GA ncorp
NCI Community Oncology Research Program

RESEARCH CONNECTIONS

VOLUME 5 – FALL 2019

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).

Notes from the PIs

We are pleased to announce that on behalf of GA NCORP, Northside Hospital has been awarded the National Cancer Institute Community Oncology Research Program (NCORP) renewal grant for nearly $11 million in projected cancer research funding over the next 6 years (8/1/19-7/31/25). Georgia NCORP is one of only 32 Community Sites selected to receive cancer research funding from the NCI for the next six years, and it is one of only 10 NCORP networks to receive "High Performance" status from the NCI. Your support, guidance, and clinical expertise were critical during our previous grant term and will continue to be key to a successful program.

With this grant renewal comes new initiatives and grant aims to further expand cancer research to a broader population and include underserved populations in cancer research:

Aim 1: To increase the percentage of eligible patients at risk for or diagnosed with cancer who have access to and enroll in a cancer clinical trial within their community.

Aim 2: To enroll participants from underrepresented populations across all study types and settings to reduce cancer disparities.

Aim 3: To create a balanced trial portfolio between treatment trials and cancer control and prevention trials.

Aim 4: To increase accrual and expand network-wide participation in cancer care delivery research (CCDR).

As represented in the aims, the NCORP network has placed a special focus on cancer disparities and has demonstrated a commitment to integrating health disparities research questions across all studies in the network. At GA NCORP, we recognize this and have created the Disparities Integration Program, which will be led by Dr. Jayanthi Srinivasiah. GA NCORP is already a leader on accrual of minorities to clinical trials, and several members have presented at national meetings, including the Susan G. Komen African American Health Equities Summit in 2017 and the ASCO Annual Meeting in 2018. We are excited to continue to pave the way for this very important initiative.

We look forward to continuing our work together supporting this exciting and very important statewide initiative. Again, thank you for all of your support!

Guilherme Cantuaria, MD, PhD
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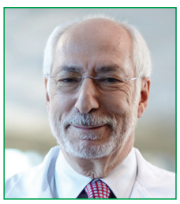


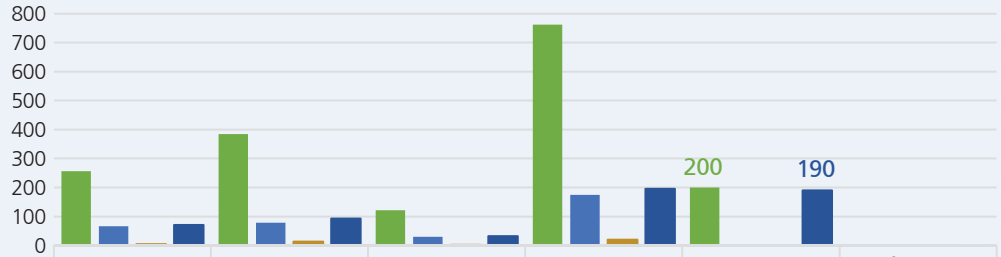
H. A. Zaren, MD, FACS
drzaren@sjchs.org

Reflections on GA NCORP

The July 2019 Performance Report (with a data cut-off date of September 3, 2019) once again demonstrates a continued community commitment to research and clinical trials. The network as a whole showed significant increases in patient enrollment, with the year-end goal being met and exceeded (**Figure 1**). Breast cancer trials continue to lead in patient accruals with multi-tumor, lung, gynecological, and prostate cancers rounding out the top five (**Figure 2**).

Figure 1.

Accruals, Ancillary Credits, and Enrollment Credits Summary (August 2018–July 2019)*



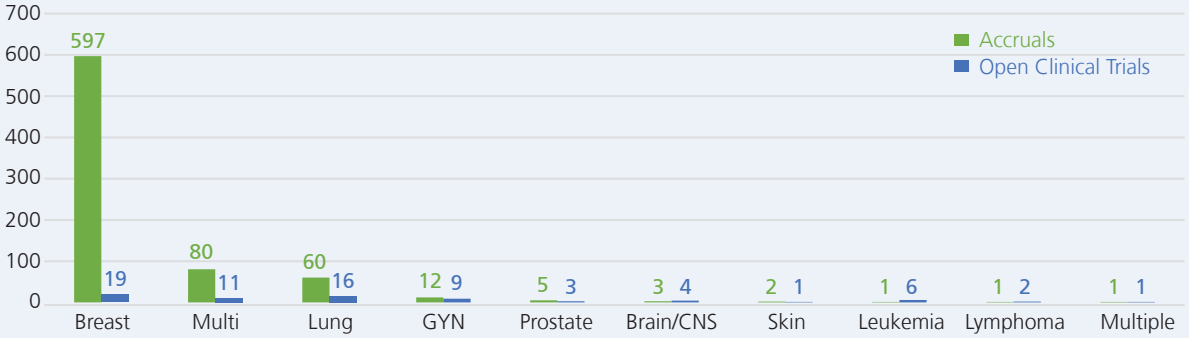
	Northside	LCRP	Network Members	Total	Year End Goal	% of Goal Met at 100% of Year
Accruals	256	3.84	122	762	200	381%
Enrollment Credits	66.544	78.706	29.806	175.056		
Ancillary Credits	4.168	13.894	2.1752	0.236		
Combined Credits	70.711	92.600	31.981	195.292	190	103%

