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| Policy Name: Specific Aims | Policy Number: 1.1 |
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1 Introduction

The Alliance for Clinical Trials in Oncology (Alliance) was created in July 2011 by the merger of three National Cancer Institute (NCI) funded cancer cooperative groups: American College of Surgeons Oncology Group (ACOSOG), Cancer and Leukemia Group B (CALGB), and North Central Cancer Treatment Group (NCCTG). Per the Alliance Constitution, the missions of the three component cooperative groups were joined in the new **vision statement**:

“To reduce the impact of cancer on people by uniting a broad community of scientists and clinicians from many disciplines, committed to discovering, validating and disseminating effective strategies for the prevention and treatment of cancer.”

The Alliance receives grant funding from the National Cancer Institute (NCI). The Alliance is one of the Network Groups for the NCI National Clinical Trials Network (NCTN) and serves as a research base for the NCI Community Oncology Research Program (NCORP). The Alliance complies with the NCTN and NCORP Program Guidelines, related NCI policies and procedures and the Code of Federal Regulations (CFR). As an NCTN and NCORP Group, the Alliance utilizes centralized NCI systems for the management of clinical trials.

1.1 Specific aims

The Alliance is founded upon more than 60 years of cooperative group experience, but re-designed to meet the current challenges of cancer clinical and translational research. The Alliance is an experienced multi-institutional cancer clinical trials group that 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.

As an integral component of the National Clinical Trials Network (NCTN), the Alliance has the leadership, experience, infrastructure, and member commitment required to achieve the scientific, operational, and collaborative aims outlined below.

1.1.1 Scientific aims

Alliance scientific programs conduct trials of highest possible clinical and translational impact that define new standards of care for patients with cancer. Programs have the following specific aims:

1. To conduct multimodality studies of adult cancers that include novel approaches to treatment and evaluation of patient outcomes based upon improved understanding of the molecular pathogenesis of these diseases

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2. To develop treatments specific for molecularly defined disease subsets
3. To develop and implement novel clinical trial designs that facilitate evaluation of target-directed therapies
4. To introduce imaging response as a biomarker to direct therapy
5. To improve treatment outcomes by studying psychosocial adaptation to cancer, symptom management, and cancer survivorship
6. To study the unique therapeutic, psychosocial, economic, functional, and biological features of cancer in special populations including those with rare tumors, the elderly, underrepresented minorities, and those who are economically disadvantaged

1.1.2 Operational aims

The infrastructure of the three component cooperative groups has been merged into a single, fully integrated system that is optimally designed to serve the NCTN and NCORP research community. The Alliance operations units have the following specific aims:

1. To support a broadly based institutional member research network that includes a balance of academic and community researchers of all disciplines who are committed to conducting high impact cancer clinical trials
2. To provide operational capabilities for clinical and translational trials that are efficient, innovative, and make maximal use of available resources to achieve accurate and timely clinical trials results
3. To maintain responsible stewardship of important public resources, including clinical trials data and outcome-linked biospecimens, so that these can be used to conduct the best possible cancer treatment discovery and biomarker validation research
4. To train the next generation of investigators to meet the continuing challenges of cancer clinical and translational research

1.1.3 Collaborative aims

The Alliance is committed to collaborating with the NCI and all NCTN members to achieve the overall goals of the NCTN. Specific aims for collaboration include the following:

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1. To participate to the fullest possible extent in clinical trials planning and management committees convened by the NCI including the Disease/Modality Specific Steering Committees, the Group Banking Committee, and other planning groups
2. To collaborate with other network groups, cancer centers, Specialized Programs of Research Excellence (SPOREs), and selected organizations outside of the NCTN to optimally leverage available resources to achieve NCTN scientific objectives
3. To promote accrual to all NCTN trials among its institutional members
4. To practice responsible resource sharing in order to achieve the goals of the NCTN as a whole.

