

## ANNUAL MEETING

# 2014 Alliance Spring Group Meeting Set in Chicago

The Alliance for the Clinical Trials in Oncology will host its 2014 Spring Group Meeting in Chicago, IL, May 7-10. Approximately 1,000 Alliance members are expected to attend the three-day meeting at the InterContinental Chicago O'Hare. Meeting attendees can attend more than 60 informative sessions led by renowned oncology researchers and clinical trials specialists from around the country. Topics on current and future innovations in cancer research and the development of cutting-edge protocols will be discussed throughout the meeting.

### Meeting Highlights

**Plenary Session** / Friday, May 9 / 1 pm - 3 pm

**Monica M. Bertagnolli, MD**, Alliance Group Chair, will welcome three distinguished researchers to engage Alliance members by presenting the latest information in cancer clinical research at this year's plenary session.

**Federico Innocenti, MD, PhD**, Associate Professor in the Division of Pharmacotherapy and Experimental Therapeutics of the UNC Eshelman School of Pharmacy at the University of North Carolina at Chapel Hill, will discuss clinical research challenges of tumor genomic analysis. Dr. Innocenti's research is currently focused on the discovery of genomic determinants of efficacy and toxicity of cancer chemotherapy, integrating clinical genomic investigation with functional evaluation of gene variation.

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### Meeting By the Numbers

1K

Alliance members expected to attend

44\*

States represented by Alliance members

31

Alliance scientific and modality sessions

151

Alliance member main institutions

18

Alliance lead academic participating sites (LAPS)

**Geoffrey R. Oxnard, MD**, Instructor in Medicine at Harvard Medical School and medical oncologist at Dana-Farber Cancer Institute, will present an update on the Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST). The trial will genotype surgically resected NSCLC tissue from patients with lung cancer for both EGFR mutations and ALK rearrangements. Patients with tumors harboring these alterations will be referred for enrollment in adjuvant clinical trials of erlotinib or crizotinib conducted by the NCTN.

**Peter O'Dwyer, MD**, Professor of Medicine at the University of Pennsylvania School of Medicine and Director of the Experimental Therapeutics Program at the University of Pennsylvania Cancer Center, will wrap-up with insights on a related trial, NCI Molecular Analysis for Therapy Choice (MATCH). This trial will sequence tumors from patients with advanced cancer whose disease has progressed on standard therapy to determine if they have a select molecular change for which a targeted agent might be beneficial.

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### Training Opportunities for CRPs

Alliance Clinical Research Professionals (CRPs) have two opportunities for training at this year's meeting:

- **Information Session** on Thursday, May 8, 1 pm - 5 pm
- **Continuing Education Workshop for CRPs** on Friday, May 9, 8 am - 12 pm

The information session will include presentations on topics about the Alliance, its procedures, and its members, as well as information about what's happening on a national level that affects clinical trials and reporting. This session is ideal for those who have questions about Alliance operations, including administrative issues, data collection and data systems, NCI initiatives, CTSU policies and other pertinent information to help CRPs troubleshoot concerns and issues.

The education workshop places strong emphasis on progressive education and refinement of data management skills. Topics alternate between disease-specific and administrative-related presentations. Alliance physicians will provide disease-specific scientific presentations about diagnosis and staging, new investigational agents and treatment modalities, as well as patient care implications, and laboratory techniques. CRP Committee members also work closely with American College of Surgeons Clinical Research Program committees to coordinate the dissemination of information to CRPs. This meeting will focus on breast cancer, lung cancer and lymphoma protocols. Session presenters include **Shelly Hwang, MD, MPH**, Duke University Medical Center; **Cynthia X. Ma, MD, PhD**, Washington University; and **Jeffrey Bogart, MD**, State University of New York Upstate Medical University.

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# Alliance Investigators Recognized by CTSU



Unzeitig



Lyss



Guenther



Linette



Razaq

Five Alliance for Clinical Trials in Oncology investigators have been recognized by the National Cancer Institute (NCI) as top-enrolling individual investigators to cooperative group treatment trials through the Cancer Trials Support Unit (CTSU) in 2013.

