

Cancer Care

2022 Report to the Community

A message from our Executive Director

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Executive Director of ECU Health Cancer Care

Dear ECU Health Cancer Care Community,

It is hard to believe that nearly a quarter of the 21st century is behind us as we embark on its 24th year. ECU Health is officially celebrating its 1st birthday and ECU Health Cancer Care is beginning to sound less awkward as the signage throughout the medical center here in Greenville and in the region transitions to our new name, logo and colors. In this year, our service line, as with the entire health care system, has experienced significant growth as well as significant challenges. Our growth continues to be fueled by new solid tumor presentations in breast, colorectal, lung and genitourinary cancers and is outlined in the pages that follow. As an introduction to this annual report, I'd like to highlight a few accomplishments in these areas from my perspective.

In breast cancer, Dr. Karinn Chambers has officially assumed the leadership role of our National Accreditation Program for Breast Cancer (NAPBC) designated program, which was reviewed in November and received full accreditation for three years. This accomplishment would not have been possible without the dedication and commitment from Ms. Phyllis DeAntonio, Ms. Merrill Bright, Ms. Kim Garner, and Mr. Micah Sam. Breast volumes continue to grow, some of which is no doubt a consequence of delayed presentation of new cancers in patients who postponed their screening due to the pandemic.

GI and specifically colorectal cancer, also continues to grow for the same reasons. Expansion of the service line across the region and into Halifax County has also fueled growth in this area. This year, under Dr. Warqaa Akram's leadership, we have begun the one-year period upon which our accreditation as a National Accreditation Program for Rectal Cancer (NAPRC) Accreditation will be based. Dr. Akram has worked in collaboration with Ms. DeAntonio to get the NAPRC accreditation approved by the hospital. In our next annual report, we hope to announce our status as an NAPRC accredited rectal cancer program.

Dr. Misbah Qadir has officially assumed the leadership role in our thoracic oncology program and, despite his ongoing part-time presence in Lenoir county and his other responsibilities as regional oncology director, we have not seen a diminution in this foundational program for our cancer center. We are indebted to Dr. Qadir for his willingness to not only lead the regional service line, but also step into this pivotal leadership role in the thoracic oncology program. Recruitment of additional faculty to assist him in this role is ongoing.

Dr. Grainger Lanneau continues to grow volumes in GU / GYN Oncology along with Dr. Nathaniel Hamilton and the entire ECU Health Urology team. In December of this year, after 30 years of service to the women of eastern North Carolina with gyn cancers, Dr. Diane Semer has retired. I'm uncertain whether the void she leaves behind will ever be completely filled, but Dr. Lanneau has successfully recruited 2 exceptional new gyn oncologists who will be joining our team in the Fall of 2023. For the first time in almost 2 decades, all gyn cancer care in our 31-county catchment area will be centralized in one practice here at the cancer center.

Dr. Liles continues to lead our medical oncology team while, along with Dr. Qadir, ensuring that our regional sites remain staffed through transitions in medical oncology leadership in Ahoskie and the Outer Banks. These are the times when being part of a system of cancer care benefits the citizens of eastern North Carolina as we navigate this particularly challenging recruitment period. We are looking forward to capitalizing on our growth in 2023 by implementing the Elsevier Care Pathways program and pursuing Cancer Care Network status with the American College of Surgeons Commission on Cancer. Each of these milestones will bring added value in our service line as standardization of care as well as adherence to COC standards at all sites where we deliver cancer care will improve quality and decrease costs.

If there is one thing that we have learned from the past 3 years of the pandemic, we can't predict with certainty what the coming year has in store for us. The milestones and achievements that you will learn about in the pages of this annual report occurred under adverse economic, regulatory and environmental circumstances. As these stressors begin to ease (and they will), there is no telling what heights our service line might reach in the coming months and years. As always, thank you for your ongoing support and confidence in ECU Health Cancer Care, we cannot serve our population without it.

In 2022, we say goodbye to Dr. Semer and thank her for 30 years of servant leadership to the women of eastern North Carolina.



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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.

The Cancer Committee has continued to work diligently to implement the synoptic operative report requirements set forth by the Commission on Cancer (CoC). Thank you to Dr. Warqaa Akram for her leadership in the cancer committee with this project, Dr. Gina Murray for her expertise with synoptic reporting, and Dr. Andrew Weil for partnering with the IT team to develop/implement. This year, a smart phrase was added to the operative note for use by the surgeons to facilitate compliance with reporting, and to streamline the process for physicians.

Additionally, the Cancer Committee has engaged with CoC initiated quality study *Just ASK* focused on lung cancer and smoking cessation. This is a PDSA project involving review of our data related to how often are we asking patients about their smoking history and documenting in the medical record with an additional, local focus on ensuring referrals to smoking cessation are made as needed. During this project, we provided multiple means of education to staff/physicians on the study and will continue sending out reminders to bolster utilization of smoking cessation services, which saw a 100%+ increase in usage during the intervention period of the study.