*Credit & accrual data collected 09.03.19, **data logged after** 09.03.19 not included. Excludes DCP-001 accruals.

Accruals have once again been robust, and we have exceeded our year-end goal of 200. For a list of open clinical trials, please visit the GA NCORP Website to access the Open Clinical Trials Report.

Figure 2.

Accruals by Disease Site & Open Clinical Trials



*Patient enrolled, study now closed.

Figure 3.

Physician Engagement

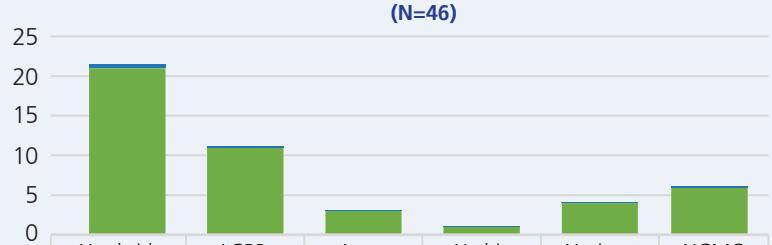
Total Number of Rostered Physicians	Number and Percent of Physicians Accruing
97	46 (47%)

Year 5 Top Accruing Investigators (5 or More Accruals)+

Northside	LCRP
Sreekanth Reddy, MD (12)	Sarah Gill, MD (15)
Cheryl Jones, MD (8)	Jennifer Yannucci, MD (7)
Jayanthi Srinivasiah, MD (7)	Grant Lewis, MD (6)
Gena Volas-Redd, MD (5)	Mark Taylor, MD (5)
	John Pablo, MD (5)
Amos	**Navicent**
Andrew Pippas, MD (5)	Sushmita Nair, MD (8)

+Excludes TMIST, CCDR & DCP-100 accruals.

Investigator Enrollment (N=46)



	Northside	LCRP	Amos	Harbin	Navicent	NGMC
Percent Accruing	46%	24%	7%	2%	9%	13%
Number Accruing	21	11	3	1	4	6

Information obtained from NCORP-SYS and CTSU. The number of rostered physicians is based on active/rostered CTEP status as of 08.26.19. Excludes DCP-001 accruals.

Clinical Trial Highlights

S1501

S1501 is a phase III trial comparing twice daily carvedilol with no intervention for the prevention of cardiac toxicity in patients with metastatic HER2+ breast cancer. Treatment or no intervention will continue for 108 weeks. Eligible patients must have an increased risk for cardiac toxicity and either be initiating or continuing trastuzumab-based HER2 targeted therapy without concurrent anthracyclines as first or second-line therapy. Therapy can also include ado-trastuzumab or trastuzumab combined with chemo- or hormonal therapy or another HER2 targeted agent, such as pertuzumab. Further, a LVEF ≥50%, which must be obtained from a validated ECHO lab, is required within 28 days prior to registration. Patients currently taking a beta-blocker, ACE inhibitor, or angiotensin II receptor blockers are eligible for a non-randomized observational cohort.

S1501 began in September 2017 and plans to enroll 817 participants who are at least 18 years of age. Enrollment completion is planned for February 2023.

Reference:
Clinicaltrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT03418961. Accessed 10/3/2019.

TMIST

Tomosynthesis Mammographic Imaging Screening Trial, or TMIST, is comparing two FDA-approved types of digital mammography, standard 2-dimensional (2-D) full-field digital mammography versus a newer 3-dimensional (3-D) breast tomosynthesis technology. TMIST opened in July 2017 and plans to enroll 165,000 women between the ages of 45 and 74 years. Once enrolled, women will be randomized to receive either the 2-D or 3-D screening mammogram for 5 years; whether screening is yearly or every other year will be determined based on participant's individual risk for developing breast cancer. Additionally, blood and buccal smears are being collected to study the genomes of the patients, demographics, and pathology specimens – both benign and malignant – in order to create models for individualized screening strategies.