- **Gary W. Unzeitig, MD**, of Doctor's Hospital of Laredo (33)
- **Alan P. Lyss, MD**, of Missouri Baptist Medical Center (19)
- **Joseph Guenther, MD**, of Saint Elizabeth Medical Center South (17)
- **Gerald P. Linette, MD, PhD**, of Washington University School of Medicine (15)
- **Wajeeha Razaq, MD**, of University of Oklahoma Health Sciences Center (15)

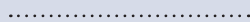
These figures include only trials available to members of every group and not limited participation trials, nor does it include lead group accruals. The list includes the number of patients the investigators enrolled (a minimum of 15 patients over the year).



## ANNUAL MEETING continued

### Academic and Community Cancer Research United (ACCRU) Scientific Program

Alliance members and meeting participants are welcome to attend the Academic and Community Cancer Research United (ACCRU) Scientific Session Saturday, May 10, 7 am – 10 am. This session will highlight the portfolio of ACCRU studies. ACCRU Disease Group leaders will present an update on trials open for enrollment and an overview of studies in development. During the Group meeting, ACCRU staff will be located in Avedon D on Friday, May 9 and Saturday, May 10. **Note:** This meeting will be open to all attendees except pharmaceutical representatives.



**For questions about the meeting:** Contact Alison Lewandowski, Alliance Meetings and Operations Coordinator, by e-mail [alewandowski@partners.org](mailto:alewandowski@partners.org) or phone (617) 525-3022.

# Alliance Study Seeks to Determine Efficacy of New Multiple Myeloma Therapy

Alliance A061202 A Phase I/II Study of Pomalidomide, Dexamethasone and Ixazomib vs. Pomalidomide and Dexamethasone for Patients with Multiple Myeloma Refractory to Lenalidomide and Proteasome Inhibitor-Based Therapy

Multiple myeloma is the second most common hematologic malignancy in adults and associated with significant mortality and morbidity. This year, it is estimated that there will be more than 22,000 new cases of multiple myeloma in the United States.<sup>1</sup> With the advent of the immunomodulatory drugs (IMiDs), thalidomide and lenalidomide, and now pomalidomide, and the proteasome inhibitors bortezomib and carfilzomib, survival of patients with multiple myeloma has significantly improved.<sup>2-13</sup>

The clinical activity of IMiD/proteasome inhibitor combinations has been promising with responses rivaling those seen with autologous stem cell transplantation.<sup>14-19</sup> Notably, the relative five-year survival rate for multiple myeloma from 1987-1989 was only 28 percent; more recently, from 2002-2008, it had increased to 43 percent, a testimony to the significant advances in therapy over the last decade.<sup>1</sup> Unfortunately, the vast majority of patients will experience repeated relapses and eventually succumb to refractory disease.<sup>20</sup>

Alliance A061202 is a randomized phase I/II trial that will study the side effects and best dose of pomalidomide and ixazomib when given together with dexamethasone and to see how well pomalidomide and dexamethasone with or without ixazomib works in treating patients with refractory multiple myeloma. Biological therapies, such as pomalidomide and dexamethasone, may stimulate the immune system in different ways and stop tumor cells from growing. Ixazomib may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. It is not yet known whether pomalidomide and dexamethasone are more effective with or without ixazomib in treating multiple myeloma.

The phase I portion of the study will determine the maximum tolerated dose for combination therapy pomalidomide/dexamethasone/ixazomib. About 24 patients will take part in this portion of the study. The phase II portion will assess whether the combination of pomalidomide/dexamethasone/ixazomib improves progression-free survival relative to pomalidomide/

dexamethasone. About 108 patients will take participate in this portion.

The phase I portion is a limited access study, available to the following institutions: UNC Lineberger Comprehensive Cancer Center, Dana-Farber Cancer Institute, Memorial Sloan-Kettering Cancer Center, and The Ohio State University Comprehensive Cancer Center. The phase II portion of the study is open to all Alliance member institutions.

