

Message

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from the Georgia NCI Community Oncology Research Program (GA NCORP)

Welcome to the inaugural edition of *Research Connections*, the GA NCORP newsletter. As the Principal Investigators for the GA NCORP, we are honored to work with such a dedicated group of cancer care professionals throughout the state to make the goals of the NCORP program a reality in Georgia.

In this issue you will learn about the NCORP program, the aims of the GA NCORP initiative, and the achievements to date of our efforts. Highlights of the five NCI high-priority trials for patients with lung and breast cancers, solid tumors and lymphoma, and patients who have been exceptional responders in previous NCI clinical trials are reviewed. Should you have any patients who would benefit from access to these trials, please contact the GA NCORP site principal investigator closest to you for more information.

We hope you will join us in celebrating the work that has been done to build infrastructure and collaborative working relationships in our first year. We will continue to keep you informed of our progress in achieving the goals of the GA NCORP through subsequent issues of the newsletter. Please contact us should you have any questions or suggestions about our work. We welcome your comments. We look forward to increasing access to cancer research and improving cancer outcomes in Georgia.



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The NCI Community Oncology Research Program (NCORP)

The NCORP is a national network of investigators, cancer care providers, academic institutions, and other organizations serving as stakeholders in the conduct of cancer research. The overall goal of the program is to bring cancer clinical trials, as well as cancer care delivery research (CCDR), to individuals in their own communities, generating evidence that contributes to improved patient outcomes and a reduction in cancer disparities (www.ncorp.cancer.gov).

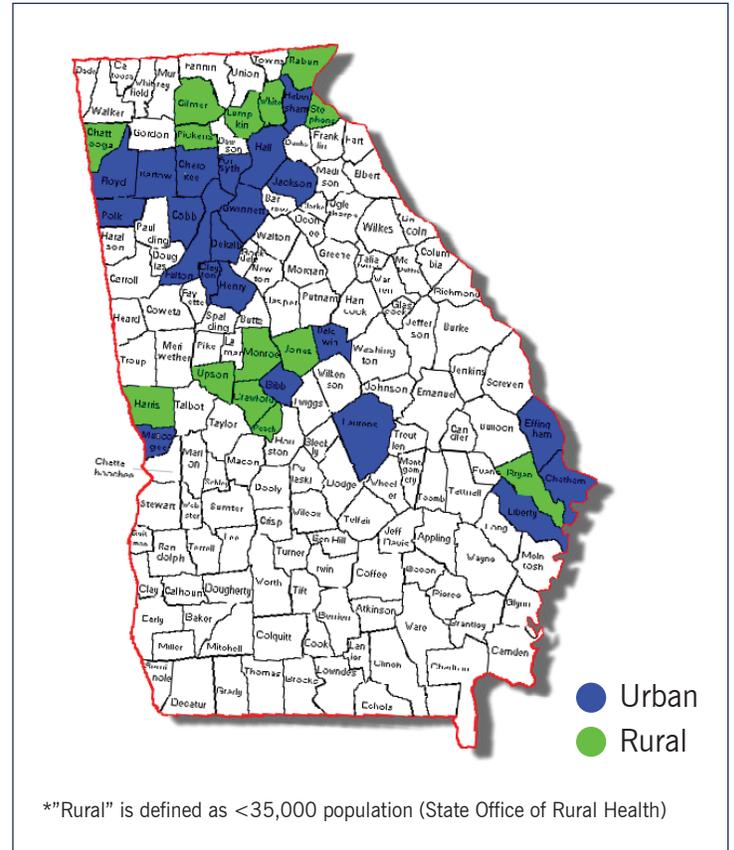
In 2014, the NCI issued a request for proposal for funding of up to 40 grants focused on the development of collaborative partnerships to implement the NCORP program in their communities. In August, 2014, Northside Hospital Cancer Institute in Atlanta in partnership with the Nancy N. and J.C. Lewis Cancer & Research Pavilion at St. Joseph's/Candler Health System in Savannah, and the Georgia Center for Oncology Research and Education (CORE), representing the John B. Amos Cancer Center in Columbus, Harbin Clinic in Rome, Navicent Health System (Medical Center of Central Georgia), in Macon, and Northeast Georgia Health System in Gainesville were successful in securing a 5-year, 5.8 million dollar NCORP grant to bring researchers together with community based physicians to conduct high quality clinical studies for cancer patients and for people at risk of cancer in local settings, where most patients receive their care.

