

REPORT

A Model Clinical Trials System for the 21st Century

A Response to the Institute of Medicine's
2010 Report

*A National Cancer Clinical Trials System
for the 21st Century:*

*Reinvigorating the NCI Cooperative
Group Program**

Today's cancer care.
Tomorrow's cancer cure.

Georgia CORE is generously supported by the Georgia Cancer Coalition
and the Georgia Society of Clinical Oncology.

Background and Overview

According to the Institute of Medicine (IOM), “the ability to translate biomedical discoveries into meaningful advances in cancer care depends on an effective clinical trials system. Clinical trials provide an essential link between scientific discovery and clinical practice. A more effective and efficient clinical trials system will speed the pace of advances in cancer patient care.”

In 2010 the IOM published a report, requested and funded by the National Cancer Institute (NCI), containing recommendations for improving the NCI Cooperative Group Program. The goals and associated recommendations contained in the report include: improving the speed and efficiency of clinical trials; incorporating innovative science into clinical trials; improving trial selection and support; and incentivizing patient and physician participation. Its authors conclude that their recommendations extend beyond the Cooperative Group Program and that “the current structure and processes of the entire clinical trials system need to be redesigned. Specifically the report asserts that “the academic, government and commercial sectors (should)...join with the public to develop a 21st century multidisciplinary clinical trials system to...leverage scientific advances and translate them into public health benefits. This whitepaper describes Georgia’s approach to and progress in addressing some of the challenges enumerated in the IOM report.

Georgia is the 9th most populous state in the US and has substantial minority, rural and elderly populations. Historically, advances in cancer care in Georgia were impeded by two primary weaknesses—limited availability of clinical trials and limited capacity to conduct research. In 2002, leaders of the Georgia Cancer Coalition (GCC) and the Georgia Society of Clinical Oncology (GASCO) joined together to develop an effective strategy for integrating clinical trials into clinical practice. The Georgia Center for Oncology Research and Education (Georgia CORE) was created in 2003 as a catalyst to help increase the availability of, access and accrual to cancer clinical trials known to be a hallmark of cancer care quality. Ongoing collaboration in clinical research among leading community oncologists, academic researchers, educators and advocates is the unifying theme of Georgia CORE’s approach.

Georgia CORE is a private, non-profit organization that receives funding from the GCC with a portion of the state’s tobacco settlement funds, from GASCO, Winship Cancer Institute of Emory University, the Wilbur and Hilda Glenn Family

*Institute of Medicine of the National Academies 2010
Copies of the IOM Report are available at www.iom.edu/reports

Foundation and from industry grants and contracts. Leading academic and community care providers, cancer researchers, educators and representatives of NCI-funded programs in Georgia comprise the organization's leadership. The Board of Directors is representative of all oncologic specialties, academic centers and geographic regions of the state; 61% are community oncologists and 40% reside outside greater Atlanta.

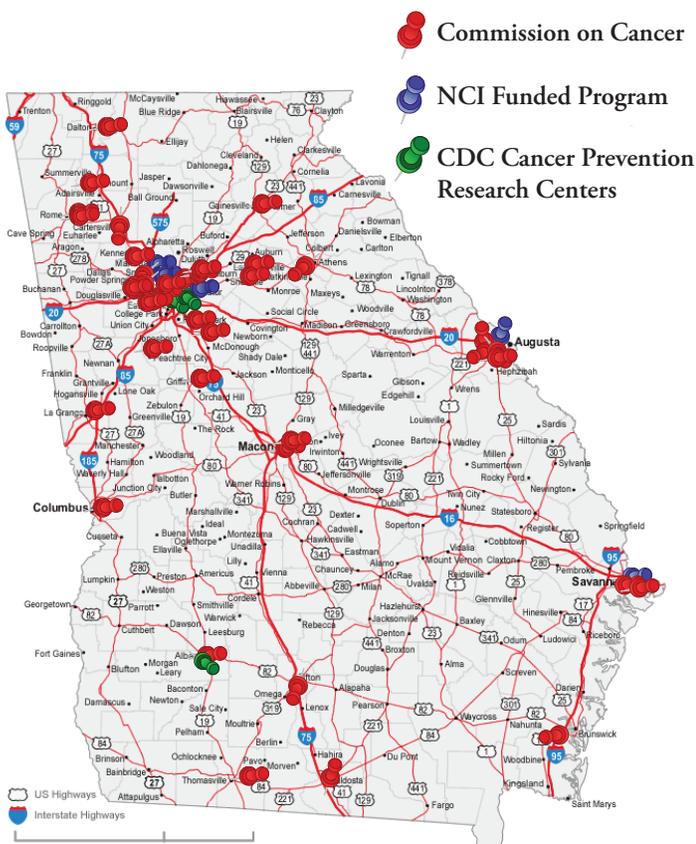
The assets that fueled Georgia CORE's development—visionary leadership, collaboration, scientific acumen and strategic investments—have contributed to Georgia's growing distinction as a leader in cancer care and research. The state has approximately 40 Commission on Cancer accredited facilities. Georgia is now home to multiple nationally recognized organizations including the NCI-designated Cancer Center at Emory's Winship Cancer Institute; NCI Community Clinical Oncology Programs (CCOP) at the Medical College of Georgia and Saint Joseph's Hospital of Atlanta and; NCI Community Cancer Center Programs (NCCCP) at Northside Hospital of Atlanta and Saint Joseph's Candler in Savannah. The Morehouse School of Medicine and Rollins School of Public Health at Emory are home to CDC funded Cancer Prevention Research Centers.

