

**SUMMER 2020** VOLUME 9 | ISSUE 2

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**Also In This Issue** ACADEMIC SIMULATION PROGRAM

# ANCER PIONEERS

#### **BAYLOR SCOTT & WHITE ONCOLOGY**

Cancer research studies at Baylor Scott & White Charles A. Sammons Cancer Center - Dallas, located on the campus of Baylor University Medical Center, part of Baylor Scott & White Health, are conducted through Baylor Scott & White Research Institute, Texas Oncology and The US Oncology Network.

HOSPITAL-BASED CANCER PROGRAMS

Baylor Scott & White has the largest network of hospital-based cancer programs in Texas with 15 cancer centers.

Baylor Scott & White is the third largest network of cancer centers accredited by the Commission on Cancer in the nation.

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From the Medical Director Advances in the Treatment of Thoracic Cancer Minimally Invasive Surgery for Gastroesophageal Cancer Academic Simulation Program Precancerous Lesions in the Esophagus Early Detection Through Lung Cancer Screening Molecular Diagnostics for Thoracic Cancers Recent Publications from Baylor Scott & White Sammons Car Baylor Scott & White Sammons Cancer Center Current Clinica



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Cover photo: Minimally invasive surgical techniques used by the Baylor Dallas lung cancer team include thoracoscopic surgery and robotic surgery.

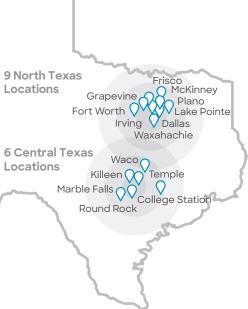
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### FROM THE MEDICAL DIRECTOR

I am pleased to share this Summer 2020 issue of the Baylor Scott & White Cancer Update. Founded in 1976, Baylor Scott & White Sammons Cancer Center is a recognized leader in excellent cancer care. This destination cancer program is located on the campus of Baylor University Medical Center and offers an unparalleled depth and breadth of cancer care.

The centralized cancer care facilities at our Dallas location include the 175,000-square-foot Baylor Scott & White T. Boone Pickens Cancer Hospital, which is the only dedicated cancer hospital in North Texas, and the 467,000-square-foot outpatient facility, one of the nation's largest cancer outpatient centers.

Our ability to provide exceptional research and patient care throughout North and Central Texas is enhanced by a network of 15 hospital-based cancer programs. This network leverages a single organizational infrastructure to offer our cancer care and clinical trials to a diverse population throughout the state of Texas and beyond. With our multidisciplinary teams of specialists at each site and robust connections among sites, we can offer patients access to the most innovative and groundbreaking cancer therapies in all aspects of cancer care.

In this issue, we focus on thoracic cancer care and research. Our Chest Cancer Research and Treatment Center brings together experts across multiple subfields to navigate complex personalized treatment strategies while providing a streamlined patient experience. The articles in this issue illustrate our three-part commitment to excellence in innovative patient care, leading-edge research and continuous quality improvement. Highlights of this issue include the following:

- Large-scale clinical trials of immunotherapies, combination therapies and cell-based therapeutics for cancers of the esophagus and lung. Our center participates in trials across the full spectrum of research, leveraging effective referral networks and industry partnerships.
- Minimally invasive surgical approaches for cancers of the esophagus and lung, including robotic surgery and endoscopic submucosal dissection.
- Comprehensive simulation resources that offer surgical skills training and facilitate research on innovative digital health technologies, such as telesurgery and kinesthetic feedback.
- Translational research to identify the molecular mechanisms of esophageal carcinogenesis and implement those insights to advance patient care.

- A screening program for early detection of lung cancer in high-risk individuals coupled with a nationally recognized lung cancer treatment program.
- A molecular diagnostics and genetic counseling program that provides analysis of somatic and germline mutations in partnership with patients and the multidisciplinary care teams.

Together, these stories illustrate our commitment to successful intervention and individualized care. We know the best outcomes are possible when cancers are detected early. With this in mind, our teams are always looking for ways to improve early identification and provide patient-centered care that maximizes quality and safety with minimal intervention. For instance, the Enhanced Recovery After Surgery program, which provides a clear workflow for perioperative care, has greatly reduced both complications and the duration of hospital stays. In recognition of our commitment to quality, the Baylor Scott & White Lung Cancer Surgery program has received the coveted three-star rating from the Society of Thoracic Surgeons in both 2018 and 2019 and is nationally ranked by U.S. News & World Report.

This is an exciting time to be in the fight against cancer. New therapies are offering impressive cure rates to patients who previously had few options. Trends toward minimally invasive surgery are reducing hospital stays and improving the quality of survivorship. Our unmatched infrastructure for cancer care and research, including a 1,800-square-foot in-house cGMP cell manufacturing facility and a dedicated facility for early-stage clinical research, positions Baylor Scott & White in a leadership role as we look toward the future.

As we use the most sophisticated weapons against cancer, we must also never lose sight of the fact that each individual is a whole person with a life story that extends across their cancer journey. As such, we work to provide world-class care in a peaceful environment that nurtures the spirit into a successful survivorship.

Ronan Kelly, MD, MBA Chief of Oncology, Baylor Scott & White Health - North Texas Director, Baylor Scott & White Charles A. Sammons Cancer Center





**Feature Article** 

### **ADVANCES IN THE TREATMENT OF THORACIC CANCER**

Baylor Scott & White Sammons Cancer Center is located at Baylor Dallas and has become a destination location for patients with thoracic cancers by combining innovative clinical research with advanced quality of care in a multidisciplinary environment. This article describes recent advances in the medical and surgical treatment of both lung cancer and esophageal cancer and explores potential practice-changing studies that have originated from our program.

### Novel immunotherapies for esophageal cancer



Researchers at Baylor Dallas are investigating a number of innovative immunotherapeutic strategies for the treatment of gastroesophageal cancer. CheckMate 577 is a randomized, double-blind, placebo-controlled, phase III study (NCT02743494), which has enrolled 794 patients across 32 countries worldwide. The investigators are evaluating whether the PD-1 inhibitor nivolumab, given after standard-of-care chemoradiation and surgery, can improve disease-free survival and overall survival in patients with operable stage II/III cancer of the esophagus or gastroesophageal junction.