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1.2 Overview of program structure

As outlined in the Alliance Constitution and Bylaws, the primary governance body of the Alliance is the Board of Directors, which represents the group’s institutional members. The Alliance is led by the group chair with assistance from the group vice chair. The Alliance is also supported by five program directors/principal investigators, each responsible for a specific program integrating discipline-related science and operational functions across all disease committees. The Executive Committee represents the Board of Directors and assists the group chair in planning and coordinating group activities.

The Alliance structure is disease-centered, with multi-modality involvement and significant input from both academic- and community-based researchers, full involvement of patient advocates, and routine participation of mentored junior investigators (see [table 1-1](#)). The group chair is responsible for the conduct and quality of scientific activities and efficient operation of the Alliance, represents the Alliance in its business with the NCI and other parties, and serves as the spokesperson for Alliance. The group chair directs eight multidisciplinary disease committees and six modality committees, and is responsible for central administration, finance, quality assurance and membership services.

Table 1-1. Alliance program structure

| | Office of the Group Chair | | Programs | | | | |
|------------------------------|--|--|--|---|---|--|--|
| | | | Statistics and Data Management | Central Protocol Operations | Translational Research | Cancer Control | ACS Clinical Research |
| Operations Units | <ul style="list-style-type: none"> Group Administration Finance Membership Services | | <ul style="list-style-type: none"> Data Management Systems Management Information Systems | <ul style="list-style-type: none"> Protocol Office | <ul style="list-style-type: none"> Integrated Biorepositories | <ul style="list-style-type: none"> NCORP Research Base | <ul style="list-style-type: none"> Commission on Cancer National Cancer Database |
| Scientific Committees | <ul style="list-style-type: none"> Breast Experimental Therapeutics and Rare Tumors Gastrointestinal Genitourinary Leukemia Lymphoma Myeloma Neuro-oncology Respiratory | <ul style="list-style-type: none"> Clinical Research Professionals Oncology Nursing Patient Advocate Radiation Oncology Transplant Young Investigators | <ul style="list-style-type: none"> Biostatistics Bioinformatics | <ul style="list-style-type: none"> | <ul style="list-style-type: none"> Leukemia Correlative Sciences Imaging Pharmacogenomics & Population Pharmacology Pathology Sequencing | <ul style="list-style-type: none"> Cancer in the Elderly Health Disparities Health Outcomes Prevention Community Oncology Symptom Intervention | <ul style="list-style-type: none"> Cancer Care Standards Development Cancer Care Delivery Research Dissemination & Implementation |

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| Administrative Committees | <ul style="list-style-type: none"> • Audit • Conflict of Interest • Constitution • Data and Safety Monitoring • Ethics | <ul style="list-style-type: none"> • Institutional Performance Evaluation • Membership • Pharmacy • Publications | | | <ul style="list-style-type: none"> • Karyotype Review • Biorepository | | <ul style="list-style-type: none"> • Education |
| | | | | | | | |

In addition to the traditional modalities of surgery, radiation oncology, medical oncology, pathology and biostatistics, Alliance research is enriched by involvement of patient advocates, oncology nurses, community oncologists, and specialists in imaging, laboratory medicine, information technology, bioinformatics, outcomes and comparative effectiveness research, research ethics, and disparities research. In order to productively manage this deep scientific scope, Alliance uses a program approach that provides a structure to support researcher involvement and innovation in these many fields, yet maintains operational efficiency.

The Alliance includes five programs, each led by an Alliance program director who operates under the direction of the Group Chair to manage scientific, administrative, and operational activities of the group (see [figure 1-1](#)). Specifically, each program includes an operational unit and one or more scientific or administrative committees that report directly to the program director. Each program effectively interacts with the disease committees, and the program director is responsible for ensuring optimal integration of their program’s activities into study development and execution. For example, each disease committee requires the involvement of biostatistics (Statistics and Data Management Program), protocol development and study concept review (Central Protocol Operations Program), biomarker development and biorepository support (Translational Research Program), and cancer control research and community oncology participation (Cancer Control Program). The fifth program, the American College of Surgeons Clinical Research Program, provides an interface between the Alliance and the American College of Surgeons (ACS), a >75,000 member

