Alliance for Clinical Trials in Oncology
NEWS
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info@allianceNCTN.org

SPOTLIGHT ON TRIALS

Three Alliance Lymphoma Trials Focus on 'Biologic Doublets'

The Alliance Lymphoma Committee is currently leveraging three main aims to help treat patients with Hodgkin lymphoma and non-Hodgkin lymphoma. These aims include building on strategic phase II studies to design and conduct definitive trials that dramatically improve clinical outcomes for patients with lymphoma; maximizing opportunities for innovation by focusing on multidisciplinary collaboration with experts in targeted therapeutics, molecular pathology, imaging, and transplantation; and utilizing correlative science endpoints that define which patients are most likely to benefit from a particular treatment, and lead to molecularly defined treatment trials.

"Under the leadership of Bruce Cheson, MD, the lymphoma committee has been focused on 'biologic doublets' with targeted agents, a treatment approach that has been quite innovative," said John P. Leonard, current chair of the committee. "Following up on this work, we are now moving toward 'targeted triplet therapy,' which is a first in lymphoma therapeutics. These are important steps as we move such "chemotherapy-free" approaches more and more into standard treatment."

The following three lymphoma studies are examples of this approach.

Alliance A051202 A Phase I Trial of Lenalidomide, Rituximab, and Idelalisib in Recurrent Follicular Lymphoma

More effective treatment options are needed for patients with recurrent follicular lymphoma, which is largely incurable. Combinations of novel treatment agents offer the potential to overcome resistance to chemotherapy and/or rituximab, and may lead to overall or progression-free survival benefits. Safety profiles of the agents appear to compare favorably to standard approaches in relapsed/refractory disease, which include chemotherapy and stem cell transplantation. A well-tolerated regimen that can provide durable remissions would be expected to enhance quality of life. A combination treatment strategy that proves effective and tolerable in relapsed/refractory follicular lymphoma would merit consideration for evaluation as an initial treatment approach in future studies, and may also warrant evaluation in other lymphoma subtypes and settings.

In A051202, the addition of the PI3K inhibitor idelalisib to lenalidomide plus rituximab is being evaluated to determine how well it is tolerated in patients with recurrent follicular lymphoma. The trial will establish the dosing, safety and preliminary activity of the three-drug (idelalisib, lenalidomide and rituximab) combination, hypothesizing that it will be sufficiently promising to warrant a follow-up randomized phase II/III trial (vs. lenalidomide plus rituximab or another standard regimen). The overall hypothesis of this line of investigation is that the three-drug regimen will be more effective than the two-drug regimen as a treatment approach for follicular lymphoma, with acceptable toxicity.

It is also anticipated that this three-drug regimen may be further explored as an alternative (based on potentially superior efficacy and/or tolerability) to chemoimmunotherapy as initial treatment for follicular lymphoma, in the relapsed setting, in other lymphoma subtypes, or as a maintenance strategy. This approach is a logical step in the development of non-chemotherapy approaches for the treatment of indolent lymphoma.

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A051202 is a limited access study, available only to the following institutions: Georgetown University, The Ohio State University, University of North Carolina-Chapel Hill, Roswell Park Cancer Institute, University of Chicago, Washington University, and Weill Cornell Medical College.

The study protocol for Alliance A051202 is available on the CTSU menu (ctsu.org). Refer to the protocol for complete information about the trial design and patient eligibility. The Study Chair is John Leonard, MD, of Weill College of Cornell University, e-mail: jpleonar@med.cornell.edu.

Alliance A051201 A Phase I/Randomized Phase II Trial of Idelalisib, Lenalidomide, and Rituximab in Patients with Relapsed/Refractory Mantle Cell Lymphoma

Mantle cell lymphoma (MCL) represents only 6 percent of non-Hodgkin lymphomas, accounting for approximately 5000 new cases a year in the United States, with no consensus on the management of either front-line or relapsed disease. There is currently no standard of care or preferential sequence of therapies for the management of patients with relapsed or refractory MCL.