Ronan Kelly, MD, MBA

Ronan Kelly, MD, MBA, medical director of Baylor Scott & White Sammons Cancer Center, is the international principal investigator for the CheckMate 577 study. "Only about 30% of patients who get standard chemoradiation followed by esophageal resection achieve a pathological complete response. The remaining 70% of patients have few treatment options other than close observation as additional adjuvant chemotherapy has not been shown to be beneficial. We are eagerly awaiting the results of this pivotal phase III trial to see if immunotherapy can offer some additional hope to these patients."

Additional esophageal cancer investigator-initiated phase I/II studies are now open with three recruitment sites, including Baylor Dallas, Johns Hopkins in Baltimore and the Allegheny Health Network in Pittsburgh. The first trial is investigating the use of neoadjuvant immunotherapy combined with chemoradiation prior to surgical resection (NCT03044613). In Arm A, patients receive nivolumab alone. In Arm B, they receive nivolumab plus the LAG-3 inhibitor relatlimab as induction therapy and concurrently with carboplatin/paclitaxel and thoracic irradiation prior to an esophagectomy.

The other trial is the REACTION study (NCT03610711), which will recruit patients with oligometastatic gastroesophageal cancer. All the patients will receive high-dose stereotactic body radiation to any sites outside the gastroesophageal region. Then, like the other study, patients in Arm A will receive nivolumab alone, and those in Arm B will receive nivolumab plus relatlimab.

Dr. Kelly is the lead investigator and author for both studies and says, "By testing the response to checkpoint inhibitor therapies across multiple disease stages and in various combinations, we hope to get a clearer picture of how much immunotherapy might benefit these patients with historically difficult to treat tumors."

### Therapeutic developments for lung cancer



Baylor Dallas also supports a robust portfolio of clinical trials for lung cancer. According to Kartik Konduri, MD, co-medical director of the Lung Cancer Research and Treatment Center at Baylor Scott & White Sammons Cancer Center, "We are seeing more strategies that combine immunotherapy with chemotherapy, especially at earlier disease stages, and more targeted therapies are emerging. We are also starting cell-based trials, including those with CAR-T cells and T cell receptor therapies. Some of these cell-based therapies can be produced in our on-campus cGMP cellular therapeutics manufacturing facility, positioning Baylor Dallas as an attractive site for innovative immunotherapy research."

Kartik Konduri, MD

One strength of the Baylor Dallas environment is the ability to participate in clinical trials through Texas Oncology and The US Oncology Network, which can utilize large referral networks across the state and the country to identify patients with rare molecular or immunological alterations so they can come to Dallas to be treated on innovative studies that may be only available to a small population of patients. Strict entry criteria limit the feasibility of opening these studies in a smaller community or outside of

large academic settings that do not possess the population of patients needed to adequately enroll in some of these trials.

Dr. Konduri mentions exciting next-generation lung cancer therapies that are now entering the clinic, "The recent vastly improved outlook for lung cancer therapies has become possible due to targeted therapies and immunotherapies. Newer targets and therapeutics have become available based on promising data from clinical trials. These have a meaningful impact on helping patients live better and longer."

Such trials available at Baylor Dallas include the ongoing ARROW phase I/II open-label trial (NCT03037385). This study is evaluating the RET inhibitor BLU-667 in patients with RET-altered solid tumors, including non-small cell lung cancer (NSCLC). Baylor Dallas is also conducting a trial with AMG 510 for a subtype of NSCLC with KRAS (G12C) mutations, which are usually hard to treat with targeted therapies (NCT03600883).

Dr. Konduri also describes the potential importance of drug combinations. "Combining immunotherapy with targeted drugs represents an exciting attempt to gain the benefits of both these strategies. We are looking at multitargeted kinase inhibitors like sitravatinib, combined with immunotherapy, to assess improved efficacy. Another trial using targeted therapy with cabozantinib combined with immunotherapy (atezolizumab) is opening shortly for patients with NSCLC who have progressed on front-line therapies. These innovative clinical trials are leading advancements of therapeutics for lung cancer patients."

The recent vastly improved outlook for lung cancer therapies has become possible due to targeted therapies and immunotherapies. Newer targets and therapeutics have become available based on promising data from clinical trials. These have a meaningful impact on helping patients live better and longer.

#### Kartik Konduri, MD

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Co-medical director of the Lung Cancer Research and Treatment Center at Baylor Dallas

> Baylor Dallas is also working with Texas Oncology for a phase I/II study (NCT03400332) to evaluate the safety and feasibility of the interleukin (IL)-8 inhibitor BMS-986253 plus nivolumab in patients with advanced solid tumors. High serum IL-8 levels correspond with poor prognosis across a variety of cancers. IL-8 blockade is expected to reduce the mesenchymal features of tumor cells and permit the success of immunotherapies.

> Together, these studies attempt to identify novel therapies based on the molecular characterization of the tumor, providing an individualized and personalized approach to lung cancer therapy.

#### **Excellence in lung cancer surgery**



Lung cancer surgery at Baylor Dallas is focused around rapid access and individualized guality of care. These attributes have won Baylor Dallas the distinguished three-star rating from the Society of Thoracic Surgeons for patient care and cancer outcomes for lobectomy in lung cancer in both 2018 and 2019. This highest ranking puts Baylor Dallas in the top five percent of programs in the US and Canada. Additionally, most lung cancer patients undergo minimally invasive surgery.

David Mason, MD

The Lung Cancer Research and Treatment Center at Baylor Scott & White

Sammons Cancer Center works alongside the Lung Nodule Clinic (see page 22) for screening and early diagnosis. Treatment of lung cancer then includes a combination of medical and surgical approaches, which are evaluated by a multidisciplinary team of pulmonary specialists, medical oncologists radiation oncologists, and thoracic surgeons. The surgical component is individualized to the patient's tumor size, location, lung function and underlying medical conditions.