Enrollment completion is planned for mid-2026 with study completion anticipated in August 2030.

References:
National Cancer Institute. Available at: https://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/tmist. Accessed 10/3/2019.
ECOG-ACRIN newsletter. Available at: https://ecog-acrin.org/news-and-info/newsletters/conversation-with-tmist-lead-etta-d-pisano-md-02-2019. Accessed 10/3/2019.

GA NCORP Monthly New Trial Alert

Disease Group	Trial Name	Eligibility	NCI Accrual Goal	Activation Date
TREATMENT TRIALS				
GU	NRG-GU007: Niraparib With Standard Combination Radiation Therapy and Androgen Deprivation Therapy in Treating Patients With High Risk Prostate Cancer	Phase I enrollment: Gleason ≥ 9, PSA ≤ 150 ng/mL, any T-stage • Phase II enrollment: Gleason ≥ 9, PSA ≤ 150 ng/mL • Any T-stage, Gleason 8, PSA < 20 ng/mL, and ≥ T2 • Gleason 8, PSA ≥ 20-150 ng/mL • Any T-stage, Gleason 7, PSA ≥ 20-150 ng/mL • Any T-stage	36	6/3/2019
GYN	NRG-GY018: Testing the Addition of the Immunotherapy Drug Pembrolizumab to the Usual Chemotherapy Treatment (Paclitaxel and Carboplatin) in Stage III-IV or Recurrent Endometrial Cancer	Stage III/IV Endometrial Cancer • No prior chemotherapy for treatment of endometrial cancer or prior adjuvant chemotherapy	810	7/16/2019

Continued on page 4

GA NCORP Monthly New Trial Alert (continued)

Disease Group	Trial Name	Eligibility	NCI Accrual Goal	Activation Date
TREATMENT TRIALS (continued)				
Head and Neck	NRG-HN005: De-intensified Radiation Therapy With Chemotherapy (Cisplatin) or Immunotherapy (Nivolumab) in Treating Patients With Early-Stage, HPV-Positive, Non-Smoking Associated Oropharyngeal Cancer	Squamous cell carcinoma of the oropharynx (tonsil, base of tongue, soft palate, or oropharyngeal walls), T1-2, N1, M0 • No prior systemic therapy for study cancer • Prior chemotherapy for a different cancer is allowable	711	7/10/2019
Heme	S1826: Immunotherapy (Nivolumab or Brentuximab Vedotin) Plus Combination Chemotherapy in Treating Patients With Newly Diagnosed Stage III-IV Classic Hodgkin Lymphoma	Stage III-IV Hodgkin Lymphoma	987	7/19/2019
CANCER CONTROL/PREVENTION TRIALS				
Breast	A221702: Axillary Reverse Mapping in Preventing Lymphedema in Patients With Breast Cancer Undergoing Axillary Lymph Node Dissection	Breast Cancer • Rates of Lymphedema & Regional recurrence • Axillary Reverse Mapping • Patients with known metastatic disease who are undergoing palliative resection are not eligible	516	4/1/2019
GU	WF-1802: Effect of Treatment on Work Experience in Patients With Stage I-III Prostate Cancer (PCW)	Anticipated initiation of primary, curative treatment for adenocarcinoma of the prostate (e.g. prostatectomy or radiation) within 90 days of enrollment and employed within 14 days prior to enrollment	220	6/4/2019
CCDR				
Breast	Increasing Socioeconomically Disadvantaged Patients' Engagement in Breast Cancer Surgery Decision Making Through a Shared Decision-Making Intervention (A231701CD)	Patients with newly diagnosed stage 0-III breast cancer	1050	3/11/2019
GU	NRG-CC007CD: Increasing the Dose of Survivorship Care Planning in Improving Care and Outcomes in Prostate Cancer Survivors Receiving Androgen Deprivation Therapy	Survivorship Care Planning • Prostate Cancer Survivors • Post Androgen Deprivation	504	3/27/2019
Heme	A231602CD: Assessment of Financial Difficulty in Participants With Chronic Lymphocytic Leukemia and Multiple Myeloma	CLL or MM • Cannot be on another trial • Treatment within past year • Survey given by Sponsor • Limited Chart Abstract • Assessing Financial Difficulty	500	3/15/2019
Other	EAQ161CD: Assessment of Current Biomarker Testing Practices for Common Solid Cancers in Precision Oncology in the Community Setting	Pathology Practice • Biomarker Survey • Selection for audit of turn-around times	N/A	1/8/2019
Other	EAQ171CD: Implementing a Virtual Tobacco Treatment for Cancer Patients in Community Oncology Practices	Pathology Practice • Biomarker Survey • Selection for audit of turn-around times	308	3/18/2019