Refer to the study protocol (Alliance A061202), which can be found on the Alliance website ([AllianceforClinicalTrialsinOncology.org](http://AllianceforClinicalTrialsinOncology.org)) for complete information on the trial design, treatment plan and patient eligibility. The Alliance Study Chair is Peter Voorhees, MD, University of North Carolina at Chapel Hill, e-mail: [peter\\_voorhees@med.unc.edu](mailto:peter_voorhees@med.unc.edu).

## Sources

1. Siegel R, Naishadham D, Jemal A: Cancer statistics, 2013. *CA Cancer J Clin* 63:11-30, 2013
2. Kumar SK, Rajkumar SV, Dispenzieri A, et al: Improved survival in multiple myeloma and the impact of novel therapies. *Blood* 111:2516-20, 2008
3. Dimopoulos M, Spencer A, Attal M, et al: Lenalidomide plus dexamethasone for relapsed or refractory multiple myeloma. *N Engl J Med* 357:2123-32, 2007
4. Weber DM, Chen C, Niesvizky R, et al: Lenalidomide plus dexamethasone for relapsed multiple myeloma in North America. *N Engl J Med* 357:2133-42, 2007
5. Zonder JA, Crowley J, Hussein MA, et al: Lenalidomide and high-dose dexamethasone compared with dexamethasone as initial therapy for multiple myeloma: a randomized Southwest Oncology Group trial (S0232). *Blood* 116:5838-41, 2010
6. Rajkumar SV, Jacobus S, Callander NS, et al: Lenalidomide plus high-dose dexamethasone versus lenalidomide plus low-dose dexamethasone as initial therapy for newly diagnosed multiple myeloma: an open-label randomised controlled trial. *Lancet Oncol* 11:29-37, 2010
7. Palumbo A, Hajek R, Delforge M, et al: Continuous Lenalidomide Treatment for Newly Diagnosed Multiple Myeloma. *New England Journal of Medicine* 366:1759-1769, 2012
8. McCarthy PL, Owzar K, Hofmeister CC, et al: Lenalidomide after Stem-Cell Transplantation for Multiple Myeloma. *New England Journal of Medicine* 366:1770-1781, 2012
9. Mateos MV, Richardson PG, Schlag R, et al: Bortezomib plus melphalan and prednisone compared with melphalan and prednisone in previously untreated multiple myeloma: updated follow-up and impact of subsequent therapy in the phase III VISTA trial. *J Clin Oncol* 28:2259-66, 2010
10. Richardson PG, Barlogie B, Berenson J, et al: A phase 2 study of bortezomib in relapsed, refractory multiple myeloma. *N Engl J Med* 348:2609-17, 2003
11. Richardson PG, Sonneveld P, Schuster M, et al: Extended follow-up of a phase 3 trial in relapsed multiple myeloma: final time-to-event results of the APEX trial. *Blood* 110:3557-60, 2007
12. Richardson PG, Sonneveld P, Schuster MW, et al: Bortezomib or high-dose dexamethasone for relapsed multiple myeloma. *N Engl J Med* 352:2487-98, 2005

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# Preoperative Breast MRI: Effects on Surgery, Costs and Quality of Life

Alliance A011104 Effect of Preoperative Breast MRI on Surgical Outcomes, Costs and Quality of Life of Women with Breast Cancer

Alliance A011104 is a randomized trial of the effect of preoperative breast magnetic resonance imaging (MRI) on surgical outcomes in patients deemed eligible for breast conserving surgery by conventional clinical criteria. This study will provide important information about the clinical and biologic relevance of occult disease identified by MRI alone.