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 Vidant 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.

2022 cancer committee

Warqaa Akram, MD
Michael Berry, MD
Brian Brodish, MD, liaison physician
Aidan Burke, MD
Karl Chiang, MD
Clint Faulk, MD
Tae Juon Lee, MD
Andrew Ju, MD
Brian Kuszyk, MD
Darla Liles, MD, chair
Mahvish Muzaffar, MD
Gina Murray, MD
Musharraf Navaid, MD
Christina Paul, MD
Sean Peach, MD
Karyn Prenshaw, MD
Chris Thomas, MD
Nasreen Vohra, MD, liaison physician
Andrew Weil, MD
Emmanuel Zervos, MD
Yaolin Zhou, MD
Thomas Alcock, RN, BSN, MBA
Jami Best, PharmD, MS
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
Susan Eubanks, RN, MSN, OCN
Liz Gottsch, PA
Leighann Henley, RN, MSN
Todd Hickey, FACHE
Ken Jones, RN, OCN
Jennifer Lewis, RN, BSN
Debra Mascarenhas, RN, BSN, CBCN
Tiffanie Moore, MPH
Jaimie Morales, CTR
Njeri Njuguna, MS, RDN, LDN, CDCES
Kelli Oldham, MS, RDN, CSO, LDN
Teresa Parent, RN, BSN, OCN
Jessica Perkins, RDN
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

Goals for 2022

Implement a 5% reduction in the annual adjustments for missing chemotherapy denials for ECU Health Medical Center Infusion patients with a stretch goal of 10% or greater. Approved by Cancer Committee in January 2022. Work was done to review and decrease denial adjustments using a variety of methods. Dashboard created to monitor denial adjustments in real time. Goal met with an 8.8% reduction in denial adjustments.

Implement PLUVICTO no later than the end of the calendar year with a stretch goal of November 1, 2022. This treatment gives us a new therapeutic treatment for patients with prostate specific membrane antigen (PSMA) positive metastatic castration resistant prostate cancer who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy. Approved by Cancer Committee in July 2022. Radiation oncology will be point of administration for the treatment. Multiple patients have been identified. Staff have completed training and weekly meetings continue. Treatment is a 6-cycle series. Goal remains in progress.

2022 Accomplishments & Recognitions

The following are some of the noteworthy accomplishments for 2022:

- Partnership continued with ECU Health Lifestyle Medicine for massage and exercise services in the Resource Center.
- Welcomed new physicians and staff: Dr. Karinn Chambers – surgical oncology; Dr. Misbah Qadir – Regional Oncology Medical Director; Matthew DeAntonio – clinical trials; Kelly Martin – clinical trials; Toria Wilson – clinical trials; Derrick Almond – clinical trials; Kayleigh Nunley – clinical trials; Alison Colao – clinical trials; Daniel Makoko – clinical trials; Michelle Donaldson, RN – surgical oncology clinic; Myisha Wheeler, RN – surgical oncology clinic; Morgan Ward, RN – surgical oncology clinic; Jeanette Whitehead, MOA – gynecology oncology clinic; Amber Rodgers, RN – surgery scheduler; Carla Smart, RN – Infusion; Linda Wheeling, RN – Infusion; Sarah Manning, RN – Infusion; Lindsie Stroud, RN – Infusion; Nihesha Little, nursing assistant – Infusion; Patricia Andrews – oncology intake coordinator; Emily Wyatt Kozuszek, CGC – Genetics Counselor; Joanna Brown-Pokakaa – oncology intake coordinator; Crystal Parker, RN – radiation oncology; Tierra Moore, RN – radiation oncology; Chandra Harris, lab support tech – cancer center lab; Heather Cates, medical lab tech – cancer center lab; Belan Salazar-Solano, PAS Representative – cancer center admissions; Dina Harris, PAS representative – cancer center admissions; Silvia De Guerrero, pharmacy tech – pharmacy; Sabrina Oleskey, NP – Service Line Advanced Practice Provider
- Provided 819.30 hours in community benefit to over 22,099 individuals.
- Gamma Knife® upgraded equipment to Vantage Frame in September.
- Vidant Radiation Oncology reaccredited by the American College of Radiology.
- Lutathera treatment provided to 53 patients.
- First patients imaged in April using PSMA PET, a cutting-edge diagnostic technique that uses a radioactive image agent to better localize prostate cancer cells.
- 4CC featured in ECU Health Medical Center Nursing Biennial Report 2020-21 for compassionate care.
- Palliative Care featured in ECU Health Evolving Perspectives for their service to our patients.
- GammaTile® continues success with 14 patients treated.
- Provided cancer awareness/prevention/screening information to more than 4,357 people. Information disseminated via radio broadcasts, educational displays and packets, presentations, health fairs and information sessions. Provided more than 188 people with free cancer screenings (breast, cervical, 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 87.34% of chemotherapy is administered on an outpatient basis.
- Clinical trials volume increased to 11% of annual caseload.
- Awarded a second American Cancer Society Transportation Grant.
- Reaccredited by the National Accreditation Program for Breast Centers (NAPBC).

