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DALLAS

CANCER UPDATE

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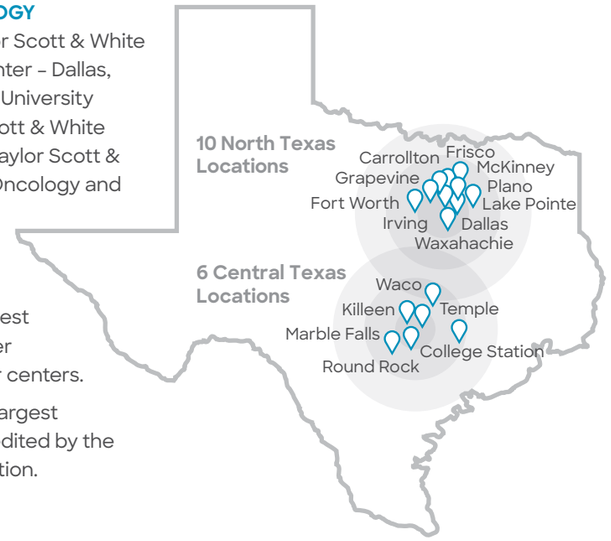
Cancer research studies at Baylor Scott & White Charles A. Sammons Cancer Center – Dallas, located on the campus of Baylor University Medical Center, part of Baylor Scott & White Health, are conducted through Baylor Scott & White Research Institute, Texas Oncology and The US Oncology Network.



HOSPITAL-BASED CANCER PROGRAMS

Baylor Scott & White has the largest network of hospital-based cancer programs in Texas with 16 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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Our **COVID-19 Safe Care** measures are in place across our hospitals, surgery centers and clinics, in accordance with CDC guidance and recommendations by our clinical experts. Learn more at **BSWHealth.com/SafeCare**.

Cover photo: Samples being removed or placed into vapor phase liquid nitrogen storage. Samples could be frozen PBMC (peripheral blood mononuclear cells) or another cellular component from blood or a finished cellular product.

For more information, call **214.820.3535** or visit us at **BSWH.md/Oncology.**

FROM THE MEDICAL

DIRECTOR

An unmatched infrastructure for cancer care in North Texas

In this issue of Cancer Update, we explore the commitment Baylor Scott & White has to unsurpassed quality in cancer care. This commitment runs from clinical research to manufacturing enhanced immune cells on-site to cancer outpatient support and lodging to inpatient hospital care. This all takes place at one of the largest cancer treatment centers in the United States—Baylor Scott & White Sammons Cancer Center and Baylor Scott & White T. Boone Pickens Cancer Hospital. Much of the industry-leading progress we are making is rooted in robust research conducted by oncologists and scientists located on the Baylor University Medical Center campus in Dallas, TX.

For many years, my passion has been the rapidly emerging field of immuno-oncology, and while significant advances have been made over the last five to 10 years, we are just at the start of this exciting new era. Baylor Scott & White has 16 cancer centers throughout Texas (3rd largest network of Commission on Cancer accredited hospital-based cancer centers in the US). By linking all of these facilities, which span a geographical footprint stretching from Dallas to Fort Worth to Temple and down to Austin, we can make major cancer discoveries across a real-world population of Texans. We are instilling a common theme of “Caring for Every Patient and Learning from Every Patient.”

The big picture of cancer care at Baylor Dallas is breathtaking in terms of breadth, scope and dedicated resources. Few healthcare organizations can offer patients what we do, all on one centralized campus:

