Alliance for Clinical Trials in Oncology
NEWS
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info@alliance-website.org

Alliance Membership Model, Governance Structure Now Set

The Alliance Transition Board of Directors recently approved amendments to the Alliance Constitution and Bylaws, including changes to the Alliance membership model and the structure of the Board of Directors.

Alliance Membership

To become a member of the Alliance, institutions must meet all requirements, including accrual, data quality and timeliness, adherence to Alliance policies and procedures, and participation in Alliance scientific activities.

The Alliance has two levels of institutional membership representing the magnitude of accrual credited to the Alliance. Main members are required to meet a level of accrual that is equal to or greater than 15 patient enrollments to treatment and cancer control studies per year, credited to the Alliance, and based on a three-year average accrual. Main members may have a network with affiliates and their accruals are combined to meet the network accrual requirement of 15 patient enrollments per year. Affiliate members are institutions that by themselves do not meet the requirements for main membership, but are granted membership by virtue of a formal association with a Main member institution. Affiliate members are required to have a three-year average accrual greater than or equal to five patient enrollments per year.

The Alliance Executive Committee has approved a partial accrual credit of 0.25 for ancillary non-treatment studies and substudies. Ancillary accruals would be added to the number of patient enrollments for evaluation of membership performance and institutional accrual ranking.

Each member institution will have a Principal Investigator, who is primarily responsible for any and all activities related to Alliance at the institution. Each Main member institution will also have a Co-Principal Investigator, who can assume responsibility in place of the Principal Investigator if for any reason the Principal Investigator is unable to perform duties required for Alliance institutional membership.

Application materials for the Alliance can be found on the Alliance web site at www.alliance-website.org, and questions can be directed to Marcia Kelly, Alliance Membership and Administrative Coordinator, by e-mail marciak@uchicago.edu or phone 773-834-7676.

Alliance Board of Directors

Selection of Alliance Board of Directors representatives shall primarily be based on institutional accrual performance. Each Main member institution that ranks among the top 40 institutions in total Alliance accrual by three-year rolling average shall designate

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Alliance Membership, Governance Structure

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one individual, who may be either the PI or a designated representative, who shall sit on the Board of Directors and have voting privileges. The remaining Main member institutions shall elect at-large individuals to sit on the Board of Directors for a three-year term and have voting privileges. The number of these individuals shall not exceed 20 percent of the total number of voting Board members (i.e., 10 elected representatives). PIs or designees of provisionary or probationary Main member institutions shall not sit on the Board of Directors, but may attend open sessions of Board meetings.

The members of the Executive Committee who are non-institutional Principal Investigators shall serve on the Board of Directors *ex officio*. Other *ex officio* members of the Board of Directors include former Group Chairs for Cancer and Leukemia Group B, the North Central Cancer Treatment Group, the American College of Surgeons Oncology Group, and the Alliance, and the current chairs of all modality committees of the Alliance. All *ex officio* members shall participate in Board of Directors meetings but shall have no vote.

The Board of Directors shall be responsible for final approval of overall policy for the Alliance; it shall elect the Group Chair and may recall the Group Chair; it shall elect and may revoke institutional membership; it shall receive reports from the Executive Committee; and it shall conduct other business as comes before it.

Alliance Membership and Governance Transition Plan

All active members of ACOSOG, CALGB and NCCTG are considered legacy members of the Alliance until the end of the transition period. To continue as members of the Alliance, institutions are required to submit an Alliance membership application. In order to be eligible for a seat on the first post-transition Alliance Board of Directors, institutions must submit an application by July 31, 2013. Upon review, the Membership Committee will make one of the following recommendations to the Board of Directors:

a. Approve Main institutional membership, without requirement for provisionary period;
b. Approve Main institutional membership, provisionary period required; or
c. Deny application for membership.

It is expected that all legacy members in good standing that apply for Alliance Main membership will be recommended for Main institutional membership without requirement for provisionary period.

Any legacy memberships that are not transitioned to Alliance memberships shall be inactivated following award of the new Alliance Cancer Therapy Evaluation Program (CTEP) grant in 2014.

The transition Board of Directors will remain in place until the November 2013 Alliance Group meeting. At the November 2013 meeting, the transition Board of Directors will approve a roster of main institutional members whose Principal Investigators or designated representatives will constitute a new Board of Directors for the Alliance from that time forward.