According to David Mason, MD, chief of thoracic surgery and lung transplantation and chief of thoracic oncology at Baylor Dallas, success is all about teamwork. "We have a team of dedicated thoracic anesthesiologists, nurses and operating room staff. Having a specialized team is what allows us to get guality outcomes for our patients. We have grown tremendously in the last years. Since 2015, thoracic surgery volumes at Baylor Dallas have grown from 280 to over 1,300 performed last year. This is due to the impressive work by our dedicated team."

Minimally invasive surgical techniques used by lung cancer surgeons on the medical staff at Baylor Dallas include thoracoscopic surgery and robotic surgery. Thoracoscopic surgery is a video-assisted procedure of the chest that permits the surgeon to find and remove cancerous areas of the lung using only small incisions. Robotic surgery provides enhanced visualization and dexterity in specific circumstances and locations that require it. The department's thoracic surgeons specializing in non-cardiac diseases of the chest have expertise in each of these techniques and tailor the surgical approach for each individual patient. Hospital stays with minimally invasive surgery are short and



Minimally invasive surgical techniques used by the Baylor Dallas lung cancer team include thoracoscopic surgery and robotic surgery.

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recovery enhanced.

Another key to the success of Baylor Dallas is facilitating access to care. Dr. Mason says, "Some patients travel a long distance to see us in Dallas. We work hard to coordinate all their testing and surgery to minimize time away from home. In addition, we offer thoracic clinics in Fort Worth. Waxahachie, Rockwall, Lubbock and Tyler for those who prefer it. Finally, we offer same-day appointments for patients. For our entire team, it is always patients first, and we are constantly striving to improve their experiences and improve outcomes."

### MINIMALLY INVASIVE SURGERY FOR GASTROESOPHAGEAL CANCER





Steven Leeds, MD

Eitan Podgaetz, MD Marc Ward, MD

Cancers of the stomach and esophagus traditionally have been labeled as aggressive and hard to treat. When diagnosed in the later stages, gastroesophageal cancers often require a combination of chemotherapy, radiation and surgery. However, when the cancers are found early, many of these interventions can be avoided. Through a multidisciplinary effort with the Departments of Minimally Invasive Surgery, Thoracic Surgery and Gastroenterology, endoscopic surgical techniques are now available at Baylor Dallas.

Steven Leeds, MD, division chief of minimally invasive surgery at Baylor Dallas, mentions that the key to success is detecting the cancer early. "Endoscopy is becoming more common, and we are seeing people get endoscopies at younger ages. This means patients are referred to our center at earlier stages of disease, when they are still good candidates for minimally invasive treatments." Dr. Leeds and his department spend significant time teaching and utilizing endoscopic techniques for minimally invasive surgery. These techniques have allowed Baylor Dallas to pioneer several procedures, including per-oral endoscopic myotomy (POEM) and endoscopic submucosal dissection (ESD). The team is also internationally recognized for research into endoscopic techniques for mitigating anastomotic leak after surgery of the gastrointestinal tract.

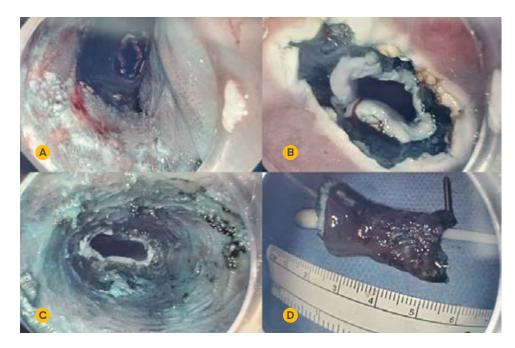
Endoscopic mucosal resection (EMR), developed in the 1980s, is the primary endoscopic technique for removing small superficial gastroesophageal lesions. EMR is routinely used at Baylor Dallas. The advantage to EMR is its ability to provide deeper biopsies than normal forceps. However, EMR cannot remove specimens en bloc larger than 1 – 2 centimeters.

A major breakthrough in endoscopic cancer treatment came with the development of ESD. Pioneered in Japan in the 2000s, ESD allows the surgeon to peel away the mucosa to resect tumors of the esophagus, stomach and other areas of the gastrointestinal tract without incisions. Eitan Podgaetz, MD, director of minimally invasive and endoscopic thoracic surgery at Baylor Dallas, says, "We perform complex endoscopic eradication therapy, including ESD, which removes the area with the tumor and the surrounding mucosa. We also perform circumferential dissection, where we remove the entire 360 degrees of mucosa endoscopically. This technically demanding approach is only performed at a few centers, and we are happy to offer it to our patients."

Marc Ward, MD, director of minimally invasive research and simulation and a surgical oncologist on the medical staff at Baylor Dallas, published the first case study demonstrating successful resection of a 2-centimeter gastric mass with ESD in a 76-year-old man with significant comorbidities. Although the mass was confined to the mucosa, it was too large for EMR. The ESD resection was successful with complete removal of the cancer, and the patient was discharged after one day with no complications.

According to Dr. Ward, "If you can remove a lesion endoscopically, the patient has a faster recovery; there are no incisions. It is very well-tolerated even in patients with comorbidities compared to laparoscopic techniques. Our collaborative environment allows us to guide each patient to the best choice for both quality and safety."

This individualized approach to cancer care is also seen in the Enhanced Recovery After Surgery (ERAS) program. The ERAS program also guides the patient throughout the perioperative period and recovery. Research at Baylor Dallas has shown that ERAS programs in minimally invasive surgery have decreased complications by 81% and shortened the hospital stay by 16%. Combining this ongoing research with advanced cancer treatment, physicians on the medical staff at Baylor Dallas are providing optimal cancer care in the least invasive way possible.



A: Endoscopic view of superficial squamous cell carcinoma. **B**: Initial endoscopic incision. **C**: Endoscopic view post circumferential resection. **D**: Photo of tubularized specimen.

