Alliance for Clinical Trials in Oncology

NEWS

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MESSAGE FROM THE GROUP CHAIR

Monica M. Bertagnolli, MD

Alliance members have faced many challenges during the three years since the release of the Institute of Medicine consensus report, which was entitled "A National Clinical Trials System for the 21st Century." This document provided a road map for improving the quality and effectiveness of federally funded cancer clinical research. Among other changes, the report led to mergers of former cooperative groups, consolidating a diverse NCI-funded infrastructure. The Alliance is a product of this merger process. Retaining the mission of our legacy groups, the Alliance is committed to discovering, validating and disseminating effective strategies for the prevention and treatment of cancer. Our members accomplish this mission by uniting a broad community of scientists and clinicians from many disciplines to conduct multidisciplinary cancer clinical trials through our comprehensive research network. In this successful scientific and operational merger of three established cooperative groups, the Alliance demonstrates an extraordinary capability to unite for the common good. We are justifiably proud of this accomplishment, which required each of us to adapt, sometimes painfully, to new faces, revised governing structures and different operating procedures.

On March 1, 2014, the former cancer cooperative groups were formally replaced by a new NCI-funded research infrastructure known as the National Clinical Trials Network (NCTN). The current portfolio of Alliance trials, approved to move into the new structure by the NCI, includes molecularly driven evaluations of targeted agents, new imaging modalities, and studies directed towards FDA registration that are being performed jointly by the NCI, NCTN and industry. In addition to these ongoing trials, the NCTN is ready to launch exciting new studies that direct treatments to patients whose individual tumor characteristics indicate that they will achieve the best anti-cancer response. This complex new type of clinical research, often referred to as "precision medicine" research, requires a broad-based, sophisticated clinical trials enterprise. The Alliance and our NCTN partners are ideally positioned to achieve the goals of this new research.

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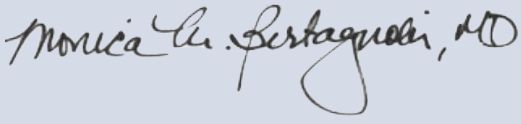
Unfortunately, the Alliance and our NCTN partners are facing significant new challenges. NCI funding has been decreased as a result of the Congressionally mandated sequester, and a promised $25 million in funding to increase per-case reimbursements at select NCTN institutions did not materialize. In response to this, the maximal number of patients planned for enrollment in 2014 is 17,000, representing a 42 percent reduction from peak enrollment in 2009. This level of support is in the context of greater than 1.4 million persons being diagnosed with cancer in the United States each year, affecting their lives and those of their loved ones. In addition, NCTN group operations budgets, which cover funding for protocol management, biostatistics and data management, biorepository operations, study auditing, regulatory affairs, institutional member management, training for study personnel, and publications, are to be reduced a further 25 to 40 percent. This level of funding unfortunately places NCTN researchers in the difficult position of deciding between completing currently ongoing studies or opening new trials that hold significant promise for progress in the fight against cancer. Finally, a downsizing in research scope is also about to be felt by our member institutions, as not all of the former CCOPs will move forward into the NCI Community Oncology Research Program (NCORP). These research centers must transition to a non-CCOP membership, consolidate with other NCTN institutional members, or stop participating in federally funded trials.

Despite the current challenges, the dedication of Alliance researchers to our mission is undiminished. Attendance at the May 2014 Alliance Spring Group Meeting was high, and although our members expressed widespread concern over changing NCI policies and reduced resources, there was no lack of ideas or enthusiasm for the innovative practice-changing research arising from Alliance scientific committees. In addition, the Membership, Advocates, and Community Oncology committees were working productively to optimize participation of researchers and patients in NCTN trials. Finally, the Alliance for Clinical Trials in Oncology Foundation Board of Trustees and Officers announced plans to significantly expand non-NCI support for publicly funded cancer clinical trials, and to execute high priority investigator-initiated trials solely funded by industry sponsors.

This year's ASCO Annual Meeting in Chicago highlighted research conducted by the U.S. cooperative groups, with four major plenary session presentations. Patients, clinicians, and scientists throughout the field on oncology have weighed in with their support for NCI-funded clinical research, and emphasized the value of the NCTN to our society. It is clear that both fiscal constraints and the NCI's implementation strategy for the new NCTN require yet another round of creative adaptation by our members. It is also clear that our members are capable of continuing to achieve great successes for our patients. The Alliance will respond to current challenges in the same way that we handled the group merger – by focusing on our core mission to eliminate suffering from cancer and by forming new partnerships to achieve our research aims.



Spotlight On: Alliance Central Protocol Operations

The **Alliance Central Protocol Operations Program (CPOP)** oversees the development, maintenance and distribution of all study protocols that are generated by Alliance scientific committees. Program staff manages the complex process of study protocol development, which involves the committee chair, statistician, data coordinator, chairs of other involved disease and modality committees, other investigators contributing scientific resources, and patient advocates. The CPOP also represents the interest of the Alliance in protocol-related negotiations with the National Cancer Institute, pharmaceutical companies, other cooperative groups and the general public.

Specifically, CPOP staff is responsible for assisting the study chairs with development and conduct of National Cancer Institute-sponsored trials, including both Cancer Therapy Evaluation Program (CTEP) and Division of Cancer Prevention (DCP) sponsored studies. This includes:

- Managing the concept review process including data sharing agreements
- Developing and maintaining the protocol document
- Submitting concept and then protocol to NCI, coordinating replies to NCI comments, keeping track of NCI Operational Efficiency Working Group (OEWG) timelines
- Submission of protocol to the Central IRB (CIRB), responding to CIRB comments and submitting annual CIRB renewals
- Developing protocol budgets e.g., for items on a protocol not covered by standard per-patient payments--such as costs for required molecular screening tests, and coordinating funding requests to cover those items to NCI [Biomarker, Imaging and Quality of Life Studies Funding Program (BIQSFP) funding applications], industry partners, or charitable foundations, and preparing protocol budget sheets for posting
- Coordinating logistics of drug procurement and distribution when agent is not supplied by NCI, including determination if an IND is needed and coordinating IND applications and annual reports and other regulatory affairs tasks
- Coordinating other protocol logistics including imaging review requirements, close collaboration with Alliance Translational Research Program (TRP) for scientific review and logistic coordination of translational protocol components such as blood specimens and tumor biopsy collections
- Protocol amendments, including implementation of recommendations by the Alliance Data and Safety Management Board (DSMB)
- Pharmacovigilance; determining reporting requirements for each protocol, reviewing safety reports and determining if change to conduct of studies is needed

BY THE NUMBERS

There are currently 228 managed NCI-sponsored Alliance studies.

