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Note from the PIs

This year is off to an exciting start for the Georgia NCORP network, and follows on the heels of an extraordinarily accomplished 2015. In early February 2016, we were informed that our application for SWOG membership was approved. Membership with SWOG will provide Georgia NCORP investigators and patients expanded access to clinical trials and cancer care delivery studies, as well as opportunities to contribute to the development of studies through committee and group meeting participation. Membership in SWOG is a great honor and will enhance GA NCORP's members' ability to provide patients the very best in clinical research opportunities.

Significantly, in 2015, GA NCORP garnered national recognition as a top NCORP network, ranking second for NRG Oncology clinical trial accruals. This ranking came as a result of the work and commitment of the GA NCORP membership, the NCI, and our stakeholder community.

Other accomplishments of note are the 2nd Annual Investigator's Meeting, held in September of 2015 in Atlanta and the Scientific Review Committee meeting at the NRG Oncology meeting in January 2016.

We have also observed positive trends in investigator participation and accruals. We have seen an increase in investigator participation from Year 1 to Year 2, evidenced by a rise from 37% to 50% of rostered investigators accruing at least one patient to an NCI-sponsored trial with several investigators having 10 or more accruals. We are already at 36% of our accrual credit goals for the first half of the grant year and are seeing an upward trend in accruals over the last 2 months. We have also increased diversification in our trial portfolio, including phase, trial type, and disease site.

Due to the closure of many trials nationally since NCORP's inception and the limited number of new trials available through CTSU, we have seen a drop in open trials from year 1 (152) to year 2 (127). Despite this drop, the Clinical Research Team continues to monitor the opening of new trials and has recommended 17 new trials so far in Year 2.

We have continued to build Cancer Care Delivery Research (CCDR) infrastructure for which we now have access and are eligible to participate. Moreover, we are actively working with ECOG on the PRO-GENESCREEN concept of identifying women with BRCA1/2 mutations prior to a cancer diagnosis.

We look forward to events planned in the coming year, including a Clinical Research Team meeting in the spring, SWOG and ECOG research base meetings, and the Annual Investigator's Meeting in Atlanta in September 2016.

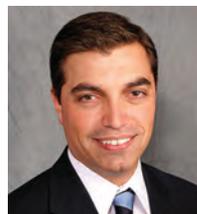
We are confident that the Georgia NCORP will continue to grow and be one of the most successful NCORP nationally, to fulfill our commitment in offering the latest cutting-edge clinical trials to patients in their communities, and to support the NCI on improving cancer care that will ultimately benefit our cancer patients in the state of Georgia.

On behalf of the entire Georgia NCORP leadership, we offer a sincere thanks to all who have contributed and worked tirelessly to make this dream come true.

NCI Community Oncology
Research Program

A program of the National Cancer Institute
of the National Institutes of Health

*Northside Hospital has been awarded
a grant by the National Cancer
Institute (NCI) as a member of the
National Cancer Institute Community
Oncology Program (NCORP).*



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Remembering Thomas Edwin Seay, MD, PhD



Dr. Thomas E. Seay, Chairman of Georgia NCORP, passed away suddenly on December 26, 2015. He was a pioneer in the Georgia oncology community who was committed to scientific research as well as equal access to cancer care for all Georgians. Dr. Seay was tremendously respected by his colleagues and patients alike.

Dr. Seay devoted his life to the advancement of treatment for cancer patients, as an investigator and clinician. A significant portion of his career involved supporting laboratory and clinical research. He served as the Principal Investigator for the National Cancer Institute-funded Atlanta Regional Community Clinical Oncology Program. He was an Assistant Professor of Medicine at Emory University School of Medicine and Winship Cancer Institute. He co-authored numerous peer-reviewed research publications appearing in professional journals such as the *Journal of Clinical Oncology* and the *New England Journal of Medicine*.

