Cancer Care 2023 Report to the Community



A message from our Executive Director

Dear ECU Health Cancer Care Community,

As 2023 closes, we reflect on and celebrate the accomplishments of our service line over the past year. Perhaps most significant is the consolidation of all our sites into one Cancer Network – the ECU Health Cancer Care Network. We submitted our application to the American College of Surgeons in September and will convene our first system wide cancer committee meeting in February of 2024. The network is currently 4 centers, Greenville (main), ECU Tarboro, Ahoskie and Washington. We hope that ECU Cancer Care Manteo will join us after their next accreditation cycle. Creation of this network streamline the accreditation process for the component members and bring us closer together with combined cancer committee meetings and systemwide quality projects which are focused on outcomes in our unique, rural cancer population. Dr. Caroline Ames will be our inaugural chair of the combined committee.

In December, we brought the service line together in one place for the first time since the pandemic began with our annual service line retreat. The retreat was well attended with keynote speakers Dr. Michael Waldrum outlining the expected impact of the NC Cares legislation which is slated to bring almost \$500 million into eastern North Carolina for the purpose of improving the health of this population. Dr. William "Billy" Irvin also spoke on the Southeast Regional Oncology Consortium NCORP (National Community Oncology Research Program) — a federally funded program designed to improve access to clinical trials for rural and underserved populations. Hopefully, I will be able to report our own progress towards that designation for our own program in next year's annual report.

As the years pass, we inevitably say goodbye to colleagues and friends and welcome new ones. This year, we will lose one of the foundational members of our regional oncology team, Dr. John Inzerillo. John served patients with cancer in eastern North Carolina for almost two decades and is preparing for a well-deserved retirement in September. John's replacement has not yet been identified but we are hoping that the improved connectivity brought about by the new network will also allow some coverage at the regional sites by specialists based in Greenville.

We added several specialists this year including Drs. Khilen Patel and Jholak Dolakia in gynecologic oncology, Dr. Michael Blute in urologic oncology and Dr. Samir Batoo in medical oncology. Mindy Waugh and Rebecca Phillips joined the administration team as the cancer conference/accreditation coordinator and multidisciplinary cancer care/quality liaison, respectively. They replace Micah Sam who became ECU business school's director of technology and operations. Dr. Sukriti Kamboj, from our Kinston practice was recently honored with a patient's choice award. She is the first service line provider to receive this designation and it is well deserved. She credits her entire team with providing an environment for her patients to bestow this recognition upon her.

What does the future hold for ECU Health Cancer Care? In 2024, we will complete some foundational accreditations including the ACS CoC cancer care network, National Accreditation Program for Rectal Cancer, and Pancreatic Center of Excellence designation. Population health will continue to grow its footprint in our model of care. In July we will have completed one full year of participating in the CMS version of population health in cancer with their Enhancing Oncology Model. By that time, we will have gained significant insight into the efficiency and accessibility of the services we provide to cancer patients in this 29-county region. Clinpath™ is a proprietary service offered by Elselvier to provide clinical decision support and guidelines. This service is tailored for our system of care which is characterized by patients and providers over expansive geography with real health and resource challenges. Finally, we aim to continue to make clinical trials available for our rural and underserved population through our existing memberships in cooperative groups such as the Alliance for clinical Trial in Oncology and the National Clinical Trials Network. We hope to receive federal grant support for these programs through the National Community Oncology Research Program (NCORP) in 2025.

ECU Health Cancer Care continues to evolve. We are poised to move into the second quarter of the 21st century with laser focus on our mission, values and our steadfast desire to realize a life *without cancer* in eastern North Carolina.

Sincerely, Emmanuel E. Zervos, MD, MBA Raab Professor of Adult Oncology Executive Director of Cancer Services

Table of Contents

A message from our Executive Director	2
Message from the cancer committee	4
Goals for 2023	5
2023 Accomplishments & Recognitions	5
Clinical Services	6
Infusion Center	7
Outpatient Clinics	8
Clinical Trials	9
Cancer Care Navigation	15
Psychosocial Distress Screening	17
Survivorship Care Plan & Clinic	17
Gamma Knife® Center	17
GammaTile [®]	19
Radiation Oncology	19
ECU Health Medical Center Community Benefit	21
Outreach Program	21
Support Services	26
Cancer Registry	27
Evidence-Based Outcome Study	28
Quality Improvement Initiative	29
Fundraising	30

Message from the cancer committee

The ECU Health/ECU Health Medical Center (ECUHMC) Cancer Care purpose is to be the premier, trusted, integrated cancer care delivery system in eastern North Carolina by developing a national model for rural healthcare that will reduce mortality and provide ready access to prevention, early intervention, and quality, coordinated patient care.

Here at ECUHMC, the Cancer Committee continues to ensure that high-quality cancer care is in place to meet the needs of cancer patients in eastern North Carolina. Our staff, in conjunction with local private practice physicians, ECU Health Physicians, and physicians from The Brody School of Medicine at East Carolina University, work together to provide comprehensive cancer care across our service area. One area where high quality cancer care is received is our Women's Health and Oncology Center, under the direction of Dr. Karinn Chambers. They were surveyed in November 2022 and reaccredited by the National Accreditation Program for Breast Center (NAPBC). During that survey, it was recommended that Dr. Chambers report to the cancer committee as the breast program director. She gave a detailed report at our October meeting focused on quality and areas of future growth.

We were surveyed in March by the American College of Surgeons Commission on Cancer and awarded the 3-year accreditation!

This year, the Cancer Committee has elected to continue with the CoC initiated quality study Beyond ASK focused on lung cancer and smoking cessation. This is a PDSA project involving review of our data related to what are we doing to help patients with their smoking habits.

ECU Health Cancer Care at ECUHMC will continue to focus on improving care by increasing clinical trial availability and accruals, reducing barriers to care through patient navigation, increasing public awareness of cancer prevention, early detection and screening, and collaborating with regional ECUH community hospitals to ensure seamless, high-quality care across the continuum. ECU Health cancer center at the Eddie and Jo Allison Smith tower serves as "the hub" for ECU Health Cancer Care providing tertiary cancer care for all of eastern North Carolina.

2023 cancer committee

Warqaa Akram, MD

Brian Brodish, MD, liaison physician Aidan

Burke, MD

Karinn Chambers, MD

Clint Faulk, MD

Tae Juon Lee, MD

Andrew Ju, MD

Brian Kuszyk, MD

Darla Liles, MD, chair Mahvish

Muzaffar, MD Gina Murray, MD

Christina Paul, MD

Sean Peach, MD

Chris Thomas, MD

Nasreen Vohra, MD, liaison physician

Emmanuel Zervos, MD Yaolin

Zhou, MD

Thomas Alcock, RN, BSN, MBA

Denise Brigham, RN

Merrill Bright, RHIA, CTR

Kathye Bennett-Chambliss, RDN, LDN

Felicia Collins, DNP, RN, MSN, CRRN, NEA-BC

Phyllis DeAntonio, RN, MSN, FAAMA

Vickie Downing, RN, MSN, OCN

Leighann Henley, RN, MSN

Todd Hickey, FACHE

Emily Kozuszek, CGC

Jennifer Lewis, RN, BSN

Debra Mascarenhas, RN, BSN, CBCN

Jaimie Morales, CTR

Njeri Njuguna, MS, RDN, LDN, CDCES

Teresa Parent, RN, BSN, OCN

Jessica Perkins, RDN

Neha Poladi, PharmD

Vanessa Polk, MRE, BCC

Micah Sam, MBA

Debra Taft, FNP-C, AOCNP

Dawn Tetterton, MSN, RN, BC

Lauren Tenace, PA-C

Robbie Tilley, ACS

Catherine Wallace, PharmD, BCOP

Ashley Williams, MSW, LCSW, OSW-C

Robynique Willis-Brown, MSW, LCSW-A

Chris Wood, RT (R)(T) MBA

Kristin Wooten, MBA

Goals for 2023

Achieve a 5% reduction in LOS index for oncology service line patients at the end of the calendar year. Stretch goal of 10% reduction or greater. Information was obtained from Vizient for observed to expected LOS index. Progress was monitored during the year with report at end of year benchmarked against other organizations of like size. Workflows and processes were developed via a cross functional team. Goal was to have LOS index at or below 1.0. Currently, metric is at 9.05 days with an index of 1.17.

Achieve Electronic Patient Reported Outcomes (ePRO) implementation and utilization by two medical oncologists at the medical center. Progress to be monitored throughout the year with end of year report benchmarked against national oncologists. A cross functional team determined workflow. Pilot was successfully implemented with several medical oncologists as well as rehab oncology. It was recommended to move forward with implementation of project with other oncologists.