- 60 studies open to enrollment
- 68 studies closed to accrual, treatment continues
- 100 studies closed to accrual, treatment completed, not yet terminated

The work of the CPOP staff is multi-faceted. Staff:

- Prepare more than 100 amendments annually
- Manage 18 active investigational new drug applications (INDs)
- Have worked with Alliance Foundation on 60 current industry agreements to provide supplemental study support
- 12 new industry agreements in 2013
- 12 active Breast Cancer Research Foundation (BCRF) awards
- 9 approved Biomarker, Imaging and Quality of Life Studies Funding Program (BIQSFP) applications since 2012

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PROTOCOL FAQs

Where do I go for questions about a protocol?

Every protocol has a list of contacts on the cover sheet with suggestions as to whom to call for what type of issue. However if you cannot figure it out and/or cannot reach the study chair, the protocol coordinator can generally point you in the right direction.

What is new in the Protocol Operations Program?

The Executive Officers (EOs) have always worked to ensure that required tests for protocols are (1) kept to what is truly essential and (2) are standard of care (unless additional funding for them is available). However with the ever-increasing complexity of the medical care landscape, the Alliance has begun working with Lisa Pitler, JD, Medicare Payment Review Specialist, for review of protocols. For three "test" protocols, her analyses will be posted on the Alliance website along with the protocols. Feedback on whether this is helpful is welcomed.

- Monthly protocol postings, including activations, closures, amendments, and Adverse Event Reports. As a result of many hours work by staff, all NCI-sponsored Alliance studies open to enrollment, including legacy ACOSOG, CALGB, and NCCTG trials, are now available on the Alliance Web site. Legacy trials that are still active but closed to enrollment are being migrated.
- Assisting study chairs with accrual issues and responses to NCI requests for accrual action plans
- Coordinating international collaborations

Central Protocol Operations Program Staff

The CPOP staff include the program PI/director, protocol operations director and associate director, executive officers, clinical trials managers (who train and supervise protocol coordinators in addition to their own protocol work), senior protocol coordinators, protocol coordinators, and protocol information specialist. Although there is flexibility in assignments as work needs dictate, protocol coordinators are primarily assigned to specific committees to help them develop expertise in the area and develop relationships with members of the committees.

Staff work closely with other Alliance programs and teams, including the regulatory and audit groups, membership, financial, biorepositories, the Alliance Statistics and Data Center and the Foundation.

Gini F. Fleming, MD, Program Director and Principal Investigator, is responsible for the oversight of the program. She is an expert in breast and gynecological cancers and is based at the University of Chicago, where she is also Professor of Medicine; Director, Medical Oncology Breast Program; and Medical Oncology Director, Gynecologic Oncology.

Michael Kelly, MA, Director of Protocol Operations, is the perennial keeper of much of the Alliance protocol office corporate knowledge. He was one of the first staff members hired when the CALGB protocol office moved to Chicago in 1995. As a protocol editor, he has worked with the AIDS Malignancy Working Group, along with Cancer in the Elderly, GI, GU, Leukemia, Leukemia Correlative Science (LCSC), Lymphoma, and Melanoma Committees.

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CENTRAL PROTOCOL OPERATIONS continued

Morgen Alexander-Young, MPH, Associate Director of Protocol Operations, serves as a resource to protocol coordinators and as a point of contact for study funding and general protocol questions. She develops study funding sheets, tracks study development, coordinates data sharing requests, and maintains and updates protocol development materials.


Fleming


Kelly


Alexander-Young

Colleen Watt, Senior Protocol Coordinator, has been with the CALGB (Alliance) since 1995. She was also one of the first staff members hired when the CALGB protocol office moved to Chicago in 1995. She works with the Alliance Respiratory Committee.


Watt


Taylor

John R. Taylor, MA, Clinical Trials Manager, started with CALGB (Alliance) in 1997. He was also part of the first protocol team hired when the CALGB protocol office moved to Chicago. He works with the Alliance Cancer Control Program and its committees.

Heather P. Becker, Senior Protocol Coordinator, has worked with the CALGB (Alliance) since 2000, She works with the Breast Committee.


Becker


Garbacz

Krista Garbacz, Protocol Specialist, started as summer staff back in 1997. She was hired full time in 2000 and ensures that all protocol documents are up-to-date and correct for the monthly posting.

Guadalupe V. Aquino, Protocol Coordinator, joined the protocol operations team in 2011. She works with Myeloma and Lymphoma committees.


Aquino


Farrell

Aimee Farrell, Protocol Coordinator, became part of the Alliance team in 2011. She works primarily with the Experimental Therapeutics Committee.

Vance N. Erese, Protocol Coordinator, joined the Alliance protocol team in 2013. He works with GI Committee.


Erese


Sublett

Samantha Sublett, Protocol Coordinator, joined the Alliance protocol team in 2013. She works with the Leukemia Committee.

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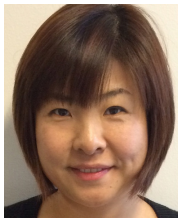
Thomas


Robles

Kimberly K. Thomas, MSc, Protocol Coordinator, joined the Alliance protocol team in 2013. She works with Symptom Intervention and Cancer in the Elderly Committees within the Cancer Control Program.

Tamara Robles, MBA, Protocol Coordinator, joined the Alliance protocol team in 2013. She works with the Neuro-Oncology Committee.


Wen


Tetzlaff

Yujia Wen MD, PhD, Director of Translational Research, joined the Alliance this year and shares responsibilities between the protocol operations and the Translational Research Program (TRP).

Executive Officers

The Executive Officers (EOs) are MDs or PhDs. EOs typically work part-time for the Alliance and have clinical and research responsibilities at their home institutions. They provide high-level medical oversight for protocol development.


Reiter


Horvath

Michael Tetzlaff, MD, PhD, will start his new role as the Executive Officer of the Alliance Translational Research Program (TRP) later this summer. He is Assistant Professor in the Department of Pathology at the University of Texas MD Anderson Cancer Center


Hahn


Smith

Paul L. Reiter, PhD, MPH, Executive Officer of the Alliance Cancer Control Program, has research interests in cancer screening and vaccination. He is Assistant Professor in the College of Medicine at The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute and works with Electra D. Paskett, PhD, Chair of the Alliance Health Disparities Committee.

Elise Horvath, MD, Executive Officer, covers the Neuro-Oncology, Experimental Therapeutics, and GI Committees. She is also responsible for pharmacovigilence and drug distribution, and the clinical portion of pharmaceutical affairs and regulatory.

Olwen M. Hahn, MD, Executive Officer, is responsible for the Breast, GU and Respiratory Committees. She is Assistant Professor of Medicine at the University of Chicago and specializes in the diagnosis and treatment of breast cancer, as well as Assistant Director for the Chicago Fellows Program.