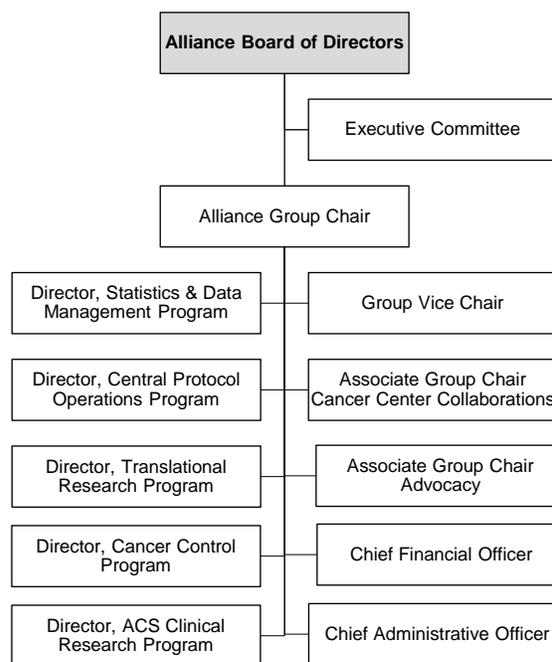


Figure 1-1. Alliance leadership

and the American College of Surgeons (ACS), a >75,000 member

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professional organization that has led cancer care and research programs since its inception in 1913. The program-based structure of the Alliance is an innovative approach to management of cooperative group research. The Alliance programs create an interactive environment that fosters integration across disciplines and operational units, and has proved to be a highly effective structure for maximizing efficiency.

1.2.1 Office of the Group Chair

The Office of the Group Chair is responsible for administrative and fiscal affairs. This includes support for scientific leadership, administrative committees, membership services, regulatory compliance/audits, travel, meetings, financial services and grants administration. The Office of the Group Chair coordinates a per-case payment program, using funds provided by the NCI and other federal agencies, to defray the costs incurred by institutions in treating and following patients on the group’s clinical trials. The Office of the Group Chair is the communications hub of the Alliance, providing regular distribution of information essential for the conduct of group business to participating members, NCI, regulatory agencies (e.g., Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), Institutional Review Board (IRB)), other NCTN groups and the general public. The office organizes all group meetings, coordinates communications, education and training, maintains the [Alliance website](#), and produces a variety of publications, including a monthly newsletter.

In addition to the group chair, three senior leaders provide support to Alliance members through this office (see [figure 1-1](#)). The group vice chair stands in for the group chair for any responsibility within the Office of the Group Chair. The associate group chair for Cancer Center Collaborations ensures that



Figure 1-2. Office of the Group Chair

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Alliance research is optimally linked to cancer center clinical and translational programs. The associate group chair for Advocacy promotes patient advocacy initiatives.

Staff working within the Office of the Group Chair are located at Brigham and Women’s Hospital in Boston, MA, University of Chicago in Chicago, IL, and Duke University in Durham, NC. The CAO, CFO and the group vice chair share responsibility for overseeing the operational functions of the Office of the Group Chair. The CAO oversees administrative operations including grant preparation, communications, education and training, member roster tracking, audit and regulatory compliance monitoring, and other member services activities [Figure 1-2](#) illustrates the administrative, financial, and regulatory operations staff and their areas of responsibility.

1.2.2 Statistics and Data Management Program

The Alliance Statistics and Data Management Program, also referred to as the Statistics and Data Center (SDC), supports the activities of the group by achieving the highest standards for the conduct of clinical trials in terms of study design, statistical methodology, data management, protection of patients and their data, and regulatory compliance. The SDC also strives to continually improve the efficiency of Alliance systems and processes.

Two scientific committees, Biostatistics and Bioinformatics, serve as core resources for Alliance investigators at all stages of the study process from design to analysis and reporting. These scientific teams are also responsible for developing innovative statistical designs to improve the efficiency and reliability of Alliance trials.