The Georgia NCI Community Oncology Research Program (GA NCORP)

The GA NCORP network member organizations represent geographically, racially, and ethnically diverse populations in urban and rural communities (*Figure 1*).

With more than 110 cancer clinicians and investigators in 41 different locations throughout the state, as well as clinical trial leadership and research management expertise, GA NCORP is poised to provide Georgians with access to the latest cancer prevention, screening, control, treatment and post-treatment trials, and cancer care delivery research. By providing cancer research trials that address the specific needs of local communities served by the network, the community-based approach has the potential to remove the barriers of location, age, race, ethnicity, and economic status for Georgians when accessing opportunities to participate in cancer research in local communities. The GA NCORP initiative represents a unique opportunity to reduce cancer risk and incidence;

Figure 1. Georgia NCORP Rural* and Urban Counties by Member Service Area



improve cancer care outcomes; expand access to cancer care; increase quality and value of care; and reduce cancer disparities in Georgia.

To achieve this goal, the GA NCORP established **three aims**. Each aim of the GA NCORP initiative is driven by a team of cancer care professionals from the participating GA NCORP network members. Over the initial eight months of the Year 01 funding period, the teams have met on a monthly schedule to build infrastructure and develop collaborative working relationships to accomplish the GA NCORP aims. The specific aims, leadership, and progress to date are presented in *Figure 2*.

Figure 2. Primary Aims, Leadership, and Progress of GA NCORP



State of the Art Cancer Research in the GA NCORP Network

The GA NCORP network has 152 unique, primarily Phase II and Phase III, clinical trials open to address 22 site-specific cancers (as of March 15, 2015). Accrual to clinical trials among network sites to date illustrates that the community approach is working (Figure 3). Forty percent of enrollees to GA NCORP clinical trials are young adult and middle adults; 42% are male; 25% non-Caucasian, and 97% non-Hispanic (Figure 4). More than two-thirds of the total accruals have been to breast, lung, and gynecological cancer trials (Figure 5). With an accrual goal of 165 during Year 01 of the grant, the initiative is well on the way to meet the goal.

Figure 4. GA NCORP Clinical Trial Accrual by Patient Demographics by Research Network Members (August 4, 2014 – March 31, 2015)