Dr. Seay practiced medical oncology for 25 years, serving as both President and Managing Partner of Atlanta Cancer Care (ACC). Dr. Seay was a founding member of the Board of Directors of the Georgia Center for Oncology Research and Education (CORE), serving as the organization's Chairman from 2009 until his death. Dr. Seay believed passionately in and advocated for equal access to cancer care, working to ensure that all Georgians can participate in clinical trials. He received the Georgia Distinguished Cancer Scholar Award Grant for these efforts to increase the availability of clinical trials.

He received a BS from the University of Georgia, a PhD in Biomedical Sciences from East Tennessee State University, and an MD from James H. Quillen College of Medicine in Johnson City, Tennessee, where he received the Upjohn Achievement Award for Academic Excellence for the Highest Academic Performance.

His unfailing commitment to oncology in Georgia leaves a legacy that will endure. We honor his memory.

Through the years...

1



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3



4



- 1) A Georgia native & a member of Atlanta Cancer Care for over 25 years: ACC President & Managing Partner
- 2) Described by Dr. Fred Schnell as a man known for his wit, wisdom, and downright "human-ness": *One of Tom's Toys in service at a charity golf tournament for children with serious diseases*
- 3) Dr. Seay knew that together we achieve more: Russ Still—Exec Director of GASCO, Dr. Seay, Nancy Paris—CEO of GACORE, Patti Owen—Director, Northside Hospital Cancer Institute
- 4) The Georgia Center for Oncology Research & Education: Chairman – Board of Directors

Select Publications Dr. Seay Co-Authored:

Anastrozole versus tamoxifen in postmenopausal women with ductal carcinoma in situ undergoing lumpectomy plus radiotherapy (NSABP B-35): a randomised, double-blind, phase 3 clinical trial. *Lancet*. 2015 Dec 10. pii: S0140-6736(15)01168-X. doi: 10.1016/S0140-6736(15)01168-X. [Epub ahead of print].

Preliminary results of centralized HER2 testing in ductal carcinoma in situ (DCIS): NSABP B-43. *Breast Cancer Res Treat*. 2013;142(2):415-21.

Gemcitabine and docetaxel for hepatocellular carcinoma: a phase II North Central Cancer Treatment Group clinical trial. *Am J Clin Oncol*. 2012;35(5):418-23.

Phase III trial assessing bevacizumab in stages II and III carcinoma of the colon: results of NSABP protocol C-08. *J Clin Oncol*. 2011;29(1):11-6.

We will miss you, Tom.

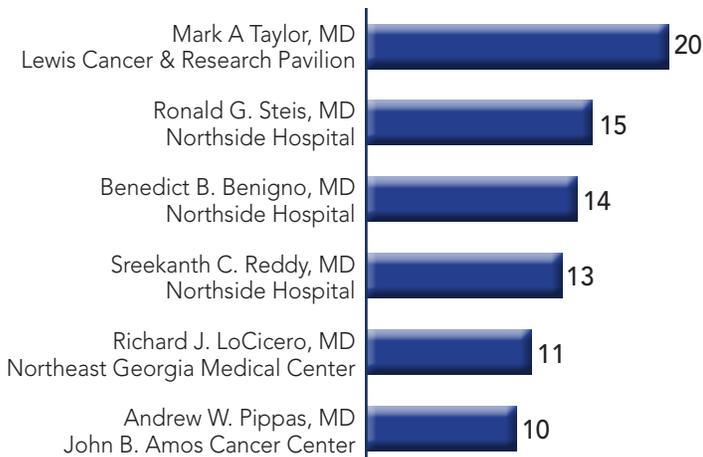
Reflections on GA NCORP

Over the course of 2015, we implemented a new statewide cancer research network to serve more Georgians in their own communities. The network brings together 101 investigators from six member sites. The Georgia NCORP (GA NCORP) initiative now provides residents with improved access to an expanded portfolio of state-of-the-art cancer prevention, control, screening, treatment and post-treatment clinical trials, and cancer care delivery research. Highlights of Year 1, 2015, are showcased here.