An understanding of the biologic processes underlying MCL pathogenesis helps guide the development of new agents. Of B-cell lymphoma subtypes, the one with the most compelling rationale for use of PI3K/Akt/mTOR inhibitors is MCL. Idelalisib is an orally bioavailable PI3K inhibitor. Lenalidomide is an immunomodulatory agent (IMid) that has established single agent activity in MCL Lenalidomide plus rituximab is an extremely active combination in relapsed indolent lymphomas, even in patients heavily exposed to rituximab-based regimens.

The phase I of the A051201 trial will determine the safety and tolerability of the combination of lenalidomide and rituximab with idelalisib in sequential dose cohorts. Phase II of the trial will determine the progression-free survival of the combination of lenalidomide and rituximab, with or without idelalisib in a randomized phase II design. The phase II portion will also determine the overall response rate, complete response rate, and overall survival of the combination of lenalidomide and rituximab, with or without idelalisib, as well as the prognostic and/or predictive significance of proliferation markers and cell cycle components in these patients.

If idelalisib plus lenalidomide shows promising activity in this patient population, it would next be tested in combination with other standard agents that have established activity in MCL perhaps even for front-line use against other biologic doublets. This combination offers the advantage of non-overlapping toxicity profile as compared to most cytotoxic agents, as well as distinct mechanisms of action compared to most standard front-line regimens.

The study protocol for Alliance A051201 is available on the CTSU menu (ctsu.org). Refer to the protocol for complete information about the trial design and patient eligibility. The Study Chair is Somali Smith, MD, of University of Chicago, e-mail: smsmith@medicine.bsd.uchicago.edu

Alliance A051103 A Phase I Study of Rituximab, Lenalidomide, and Ibrutinib in Previously Untreated Follicular Lymphoma

Front-line regimens for consist of chemoimmunotherapy. While the response rates with these types of regimens are typically high, patients inevitably relapse and further treatment options are necessary. Traditional chemotherapy is associated with significant toxicity; therefore, targeted therapy is favored to improve upon efficacy as well as tolerability.

Rituximab, a CD20 monoclonal antibody, has shown significant efficacy in follicular lymphoma both as a single agent as well as in combination with other chemotherapeutics. Lenalidomide is a novel immunomodulatory agent that has been approved for the treatment of multiple myeloma and myelodysplastic syndromes with del 5q and is currently undergoing evaluation in non-Hodgkin lymphoma. Ibrutinib is a novel BTK inhibitor currently in clinical development in both NHL and chronic lymphocytic leukemia.

In A051103, a combination of rituximab, lenalidomide and ibrutinib is proposed to help further expand the rate and durability of response previously achieved in follicular lymphoma. By targeting NF-kB through multiple pathways, the study team believes this regimen will produce superior antitumor efficacy. Based on the preliminary data from the CALGB 50803 trial, this phase I study has been designed to further evaluate this three-drug combination as front-line treatment for follicular lymphoma. By providing multi-targeted therapy, we hope to improve upon the survival of this incurable disease as well postpone the need for aggressive chemotherapy and its associated toxicities. Data from this trial and CALGB 50803 will be used in the design of a multi-arm phase III Alliance trial evaluating the rituximab and lenalidomide backbone in combination with novel small molecule targeted agents in previously untreated follicular lymphoma.

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This trial is a limited access study, and available only to the following institutions: Dana-Farber Cancer Institute, Georgetown University Lombardi Comprehensive Cancer Center, The Ohio State University Comprehensive Cancer Center, Roswell Park Cancer Institute, UNC Lineberger Comprehensive Cancer Center, University of Chicago Comprehensive Cancer Center, Washington University School of Medicine, and Weill Cornell Medical College.

The study protocol for Alliance A051103 is available on the CTSU menu (ctsu.org). Refer to the protocol for complete information about the trial design and patient eligibility. The Study Chair is Chaitra Ujjani, MD, Georgetown University Lombardi Comprehensive Cancer Center, e-mail: Chaitra.S.Ujjani@gunet.georgetown.edu

Alliance Carcinoid Tumors Trial to Evaluate Survival Rates

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. As such, additional therapeutic options are sorely needed. Advances in understanding the potential mechanisms underlying tumor progression have suggested several therapeutic targets (including the VEGF- and mTOR signaling pathways), but the precise role of targeted agents in carcinoid has not been established.