In determining eligibility for a voting seat on the Board of Directors, the Membership Committee and Transition Board of Directors will review the three-year time period September 1, 2010 – August 31, 2013. Patient enrollments credited to ACOSOG, CALGB and NCCTG during this time period will be included.

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Timeline

September 1, 2010

– Start of accrual evaluation period for Alliance institutional membership requirements and Alliance Board of Directors membership.

July 31, 2013

– Deadline for Alliance membership applications for legacy institutions wishing to be eligible for Alliance Board membership.

August 31, 2013

– End of accrual evaluation period for Alliance institutional membership requirements and Alliance Board of Directors membership.

September 2013

– Group Chair appoints Nominating Committee for Board elections.
– 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.
– 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 to the Alliance Board of Directors.
– Nominations and required documentation for institutional representatives wishing to run for election, due to Nominating Committee.

October 2013

– Nominating Committee selects and announces Board of Directors candidates.

November 2013

– Final Board meeting of Alliance Transition Board of Directors: Elect Board of Directors by secret ballot (representatives from main members not on Alliance Board by top 40 ranking). Approve Alliance Board of Directors representatives.

Questions?

For questions regarding the Alliance Membership and Governance Transition Plan, contact Trini Ajazi, Alliance Chief Administrative Officer, by e-mail tajazi@uhicago.edu or phone 773-702-8672.

Improving Outcomes for Brain Tumor Patients Key for Alliance Neuro-Oncology Committee

Evanthia Galanis, MD

The Alliance Neuro-Oncology Committee focuses on the development and conduct of clinical trials in order to improve the outcome of patients with brain tumors, including those with primary brain tumors such as gliomas, and metastatic disease to the brain. The committee's clinical portfolio includes both early phase and translational studies, and larger randomized phase II and phase III trials, to systematically evaluate rationally designed novel therapies, according to Evanthia Galanis, MD, Committee Chair, Professor of Oncology at the Mayo Clinic College of Medicine and Chair of the Department of Molecular Medicine. Committee Vice Chairs are Patrick Wen, MD, of Dana-Farber Cancer Center; Frederick Barker, II, MD, of Massachusetts General Hospital; Paul Brown, MD, of MD Anderson; and Jann Sarkaria, MD, of Mayo Clinic.

The committee's current clinical trials and studies in development focus on the testing of targeted agents to improve radiosensitization in patients with newly diagnosed glioblastoma multiforme, development of novel approaches for treatment of patients with recurrent glioma who have failed bevacizumab, and exploration of synergistic strategies to prevent the emergence of bevacizumab resistance. In addition, the committee is placing special emphasis on improving clinical trial methodology with the incorporation of innovative trial designs and the use of pooled database studies to validate glioma trial endpoints.

The committee is also working to advance the scientific understanding and treatment of brain tumors by identifying and validating prognostic and predictive markers of outcome. For example, the committee is leading a large international intergroup study that involves the selection of a treatment strategy in patients with high-grade glioma based on the presence of 1p and 19q co-deletion, a prognostic and predictive marker of outcome in these patients. In collaboration with Alliance Pathology and Imaging committees, correlative analyses in other ongoing trials aim to identify other new biologic and neuroimaging markers. The committee also aims to improve the quality of life for patients with brain tumors through a systematic validation of neurocognitive and quality of life instruments and exploration of their role as primary endpoints in clinical trials. This is being accomplished by close collaboration with the Alliance Cancer Control Program and its Health Outcome and Symptom Intervention committees.

The multidiscplinary nature of the committee comprises neurology, medical oncology, radiation oncology and neurosurgery representation. The committee's expertise is greatly strengthened by the interaction between neuro-oncology leaders from multiple centers in the Alliance, as well as the participation of community-based oncologists. The Neuropathology Core group, statistical team and Neuro-Imaging Core group also provide strong support. The committee has a strong "bench-to-bedside" trajectory founded on multiple interactions with basic research laboratories and close ties with three brain tumor Specialized Programs of Research Excellence (SPOREs) based on member institutions (Mayo Clinic, University of California,

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Alliance Clinical Research Professionals Ensure Successful, Quality Research