Recognition

- Emily Wyatt Kozuszek passed boards and is a Certified Genetics Counselor.
- Whitney Stovall, RN, and Danielle Hill, RN, are OCN.
- Beverly Willoughby, RN, OCN completed her MSN in nursing education in August.
- Clinical Trials recognized by Alliance for performing above standard with a score of 9.

Clinical Services

Our Doctors and APPs:

Gynecological Oncology Providers	Medical Oncology Providers	Palliative Care Providers	Surgical Oncology Providers
Grainger Lanneau, MD	Jorge Abdallah, MD	Margaret Clifton, MD	Warqaa Akram, MD
Diane Semer, MD	Jessica Hildebrand, MD	Tae Lee, MD	Michael Honaker, MD
Gail Zeisler, FNP	Jasmin Jo, MD	Rima Panchal, MD	Alexander Parikh, MD
	Charles Knupp, MD	Nicole Averett, NP	Rebecca Snyder, MD
	Pamela Lepera, MD	Laura Carmon, NP	Nasreen Vohra, MD
	Darla Liles, MD	Barbara Connold, NP	Emmanuel Zervos, MD
	Mahvish Muzaffar, MD	Shauna Everett, NP	Abigail Foster, PA
Cardio-Oncology Provider	Praveen Namireddy, MD	Heather Hill, NP	Nancy Lopez, PA
Sivakumar Ardhanari, MD	Musharraf Navaid, MD	Crystal Vance, NP	
	Maria Picton, MD	Elizabeth Gottsch, PA-C	
	Misbah Qadir, MD		
	Andrew Weil, MD		
	Heather White, MD		
	Cynthia Cherry, NP		
	Liz Gottsch, PA		
	Debra Taft, NP		
	Lauren Tenace, PA		

Inpatient Medical Oncology - 4th Floor Cancer Center

The Medical Oncology unit, 48 beds, is able to provide 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/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 and social work case managers, a recreational therapist, a pharmacist, physical therapists, occupational therapists, a dietitian, and a 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 of the patients, to include 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 Vidant 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 Infusion Center was instrumental in the treatment of COVID patients. A separate space of 4 rooms was configured for safe patient care delivery. Last fiscal year, we did over 1,100 COVID infusions using various FDA Emergency use drugs found to improve symptoms and decrease hospitalizations.

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 is 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. There is a Prevention clinic held once a month, which works with family members of cancer patient who may be at higher risk of developing cancer. This clinic is led by a nurse practitioner, and offers information about genetics, lifestyle management, and smoking cessation.

Genetics

In June 2022, the genetics clinic on-boarded a new full-time genetics counselor, who began seeing patients in July 2022. Our certified genetic counselor provides comprehensive assessment of personal and family history, educates patients on genetic testing, and provides follow-up counseling for patients with positive test results. Genetic counseling appointments are available both in person at ECU Health Medical Center and over the phone, allowing flexible access to in-house 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. In her first 4 months, the genetic counselor saw over 170 unique patients, including 16 individuals who tested positive for a hereditary cancer predisposition syndrome.

Symptom Management Clinic

The Symptom Management Clinic (SMC) is located within the Infusion Center. The clinic began seeing patients in July 2017. It is open 5 days a week from 8am until 5pm, with the last appointment available at 3:30. There are significant side effects to many cancer treatments, and this clinic was created to help patients to deal with those symptoms as early as possible. The goals for the SMC are to: avoid emergency room visits; provide better access to care; improve clinic workflow; reduce length of stay / readmission; increase patient centered care; and decrease cost. Patients may call the clinic nurse or their navigator to report symptoms. Referrals are made for a same day appointment. Patients will be seen in the SMC for the following: fever / chills / generalized fatigue; nausea / vomiting / diarrhea; dyspnea; pain; decreased appetite; wound/drain issues; and other symptoms needing managed. The clinic is staffed by an oncology nurse practitioner. Any cancer patient undergoing treatment can be seen. All patients, physicians and staff are encouraged to utilize the 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.

CivaTech CT005- Feasibility trial for treatment of resectable pancreatic cancer with the permanently implantable LDR CivaSheet; 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.

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

EA2185- Comparing the Clinical Impact of Pancreatic Cyst Surveillance Programs; Emmanuel Zervos, 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 PATHOLOGIC HIGH-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.

NCCAPSNCI 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 Positive 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 Trial of 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.

TCBIO-001-0710- The Caris Biorepository Research Protocol, Mahvish Muzaffar, 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.

BDX-00146- An Observational Study Assessing the Clinical Effectiveness of VeriStrat® and Validating Immunotherapy Tests in Subjects with Non-Small Cell Lung Cancer; Darla Liles, 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 Nemvalleukin 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.