Scott E. Smith, MD, PhD, Executive Officer, covers the Leukemia, Lymphoma, Myeloma, and Transplant Committees. He is Associate Professor of Hematology and Oncology and Director of Hematologic Malignancies Research Program at Loyola University where his specialties include leukemia, non-Hodgkin lymphoma, refractory lymphoma, relapsed lymphoma and bone marrow disorders.

Alliance Study Focuses on Targeted Therapy in Patients with Metastatic Renal Cell Cancer

Alliance A031203 Randomized Phase II Study Comparing Cabozantinib (NSC #761968 and IND #116059) with Commercially Supplied Sunitinib in Patients with Previously Untreated Metastatic Renal Cell Carcinoma

More than 60,000 patients will develop renal cell carcinoma (RCC) in the United States each year, approximately 20 to 30 percent will present with metastatic disease and a significant number of patients with localized disease (20 to 40 percent) will experience systemic recurrence.[1]

Treatment options have improved in recent years, with the availability of targeted therapies. Current first-line therapies include several options with the vast majority of patients receiving treatment with a vascular endothelial growth factor (VEGF)-targeted tyrosine kinase inhibitor (TKI) such as sunitinib. VEGF-targeted therapy has proven to be a successful strategy in RCC since most patients with clear cell RCC carry alterations in the von Hippel-Lindau (VHL) tumor suppressor gene.[2] Loss of VHL function leads to increases in hypoxia-inducible factor (HIF) levels, which in turn lead to increases in HIF-regulated genes, including VEGF.

In large randomized clinical trials, the use of VEGF-targeted therapies including sunitinib, sorafenib, bevacizumab, and pazopanib has resulted in marked gains in progression free survival, and trends towards improvements in overall survival.[3] However, patients treated with these agents generally have disease progression within six to 11 months and more potent VEGF inhibitors are needed.[4] Furthermore, mechanisms of resistance to VEGF-targeted therapies are under active investigation.[5]

Cabozantinib is a potent inhibitor of VEGFR2 and compares favorably with two FDA-approved front-line VEGF TKIs: sunitinib and pazopanib. In addition, cabozantinib is a potent inhibitor of MET, which also plays an important role in RCC.[6]

A031203 is a randomized phase II trial that will study how well cabozantinib-s-malate works compared to sunitinib malate in treating patients with previously untreated kidney cancer that has spread to nearby areas of the body. Cabozantinib-s-malate and sunitinib malate may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. Both medications target special proteins that are on the surface of the kidney cancer cell and both drugs are taken by mouth. It is not yet known whether cabozantinib-s-malate or sunitinib malate is more effective in treating patients with kidney cancer.

About 150 people will take part in this study. Eligible patients include those with locally advanced (defined as disease not amenable to curative surgery or radiation therapy) or metastatic renal cell carcinoma (RCC) (equivalent to stage IV RCC); must be intermediate/poor risk; have no radiographic evidence of cavitating pulmonary lesions, no tumor in contact with, invading or encasing any major blood vessels; have no evidence of tumor invading the gastrointestinal tract, or any evidence of endotracheal or endobronchial tumor within 28 days prior to registration; and have no prior systemic treatment for RCC (supportive therapies such as bisphosphonates: zoledronic acid or denosumab are permitted).

The primary study objective is to determine if patients with renal cancer treated with cabozantinib (cabozantinib-s-malate) will have improved progression-free survival compared to patients treated with sunitinib (sunitinib malate). Secondary objectives are to determine whether the response rate of patients with renal cancer treated with cabozantinib will be higher when compared with patients treated with sunitinib, and whether patients with renal cancer treated with cabozantinib will have an improved overall survival when compared with patients treated with sunitinib. In addition, the study will determine whether renal cancer patients with high met proto-oncogene (MET) expression by immunohistochemistry (IHC) have improvement in progression-free survival compared to patients with low MET expression on both arms of this study.

Refer to the study protocol (Alliance A031203), which can be found on the Alliance website (www.AllianceforClinicalTrialsinOncology.org) for complete information on the trial design, treatment plan and patient eligibility. The Alliance Study Chair is Toni K. Choueiri, MD, Dana Farber Cancer Institute, e-mail: toni_choueiri@dfci.harvard.edu.

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Alliance Investigators Study Effects of Pazopanib in Patients with Carcinoid Tumors

Alliance A021202 Prospective Randomized Phase II Trial of Pazopanib (NSC # 737754, IND 75648) Versus Placebo in Patients with Progressive Carcinoid Tumors

Carcinoid tumors are relatively indolent, but treatment of advanced disease remains a challenge. Somatostatin analogs are routinely used to control hormone-mediated symptoms (carcinoid syndrome), but the identification of agents with anti-tumor efficacy has proven difficult.[1,2] Aside from octreotide for small bowel carcinoid, no treatment has proven anti-tumor activity.[3] In the setting of liver-dominant disease, liver-directed treatment such as resection, ablation, and embolization are often employed. No standard chemotherapy exists, and the use of interferon is controversial. New treatments are desperately needed for patients with progressive disease.

Advances in understanding the potential mechanisms underlying tumor progression have suggested several therapeutic targets including the vascular endothelial growth factor (VEGF)- and mTOR signaling pathways, but the precise role of targeted agents in carcinoid has not been established. (In contrast, everolimus and sunitinib are approved by the FDA for the treatment of patients with pancreatic neuroendocrine tumors (NET)). Progress in the field has been hampered by several factors, including the rarity of the disease, the heterogeneity that characterizes patients with the same diagnosis, and challenges related to interpreting the radiological response to treatment.

Pazopanib is an oral multi-targeted receptor tyrosine kinase inhibitor with activity against vascular endothelial growth factor receptor (VEGFR) -2, and -3, PDGFR-alpha and beta, and stem cell factor receptor (c-KIT).[4-5] It is a promising agent for treatment of metastatic carcinoid tumors because its spectrum of kinase inhibition matches receptor expression in carcinoid and other NETs.[6-8] VEGF is upregulated in primary tumors, and in some studies expression correlates with angiogenesis and decreased progression-free survival.[9]

In the randomized phase II trial A021202, Alliance researchers will study how well pazopanib hydrochloride works in treating patients with progressive carcinoid tumors. Pazopanib hydrochloride may stop the growth of tumor cells by blocking VEGF signaling and tumor-associated angiogenesis. It is hypothesized that the use of pazopanib will result in prolonged disease stability among patients with progressive advanced carcinoid tumors – activity that will be clinically meaningful. The drug has been approved by the FDA for the treatment of kidney cancer and advanced soft tissue sarcoma.