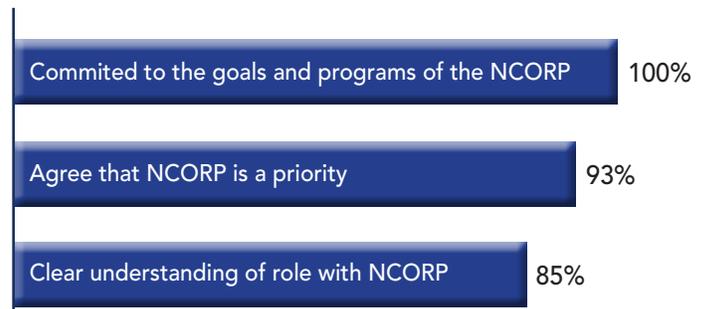
- Hosted Annual GA NCORP Investigators & Administrators Meeting September 11, 2015 at the 2015 GASCO Annual Meeting
- Hosted in-person Scientific Review Committee and GA NCORP reception at NRG meeting in Atlanta, January 21st, 2016

- Designed and implemented a network-wide communication platform (GA NCORP website and newsletter)
- Our efforts were acknowledged by the National Cancer Institute (NCI), as GA NCORP was recognized as **Best Practice** for NCORP Model of Infrastructure and Operations.
- Initiated several high priority NCI trials, including:
 - LungMAP (3rd highest accrual)
 - ALCHEMIST (3rd highest accrual)
 - Exceptional Responders
 - MATCH
- Ranked as the **#2 NCORP Community site** in the U.S. for accruals to NRG Oncology research protocols.

Top Accruing Investigators, August 2014 – December 2015 (10 or more accruals)



Findings of a Research Network Member Survey of NCORP Benefits, Value, and Effectiveness*



*Distributed December 14, 2015 with a 77% response rate (40/52)

DID YOU KNOW?

Participation in GA NCORP assists Research Network Members in meeting NCCN guidelines and achieving COC goals. In each of its treatment guidelines algorithms, the NCCN includes the following statement: **Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.**

Precision Medicine Trials

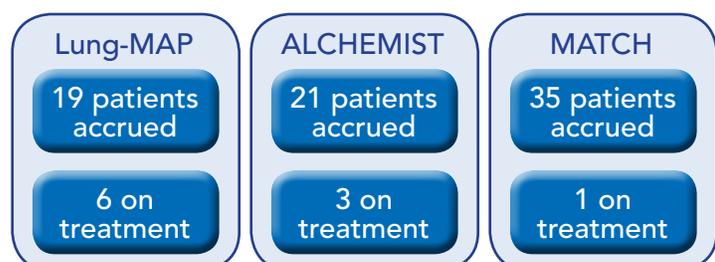
Cancer presents an exceptionally promising opportunity to refine the principles and practices that will serve as the foundation for precision medicine. The NCI now has a Precision Medicine Initiative to amass and analyze genomic data sets to increase the understanding of cancer genomes and their relationship to a patient's inherited gene variants. Genomic findings will allow the NCI to test new therapies against childhood cancers and several common adult cancers. The NCI will also develop better animal and cell-based models of cancer, study mechanisms of drug resistance, and identify new therapies and therapy combinations to overcome drug resistance.

With additional resources in its 2016 budget, the NCI will increase funding to support clinical trials that offer two distinct approaches to advancing precision medicine. The first approach recruits patients with all types of cancer, and then selects a targeted drug based on the specific genetic abnormalities of the patient's tumor. The NCI is using this approach in its Molecular Analysis for Therapy Choice (NCI-MATCH) Program, which enrolls pediatric and adult patients with tumors that no longer respond to standard therapy. The second approach, demonstrated in the NCI Lung-MAP study, recruits patients with one type of cancer and then subdivides patients into genomically defined subsets, treating each subset with a different targeted drug.