Summary and Significance of the IOM Report

The NCI supports the largest US network for clinical trials. Georgia CORE is a member of the Gynecologic Oncology Group, one of the NCI's 10 Cooperative Groups. Many Georgia investigators participate in NCI-sponsored trials either as cooperative group members (for instance, Winship Cancer Institute of Emory University is a member of ECOG and RTOG) or as members of Georgia's two NCI-funded Community Clinical Oncology Programs, one at Saint Joseph's Hospital of Atlanta and the other at the Medical College of Georgia.

In spite of a long record of important contributions and accomplishments, the NCI Cooperative Group Program has been criticized for falling short of its potential to conduct timely, large-scale, innovative clinical trials. The IOM report emphasizes the need to preserve the historical strengths of the Cooperative Group Program while redesigning the structure and processes of the entire system. Unfortunately, the deficiencies noted in the report—burdensome oversight, average activation time of two years for clinical trials and successful completion of 60% of all trials—are not confined to the Cooperative Group Program.

Over five years ago, Georgia CORE developed a statewide approach to improving availability of, accessibility of and accrual to clinical trials. The organization has made substantial progress fulfilling its mission and goals; Georgia's oncologists have a commitment to improving both the state's clinical trials system and the NCI cooperative group program. One of the solutions posited in the IOM report is "facilitation of more public-private partnerships guided in part by successful models. Georgia CORE is one such model.



Georgia CORE. An Innovative Model with Demonstrated Results

Georgia CORE was established to ensure that Georgians have access to the highest quality cancer care based on the latest trials, treatments and discoveries. The organization's model offers novel yet practical solutions for systemic improvement of the clinical trials system as called for by the IOM.

Georgia CORE was developed by clinical, scientific and educational leaders who provide the majority of cancer care in Georgia, translate new discoveries into improved treatments, and educate cancer patients and professionals. The organization's approach is designed to strengthen existing research capacity through education and training; develop resources to increase efficiency of research processes; improve awareness of clinical trials offered in Georgia; and promote and develop new studies to fill in gaps in the state's clinical trials offerings. The organization relies on innovation diffusion strategies to overcome the slow pace of adoption of healthcare improvements. By demonstrating value, encouraging adoption and disseminating results, Georgia CORE has grown dramatically and has implemented multiple programs to create an "accessible clinical trials system" in Georgia as recommended by the IOM.

Mission

Enhance the quality of cancer care in Georgia through research and education.

Vision

Georgia CORE will drive improvements in cancer outcomes, contributing measurably to the state's distinction as a national leader in cancer care and research and to better health for Georgians.

Goals

Create a statewide cancer research network linking community oncologists and cancer centers with researchers and academic centers.

Enhance research capacity and infrastructure via professional education.

Increase access and accrual to clinical trials through outreach and community awareness programs.

Adopt and adapt 21st century information technology to improve research quality and efficiency.

Advance the quality of care by promoting and conducting research, disseminating findings and facilitating knowledge transfer.