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## **ACADEMIC SIMULATION** PROGRAM



The Academic Simulation Program at Baylor Dallas offers comprehensive simulation resources for education and quality improvement throughout Baylor Scott & White and beyond. These centralized resources permit a wide range of medical professionals to receive skills training in a standardized, low-risk and cost-effective environment.

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Sanket Chauhan, MD, MBA, co-founder and medical director of clinical simulation, describes what makes the Baylor Dallas program unique. "There are very few fully integrated simulation programs in the country. We support physicians, medical students, residents, advanced service providers, nurses and allied health professionals. We are also integrated with the clinical service lines to support patient safety and quality improvement initiatives." This strategy positions Baylor Dallas to innovate and standardize approaches across multiple disciplines.



The Academic Simulation Center is integral to the formal training of medical students and residents at Baylor Dallas.

The Academic Simulation Program is divided into three divisions:

- Seeger Surgical Simulation Center. The newly renovated facility contains a wide array of task-based training stations, including several manikins and virtual reality simulators.
- Baylor Operative Skills Simulation (BOSS) center. This 2,400-square-foot facility is a centralized resource for cadaver-based bioskills training. It is equipped with eight stations, including both laparoscopic and open surgical instrumentation, and can be outfitted with specialty equipment. The BOSS center is also fully networked for HD video recording and livestreaming.
- Center for Evidence Based Simulation (CEBS). This is the research and development wing of the Academic Simulation Program. Funded by over \$4 million in external funding, including an R01 grant from the National Institute of Biomedical Imaging and Bioengineering, the CEBS develops simulation programs in partnership with collaborators throughout academia and industry. Ongoing research includes exploring the capacity for telesurgery, integrating artificial intelligence into skills assessment, and incorporating kinesthetic (haptic) feedback into laparoscopic training.

The Academic Simulation Program is integral to the formal training of medical students and residents at Baylor Dallas. Residents at all levels can develop skills in laparoscopy, robotic surgery, endoscopy and open surgery.

James Fleshman, MD, FACS, FASCRS, chief of the Department of Surgery at Baylor Dallas and co-founder of the Academic Simulation Program, notes that the simulation resources have also been used to train practicing surgeons in laparoscopy for resection of colon and rectal cancer. "The result was a safe and reproducible technique that benefitted the patient with less pain and earlier recovery, without compromising the chance of cure." Thus, simulation can be integrated at all levels of care to improve the quality of cancer care delivery.



## **PRECANCEROUS LESIONS IN THE ESOPHAGUS**





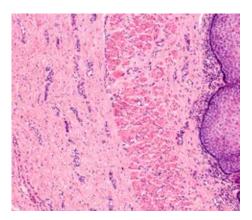




internationally recognized for excellence in research and treatment for esophageal precancerous lesions. The

Baylor Dallas is

precursor lesion for esophageal adenocarcinoma is Barrett's esophagus, a complication of chronic gastrointestinal reflux disease (GERD). In Barrett's esophagus, the esophageal squamous epithelium is converted to columnar epithelium with goblet cells, causing the esophageal lining to resemble the lining of the intestine. The progression of Barrett's esophagus from metaplasia through dysplasia and into cancer is managed using endoscopic monitoring.



Normal Esophagus

Barrett's Intestinal Metaplasia

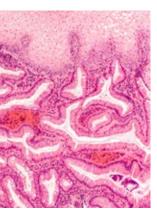
Vani Konda, MD, gastroenterologist on the medical staff and director of clinical operations of the Endoscopy Center at Baylor Dallas, describes the clinical services that set Baylor Dallas apart. "Unlike other centers, we offer the full armamentarium of tools available, from radiofrequency ablation (RFA) and EMR for milder disease to ESD and esophagectomy for more advanced disease. We also use a combined consult system for early cancer, which allows the patient to see both the surgeon and gastroenterologist in the same appointment and decide on a treatment plan in real time. This streamlined approach facilitates consensus and minimizes stress for the patient."

Despite the best clinical management of Barrett's esophagus, some patients still progress to adenocarcinoma, and the research team at Baylor Dallas wants to know why. For instance, Barrett's metaplasia can recur after RFA at a rate of nearly 10% per year. This recurrence is caused by a unique ability of the Barrett's cells to burrow into the submucosa and escape the thermal injury of RFA.

In a 2019 publication in Gastroenterology, researchers at Baylor Dallas gained critical insight into how Barrett's cells escape RFA. They identified a mechanism whereby the components of acid reflux cause Barrett's cells to undergo epithelialmesenchymal transition (EMT), a reversible transformation that permits stationary cells to migrate. Rhonda Souza, MD, co-director of the Endoscopy Center and senior author on the Gastroenterology paper, says, "We identified vascular endothelial growth factor (VEGF) as the trigger for EMT, and with the help of recent R01 funding from the National Institute of Diabetes and Digestive for Kidney Diseases, we can now identify the detailed mechanism, including the role of the hypoxia-induced factor HIF-1a."

Stuart Spechler, MD, chief of gastroenterology and co-director of the Endoscopy Center, who is also a co-author on the Gastroenterology publication and co-principal investigator on the R01 grant, adds, "We will also test candidate therapies based on the molecular mechanisms that we have elucidated. This is what really makes our work unique. We can do true translational research to identify the fundamental mechanisms underlying our patients' clinical conditions. The knowledge we gain from this research enables us to develop novel treatments and procedures that directly impact patient care."

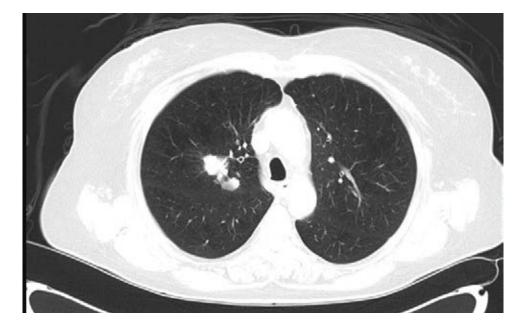




## **EARLY DETECTION THROUGH LUNG CANCER SCREENING**

Lung cancer is the leading cause of cancer death for both men and women. However, early detection improves outcomes. As early as 2011, the National Lung Screening Trial showed that annual screening of people at risk for lung cancer reduced lung cancer-specific mortality by 20%. Based on these findings, Baylor Dallas has developed a comprehensive lung cancer screening program to identify and treat people who might have early-stage lung cancer.