About 165 people will take part in this study. Eligible patients include those with locally unresectable or metastatic carcinoid tumors; histologic documentation or clinical evidence of a carcinoid tumor of primary site; radiological evidence for progressive disease (measureable or non-measurable) within 12 months prior to registration; no known endobronchial lesions and/or lesions infiltrating major pulmonary vessels that increase the risk of pulmonary hemorrhage; measurable disease per RECIST 1.1 by computed tomography (CT) scan or magnetic resonance imaging (MRI); lesions must be accurately measured in at least one dimension (longest diameter to be recorded); and no prior treatment with an inhibitor of VEGF or VEGFR.

The primary objective of the study is to compare progression-free survival (PFS) between patients randomized to treatment with pazopanib versus placebo (as determined by central review). Secondary objectives are to compare overall survival (OS) between treatment arms; to compare objective response rate (ORR), duration of response, and time to treatment failure between treatment arms; and to compare overall PFS and PFS within treatment arms. Other objectives include evaluating safety and tolerability of treatment with pazopanib/placebo within treatment arms. Of note, patients originally assigned to placebo can cross-over to pazopanib at the time of progression (as determined by central review).

This study may provide support for a phase III study with pazopanib in carcinoid (e.g., pazopanib vs. placebo). Study results could lay the foundation for future trials in first-line treatment of carcinoid.

Refer to the study protocol (Alliance A021202), which can be found on the Alliance website (www.AllianceforClinicalTrialsinOncology.org) for complete information on the trial design, treatment plan and patient eligibility. The Alliance Study Chair is Emily Bergsland, MD, University of California at San Francisco Comprehensive Cancer Center, e-mail: emilyb@medicine.ucsf.edu.

Sources

1. Oberg K, Ferone D, Kaltsas G, et al: ENETS Consensus Guidelines for the Standards of Care in Neuroendocrine Tumors: biotherapy. Neuroendocrinology 90:209-13, 2009
2. Kulke MH, Anthony LB, Bushnell DL, et al: NANETS treatment guidelines: well-differentiated neuroendocrine tumors of the stomach and pancreas. Pancreas 39:735-52, 2010
3. Rinke A, Muller HH, Schade-Brittinger C, et al: Placebo-controlled, double-blind, prospective, randomized study on the effect of octreotide LAR in the control of tumor growth in patients with metastatic neuroendocrine midgut tumors: a report from the PROMID Study Group. J Clin Oncol 27:4656-63, 2009

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Alliance ASCO Abstracts from 2014 Annual Meeting

This year, more than 5,000 abstracts were submitted to the annual meeting of the American Society of Clinical Oncology (ASCO) from 70-plus countries. ASCO is one of the largest medical gatherings in the United States, drawing nearly 30,000 oncology professionals for four and a half days of scientific and educational presentations.

The Alliance for Clinical Trials in Oncology had 24 abstracts approved for inclusion, on topics ranging from breast to colon cancers to the genetics of cancer, cancer prevention, lymphoma and more. The meeting was held in Chicago, IL from May 30 through June 3.

Below is a list of Alliance abstracts, with conclusions.

Long-term cardiac safety analysis of NCCTG (Alliance) N9831 adjuvant trastuzumab (H) trial

Advani PP, Ballman KV, Dockter TJ, Colon-Otero G, Perez EA

J Clin Oncol 32 (5s), 2014 (suppl; abstr 603)

Conclusions: 6-yr cumulative incidence of cardiac events (CE) was higher by 2.8% in the H-containing arms vs control arm. We noted minimal difference in the cumulative incidence of CE beyond 3-yr (Perez, JCO 2008), suggesting that late development of CE with H is infrequent. Hence, H (in context of anthracycline and taxane-based therapy) continues to have a favorable benefit-risk ratio (5-yr absolute OS benefit: 3.5%; DFS benefit: 12.7%). Older age, lower registration LVEF and antihypertensive medication use were predictive of increased risk of cardiac dysfunction (CD) with H.

Impact of vaginal dehydroepiandosterone (DHEA) on vaginal symptoms in female cancer survivors: Trial N10C1 (Alliance)

Barton DL, Sloan JA, Shuster LT, Gill P, Bearden JD, Johnson DB, Stella PJ, Terstriep SA, Rana FN, Anderson DM, Loprinzi CL

J Clin Oncol 32 (5s), 2014 (suppl; abstr 9507)

Conclusions: These data support use of a daily vaginal moisturizer to improve vaginal atrophy symptoms. Vaginal DHEA significantly improves sexual desire, arousal, pain and overall sexual function, compared to this bioadhesive moisturizer alone.

Gene expression signatures in pre- and post-therapy (Rx) specimens from CALGB 40601 (Alliance), a neoadjuvant phase III trial of weekly paclitaxel and trastuzumab with or without lapatinib for HER2-positive breast cancer (BrCa)

Carey LA, Barry WT, Pitcher B, Hoadley KA, Cheang MCU, Anders CK, Henry NL, Tolaney SM, Dang CT, Krop IE, Harris L, Berry DA, Perou CM, Winer EP, Hudis CA

J Clin Oncol 32 (5s), 2014 (suppl; abstr 506)

Conclusions: HER2-Enriched had substantially higher pCR rates to chemotherapy + HER2-targeting than other subtypes. Residual disease was enriched for Luminal A and Normal Breast-like profiles. Among HER2-Enriched, taxane plus trastuzumab alone produced pCR rates in excess of 70%, which suggests that dual HER2-targeting or more aggressive chemotherapy may not be needed in this biologic subtype.

Alliance A091103: A multicenter phase II study of the angiopoietin-1 and -2 peptibody trebananib (AMG386) for the treatment of angiosarcoma (AS)

D'Angelo SP, Mahoney MR, Van Tine BA, Adkins D, Grosse Perdekamp MT, Condy MM, Hartley EW, Antonescu CR, Schwartz GK, Tap WD

J Clin Oncol 32 (5s), 2014 (suppl; abstr 10568)

Conclusions: Trebananib was well-tolerated in this phase II study of AS, with no partial/complete responses. Prolonged PFS was observed in 4 pts, lasting 3.5-5.5 mos. Forthcoming results of the associations of correlatives (EG, ANG/TIE2 IHC expression and serum ANG levels) with outcome may help identify patients most likely to benefit.

Quality of life (QOL) among patients (pts) with HER2+ breast cancer (bc) treated with adjuvant lapatinib and/or trastuzumab in the ALTTO study (BIG 2-06, Alliance N063D)

Dueck AC, Hillman DW, Kottschade LA, Halyard MY, Sloan JA, Flickinger LM, Wolff AC, Harris L, Gralow J, Pritchard KI, Ellard S, Le-Lindqwister N, Boyle FN, De Azambuja E, McCaskill-Stevens WJ, Zujewski JA, Piccart-Gebhart MJ, Perez EA

J Clin Oncol 32 (5s), 2014 (suppl; abstr 647)

Conclusions: While L (lapatinib) had a larger negative impact than T (trastuzumab) on diarrhea and rash, QOL did not appear to differ across arms. Patient QOL was negatively impacted similarly across arms at w12 but returned to baseline by the end of the treatment period at w52. These data enhance the understanding of QOL impact of anti-HER2 therapy in pts with early stage bc. Long term QOL collection is ongoing.