Currently, the importance of these additional MRI-detected foci remains controversial and there is concern that the enhanced sensitivity of breast MRI may result in unnecessary mastectomy. The results of this trial evaluating local recurrence rates in women who do and those who do not undergo preoperative MRI will provide critical information about the significance of these additional MRI detected foci. If the trial results demonstrate that women who undergo breast conservation therapy (BCT) without the benefit of preoperative MRI have higher local recurrence rates compared to women staged preoperatively with breast MRI, then this would suggest that the occult areas of carcinoma, detected by MRI alone, are clinically relevant and if not surgically addressed, result in inferior local control. This finding would justify the routine use of preoperative MRI for staging of patients and selection for BCT.

However, if the use of preoperative breast MRI does not improve on long-term local control rates, this would suggest that the increased sensitivity of breast MRI in detecting otherwise occult disease is not clinically significant and/or these additional areas are well controlled through the use of adjuvant radiation and systemic therapies. Therefore, the use of preoperative MRI for routine staging of women prior to breast surgery would not be warranted and the increased rates of mastectomy seen with utilization of breast MRI would not be justified.

In this study, patients eligible for breast conserving surgery will be randomized to standard preoperative breast cancer local-regional staging without the addition of MRI or standard preoperative breast cancer local-regional staging with the use of MRI. The primary objective is to compare the rates of local-regional recurrence (LRR) following attempted breast conserving therapy in a cohort of women with triple negative or HER-2 amplified breast cancer. Secondary endpoints and correlative studies include a comparison of the rates of re-excision between the arms as well as a cost efficacy analysis.

The cost effectiveness component to this study will capture significant data about the costs associated with the two treatment strategies and test the hypothesis that although preoperative breast MRI is expensive, these costs will be offset, in the short term, by reducing the number of operative interventions required to achieve margin negative BCT and, in the long term, by reduction in local recurrence events. In addition, QOL measurements of fatigue and overall perception of QOL will be assessed upon registration in this study. Evidence shows that baseline single-item assessments of fatigue and overall QOL are strong prognostic indicators for survival in cancer patients, independent of performance status.

Refer to the study protocol (Alliance A011104), which can be found on the Alliance website ([AllianceforClinicalTrialsinOncology.org](http://AllianceforClinicalTrialsinOncology.org)) for complete information on the trial design, treatment plan and patient eligibility. The Alliance Study Chair is Isabelle Bedrosian, MD, University of Texas MD Anderson Cancer Center, e-mail: [ibedrosian@mdanderson.org](mailto:ibedrosian@mdanderson.org).

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13. San Miguel JF, Schlag R, Khuageva NK, et al: Bortezomib plus melphalan and prednisone for initial treatment of multiple myeloma. *N Engl J Med* 359:906-17, 2008
14. Richardson PG, Weller E, Lonial S, et al: Lenalidomide, bortezomib, and dexamethasone combination therapy in patients with newly diagnosed multiple myeloma. *Blood* 116:679-86, 2010
15. Richardson PG, Weller E, Jagannath S, et al: Multicenter, phase I, dose-escalation trial of lenalidomide plus bortezomib for relapsed and relapsed/refractory multiple myeloma. *J Clin Oncol* 27:5713-9, 2009
16. Jakubowiak AJ, Griffith KA, Reece DE, et al: Lenalidomide, bortezomib, pegylated liposomal doxorubicin, and dexamethasone in newly diagnosed multiple myeloma: a phase 1/2 Multiple Myeloma Research Consortium trial. *Blood* 118:535-43, 2011
17. Pineda-Roman M, Zangari M, van Rhee F, et al: VTD combination therapy with bortezomib-thalidomide-dexamethasone is highly effective in advanced and refractory multiple myeloma. *Leukemia* 22:1419-27, 2008
18. Cavo M, Tacchetti P, Patriarca F, et al: Bortezomib with thalidomide plus dexamethasone compared with thalidomide plus dexamethasone as induction therapy before, and consolidation therapy after, double autologous stem-cell transplantation in newly diagnosed multiple myeloma: A randomised phase 3 study. *Lancet* 376:2075-85, 2010
19. Palumbo A, Bringhen S, Rossi D, et al: Bortezomib-melphalan-prednisone-thalidomide followed by maintenance with bortezomib-thalidomide compared with bortezomib-melphalan-prednisone for initial treatment of multiple myeloma: a randomized controlled trial. *J Clin Oncol* 28:5101-9, 2010
20. Kumar SK, Therneau TM, Gertz MA, et al: Clinical course of patients with relapsed multiple myeloma. *Mayo Clin Proc* 79:867-74, 2004



