

The Georgia Center for Oncology Research and Education:

Background and History

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The Georgia Center for Oncology Research and Education (Georgia CORE) is a novel collaboration of clinicians, scientists, educators, public health practitioners and those affected by cancer. Created to improve the quality of cancer care in Georgia through clinical cancer research, Georgia CORE is governed by a voluntary Board of Directors comprised of physicians and cancer researchers representing leading oncology practices and the state's four medical schools. The organization's business plan calls for increasing awareness of clinical research, developing a research network and expanding access to and availability of clinical trials with a particular focus on minorities and the underserved. These goals are accomplished through a collaborative process which engages leading oncologists, establishes linkages with academic scientists, educators and public health practitioners and brokers relationships with industry, government and private funders.

When Georgia CORE was conceived in 2002, the State of Georgia was fighting to counteract a general perception that "better cancer care was available elsewhere." Each neighboring state boasted at least one NCI-designated Comprehensive Cancer Center while Georgia had none. Cancer patients with computers, medical insurance and travel funds demonstrated effectively that access to research contributed significantly to their

treatment decision-making. In record numbers, Georgians sought second opinions, if not care, in states with leading cancer research centers.

In this climate then-Governor Roy Barnes unveiled a bold initiative to channel a portion of the state's tobacco settlement funds into the newly formed Georgia Cancer Coalition (GCC.) The new entity's goal was to make Georgia a national leader in cancer while saving lives lost to the disease. One of the Governor's most emphatic demands was that no Georgian should leave the state to obtain quality cancer care.

The directive of the Governor combined with the increasing awareness of the relationship between research and quality proved powerful motivators for the Georgia Cancer Coalition. The GCC joined with the Georgia Chapter of the American Society of Clinical Oncology (GASCO), the American Society of Clinical Oncology (ASCO), the American Cancer Society and the Oncology Nursing Foundation to develop a business plan for a model statewide research network.

Based on interviews and focus groups conducted across the state, a business plan was developed for the Georgia Center for Oncology Research and Education. The plan called for creation of a non-profit organization whose purpose was "to improve access, entry, conduct and outcomes of cancer control and therapeutic clinical trials for Georgia residents." Full implementation of the plan was estimated at \$7.1 million and relied largely on investments from the pharmaceutical industry and grants from the GCC. The plan was presented for review and comment at a conference late in 2002. It was received with wide-spread affirmation from physicians, care providers, educators and scientists.

Clearly, the creation of Georgia CORE was stimulated by the leadership of a visionary Governor, the availability of funding from the tobacco settlement, the

establishment of the Georgia Cancer Coalition and the endorsement of key stakeholders. But the plan was both so detailed and comprehensive that the Board had a challenging time determining how to begin the implementation phase. Prospective partners had some difficulty identifying where their contemplated investments could have the most impact. In the absence of a full-time leader, the Board was stymied. As a result, it was two+ years between the introduction of the plan and implementation – and, predictably, the external environment altered significantly during this period. Awareness of Georgia’s clinical research ‘deficit’ stimulated a natural expansion in clinical trials activity. The Winship Cancer Institute at Emory University received a planning grant for an NCI-funded Comprehensive Cancer Center which would correct an obvious infrastructure defect. The GCC rolled out its initiatives: to recruit Distinguished Cancer Clinicians and Scientists to the State, establish a bio-repository for serum and tissue banking and support development of Regional Cancer Coalitions. The Robert W. Woodruff Foundation also provided funding for an Institute of Medicine analysis of metrics for measurement of quality cancer outcomes.

While each of these developments stimulated cancer research and quality, they were not operating under the banner of Georgia CORE as its founders had envisioned. More troubling were changes in regulations and reimbursement which impacted the formative organization’s potential to secure funding and attract partners. The pharmaceutical industry’s methods of funding providers was first curtailed and then revamped. Soon after, reductions in Medicare reimbursement to oncologists provided a ‘direct hit’ to practices which were then reluctant to take on additional unfunded research activities.

The Board struggled to find its niche in this changing environment. Ultimately a streamlined “value proposition” (graphic attached) was developed with the newly engaged CEO which placed a priority on involving oncologists and providing programs they determined to be of value. In order to be successful, the Board agreed to scale down its original expectations and prioritize goals. The Board identified key opportunities for programmatic success which would provide value to oncology practices, increase visibility of academic and community investigators and develop new research opportunities while establishing the presence and credibility of Georgia CORE. The Board remained committed to collaboration with founding partners and sought new ways to engage related GCC initiatives, industry partners, academic centers, hospitals, multi-disciplinary health care providers and survivors.

Georgia CORE became fully operational in 2005 with the opening of offices donated by the Georgia Cancer Coalition and the leadership of the Board combined with a small group of staff, interns and consultants. The organization focused on three key areas:

Enhancing awareness about clinical cancer research and its impact on quality;

Creating a cancer research network;

Increasing access to and availability of clinical trials.