Measurable and Impactful Results Aligned with IOM Goals and Recommendations

IOM Goal I

Improve the speed and efficiency of the design, launch and conduct of clinical trials

IOM RECOMMENDATION

Improve Collaboration among Stakeholders Guided by Successful Models

GEORGIA CORE'S APPROACH

- 371 (66%) of the physicians who diagnose and treat cancer patients in Georgia are affiliates of Georgia CORE including medical and pediatric oncologists, surgeons, radiation therapists and pathologists
- Georgia CORE's Board of Directors includes academic researchers, educators and community based providers
- Public and private support for Georgia CORE comes from the Georgia Cancer Coalition, the Georgia Society of Clinical Oncology, Winship Cancer Institute, foundation grants and research contracts

IOM RECOMMENDATION

Develop standard licensing language and contract templates

GEORGIA CORE'S APPROACH

- Master Clinical Research Agreements with oncology practices, academic and community-based cancer centers enable Georgia CORE to conduct multi-site clinical trials

IOM Goal II

Incorporate Innovative Science into Cancer Clinical Trials

IOM RECOMMENDATION

Support and Use Biorepositories

GEORGIA CORE'S APPROACH

- Strategic plan identified need for a statewide biospecimen repository; BioRepository Alliance of Georgia for Oncology (BRAG-Onc) subsequently funded by the Georgia Cancer Coalition
- Developed plan to build capacity and quality of repositories (R13 symposium funding under review by NCI) with partners including Children's Healthcare of Atlanta, Emory University/Winship Cancer Institute, Georgia State University, Georgia Tech, Medical College of Georgia/BRAG-Onc, Morehouse School of Medicine, University of Georgia and others

IOM Goal III
Improve prioritization, selection, support and completion of cancer clinical trials

IOM RECOMMENDATION

Increase the Speed, Volume and Diversity of Patient Accrual

GEORGIA CORE'S APPROACH

- Timely activation of Georgia CORE-sponsored trials (reduced from 2 years to less than six months) and simplified contracting are a result of the Master Clinical Research Agreement and use of a Central IRB
- Conduct selected clinical trials via CORE affiliates to fill strategic gaps; report results and disseminate findings
 - Minority accrual of 56% (40/72) in two Georgia CORE-sponsored Phase II Investigator Initiated breast cancer trials in 2009
 - Minority accrual of 22% (11/51) to 22 Georgia CORE-sponsored Gynecologic Oncology Group trials in 2009

IOM RECOMMENDATION

Strive to make participation in clinical trials a key component of clinical practices, including high accrual rates of 10% or more

GEORGIA CORE'S APPROACH

- Georgia CORE affiliated cancer research sites grew nine-fold—from 7 to 68—between 2006 and 2009
- Statewide trends in accrual to clinical trials are monitored and reported by Georgia CORE as a result of a data sharing agreement with ACOS Commission on Cancer/ National Cancer Database

Self reported accrual to clinical trials from
 Commission on Cancer Accredited Facilities
 in Georgia

Preliminary Data

American College of Surgeons Commission
 on Cancer/National Cancer Database

2006	6.77%
2007	7.16%
2008	10.51%

IOM Goal IV
Incentivize the Participation of Patients and Physicians in Clinical Trials

IOM RECOMMENDATION

Support Clinical Investigators

GEORGIA CORE'S APPROACH

- Education and training provided to 500 investigators, nurses and research managers with funding from GASCO and ASCO (2006–2009)
- Successful recommendation of 5 community-based oncologists as GCC Distinguished Cancer Scholars who receive funding over 5 years to further community-based research
- Investigators serve as co-authors on research papers, presenters at meetings and conferences

IOM RECOMMENDATION

Cover the Cost of Patient Care in Clinical Trials

GEORGIA CORE'S APPROACH

- The Georgia Cancer Coalition executed a Clinical Trials Coverage Agreement with Georgia's Major Insurers.

Future Priorities
Needs for Cancer Clinical Trials in 2015

IOM RECOMMENDATION

A robust, standardized and accessible clinical trials infrastructure

GEORGIA CORE'S APPROACH

- Promote expansion of statewide research infrastructure
 Seven fold increase in oncologists affiliated with Georgia CORE —from 46 to 371— between 2006 and 2010
 Research sites grew outside greater Atlanta to cities (listed by size) including Augusta, Columbus, Savannah, Athens, Macon, Albany, Rome and Gainesville
 42% of clinical trials are located outside greater Atlanta where 46% of the population reside.
- Strategically expand IT capabilities as demand for research infrastructure grows using CABIG as a guide

IOM RECOMMENDATION

A complete database of active and planned trials

GEORGIA CORE'S APPROACH

- Create a comprehensive, publically assessable database of all cancer clinical trials; distribute via GeorgiaCancerTrials.org
 3,938 searches for clinical trials were conducted in 2009
- Link clinical trials listings to profiles of oncologists/ investigators and cancer centers
- Monitor, analyze and report on clinical trials access and availability in Georgia