Leonidas Tapias, MD, thoracic surgeon on the medical staff at Baylor Dallas, describes the target population. "People between 55 and 75 years old with a history of 30 packs per year and either current smoking or quitting within the last 15 years are at increased risk of lung cancer. Our goal is to help these people get into annual screening."



people with lung nodules identified either through screening or incidentally.

The primary modality for screening is low-dose computed tomography (CT) scanning. Biomarker analyses, such as antibody tests and genomic profiling, can be used to generate a combined risk calculator. Research is ongoing as to the best specimen collection method for biomarker analysis, and process improvements may further improve risk assessment.

People already know to undertake screening for other cancers, but because lung cancer screening is still in the early stages, people are not yet aware of the benefits. We encourage them to join our screening program.

Leonidas Tapias, MD Thoracic Surgeon at Baylor Dallas

Working with the lung cancer screening program, Baylor Scott & White Sammons Cancer Center is a destination treatment resource for people with lung nodules identified either through screening or incidentally. One key advantage of Baylor Dallas is a multidisciplinary team approach, which includes radiologists, pulmonologists, oncologists and surgeons, who streamline care and coordinate the steps from identification through therapy, if necessary. Smoking cessation counseling is also available. All of this takes place in collaboration with the referring physician to reduce stress and confusion for the patient.

Although early detection can reduce lung cancer mortality, only 3 - 5% of eligible candidates enter a screening program. Given that approximately 90% of identified nodules turn out to be benign, finding ways to increase screening acceptance are important. Dr. Tapias mentions, "People already know to undertake screening for other cancers, but because lung cancer screening is still in the early stages, people are not yet aware of the benefits. We encourage them to join our screening program." 
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Baylor Scott & White Sammons Cancer Center is also a destination treatment resource for

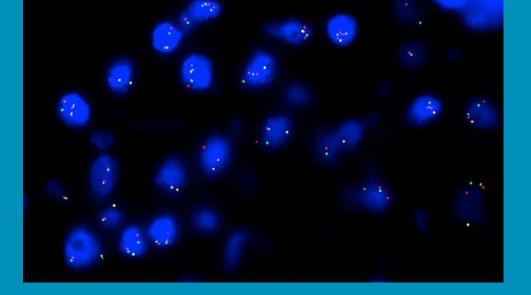
### MOLECULAR **DIAGNOSTICS FOR THORACIC CANCERS**



Baylor Dallas has embraced the growing recognition of molecular markers as tools for navigating the cancer treatment journey. The molecular diagnostics services available at Baylor Dallas include analysis of somatic molecular alterations in the tumor and, depending on the cancer type, evaluation of germline mutations.

S. Michelle Shiller, DO, MSPT, molecular pathologist and co-medical director of the Genetic Counseling Program at Baylor Dallas, describes how molecular analysis of somatic

alterations fits into the multidisciplinary team approach that makes Baylor Dallas a leader in the treatment of complex disease. "As a member of the multidisciplinary team, I consult about the role of particular oncogenic drivers and educate about testing and its optimal implementation. Molecular profiling is performed on every tumor, and the analysis of those results adds an important piece to the development of a treatment plan." The routine molecular tumor profiling assays include evaluation of point mutations, genomic rearrangements, gene amplifications and protein expression levels.



The routine molecular tumor profiling assays include evaluation of point mutations, genomic rearrangements, gene amplifications and protein expression levels.



The Genetic Counseling Program provides genetic testing and support services for individuals and families who might have germline mutations that increase the risk of cancer.

For example, somatic mutations in the growth factor receptor gene EGFR are present in 25% of patients with non-squamous NSCLC and a small percentage of those with squamous cell NSCLC. Given that tyrosine kinase inhibitors are first-line therapies for NSCLC patients with most EGFR mutations, integrating molecular profiling as early as possible can clearly impact the therapeutic approach.

The Genetic Counseling Program also provides genetic testing and support services for individuals and families who might have germline mutations that increase the risk of cancer. According to Kelly Johnson, MS, MPH, certified genetic counselor at Baylor Dallas, "Chest and lung cancers were initially thought to be largely sporadic or environmental, but in rare cases, there are hereditary genetic mutations that increase risk for these tumors (Table 1). For patients with non-small cell lung cancer, malignant mesothelioma, and thymic or bronchial carcinoid tumors, we encourage physicians to discuss the family history, evaluate the patient for other features of the genetic conditions and consider a referral to Baylor Dallas for genetic counseling."

### Table 1. Germline mutations in thoracic cancer.

Cancer/tumor type	Gene	Syndrome	Mode of Inheritance	Other features seen in the personal/family history
Non-small cell lung cancer	EGFR	Hereditary lung cancer syndrome	Autosomal dominant	<ul> <li>EGFR T790M somatic mutations in the tumor prior to therapies</li> <li>Family history of young lung cancers and/or lung cancer in non-smokers</li> </ul>
Mesothelioma	BAP1	<i>BAP1</i> -hereditary cancer predisposition syndrome	Autosomal dominant	Uveal melanoma, cutaneous melanoma, kidney cancer, multiple nevi or atypical Spitz-like tumors, meningiomas
Thymic and MEN1 Multiple endocrine bronchial neoplasia type 1 carcinoids (MEN1)		Autosomal dominant (10% <i>de novo</i> mutations)	Hyperparathyroidism, pituitary tumors, well-differentiated tumors of the gastro-entero-pancreatic tract (gastrinomas, insulinomas, etc.), neuroendocrine tumors (such as PNETs), adrenocortical tumors, ependymomas	