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; Sriaksha Jayananda, MD, principal investigator

TAK-981-1501- Phase 1/2 Study of TAK-981 in Combination with Rituximab in Patients with Relapsed/Refractory CD20-Positive Non-Hodgkin Lymphoma; Darla Liles, MD, principal investigator.

GCT3013-05- A Randomized, Open-Label, Phase 3 Trial of Epcoritamab vs Investigator's Choice Chemotherapy in Relapsed/Refractory Diffuse Large B-cell Lymphoma; Darla Liles, MD, principal investigator.

ACE-536-MDS-002- A Phase 3, Open-Label, Randomized Study to Compare the Efficacy and Safety of Luspatercept (ACE-536) Versus Epoetin Alfa for the Treatment of Anemia Due To IPSS-R Very Low, Low or Intermediate Risk Myelodysplastic Syndrome (MDS) In ESA Naïve Subjects Who Require Red Blood Cell Transfusions -The "COMMANDS" Trial; Darla Liles, MD, principal investigator.

Alliance A021703 (SOLARIS)- Randomized Double-Blind Phase III Trial of Vitamin D3 Supplementation in Patients with Previously Untreated Metastatic Colorectal Cancer (SOLARIS); Mahvish Muzaffar, MD, principal investigator.

BMS CA180-653- Studying Interventions for Managing Patients with Chronic Myeloid Leukemia (CML) in Chronic Phase: The 5-Year Prospective Cohort Study (SIMPLICITY); Darla Liles, 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 Irinotecan in 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.

BGB-3111-306- A Phase 3 Randomized, Open-Label, Multicenter Study Comparing Zanubrutinib (BGB-3111) plus Rituximab Versus Bendamustine plus Rituximab in Patients with Previously Untreated Mantle Cell Lymphoma Who Are Ineligible for Stem Cell Transplantation; Darla Liles, 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.

SPARC CLR_15_03- A Two-Part Phase 1/2 Study to Determine Safety, Tolerability, Pharmacokinetics, and Activity of K0706, a Novel Tyrosine Kinase Inhibitor (TKI), in Healthy Subjects and in Subjects with Chronic Myeloid Leukemia (CML) or Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia (Ph+ ALL); 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- 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.

NCTC- North Carolina Tissue Consortium; Alexander Parikh, MD, principal investigator.

Benign Hematology:

INCB-MA-MF-401 (MOST)- Prospective, Longitudinal, Non-Interventional Study of Disease Burden and Treatment of Patients with Low-Risk Myelofibrosis (MF) or High-Risk Essential Thrombocythemia (ET) or ET Patients Receiving ET-Directed Therapy; 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.

OSCO-P2101- A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Dose Study to Evaluate the Efficacy and Safety of Oral SKI-O-703, SYK Inhibitor, in Patients with Persistent and Chronic Immune Thrombocytopenia; Darla Liles, MD, principal investigator.

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

AbbVie M19-753- A Phase 1, Open-Label Study Evaluating the Safety and Tolerability, and Pharmacokinetics of Navitoclax Monotherapy and in Combination with Ruxolitinib in Myeloproliferative Neoplasm Subjects; Darla Liles, MD, principal investigator.

INCB 50465-309- A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of Parsaclisib in Participants with Warm Autoimmune Hemolytic Anemia; Darla Liles, MD, principal investigator.

INCB 50465-206- A Phase 2, Open-Label Study of INCB050465 in Participants with Autoimmune Hemolytic Anemia; Darla Liles, MD, principal investigator.

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

STERIO-SCD- A Phase IIb Randomized, Double-Blind, Placebo-Controlled Multi-Center Study to Assess the Safety, Tolerability, and Efficacy of Riociguat in Patients with Sickle Cell Diseases; 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.

Shire SHP655-101-Part A- A Phase 1/2 randomized study of SHP655 (rADAMTS13) in sickle cell disease; Darla Liles, MD, principal investigator.

ANX-wAIHA-01- A Study to Evaluate the Complement Signature of Subjects with Warm Autoimmune Hemolytic Anemia; 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.

CSL889_1001- A 2 Part Phase 1, Multi-Center, Open-Label, Single Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of CSL889 in Adult Patients with Stable Sickle Cell Disease; 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, a 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 + standard of care to standard of care alone on renal function in sickle cell disease patients ≥ 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.

The following summarizes accrual information for calendar year 2022.

Adult		Pediatric	
Prevention trials	0	Prevention trials	0
Screening trials	0	Screening trials	38
Treatment trials	15	Treatment trials	0
Quality of life trials	10	Quality of life trials	0
Other	67	Other	0
NCTC	165	Total pediatric patients accrued	38
Total adult patients accrued	257	Total accruals	295

Clinical trials: January 1 – December 31, 2022

Cancer Care Navigation

Receiving a diagnosis of cancer has a profound impact on patients, families and caregivers. This diagnosis is nothing that can be prepared for in advance. The fears and uncertainties associated with the initial shock 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. In 2022, our navigation team met with an average of 600 patients and families per month with over 13,500 total encounters throughout the year.