2023 Accomplishments & Recognitions

The following are some of the noteworthy accomplishments for 2023:

- Partnership continued with ECU Health Lifestyle Medicine for massage and exercise services in the Resource Center.
- Welcomed new physicians and staff: Dr. Sameer Batoo –Medical Oncology; Drs. Jhalak Dholakia and Khilen Patel Gyn Oncology; Melinda Waugh Cancer Center Cancer Conference Coordinator; Pamela Hawkins Program Assistant; Rebecca Phillips Multidisciplinary Cancer Care Coordinator & Quality Liaison; Bonnie Kmon, RN Nurse Navigator; Angelina Brittle Social Work Navigator; Elizabeth Dyer, RN Gamma Knife; Veronica Ward, RN and Kelly Wingard, RN Symptom Management Clinic; Rachel Stephenson, PA Medical Oncology; Lindsay Roberson, PA Medical Oncology; Ashley Baldree, RTT and Kristen Chambers, RTT Radiation Oncology; Sylvia Peele Lab.
- Provided 836 hours (\$39,155) in community benefit to over 9,571 individuals.
- Gamma Knife® upgraded to Espirit in December.
- Lutathera treatment provided to 35 patients.
- GammaTile® continues success with 13 patients treated.
- Provided cancer awareness/prevention/screening information to more than 6,300 people. Information
 disseminated via radio broadcasts, educational displays and packets, presentations, health fairs and
 information sessions. Provided more than 212 people with free cancer screenings (breast, prostate, skin,
 and lung).
- The cancer registry responded to over 100 data requests for research and outcome studies, including county-based data, follow-up, and case totals.
- Over 89.94% of chemotherapy is administered on an outpatient basis.
- Clinical trials volume increased to 23% of annual caseload.
- Awarded a third American Cancer Society Transportation Grant.
- Reaccredited by the American College of Surgeons Commission on Cancer (ACoS CoC).
- Service Line APP provided 89 days of coverage in the region.

Recognition

Dr. Misbah Qadir, Medical Oncology Outreach Director – Patient Choice Award Recipient

Clinical Services

Our Doctors and APPs:

Gynecological Oncology Providers	Medical Oncology Providers	Palliative Care Providers	Surgical Oncology Providers
Jhalak Dholakia, MD	Jorge Abdallah, MD	Margaret Clifton, MD	Warqaa Akram, MD
Grainger Lanneau, MD	Sameer Batoo, MD	Tae Lee, MD	Karinn Chambers, MD
Khilen Patel, MD	Jessica Hildebrand, MD	Rima Panchal, MD	Michael Honaker, MD
Diane Semer, MD	Jasmin Jo, MD	Nicole Averett, NP	Nasreen Vohra, MD
Gail Zeisler, FNP	Charles Knupp, MD	Laura Carmon, NP	Emmanuel Zervos, MD
	Pamela Lepera, MD	Barbara Connold, NP	Abigail Foster, PA
	Darla Liles, MD	Shauna Everett, NP	Nancy Lopez, PA
Cardio-Oncology Provider	Mahvish Muzaffar, MD	Heather Hill, NP	
Sivakumar Ardhanari, MD	Musharraf Navaid, MD	Crystal Vance, NP	
	Maria Picton, MD	Elizabeth Gottsch, PA-C	
	Misbah Qadir, MD		
Oncology Rehab Provider	Andrew Weil, MD	Radiation Oncology Providers	
Christina Paul, MD	Heather White, MD	Hyder Arastu, MD	
	Cynthia Cherry, NP	Aidan Burke, MD	
	Sabrina Oleskey, NP	Andrej Hnatov, MD	
Urology Oncology Provider	Lindsay Roberson, NP	Andrew Ju, MD	
Michael Blute, MD	Rachel Stevenson, PA	Mohit Kasibhatla, MD	
	Debra Taft, NP	Sean Peach, MD	
	Lauren Tenace, PA	Suzanne Woolard, NP	

Inpatient Medical Oncology - 4th Floor Cancer Center

The Medical Oncology 48 bed unit provides intermediate, general, monitored, and observation levels of care to our patient population. Providing multiple levels of care allows for the progression of our patients without having to move them from their room as their level of care improves. This provides the same physical space with the same specialized nursing care which supports our goal of providing continuity of care for patients throughout their treatment plan.

Specialty-trained physicians, providers, and nurses provide comprehensive care to adult patients with all types of hematologic and oncologic diseases. This team works seamlessly with the other services throughout the cancer center. The medical oncology team consists of hematology and oncology providers, as well as hospitalists and advanced practice providers who collaborate to develop and execute a comprehensive plan of care. The interdisciplinary team also includes nurses, nursing assistants, unit secretaries, nurse case managers, social work case managers, a recreational therapist, a pharmacist, physical therapists, occupational therapists, a dietitian, and a staff professional development specialist.

Staff nurses are encouraged and supported in their professional development. The Medical Oncology unit supports and participates in the local Oncology Nursing Society Chapter and the Coastal North Carolina Chapter. The chapter and the hospital system, provides educational opportunities for nurses. There are seven experienced nurses that are Oncology Certified Nurses (OCN), which validates expertise in Oncology Nursing. We continue to have nurses seeking advanced degrees, certifications and leadership opportunities through our active Unit Based Council, Quality Council, and the Retention/Recognition Committee.

Promoting a healing environment is necessary to achieve holistic patient outcomes, as well as promoting an engaged team. On the Medical Oncology Unit, this has been a joint effort between the team, patients, and their families. Hospitalized patients have access to support and survivorship services, healing gardens, and an indoor and outdoor labyrinth to help promote their overall well-being.

The Unit Based Councils are interdisciplinary, as well and have had great successes in bringing not only clinical expertise and improvement in quality initiatives. They also have worked together to bring joy to our patients and each other by celebrating patient birthdays and weddings on the unit. A successful collaborative effort during the holidays has been achieved to supply and run a Santa's Workshop where all the patients, including the immunocompromised patients, and their loved ones can shop at no cost, enjoy team members singing songs of the season and hot chocolate.

Inpatient Surgical Oncology - 2nd Floor Cancer Center

The Surgical Oncology unit is a 32-bed unit that provides care to patients requiring the following surgical sub-specialties: gastrointestinal, genitourinary, head/neck, and gynecology. We offer a seamless transition from surgical oncology to medical oncology. Our astounding care team members are equipped to provide care to general, general monitored, and intermediate levels of care. Our Surgical Oncology interdisciplinary team is comprised of physicians, advance practice practitioners, nurses, a nurse care manager, nursing assistants, environmental service workers, unit secretaries, social work case managers, dietitians, pharmacists, and physical/occupational, respiratory and speech therapists. The surgical oncology staff utilize a collaborative approach to provide high quality patient and family centered care. From the first day of admission to the date of discharge we incorporate a professional, compassionate learning environment that helps facilitate the healing process. This collaborative approach provides our patients and their families with the knowledge and the proper skills necessary for transitioning to independence and recovering in their home environment.

Our nursing team focus is based on competency training, best practice standards, and a commitment to continuously seek out opportunities to improve. We support and encourage nursing development through advancement in higher level degrees, professional organizations, and specialty certifications. Physicians and nurses engage in the unit and hospital practice councils for decision making and clinical practice recommendations.

Palliative Care Unit - 2nd Floor Cancer Center

A 16 bed Palliative Care Unit provides services to cancer patients and others requiring symptom management and care for life-limiting illnesses. Hospice in Palliative Care is a specialized service provided to patients whose symptom burden requires frequent assessment and intervention.

The palliative care outpatient clinic has been able to continue providing advance care planning and goals of care conversations with patients and families both virtually and in clinic. Some of our most vulnerable patients benefited from consultation without having to leave home. This approach also allowed for broader reach of outpatient palliative care consults to people who live far away from ECU Health Cancer Center.

Infusion Center

The ECU Health Medical Center Infusion Center is located inside the Eddie and Jo Allison Cancer Tower on the first floor. It is designed to deliver chemotherapy, blood products, and other infusions in an outpatient setting. The Infusion Center delivers necessary treatments and therapies to patients while allowing them to maintain their normal life routines as much as possible. The center provides the best of both worlds by providing an outpatient service located within a major medical center.

The Infusion Center has 60 treatment beds/chairs and treats 110-120 patients daily from across eastern NC. Currently, Infusion has 12 private rooms and 48 infusion chairs. We also offer a dedicated space for quick treatments such as injections and port flushes. The center offers the following amenities to keep patients comfortable and entertained during their stay: reclining chairs with heat and massage, beautiful views of our gardens, and TVs for every patient with individual

controls. These televisions are equipped with state- of-the-art patient engagement technology offering education, entertainment, and relaxation features. Massage and exercise are two complimentary therapies that are provided as needed for patients. The infusion suites are built around a beautiful healing garden that is accessible from inside of the center. This garden is open to patients and families, and has tables, benches, and a walking labyrinth.

The lab is located adjacent to the Infusion center to make lab results available in the most efficient time. There is also an onsite pharmacy to provide safe and timely access to chemotherapy, decreasing patient wait times and increasing patient satisfaction. Shuttle and valet services are available to all patients to assist with transportation to and from the parking areas.

The Infusion center staff of nurses, care partners and unit secretaries work closely with all referring providers. Nurses are chemotherapy certified with an average of 15 years of nursing experience. There are a total of 20 nurses, of which seven are certified oncology nurses and others are working toward this goal. Certification is the gold standard of oncology nursing, and every nurse in Infusion has a true passion for oncology patients.

Patients at the outpatient Infusion Center receive the highest quality, most efficient care possible, allowing patients to spend more time at home with loved ones.

Outpatient Clinics

We currently have clinics serving the needs of several specialties in oncology. We have four clinics, each with 12 rooms. These clinics serve a variety of patients including medical oncology, surgical oncology, and gynecology oncology.

We offer several specialized clinics such as clinics for cardio oncology, palliative care, survivorship, and this year, lymphedema was added. Smoking cessation appointments are scheduled with either Teresa Parent, RN, or Lynne Bair, SW.