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RECAP: ALLIANCE/ASCO ABSTRACTS

Phase II trial of vorinostat (VOR) combined with temozolomide (TMZ) and radiation therapy (RT) for newly diagnosed glioblastoma (GBM) (Alliance N0874/ABTC-0902)

Galanis E, Anderson SK, Miller CR, Sarkaria JN, Jaeckle KA, Buckner JC, Ligon KL, Ballman KV, Moore DF, Ahluwalia MS, Lee EQ, Gerstner ER, Lesser GJ, Prados M, Grossman SA, Giannini C, Wen PY

J Clin Oncol 32 (5s), 2014 (suppl; abstr 2030)

Conclusions: The HDAC inhibitor VOR in combination with TMZ and RT has tolerable toxicity in newly diagnosed GBM patients. Initial analysis based on mature outcome data in 70% of the evaluable patients does not indicate an improvement in outcome; final data will be presented at the meeting. Ongoing RNA sequencing analysis of baseline tumor tissue in 80 pts will assess if a 43 gene VOR responsive signature, identified in preclinical models, can define subgroups of patients deriving benefit from treatment.

The site of visceral metastases (mets) to predict overall survival (OS) in castration-resistant prostate cancer (CRPC) patients (pts): A meta-analysis of five phase III trials

Halabi S, Kelly WK, Zhou H, Armstrong AJ, Quinn D, Fizazi K, Solomon NC, Tannock I, Petrylak DP, Morris MJ, Small EJ

J Clin Oncol 32 (5s), 2014 (suppl; abstr 5002)

Conclusions: As anticipated, CRPC patients with liver mets had the worst OS (12.1 m). While pts with lung mets had better OS (16.5 months) compared to liver mets pts, they had significantly worse survival than pts with non-visceral bone mets (20 months). These data may help in treatment decisions and in the design of future clinical trials in mCRPC pts.

Randomized phase II trial of capecitabine and lapatinib with or without cixutumumab in patients with HER2+ breast cancer previously treated with trastuzumab and an anthracycline and/or a taxane: NCCTG N0733 (Alliance)

Haluska P, Bernath AM, Ballman KV, Dueck AC, Linden HM, Goetz MP, Northfelt DW, Hou X, Tenner KS, Tienchaiananda P, Flickinger LM, Chen B, Chen HX, Lingle WL, Pellegrino CM, Sponzo RW, Reinholz MM, Perez EA

J Clin Oncol 32 (5s), 2014 (suppl; abstr 632)

Conclusions: CIX (cixutumumab) is reasonably tolerated in combination with cape/lap following a dose reduction, but does not improve PFS in unselected pts with HER2+ mbc. IGFBP5 may be an important determinant of benefit from IGF targeted therapy and warrants further investigation.

Prognostic and predictive blood-based biomarkers of overall survival (OS) in patients (pts) with advanced colorectal cancer (CRC) treated with cetuximab (C): Results from CALGB 80203 (Alliance)

Hatch AJ, Pang H, Starr MD, Brady JC, Jia J Jiang C, Sibley A, Owzar K, Niedzwiecki D, Venook AP, Cushman SM, Hurwitz H, Nixon AB

J Clin Oncol 32 (5s), 2014 (suppl; abstr 11022)

Conclusions: Blood-based profiling of EGFR axis members identified sHER3 and EGF as candidate predictors for benefit from C. These data are consistent with our findings using mRNA expression from archived tumor samples and suggest a role for receptor shedding in HER3 biology. If further validated, these markers may help guide the development and use of anti-EGFR therapies and combination regimens.

A genome-wide association study (GWAS) of docetaxel-induced neutropenia in CALGB 90401/60404 (Alliance)

Hertz DL, Jiang C, Owzar K, Halabi S, Kelly WK, Mulkey F, Patel JN, Carducci MA, Kelley MJ, Stadler WM, Mohamed MK, Morris MJ, Nakamura Y, Zembutsu H, Ratain MJ, McLeod HL

J Clin Oncol 32 (5s), 2014 (suppl; abstr 9612)

Conclusions: GWAS in a prospectively enrolled mCRPC patient cohort identified SNPs that may influence risk of docetaxel-induced neutropenia, adjusted for bevacizumab treatment. Replication in independent cohorts of docetaxel treated patients is necessary to verify the influence of these SNPs on neutropenia risk.

Feasibility of geriatric assessment for older adults with acute myeloid leukemia (AML) receiving intensive chemotherapy on a cooperative group trial: CALGB 361006 (Alliance)

Klepin HD, Ritchie EK, Sanford BL, Marcucci G, Zhao W, Geyer SM, Ballman KV, Powell BL, Baer MR, Stock W, Cohen HJ, Stone RM, Larson RA, Uy GL

J Clin Oncol 32 (5s), 2014 (suppl; abstr 7102)

Conclusions: Recruitment to and implementation of a primarily self-administered GA (geriatric assessment) is feasible prior to intensive induction for older adults with AML in the multi-site cooperative group setting. Next steps will explore the predictive utility of GA on toxicity.

Prognostic and predictive tumor-based biomarkers in patients (pts) with advanced renal cell carcinoma (RCC) treated with interferon alpha (IFN) with or without bevacizumab (Bev): Results from CALGB (Alliance) 90206

Kluger HM, Halabi S, Solomon NC, Jilaveanu L, Zito C, Sznol J, Nixon AB, Rini BI, Small EJ, George DJ

J Clin Oncol 32 (5s), 2014 (suppl; abstr 4532)

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Conclusions: Expression of HGF in pre-treatment

specimens was prognostic for PFS in RCC patients and IL-6 was predictive of PFS in Bev treated patients, consistent with our findings in plasma. If validated, these data suggest that IL-6 may help guide use of anti-VEGF based therapies.

CALGB 50803 (Alliance): A phase II trial of lenalidomide plus rituximab in patients with previously untreated follicular lymphoma

Martin P, Jung SH, Johnson JL, Pitcher B, Elstrom RL, Bartlett N, Blum KA, Richards KL, Leonard J, Cheson *BD*

J Clin Oncol 32 (5s), 2014 (suppl; abstr 8521)

Conclusions: Lenalidomide plus rituximab was well tolerated and effective in pts with untreated FL. These data are similar to those reported with chemotherapy-based therapy and support evaluation of this regimen in randomized trials.