*Bartlett*

## Washington University School of Medicine

Principal Investigator – Nancy L. Bartlett, MD

Washington University School of Medicine (WUSM), located in St. Louis, MO, is one of the top biomedical research institutions in the United States. It is affiliated with Barnes-Jewish Hospital, St. Louis Children's Hospital, the St. Louis Veteran's Administration Hospital, Shriner's Hospital for Children and several other community sites.

The Alvin J. Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine is the only cancer center in Missouri and within 240 miles of St. Louis to be designated a Comprehensive Cancer Center by the National Cancer Institute (NCI). Siteman – a cancer treatment, research and education institution – is also the only area member of the National Comprehensive Cancer Network, a nonprofit alliance of 21 cancer centers dedicated to improving the quality and effectiveness of cancer care.

In 2011, Siteman treated more than 8,500 newly diagnosed cancer patients and every year provides continuing care to about 40,000 people, making it one of the largest cancer centers in the United States. Scientists and physicians affiliated with Siteman hold more than \$160 million in cancer research and related training grants. The results of basic laboratory research are rapidly incorporated into treatment advances. This process is enhanced by patient access to more than 240 therapeutic clinical studies, including many collaborative efforts with other leading cancer centers throughout the country.

Siteman excels in prevention and cancer control, developmental therapeutics, nanotechnology and molecular imaging. It also has a world-renowned genome center, The Genome Institute, which is one of three NIH funded large-scale sequencing centers in the United States. The institute center creates, tests and implements new approaches to the study of genomics to better understand human health and disease, and the evolution and biology of other organisms.

Washington University's affiliate network includes three active affiliates: St. Anthony's Medical Center, St. Luke's Hospital and Quincy Medical Group.

"We enrolled the highest number of patients to Alliance lymphoma, GI and respiratory protocols, and across all CTSU protocols," said Nancy T. Bartlett, MD, Alliance Principal Investigator at Washington University. "Our institution has been praised for the high quality of our work and audits. In addition, our institution's investigators actively participate in the scientific committees of the Alliance."

Nearly 20 Washington University faculty members serve on Alliance scientific and modality committees, including three of which serve as committee vice chairs.



*Anderson*

## **Metro-Minnesota Community Clinical Oncology Program (MMCCOP)**

Principal Investigator – Daniel Anderson, MD

The Metro-Minnesota Community Clinical Oncology Program (MMCCOP) is a consortium of hospitals and clinics that bring the advantages of cancer research to the community.

MMCCOP is a nonprofit research program sponsored by the National Cancer Institute (NCI) and participating hospitals and clinics. The program provides individuals within the community access to the newest therapies available for cancer treatment, management of treatment side effects and disease symptoms, and cancer prevention. Combined, MMCCOP consortium members see approximately 16,000 new cancer patients per year.

Currently, the MMCCOP represents 21 hospitals and clinics in Minneapolis-Saint Paul and the surrounding suburbs, as well as Stillwater, Hutchinson, Willmar, New Ulm and New Richmond, Wisconsin. More than 160 physician-investigators participate, representing medical oncology, radiation oncology, surgical oncology, neurosurgery, thoracic surgery, gynecologic oncology and pulmonology. All member sites are affiliated with the Institutional Review Board for the Community Oncology Programs, administered by Park Nicollet Institute, which facilitates centralized review and oversight of all studies conducted by the MMCCOP consortium.

The MMCCOP consortium represents an established community program that began in 1979 through a NCI-funded Community Hospital Cancer Program (CHCP) Award. In 1983, MMCCOP received one of the initial Community Clinical Oncology Program grant awards and have been funded by CCOP grant funding since then.