Genetic Counseling & Risk Assessment

Patients referred to genetic counseling are seen by an ABGC certified genetic counselor for risk assessment and pre-test counseling, as well as post-test counseling when indicated. Genetic counseling appointments are available both in person at ECU Health Medical Center and over the phone, allowing flexible access to genetic counseling services for patients across eastern North Carolina. Both ECU and Non-ECU providers have continued to refer patients to the ECU genetics program.

578 unique patients were referred for genetic counseling between 1/1/2023 and 9/30/2023. Approximately 80% of referred patients who schedule and attend a genetic counseling appointment complete genetic testing. 15.9% of patients who complete genetic testing had a positive genetic test result. Pathogenic and likely pathogenic mutations were identified in 19 unique genes. Personal or family history of breast cancer were the most common reason for referral, representing 45% of all referrals. Other common referral reasons including personal/family history of colorectal cancer (12%), pancreatic cancer (8%), prostate cancer (8%), and ovarian cancer (7%).

Our site-specific focus for the year was colorectal cancer. 74 patients were referred for genetic counseling due to a personal or family history of colon cancer and/or colon polyposis. 46 patients completed genetic testing, 28% of whom had a positive genetic test result. With an average of 62 patients referred per month, the genetics program is on track to have received between 700-800 total unique referrals by the end of 2023, which would be an increase from 683 referrals in 2022. Program goals for 2024 include expansion of genetic testing for family history of breast cancer through identification of patients during routine mammogram and routine OB/GYN care and referral to a high-risk clinic staffed by a physician or APP in addition to the genetic counselor. With expanded availability of low-cost genetic testing offered by the labs used by ECU Health, the program also hopes to expand genetic testing and counseling for patients with diagnoses of breast, ovarian, prostate, pancreatic, and colorectal cancer.

Symptom Management Clinic

Cancer may cause many symptoms and its treatment (i.e., chemotherapy, immunotherapy, radiation therapy, surgery) can cause significant side effects. The Symptom Management Clinic (SMC) was created to help treat these issues as quickly as possible. The clinic is located within the Infusion Center and began seeing a limited number of patients in July 2017. A grand opening was held on November 8, 2023 to honor the clinic's expansion with dedicated staff including a physician assistant and two nurses. This expansion has allowed for more patients to be seen daily with the hope of further meeting the SMC's goals of avoiding emergency room visits where possible, providing better access to care, improving clinic workflow, reducing length of stay and readmission rates, increasing patient centered care, and decreasing costs. The SMC is open five days a week from 8 am until 5 pm, with the last appointment available at 3:30pm. To be seen, cancer patients currently undergoing treatment may call their clinic nurse or navigator to report symptoms, and an appointment will be scheduled for the same day or next. The SMC is equipped to assess and treat fevers, generalized fatigue, nausea, vomiting, diarrhea, dyspnea, pain, decreased appetite, rashes, edema, and wound or drain issues. Staff can also provide transfusion support. All patients, physicians, and staff are encouraged to utilize this service to avoid unnecessary visits to the Emergency Department.

Clinical Trials

The joint East Carolina University/ECU Health Cancer Care Oncology Clinical Trials Office coordinates and facilitates clinical research to improve the cancer care of tomorrow and to provide patients in eastern North Carolina access to novel therapies and the latest advancements in cancer care. Patients are seen in the outpatient setting at the Eddie and Jo Allison Smith Cancer Clinics and in all areas of ECU Health Medical Center. ECU currently has a main membership with the Alliance for Clinical Trials in Oncology. Our participation in the research process establishes a connection with the National Cancer Institute and The National Clinical Trials Network (NCTN) oncology cooperative groups that currently include NRG, ECOG-ACRIN, SWOG. Our ECU pediatric hematology oncology physicians are active members of the Children's Oncology group which allows them to provide the latest therapies to our children diagnosed with cancer. ECU maintains a collaborative relationship with UNC-Chapel Hill Cancer Network. Through this collaboration, our ECU surgical oncologists maintain a tumor tissue bank which allows bench research physicians access to clinical tumor samples for development of new therapies. In addition, our own oncology physicians write protocols to specifically meet the needs of our patient population. Some of these include translational research that provide the backbone for which bench research may reveal relevance in clinical treatment. We work directly with pharmaceutical companies on selected studies which can offer emerging new therapies not otherwise available. The following is a current list of trials by specialty:

Surgical Oncology:

Cancer Care Access for Rural Patients - Developing and Implementing a Validated Measure to Identify Patients at High Risk of Transportation Barriers. Michael Honaker, MD, principal investigator.

COMET AFT-25- Comparison of Operative to Monitoring and Endocrine Therapy (COMET) Trial for Low-Risk DCIS: A Phase III Prospective Randomized Trial; Mahvish Muzaffar, MD, principal investigator.

Renovo TIGeR-PaC - Trans(Intra)-arterial Gemcitabine vs. Continuation of IV Gemcitabine and Nab-Paclitaxel following Radiotherapy for Locally Advanced Pancreatic Cancer; Emmanuel Zervos, MD, principal investigator.

Alliance A021502- Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair; Mahvish Muzaffar, MD, principal investigator.

Alliance A022104- The Janus Rectal Cancer Trial: A Randomized Phase II Trial Testing the Efficacy of Triplet versus Doublet Chemotherapy to Achieve Clinical Complete Response in Patients with Locally Advanced Rectal Cancer; Michael Honaker, MD, principal investigator.

AHPBA (NSQIP Whipple Trial MSK 17-418) - A Phase III Multicenter, Open Label Randomized Controlled Trial of Cefoxitin Versus Piperacillin-Tazobactam as Surgical Antibiotic Prophylaxisin Patients Undergoing Pancreatoduodenectomy; Emmanuel Zervos, MD, principal investigator.

EA2185- Comparing the Clinical Impact of Pancreatic Cyst Surveillance Programs; Emmanuel Zervos, MD, principal investigator.

EA3161- A Phase II/III Randomized Study of Maintenance Nivolumab versus Observation in Patients with Locally Advanced, Intermediate Risk HPV Positive OPSCC; Andrew Ju, MD, principal investigator

NRG-HN005 - A Randomized Phase II/III Trial of De-Intensified Radiation Therapy for Patients with Early-Stage, P16-Positive, Non-Smoking Associated Oropharyngeal Cancer; Andrew Ju, MD, principal investigator

EA6174- STAMP- A Phase III Randomized Trial Comparing Adjuvant MK-3475 (Pembrolizumab) to Standard of Care Observation in Completely Resected Merkel Cell Carcinoma (NCT); Nasreen Vohra, MD, principal investigator.

RTOG 1216- RANDOMIZED PHASE II/III TRIAL OF ADJUVANT RADIATION THERAPY WITH CISPLAN, DOCETAXEL-CETUXIMAB, OR CISTPLATIN-ATEZOLIZUMAB IN PATHOLOGICHIGH-RISK SQUAMOUS CELL CANCER OF THE HEAD AND NECK; Andrew Ju, MD, principal investigator.

S1801- A Phase II Randomized Study of Adjuvant Versus NeoAdjuvant MK-3475 (Pembrolizumab) for Clinically Detectable Stage III-IV High Risk Melanoma; Nasreen Vohra, MD, principal investigator.

Medical Oncology:

Literacy Protocol- Pilot study of Health literacy in cancer patients undergoing systemic chemotherapy in a rural eastern NC healthcare system and the impact on utilization of a symptom management clinic and admission rates. Darla Liles, MD, principal investigator.

ASCO Survey on COVID-19 in Oncology (ASCO Registry) - Darla Liles, MD, principal investigator.

NCCAPS NCI COVID-19 in Cancer Patients Study (NCCAPS) - A Longitudinal Natural History Study. Darla Liles, MD, principal investigator.

Alliance A151804- Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events. Mahvish Muzaffar, MD, principal investigator.

ON-TRK-Prospective Non-interventional Study in Patients with Locally Advanced or Metastatic TRK Fusion Cancer Treated with Larotrectinib; Mahvish Muzaffar, MD, principal investigator.

Alliance A011202- A Randomized Phase III Trial Evaluating the Role of Axillary Lymph Node Dissection in Breast Cancer Patients (cT1- 3 N1) Who Have Position Sentinel Lymph Node Disease after Neoadjuvant Chemotherapy; Mahvish Muzaffar, MD, principal investigator.

NRG-BR003- A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer; Mahvish Muzaffar, MD, principal investigator.

Alliance A071401- A study looking at targeted therapy according to tumor markers for people with meningiomas: Phase II Trialof SMO/AKT/NF2 inhibitors in progressive meningiomas with SMO/AKT/NF2 mutations; Darla Liles, MD, principal investigator.

EAF151- Change in Relative Cerebral Blood Volume as a Biomarker for Early Response to Bevacizumab in Patients with Recurrent Glioblastoma; Jasmin Jo, MD, principal investigator.

CCTG CE.7- A Phase III Trial of Stereotactic Radiosurgery Compared with Whole Brain Radiotherapy (WBRT) For 5-15 Brain Metastases; Jasmin Jo, MD, principal investigator.

P-MAIT- Predictive value of the Modified Glasgow prognostic score among patients undergoing immunotherapy with PD-1 targeted agents; Mahvish Muzaffar, MD, principal investigator.

SNAP- Prognostic Value of the Modified Glasgow Prognostic Score in A North American Population of Thoracic Oncology Patients; Mahvish Muzaffar, MD, principal investigator.

Aparna Hegde Research Fellowship - Biomarkers of Immunotherapy Related Thromboembolic Events; Li Yang, MD, principal investigator.