In addition to its scientific committees, the Alliance SDC houses key operational functions for data management, study monitoring, and information systems. The SDC is primarily located at the Mayo Clinic in Rochester, MN with additional statistical staff at other locations. The leadership at each site works collaboratively to ensure optimal collaboration with Alliance investigators. [Figure 1-3](#) illustrates the SDC senior leadership roles.

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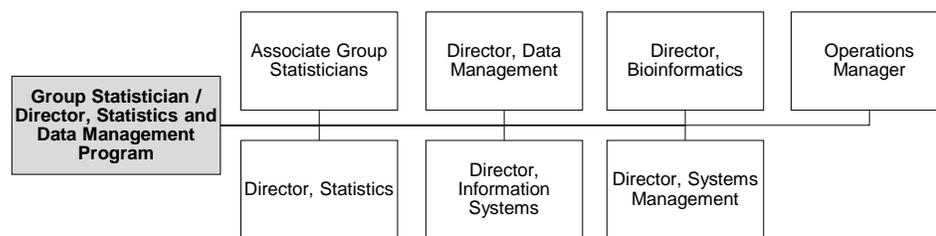


Figure 1-3. Statistics and Data Management Program

1.2.3 Central Protocol Operations Program

The Central Protocol Operations Program oversees the development and maintenance of all study protocols generated by Alliance scientific committees. Staff members manage the complex process of study protocol development, including scientific team coordination, study concept review and prioritization, including collaboration with the Translational Research Program (TRP) for their scientific review, NCI submission, protocol document development and maintenance, study budgeting, and coordination of study-specific logistics such as biomarker study funding (including collaboration with TRP to prepare BIQSFP applications), pharmaceutical and regulatory affairs (e.g., drug distribution and IND reporting), other regulatory logistics (e.g., NCI CIRB submission and credentialing) and implementation of accrual management plans. This process adheres to NCI Operational Efficiency Working Group (OEWG) timelines, which are carefully monitored by Protocol Operations Office staff. The Protocol Office also distributes protocols to sites and serves as focal point of communication for both study chairs and investigators throughout Alliance member institutions.

Once a protocol is activated, Protocol Office staff implement protocol amendments and other protocol communications, maintain all regulatory

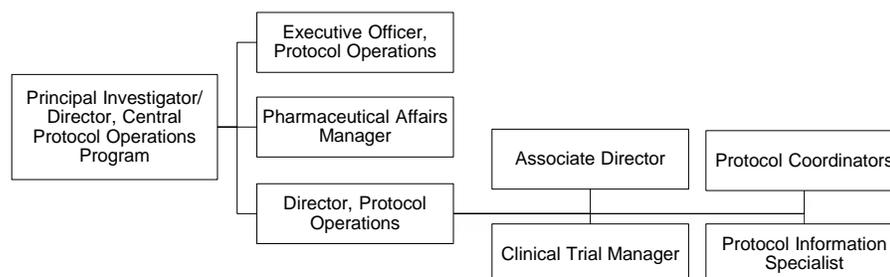


Figure 1-4. Central Protocol Operations Program

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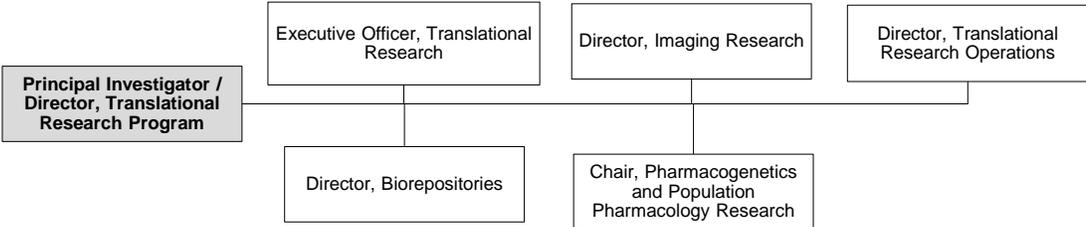
support documentation, and serve on numerous NCI committees that work to improve the cooperative group process. The Central Protocol Operations Program represents the interests of the group in many study-specific negotiations with the NCI, pharmaceutical firms, other network groups, international collaborators, and the public. [Figure 1-4](#) illustrates the Protocol Office staff and their areas of responsibility.