Randomized phase II pilot study of loratadine for the prevention of bone pain caused by pegfilgrastim

Moukharskaya J, Abrams DM, Khan FB, Schwartz J, Ades S, Ashikaga T, Openshaw TH, Verschraegen CF, Grunberg SM

J Clin Oncol 32 (5s), 2014 (suppl; abstr 9628)

Conclusions: Administration of prophylactic loratadine does not decrease the incidence of significant PIP.

Clinical course of patients with oxaliplatin-associated neuropathy: N08CB (Alliance)

Pachman DR, Qin R, Seisler DK, Smith EML, Beutler AS, Ta LE, Lafky JM, Wagner-Johnston N, Ruddy KJ, Dakhil SR, Grothey A, Loprinzi CL

J Clin Oncol 32 (5s), 2014 (suppl; abstr 3595)

Conclusions: Acute oxaliplatin-associated neuropathy Sxs (symptoms) do not completely resolve between treatment cycles and are only half as severe on the first cycle compared with subsequent cycles. There is a correlation between the severity of acute and chronic neuropathy. Hand Sxs are more severe during therapy, while feet symptoms become more prominent during follow up.

Bevacizumab (BEV) and risk of hemorrhage (HEM) in metastatic castration-resistant prostate cancer (mCRPC) patients treated on CALGB 90401 (Alliance)

Patel JN, Jiang C, Hertz DL, Mulkey F, Friedman PN, Halabi S, Ratain MJ, Morris MJ, Small EJ, Owzar K, Kelly WK, McLeod HL

J Clin Oncol 32, 2014 (suppl; abstr e16061)

Conclusions: We identified risk factors associated with HEM in a large cohort of mCRPC patients. Although BEV is not standard treatment in this patient population, such identified risks should be examined in other oncologic contexts. Understanding risk factors for developing BEV-related HEM is essential to mitigate the risks of these complications in cancer care.

Association of genomic analysis of immune function genes and clinical outcome in the NCCTG (Alliance) N9831 adjuvant trastuzumab trial

Perez EA, Thompson EA, Anderson SK, Asmann YW, Kalari KR, Eckel-Passow J, Dueck AC, Tenner KS, Jen J, Fan JB, Geiger X, McCullough AE, Chen B, Zschunke M, Jenkins RB, Sledge GW, Winer EP, Gralow J, Reinholz MM, Ballman KV

J Clin Oncol 32 (5s), 2014 (suppl; abstr 509)

Conclusions: Improved RFS following treatment with adjuvant H (trastuzumab) appears to be associated with a heightened state of immunological function. This observation may define a significant biological process that is linked to the efficacy of HER2-targeted therapy, may provide a means of predicting probability of relapse following adjuvant trastuzumab, and suggests possible routes of therapeutic enhancement.

First results from the phase III ALTTO trial (BIG 2-06; NCCTG [Alliance] N063D) comparing one year of anti-HER2 therapy with lapatinib alone (L), trastuzumab alone (T), their sequence (T–>L), or their combination (T+L) in the adjuvant treatment of HER2-positive early breast cancer (EBC)

Piccart-Gebhart MJ, Holmes AP, Baselga J, De Azambuja E, Dueck AC, Viale G, Zujewski J, Goldhirsch A, Santillana S, Pritchard KI, Wolff AC, Jackisch C, Lang I, Untch M, Smith IE, Boyle F, Xu B, Gomez HL, Gelber RD, Perez EA

J Clin Oncol 32 (5s), 2014 (suppl; abstr LBA4)

Conclusions: L+T has lower risk of a DFS event compared with T, and T–>L appeared non-inferior to T, but neither finding was statistically significant. The first DFS results of dual HER2 blockade in the adjuvant ALTTO at 4.5 years MFU are unexpected considering the effect shown by doubling the pCR rate with L+T vs. T in the NeoALLTO trial. Follow up continues.

Normative data and clinically significant effect sizes for single-item numerical linear analogue self-assessment (LASA) scales

Singh JA, Locke DE, Satele D, Puttabasavaiah S, Buckner JC, Sloan JA

J Clin Oncol 32, 2014 (suppl; abstr e17619)

Conclusions: This study provides normative data for cancer patients and healthy volunteers for overall QOL using the LASA, indicating that overall QOL is independent of performance status and tumor response. These data can serve as benchmarks for future studies.

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RECAP: ALLIANCE/ASCO ABSTRACTS

Molecular subtyping of colon cancers and distinct prognostic groups [NCCTG N0147 (Alliance)]

Sinicrope FA, Shi Q, Thibodeau SN, Goldberg RM, Sargent DJ, Alberts SR

J Clin Oncol 32 (5s), 2014 (suppl; abstr 3512)

Conclusions: Subtype categorization of CCs reveals distinct clinical features and prognoses. Alternate and serrated pMMR subtypes show poor DFS whereas more prevalent traditional CCs have favorable DFS that is similar to dMMR CCs.

Overall survival result and outcomes by KRAS, BRAF, and DNA mismatch repair in relation to primary tumor site in colon cancers from a randomized trial of adjuvant chemotherapy: NCCTG (Alliance) N0147

Sinicrope FA, Yoon HH, Mahoney MR, Nelson GD, Thibodeau SN, Goldberg RM, Sargent DJ, Alberts SR

J Clin Oncol 32 (5s), 2014 (suppl; abstr 3525)

Conclusions: The addition of cetuximab to mFOLFOX6 resulted in significantly poorer OS. The prognostic impact of biomarkers on OS differed significantly by tumor site. Novel findings include poor OS of KRAS mutant tumors that was restricted to the distal colon, and a divergent prognosis for dMMR by primary tumor site.

Sunitinib (S) switch maintenance in advanced non-small cell lung cancer (NSCLC): An Alliance (CALGB 30607), randomized, placebo-controlled phase III trial

Socinski MA, Wang XF, Baggstrom MQ, Gu L, Stinchcombe TE, Edelman MJ, Baker Jr. S, Mannuel HD, Crawford J, Vokes EE

J Clin Oncol 32 (5s), 2014 (suppl; abstr 8040)

Conclusions: CALGB 30607 met its primary endpoint by demonstrating a significant improvement in PFS for S switch maintenance therapy in advanced NSCLC. No effect on the secondary endpoint of OS was seen.