Cancer/tumor type	Gene	Syndrome	Mode of Inheritance	Other features seen in the personal/family history
Non-small cell lung cancer	EGFR	Hereditary lung cancer syndrome	Autosomal dominant	• EGFR T790M somatic mutations in the tumor prior to therapies
				<ul> <li>Family history of young lung cancers and/or lung cancer in non-smokers</li> </ul>
Mesothelioma	BAP1	<i>BAP1</i> -hereditary cancer predisposition syndrome	Autosomal dominant	Uveal melanoma, cutaneous melanoma, kidney cancer, multiple nevi or atypical Spitz-like tumors, meningiomas
Thymic andMEN1Multiple endocrinebronchialneoplasia type 1carcinoids(MEN1)		Autosomal dominant (10% <i>de novo</i> mutations)	Hyperparathyroidism, pituitary tumors, well-differentiated tumors of the gastro-entero-pancreatic tract (gastrinomas, insulinomas, etc.), neuroendocrine tumors (such as PNETs), adrenocortical tumors, ependymomas	

December 2019 through May 2020

# RECENT PUBLICATIONS

FROM BAYLOR SCOTT & WHITE SAMMONS CANCER CENTER

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### **CURRENT CLINICAL TRIALS**

Study ID	DX	NCT#	Principal Investigator	Study Title
			Preskitt, John	Creation and Maintenance of a Longitudinal Surgical Oncold (SOCRD)
013-249	Pancreatic Cancer	n/a	Preskitt, John	(Pancreas MDT) A Retrospective and Prospective Longitudi Multidisciplinary Tumor Conferences (MDTC)
014-129	AML, MDS	NCT02267863	Levy, M Yair	(APTOSE) A Phase I Dose Escalation with Two Disease Spec label, Safety, Pharmacokinetic and Pharmacodynamic Stud or Refractory Hematologic Malignancies
014-197	Melanoma	n/a	Preskitt, John	(Melanoma MDT) A Retrospective and Prospective Longituc for Multidisciplinary Tumor Conferences (MDTC)
014-248	Lung Cancer	n/a	Preskitt, John	(Lung MDT) A Retrospective and Prospective Longitudinal L Multidisciplinary Tumor Conferences (MDTC)
015-196	Pancreatic Cancer	n/a	Celinski, Scott	(ROC) (w/TGen) Circulating Tumor DNA, Non-Coding RNA, Early Detection of Recurrence and Prognostication of Panci
015-312	MCL	NCT02601313	Holmes, Houston	A Phase 2 Multicenter Study Evaluating the Efficacy of KTE- Refractory Mantle Cell Lymphoma (r/r MCL)
016-068	ММ	NCT02884102	Levy, M Yair	Clinical-grade Molecular Profiling of Patients with Multiple M Malignancies (MMRF-002)
016-077	Other	n/a	Levy, M Yair	(ROC) (AMPS) A Two-Stage Blinded Study to Assess Accele Physical Activity as Surrogate Indicator of Clinical Performan
016-126	AML	NCT02665065	Koshy, Nebu	(IOMAB) A Multicenter, Pivotal Phase 3 Study of Iomab-B Pri Transplantation Versus Conventional Care in Older Subjects Acute Myeloid Leukemia
016-130	Anaplastic Astrocytoma	NCT02796261	Fink, Karen	A Phase 3, Randomized, Open-Label Study to Evaluate the E Lomustine Compared to Lomustine Alone in Patients with A Recur After Irradiation and Adjuvant Temozolomide Chemor
016-137	Pancreatic Cancer, Gastric and Prostate	NCT02744287	Becerra, Carlos	A Phase 1/2 Feasibility, Safety, and Activity Study of PSCA-S Engineered T Cells (BPX-601) in Subjects with Previously Tre
016-241	MM	NCT02998047	Levy, M Yair	A Phase I Study of Lintuzumab-Ac225 in Patients with Refrac
016-260-5	MM	n/a	Levy, M Yair	(TGen Sample Study) Characterizing Mechanisms of Resista Myeloma

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ology Clinical Research Database

udinal Pancreas Data Collection Study for

ecific Expansions, Multicenter, Openudy of LOR-253 in Patients with Relapsed

tudinal Melanoma Data Collection Study

al Lung Data Collection Study for

A, and DNA Methylation Biomarkers for ncreatic Cancer: A Pilot Study

E-C19 in Subjects with Relapsed/

e Myeloma and Related Plasma Cell

elerometry-Tracked Pre-Treatment nance Status

Prior to Allogeneic Hematopoietic Cell cts with Active, Relapsed or Refractory

e Efficacy and Safety of Eflornithine with Anaplastic Astrocytoma That Progress/ notherapy