Neuroendocrine tumors (NETs) are highly vascular and express VEGF as well as the VEGF receptor.4,5 Phase II studies with TKIs targeting the VEGF receptor, including sunitinib, sorafinib and pazopanib, have also suggested activity in NETs (pancreatic neuroendocrine tumors and carcinoid).6-8 Pazopanib is an oral multitargeted receptor tyrosine kinase inhibitor with activity against VEGFR-2, and -3, PDGFR-alpha and beta, and stem cell factor receptor (c-KIT).9,10 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.4,11,12 VEGF is upregulated in primary tumors, and in some studies expression correlates with angiogenesis and decreased progression-free survival.13

Beyond somatostatin analogs, there are no proven agents for treatment of metastatic carcinoid tumors, and the relative benefits of VEGFR TKIs compared to mTOR inhibitors in this patient population are not known. New treatments are needed for patients with progressive disease.

In this randomized, double-blind trial for patients with progressive carcinoid tumors (A021202), progression-free survival will be compared between patients randomized to treatment with pazopanib versus placebo. In addition, overall survival will be compared between treatment arms. A correlative study will also assess the effects of pazopanib on quality of life, sexual function, bowel function and recovery parameters.

The study protocol for Alliance A021202 is available on the CTSU menu (ctsu.org). Refer to the protocol for complete information about the trial design and patient eligibility. The Study Chair is Emily Bergsland, MD, University of California, 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. 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. 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
4. 4. Terris B, Scoazec JY, Rubbia L, et al: Expression of vascular endothelial growth factor in digestive neuroendocrine tumours. Histopathology 32:133-8, 1998
5. La Rosa S, Uccella S, Finzi G, et al: Localization of vascular endothelial growth factor and its receptors in digestive endocrine tumors: correlation with microvessel density and clinicopathologic features. Hum Pathol 34:18-27, 2003
6. Kulke M, Lenz H, Meropol N, et al: Activity of sunitnib in patients with advanced neuroendocrine tumors. J Clin Oncol 26:3403-10, 2008
7. Raymond E, Niccoli-Sire P, Bang Y, et al: Updated results of the phase III trial of sunitinub (SU) versus placebo (PBO) for treatment of advanced pancreatic neuroendocrine tumors (NET). ASCO-GI Symposium, 2010, pp abstract #127
8. Phan A, Yao JC, Fogleman DR, et al: A prospective, multi-institutional phase II study of GW786034 (pazopanib) and depot octreotide (sandostatin LAR) in advanced low-grade neuroendocrine carcinoma (LGNEC). Pro Am Soc Clin Oncol.:abstract # 4001, 2010
9. Hurwitz H, Dowlati A, Saini S, et al: Phase I trial of pazopanib in patients with advanced cancer. Clinical Cancer Research 15:4220-7, 2009

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SPOTLIGHT ON LEADERSHIP

A Closer Look at Who's Who in the Alliance

This article is the first in a four-part, monthly series that will feature an overview of the Alliance, along with short biographies of leaders within each segment of the Alliance. This month's series will introduce chairs of the Alliance disease committees.

Who We Are The Alliance for Clinical Trials in Oncology is a multi-institutional cancer clinical trials group that emerged in response to the Institute of Medicine's consensus report and National Cancer Institute (NCI) directives for cooperative group reorganization. ***What We Do*** The Alliance, as a member of the NCI National Clinical Trials Network (NTCN) Program, provides a comprehensive and highly efficient clinical trials infrastructure, access to experienced collaborators across all disciplines of oncology clinical trials research, and a diverse portfolio of trials for patients with breast, gastrointestinal, genitourinary, respiratory, central nervous system, hematological malignancies, and selected rare tumors. The Alliance relies heavily on the long-standing tradition of collaborative research of its legacy members, including many who have participated in cooperative group research since its inception in 1955.

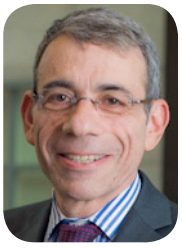
How We Function The Alliance is governed by a Board of Directors and Executive Committee, and led by a Group Chair and Principal Investigator. The Alliance is organized into five programs, each led by a Co-Principal Investigator. These programs include the Statistics and Data Management Program, Central Protocol Operations Program, Translational Research Program, Cancer Control Program and the American College of Surgeons Clinical Research Program. Within the programs, there are administrative and scientific committees that help facilitate the work of the Alliance.