Both types of trials have important and achievable goals: (1) making the molecular characterization of cancers the clinical standard for accurate diagnosis and treatment; (2) identifying or developing an array of treatments that can be matched to the molecular features of a tumor to successfully control the disease. Another feature of these trials is the opportunity to link their genomic findings to clinical data, lifestyle risks such as tobacco use and obesity, environmental mutagens, and viral infections. This additional feature will become a resource to support further discovery and identify new strategies for cancer prevention, early diagnosis and early intervention.

Cancer research funding recently received a considerable boost, with the White House announcing a 2017 budget request to include \$680 million of additional funding for the NCI to support the cancer research initiative inspired by Vice President Biden.

GA NCORP Participation in NCI Precision Medicine Initiative



Biospecimen Samples: a Critical Component to Precision Medicine

Individualized molecular and genomic diagnosis and classification have transformed how patients with cancer are treated. Precision medicine, the designation for this new science, has and will dramatically change clinical research and personalized therapeutics. For personalized precision medicine to succeed, optimal procurement and characterization of human biospecimens are critical elements. Pathology, the central specialty of precision medicine, is the key driver for high-quality biospecimen analyses in today's healthcare setting.

The National Cancer Institute (NCI), through its Biorepositories and Biospecimen Research Branch (BBRB), is leading a national initiative to methodically address and resolve the lack of standardized, high-quality biospecimens, a significant roadblock to cancer research. The GA NCORP is committed to executing the BBRB's initiative by implementing the standards set forth as shown below.

Improving the Quality and Consistency of Human Biospecimens: a GA NCORP Initiative

- Scientific Research** To bolster the evidence base for biospecimen collection, handling and processing practices
- Policies & Procedures** For collection and management of biospecimen resources
- Education & Communication** Providing materials and forums around biospecimen-related issues
- Partnership & Harmonization** Partner nationally and internationally to harmonize biospecimen and biobanking standards
- Support & Service** Provide a resource for direct support of NCI and NIH programs and services to the research community



Clinical Research Team Accomplishments

Dr. Frederick M Schnell

- Held five Clinical Research Team conference calls (August 2015 – February 2016)
- Schedule for the monthly Clinical Research Team conference call changed to the 3rd Tuesday of each month from 5:30-6:30 pm
- Received reports from 10 of the Site-specific Working Groups
- Accepted recommendations for activation of an additional 17 clinical trials at local GA NCORP sites
- Participated in the 2nd Annual Investigator’s Meeting in Atlanta in September 2015
- Conducted a Year 02 analysis on changes in GA NCORP clinical trial portfolio (March 2015 – October 2015)
- Analyzed GA NCORP member investigator participation in clinical trial accruals (Year 01)
- Reviewed results of GA NCORP eSurvey (January 2016)
- Identified opportunities to enhance trial accrual, member investigator engagement, and collaboration and communications among Clinical Research Team and other GA NCORP teams, committees, and member site personnel
- Held face-to-face meeting of the Clinical Research Team during March 2016
- Developed goals for GA NCORP Clinical Research Team for 2015-2016

Clinical Research Team Report

Year 02 Analysis of GA NCORP Clinical Trials Portfolio 01.21.16

Highest Number of Trials by Site-specific Cancer	Number of Unique Trials Open
Breast	26 Trials
Lung	12 Trials
Leukemia	11 Trials
Ovarian	8 Trials
Prostate	6 Trials
Melanoma	6 Trials



Biospecimen Team Actions and Accomplishments

Dr. Jonathan Lee

- Determination and/or establishment of biospecimen processing capability and capacity at each of Georgia NCORP member organizations
- Provide recommendations regarding uniform standardization and quality control of biospecimen processing throughout GA NCORP
- Evaluate and provide biospecimen-related recommendations to the Scientific Review Committee for selection of GA NCORP network trials that call for collection of biospecimens
- Increase the number of high-quality, well-annotated specimens available for research
- Develop processes and metrics to assist operations of, and to assess outcomes for, the GA NCORP Biospecimen initiative