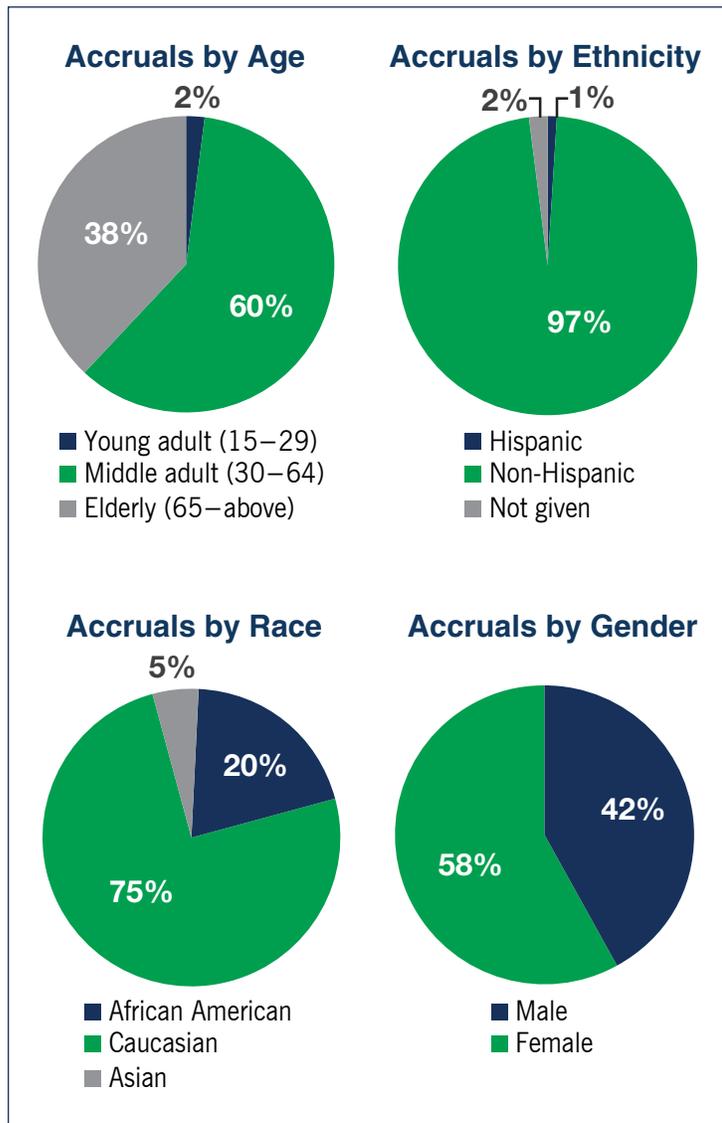


Figure 3. Accruals by Research Network Members (August 4, 2014 – March 31, 2015)

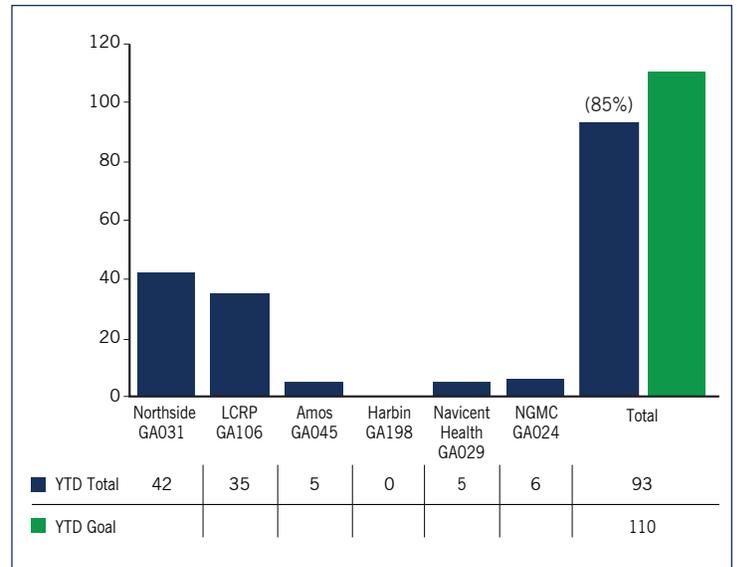
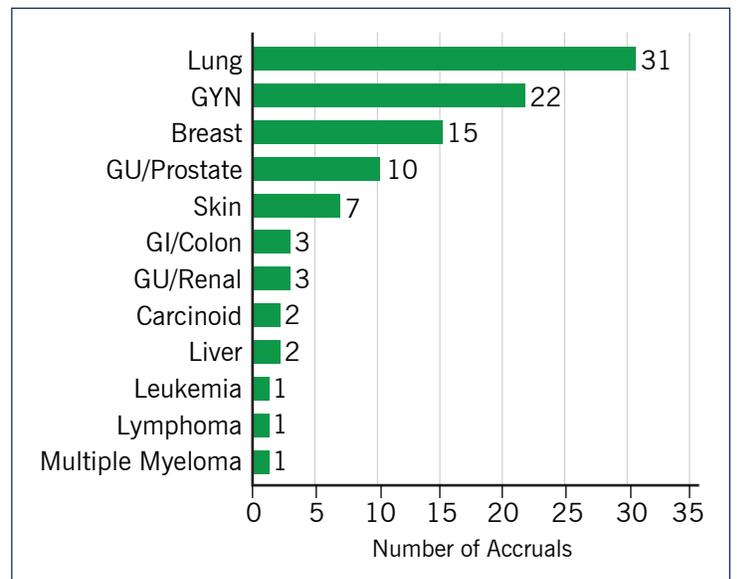


Figure 5. Accruals by Cancer Type by Research Network Members (August 4, 2014 – March 31, 2015)



The NCI High-Priority Clinical Trials

The NCI has identified five high-priority trials to lead the progress in screening and personalized treatment choices for patients with lung, breast, solid tumors, and lymphoma cancers in the future. Three of the trials are currently open to accrual in the identified GA NCORP sites (Table 1). Initiation of two additional trials is expected in the near future (Table 2).