ECU032019- Surveillance of Stage III Non-Small Cell Lung Cancer using circulating tumor DNA; Sara Cowles, DO, principal investigator.

NRG-GY019- A Randomized Phase III Trial, Two-Arm Trials of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum; Grainger Lanneau, MD, principal investigator.

ARTISTRY-7- A Phase 3, Multicenter, Open-Label, Randomized Study of Nemvaleukin Alfa in Combination with Pembrolizumab Versus Investigator's Choice Chemotherapy in Patients with Platinum-Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (ARTISTRY-7); Grainger Lanneau, MD, principal investigator.

UP-NEXT- A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Upifitamab Rilsodotin(XMT-1536) as Post-platinum Maintenance Therapy for Participants with Recurrent, Platinum-sensitive Ovarian Cancer (UP-NEXT); Grainger Lanneau, MD, principal investigator.

ARCHES- A Multinational, Phase 3, Randomized, Double-blind, Placebo-controlled Efficacy and Safety Study of Enzalutamide Plus Androgen Deprivation Therapy (ADT) Versus Placebo Plus ADT in Patients with Metastic Hormone Sensitive Prostate Cancer (mHSPC); Johnathan Hamilton, MD, principal investigator.

ARCHES ROLLOVER- A Phase 2 Open-label Extension Study for Subjects with Prostate Cancer Who Previously Participated in an Enzalutamide Clinical Study; Johnathan Hamilton, MD, principal investigator.

Neurocognitive Assessment in Late Stage Lung Cancer- A prospective observational study of late stage lung cancer patients' neurocognitive changes over time as treatment is administered; Carol Velez Martinez, MD, principal investigator.

Connect the Myelodysplastic Syndromes (MDS) and AML Registry- Darla Liles, MD, principal investigator.

CMP-001-009- A multicenter, open-label, Phase 2 study of intratumoral CMP-001 in combination with an intravenous PD-1-blocking antibody in subjects with selected types of advanced or metastatic cancer; Nasreen Vohra, MD, principal investigator.

MOR208C414-REAL-MIND: Prospective multicenter observational study of patients with relapsed or refractory diffuse large B-cell lymphoma starting second- or third-line therapy and not receiving autologous stem cell transplant; Darla Liles, MD, principal investigator.

D18-11141- A Phase III, multicenter, randomized study with two arms (1:1 ratio) enrolling patients with AML relapsed/refractory after 2, 3, or 4 prior induction regimens; Darla Liles, MD, principal investigator.

FISHER-WELLMAN-MITO- Bioenergetic characterization of solid tumors and primary leukemias; Kelsey Fisher-Wellman, MD, principal investigator.

Alliance A191901- Optimizing Endocrine Therapy Through Motivational Interviewing and Text Interventions; Mahvish Muzaffar, MD, principal investigator.

EA2186 (GIANT)- A Randomized Phase II Study of Gemcitabine and Nab-Paclitaxel Compared with 5-Fluorouracil, Leucovorin, and Liposomal Irinotecanin Older Patients with Treatment Naïve Metastatic Pancreatic Cancer (GIANT); Mahvish Muzaffar, MD, principal investigator.

Alliance A021806- A Phase III Trial of Perioperative Versus Adjuvant Chemotherapy for Resectable Pancreatic Cancer; Mahvish Muzaffar, MD, principal investigator.

Alliance A211901- Reaching Rural Cancer Survivors Who Smoke using Text-Based Cessation Interventions; Mahvish Muzaffar, MD, principal investigator.

FAETH-SER-ISD-001 - A Phase 1b Study of Serabelisib in Combination with an Insulin Suppressing Diet (Study ISD) in Subjects with Advanced Solid Tumors with PIK3CA Mutations with or without PTEN loss; Mahvish Muzaffar, MD, principal investigator.

Alliance A041701- A Randomized Phase II/III Study of Conventional Chemotherapy +/- Uproleselan (GMI-1271) in Older Adults with Acute Myeloid Leukemia Receiving Intensive Induction Chemotherapy; Darla Liles, MD, principal investigator.

Alliance A041702- A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients (>/= 70 Years of Age) With Chronic Lymphocytic Leukemia (CLL); Darla Liles, MD, principal investigator.

Alliance A041501- A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (a Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) With Newly Diagnosed Precursor B-Cell ALL; Darla Liles, MD, principal investigator.

ASTX-727-07- A Phase 1/2 single-arm, open-label, multicenter, non-randomized interventional study to evaluate the PK, safety, and efficacy of ASTX727 when given in combination with venetoclax for the treatment of newly diagnosed AML in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy; Darla Liles, MD, principal investigator.

PrE0905- Randomized Trial of Gilteritinib vs Midostaurin in FLT3 Mutated Acute Myeloid Leukemia (AML); Darla Liles, MD, principal investigator.

DELFI-L201- CASCADE-LUNG Cancer Screening Assay using DELFI: A Clinical Validation Study in Lung; Darla Liles, MD, principal investigator.

NCTC- North Carolina Tissue Consortium; Nasreen Vohra, MD, principal investigator.

Benign Hematology:

TAK-755-2001 - A Phase 2b, multicenter, randomized, double-blind study of safety and efficacy of TAK-755 (rADAMTS13) with minimal to no plasma exchange (PEX) in the treatment of immune-mediated thrombotic thrombocytopenic purpura (iTTP); Darla Liles, MD, principal investigator.

MO42623 - A MULTICENTER, OPEN-LABEL PHASE IV STUDY TO EVALUATE OVERALL HEALTH, PHYSICAL ACTIVITY, AND JOINT OUTCOMES, IN PARTICIPANTS AGED ≥ 13 AND < 70 YEARS WITH SEVERE OR MODERATE HEMOPHILIA A WITHOUT FVIII INHIBITORS ON EMICIZUMAB PROPHYLAXIS; Darla Liles, MD, principal investigator.

USTMA TTP- United States Thrombotic Microangiopathy (USTMA) Thrombotic Thrombocytopenic Purpura (TTP) Clinical Data and Biologic Sample Repository; Darla Liles, MD, principal investigator.

TTP Registry- Thrombotic Thrombocytopenic Purpura Registry; Darla Liles, MD, principal investigator.

PRN1008-010- An Adaptive, Open-Label, Dose-Finding, Phase 1/2 Study Investigating the Safety, Pharmacokinetics, and Clinical Activity of PRN1008, an Oral BTK Inhibitor, in Patients with Relapsed Immune Thrombocytopenic Purpura; Darla Liles, MD, principal investigator.

MOM-M281-006- Efficacy and Safety of M281 in Adults with Warm Autoimmune Hemolytic Anemia: A Multicenter, Randomized, Double-blind, Placebo-controlled Study; Darla Liles, MD, principal investigator.

AP-0105 - A Global, Non-interventional Study to Prospectively Evaluate Bleeding Episodes and Treatment Use in Patients with Hemophilia; Darla Liles, MD, principal investigator.

CADENCE Registry OBS16454- Cold Agglutinin Disease Real World Evidence Registry; Darla Liles, MD, principal investigator.

Sobi.PEGCET-101 - A Phase 3, Randomized, Double-blind, Placebo-controlled Multicenter Study to Evaluate the Efficacy and Safety of Pegcetacoplan in Patients with Cold Agglutinin Disease (CAD); Darla Liles, MD, principal investigator.

Ash RC COVID-19 Registry- The ASH Research Collaborative COVID-19 Registry for Hematology; Darla Liles, MD, principal investigator.

CSEG101AUS05-SPARTAN- A Prospective Phase II, Open-Label, Single-arm, Multicenter, Study to Assess Efficacy and Safety of SEG101 (crizanlizumab), in Sickle Cell Disease Patients with Priapism (SPARTAN); Darla Liles, MD, principal investigator.

TAK-079-1004- A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Safety, Tolerability, and Efficacy of TAK- 079 in Patients with Persistent/Chronic Primary Immune Thrombocytopenia; Darla Liles, MD, principal investigator.

SCD-CARRE- Sickle Cell Disease and Cardiovascular Risk-Red cell Exchange Trial (SCD-CARRE); Darla Liles, MD, principal investigator.

4202-HEM-301- An Adaptive, Randomized, Placebo-controlled, Double-blind, Multi-center Study of Oral FT-4202, a Pyruvate Kinase Activator in Patients with Sickle Cell Disease (PRAISE); Darla Liles, MD, principal investigator.

VIT-2763-SCD-202- A Phase 2a, double-blind, randomized, placebo-controlled, ascending dose and maintenance dose, efficacy, and safety study of multiple doses of VIT-2763 in subjects with sickle cell disease; Darla Liles, MD, principal investigator.

CSEG101A2203 (STEADFAST)- A Phase II, multicenter, randomized, open label two arm study comparing the effect of crizanlizumab m+ standard of care to standard of care alone on renal function in sickle cell disease patients \geq 16 years with chronic kidney disease due to sickle cell nephropathy (STEADFAST); Darla Liles, MD, principal investigator.

C1131003- An Interventional Phase 2, Open-Label, One-Arm, Multi-Center Study to Evaluate the Safety and Efficacy of PF06835375 in Adult Participants with Moderate to Severe Primary Immune Thrombocytopenia; Darla Liles, MD, principal investigator.

AVA-ITP-401 DOVA- Prospective, Multi-center, Open-label Study Measuring Safety and Treatment Satisfaction in Adult Subjects with Chronic Immune Thrombocytopenia (ITP) after Switching to Avatrombopag from Eltrombopag or Romiplostim; Darla Liles, MD, principal investigator.