Site Visit Progress

Northside Hospital (Feb 2015)

- Established biospecimen repository
- Infrastructure to process blood, bone marrow, and FFPE tissue; store liquid and solid biospecimens
- Long-term storage capabilities

Nancy N. and J.C. Lewis Cancer & Research Pavilion at St. Joseph’s/Candler (Apr 2015)

- Prospective biobank (demand-based biospecimen collection)
- Infrastructure to process blood and FFPE tissue; store liquid and solid biospecimens
- Short- to intermediate-term storage capabilities

John B. Amos Cancer Center (Jun 2015)

- Prospective BioBank (demand-based biospecimen collection, but plan for long-term repository)
- Infrastructure to process blood, bone marrow and FFPE blocks/ slides tissue; store liquid and fluids short-term
- Long-term storage capabilities

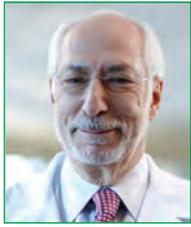
Northeast Georgia Medical Center (Oct 2015)

- Prospective BioBank (demand-based biospecimen collection)
- Infrastructure to collect tissue for clinical trials
- Short-term storage capabilities

Navicent, Medical Center (Dec 2015)

- Prospective BioBank (demand-based biospecimen collection)
- Infrastructure to process blood, bone marrow, and serum/ plasma
- Short-term storage capabilities

Harbin Clinic (to be evaluated)



Dr. H. A. Zaren

CCDR Corner

Cancer Care Delivery Research (CCDR) is an essential component of NCORP. CCDR encompasses a multidisciplinary field of scientific investigation. It examines how social factors, financing systems, organizational structures and processes,

health technologies, and healthcare provider and individual behaviors affect cancer outcomes, access to and quality of care, cancer care costs, and the health and well-being of cancer patients and survivors.

Through Georgia NCORP we are leveraging Cancer Care Delivery Research (CCDR) to strengthen patient care. Our goal through Georgia NCORP's CCDR work is to increase the ability of NCORP sites to participate in CCDR in the communities they serve. For example, we have continued to build CCDR infrastructure throughout Georgia NCORP in Year Two so that when CCDR trial become available for which we are eligible to participate, we can respond and open the trial in a timely manner in order to provide exceptional care to our patients.

Importantly, we responded to the CCDR Metrics Working Group Survey which is being used to gauge site capacity at NCORPS throughout the nation to open and respond to CCDR trials. In addition, we have had Georgia NCORP representation at CCDR sections of every national clinical trials meeting in order to stay abreast of new developments and as individual component sites we are participating in CCDR projects outside of NCORP including a palliative care study at Nancy N. and J.C. Lewis Cancer & Research Pavilion at St. Joseph's/Candler and a genetic counseling study at Northside.

We are measuring and documenting Georgia NCORP's work nationally through our Georgia NCORP CCDR dashboard, reflecting our CCDR metrics and activities. This dashboard is used to document, measure, and evaluate all Georgia NCORP CCDR activities and ensure timely progress towards our objectives.

Georgia NCORP Submission of a CCDR Proposal Concept

Continuing efforts through GA NCORP to develop CCDR research is evidenced by the group's proposed PRO-GENESCREEN concept. PRO-GENESCREEN aims to increase identification of women who harbor BRCA1/2 mutations prior to a cancer diagnosis by increasing referral rates of at-risk healthy women in the primary care setting who are appropriate for genetic counseling. PRO-GENESCREEN will accomplish this by use of a multi-step educational intervention designed to increase provider knowledge.

Physician Perspective



Dr. Mark A. Taylor



Dr. Ronald Steis

We talked with Drs. Mark A. Taylor of the Nancy N. and J.C. Lewis Cancer & Research Pavilion at St. Joseph's/

Candler in Savannah and Dr. Ronald Steis of Atlanta Cancer Care affiliated with Northside Hospital Cancer Institute about their experience enrolling patients on clinical trials via GA NCORP. Drs. Steis and Taylor accrued the most patients on GA NCORP clinical trials in 2015. Highlights of the discussion are featured herein.