1.2.4 Translational Research Program (TRP)

With the advent of molecularly driven oncology, the Translational Research Program is essential for the development and execution of trials performed by each Alliance disease and modality committee. The TRP facilitates the scientific agenda by supporting the basic and translational researchers who work within Alliance committees. The TRP director, in collaboration with the chairs of disease committees, names a translational research leader for each disease. These individuals work within the TRP to ensure optimal integration of translational endpoints into Alliance trials. These researchers also promote successful collaboration between Alliance committees and researchers within Specialized Programs of Research Excellence (SPOREs), cancer centers, and other research groups. In addition, discipline committees within the TRP, such as Pharmacogenomics and Population Pharmacology, Imaging, and Pathology provide both scientific input and operational support for Alliance translational research. [Figure 1-5](#) illustrates the TRP senior leadership roles.

A key TRP operational component involves management of tissue resources collected during Alliance clinical trials. The TRP coordinates the Alliance Integrated Biorepositories, an operations unit with locations at The Ohio State University, Washington University Medical Center, the Mayo Clinic, and Brigham and Women’s Hospital. The TRP also manages a network of Molecular Reference Laboratories that provide specialty biospecimen services that are required for Alliance research protocols.

Figure 1-5. Translational Research Program



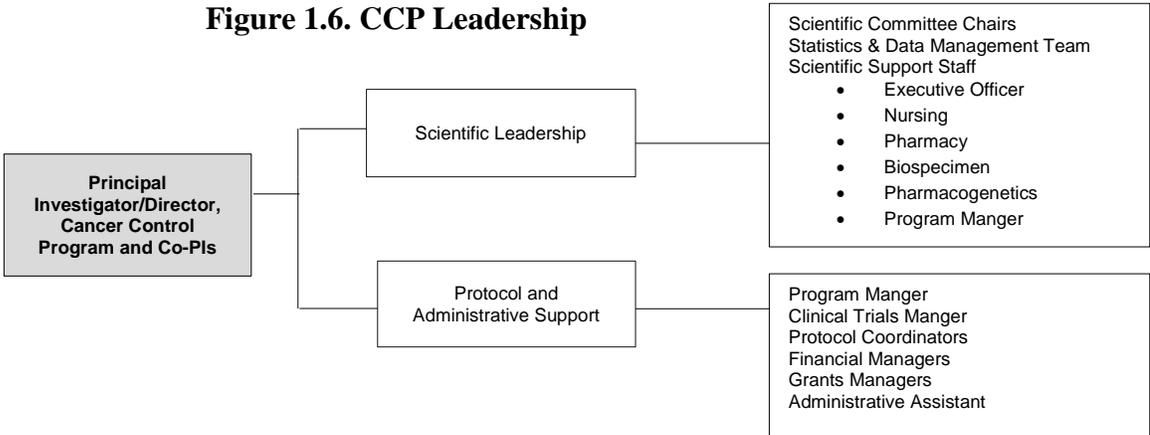
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1.2.5 Cancer Control Program

Research in cancer control is integrated throughout the scientific programs and operations of the Alliance. The Cancer Control Program serves as the research base for the NCI Community Research Oncology Program (NCORP), as well as non-NCORP community oncology members. There are five scientific domains of the Cancer Control Program (CCP): Cancer Prevention, Symptom Intervention, Health Outcomes, Cancer in the Elderly, and Health Disparities. The Office of Director for Cancer Control oversees administrative components of the Cancer Control Program, including Leadership, Community Oncology Membership Services (including the Community Oncology Committee), Administrative/ Operations, and Pilot Projects/Consulting. Research conducted by the scientific committees of the Cancer Control Program is integrated with the Alliance disease committees and TRP so that each Alliance treatment study can be leveraged as appropriate to include cancer control endpoints. This integration occurs by placement of cancer control researchers and community oncology members in disease and modality committees. In addition, a leadership team reviews each Alliance trial concept for opportunities to contribute to cancer control research.