- The only dedicated cancer hospital in North Texas—Pickens Cancer Hospital—and one of the largest cancer outpatient centers in the nation—Baylor Scott & White Sammons Cancer Center.
- The Oncology Evaluation and Treatment Center, the only 24-hour urgent care service specifically for cancer patients in North Texas.
- Swim Across America Innovative Clinical Trials Center sponsoring an active roster of immunotherapy and other cancer-related studies and trials.
- The only good manufacturing practice (GMP) facility in North Texas aligned with a hospital system, which produces human cellular products for novel immunotherapy phase I and II clinical trials. Many of these trials are first-in-human studies and are not available anywhere else in the world. We are committed to a process of continual innovation as we seek to offer our patients the most novel and exciting next-generation treatments for cancer.
- The Gene and Jerry Jones American Cancer Society Hope Lodge (opening in 2021), a 40,000-square-foot facility with 50 private guest suites and a communal kitchen providing 16,000 nights of free lodging annually for cancer patients and their families.
- Patient Resource Center offering innovative programs specifically to help cancer patients deal with their disease and recovery. These include art therapy, music therapy, psycho-oncology programs, a chef-led cooking class to help regain weight and to learn how to prepare foods that are tolerable post-surgery or radiation, FitSteps® personalized exercise program to help patients regain muscle strength, and ReVital rehabilitation, which offers a one-stop shop of physical therapy, occupational therapy and speech therapy programs all under one roof.

Our cancer center has become a destination location in the United States for next-generation cellular immunotherapy clinical trials involving novel strategies investigating CAR-T, TCR and NK cells. Our plan is to link our GMP facility with the new Hope Lodge so patients who travel long distances for treatment can avail themselves of advanced care without having to worry about the costs of accommodations.

Additionally, we are creating the Texas Immuno-Oncology Biorepository so we can start to understand the evolving immune microenvironment of patients who are receiving FDA-approved immunotherapeutics. This will position us as the epicenter of cancer discoveries, allow us to identify resistance mechanisms that tumors use to overcome immune attack, and allow us to optimally design next-generation strategies to overcome this resistance.

While these multimillion-dollar investments in facilities, technologies and staff are critically important in order to deliver personalized cancer care, we never lose sight of the one reason we are in this fight—our patients. We don’t just focus on treating a patient’s cancer—we treat the whole individual with a special emphasis on the emotional, spiritual and psychological impact of his or her disease from diagnosis, through treatment and into survivorship.

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

BAYLOR SCOTT & WHITE SAMMONS CANCER CENTER

CURRENT CLINICAL TRIALS

Site	Study ID	Clinical Trial Number	Principal Investigator	Study Title
Breast	018-745	NCT04032080	Joyce A. O'Shaughnessy, MD	Pilot Clinical Trial of Treatment with Oral LY3023414 to Inhibit Homologous Recombination (HR) Followed by Prexasertib in Patients with Chemotherapy-Pretreated Metastatic Triple Negative Breast Cancer
	17026	NCT03056755	Joanne L. Blum, MD, PhD, FACP	BYLieve: A Phase II, Multicenter, Open-label, Three-cohort, Non- Comparative Study to Assess the Efficacy and Safety of Alpelisib Plus Fulvestrant or Letrozole in Patients With PIK3CA Mutant, Hormone Receptor (HR) Positive, HER2-negative Advanced Breast Cancer (aBC), Who Have Progressed on or After Prior Treatments
	17188	NCT03725059	Joyce A. O'Shaughnessy, MD	A Randomized, Double-Blind, Phase III Study of Pembrolizumab Versus Placebo in Combination With Neoadjuvant Chemotherapy and Adjuvant Endocrine Therapy for the Treatment of High-Risk Early-Stage Estrogen Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative (ER+/HER2-) Breast Cancer (KEYNOTE-756)
	18238	NCT03858972	Joyce A. O'Shaughnessy, MD	Multinational, Multicenter, Phase 2 Study of Tesetaxel Plus a Reduced Dose of Capecitabine in Patients With HER2 Negative, Hormone Receptor Positive, Locally Advanced or Metastatic Breast Cancer Who Have Not Previously Received a Taxane
	19009	NCT03952325	Joanne L. Blum, MD, PhD, FACP	A Multicenter, Phase 2 Study of Tesetaxel Plus 3 Different PD-(L)1 Inhibitors in Patients With Metastatic TNBC and Tesetaxel Monotherapy in Elderly Patients With HER2 Negative MBC
	19017	NCT03955939	Joanne L. Blum, MD, PhD, FACP	A Phase 1b Study of Aurora A Kinase Inhibitor LY3295668 Erbumine in Monotherapy and Combination Therapy in Patients With Metastatic Breast Cancer Post CDK4/6 Inhibitor and Endocrine Therapy
	19054	NCT03975647	Joyce A. O'Shaughnessy, MD	Randomized, Double-blind, Phase 3 Study of Tucatinib or Placebo in Combination With Ado-trastuzumab Emtansine (T-DM1) for Subjects With Unresectable Locally-advanced or Metastatic HER2+ Breast Cancer (HER2CLIMB-02)
	T01862	NCT03639948	Joyce A. O'Shaughnessy, MD	Neoadjuvant Phase II Study of Pembrolizumab And Carboplatin Plus Docetaxel in Triple Negative Breast Cancer
Chest	19024	NCT03600883	Kartik Konduri, MD	A Phase 1/2, Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 510 Monotherapy in Subjects With Advanced Solid Tumors With KRAS p.G12C Mutation and AMG 510 Combination Therapy in Subjects With Advanced NSCLC With KRAS p.G12C Mutation (CodeBreak 100)
GI	18261	NCT04008030	A. Scott Paulson, MD	A Phase 3b Randomized Clinical Trial of Nivolumab Alone, Nivolumab in Combination With Ipilimumab, or an Investigator's Choice Chemotherapy in Participants With Microsatellite Instability High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer
	19096	NCT04126733	A. Scott Paulson, MD	An Open-label, Single-arm, Phase II Study of Regorafenib and Nivolumab in Patients With Mismatch Repair-Proficient (pMMR)/Microsatellite Stable (MSS) Colorectal Cancer (CRC)
GU	19032	NCT03955913	Thomas E. Hutson, DO, PharmD	Biomarker Study to Identify Subjects With Advanced Urothelial Cancer and Fibroblast Growth Factor Receptor Gene Aberrations
	T01860	NCT03634540	Thomas E. Hutson, DO, PharmD	A Phase 2 Trial of PT2977 in Combination With Cabozantinib in Patients With Advanced Clear Cell Renal Cell Carcinoma