With this simplified plan and a staff committed to execution, Georgia CORE promptly secured a multi-year commitment of \$2.5 million from the Georgia Cancer Coalition which required a 1:1 match of earned income, grants and gifts in kind.

Additional start up funding was provided by the Georgia Society of Clinical Oncology, Siemens Medical Solutions, the Oncology Nursing Society and the Schools of Medicine

at Emory University, the Medical College of Georgia and Mercer University. Industry sponsorship for clinical trials and educational programs was readily made available.

In the intervening two years, Georgia CORE has achieved significant results in all three of its priority areas. Public relations and educational programs have increased awareness of cancer research, the role of oncologists in clinical trials and the mission of Georgia CORE. Media coverage, requests for speaking engagements, web site activity, attendance at educational programs, office call volume and number of contract negotiations are used to benchmark progress in this arena. The central message that clinical cancer research is crucial to providing Georgians with the best available cancer treatment is delivered consistently.

The research network began with master contractual agreements between Georgia CORE and six private practices comprised of 46 oncologists. Since that time, contracts have been negotiated covering 178 (more than half) of the adult oncologists in Georgia. In addition, agreements are in place with industry sponsors of Georgia CORE investigator initiated trials, the NCI-sponsored Gynecologic Oncology Group as well as with medical schools and health care systems and across the state. Contract negotiations continue and the organization anticipates having 75% coverage of adult oncologists during 2008. Georgia CORE has established a contracting mechanism (graphic attached) which provides for the statewide introduction of investigator initiated trials. This is highly valued by community oncologists, academic centers and industry.

Multidisciplinary groups of oncologists, scientists, clinical research associates, nurses and educators have been established to develop and initiate clinical trials through working groups. This approach is deemed to be more effective at achieving a balance

between scientific interest and clinical relevance in research design. It also stimulates intellectual engagement and shared ownership of both the network and research initiatives. Effectiveness is gauged by evaluations of members who prioritize research concepts and programs. Rankings determine which concepts will receive the sponsorship necessary for further development.

Research education programs are offered which include annual principal investigator training, quarterly continuing education for investigators and research associates, and semi-annual intensives for new clinical research associates. Briefing papers and newsletters on Georgia specific issues are distributed to members of the research network. Attendance at Georgia CORE programs, results of program evaluations, requests for publications and educational materials, number of contract negotiations and geographic coverage of the research network are used to assess impact.

In the Summer of 2008, the first edition of The Georgia CORE Directory was published. This is a unique source of information on over 535 adult and pediatric oncologists in Georgia, their contact information and practice locations, educational backgrounds, research interests and network affiliations. It also contains complementary profiles of selected clinical trials leaders from nursing, pharmacy, bio-statistics and public health and provides information on the distribution of clinical trials, research sites, oncologists, research institutes and cancer centers in Georgia.

Increasing access to clinical trials began by developing a searchable database of cancer clinical trials offered throughout the state in partnership with the Coalition of Cancer Cooperative Groups. The database called Georgia Cancer Trials (www.georgiacancertrials.org) is web-based and is developed from both downloads of

national registries and information provided by members of the research network. Initial scrutiny of national registries found them less effective for patient decision-making and referrals for trials because they did not consistently include the names of local sites where trials were open and they frequently included trials that had been closed at the local site. Survivors, advocates and clinical research associates provided input on their needs for access to information on clinical trials. As a result, Georgia CORE established a mechanism for augmenting the title, protocol ID, sponsor and description available via the national registries with regular updates provided by members of the research network. The result is more complete, reliable and timely information on clinical trials offered in Georgia.

Over a two year period the number of trials captured in Georgia Cancer Trials has doubled and searches have more than quadrupled. Currently there are 386 adult cancer trials offered in 53 research sites in 27 cities across the state. 59% are in the Atlanta area and 78% of the trials are in community practices.

Plans are underway to enhance Georgia Cancer Trials by integrating the clinical trials database with The Georgia CORE Directory. The new web site, also in partnership with the Coalition of Cancer Cooperative Groups, will have nimble, simplified search capacity allowing users to search by cancer, doctor or location (individually or in combination) to find clinical trials. Members of the research network will have the capacity to generate reports, migrate data to their web-sites, and update profiles.

Though still a young organization, Georgia CORE has demonstrated the need for and effectiveness of a statewide clinical research network. Since its creation, the number and geographic reach of clinical trials in Georgia has grown, a network has been

developed which has expanded research activity and infrastructure beyond the boundaries of institutions or practices. These results, though early, demonstrate that such a network can expanded both the number and reach of clinical trials and achieve the dream of many Georgians to have access to high quality cancer care and research throughout the state.