Who's Who Alliance Disease Committees

Breast Committee Co-Chairs

Hudis

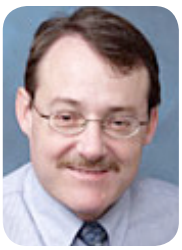
Clifford A. Hudis, MD, Chief, Breast Cancer Medicine Service at Memorial Sloan-Kettering Cancer Center. Dr. Hudis' research interests are in all areas of care related to breast cancer, focusing on the disease, prevention of recurrence after surgery, and treatment of recurrences. His work with clinical and translational studies aim to develop better hormone therapies, improved chemotherapy drugs, more-effective and less toxic methods of drug delivery, and newer highly specific agents.



Winer

Eric P. Winer, MD, Professor of Medicine at Harvard Medical School; Director, Breast Oncology Center and Thompson Senior Investigator in Breast Cancer Research at Dana-Farber Cancer Institute. Dr. Winer's research focus is on clinical research in breast cancer. He conducts a wide variety of phase I, II, and III trials for patients with all stages of breast cancer, and is interested quality of life, psychosocial aspects of cancer, medical decision-making, and doctor-patient communication.

Gastrointestinal (GI) Committee Chair



Venook

Alan P. Venook, MD, Professor of Clinical Medicine, Division of Hematology Oncology and Chairman, UCSF Committee on Human Research at the University of California San Francisco. Dr. Venook is a nationally renowned expert in colorectal and liver cancers. In his research, he focuses on treating liver tumors with directed approaches, including infusional chemotherapy and biological agents.

Genitourinary (GU) Committee Chair

Michael J. Morris, MD, Associate Professor of Medicine at Weill Cornell Medical College and Associate Attending Physician in the Genitourinary Oncology Service at the Memorial Sloan-Kettering Cancer Center. Dr. Morris specializes in the

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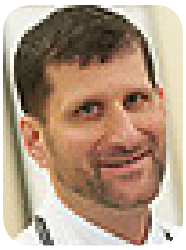

Morris

treatment of prostate cancer, particularly in patients who have metastatic disease or are at high risk of developing metastatic disease. His research bridges the fields of medical oncology and nuclear medicine and he is currently exploring bone-seeking radiopharmaceuticals used in combination with chemotherapy. Dr. Morris is also developing new ways to image prostate cancer in the bones using prostate-cancer specific PET scans.

Leukemia Committee Chair

Stone

Richard M. Stone, MD, Professor of Medicine at Harvard Medical School and Director, Adult Acute Leukemia Program at Dana-Farber Cancer Institute. Dr. Stone's research interests involve developmental therapeutics for patients with bone marrow stem cell disorders, including the acute leukemias, myelodysplasia, and the myeloproliferative disorders. His focus is also on areas of differentiation-based therapy and cell signal modification therapy (kinase inhibitors) with agents that act on protein kinase-C and immunologically-based therapy.

Lymphoma Committee Chair

Leonard

John P. Leonard, MD, Attending Physician at New York-Presbyterian Hospital; Richard T. Silver Distinguished Professor of Hematology and Medical Oncology; Professor of Medicine and Associate Dean for Clinical Research at Weill Cornell Medical College New York Presbyterian/Weill Cornell. Dr. Leonard's research interest focuses on novel immunotherapies and other translational strategies for lymphoma and other malignancies. His ultimate goal, in addition to providing the best possible care to patients and access to promising new treatments, is to improve the chance of cure for patients with lymphoma, while potentially minimizing treatment-related toxicity to improve quality of life.

Myeloma Committee Chair

Richardson

Paul Richardson, MD, R.J. Corman Professor, Department of Medicine at Harvard Medical School and Clinical Director, Jerome Lipper Center for Multiple Myeloma at Dana-Farber Cancer Institute. Dr. Richardon's primary research interest is in novel therapies for myeloma. He has been a leader in the clinical development of bortezomib, lenalidomide and pomalidomide for the treatment of myeloma, and currently leads multiple efforts studying the use of combination therapies in relapsed and refractory myeloma.