Continued on page 5

GA NCORP Monthly New Trial Alert (continued)

Disease Group	Trial Name	Eligibility	NCI Accrual Goal	Activation Date
CCDR (continued)				
Other	A231601CD: Use of a Pre-Surgical Toolkit in Improving Surgical Care and Outcomes in Older Participants With Cancer	Older cancer patients 70+ • Surgical practice Gastrectomy, Colectomy, Proctectomy, Esophagectomy, Pancreatectomy, Hepatectomy, Total Cystectomy, Total Nephrectomy, Lung Lobectomy/Pneumonectomy	450	4/1/2019
Other	WF-1804CD: Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among Survivors (AH-HA)	This study is activated but is a limited access study - 12 affiliates & sub-affiliates	600	5/23/2019

Resources

Treatment Trial (NCTN) Disease Specific Trial Portfolios: **https://ctep.cancer.gov/initiativesPrograms/nctn_trials_by_disease.htm**

Cancer Control / Prevention / CCDR (NCORP) Trials: **https://ncorp.cancer.goc/fin-a-study/**

New trial reports are distributed monthly. Contact Michelle Young (michelle.young@northside.com) to be added to the distributions list.

Physician Highlights

Physicians from some of our top-accruing sites share their words of wisdom on successful patient accrual as well as highlights of these trials. Additionally, they share information about the latest trials that they believe show great promise.

Melissa Dillmon, MD
Harbin Clinic

Describe some of the highlights of the top accruing trials. What makes them unique?

One of our top enrolling trials at the Harbin Clinic has been NRG-BR003. We have a very large breast cancer practice, with prompt referrals to our clinic after evaluation at one of our two breast cancer centers and discussion at our prospective breast cancer tumor board, which is held weekly. Patients with triple-negative breast cancer are at high-risk for early recurrence, and this clinical trial is looking at changing our approach to adjuvant therapy in this high-risk population.

Our breast cancer population that fits the criteria for this trial has been eager to enroll to help improve our knowledge of how to best treat this disease. Due to our success in enrolling in this study coupled with our prospective breast cancer conference, we are looking forward to potentially opening SWOG 1418, which will evaluate adjuvant immunotherapy (IO) in patients who have received neoadjuvant therapy for the triple-negative disease. Our surgeons who present at our breast cancer tumor board are already very comfortable in referring for neoadjuvant therapy where appropriate, which should make enrollment easier. As we look at these clinical trials and our success as an NCORP, I would encourage ensuring that our Medicaid population can enroll in these studies in the coming years. We need to ask our state government to add protections to allow routine cost of care on clinical trials to guarantee that this population has access to these trials in the future.

Sarah Gill, MD
St. Joseph's/Candler Gynecologic Oncology & Surgical Specialists

Describe some of the highlights of the top accruing trials. What makes them unique?

In general, top accruing trials in gynecologic oncology address important clinical questions that aim to advance our knowledge of disease processes and dictate best practices regarding treatment, especially in cancers with high recurrence rates and poor responses to primary therapy. Despite the availability of an evidence-based chemotherapy regimen that produces remissions in the majority of patients, 75% of patients who present with advanced ovarian, fallopian tube, or primary peritoneal carcinomas eventually have disease recurrence. There is a great need to test novel therapies in the primary and recurrent settings to improve outcomes in this patient population.

NRG Oncology trial GY007, a phase I/II study of ruxolitinib with front-line neoadjuvant and post-surgical therapy in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, is one of the top accruing gynecologic cancer trials at our institution, the Lewis Cancer and Research Pavilion in Savannah. We are currently enrolling in the phase II portion, where patients are randomized to receive carboplatin and dose-dense paclitaxel plus either ruxolitinib (a JAK inhibitor) or placebo. We currently have several patients enrolled in this trial, and they are tolerating the treatments well.