Table 1. NCI High-priority Cancer Clinical Trials Currently OPEN to Accrual (April 15, 2015)

Cancer Site/NCT Trial Identifier/Trial Title	Availability	Purpose	Intervention	Primary Endpoint
Lung Cancer NCT02201992 Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials (ALCHEMIST)	JBACC LCRP NEGA NSH	Match patients with ALK or EGRF mutations with targeted treatments	Integrated lung cancer research effort with 3 component trials: <ul style="list-style-type: none"> • Screening Trial - A151216: Eligible patients will have tumor tissue tested for genetic changes in ALK or EGFR. If tissue testing is positive, referral to one of the treatment trials. If negative, patient followed for 5 years. All patients contribute information to the national public resource for research. • Erlotinib Treatment Trial (A081105): Erlotinib vs placebo in patients with activating EGFR mutations following standard of care adjuvant therapy • Crizotinib Treatment Trial (E4512): Crizotinib vs placebo in patients harboring the anaplastic lymphoma kinase (ALK) fusion protein following standard of care adjuvant therapy 	Efficacy
Squamous Cell Lung NCT02154490 Lung Map (S1400)	JBACC LCRP NEGA NSH	Match patients based on genomic profiling to sub-studies testing investigational treatment that target the genomic alteration, mutations, or found to be driving the growth of the cancer	<ul style="list-style-type: none"> • A multi-drug, multi-sub-study, biomarker-driven squamous cell lung cancer phase II/III trial based on genomic profiling for trial assignment 	Efficacy
Multiple Site-specific Cancers NCT02243592 Exceptional Responders Initiative (ERI) Pilot Study	JBACC LCRP NEGA NSH	Understand the molecular underpinnings of exceptional responses to treatment, primarily via chemotherapy, in cancer patients	<ul style="list-style-type: none"> • Malignant tissue (and normal tissue, when possible) and clinical data will be obtained from a group of exceptional responders and analyzed in detail (DNA and RNA will be isolated from tissues submitted to the ERI and will undergo whole exome sequencing and/or mRNA sequencing) • Exceptional responders defined as patients who have a unique response to treatments that are not effective for most other patients (identified from patients those enrolled in early-phase trials in which <10% of patients responded to study treatments; patients treated with drugs not found to be generally effective for their disease; patients treated in later-phase clinical trials of single agents or combinations; and patients treated with established therapies 	Observation

JBACC=John B. Amos Cancer Center; NEGA=Northeast Georgia Medical Center; LCRP=Nancy N. and J.C. Lewis Cancer & Research Pavilion at St. Joseph's/ Candler Health System; NSH=Northside Hospital Cancer Institute.

Additional information about each of the trials listed in Table 1 can be accessed at www.GeorgiaCancerInfo.org or contact the site principal investigators at GA NCORP sites where the trial is open.

Table 2. NCI High-priority Cancer Clinical Trials Currently Watch List (April 15, 2015)

Cancer Site/NCT Trial Identifier/Trial Title/Availability	Trial Description
Non-responding Advanced Solid Tumors and Lymphoma NCI Molecular Analysis for Therapy Choice Program (MATCH) <i>Not open to accruals (04.15.15)</i>	<p>Purpose: Match patient with tumor genetic abnormalities to selected targeted drugs to determine tumor response.</p> <p>Intervention: Biopsies from tumors from as many as 3,000 patients will undergo next-generation DNA sequencing to identify individuals whose tumors have genetic abnormalities that may respond to selected targeted drugs (20-25 drugs initially available for the trial)</p> <p>Target Genetic Abnormalities: EGFR, HER2, MET, BRAF, NF1, GNAQ, GNA11, TSC1/2, PTEN, Patch, NF2, ALK, ROS, FGFR</p> <p>Primary Endpoint: Tumor response</p>
Breast Tomosynthesis Mammographic Imaging Screening Trial (TMIST) <i>Not open to accruals (04.15.15)</i>	<p>Purpose: Compare the number of advanced cancers detected using tomosynthesis versus digital mammography, with advanced cancers defined as all tumors diagnosed at stage II or higher and all tumors that are >6 mm in size and which have markers that suggest they are aggressive</p> <ul style="list-style-type: none"> • Will enroll approximately 60,000 women at least 40 years of age who seek screening for breast cancer • Three consecutive 1-year screening rounds

GA NCORP Contact Information:

For general GA NCORP program information, contact Tina Berry, Project Manager, at tina.berry@northside.com.