CALGB/SWOG 80405: Phase III trial of irinotecan/5-FU/leucovorin (FOLFIRI) or oxaliplatin/5-FU/leucovorin (mFOLFOX6) with bevacizumab (BV) or cetuximab (CET) for patients (pts) with KRAS wild-type (wt) untreated metastatic adenocarcinoma of the colon or rectum (MCRC)

Venook AP, Niedzwiecki D, Lenz HJ, Innocenti F, Mahoney MR, O'Neil BH, Shaw JE, Polite BN, Hochster HS, Atkins JN, Goldberg RM, Mayer RJ, Schilsky RL, Bertagnolli MM, Blanke CD

J Clin Oncol 32 (5s), 2014 (suppl; abstr LBA3)

Conclusions: Chemo/CET and chemo/BV equivalent in OS in pts KRAS wt (codons 12 + 13) MCRC; either is appropriate in first line. Overall OS of 29 + mos and 8% long-term survivors confirms progress in MCRC. The preference for FOLFOX limits chemotherapy comparison. Expanded RAS and other molecular and clinical analyses may identify subsets of pts who get more or less benefit from specific regimens.

Racial differences in KRAS/BRAF mutation rates and survival in colon cancer (NCCTG N0147 [Alliance])

Yoon HH, Shi Q, Alberts SR, Goldberg RM, Thibodeau SN, Sargent DJ, Sinicrope FA

J Clin Oncol 32 (5s), 2014 (suppl; abstr 3536)

Conclusions: These data, to our knowledge, are the first to show that Asians have a significantly lower rate of KRAS/BRAF mutations than blacks or whites. We also report a novel interaction of race with N stage and age, showing that racial disparities in survival persist despite uniform stage and enrollment in a phase 3 trial.

RECAP: ALLIANCE COMMITTEE MEETINGS

What follows are quick recaps of meetings held during the 2014 Alliance Spring Group Meeting from the Alliance Oncology Nursing Committee and Alliance Patient Advocate Committee.

Alliance Oncology Nursing Committee (A-ONC)

Contributing Writer: Lisa A. Kottschade, RN, CNP

Planning is underway for an A-ONC sponsored educational session at the 2014 Alliance Fall Group Meeting in November. The global topic will focus on cancer care in the elderly, and the A-ONC is planning to offer continuing education (CE) credits for this session.

A-ONC members also strategized and discussed ways to engage the larger network of nurses within the Alliance, outside of the committee meeting both at Alliance meetings and throughout the year.

Plans are also underway to form project teams to address issues or projects that are relevant to oncology nursing within the Alliance. Ideally, these projects would be co-lead by at least one or two A-ONC members and at least one other Alliance member nurse. Several project ideas have been discussed as preliminary starting points for this endeavor. After the initial project is developed, a call to all Alliance nurses will go out for applications to be a part of the project team, similar to what is currently done for Oncology Nursing Society (ONS).

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Additionally, the A-ONC sponsored an educational session where Alliance Group Statistician Daniel J. Sargent, PhD, presented a talk entitled "The Role of Statistics in Cancer Research." Dr. Sargent provided a high-level overview of clinical trial design, the rationale for specific study endpoints, and trial decision-making. The talk was very well received with good discussion afterwards.

Finally, the inaugural Nurses Open Forum was held immediately following the session. It provided an opportunity for nurses to network and openly discuss any issues or generalized questions they had about clinical trials, side effect management, educational needs and other topics. Feedback from the forum was very positive. The A-ONC will plan to offer it again in the future.

Alliance Patient Advocate Committee

Contributing Writer: Patrick Gavin, RPh, and Patricia Spears

The Patient Advocate Committee (PAC) touches every committee within the Alliance. The PAC offers the perspective of the cancer patient in the important work being done by the Alliance. The PAC is very fortunate to be the recipient of valuable education during face-to-face Group meetings. The spring Alliance meeting in Chicago was no exception.

The PAC meeting began with a discussion with Alliance Group Vice Chair Edith A. Perez, MD, a mentor to the committee. Dr. Perez provided updates on various Alliance activities and important information regarding the major funding issues the Alliance is currently facing. She also discussed the important work being done by the Alliance Publication Committee and asked for the committee's help with various initiatives. Dr. Perez asked for input on how she could help PAC members be an effective part of the Alliance through the committee's work. She stressed the importance of the patient advocates being involved on the monthly committee calls and asked for feedback if that was not happening.

Katherine A. Yao, MD, FACS, of NorthShore University HealthSystem, presented her breast cancer study, "Impact of a Decision Intervention on Utilization of Contralateral Prophylactic Mastectomy for Early Stage Breast Cancer Patients," to the committee and asked for input on the development and utilization of a decision support tool. There was a lot of good discussion and advice was given about how to capture the interest of the patient in this study.

"Feedback from the Patient Advocate Committee was extremely valuable in helping me design a decision aid for a clinical trial that I am developing looking at surgical decision making," Dr. Yao said following the meeting.

Alliance Group Statistician Daniel J. Sargent, PhD, gave a presentation about the work of the Alliance Data and Safety Monitoring Board (DSMB), how its work interacts with other committees and ensures the safety and viability of Alliance studies.

Michael Kelly, MA, Director of Alliance Protocol Operations, discussed the work of Alliance staff and how the development of a protocol proceeds from initial concept design through protocol development. He highlighted those points in protocol development where patient advocate input is essential. According to Jim Omel, MD, a PAC member, he "helped us understand what happens in the 'black hole' of "protocol development" and gave us greater appreciation and understanding of the difficult and timely work of Alliance's protocol coordinators."

Two-way conversations are key at PAC meetings. Advocate education is essential as well as providing input on Alliance activities, including the development of concepts and protocols.

This meeting saw the retirement of two long-time patient advocates, Jim Williams and Pam McAllister. Both announced their retirement from the Alliance and the PAC. Both have served for more than a decade on legacy groups and the Alliance. They will be missed.

Unfortunately, the disease we all fight continues to be ever-present with the PAC. A couple of PAC members have experienced recurrence of their disease or new cancers since the last time the committee met. Although setbacks, this further encourages the PAC to continue to bring the best clinical trials to patients. As Sara Whitlock, a PAC member, stated in a letter to the committee: "In my life alone, the information I have gathered from being around each of you has opened up so many more doors for me. Knowing to ask about clinical trials led to free testing of my tumor, which revealed my genetic mutation and has given us many more drugs in our arsenal. It has helped me stay focused and hopeful about my continued survival. The awareness that you raise in all aspects of your work is making such a difference."

The PAC meeting closed with a moving announcement from Bettye Green, RN, Vice Chair of the PAC, she will retire from the Alliance at the end of the year. She has served several decades as an advocate in many areas of cancer research, and has held multiple leadership positions with numerous cancer research organizations, including the Alliance. The PAC will pay tribute to her advocacy work and celebrate her retirement at the 2014 Alliance Fall Group Meeting in November.