Kandie Dempsey, MS, RN

The Alliance is dedicated to developing and implementing training programs that will enhance the skills and abilities of Clinical Research Professionals (CRPs) involved in all aspects of data collection and research, according to Kandie Dempsey, MS, RN, OCN, Chair of the Alliance Clinical Research Professionals Committee, and Cancer Research Director at Delaware/Christiana Care CCOP. Training programs not only improve overall knowledge and professionalism, but also improve the quality of data integrity. The committee is a modality resource committee of the Alliance, and does not conduct research or sponsor protocols. However, it plays a critical role in educating Alliance CRPs regarding clinical research methods, Alliance policies and procedures, National Cancer Institute initiatives and Alliance scientific priorities and directions. Educational programs provided by this committee are a key underpinning of the success and quality of Alliance research.

Knowledgeable CRPs who are thoroughly trained in all aspects of clinical research enhance the conduct of clinical trials. CRP expertise promotes protocol adherence and tends to prevent protocol violations. The committee offers a variety of educational opportunities for CRPs to learn and exchange information contributing to professional growth, improving job satisfaction, and building fundamental skills for successful clinical research outcomes. Continuing education credits (CEUs) are typically provided for nurse attendees and most sessions are appropriate for obtaining credits through the Society of Clinical Research Associates (SoCRA). Alliance members are welcome and encouraged to attend the CRP offerings provided at each Group meeting. Listed below is a summary of current educational programs. Additional programs may be added as the committee matures and the Alliance evolves. The following sessions are generally available at the Alliance Group Meetings:

Clinical Research Professionals Information Meeting

The Clinical Research Professionals Information Meeting will be held at each Group Meeting. At these meetings, Alliance staff, including the chief administrative officer, protocol coordinators, the regulatory affairs manager and/or director, and web manager, present Alliance policies and procedures and other pertinent information to the CRPs. Liaisons from other committees, study chairs and statisticians may use this meeting to introduce new studies to the CRPs or to provide updates regarding accrual or data issues. Staff from the Statistics and Data Center relay new information about data collection, and clarify data and information systems issues. The remaining meeting time is used to provide information on topics of general interest to CRPs such as NCI initiatives, CTSU updates, ethics, institutional review board policies, and more. CRP members are encouraged to provide feedback at these interactive meetings. This meeting is typically offered on the Thursday preceding disease committee meetings from 1 p.m. and 5 p.m.

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Alliance Clinical Research Professionals

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Continuing Education Workshop for CRPs

The emphasis of the Continuing Education Workshop for CRPs is on progressive education and refinement of data management skills. This workshop will be held at each Alliance Group meeting and occasionally may be combined with the other Alliance committees such as the Oncology Nursing Committee, Pharmacy Committee or Cancer Control Program committees. Topics alternate between disease-specific presentations and administrative-related presentations. Alliance physicians may provide disease-specific scientific presentations about diagnosis and staging, new investigational agents and/or treatment modalities, as well as patient care implications, and laboratory techniques. CRP Committee members will also work closely with American College of Surgeons Clinical Research Program committees to coordinate the dissemination of information to the CRPs. Specific issues regarding data management of surgical studies may also be provided at this workshop to share information regarding surgical studies, and to identify and solve difficulties CRPs may encounter with surgical studies. This workshop is typically offered on the Friday preceding disease committee meetings from 8 a.m. to 12 p.m.

Audit Preparation Workshop

The Audit Preparation Workshop includes presentations by Audit Committee members. Topics presented include relevant elements from policy and procedures; IRB Documents and Informed Consent, Patient Case Records Review, Review of Accountability of Investigational Agents and Pharmacy Operations, and Responding to Your Audit Findings plus Preparing a Corrective Action Plan. This workshop is offered on an annual basis.

Society of Clinical Research Associates (SoCRA) Certification Exam

In addition to the formal sessions listed above, as a courtesy to Alliance members, the committee also organizes a Certified Clinical Research Professional certification examination. SoCRA administers the exam at each Group meeting. SoCRA established this statistically and psychometrically validated certification program for CRPs in order to create an internationally accepted standard of knowledge, education, and experience to be recognized by the health care research community. Those individuals so approved may use the title, "Certified Clinical Research Professional" or CCRP. This session is offered on the Thursday preceding disease committee meetings from 9 a.m. to 1 p.m. Individuals interested in attaining SoCRA certification would be required to contact SoCRA directly (http://www.socra.org/) to register for the exam and to learn more about the certification.