“Our program has consistently achieved or succeeded the accrual goals to cooperative group trials for the past 31 years as required by our NCI grant,” said Daniel Anderson, MD, Alliance Principal Investigator at Metro-Minnesota Community Clinical Oncology Program.

MMCCOP is currently to the highest accruing CCOP within the Alliance.

# Alliance Members on the Move



*Brown*



*Williams*

Egbert C. (Bert) Brown, recently joined the Alliance Patient Advocate Committee. Mr. Brown is an experienced mentor, coach and leader in cancer programs such as the U.S. Department of Defense Prostate Cancer Research Program; active in nonprofit cancer organizations, and works as a business consultant. A prostate cancer survivor since September 1997, he is an inaugural member of the CADRE Project of The Prostate Net, Prostate Cancer Patient Outreach and Research Advocate, and an affiliate member of the American Association for Cancer Research (AACR). Mr.

Brown will serve on the Alliance GU Committee, replacing **COL (Ret) James E. Williams, Jr.**, a dedicated advocate for many years and Chair of the Pennsylvania Prostate Cancer Coalition (PPCC).



*Sequist*

The Massachusetts General Cancer Center in Boston has named **Lecia V. Sequist, MD, MPH**, the first incumbent of the newly established Mary B. Saltonstall Endowed Chair in Oncology. Dr. Sequist, Associate Professor, Department of Medicine, Harvard Medical School, and Assistant Physician, Medicine, Massachusetts General Hospital, works to bring novel treatments for lung cancer to the clinic and to define methods of tailoring therapeutic recommendations to individual patients with lung cancer.



*Schilsky*

**Richard L. Schilsky, MD, FACP, FASCO**, ASCO's Chief Medical Officer, has been elected to the Board of Directors of the Reagan-Udall Foundation for the Food and Drug Administration (FDA), a not-for-profit organization created by Congress to advance the mission of the FDA by advancing regulatory science and research. Dr. Schilsky is a member of the Alliance Board of Directors.

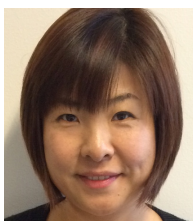


*O'Neil*

**Bert H. O'Neil, MD**, has been named the inaugural Joseph W. and Jackie J. Cusick Professor of Oncology at the Indiana University School of Medicine. Dr O'Neil, Professor of Medicine and Director of Gastrointestinal Cancer Research Program and Phase I clinical trials programs at IU, Gastrointestinal Cancer Research Program and Phase I clinical trials programs at IU, has expertise in gastrointestinal cancers, with a concentration on pancreas, colorectal, and hepatocellular carcinomas.

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## Alliance Welcomes New TRP Ops Director



*Wen*

**Yujia Wen, MD, PhD**, recently joined the Alliance as Director of Translational Research Operations. Dr. Wen was previously a Postdoctoral Fellow/Scholar at the University of Chicago where she acquired vast knowledge and skills of biomarkers, early clinical trials, regulatory affairs, pharmacogenomics, next generation sequencing, cancer biology and statistical data analyses. In her current role, Dr. Wen oversees and directs Alliance translational research related protocol development and execution under the Central Protocol Operations Office and Translational Research Program.



## Alliance Launches Online Training Program for Members

The Alliance for Clinical Trials in Oncology is committed to providing its members with education and training to enhance and support clinical research studies. Over the past year, the Alliance identified training needs, developed content for new courses, and deployed a learning management system. The Alliance proudly announces the launch of its new **Online Training** program. Online Training is self-paced, and will guide Alliance members through role-specific responsibilities and Alliance policies and procedures.

For site staff, courses are available for Audit Preparation, Informed Consent, and Institutional Review Boards. A general overview of Resources for Clinical Research Professionals is also available. What's more, the Cancer in the Elderly Committee created a training course on how to administer the Geriatric Assessment, which is used in some Alliance protocols (currently A041202).