Site	Study ID	Clinical Trial Number	Principal Investigator	Study Title
GYN	17218	NCT03602859	Laura M. Divine, MD	ENGOT-0V44 The FIRST (First-line Ovarian Cancer Treatment With Niraparib Plus TSR-042) Study: A Randomized, Double-Blind, Phase 3 Comparison of Platinum-Based Therapy With TSR-042 and Niraparib Versus Standard of Care Platinum-Based Therapy as First-Line Treatment of Stage III or IV Nonmucinous Epithelial Ovarian Cancer
	19034	NCT03981796	Carolyn M. Matthews, MD	A Phase 3, Randomized, Double-blind, Multicenter Study of Dostarlimab (TSR-042) Plus Carboplatin-paclitaxel Versus Placebo Plus Carboplatin-paclitaxel in Patients With Recurrent or Primary Advanced Endometrial Cancer
Head and Neck	18182	NCT03689712	Eric S. Nadler, MD, MPP	ROMAN: Reduction in Oral Mucositis With Avasopasem Manganese (GC4419) - Phase 3 Trial in Patients Receiving Chemoradiotherapy for Locally-Advanced, Non-Metastatic Head and Neck Cancer
Hematologic Malignancies	018-069	NCT03570892	Houston Holmes, MD	Tisagenlecleucel Versus Standard of Care in Adult Patients With Relapsed or Refractory Aggressive B-cell Non-Hodgkin Lymphoma: A Randomized, Open Label, Phase III Trial (BELINDA)
	018-635	NCT03677154	Houston Holmes, MD	A Phase I/II Trial of Mosunetuzumab (BTCT4465A) as Consolidation Therapy in Patients With Diffuse Large B-Cell Lymphoma Following First-Line Immunochemotherapy and as Therapy in Patients With Previously Untreated Diffuse Large B-Cell Lymphoma Who Are Unable to Tolerate Full-Dose Chemotherapy
	018-651	NCT03682536	Andrew Whiteley, MD	A Phase 3, Open-label, Randomized Study to Compare the Efficacy and Safety of Luspatercept (ACE-536) Versus Epoetin Alpha for the Treatment of Anemia Due to IPSS-R Very Low, Low or Intermediate Risk Due to Myelodysplastic Syndrome (MDS) ESA in Native Subjects Who Require Red Blood Cell Transfusions
	018-741	NCT03269136	M. Yair Levy, MD	A Phase I, Open Label Study to Evaluate the Safety, Pharmacokinetic, Pharmacodynamic and Clinical Activity of PF-06863135, a B-Cell Maturation Antigen (BCMA)-CD3 Bispecific Antibody, in Patients with Relapsed/Refractory Advanced Multiple Myeloma (MM)
	019-029	NCT03504410	M. Yair Levy, MD	Phase III Multicenter Open-Label Randomized Trial to Evaluate Efficacy and Safety of CPI-613 in Combination with High Dose Cytarabine and Mitoxantrone (CHAM) Compared to High Dose Cytarabine and Mitoxantrone (HAM) in Older Patients (>60 years) with Relapsed/Refractory Acute Myeloid Leukemia (AML)
	019-030	NCT03394365	Luis Pineiro, MD	Multicenter, Open Label, Phase 3 Study of Tabelecleucel for Solid Organ or Allogeneic Hematopoietic Cell Transplant Subjects With Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disease After Failure of Rituximab or Rituximab and Chemotherapy
	019-046	NCT03624036	Houston Holmes, MD	A Phase 1/2 Multicenter Study Evaluating the Safety and Efficacy of KTE-X19 in Adult Subjects With Relapsed/Refractory Chronic Lymphocytic Leukemia
	019-055	NCT03392142	Luis Pineiro, MD	Multicenter, Open-Label, Phase 3 Study of Tabelecleucel for Allogeneic Hematopoietic Cell Transplant Subjects With Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disease After Failure of Rituximab
	019-088	NCT02180711	M. Yair Levy, MD	An Open-label, Phase 1b/2 Study of Acalabrutinib Alone or in Combination Therapy in Subjects With B-cell Non-Hodgkin Lymphoma
	019-137	NCT03651128	Houston Holmes, MD	A Phase 3, Multicenter, Randomized, Open-Label Study to Compare the Efficacy and Safety of b2121 Versus Daratumumab (DARA) in Combination with Pomalidomide (POM) and Low-dose Dexamethasone (dex) (DPd) in Subjects with Relapsed and Refractory Multiple Myeloma (RRMM)
	019-140	NCT03657160	Luis Pineiro, MD	A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Vedolizumab in the Prophylaxis of Intestinal Acute Graft Versus-Host Disease in Subjects Undergoing Allogeneic Hematopoietic Stem Cell Transplantation