The activities of the Cancer Control Program are central to the work of the Alliance. In particular, the Cancer in the Elderly, Health Disparities, and Health Outcomes Committees are essential for achieving the goals of the cancer treatment trials program. Figure 1.6 illustrates CCP leadership roles. In addition, the Community Oncology Committee is responsible for ensuring participation by community oncology leaders in treatment trial and translational research study design and execution. A community oncology co-chair is required for every protocol.

Figure 1.6. CCP Leadership



1.2.5.1 NCORP Specific Aims

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The overarching aim of the Alliance National Cancer Institute Community Oncology Research Program (NCORP) Research Base is to reduce the burden of cancer by conducting high-quality multidisciplinary, multi-site interventional and observational clinical trials, as well as database analyses. The NCORP places special emphasis upon issues affecting minority, underserved and elderly patient groups, and upon building strong collegial relationships with NCORP Community sites and Minority/Underserved Community sites. There are three specific aims within the overall research base:

1. To reduce the incidence and prevalence of clinically significant cancers

In support of aim 1, NCORP will reduce the incidence and prevalence of clinically significant cancers by a) identifying patients at greatest risk for developing specific cancers, b) screening those patients to detect early stage disease amenable to curative therapies, c) employing effective pharmaceutical interventions in at risk patients, and d) developing effective strategies to reduce individual behaviors that increase cancer risk. NCORP will also develop strategies to identify pre-symptomatic recurrent cancers in patients with a prior diagnosis of cancer, and who were previously treated with curative intent, in order to intervene with potentially curative therapies.

2. To alleviate the symptoms of cancer and the toxicities of cancer treatment, and

In support of aim 2, NCORP will alleviate the symptoms of cancer and the toxicities of cancer treatment by a) understanding the pathophysiology and natural history of untoward symptoms associated with cancer and/or cancer therapy, b) identifying factors that increase patient risk for these symptoms, and c) finding effective strategies for the prevention and treatment of such symptoms.

3. To improve the delivery of cancer care in community and academic practices.

In support of aim 3, to improve the delivery of cancer care in community and academic practices, NCORP will focus upon three strategies; a) patient-centered outcomes and

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comparative effectiveness research, b) cancer economics, and c) systems redesign and organizational change.

To support each of these three primary aims, NCORP will conduct health outcomes research to improve understanding of the patient experience with disease, treatment, and survivorship. To achieve this mission, four research priorities were identified: a) to embed patient-reported outcomes (PROs) in Alliance clinical trials; b) to conduct primary PRO methodology research; c) to study relationships of genetic/biological mechanisms with PROs; and d) to evaluate the use of PROs to improve care delivery and quality.

NCORP will also identify and intervene to eliminate disparities in cancer incidence, morbidity, mortality, and clinical trial participation among underserved and minority populations. Strategies to reduce disparities are: a) to conduct stand alone and companion trials to assess and/or intervene to improve health disparities; b) to examine existing data in the Alliance to assess and/or monitor disparities among populations that experience disparities; c) to provide education, strategies on, and monitoring of accrual of underserved and minority populations to Alliance studies; and d) to integrate relevant community members and providers into the Alliance to facilitate identification of eligible populations, health disparities, and solutions to address disparities in cancer outcomes.

Finally, in support of each specific aim, NCORP will a) address treatment issues including efficacy among older cancer patients, b) improve quality of life and maintain and/or improve function among older cancer patients; and c) assess the role and potential value of geriatric assessment tools in cooperative group trials and to develop models for predicting toxicity and functional decline.

1.2.6 American College of Surgeons Clinical Research Program

The American College of Surgeons (ACS) has long-standing programs that define and improve the quality of cancer care. ACS is the parent organization of the Commission on Cancer (CoC), a consortium of professional societies that improves survival and quality of life for cancer patients through standard-setting, prevention, research, education, and the monitoring of quality care. ACS is also the sponsor of the National Cancer Database (NCDB), a joint program of CoC and the American Cancer Society. CoC develops and disseminates cancer care standards and tracks quality metrics to improve patient outcomes. One of the most important CoC quality metrics is participation in clinical trials, and each of the more than 1500 CoC sites across the United States has a clinical trials participation target of at least 5% of its cancer patients.