For study chairs, courses are intended to enhance the understanding of roles and responsibilities as they navigate clinical trials from concept development through manuscript publication. With input from all five Alliance programs, these courses include Concept Development, Protocol Development, and Study Conduct, as well as a Concept and Protocol Development course specific to correlative science. Also, the Publications Committee created the Publications Overview course.

For Alliance auditors, the Audit Committee created the Auditor Training course.

The goal of Online Training is to improve the quality and integrity of clinical trial data by enhancing the skills and abilities of those involved in research and data collection. Activity for most courses is tracked, and if needed, users can print documentation of course completion. Additional training topics are being considered.

Alliance members are encouraged to access Online Training, located under the *Education & Training* menu on the Alliance member website, and download the Online Training User Guide.

**Link to training site:** <https://www.allianceforclinicaltrialsinoncology.org/main/member/standard.xhtml?path=%2FMember%2FOnline-Training>

**For more information.** Questions and comments can be e-mailed directly to the Online Training mailbox at [training@allianceNCTN.org](mailto:training@allianceNCTN.org).

## Alliance Website Survey . . .

### The Alliance wants your feedback!

The Alliance for Clinical Trials in Oncology launched its inaugural website more than one year ago. Now, it's time to re-assess and evaluate it. The goal is to ensure that the website is meeting the needs of its users, especially Alliance members.

The Alliance Web Team has developed a brief survey to help determine what's working and what can be improved. So, please take a few minutes to complete the website survey and provide some valuable feedback. All comments are welcome and will be important to enhancing the overall usability and functionality of the website.

Here's the link: <https://www.surveymonkey.com/s/AllianceWebsite>

Be sure to include your name, institution and e-mail address at the end of the survey to be eligible to receive a \$25 Amazon gift card. Four names will be selected and announced at the 2014 Alliance Group Meeting Plenary Session Friday, May 9, 1pm - 3pm, at the InterContinental Chicago O'Hare. *(Those selected need not be present.)*

## Revised CTMB Guidelines, New Accountability of NCI-Supplied Oral Agents

The NCI Cancer Therapy Evaluation Program's Clinical Trials Monitoring Branch (CTMB) recently updated its guidelines. The new guidelines can be accessed online at [http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring\\_coop\\_ccop\\_ctsu.htm](http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring_coop_ccop_ctsu.htm).

It is important to note that special attention should be directed to section 5.3 Review of Accountability of Investigational Agents and Pharmacy Operations. In addition, the Pharmaceutical Management Branch of the NCI has required the use of the new NCI Investigational Agent Accountability Record for Oral Agents (Oral DARF).

In summary, the new guidelines for the Oral DARF state:

- Agent disposition (receipt, dispensing, transfer, return or authorized local destruction of un- dispensed agent) of NCI-supplied oral agent formulations must be documented on the new NCI Oral DARF. Accountability of all other agent formulations will continue to be maintained on the current version of the original NCI Investigational Agent (Drug) Accountability Record (DARF).
- For existing studies, sites have the option to start a new page of the accountability record using the Oral DARF, or may continue to use the existing original DARF until all lines of the page have been completed. When a new page number is started, the Oral DARF must be implemented.
- Patient returns of dispensed oral agents should be documented on the Oral DARF only if dispensing was documented on the Oral DARF. A FAQ regarding this can be found at "Patient Returns of Oral Clinical Supplies" for guidance on patient return documentation at <http://ctep.cancer.gov/branches/pmb/faq.htm>

The policy and a copy of the new NCI Investigational Agent Accountability Record for Oral Agents (Oral DARF) may be obtained at [http://ctep.cancer.gov/protocolDevelopment/requisition\\_agents/docs/oral\\_agent\\_accountability\\_policy.pdf](http://ctep.cancer.gov/protocolDevelopment/requisition_agents/docs/oral_agent_accountability_policy.pdf) and [http://ctep.cancer.gov/forms/docs/oral\\_agent\\_accountability.pdf](http://ctep.cancer.gov/forms/docs/oral_agent_accountability.pdf)

**Questions or comments** regarding accountability and storage of investigational agents should be addressed to the Pharmaceutical Management Branch by phone (240) 276-6575 or e-mail [PMBAfterhours@mail.nih.gov](mailto:PMBAfterhours@mail.nih.gov).