-Specific Chimeric Antigen Receptor Treated Advanced Solid Tumors

ractory Multiple Myeloma

istance to Novel Agents in Multiple

Study ID	DX	NCT#	Principal Investigator	Study Title
016-262	Other	NCT03002519	Escobar, Carolina	Phase I Dose-Escalation Study to Evaluate the Safety of a C Placental Stromal Cells, in Subjects Suffering From Incomp Hematopoietic Cell Transplantation (HCT)
016-264	ALL, CML	NCT02629692	Whiteley, Andrew	A Two-Part Phase 1/2 Study to Determine Safety, Tolerabilit K0706, a Novel Tyrosine Kinase Inhibitor (TKI), in Healthy Sul Myeloid Leukemia (CML) or Philadelphia Chromosome Pos (Ph+ ALL)
016-266	Pancreatic Cancer	n/a	Celinski, Scott	Retrospective Assessment of Candidate Molecular Prognomic with Localized Disease
017-200	Pancreatic Cancer	n/a	Celinski, Scott	(TGen) Integrated Genomic Biomarkers for the Early Detec
017-330	Lung, Pancreatic, Solid Tumors, Urothelial Cancer	NCT03139370	Becerra, Carlos	A Phase 1 Study Evaluating the Safety and Efficacy of MAGE Cells (KITE-718) in HLA-DPB1*04:01 Positive Subjects with A
017-478	Breast Cancer	NCT03255070	O'Shaughnessy, Joyce	A Phase 1, Multicenter, Open-label, Multiple Dose-escalation Administered as a Single Agent in Subjects with Advanced
018-127	DLBCL, Lymphoma	NCT03263026	Levy, M Yair	A Randomized, Placebo-Controlled, Phase 3 Study to Evalu Biomarker to Predict Survival of Treatment Naïve, High-Risk Lymphoma Treated with R-CHOP plus Enzastaurin
018-159	Solid Tumors	NCT02549937	Paulson, Scott A	A Multi-Center, Open-Label, Clinical Trial to Evaluate the Sa Sulfatinib in Advanced Solid Tumors
018-170	LTFU	NCT02840110	Holmes, Houston	Long-term Follow-up Study of Subjects Treated with an Au Antibody Coupled T Cell Receptor (ACTR)
018-503	AML	NCT03435848	Burch, Micah	A Phase 2b Open-Label, Single Arm, Multi-Center Study to 236 as a Single Agent for the Treatment of Adult Patients w Leukemia (AML), not Eligible for Standard Induction Therap
018-566	ММ	NCT03544281	Levy, M Yair	(DREAMM-6) A Phase I/II, Open-label, Dose Escalation and Tolerability, and Clinical Activity of the Antibody-Drug Conju in Combination with Lenalidomide Plus Dexamethasone (Tr Dexamethasone (Treatment B) in Participants with Relapse
018-597	Colorectal	NCT03439462	Becerra, Carlos	A Phase 1/2 Multi-Center Investigation of ABI-009 (Nab-Rap and Bevacizumab As First-Line Therapy in Patients with Adv
018-617	DLBCL, NHL	NCT03575351	Holmes, Houston	A Global Randomized Multicenter Phase 3 Trial to Compare to Standard of Care in Adult Subjects with High-Risk, Transp Aggressive B-Cell Non-Hodgkin Lymphomas (TRANSFORM
018-634	ALL, AML, MDS, Other	NCT03555955	Burch, Micah	A Phase 1 Trial to Evaluate the Potential Impact of Renal Imp and Safety of CPX-351 (Daunorubicin and Cytarabine) Lipos Patients with Hematologic Malignancies

a Cell-Based Therapy, Comprised of nplete Hematopoietic Recovery Following

ility, Pharmacokinetics, and Activity of Subjects and in Subjects with Chronic ositive Acute Lymphoblastic Leukemia

nosticators in Pancreas Cancer Patients

ection of Pancreatic Cancer

GE-A3/A6 T Cell Receptor Engineered T Advanced Cancers

tion Study of ARX788, Intravenously ad Cancers with HER2 Expression

aluate the Ability of a Novel Genomic isk Subjects with Diffuse Large B-Cell

Safety, Tolerability, Pharmacokinetics of

Autologous T Cell Product Expressing an

to Assess the Efficacy and Safety of BSTwith Newly Diagnosed Acute Myeloid apy

nd Expansion Study to Evaluate Safety, njugate GSK2857916 Administered (Treatment A), or Bortezomib Plus osed or Refractory Multiple Myeloma

apamycin) in Combination with FOLFOX dvanced or Metastatic Colorectal Cancer

are the Efficacy and Safety of JCAR017 nsplant-Eligible Relapsed or Refractory RM)

npairment on the Pharmacokinetics posome for Injection Treatment in Adult

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Study ID	DX	NCT#	Principal Investigator	Study Title
018-635	DLBCL, Lymphoma, NHL	NCT03677154	Holmes, Houston	A Phase I/II Study of BTCT4465A in Patients Who Do Not Adas IL Therapy for Patients Unfit to Receive Full-dose Anthra
018-651	Other, MDS	NCT03682536	Whiteley, Andrew	A Phase 3, Open-label, Randomized Study to Compare the (ACE-536) Versus Epoetin Alpha for the Treatment of Aner Intermediate Risk Myelodysplastic Syndromes (MDS) in ES Blood Cell Transfusions
018-679	DLBCL	NCT03570892	Holmes, Houston	Tisagenlecleucel Versus Standard of Care in Adult Patients Aggressive B-Cell Non-Hodgkin Lymphoma: A Randomize
018-741	MM	NCT03269136	Levy, M Yair	A Phase I, Open-Label Study to Evaluate the Safety, Pharm Clinical Activity of PF-06863135, a B-Cell Maturation Antige Patients with Relapsed/Refractory Advanced Multiple Mye
018-745	Breast		O'Shaughnessy, Joyce	Pilot Clinical Trial of Treatment with Oral LY302023414 to Inf Followed by Prexasertib in Patients with Chemotherapy-P Breast Cancer
019-021	Esophageal, Gastroesophageal	NCT03044613	Kelly, Ronan	Phase IB trial of induction nivolumab or nivolumab/relatlim plus nivolumab or nivolumab/relatlimab in patients with op
019-029	AML	NCT03504410	Levy, M Yair	A Phase III, Multicenter, Open-Label Randomized Trial to Ev in Combination with High Dose Cytarabine and Mitoxantro Cytarabine and Mitoxantrone (HAM) in Older Patients (>60 Acute Myeloid Leukemia (AML)
019-030	Other	NCT03394365	Pineiro, Luis	Multicenter, Open-Label, Phase 3 Study of Tabelecleucel for with Epstein-Barr Virus-Associated Post-Transplant Lymp Rituximab or Rituximab and Chemotherapy (ALLELE)
019-038	Gastric/Cholangio- carcinoma	NCT03656536	Paulson, Scott A	A Phase 3, Open-Label, Randomized, Active-Controlled, M and Safety of Pemigatinib (INCB054828) Versus Gemcitab First-Line Treatment of Participants with Unresectable or N FGFR2 Rearrangement
019-046	CLL, Leukemia	NCT03624036	Holmes, Houston	(ZUMA-8) A Phase 1/2 Multicenter Study Evaluating the Sa Subjects with Relapsed/Refractory Chronic Lymphocytic
019-074	GBM	NCT03018288	Fink, Karen	A Randomized, Double Blind Phase II Trial of Radiation Ther Pembrolizumab with and without HSPPC-96 in Newly Diag
019-075	Neuroendocrine	NCT04042714	Paulson, Scott A	An Open-Label, Phase II Investigation of TAS-102 in Patient Neuroendocrine Carcinoma
019-088	NHL	NCT02180711	Levy, M Yair	An Open-Label, Phase 1b/2 Study of Acalabrutinib Alone o Subjects with Indolent B-Cell Non-Hodgkin Lymphoma