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The mission of the Alliance/American College of Surgeons Clinical Research Program (ACS CRP) is to reduce the impact of cancer by increasing knowledge and awareness of new evidence and practice standards; increase the participation of community oncology surgeons in cancer research and cancer care activities; develop and implement evidence-based practices in surgical oncology; and create opportunities for meaningful health services research. The program has four committees that have unique goals and activities and that work together to reach the program's overall research goals. These committees include the Education Committee, Dissemination & Implementation Committee, Cancer Care Standards Development Committee, and Cancer Care Delivery Research Committee. The ACS CRP shares responsibility with the Alliance, ACS and the CoC for developing surgical standards for use in Alliance clinical trial protocols and CoC accreditation as well as for disseminating new evidence-based knowledge.

1.2.7 Member institutions

Membership in a network group is required for enrollment of patients on group protocols. Alliance member networks may be Lead Academic Participating Sites (LAPS) or NCORP networks. LAPS and NCORP institutional networks receive grants from the NCI to support their infrastructure and participation in NCI-funded clinical trials. Non-LAPS and non-NCORP institutions receive per-case payments from the Alliance NCI-grants to support their clinical trial participation.

A principal investigator and a co-principal investigator, who are responsible for managing the site according to all Alliance and NCTN policies, lead Alliance member institutions. Membership evaluation involves assessment of each site's past clinical trials accrual and audit history, and requires that each potential member agree to adhere to the policies and procedures of the Alliance.

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1.3 Committees

Alliance organizational structure, as defined in its Constitution and Bylaws, calls for its research agenda to be driven by a number of scientific committees, whose activities are supported by administrative committees with research infrastructure needs executed by operations units. Alliance is a large and diverse organization, working across many institutions. To permit optimal leadership and accountability, the group is structured into programs (see [section 1.2](#)). The assignment of Alliance committees and operations units to the group chair and to the programs is shown in [table 1-1](#).

1.3.1 Scientific committees

Alliance trials are conducted by scientific committees of two types: disease committees and modality/discipline committees. Disease committees serve as the primary site of study concept generation. Modality/discipline committees foster cross-disease participation of a modality or discipline in Alliance research. Scientific committee chairs are either proposed by the group chair or, for those committees within Alliance programs, are nominated by the appropriate program director. The Alliance Executive Committee approves all chair appointments. Each scientific committee chair names several vice chairs, who are also approved by the Executive Committee. Committee members are appointed by the committee chair with input from the vice chairs and from modality/discipline committee leaders.

Diversity of leadership and membership is built into the scientific committee structure. The committee leadership (chair plus several vice chairs) must include representatives from medical oncology, surgical oncology (for solid tumor committees), radiation oncology, translational research, and transplantation (leukemia and myeloma committees). Alliance disease committees include, at a minimum, two representatives each from the disciplines of medical oncology, surgical oncology (solid tumor committees), translational research, radiation therapy, community oncology practices and young investigators (those within five years of fellowship completion), as well as patient advocates and liaisons from Cancer Control committees, as applicable.

Alliance research is supported by a number of committees that ensure participation of essential modalities and disciplines in trial design and execution. As cancer research has become more complex and specialized, the number and variety of these committees has increased. Several committees play important roles in designing and executing Alliance trials. Some modality/discipline committees, however, are not sites of study concept development, but instead provide focal points for member involvement,

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enable collaboration and increase the impact of Alliance trials by promoting interactions with key member groups.

1.3.2 Administrative committees

Administrative committees conduct business as required to ensure the effective and ethical operation of the Alliance. Administrative committees reporting directly to the Board of Directors include the following: Membership, Institutional Performance Evaluation, Audit, and Constitution and Bylaws. The chairs of each of these committees are proposed by the group chair, and approved by the Board of Directors. Administrative committees reporting directly to the Executive Committee include: Data and Safety Monitoring Board, Conflict of Interest, and Publications.