CRP Committee Membership

The committee provides liaisons to each Alliance disease and modality committee. CRP liaisons attend disease and modality committee meetings and are available to assist with protocol development and implementation. In addition to reviewing draft protocols, CRP liaisons evaluate new and revised data collection forms and instructions. The following is a list of CRPs, their liaison responsibilities and contact information.

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Clinical Research Professionals Committee

Committee Member	Institutional Affiliation	Committee Assigments	Phone Number	E-mail Address
Kandie Dempsey, MS, RN, OCN *Chair*	Delaware/Christiana Care CCOP, Newark, DE		302-623-4492	Kdempsey@christianacare.org
M. Cathie Smith, CCRP *Vice Chair*	Mayo Clinic, Jacksonville, FL		904-953-2865	smith.marycatherine@mayo.edu
Betsy M. Barnick	Carle Cancer Center, Urbana, IL	Symptom Intervention	217-383-6963	betsy.barnick@carle.com
Shar Allen, RN	Mayo Clinic, Rochester, MN	GI	507-538-1983	allen.sharlene@mayo.edu
Kathryn A. Dixon	St. Joseph Mercy Hospital, Ann Arbor, MI	Breast	734-712-8622	dixonka@trinity-health.org
Debra Herzan, RN, BSN, OCN, CCRP	University of Minnesota, Minneapolis, MN	GU, Respiratory	612-626-4495	herza001@umn.edu
Diana M. Kucmeroski	The University of Hawaii Cancer Center, Tripler Army Medical Center, Honolulu, HI	Health Outcomes	808-433-1951	diana.kucmeroski@amedd.army.mil
Andrea Medders, CCRC	Wichita CCOP, Wichita, KS		316-268-8627	andrea.medders@viachristi.org
Peg Reamer, RN, BSN	University of Pittsburgh, Pittsburgh, PA	Translational Research Program	412-623-3776	pmreamer@gmail.com
Maggie So, MPH, CCRP	Washington University School of Medicine, St. Louis, MO	Lymphoma, Transplant	314-747-4678	mso@dom.wustl.edu
Heather Sampson, RN, MHSc, CCRA, PhD candidate	University of Toronto, Ontario, Canada	Ethics	416-978-1911	Heather.sampson@utoronto.ca
Patricia Green Sharpe, RN, MSN, MHSA	Memorial Health University Medical Center, Savannah, GA	Radiation Oncology	912-350-7887	sharppa1@memorialhealth.com
Susan Tuttle, RN	Southeast Cancer Control Consortium, Inc., Winston-Salem, NC	Prevention, Cancer in the Elderly	336-777-3098	stuttle@wfubmc.edu
Linda Veit, CCRP, CCRA	SUNY Upstate Medical University, Syracuse, NY	Respiratory, ACS Clinical Research Program, Health Outcomes, Comparative Effectiveness Research	315-464-6303	veitl@upstate.edu

Alliance Neuro-Oncology Committee

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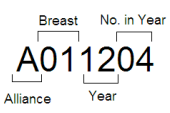
San Francisco, and MD Anderson). Partnerships with industry will allow further investigation of state-of-the-art therapeutic approaches, while collaborations with the Neuro-Oncology committees of the Radiation Therapy Oncology Group (RTOG), European Organisation for Research and Treatment of Cancer (EORTC), and American Brain Tumor Consortium (ABTC) will foster national and international collaborative initiatives.

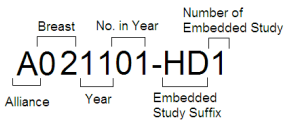
New Alliance Protocol Numbering System

A standard protocol numbering system has been established for Alliance studies based on work completed by the Alliance Protocol Numbering Working Group. The working group included members from all three legacy groups (ACOSOG, CALGB and NCCTG), and staff from the Alliance Statistics and Data Center ensured that Alliance systems could support the numbering system. The system was implemented in September 2011, and the first studies bearing this nomenclature will be activated soon.