GBT440-4R2- An Open Label, Observational, Prospective Registry of Participants with Sickle Cell Disease (SCD) Treated with Oxbryta (Voxelotor; Darla Liles, MD, principal investigator.

AG348-C-020- A Phase 2/3, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Mitapivat in Subjects with Sickle Cell Disease; Darla Liles, MD, principal investigator.

CaRISMA- Cognitive Behavioral Therapy and Real-Time Pain Management Intervention for Sickle Cell via Mobile Applications (CaRISMA); Darla Liles, MD, principal investigator.

AB1_IIS - A Phase 1/2, Open-Label, Dose Escalating Study Evaluating the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of AB1 in Adult Patients with Sickle Cell Disease (SCD); Darla Liles, MD, principal investigator.

NN7088-4928 - Non-Interventional Study of the Change in Joint Health in Adult Patients with Haemophilia A after Switching to Prophylaxis with Turoctocog Alfa Pegol (N8-GP); Darla Liles, MD, principal investigator.

APL2-PNH-402 - Observational Registry Study of Patients with Paroxysmal Nocturnal Hemoglobinuria Treated with Empaveli (pegcetacoplan); Darla Liles, MD, principal investigator.

AIS-D04 - A Phase 1b, Open-Label Study to Assess the Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of ALPN-303 in Subjects with Autoimmune Cytopenias (RUBY-4); Darla Liles, MD, principal investigator.

The following summarizes accrual information for calendar year 2023.

Adult		Pediatric		
Prevention trials	0	Prevention trials	0	
Screening trials	0	Screening trials	24	
Treatment trials	46	Treatment trials	10	
Quality of life trials	10	Quality of life trials	0	
Other	19	Other	0	
NCTC	345	Total pediatric patients accrued	34	
Total adult patients accrued	420	Total accruals	454	

Clinical trials: January 1 – December 31, 2023

Cancer Care Navigation

Receiving a diagnosis of cancer has a profound impact on patients, families, and caregivers. This diagnosis is not one that patients can be prepared for in advance. The fears and uncertainties associated with the initial shock of a cancer diagnosis can be daunting. Oncology navigation is essential in assisting patients with education related to their disease and treatment options, connecting with both financial and supportive resources and provides a direct connection with an oncology specialized nurse or social worker to assist with the journey that lies ahead. Our navigation team provides continuous assessment of barriers that may impact the ability for the patient to complete their treatment plan. Patients that are followed by our navigation program have improved satisfaction with their care, as noted in our Press Gainey Patient Experience Survey. In 2023, our navigation team met with an average of 550 patients and families per month with over 11,000 total encounters throughout the year.

In the 29 counties of Eastern North Carolina that we serve, we have found that our patients often incur transportation difficulties. Our team assists with transportation concerns by arranging care closer to home at one of our regional oncology centers or assist with accommodations at the ACS Hope Lodge for overnight stays. Our team was able to link over 70 uninsured patients with medical coverage and has assisted with connecting nearly 1700 patients with local and national resources to assist with medical, transportation and living expenses.

Navigation has continued to provide financial and emotional support while seeking new opportunities to support the ever-changing needs of our patients. Our Resource Library has fully re-opened and with this we have been able to reintroduce our support and survivorship programs. We currently offer massage therapy to both patients and caregivers receiving active treatment as well as small group exercise and yoga classes. Our Art is Good Medicine program, a collaboration with the Emerge Art Gallery, resumed last October and has provided a creative outlet for both patients and caregivers during this often-difficult journey. Emerge has been coming weekly to meet with patients while receiving their treatment as well as offering monthly group projects. Looking ahead, we are excited to begin offering a patient and caregiver support group in 2024.

We currently have one non-clinical navigator that works closely with our breast nurse and SW navigator to provide additional one-on-one support and guidance to our breast cancer patient population. We also have two non-clinical navigator that has been working with our support and survivorship programs. These non-clinical navigators have proven to be an essential part of the navigation program in their support of patients and families.

Our team continues to work on professional growth with opportunities to participate in local, regional, and national oncology navigation programs. In October our team was able to participate in the North Carolina Oncology Nurses Association conference allowing us to collaborate with navigators across the region. We have welcomed two new members to our team. Bonnie Kmon, RN will be working with our GI patient population and brings with her a wealth of oncology experience. Angelina Brittle, SW will be working with our radiation oncology patients and coordinating our support and survivorship programs.

Nurse Navigators	Social Work Navigators	Lay Navigators
Teresa Parent, RN, BSN, OCN (Manager) Phone: (252) 814-3580	Angelina Brittle, BSW Phone: (252) 714-0680	Annabelle Foery
Thomas Alcock, RN, BSN (Cancer Screening / Prevention/Genitourinary Cancers / Melanoma) Phone: (252) 816-RISK	Ashley Williams, MSW, LCSW, OSW-C Phone: (252) 717-9681	Susan Waldrum, MA, NBC-HWC
Bonnie Kmon, RN, BSN, OCN (Gastrointestinal Cancers) Phone: (252) 717-1931	Robynique Willis-Brown, MSW, LCSW- A Phone: (252) 341-0319	
Debra Mascarenhas, RN, BSN, CBCN, ONN-CB (Breast Cancer) Phone: (252) 341-0917		
Shana Smith, RN, MSN (Hematologic Malignancies) Phone: (252) 531-2680		
Heather Williams, RN (Brain Cancers) Phone: (252) 714-5072		
Beverly Willoughby, RN, MSN, OCN (Lung & Esophageal Cancers) Phone: (252) 341-0834		
Cynthia Worthington, RN, BSN, OCN (Head & Neck Cancers, Gynecologic Cancers) Phone: (252) 341-3688		

Psychosocial Distress Screening

The NCCN Psychosocial Distress Screening Thermometer Tool and Problem List is given to patients in the outpatient setting at least once during their treatment trajectory to assess psychosocial distress. October 2022 through September 2023, there were 1,322 screenings completed with clinic patients.

The top 10 commonly reported concerns were: fatigue (206), Insurance/financial (204), worry (187), nervousness (152), pain (124), depression (90), transportation (89), sadness (85), sleep (83), and skin dry/itchy (81).

Based on the reported distress level, on-site referrals were made for patients to case managers, medical professionals (provider or nurse), hospital chaplains, and licensed clinical social workers. Services for support and survivorship programs, including journaling, knitting, yoga, and exercise were provided. All these programs are in place to support patients and their families with coping and improving mood, relationships, and overall distress level.

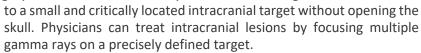
Survivorship Care Plan & Clinic

Our survivorship care team consists of a coordinator, physician specialists, advanced practice providers, a nurse navigator, a social worker, and a registered dietician. Patients seen in the survivorship clinic receive three defined services: completion of a treatment summary and survivorship care plan; screening for cancer recurrence and new/secondary malignancies; and lifestyle modification addressing diet/nutrition, physical activity, and smoking cessation. Our goal was to provide these three main services to at least 100 patients this year, and we surpassed this goal by providing the services to 270 patients. In addition, the lymphedema clinic, was offered to patients on an as needed basis.

Gamma Knife® Center

Gamma Knife[®] radiosurgery offers hope for patients with brain lesions that were once considered inoperable. The use of the Leksell Gamma Knife[®] alleviates much of the pain, scarring and long recovery time normally associated with cases treated with intracranial surgery.

Gamma Knife® radiosurgery gives physicians the ability to effectively treat abnormalities in the brain through stereotactic radiosurgery. Stereotactic radiosurgery is defined as the delivery of a one to five high doses of radiation





After several months of planning, we transitioned to the Gamma Knife Espirit in December 2023. ECUHMC was the first hospital in North Carolina, South Carolina, and Virginia to install the Gamma Knife Espirit. The Espirit is the latest in technology as it guarantees precision sparing healthy tissue to help protect the mind and the person. The Espirit features continuous advances in design which ensure optimized treatment planning and delivery with flexible workflow delivery. The system is also integrated, which allows for ease of use by the team. Treatment planning can be completed in less than 60 seconds.

Gamma Knife® therapy avoids many risks associated with open brain surgery. Patients experience a minimal amount of pain, and they typically tolerate the procedure with only local anesthesia. The procedure is a less invasive surgery and is usually performed on an outpatient basis, making Gamma Knife® radiosurgery a more costeffective option than conventional neurosurgery.

Patients undergoing Gamma Knife radiosurgery are evaluated by a team of specialists including neurosurgeons, radiation oncologists, a neuro-oncologist, neuroradiologists, and nurses. During the past fiscal year (Oct 22-Sept 23), the Gamma Knife team treated 205 patients. In August 2023, we achieved a milestone of 2500 cases!