Serving 29 counties of Eastern North Carolina, our patients often incur transportation difficulties.

Our team is able to assist with transportation concerns, arrange care closer to home in one of our regional oncology centers or assist with coordination of a room at the ACS Hope Lodge for overnight stay. Our team was able to link nearly 100 uninsured patients with medical coverage and has assisted with connecting over 2000 patients with local and national resources to assist with medical, transportation and living expenses.

The past couple of years have been challenging amid the worldwide pandemic and navigation has continued to provide financial and emotional support to our patients while seeking new opportunities to support the ever-changing needs of our patients. We were able to reopen our Resource Library and with this have been able to re-introduce 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 social work team was able to resume our Dove Retreat at the Trinity Center at Pine Knoll Shores with 38 patients and caregivers in attendance. Our Art is Good Medicine program, a collaboration with the Emerge Art Gallery, will be resuming in October and provides a creative outlet for both patients and caregivers during this often-difficult journey.

We currently have two lay navigators that work closely with our breast nurse and SW navigator to provide additional one-on-one support and guidance to our breast cancer patient population. These non-clinical navigators have proven to be an essential asset to the breast program. We are hoping to expand this service to our other disease sites during the next year.

Our team continues to work on professional growth with opportunities to participate in both local and national oncology navigation programs. Our team was able to participate virtually in the North Carolina Oncology Nurses Association conference in February. We were also able to join the AONN's mid-year conference virtually in May. Shana Smith was co-author of an article that was printed in the Journal of Oncology Navigation & Survivorship (JONS) in March: "Multiple Myeloma: Overview, Treatments, and the Navigator's Role in Clinical Trials." Shana was also the first nurse navigator to provide a "navigation catch" for the AONN's CATCH Initiative, Catching & Addressing Threats to Care & Health that appeared in the JONS July issue. Teresa Parent participated in the Cancer Advocacy & Patient Education (CAPE) lung cancer initiative research study through the AONN. Beverly Willoughby, the newest member of our team, completed her Master's in Nursing Education in August.

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

Psychosocial Distress Screening

The Oncology Distress Screening Tool is given to patients in the outpatient setting at least once during their treatment trajectory to assess psychosocial distress. October 2021 through December 2022, there were 1,350 screenings completed with clinic patients.

The top 10 commonly reported concerns were: Insurance/financial (280), fatigue (192), transportation (138), nervousness (136), pain (115), sleep (99), depression (96), sadness (89), treatment decisions (73), and skin dry/itchy (82).

For reference, the previous 10 commonly reported concerns were: fatigue (212), insurance/financial (195), pain (151), sleep (126), sadness (94), nervousness (90), depression (89), tingling in hands/feet (87), eating (86), and transportation (79).

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. This year, many of our programs and services were on hold due to COVID. However, our team found ways to continue providing services through virtual programming for support and survivorship programs, including journaling, knitting, yoga, and exercise. All of these programs are in place to support patients and their families with coping and improve 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 dietitian. Patients seen in the survivorship clinic receive three defined services including: 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 achieved this goal by providing the services to 165 patients. In addition, the lymphedema clinic, in partnership with Rehabilitation Medicine, began receiving referrals at the end of October.

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 to a small and critically located intracranial target without opening the skull. Physicians can treat intracranial lesions by focusing multiple gamma rays on a precisely defined target.

The Gamma Knife® ICON gives clinicians the option to perform single or fractionated frame-based or frameless treatments, allowing for more individualized delivery – without sacrificing precision and accuracy. Addressing the growing radiosurgery market, the ICON makes Leksell Gamma Knife® radiosurgery more flexible and easier to use.

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 cost-effective option than conventional neurosurgery.

Patients undergoing Gamma Knife® radiosurgery are evaluated by a team of specialists including neurosurgeons, radiation oncologists, a neuro-oncologist, radiologists, and nurses. During the past fiscal year (Oct 21-Sept 22), the Gamma Knife team treated 210 patients. In September, an upgrade to the Vantage Frame System was completed. This new technology allows for better patient view by the team and enhances the treatment capability.