Neuro-Oncology Committee Chair

Galanis

Evanthia Galanis, MD, Professor of Oncology and Sandra J. Schulze Professor of Novel Therapeutics, College of Medicine at Mayo Clinic. Dr. Galanis, an expert in molecular medicine-oncology, has interests in the development and optimization of novel virotherapy approaches in the treatment of cancer with special emphasis on paramyxoviruses. A significant impetus for her research has been the translation of laboratory advances into clinical trials of novel virotherapeutics in cancer patients.

Respiratory Committee Chair

Vokes

Everett E. Vokes, MD, John E. Ultmann Professor of Medicine and Radiation Oncology; Physician-in-Chief, University of Chicago Medicine and Biological Sciences, and Chair, Department of Medicine at the University of Chicago. Dr. Vokes is an internationally renowned expert in the treatment of head and neck cancer. His work has shown that intense treatment combining radiation and chemotherapy can bring locally advanced head and neck cancer under control and improve survival. His research in lung cancer is directed at identifying new active therapeutic agents and the interaction of chemotherapy and radiation therapy.

Next month, this series will feature chairs of the Alliance modality committees, including Clinical Research Professionals (CRP), Experimental Therapeutics, Oncology Nursing, Patient Advocate, Radiation Oncology and Transplant.

IN MEMORIAM

Keith Amos, MD: Promising Surgical Oncologist

Keith D. Amos, MD, Assistant Professor of Surgery in the Department of Surgery at the University of North Carolina at Chapel Hill, died suddenly in Edinburgh, Scotland on June 17, while conducting research on a Claude Organ, Jr. Travel Award from the American College of Surgeons. He was 42.

Dr. Amos was a member of the Alliance Cancer Care Standard Development Committee within the American College of Surgeons Clinical Research Program (ACS CRP), and recently elected Vice Chair of the Alliance Health Disparities Committee. He led the ACS CRP Surgical Standards Manual Breast Group, a team of more than 20 subject matters experts from the ACS, the Commission on Cancer (CoC), American Society of Breast Surgeons and other professional organizations, who are currently writing the breast cancer section of the ACS CRP Surgical Standards Manual. Dr. Amos was instrumental in organizing the team, defining content and prioritizing the work.

Dr. Amos earned his medical degree from Harvard University, and completed surgery residency at Washington University in Saint Louis. His passion for cancer education and care led him to a Surgical Oncology fellowship at the MD Anderson Cancer Center in Houston. He was recruited to UNC in 2007. His academic and clinical practice interests were in the surgical treatments for breast, skin and endocrine malignancies and eliminating cancer treatment disparities.

Dr. Amos is survived by his wife, Ahaji, and three daughters. The Alliance sends our deepest condolences to his family, friends and colleagues.

The Department of Surgery at Washington University School of Medicine has created the Keith David Amos Residency Alumni Award and UNC has established the Keith Amos Memorial Fellowship in Surgical Oncology in his memory.

2013 Meeting Abstract Submission Deadlines

All draft abstracts from Alliance for Clinical Trials in Oncology (including all three legacy groups: ACOSOG, CALGB and NCCTG) must be submitted to the Alliance by the date indicated in the table below. Please submit by e-mail to **Publications@AllianceNCTN.org**. This deadline is firm, and is required to ensure time for central review of content, as well as review of author lists. Adherence to the deadline will allow sufficient time for the each lead author to submit to the association.

All Alliance abstracts must follow this process. Independent submission of work related to the Alliance without this proper review is not permitted.

Meeting/Association	Deadline to Submit to the Alliance (Publications@AllianceNCTN.org)	Deadline to Submit to Meeting/Association	Meeting Date
ASCO Gastrointestinal (GI) Cancers Symposium	Sept 3, 2013	Sept 17, 2013	Jan 16-18, 2014
ASCO Genitourinary (GU) Cancers Symposium	Sept 17, 2013	Oct 1, 2013	Jan 30-Feb 2, 2014
European Breast Cancer Conference (EBCC)	Oct 25, 2013	Nov 15, 2013	Mar 19-21, 2014
European Society for Radiotherapy & Oncology	Oct 25, 2013	Nov 14, 2013	Apr 4-8, 2014

Abstract Requirements

An Alliance abstract should contain the following information:

Study number(s)

- For an Alliance study X, the study number should appear in the title as "Alliance X"
- For a legacy study, the study number should appear in the title as "[Legacy Group Name] X (Alliance)" (e.g., "CALGB 40101 (Alliance)")
- If multiple studies are involved and the title cannot accommodate all of the numbers, the study numbers must appear in the text of the abstract.