Site	Study ID	Clinical Trial Number	Principal Investigator	Study Title
Hematologic Malignancies	019-157	NCT03331198	Houston Holmes, MD	An Open-Label, Phase 1/2 Study of JCAR017 in Subjects With Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (017004)
	019-177	NCT02718300	Houston Holmes, MD	A Phase 2 Study of the Safety, Tolerability, and Efficacy of INCB050465 in Combination With Ruxolitinib in Subjects With Myelofibrosis
	019-227	NCT03217838	M. Yair Levy, MD	A Phase I/II, Open-Label, Multicentre 2-Part Study to Assess the Safety, Tolerability, Pharmacokinetics, and Efficacy of AZD2811 Nanoparticle as Monotherapy or in Combination in Treatment–Naïve or Relapsed/Refractory Acute Myeloid Leukemia/Myelodysplastic Syndrome Patients Not Eligible for Intensive Induction Therapy
	019-230		Jana Reynolds, MD Askar Medhat, MD	Applying a novel, highly-multiplexed proteomics assay to predict alloimmunity (GvHD)
	019-256	NCT03786926	Micah Birch, MD	A Phase 1, Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of HMPL-689 in Patients With Relapsed or Refractory Lymphoma
	17212	NCT03424122	M. Yair Levy, MD	A Phase 1, Open-Label, Dose-Finding Study of INCB050465 in Combination With Investigator Choice of Rituximab, Bendamustine and Rituximab, or Ibrutinib in Participants With Previously Treated B-Cell Lymphoma (CITADEL-112)
	18028	NCT03593915	M. Yair Levy, MD	A Phase 1b/2, Open-label Clinical Study to Determine Preliminary Safety and Efficacy of Alvocidib When Administered in Sequence After Decitabine in Patients With MDS
	18263	NCT03206918	M. Yair Levy, MD	A Single-Arm, Open-Label, Multicenter Phase 2 Study to Evaluate Safety and Efficacy of BGB-3111, a Bruton's Tyrosine Kinase (BTK) Inhibitor in Relapsed or Refractory Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma (CLL/SLL)
	T01845	NCT03147742	Luis Pineiro, MD	An Open-Label, Expanded Access Program of Ruxolitinib for the Treatment of Graft-Versus-Host Disease Following Allogeneic Hematopoietic Stem Cell Transplant
Neuro-oncology	019-074	NCT03018288	Karen Fink, MD, PhD	A Randomized Double Blind Phase II Trial of Radiation Therapy Plus Temozolomide and Pembrolizumab With and Without HSPPC-96 in Newly Diagnosed Glioblastoma (GBM)
Neuro-endocrine	019-075	NCT04042714	A. Scott Paulson, MD	An Open-label, Phase II Investigation of TAS-102 in Patients with High Grade, Extra-pulmonary Neuroendocrine Carcinoma
Pancreas	17160	NCT03377491	Carlos H.R. Becerra, MD	Pivotal, Randomized, Open-label Study of Tumor Treating Fields (TTFields, 150kHz) Concomitant With Gemcitabine and Nab-paclitaxel for Front-line Treatment of Locally-advanced Pancreatic Adenocarcinoma
Solid Tumors	18027	NCT02729298	C. Lance Cowey, MD	A Phase 1a / 1b, First-in-human, Open-label, Dose-escalation, Safety, Pharmacokinetic, and Pharmacodynamic Study of Oral TP-0903 Administered Daily for 21 Days to Patients With Advanced Solid Tumors