Gamma Knife® can be used to treat:

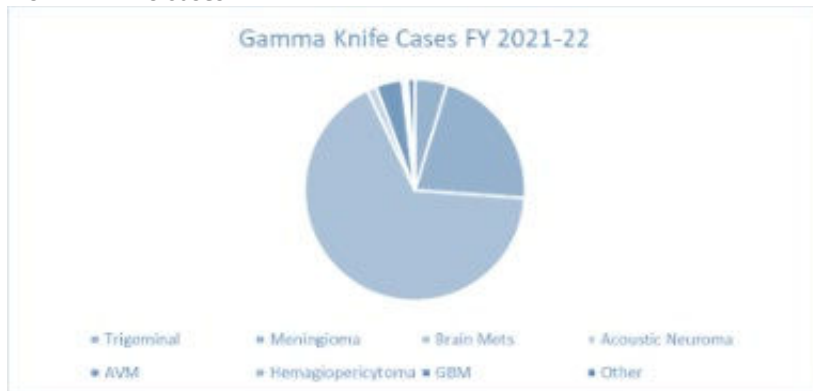
- Meningiomas
- Metastatic brain tumors (the most frequently performed indication for Gamma Knife® radiosurgery)
- Vestibular Schwannomas
- Trigeminal Neuralgia
- Vascular malformations of the brain (arteriovenous malformations and cavernous malformations)
- Other benign tumors
- Pituitary Adenomas
- 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 2021-22: 210 cases



GammaTile®

Since the first patient at ECU Health Medical Center (ECUHMC) was treated with GammaTile® in December 2019, there have been approximately 40 patients who have undergone GammaTile® therapy. ECUHMC is one of 14 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® brings 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 about 40 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. After the first 10 days following surgery, over 50% of the radiation dose has been delivered. Over 95% of the dose is delivered after 6 weeks. 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 ECU Health Medical Center 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. Tumor boards 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 2022, VRO provided over 29,000 radiation treatments to patients within eastern North Carolina. This is an increase of 8% from FY21 to FY22. VRO also continues to utilize telehealth visits for consults and followup appointments to allow for expansion and access to healthcare. Vidant Radiation Oncology holds accreditations with both the American College of Radiology as well as the American College of Radiation Oncology. Current locations for Vidant Radiation Oncology 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 2023. 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 will soon be administered in VRO.

VRO is currently involved in multiple clinical trials. This will soon include the NRG-GU011 trial, which Dr. Bridget Koontz is the national Principle Investigator for. 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 as a whole. 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 819.30 hours in community services to over 22,099 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	13	1000				
Breast cancer	19	2,652	1	13	141	13 with no positives
Cervical cancer	1	30	2			
Colorectal cancer	4	298	1			
Head & Neck cancer			1			
Lung cancer/Tobacco	4	47		12	45	4 abnormal. 1 of which being suspicious for malignancy (f/u ongoing)
Skin Cancer	4	300	1	1	20	3 with f/u ongoing
Prostate cancer	1	30	1			
Hematologic cancers						
Pancreatic Cancer						
Total	46	4,357	7	25	206+	17

Jan 1, 2022- November 21, 2022Cancer Awareness and Prevention

As COVID restrictions have continued to lessen this year, we have been able to safely reconnect in our surrounding communities providing much needed education regarding awareness, prevention and early detection of the most prevalent cancers in our area. During the month of March, ECU student interns shared colorectal cancer awareness throughout the region through engaging presentations that included interactive Jeopardy games. As spring temperatures warmed, our outreach team focused on skin cancer awareness by utilizing peer instruction through having our ECU student interns rove their campus to share the importance of skin protection over 200 ECU students. Later in the summer, we were able to connect with younger population of students at a local middle school summer camp to stress the importance of skin cancer prevention by fostering sun-safety habits early in life.



ECU student interns sharing importance of skin cancer information at ECU

During breast cancer awareness month and throughout the year, we kept a strong presence in surrounding communities providing valuable education regarding breast cancer signs and symptoms, risk factors, and screening recommendations. Additionally, to better address reasons why women may be avoiding breast screening, we introduced a role-playing activity meant to dispel common myths of mammography. Through role-playing, women of all ages were given the opportunity to meaningfully interact with each other during breast cancer awareness presentations. These roles allowed for increased learning, engagement and laughter, while remaining focused on the importance of not foregoing an annual screening mammograms.



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 continues to meet regularly to review screening rates, discuss screening initiatives, and find opportunities of collaboration to maximize our outreach efforts.

In 2022, we were able to continue providing free breast screening clinics through our uninsured program. Through these monthly screening clinics, 130 were screened, with 10 patients needing additional diagnostics or follow up. Each woman screened received a free clinical breast exam, free mammogram, and an education session about their breast cancer risk, importance of mammograms, and resources for free mammograms in the future. An additional partnership with Health Assist allowed each woman to learn about additional resources including medication assistance, specialist assistance, and free clinics in the area. We are excited to offer increased capacity in 2023 by adding an additional free breast screening clinic each quarter. The additional screenings will increase our clinics from 12 to 16 annually.