Authors

- The Alliance statistician must appear in the list of authors, usually as second author
- The list of authors should reflect study participation, including patient accrual and scientific input

Affiliation and grant support

- Provide institutional affiliation for each author

Corresponding author

- Provide the name and contact information of the corresponding author

Accepted Abstracts

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

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

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10. Kumar R, Knick V, Rudolf S, et al: Pharmacokinetic-pharmacodynamic correlation from mouse to human with pazopanib, a multitkinase angiogenesis inhibitor with potent antitumor and antiangiogenic activity. Mol Cancer Ther 6:2012-21, 2007
11. Welin S, Fjallskog M, Saras J, et al: Expression of tyrosine kinase receptors in malignant midgut carcinoid tumors. Neuroendocrinology 84:42-48, 2006
12. Granberg D, Wilander E, Oberg K: Expression of tyrosine kinase receptors in lung carcinoids. Tumour Biol 27:153-7, 2006
13. Zhang J, Jia Z, Li Q, et al: Elevated expression of vascular endothelial growth factor correlates with increased angiogenesis and decreased progression-free survival among patients with low-grade neuroendocrine tumors. Cancer 109:1478-86, 2007

ACS CRP to Develop New Surgical Standards

The American College of Surgeons Clinical Research Program (ACS CRP) is currently developing a manual detailing operative standards complete with surgical checklists that is similar to the American Joint Committee on Cancer (AJCC) Staging Manual and the College of American Pathologists (CAP) Guidelines for Pathology Reporting.

"The time is right because many if not all of the essential elements have been developed in the context of either clinical trials or as part of Commission on Cancer (CoC) standards for accreditation, said Heidi Nelson, MD, Director of Principal Investigator of the ACS CRP. "For those cancers covered by the NCI cooperative group networks and the CoC, there have been substantial efforts to standardize surgical procedures and establish measurable metrics."

The ACS CRP Cancer Care Standards Development (CCSD) Committee led by Kelly Hunt, MD, has accepted the challenge of collating available surgical standards to launch the first edition of a surgical standards manual. The manual will initially focus on four disease sites (breast, colon, lung and pancreas) with future editions to include seven additional sites. The four disease sites are being led by Sarah Blair, MD, (breast); George Chang, MD, (colon); Nirmal Veeramacheneni, MD, (lung); and Matthew Katz, MD, (pancreas).

Goals of the new ACS CRP Surgical Standards Manual are fivefold:

1. To promote surgical uniformity for clinical trials
2. To inform protocol standards
3. To recommend evidence-based best practices in surgical oncology
4. To establish surgical checklists
5. To serve as a gap analysis for research

The scope of the manual will be limited to the intra-operative experience (i.e., from skin incision to skin closure). The standards will not duplicate the efforts of National Comprehensive Cancer Network (NCCN) guidelines since these guidelines already cover pre- and post-operative diagnostics and therapeutics. The manual will provide an assessment of the level of evidence in support of recommended standards and suggest areas in need of more research.

Volunteers were solicited from professional societies and other cooperative groups to provide input and contribute to content. Each of the disease site teams identified one to four procedures with critical surgical elements that they have determined to have the greatest impact on the oncologic outcomes for that disease site, and will describe those critical elements in detail. In addition, the teams identified two or three controversial questions, conducted evidence reviews and will recommend evidence-based standards for those controversial areas. A surgical operative checklist will also be developed for each disease site that can be used as part of the patient's medical records.

It is expected that the manual will be published in both print and electronic formats by October 2014. Subsequent editions of the print manual will be published as new disease sites are added. The electronic version will be updated regularly as new information becomes available and new disease sites are added.

Those interested in becoming involved in this project, please contact the ACS CRP at clinicalresearchprogram@facs.org. Ideas and contributions are welcomed.