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

NRG Oncology trial GY018 is a recently activated study

Continued on page 6

Physician Highlights (continued)

for patients with advanced or recurrent endometrial cancer to evaluate standard treatment with carboplatin and paclitaxel with or without pembrolizumab. PD-1 inhibitors were recently approved by the FDA for the treatment of PD-1 positive endometrial cancers, so their addition to upfront chemotherapy in this patient population is quite exciting.

Another exciting trial is NRG Oncology trial GY012, a randomized phase II study comparing single-agent olaparib, single-agent cediranib, and the combination of cediranib and olaparib in women with recurrent, persistent, or metastatic endometrial cancer. The novel design of this trial, which includes a rolling addition of new novel targeted therapies, will allow many different combinations to be compared to the control arm, cediranib alone. The initial trial with the study arms listed above has closed, but two additional arms have been added to compare to the control arm: olaparib plus capivasertib and bevacizumab plus capivasertib. Additional regimens to be offered in the future are being discussed within the NRG at this time.

Cheryl Jones, MD
Georgia Cancer Specialists

Can you share some words of wisdom on successful patient accrual?

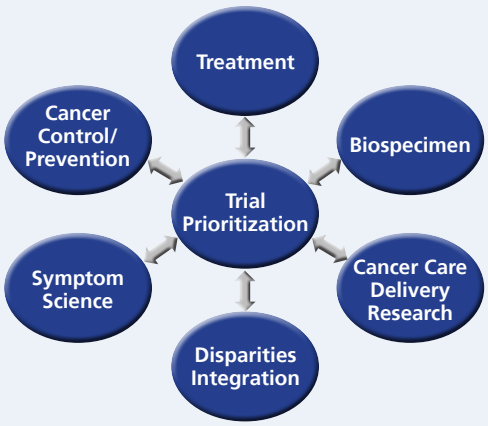
Clinical trial participation requires dedication and a time commitment by clinicians and their staff to identify the most appropriate trials for their patients and to educate staff and patients of the fundamental role that clinical trials have made in advancing the field of oncology with chemotherapy, biological agents, immunotherapy, and supportive care agents. This effort has resulted in improved cure rates and quality of life for patients. The ability to offer a patient a clinical trial opportunity with the most advanced medical care and cutting-edge therapies in a community setting is rewarding for physicians and their staff. The clinical trial portfolio available should provide the patient and their families with the hope and confidence that their care team has not only their best interest in mind when offering an opportunity to participate, but also the interest of advancing science for future generations.

This is an exciting time in clinical trials as a better understanding of molecular features of cancer has led to a greater breadth of clinical trials, leading to more personalized treatment options, better outcomes, and improved quality of life for the patient. It is not only the physician's responsibility to present the trial opportunities to the patient, but also the team of nurses and pharmacists to educate the patient on available opportunities. Once patients and the public are more educated on the opportunities that clinical trial participation affords and lose the stigma of "guinea pig," we will make even greater strides.

Network Program Team

A new organizational structure was recently implemented at GA NCORP with the addition of two new program teams – Symptom Science Background and Disparities Integration. We are excited for these new teams to commence work, and we are also excited to have representation from five of our member sites on our Executive Committee (**Figure 4**).

Figure 4. **Network Program Team**



Symptom Science Background

Symptom management research is operationally defined as any clinical study focusing on cancer and treatment-related symptoms and/or related psychological, social and spiritual problems. The primary endpoint in these studies is measured by a patient-reported outcome (PRO).

Program Director: Andre Kallab, MD / Andrew Pippas, MD

Program Coordinator: Alaina Underberg

Disparities Integration

GA NCORP is diligent in collecting, analyzing, and presenting data on enrollment of racial and ethnic minorities, rural residents, adolescents, young adults, and the elderly onto clinical trials. Dr. Jayanthi Srinivasiah, a highly experienced minority investigator recognized by the NCI for community accrual to clinical trials, will lead the newly formed Community Site Disparities Initiative as Program Director of the Disparities Integration Team. GA NCORP data for Years 3 and 4 indicate strong minority accrual at 27%; this is more than ten times the accepted national average. Each affiliate contributed significantly to this outcome, with 14 GA NCORP investigators accruing 3 or more minorities during this period.