As lung cancer remains the number 1 cause of cancer-related death in the state and the nation, we continued focus on its early detection on high-risk individuals through our Low Dose-CT Lung Cancer Screening grant funded program. In late 2021, through partnership with Dr. Matthew Peach, ECU and the Brody School of Medicine, the Vidant Health Foundation awarded grant funds to provide lung cancer screenings free of charge to community members that are uninsured. This program's monthly clinics have been steadily gaining momentum throughout the year with 45 low-dose CT lung cancer screenings being completed with three patients needing additional follow-up of suspicious nodules. We look forward to continuing to offer this valuable screening opportunity in greater volume in the upcoming year.

In November, we returned our focus to skin cancer awareness through partnership with ECU Health Beaufort Hospital and ECU Physicians Dermatology by offering a free skin cancer screening targeting at-risk outdoor workers such as farmers and fisherman. The screening was held aboard ECU Health Beaufort Hospital's Community Health Improvement Coach in the rural farming community of Pinetown located in Beaufort County. The screening was held in conjunction with Pinetown Fire & Rescue's Annual BBQ sale which allowed for increased visibility from community members. Twenty individuals received skin cancer screens while other community members received sun-safety education as well as free sunscreen during the event.

As we look forward into 2023, 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.



The Wear Pink Day was held October 21, 2022 – ECU Women's Basketball Team members along with Jennifer Lewis, Dr. Emmanuel Zervos, Phyllis DeAntonio, Tom Stanley, and Kim Garner greeted patients/families and provided information on breast cancer awareness

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. Despite COVID-related challenges this year, we were able to offer small-group sessions for journaling, art, knitting, and massage within our resource library. In June we celebrated Survivorship Day with healthy treats on behalf of our local Fresh Vibes. We also had the opportunity to partner with Greenville Art Museum, offering an exhibit tour and art activity event. Recently we hosted the Dove Retreat, a three-day retreat at Pine Knoll Shores, where patients and caregivers were provided with activities to improve overall wellness and relaxation, along with many other events. We are currently seeking patients to attend our yoga and small group exercise programs. We look forward to hosting more onsite programs again in 2023. For additional information about our programs and services, please call 252-847-9450.



Dove Retreat participants & staff



Dove Retreat participants enjoying art activity



Dove Retreat participants doing yoga

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 of 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 in order 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 include: 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 first NAPBC accreditation and ECU Health Medical Center was reaccruited. 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 in order 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 our patients.

ECU Health Medical Center CANCER CASES DIAGNOSED 2021						
*NATIONAL COMPARISON OF SELECTED CANCER SITES						
*Estimated Numbers of New Cases from: The American Cancer Society Cancer Facts & Figures 2021						
	ECU Health Medical Center & DATA		North Carolina		NATIONAL	
PRIMARY SITE	CASES	PERCENT	CASES	PERCENT	CASES	PERCENT
BREAST	607	19.9%	9,850	15.4%	281,550	14.8%
LUNG	504	16.6%	8,030	12.6%	235,760	12.4%
PROSTATE	277	9.1%	8,970	14.0%	248,530	13.1%
COLORECTAL	195	6.4%	4,650	7.3%	149,500	7.9%
BLADDER	77	2.5%	2,650	4.1%	83,730	4.4%
NH LYMPHOMA	93	3.1%	2,480	3.9%	81,560	4.3%
CORPUS UTERI	149	4.9%	2,110	3.3%	66,570	3.5%
MELANOMA OF SKIN	66	2.2%	4,250	6.6%	106,110	5.6%
LEUKEMIA	80	2.6%	2,050	3.2%	61,090	3.2%
CERVIX	33	1.1%	430	0.7%	14,480	0.8%
ALL OTHERS	964	31.7%	18,460	28.9%	569,280	30.0%
TOTAL CASES	3,045	100.0%	63,930	100.0%	1,898,160	100.0%

Evidence-Based Outcome Study

Study to Monitor Compliance with prognostic indicators

Author

Nasreen Vohra, MD, FACS

Presented by

Nasreen Vohra, MD, FACS

Purpose

To verify that pre-treatment diagnosis and first course of therapy for melanoma patients are concordant with prognostic indicators, and utilize a reporting format that permits analysis and provides opportunity for performance improvement recommendations based on data.

Source

ECU Health cancer registry cases January-December 2021 for Melanoma

Sample

49 melanoma cancer patients

Method

44 had stage documented (stage I 18; stage II 12; stage III 7; stage IV 6); 4 had no clinical stage due to no lymph node removal; 1 had lymph node removal but was negative

Outcomes

- Stage distribution: stage 0 - 1; stage I (A & B) - 18; stage IIA - 4; stage IIB - 5; stage IIC - 3; stage IIIA - 1; stage IIIB - 2; stage IIIC - 4; stage IV - 6.
- Concordance with guidelines. Stage I: Surgery - WLE +/- SLN; No Chemotherapy; No Radiation. Stage II: Surgery - WLE + SLN; Immunotherapy (stage IIB/C); No Radiation (except special subtypes). Stage III: Surgery - WLE + SLN; Immunotherapy;

No Radiation (except special subtypes or bulky disease). Stage IV: Surgery (only in select cases); Immunotherapy; Radiation (symptomatic brain mets/bulky nodal disease); Palliative therapy.