Describe some of the highlights of the top accruing trials and what makes them unique.

Dr. Taylor: The ALCHEMIST study is particularly interesting because it is looking at adding a very effective and (relatively) non-toxic agent (crizotinib or erlotinib) to a selected group of patients with early-stage non-small cell lung cancer (NSCLC) with a particular mutation.

Dr. Steis: What makes the top accruing trials unique really boils down to whether the patients are available (do we have the right population) and the number of interesting trials we can offer. There are many standard options for research, and often, patients, together with their physicians, may opt to not go on trial and prefer standard therapy in a particular clinical setting. The availability of interesting trials, and the patients who might want to participate, coupled with the willingness of physicians to enroll a patient on trial are the biggest factors. There are physicians who have no interest in enrolling patients on trials, and generally lack interest in research. It takes time and care to enroll a patient on a trial and to continue to follow as per the protocol. The key is having a solid research team, else the enrollment will suffer.

What are the latest trials to open enrollment that you believe show great promise?

Dr. Taylor: For 2016, we are excited about the MATCH study, which is for any type of cancer. A biopsy is performed, and if there is a match between a particular genetic mutation and the drug that targets the mutation, the patient is placed on the drug targeting the mutation.

Dr. Steis: I really look forward to enrolling onto EA6141 and SWOG1404

(continued on page 7)

Physician Perspective (continued)

How does participating in the GA NCORP clinical trials benefit Georgian patients?

Dr. Taylor: The collaboration among various cancer centers in Georgia has attracted cutting-edge clinical trials to the state, to which Georgians now have access. By collectively working within the same clinical trial system, trials are completed quickly and efficiently.

Dr. Steis: We really need better and less toxic therapies. Consider EA6141; this will be a potential “game changer.” Metastatic melanoma is a common disease. This trial could help the typical oncologist manage the complex side effects related to treatment. The Melanoma community has grown tired of interferon. It has marginal benefit and patients don’t like it as it makes them so sick and tired and weak. We need to look towards less toxic therapy, which brings me to SWOG1404. We need to look beyond Interferon. EA6141 and SWOG1404 are answering very important questions for our patients.

How do Georgians learn about the GA NCORP trials?

Dr. Taylor: Though we are still in an era where the minority of patients seek a clinical trial, the consumerism of health care has pushed patients toward doing their own research and looking for clinical trial opportunities. The internet has a wealth of resources, including clinicaltrials.gov, a searchable database of publicly and privately supported clinical studies conducted around the world.

Dr. Steis: Website. NHCI. Engaged physicians and staff.

How do the multidisciplinary disease site network groups assist with accrual?

Dr. Taylor: A successful clinical trial program is the combined effort of many components. These include cooperation and regular communication among various disciplines, good coordinators to help screen a high volume of patients, and a proactive clinical trial environment.

Dr. Steis: Multidisciplinary disease site network groups demonstrate expertise in a particular disease side. It is a way to get patients referred for expert opinions. It helps with trial selection, and also helps to guide other physicians. Overall, it helps patients and accrual, even with decreased access in some areas it can raise awareness of the importance of clinical research.

Why do patients choose to enroll in clinical trials?

Dr. Taylor: While clinical trials are the standard of care for pediatric cancer patients, this is not the case in adults. Our eligible patients generally choose a clinical trial as their treatment option over standard therapy because they see the benefit in potentially receiving tomorrow’s treatment today. We educate them on the upside and downside of a particular clinical trial, with the understanding that we hope the experimental treatment will build on the current standard of care. If there were a cure for cancer, there would be no need for clinical trials.