26

Achieve CR to 1L Therapy for DLBCL and hracycline-based Chemotherapy

the Efficacy and Safety of Luspatercept nemia Due to IPSS-R Very Low, Low or ESA Naïve Subjects Who Require Red

nts with Relapsed or Refractory zed, Open Label, Phase III Trial (BELINDA)

armacokinetic, Pharmacodynamic and igen (BCMA) - CD3 Bispecific Antibody, in Iyeloma

Inhibit Homologous Recombination (HR) -Pretreated Metastatic Triple Negative

limab prior to concurrent chemoradiation operable stage II/III

Evaluate Efficacy and Safety of CPI-613 trone (CHAM) Compared to High Dose •60 years) with Relapsed/Refractory

l for Solid Organ Transplant Subjects phoproliferative Disease After Failure of

Multicenter Study to Evaluate the Efficacy abine Plus Cisplatin Chemotherapy in or Metastatic Cholangiocarcinoma with

Safety and Efficacy of KTE-X19 in Adult ic Leukemia

herapy Plus Temozolomide and agnosed Glioblastoma (GBM)

ents with High Grade, Extrapulmonary

or in Combination with Rituximab in

Study ID	DX	NCT#	Principal Investigator	Study Title
019-101	AML, Other	NCT03386513	Holmes, Houston	A Phase 1, Multi-center, Open-label Study of IMGN632 Adm with Relapsed/Refractory CD123-positive Acute Myeloid Le Hematologic Malignancies
019-137	MM	NCT03651128	Holmes, Houston	A Phase 3, Multicenter, Randomized, Open-Label Study to b2121 Versus Daratumumab (DARA) in Combination with P Dexamethasone (dex) (DPd) in Subjects with Relapsed an
019-140	GvHD	NCT03657160	Pineiro, Luis	A Randomized, Double-Blind, Placebo-Controlled, Multice Safety of Vedolizumab in the Prophylaxis of Intestinal Acut Undergoing Allogeneic Hematopoietic Stem Cell Transplar
019-157	CLL, Leukemia	NCT03331198	Levy, M Yair	(TRANSCEND) An Open-Label, Phase 1/2 Study of JCAR01 Refractory Chronic Lymphocytic Leukemia or Small Lymp
019-177	MPN	NCT02718300	Holmes, Houston	A Phase 2 Study of the Safety, Tolerability, and Efficacy of I Ruxolitinib in Subjects with Myelofibrosis
019-207	NHL	NCT01796171	Maisel, Christopher	A Phase I/II Study of Lutetium (177Lu)-Lilotomab Satetraxe conjugate for Treatment of Relapsed Non-Hodgkin Lymph
019-227	AML	NCT03217838	Levy, M Yair	A Phase I/II, Open-Label, Multicentre 2-Part Study to Asse Pharmacokinetics, and Efficacy of AZD2811 Nanoparticle a Treatment-Naïve or Relapsed/Refractory Acute Myeloid Le Patients Not Eligible for Intensive Induction Therapy
019-256	CLL, Lymphoma, NHL	NCT03786926	Burch, Micah	A Phase 1, Open-Label Study to Evaluate the Safety, Tolera Efficacy of HMPL-689 in Patients with Relapsed or Refract
019-377	AML, MDS	NCT03248479	Whiteley, Andrew	A Phase 1b Trial of Hu5F9-G4 Monotherapy or Hu5F9-G4 in Patients with Hematological Malignancies
019-410	Head & Neck	NCT03937141	Nadler, Eric	A Phase 2 Efficacy and Safety Study of ADU-S100 and Per Neck Cancer
019-451	AML	NCT03969420	Burch, Micah	A Phase 2, Open-Label, Randomized, Two-Stage Clinical Stu Refractory Acute Myeloid Leukemia Following Treatment w
019-491	AML	NCT03616470	Burch, Micah	A Phase III Randomized, Double-Blind Trial to Evaluate the Administered with Chemotherapy Versus Chemotherapy Refractory Acute Myeloid Leukemia (GMI-1271-301)
020-031	Melanoma	NCT04068181	Cowey, Lance	Phase 2 Study of Talimogene Laherparepvec in Combinati Unresectable/Metastatic Stage IIIB-IVM1D Melanoma Who Based Therapy

4 / Advances in the Treatmen of Thoracic Cancer dministered Intravenously in Adult Patients d Leukemia and Other CD123-positive

to Compare the Efficacy and Safety of Pomalidomide (POM) and Lowdose and Refractory Multiple Myeloma (RRMM)

center Study to Evaluate the Efficacy and cute Graft-Versus-Host Disease in Subjects plantation

2017 in Subjects with Relapsed or nphocytic Lymphoma (017004)

of INCB05465 in Combination with

axetan (Betalutin®) Antibody-radionuclide-Iphoma

sess the Safety, Tolerability, e as Monotherapy or in Combination in I Leukemia/Myelodysplastic Syndrome

erability, Pharmacokinetics and Preliminary actory Lymphoma

in Combination with Azacitidine in

Pembrolizumab in Adults with Head and

Study of Alvocidib in Patients with Relapsed/ with Venetoclax Combination Therapy

ne Efficacy of Uproleselan (GMI-1271) by Alone in Patients with Relapsed/

ation with Pembrolizumab in Subjects with ho Have Progressed on Prior Anti PD-1



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#### Editor-in-Chief:

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