Gamma Knife® can be used to treat:

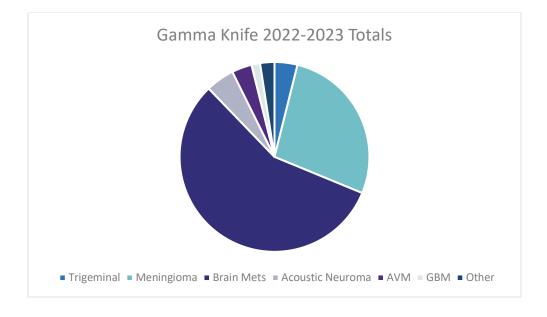
- Meningiomas
- Metastatic brain tumors (the most frequently performed indication for Gamma Knife® radiosurgery)
- Vestibular Schwannomas
- Trigeminal Neuralgia
- Vascular malformations of the brain (arteriovenous malformations and cavernous malformations)
- Other benign tumors
- Pituitary Adenomas
- Other Malignancies
- Glioblastomas and other gliomas in certain cases

Gamma Knife® Outcomes:

- Effective tumor control while sparing essential brain tissue at risk
- 2-4 times lower dose to normal brain tissue
- Highest possible accuracy for both frame-based and frameless treatments
- For patients with metastatic brain tumors, there is excellent local control of the tumors
- There is superb control of tumor size (>95% of cases) in patients with benign tumors such as meningiomas and vestibular schwannomas

Gamma Knife® cases

FY 2022-23: 205 cases



GammaTile®

Since the first patient at ECU Health Medical Center (ECUHMC) was treated with GammaTile in December 2019, there have been approximately 50 patients who have undergone GammaTile therapy. ECUHMC is one of approximately 20 Elite GammaTile centers in the United States based on the number of completed cases. ECUHMC has also treated the youngest patient in the country to receive GammaTile therapy after recently treating a teen-aged patient with a recurrent brain tumor. In November 2020, ECUHMC enrolled the first 2 patients in the country in a multicenter long-term registry for patients treated with GammaTile. Subsequently, there have been many additional patients enrolled in the registry, making ECUHMC the top enrollment site for the study. ECUHMC was recently selected as one of six centers in the country to participate in the treatment of glioblastoma (a highly malignant primary brain tumor) using GammaTile as part of the initial treatment of the tumor. ECUHMC is also participating in a trial for metastatic brain tumors in which a patient who is undergoing surgery to remove a metastatic tumor is randomized to receive GammaTile therapy or to receive stereotactic radiosurgery to the tumor cavity. GammaTile treatment involves placement of radioactive implants into the brain once a brain tumor has been surgically resected. Led by ECUHMC Chief of Neurosurgery, Dr. Stuart Lee and Associate Professor of Radiation Oncology, Dr. Sean Peach from the ECU Brody School of Medicine, GammaTile provides a treatment option for many patients for whom alternative options may not exist.

"Keeping care close to home is an important part of ECU Health's mission to improve the health and well-being of eastern North Carolina," said Dr. Stuart Lee. "This procedure enables us to meet that goal while providing effective treatment and improving quality of life for those battling brain tumors. I am incredibly proud of the care team here at ECU Health as well as our partners at ECU for their tireless work in making this new treatment a reality in the East."

GammaTile was approved by the FDA for commercial use in late 2018. ECU Health Medical Center was the first hospital between Atlanta and New York to offer GammaTile therapy and is one of approximately 60 centers across the United States who offer this form of complex therapy. The treatment employs four, small radioactive cesium131 rods implanted in a Duragen (collagen) wafer. The number of wafers needed are calculated based on the anticipated resection volume. A radiation physicist then performs post planning scans and overlays the dosage lines to confirm the delivery of the radiation dose. Within the first 10 days following surgery, over 50% of the radiation dose has been delivered, by 6 weeks over 95% of the dose is delivered. Patients remain in hospital after surgery for short stays, and then can be discharged to home with no radiation safety concerns.

ECU Health Cancer Care is proud to be able to offer this cutting-edge treatment modality for this subset of patients. Delivery of this complex treatment could have only been achieved through the close collaboration of ECUHMC and ECU Brody School of Medicine Physicians. This technology further advances the neuro-oncology treatment options for patients in eastern North Carolina.

Radiation Oncology

Vidant Radiation Oncology (VRO) is an interdisciplinary oncology center that is part of the Eddie and Jo Allison Smith Tower at ECU Health Medical Center. VRO has a team that includes radiation oncologists, a nurse practitioner, physicists, dosimetrists, radiation therapists, certified nursing assistants, registered nurses, a financial counselor, social workers, nurse navigators, dietician, and patient access staff. Our physicians have over 120 years of combined experience in radiation oncology. VRO utilizes a multidisciplinary approach through cancer conferences and peer review to provide individualized, specialized care to oncology patients. Throughout the year, cancer conferences are held in collaboration with medical oncologists, surgical oncologists, surgical subspecialists, radiologists, and pathologists to discuss the best treatment options for patients diagnosed with cancer.

VRO treats an average of 140 patients daily. During 2023, VRO provided over 29,000 radiation treatments to patients within eastern North Carolina. This is an increase of 8% from FY22 to FY23. VRO also continues to utilize telehealth visits for consults and follow up appointments to allow for expansion and access to healthcare. VRO holds accreditations with both the American College of Radiology as well as the American College of Radiation Oncology. Current locations for VRO include Greenville as the academic hub as well as Roanoke Rapids and Ahoskie NC.

VRO treats various cancers and some non-cancerous disease processes with the most current technology. VRO clinics use state-of- the-art equipment and multiple radiotherapy modalities to provide effective radiation therapy. These modalities include Varian TrueBeam® linear accelerators, CyberKnife® and Gamma Knife® radiosurgery, high dose-rate brachytherapy, Y-90 radioembolization, GammaTile® and CivaSheet® intraoperative brachytherapy, Lutathera® Dotatate and Radium-223 (Xofigo).

Construction of a new Elekta Unity MR-LINAC will begin in 2024. The MR-LINAC merges the strength of a magnetic resonance imaging machine to image soft tissues including tumors and a linear accelerator into a single device. VRO has joined the international MR-LINAC Consortium.

Novartis Pluvicto has been approved by the FDA as a targeted therapy for treatment of PSMA-positive metastatic castration- resistant prostate cancer. This treatment is offered in the Nuclear Medicine Department.

VRO is currently involved in multiple clinical trials. This will soon include the NRG-GU011 trial. We have also continued to treat patients enrolled in various Alliance and Children's Oncology Group trials through ECU Health, and we will be enrolling NRG patients through a collaboration with our partners in GenesisCare. We continue to conduct research in the various advanced treatment modalities available at VRO. The following is a list of selected clinical presentations and publications in the past year:

- Belcher W, Jung JW. How Fiducial Bracketing Affects Lung Tumor Tracking. 64th Annual Meeting of the American Association of Physicists in Medicine (AAPM). 2022.
- Bhandari S, Jung JW. Determination of the Elastostatic Force Exerted in the Lungs During Breathing from Image Registration. 64th Annual Meeting of the American Association of Physicists in Medicine (AAPM). 2022.
- Burke AM, Carrasquilla M, Jean WC, et al. Volume of Disease as a Predictor for Clinical Outcomes in Patients with Melanoma Brain Metastases Treated with Stereotactic Radiosurgery and Immune Checkpoint Therapy. Frontiers in oncology. 2022;11:794615.
- Corns R, Yang K, Ross M, Bhandari S, Aryal M, Ciaccio P. A 3D star shot to determine the gantry, collimator, and couch axes positions. J Appl Clin Med Phys. April 2022.
- Ju AW, Middleton S, Dimbath E, et al. Towards a multi-scale computer modeling workflow for simulation of pulmonary ventilation in advanced COVID-19. Computers in Biology and Medicine. 2022.
- Lee C, Jung JW. Detailed Pediatric Heart Models for Dose Reconstruction of Children in the National Wilms Tumor Study. 64th Annual Meeting of the American Association of Physicists in Medicine (AAPM). 2022.
- Middleton ST, Dimbath E, Pant A, et al. A physics-based multi-scale modeling pipeline for simulation of ventilation in advanced COVID-19. Summer Biomechanics, Bioengineering and Biotransport Conference. 2022.
- Nikakhtar M, Jung JW. Block Modeling for Pediatric Patients Treated by Co-60 Radiotherapy in the National Wilms Tumor Study Cohort. 64th Annual Meeting of the American Association of Physicists in Medicine (AAPM). 2022.
- Saha M, Jung JW. Automatic Multi-Organ Segmentation Using a Deep Neural Network for Assessing Dose to Organs at Risk During Breast Radiotherapy. 64th Annual Meeting of the American Association of Physicists in Medicine (AAPM). 2022.
- Schmidt MC, Pryser EA, Baumann BC, et al. Technical Report: Development and Implementation of an Open Source Template
 - Interpretation Class Library for Automated Treatment Planning. Practical radiation oncology. 12(2):e153-e160.
- Yeom YS, Griffin K, Mille M, Lee C, Jung JW, Lee C. Fetal dose from proton pencil beam scanning craniospinal irradiation during pregnancy: a Monte Carlo study. Physics in Medicine & Biology. 2022.

ECU Health Medical Center Community Benefit

Community benefit is designed to promote the health of a population broad enough to assist the community. ECU Health Medical Center defines community benefit as a program or activity that responds to a demonstrated health-related community need and seeks to achieve at least one of the four community benefit objectives: improve access to health services, enhance public health, advance knowledge or relieve government burden.

ECU Health Medical Center's mission statement is "to improve the health and well-being of eastern North Carolina." These words have deep significance and provide a framework for service to community. ECU Health Cancer Care takes a proactive approach to healthcare through its involvement in various community service events. During the past year, we provided 836 hours (\$39,155) in community services to over 9,571 individuals. Meetings continued to be held virtually, while events such as awareness presentations, screenings, and health fairs were held in person.

Community benefit activities include support group meetings, cancer screenings, awareness presentations, resource fairs/clinics, health symposiums, student internships, survivorship programs and health information sessions. This information is detailed in various sections of our report. For our staff, the ultimate reward comes from the participants' expressions of appreciation for the services and information they received.