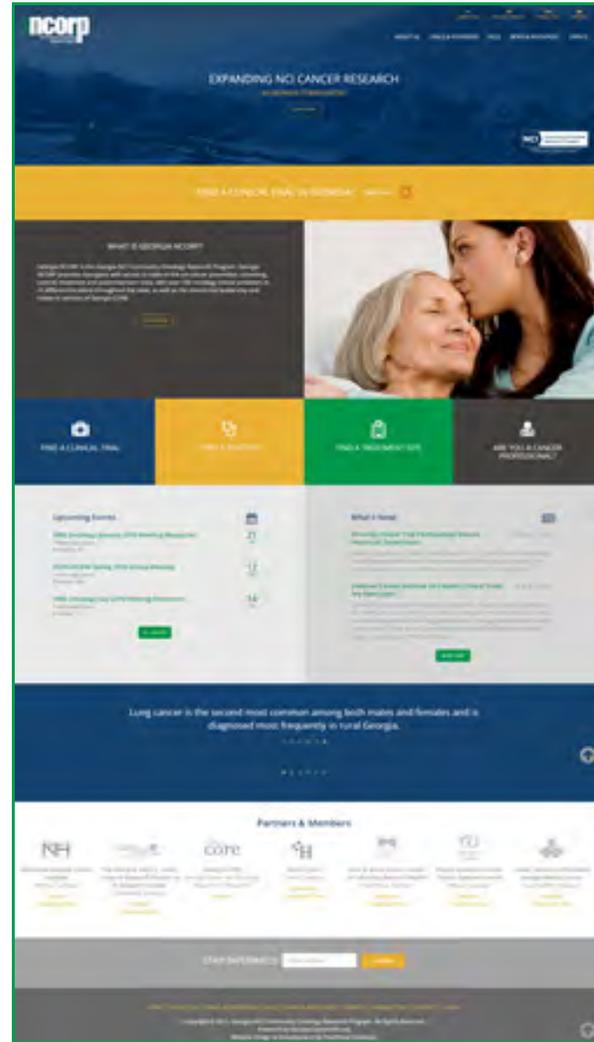
Dr. Steis: Patients are more informed about cancer in general; they are in touch with via internet access. Patients come to me well informed about their disease. They realize we (physicians/researchers) want to fill gaps in knowledge for particular cancers and the only way to do so is with clinical trials. Once I have an opportunity to speak with a patient, and get him/her over the fear that there is always going to be a placebo, they most always choose to participate and enroll. I tell my patients that we rarely, if ever, have a placebo-only arm of the trial as that is for a disease when there is no standard of care. The specifics of the trial and the disease itself drive the decision about whether it is placebo controlled. I make this clear to my patients during our discussion about clinical trials. Generally speaking, placebo controlled trials are harder to enroll to, and the study would really need a strong case for a placebo control arm. Having open dialogue with patients is the best measure we can take to ensure they are enrolling, and are fully informed of what their participation really entails.

GA NCORP Website Launches

Georgia NCORP is pleased to announce the launch of its new website. In keeping with GA NCORP's mission of increasing access and accrual to cancer research to Georgians at risk or with a diagnosis of cancer in their own communities, the website's essential purpose is to house vital information for patients and their clinicians seeking enrollment in clinical trials. Easily navigable links from a dropdown menu provide access to databases which are searchable by clinical trial, physician, and treatment. The website's simple user interface furthers the aim of expanding NCI cancer research in Georgia communities by making these resources equally accessible to all Georgians.

The website also contains general information about GA NCORP, profiles of each research network member, current news and resources, and a calendar of upcoming events.

Visit the new website: <https://www.gancorp.org>.



Upcoming Events

April 27–30

SWOG Spring 2016
Group Meeting

Hyatt Regency San Francisco
San Francisco, CA

May 12–14

ECOG-ACRIN Spring 2016
Group Meeting

Boston Marriott Copley Place
Boston, MA

July 14–17

NRG Oncology July 2016
Meeting Resources

Sheraton Dallas Downtown
Dallas, TX