting that is not yet full will automatically display. Click the drop-down list to select a different date. Fill in the required information and click "Register" at the bottom of the page.

New Task Force to Enhance Study Accrual

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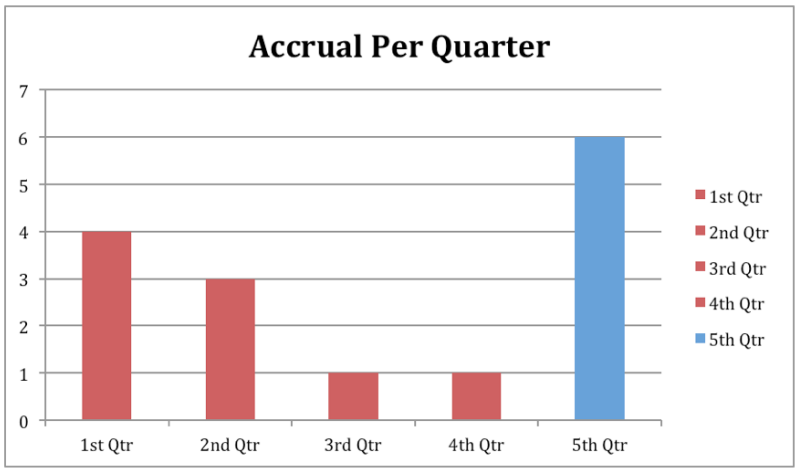
what they felt the barriers were. This was accomplished with site e-mails and phone calls from an Alliance executive officer. The results of the accrual plan are below:



The quarters in red are before the plan, and blue is after the plan was instituted. Plan activation resulted in a six-fold increase in accrual over the two preceding quarters.

There are multiple other subgroups in the accrual task force that address other areas, such as development of standard operating procedures, templates, strategic development, etc. The task force aims to be inclusive and is open to new members and suggestions.

Administrative Committees

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scientific publication authorship, and recommending any appropriate changes to the Executive Committee. The committee coordinates review of Alliance manuscripts, abstracts, and other publications prior to submission, and adjudicates in a timely manner any issues related to publication of Alliance research. The committee also prepares an annual Alliance Published Manuscripts book that is distributed to all members at the annual Group-wide meeting. In addition, the committee recently developed the current Alliance Publications Policy and has been posting brief summaries highlighting recently published Alliance results to the Public Summaries page of the Alliance website.

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**