All Institutions Welcome to Apply for Membership

The Alliance offers two levels of membership: main members and affiliate members. All institutions are welcome to apply for membership. Successful applicants will meet all membership requirements, including accrual, data quality and timeliness, adherence to Alliance policies and procedures, and participation in Alliance scientific activities.

To learn more about Alliance membership, contact Marcia Kelly, Membership and Administrative Manager, by e-mail marciak@uchicago.edu or phone 773-834-7676. Information about Alliance membership can also be found on the Alliance website at AllianceforClinicalTrialsinOncology.org

For those institutions that have submitted applications by July 31 and are seeking Alliance Board membership, here are some dates to remember:

- **September 1, 2013** Group Chair appoints Nominating Committee for board elections.
- **September 13, 2013** Membership Committee and Transition Board of Directors review accrual reports and confirm institutional eligibility for board membership. Transition board approves membership applications submitted by July 31, 2013 and recommended by the Membership Committee.
- **September 20, 2013** Institutional principal investigators notified of board eligibility. This includes PIs of institutions that ranked in the top 40 with seats on the board and PIs of main members eligible for election "at large" to the Alliance Board of Directors.
- **September 30, 2013** Nominations and required documentation are due to the nominating committee for institutional representatives wishing to run for election as at-large board members.
- **October 11, 2013** Nominating Committee selects and announces board candidates.
- **November 7, 2013** Final board meeting of Alliance Transition Board of Directors: the transition board elects the at-large members of the new board of directors by secret ballot (representatives from main members not on Alliance board by top 40 ranking).

Photos!
Alliance Website

Want to see your institution featured prominently on the new Alliance website? If so, send us your photos. We welcome photos of all Alliance members and institutions. Just send them to us with a confirmation that all individuals pictured have given their consent for web posting to *Alliance News* at jowens@uchicago.edu. Also, make sure to include a caption with the date, location, and names of individuals in the photos.

Alliance
Web Corner

Alliance Launches Website Enhancements

The Alliance is continually working to enhance our website (AllianceforClinicalTrialsinOncology.org) with increased functionality and content. We are happy to announce the addition of a search function. Users are now able to search the contents of the public side and, when logged on as a member, content from both public and member sides. The advanced search function, which remains in beta, allows users to query the site and refine the results.

Furthermore, we have improved the directory search function, upgraded the site menus, and added new content, including a list of Alliance main members by state (can be downloaded), summaries of the research conducted by each Alliance committee, updated protocol listings, and educational resources.

We hope the addition of the search function and updated content will enhance your browsing experience. Future enhancements to the protocol content and single sign-on for accessing BioMS will be launched soon. Please send any feedback that you may have to info@allianceNCTN.org.

Call for Posters

Upcoming Alliance Group Meeting

The Alliance will sponsor a poster session at the Group meeting held November 7-10, 2013. If you presented at a meeting between November 2012 and November 2013, please contact Mary Cate Zipprich (mzipprich@partners.org) to express your interest in participating in the poster session and to obtain more details.

Future Meeting Dates

2013 Group Meeting

November 7-10, 2013
Open to Alliance members

**Breast Committee will meet Sunday, November 10*

ACCRU Group Meeting will be held in conjunction with the Alliance Group Meeting.

**ACCRU Operations will meet on November 8, 4p-6p*

**ACCRU Scientific Program will meet on November 9, 7a-10a*

Visit the ACCRU website at www.accru.org for more information.

2014 Committee Meetings

May 8-10, 2014
Open to Alliance committee members only

Group Meeting

November 6-8, 2014
Open to Alliance members

All meetings will be held at the
InterContinental Chicago O'Hare
5300 N. River Road, Rosemont, IL

For meeting and travel inquiries,
contact Holly DeSimone
e-mail: hdesimone@partners.org
phone: 617-525-3022

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

Did You Know

The new **Alliance Service Center** is now open! It offers **triage support** for Alliance information systems, along with user authorization, access, connectivity and password resets. Hours are **8 am to 5:30 pm ET** Monday through Friday, excluding holidays. For general information, **call** 877-442-2542 or **e-mail** AllianceServiceCenter@allianceNCTN.org.