Outreach Program

Targeted Cancer	Awareness and prevention events	Attendance	Broadcast and media awareness events	Screenings	Attendance	Number of abnormal results
General cancer	14	1,740				
Breast cancer	10	3,090	1	14	147	17 abnormal (0 positive)
Cervical cancer						
Colorectal cancer	3	140	1			
Head & Neck cancer						
Lung cancer/Tobacco	2	250		11	42	4 suspicious
Skin Cancer	3	550		1	17	4 referrals for biopsy
Prostate cancer	3	320	3	1	18	2 abnormal (1 positive)
Hematologic cancers						
Pancreatic Cancer						
Total	35	6,090	5	27	224	27 abnormal & 1 positive

Jan 1, 2023- December 31, 2023

Cancer Awareness and Prevention

After three years of COVID either halting or hampering cancer outreach efforts, we finally experienced a normal year that provided many opportunities to safely reconnect with our surrounding communities. We have been able to share much needed education about awareness, prevention, and early detection of the most prevalent cancers in our area. Throughout the year our cancer awareness and prevention efforts follow closely along with the cancer awareness months recognized by the American Association for Cancer Research. In doing so, we allow intentional space to provide valuable, focused cancer education that will increase knowledge and encourage cancer screenings in the communities we serve. These efforts contribute to early detection and diagnosis of cancer, leading to better outcomes for our patients.



Strong community partnerships increase the success of our outreach efforts. Through continued partnership with East Carolina University's Public Health undergraduate program, we hosted three interns during the spring and fall semesters. Our interns gain practical experience by providing cancer awareness education through speaking engagements, vendor events and assisting with cancer screening clinics. This not only prepares them for professional careers in health care, it also greatly enhances our outreach efforts. Throughout the year, many dedicated churches, schools, businesses, and civic organizations entrust us to share up-to-date, accurate and understandable cancer education with their groups. This year we have hosted and/or participated in over 62 events including cancer screening clinics and awareness and prevention events. Each event is considered a special opportunity to forward the message of early detection being key in the fight against cancer. Another partnership that continues to grow is with the ECU Pirates Women's Basketball team. Each February, the team hosts its Pink Game to support the fight against breast cancer. ECU Health Cancer Care patients and team members

received special invitations to attend the Pink Game in recognition of our partnership in the fight. For the third year, the team showed their support by joining us on ECU Health's Wear Pink Day in October to greet patients, visitors, and team members by passing out pink ribbons, breast health education and invites to their 2024 Pink Game.

During colorectal cancer awareness month, Stephen Braddy, colon cancer survivor, shared his impactful story of his diagnosis with stage 3 colon cancer at the age of 53 despite maintaining a healthy, active lifestyle. Stephen shared his journey with the staff and faculty of SW Snowden Middle School in Aurora where he emphasized the importance of adhering to screening recommendations.



In August and September, we focused on prostate cancer awareness initiatives by visiting 22 local barbershops, along with other public establishments to provide prostate cancer education as well as promote the free Prostate Cancer Screening held in September. Our efforts were targeted towards men considered to be high-risk for the disease, without a primary care provider or recent prostate screening. Increased media attention added to the success of our campaign. Barbers were receptive and appreciative of our outreach efforts. Many verbalized willingness to share prostate cancer awareness with their clients.



Throughout the year and especially during Breast Cancer Awareness month in October, we kept a strong presence in surrounding communities providing valuable information regarding breast cancer signs and symptoms, risk factors, and screening recommendations. Specific attention focused on addressing myths and reasons women may be avoiding breast cancer screening through mammography.

At the end of the year, our outreach team partnered with the NC Lung Cancer Initiative to host the Inaugural Greenville LUNGe Forward 5K Run, Walk and Celebration to advance survivorship and provide support to those affected by lung cancer through research, education and access programs.



Courtney Johnson, Teresa Parent, Dr. Andrea Oliver, Phyllis DeAntonio, Sidney Long and Jennifer Lewis at the inaugural Greenville LUNGe Forward event.

Cancer Screening

Through increased outreach efforts set in place by ECU Health Cancer Care's Screening Workgroup, we are pleased to see cancer screening rates continue to increase to pre-pandemic levels. Our screening workgroup is comprised of ECU Health team members throughout the region that are involved in cancer screening and outreach initiatives. The group continues to meet regularly to review screening rates, discuss screening initiatives, and find opportunities of collaboration to maximize our outreach efforts.

Here at ECU Health Medical Center in 2023, we were able to continue and increase the amount of free breast screening clinics offered through our uninsured program. Fourteen breast clinics took place providing screenings for 147 ladies ages 40 and over, without health insurance and of low-income. At each screening, ladies receive a clinical breast exam by a skilled provider followed by a 3D screening mammogram, both are cost-free to the patient. Patients requiring additional diagnostics are supported through this program. If the need for biopsy is indicated, patients are referred to the Pitt County Health Department for financial assistance from North Carolina's Breast and Cervical Cancer Control Program (BCCCP). No positives were identified in this year's program. At the end of their visit, ladies are given breast health education about risk factors, signs and symptoms of breast cancer, and the importance of prioritizing future annual mammograms. Patients also meet with a social worker from Access East to learn about other health-related resources available such as assistance with obtaining prescription medications, specialty care, as well as free clinics available in the area.

Lung cancer remains the leading cause of cancer-related death in both North Carolina and the United States; therefore, through continued partnership with ECU Brody School of Medicine and the ECU Health Foundation, we continue to focus on early detection in high-risk individuals through the Low Dose-CT Lung Cancer Screening grant funded program. In this third year of the program, through our monthly clinics, we have provided 42 free LDCT lung cancer screenings to high-risk, uninsured community members of eastern NC. We look forward to continuing to offer this valuable screening opportunity in greater volume in the upcoming year.



In September, through partnership with ECU Health Urology, we hosted our first, drive-up Prostate Cancer Screening event held in the Radiation Oncology parking area of the cancer center. Eighteen men, considered high-risk for prostate cancer, received free Prostatic Specific Antigenblood (PSA) testing. Of those screened, two had abnormal results, with one being positive for prostate cancer. The men also received educational information regarding prostate and other cancers.

From left to right Savannah Ebron, Social Worker, Access East; Jennifer Lewis, RN; Mohamed E. Keheila, MD, Urologist; Caroline Ames, MD, Urologist; Rosiland Buck, FNP, ECU Urology; Sydney Long, ECU intern; Melissa Dickens, MLT at the Prostate Cancer Screening.

Due to last year's success, in November we rejoined ECU Health Beaufort Hospital for a second year to host a free skin cancer screening aboard their Community Health Improvement Coach in the rural farming community of Pinetown located in Beaufort County. A provider from Eastern Dermatology, provided 17 free skin screenings at the event held in conjunction with the well-attended Pinetown Fire & Rescue's Annual BBQ sale. Of those patients screened, four were referred for biopsy. While this event was not held during skin cancer awareness month, we found this to be an excellent venue to care for our farming neighbors close to home.

As we look forward into 2024, our Cancer Care Outreach team strives to continue to discover innovative, engaging methods to educate the communities ECU Health serves regarding the importance of early detection through cancer screenings and increased awareness in the fight against cancer. We express sincere gratitude to all our community partners as they have enhanced our outreach efforts in 2023.



Patients, caregivers, and staff were greeted by members of the ECU Women's Basketball team and their coaches/staff along with Phyllis DeAntonio, Kim Garner, Todd Hickey, Jennifer Lewis, Sidney Long, and Tom Stanley for Wear Pink Day.

Support Services

We proudly place patient centered care in the forefront of all treatment at ECU Health. Our Support and Survivorship Programs specialize in caring for the patients and caregivers of our cancer communities of eastern North Carolina. Throughout the region we place great effort in offering a wide variety of supportive programs and services intended to improve the overall health and well-being of those who participate. We recognize and honor the need for regional support and encourage patients from all surrounding ECU Health organizations to attend.

At ECU Health, we provide services including support groups, complimentary therapies, integrative medicine, and community partnership programs including nutrition and exercise events. We were able to offer small-group sessions for art and massage within our resource library. In June we celebrated Survivorship Day with healthy treats on behalf of our local Fresh Vibes as well as sessions from the Wellness Center. We look forward to hosting more onsite programs again in 2024. For additional information about our programs and services, please call 252-847-9450.



A group of participants doing yoga.



 $Table\ set\ up\ by\ Juice\ Vibes,\ owner\ Jessica\ Albea\ for\ Survivor's\ Day.$

Cancer Registry

A cancer registry is a data system for the collection, management, and analysis of data on persons with a cancer diagnosis. The ECU Health Medical Center (ECUHMC) cancer registry accessions over 3,000 cases annually. The ECU Health nine hospitals combined accession over 4,000 cases annually. The top five sites diagnosed and treated at ECUHMC are breast, lung, prostate, colorectal, and uterine/cervical cancer.

The Cancer Registry Team

The registry team consists of a Supervisor, Assistant Outreach Supervisor, four oncology data abstractors, all which are Certified Tumor Registrars (CTR's), and one follow up analyst. A Certified Tumor Registrar is a nationally certified data collection and management expert with the training and specialized skills to provide the high-quality data required in all avenues of cancer statistics and research. They review, interpret, and capture a complete summary of patient history, demographic, diagnosis, staging, treatment modality and follow-up information. They also provide a valuable service to the hospital and public health professionals in determining needs in the community for resources for cancer prevention, diagnosis, and treatment services to address the cancer burden in eastern North Carolina. Cancer registrars provide a valuable service leading to better monitoring of trends, designing and evaluating programs and providing data for cutting-edge research.