Requirements/Conclusions

- Overall care rendered was concordant with guidelines for all stages of disease

Recommendations from Cancer Committee

- Work towards more frequent presentation of patients with stage IV disease at diagnosis to the Melanoma cancer conference

Quality Improvement Initiative

Just ASK Study

Authors

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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. An analysis of data via the Surgeon General's report has shown that smoking post diagnosis has effects on biological outcomes such as decreased cancer efficacy, clinical outcomes such as cancer recurrence, toxicity and mortality, and value outcomes such as cost of cancer treatment, quality of life, toxicity and mortality. However, quitting smoking after diagnosis can assuage these concerns, including reducing the risk of mortality by almost 45%. This national study is aimed at the first step in the process to address this unmet need – ensuring all cancer patients are asked whether or not they smoke, with subsequent goals aimed at ensuring appropriate patients are forwarded to smoking cessation services.

Method

PDSA cycles completed from June-December 2022. A menu of interventions was reviewed with select activities implemented to foster increased asking and referral to smoking cessation. Our ask rate for new patients was already well above the recommended 90% threshold, with over 97% of patients being asked about their smoking status. Accordingly, focus shifted to improving referral to smoking cessation, with presentations at tumor conferences, staff meetings, articles in the Quarterly Newsletter, provided to both foster awareness of available smoking cessation capabilities, as well as how to properly refer. In addition, existing staff with smoking cessation training were added to the team to help facilitate additional appointments.

Conclusions

Our ask rates remained steady throughout (~97%) with the asking rate trending upwards throughout (with a small dip in October). Likewise, our referrals post the intervention period saw gains, with an upward trend through the end of the calendar year (with a modest dip during the month of October). We are pleased to note that our actual smoking cessation appointments scheduled/completed in the last half of 2022 (post interventions) showed over a 100% increase. For context, over the baseline metrics reported for 2021, the appointments for 2022 more than doubled in only the first 3 quarters of the year.

Recommendations

To address the small dip late in the year, and after discussion with the Cancer Committee, recommendations to assure continued success with this project include: Reminder to disease group leaders on importance of smoking cessation. Redistribute slides on how to schedule with smoking cessation. Continue to work on additional slots, weekly appointments, for smoking cessation. Reminder to MOAs to Just ASK and document in the medical record. Query no shows and cancellations for smoking cessation visits to identify/address cause.

Fundraising

As we continue to celebrate the success of the \$50 million-dollar Cancer Campaign, the Vidant Health Foundation remains steadfast in continuing to raise funds for cancer patients. Philanthropic donations support cancer patients with essential programs and services such as gas, food, electricity, lodging, prescriptions, and child care, as well as support for free mammograms, colonoscopies and low-dose CT lung scans. Without our generous donors, we would not be able to provide these resources.

On January 24, 2022, the Vidant Health Foundation held a special plaque unveiling for Dr. Mary J. Raab and for her late husband, Dr. Spencer O. Raab. Their lifelong dedication to medicine and cancer care led to them moving to eastern North Carolina to co-found the first division of Hematology and Oncology at East Carolina University Brody School of Medicine in the late 1970's. Most recently, Dr. Mary J. Raab served as Honorary Chair for the Cancer Care Campaign that secured over \$50 million dollars to help fund the Cancer Center in Greenville and to provide essential programs and services for our patients. It is with great appreciation that we dedicated this plaque in her honor and his memory.



Dr. Mary Raab McConnell stands next to the plaque at the unveiling held in January



Friends and colleagues gather to celebrate and recognize Drs. Spencer & Mary Raab

What started as a small idea to help those he knew battling cancer turned into a hugely successful fundraising campaign for ECU Health Cancer Care. Greg Parker not only wanted to raise money for cancer care, but he also wanted to raise awareness while making an impact. And he did just that! For 24 hours, Greg committed to walking on the treadmill in order to honor those he knew personally affected by cancer as well as the countless others in our community in similar situations. He invited friends, family, colleagues, and community notables to participate by walking beside him on adjoining treadmills for 15-minute increments in exchange for donations. ECU baseball coach Cliff Godwin and new Greenville Fire-Rescue Chief Carson Sanders also logged miles on the treadmill. Additionally, A Good Long Walk was recognized all over the country thanks to the promotion it received on the nationally syndicated Bobby Bones Show. A huge thanks to Greg Parker and Champions Fitness, host of the event, for providing HOPE for the patients and families of eastern North Carolina. Over \$25,000 was raised for ECU Health Cancer Care in a single 24-hour period!

We give a special thank you to all of our donors for their support because every day counts and we believe in life without cancer.



Mr. and Mrs. Greg Parker present check to Mr. Scott Senator, Foundation President, and Ms. Phyllis DeAntonio, System Service Line Administrator Cancer Care.



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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