How the System Works

The system is quite simple. When a concept is submitted for review to the Alliance Study Concept Review Committee (SCRC), a study ID is generated and assigned by the Alliance database. The working group used an an alphabetical and numerical system to identify study assignments. Committees are divided into three categories: disease, scientific discipline and Cancer Control Program (CCP). The committee number is assigned alphabetically within each group. The first character of the study ID is an A (to indicate "Alliance"), followed by two digits that indicate the committee associated with the protocol. The next two digits indicate the year the concept was introduced. The final two digits are assigned consecutively for that committee as concepts are submitted to the SCRC. Study suffixes based on the scientific discipline and CCP studies are added to the study number to show an embedded companion study.





The following tables list committees and their numbers, sample study numbers, and assigned protocol coordinators.

Alliance Disease Committees	Committee Number	Sample Study Number	Protocol Coordinator
Breast	A01	A011101	Heather Becker
Gastrointestinal	A02	A021101	Shivani Shah
Genitourinary	A03	A031101	John Taylor
Leukemia	A04	A041101	Michele Seiler
Lymphoma	A05	A051101	Morgen Alexander-Young
Myeloma	A06	A061101	Guadalupe Aquino
Neuro-Oncology	A07	A071101	Ellen Aiken
Respiratory	A08	A081101	Colleen Watt
Alliance Scientific Discipline Committees	**Committee Number**	**Sample Standalone Study Number**	**Protocol Coordinator**
Experimental Therapeutics	A09	A091101	
Imaging	A10	A101101	Morgan Alexander-Young
Leukemia Correlative Sciences	A11	A111101	Michele Seiler
Pathology	A12	A121101	Morgan Alexander-Young
Pharmacogenomics and Population Pharmacology	A13	A131101	Aimee Farrell
Radiation Oncology	A14	A141101	Ellen Aiken
Solid Tumor Correlative Sciences	A15	A151101	Aimee Farrell Guadalupe Aquino
Transplant	A16	A161101	Morgen Alexander-Young
Alliance Cancer Control Program	**Committee Number**	**Sample Standalone Study Number**	**Protocol Coordinator**
Cancer in the Elderly	A17	A171101	Lynn Flickinger Sanna McKinzie Brandon Messmer Jennifer Sickle
Comparative Effectiveness Research	A18	A181101	
Health Disparities	A19	A191101	
Health Outcomes	A20	A201101	
Prevention	A21	A211101	
Symptom Intervention	A22	A221101	

To more easily connect any embedded companion trial with a treatment study, a two letter and number extension is added. So, "A021101-ST1" is a solid tumor correlative sciences embedded companion study that appears in study A021101. If more than one type of embedded companion is included in the treatment or intervention study, then sequential numbers are assigned (i.e., A021101-ST2, A021101-ST3, etc).

Committee	Embedded Study Suffix	Sample Study Number
Health Disparities	HD	A021101-HD1
Health Outcomes	HO	A021101-HO1
Prevention	PR	A021101-PR1
Symptom Intervention	SI	A021101-SI1
Imaging	IM	A021101-IM1
Leukemia Correlative Sciences	LC	A041101-LC1
Pathology	PA	A021101-PA1
Pharmacogenomics and Population Pharmacology	PP	A041101-PP1
Solid Tumor Correlative Sciences	ST	A021101-ST1

Call for Photos! >>> New Alliance Web Site

The new Alliance web site is currently under development. We would like to highlight pictures of our members and institutions in action on the web site. Send in your photos for consideration with a confirmation that all individuals have given their consent for web posting by May 14, 2012 to Jamilah Owens at jowens@uchicago.edu. Also, make sure to include a caption with the location, date, and names of individuals in the photos.

Future Meeting Dates

2012 Group Meeting
Open to all Alliance members
June 28-30, 2012
InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018
**Registration is now open; visit the Alliance web site for more information*

2012 Fall Committee Meetings
Open to Alliance committee members only
November 15-17, 2012
InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018
**Draft meeting schedule now available on the Alliance web site*

2013 Committee Meetings
Open to Alliance committee members only
March 14-17, 2013
InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018
**Breast Committee will meet on Sunday, March 17*

2013 Group Meeting
Open to all Alliance members
November 7-9, 2013
InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018

2014 Committee Meetings
Open to Alliance committee members only
March 27-29, 2014
InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018

2014 Group Meeting
Open to all Alliance members
November 6-8, 2014
InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018

For meeting and travel queries, contact Katherine Faherty
phone: 617-525-3022
e-mail: kefaherty@partners.org

For more information on the Alliance and updates to meeting information, visit www.alliance-website.org