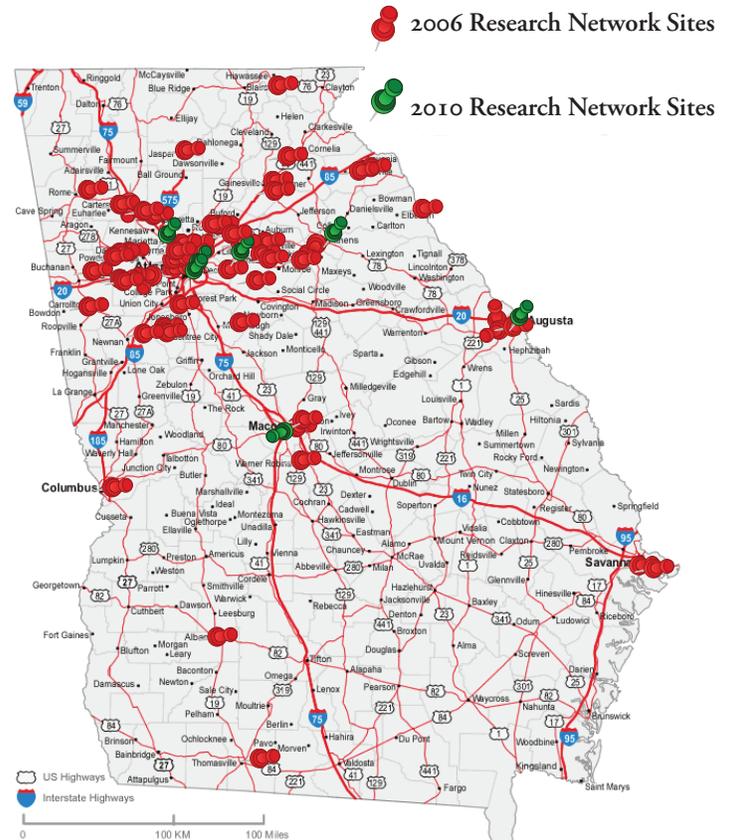
Georgia currently has 316 adult cancer trials;
 92 pediatric cancer trials
 67% increase in cancer trials in the 4 major cancer types between 2006 and 2009 (breast, colorectal, lung and prostate)
 52% of cancer trials in 4 major cancer types that account for 53% of cancer deaths
 75% of trials are Phase II and Phase III; 80% study new cancer treatments

IOM RECOMMENDATION

Publically accessible tissue repositories

GEORGIA CORE'S APPROACH

- Convene leaders to develop plans for statewide symposium to build quality and capacity of Georgia's biospecimen repositories
- Promote development of "publically accessible tissue repositories with high quality, fully annotated and inventoried samples collected and store in a standardized fashion" as envisioned by IOM



Conclusions and Next Steps

Georgia CORE has a demonstrated track record of success having effectively engaged physicians, scientists and educators, leveraged existing resources, expanded research infrastructure, provided educational support for clinical investigators and research sites, increased patient access to trials and reported improvements in accrual to clinical trials. Like the NCI Cooperative Groups, however, Georgia CORE is at a critical juncture and limited resources will curtail the implementation new initiatives, and impede Georgia's ability to improve cancer care outcomes through the delivery of new therapies.

Georgia CORE is well positioned to become a leading model for community oncology based clinical research designed to improve cancer care. In order to do so, Georgia CORE is seeking funders and strategic partners to further develop and refine the model and to implement priority programs including novel research design, activation of early phase clinical trials, upgrades to the clinical trials web site and patient resource portal; development of a biospecimen database and quality initiative; IT integration with electronic medical records to facilitate data capture and clinical trials matching.

The IOM recommendations will guide Georgia CORE's continued efforts to improve its network and the efficiency and effectiveness of clinical research administration. The organization's leadership is interested in collaborating with organizations, cancer centers, networks and industries that share a common commitment to improving the quality of oncology care through research. Desirable collaborations will focus on expanding funding, research capacity and infrastructure.

Furthering Georgia CORE's mission in collaboration with those committed to bringing new and more effective cancer treatments to patients through clinical research Georgia CORE's top priority. and the focus of its President, Nancy M. Paris. Ms. Paris can be reached by phone at 404-588-4083 or by e mail at nparis@georgiacore.org.