## 2014 Alliance Meeting Abstracts

Abstract submission deadlines for the following meetings are approaching. All drafts from Alliance for Clinical Trials in Oncology (including all three legacy groups: ACOSOG, CALGB and NCCTG) must be submitted by the date indicated in the table below to [Publications@AllianceNCTN.org](mailto:Publications@AllianceNCTN.org).

- **May 21** American Society of Human Genetics (October 18-22, San Diego, CA)
- **May 21** Society of Neuro-Oncology (November 13-16, Miami, FL)
- **May 22** ASCO Breast Cancer Symposium (September 4-6, San Francisco, CA)
- **May 22** San Antonio Breast Cancer Symposium (December 9-13, San Antonio, TX)

**Questions:** If you have questions about the abstract review process, contact the publications coordinator at [Publications@AllianceNCTN.org](mailto:Publications@AllianceNCTN.org).

## 2014 Richard L. Schilsky Cancer and Leukemia Group B Achievement Award

The Richard L. Schilsky Cancer and Leukemia Group B Achievement Award was established in 2010 to recognize the 15-year tenure of Dr. Schilsky as Group Chair of CALGB. The award acknowledges the significant contributions of an individual to cooperative group research. As an organization, it is vital for the Alliance to identify and honor the talented people responsible for its success. The award was made possible through generous donations from our members and industry supporters. The award will be presented each year during the Plenary Session of the Alliance Group Meeting.

All Alliance members are welcome to submit nominations for this award.

**2014 Nominations:** The deadline for nominations is June 2, 2014. Please submit a letter via e-mail that describes the contributions of the nominee to:

**Denise Collins-Brennan**

Treasurer, Alliance for Clinical Trials in Oncology Foundation  
Dcollinsbrennan@partners.org

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## 2015 Alliance Scholar Award

Applications are currently being accepted for the **Alliance for Clinical Trials in Oncology Foundation 2015 Alliance Scholar Award**.

Applications must be submitted by midnight CST July 2, 2014.

Application requirements and the link to the online submission portal can be found on the Foundation page of the Alliance website (under Awards) at [AllianceforClinicalTrialsinOncology.org](http://AllianceforClinicalTrialsinOncology.org)

**Alliance Scholar applicants** must be oncology junior faculty at Alliance institutions and within five years of training (rank below Associate Professor), and have completed training in an oncology clinical specialty (e.g., medical, surgical, radiation, gynecologic, etc.). Additionally, proposals must include a letter of support from the appropriate Alliance Scientific Committee Chair to ensure the proposal is closely tied to the research agenda of the Alliance.

Alliance Scholar awardees will receive a two-year, non-renewable cancer research grant of \$40,000 direct costs per year, plus 10 percent overhead each year for two years. Successful applicants will be announced at the 2014 Alliance Fall Group Meeting, held in Chicago November 5-8, 2014. Funding will begin approximately January 1, 2015.

A Scientific Review Committee, co-chaired by **Drs. Richard Goldberg** and **W. Fraser Symmans**, will review applications and select the award recipients.

## 2014 Meeting Dates

### Spring Group Meeting

May 7-10



### Fall Group Meeting

November 5-8

Registration for the May meeting is still open to Alliance members. Visit the Alliance website at [AllianceforClinicalTrialsinOncology.org](http://AllianceforClinicalTrialsinOncology.org)

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](mailto:alewandowski@partners.org)  
phone: 617-525-3022

For more information on the Alliance and updates about meetings, visit [AllianceforClinicalTrialsinOncology.org](http://AllianceforClinicalTrialsinOncology.org)