Program Director: Jayanthi Srinivasiah, MD

Program Coordinator: Aprille Belgrave

Highlights and Recognition

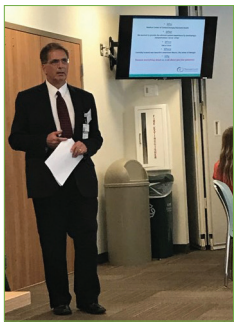
Member Site Highlight: Peyton Anderson Cancer Center, Navicent Health

The Peyton Anderson Cancer Center (PACC) of Navicent Health, located in Macon GA, provides a variety of services to its patients, including proactive treatment with faster diagnosis and personalized care that results in healing and improvement in the quality of life. In addition to having a Cancer Life Center that is accredited by the Commission on Cancer (CoC) with Commendation – Gold Level, the PACC also has a renowned Breast Cancer Program that is accredited by the National Accreditation Program for Breast Centers (NAPBC) and a certified Quality Breast Center of Excellence (National Consortium of Breast Centers National Quality Measures for Breast Centers). Several services such as genetic testing and counseling, patient navigation, and survivorship care are available for cancers besides breast, including colon, lung, prostate, head and neck, skin, and prostate cancers.

Children's Oncology Group (COG) Now Offering Pediatric Clinical Trial

Dr. Sushmita Nair, a pediatric/hematologist oncologist at Navicent Health is excited to be able to offer a clinical trial to her pediatric patients. Dr. Nair completed her medical education in India at JIPMER, Pondicherry and PGIMER, Chandigarh. Her passion for Pediatric Oncology led her to the United States where she completed a residency at Nicklaus Children's Hospital in Miami and a fellowship in Pediatric Hematology/Oncology from the University of Florida, Gainesville. Dr. Nair's fellowship research focused on immunotherapy for refractory pediatric leukemias with Chimeric Antigen Receptor (CAR) T-cells. She has been with Children's Oncology Group at Navicent Health since May 2016 and is currently accepting new patients with benign and malignant blood disorders as well as solid tumors and related conditions.

Photos from the Recent Bi-annual Investigators & Administrators Meeting



Dr. Fred Schnell welcomes the team to GA NCORP Year 5 semi-annual meeting in Macon, GA

Dr. Guilherme Cantuaria provides GA NCORP program updates to the team

GA NCORP team members listen attentively

Recognition

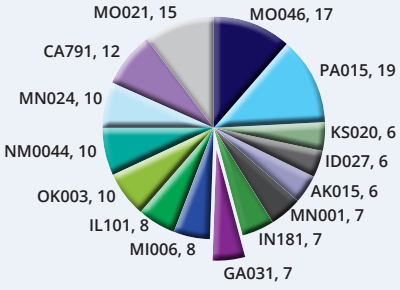
Key Accomplishments Years 1-5

- Accrued 2680 patients to NCI-approved, cancer control, cancer prevention, and CCDR trials (8/4/14 – 7/31/19)
- Ranked in the top 10 accruing sites for 16 NCI & GA NCORP high-priority trials (**Figure 5**)
- Exceeded our accrual goals in Year 5 (106%)
- Received Six Certificate of Excellence Awards for Exceptional Achievement in Patient Enrollments in NCI Treatment and Cancer Control trials August 2014 – June 2017
- GA NCORP – Platinum Certificate of Excellence - 1 of 19 NCORPS to receive the award for accruals to Treatment & Cancer Control Trials
- Ranked as the 8th top accruing NCORP site for NRG Oncology
- Partnered with NCI on a Social Marketing Project to increase African American awareness on multiple myeloma
- Selected to participate in Moonshot Initiative - Funding to translate/validate Patient Reported Outcomes (PRO) measures

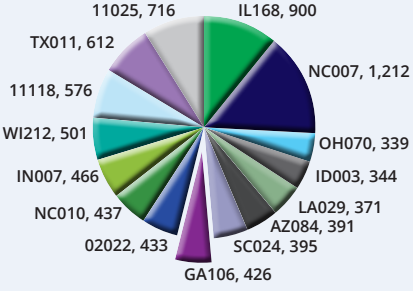
Figure 5.

Top 15 Enrolling Trials as of July 31, 2019

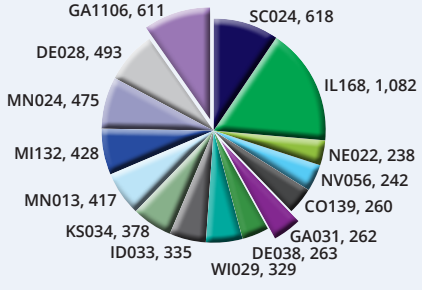
LUNGMAP (Only SCREENING Steps)



EA1151 (Only INTERVENTION Steps)



Top 15 Enrolling Sites for DCP-001 (Only OTHER Steps)



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