Alliance Members on the Move

Crespo-Elliott

Coleen Crespo-Elliott, MS, recently joined the Alliance Patient Advocate Committee. Mrs. Crespo-Elliott is a patient advocate for various Duke University and University of North Carolina-Chapel Hill research topics, reviewing proposals for approval and funding of clinical trials. In addition, she serves on committees for the American Cancer Society and the Komen Foundation, and is the Assistant Secretary/Treasurer of Sisters Network Triangle NC chapter, national organization committed to heightening awareness of the impact that breast cancer has in the African-American community. Mrs. Crespo-Elliott will serve on the Alliance Health Outcomes Committee.

Green

Antoinette (Toni) Green, MA, recently joined the Alliance Patient Advocate Committee. In 2007, Ms. Green participated in a radiotherapy clinical trial to combat breast cancer and is now a breast cancer survivor. She is a certified mediator for Alternative Dispute Resolution and recently completed the Disparities Leadership Program at Massachusetts General Hospitals, Disparities Solutions Center. She is co-chair of the REAL Committee at the Greater Detroit Health Council, a committee that ensures that hospitals and ambulatory providers in southeast Michigan are collecting self-reported race, ethnicity, and primary language data consistently. Ms. Green will serve on the Alliance Health Disparities Committee.

Alliance Welcomes New Ethics Co-Chair

Fay J. Hlubocky, PhD, of University of Chicago, recently has been appointed Co-Chair of the Alliance Ethics Committee. Dr. Hlubocky joins Jeffrey M. Peppercorn, MD, of Duke University Medical Center, as Co-Chair. The committee provides in depth review and commentary concerning important issues facing Alliance researchers that are used by the Group Chair and Board of Directors to adjust Alliance polices when changing circumstances are warranted.

SPOTLIGHT ON TRIALS continued

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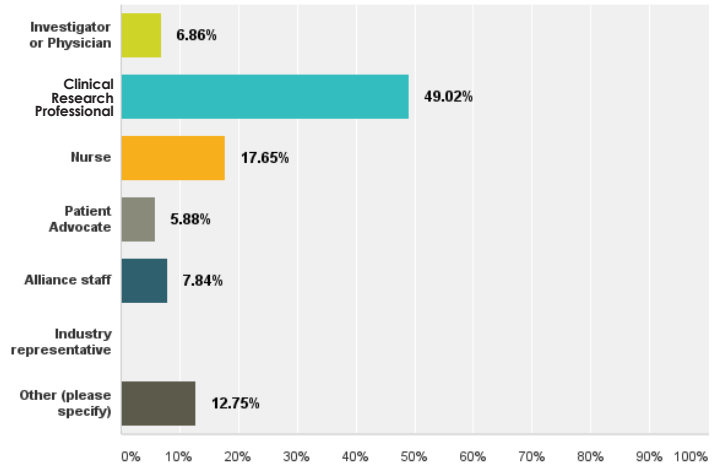
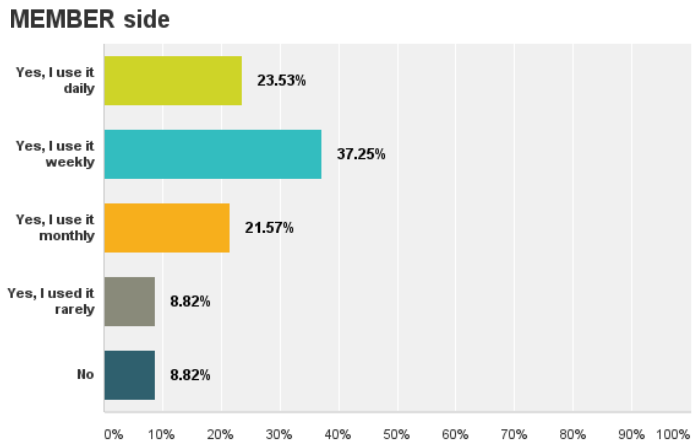
Results from the Alliance Website Survey

The Alliance for Clinical Trials in Oncology launched its inaugural website more than one year ago. Recently, the Alliance Web Team developed and distributed a brief survey to help determine what's working and what can be improved on the website. Below are the results of the survey. Based on this feedback, the team is currently implementing improvements. Be sure to visit the website often at www.AllianceforClinicalTrialsinOncology.org to keep track of the team's progress. In a nutshell, here's what the team learned.

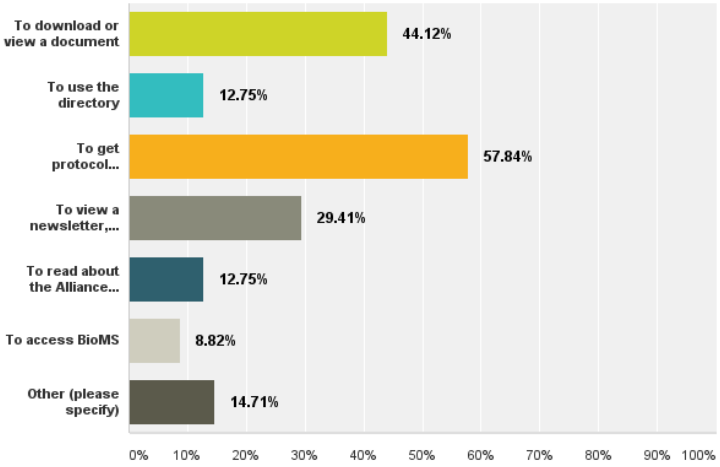
Who uses the Alliance website?



Which side gets the most traffic and how often?



How do members use the site?



What challenges member users most about the site? What should be improved?

- I don't know my username and/or password
- Difficult to go through multiple protocol pages
- Simple terms should be used for quick navigation
- More concise topics ex: monthly updates; ordering memos oldest to newest
- Why are tabs on top and bottom? / remove tabs from bottom
- Need better search for protocols
- Need visible links to DSMB reports, study summaries
- Improve functionality of directory
- Needs to be optimized for mobile use

Four Alliance Members Receive $25 Amazon Gift Cards

Thank you to everyone who completed the Alliance Website Survey. Your suggestions, overall feedback and general comments are greatly appreciated. Hats off to four Alliance members who received $25 Amazon gift cards for completing the survey:

- **Melissa Strawhun** (Regulatory Specialist, Oklahoma Health Sciences Center)
- **Belenda Slate** (Protocol Specialist/Lead CRA, Southeast Cancer Control)
- **Suzanne Stoddard** (Clinical Research Data Manager, Naval Medical Center San Diego / NMCSD)
- **Judy Petz (RN OCN CBCN**, Marshfield Research Foundation)

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 July 15, 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

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 August 1, 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

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.

Next Meeting Date

2014 Alliance Fall Group Meeting
November 5-8
InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL

Registration to begin in September.
For updates, visit the Alliance website at www.AllianceforClinicalTrialsinOncology.org

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**