Data Usage

Cancer registry data are used continuously throughout the year. Over 100 data requests were provided for research and outcome studies. Data for these studies included: county-based data, follow up, and annual case load statistics. Hospital specific case totals and other information were reported for Edgecombe, Outer Banks, Beaufort, and Roanoke-Chowan hospitals. Treatment related data requests such as the number of patients that received radiation and many breast-cancer-correlated study requests were fulfilled.

Information was analyzed and reported for the ECU Health Medical Center and Outer Banks Hospital National Accreditation Program for Breast Center (NAPBC) Surveys. Outer Banks received their first NAPBC accreditation and ECU Health Medical Center was reaccredited. Cancer registry data is utilized to report standard compliance to the American College of Surgeons Commission on Cancer for accreditation purposes. The cancer registry reports annually the National Cancer Data Base (NCDB) and monthly to the North Carolina Central Cancer Registry. Data reported to the NCDB is used in the Cancer Programs Cancer Profile Practice Profile Reporting tool to monitor the facilities compliance with national standard treatment guidelines of care.

Rapid Cancer Reporting System (RCRS)

The ECU Health Medical Center Accredited Cancer Program participates in the American College of Surgeons Commission on Cancer Rapid Cancer Reporting System (RCRS). The objective of the RCRS is to promote and facilitate evidence-based cancer care at Commission on Cancer accredited cancer programs. The RCRS serves to assess compliance with eleven National Quality Forum-endorsed quality performance measures for breast, colon, gastric, lung and rectal cancers. Participation in RCRS provides our cancer program with real clinical time alerts for individual cases in which pending adjuvant treatment has not been reported to the system. These alerts are developed to provide a warning system for cancer programs to prevent patients from "slipping through the cracks."

The ECU Health Accredited Cancer Program uses the RCRS alerts to help ensure the utmost quality of care is provided to patients.

ECUHMC CANCER CASES DIAGNOSED 2023

*NATIONAL COMPARISON OF SELECTED CANCER SITES

*Estimated Numbers of New Cases from: The American Cancer Society Cancer Facts & Figures 2023

	ECUHMC		North Carolina		NATIONAL	
PRIMARY SITE	CASES	PERCENT	CASES	PERCENT	CASES	PERCENT
BREAST	646	20.6%	10,730	15.9%	297,790	15.2%
LUNG	488	15.6%	8,810	13.0%	238,340	12.2%
PROSTATE	331	10.6%	10,040	14.8%	288,300	14.7%
COLORECTAL	180	5.8%	4,740	7.0%	153,020	7.8%
BLADDER	96	3.1%	2,760	4.1%	82,290	4.2%
NH LYMPHOMA	90	2.9%	2,560	3.8%	80,550	4.1%
CORPUS UTERI	121	3.9%	2,180	3.2%	66,200	3.4%
MELANOMA OF SKIN	80	2.6%	3,950	5.8%	97,610	5.0%
LEUKEMIA	78	2.5%	2,100	3.1%	59,610	3.0%
CERVIX	33	1.1%	420	0.6%	13,960	0.7%
ALL OTHERS	986	31.5%	19,400	28.7%	580,640	29.7%
TOTAL CASES	3,129	100.0%	67,690	100.0%	1,958,310	100.0%

Evidence-Based Outcome Study

Study to Monitor Compliance with prognostic indicators

Author

Michael Honaker, MD, FACS, FASCRS

Presented by

Michael Honaker, MD, FACS, FASCRS

Purpose

To review the trend over time of the biomarker Microsatellite Instability (MSI) testing in colon cancer and determine if statistically significant or practice changing.

Source

ECU Health cancer registry cases for last 6 years; 2017-2022

Sample

113 cases in 2017, 112 in 2018, 139 in 2019, 115 in 2020, 125 in 2021, and 120 in 2022.

Method

Stage IV colon cancer does not dictate/require MSI testing. Other components were not teased out during the case review. The breakdown of data is as follows:

	Had MSI Testing	No MSI Testing
2017	9	104
2018	24	88
2019	39	100
2020	46	69
2021	53	72
2022	59	61

Outcomes

- Positive trend over time and is statistically significant.
- Biomarker testing has an important role in diagnosis, classification, and molecular characterization of colorectal cancer. We have a study opening for colorectal cancer. This also supports using immunotherapy.

Requirements/Conclusions

This is practice changing in colorectal cancer.

Recommendations from Cancer Committee

Cancer Committee supports the use of MSI testing as it supports treatment planning/options.

Quality Improvement Initiative

Beyond ASK: Towards Advising and Assisting Study

Authors

Phyllis DeAntonio, RN, MSN, FAAMA Leighann Henley, RN, MSN, OCN Andrew Ju, MD Darla Liles, MD Teresa Parent, RN, BSN, OCN Micah Sam, MBA

Presented by

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Purpose

While smoking has long been identified as a cause for cancers of all types, historically there has been limited awareness of the effects of smoking after a cancer diagnosis. It is important to address smoking during cancer treatment to reduce mortality and lessen the financial burden. Smoking cessation at any time reduces non-cancer mortality. Smoking cessation after diagnosis is associated with a 45% decrease in mortality. The focus of the study, therefore, is smoking cessation.

Method

PDSA cycle completed. Referrals to smoking cessation increased after a reminder was sent out in December. Baseline REDCAP data was submitted: ASK rate during baseline is 98.7%, which is an improvement over prior year; Assist rate was 8.13%. Focus is on improving offering of smoking cessation to new cancer patients. Work was done with Dr. Liles on smoking cessation study for survivorship and curative intent patients. Process established for radiation oncology patients using paper forms and communication with Ms. Teresa Parent. Expanded smoking cessation appointments to additional Fridays. Starting in May, Ms. Debra Taft, NP, will manage these appointments. Educational material from the American Cancer Society was received and distributed.

Conclusions

During the first two months of the year, there were 7 completed smoking cessation appointments. That increased to 9 completed appointments during March-April. More than 10 referrals back to clinic for smoking cessation from the smoking cessation study. During Aug-Sept, the ASK rate was 97.1% and the assist rate increased to 17.58%. There were 29 referrals for smoking cessation with 13 not able to be reached. Although the ASK rate dropped slightly, our assist rate increased, indicating we are getting patients the help they need with their smoking.

Recommendations

Continue to push education on how to refer to smoking cessation. Provide financial support for smoking cessation counseling and medication. Provide educational materials on smoking cessation.

Fundraising



In April of 2023 the Vidant Health Foundation went through a significant alignment to mirror ECU Health's rebranding. An agreement between the ECU Medical & Health Sciences Foundation and Vidant Health Foundation was signed and executed, creating the ECU Health Foundation. The two entities aligned to operate as one philanthropic arm supporting ECU Health and ECU's health sciences. The alignment follows the joint operating agreement between East Carolina University's Brody School of Medicine and then-Vidant Health that has been in place for almost two years, enabling the organizations to create ECU Health and work together to improve health care delivery to the 1.4 million residents of eastern North Carolina.

Under the agreement, the two foundations remain separate legal entities, but integrated under a shared brand known as ECU Health Foundation. As part of the agreement, Scott Senatore has become the Chief Philanthropy Officer for the ECU Health Foundation, overseeing the work of both entities.

The ECU Health Foundation was created to align the fundraising and stewardship operations of the ECU Medical & Health Sciences Foundation and the Vidant Health Foundation to boost philanthropic support for ECU Health, the ECU Schools and Colleges of the health sciences, and Laupus Library.



As always, the ECU Health Foundation continues to raise funds to support cancer care programs and services for our region. The Foundation also greatly appreciates the support of long-time donors that continue to support the cancer care service line. Most recently, the 1 of Us organization gave a \$50,000 grant which totals \$190,000 since 2016. Their grant supports women going through breast and/or gynecologic cancers with essential resources such as transportation, groceries, utilities, lodging and prescriptions.

This past summer 1 of Us expanded their grant from solely Greenville to the entire health system to support all 29-counties.



Eastern Radiologists, Inc. gives donation to Phyllis DeAntonio and Varessa Wall from Ride for the Cure.

Also, Greg Parker hosted his 2nd annual "A Good Long Walk" where he walks on a treadmill for 24-hours to bring and raise awareness to those going through cancer. What inspired him to start this event was he personally had 8 friends diagnosed in 4 short months with different types of cancer.

Over the last two years, he has been able to raise over \$65,000 to support cancer care programs and services throughout the region.





Scott Senatore, Chief Philanthropy Officer, ECU Health Foundation Jason Arnold, VP of Finance, T.A. Loving Tom Daniel, Project Executive, T.A. Loving

As always, the ECU Health Foundation continues to raise funds to support cancer care programs and services for our region. The Foundation also greatly appreciates the support of long-time donors that host events to support cancer care. Most recently, T.A. Loving hosted an event that benefitted three organizations including the ECU Health Foundation. This year, the Foundation received \$16,000 from T.A. Loving which brings the total donated from them to over \$115,000 since the event started 9 years ago.

This generous donation will go directly to support our cancer patients most in need with essential resources such as transportation, groceries, utilities, lodging and prescriptions.





A QUALITY PROGRAM of the AMERICAN COLLEGE OF SURGEONS

ECU Health Medical Center is accredited by the American College of Surgeons Commission on Cancer and the National Accreditation for Breast Cancer Programs.

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