Feature Article

CREATING LIVING DRUGS IN THE MOST EXPERIENCED cGMP CELL MANUFACTURING FACILITY IN NORTH TEXAS

Jennifer Finholt, MS

Cell therapy manufacturing at Baylor Dallas dates back to the late 1990s. At this time, cancer immunotherapy was in its infancy, and Baylor Dallas immunology researchers, including Karolina Palucka, MD, PhD; Joseph Fay, MD; and Jacques Banchereau, PhD, were exploring the potential for cellular vaccines in the fight against cancer. They were among the first scientists to begin studying the concept that dendritic cells, as master regulators of T cell responses, could be harnessed to overcome immunotolerance and kill tumor cells. This idea would grow into a burgeoning new therapeutic field. Today, there are a number of FDA-approved cellular anticancer therapies, including two CAR-T drugs and many more, being evaluated both in early- and late-stage clinical trials for a wide range of hematological and solid tumors.

Image: Samples being removed or placed into vapor phase liquid nitrogen storage. Samples could be frozen PBMC (peripheral blood mononuclear cells) or another cellular component from blood or a finished cellular product.

Left: GMP manufacturing process in a biosafety level II cabinet in full sterile gowning.
Right: Samples being incubated in a heated dry batch (metal beads instead of water).

This pioneering work at Baylor Dallas was done in collaboration with Ralph Steinman, PhD, of Rockefeller University, who would go on to win the Nobel Prize in 2011 for the discovery and functional characterization of dendritic cells. Given that resources for immunotherapy were limited, the investigators established an on-site laboratory for developing the dendritic cell vaccines for their early clinical trials. This laboratory would grow to become the Baylor Scott & White Research Institute (BSWRI) current good manufacturing practices (cGMP) cell manufacturing facility, a destination resource for research and development in cellular immunotherapies.

Their research focused on taking advantage of the fact that immature CD34+ dendritic cells are able to process and present antigens to the T cells. As described in their early work (*Cancer Research*, 2001), autologous CD34+ dendritic cell progenitors could be loaded ex vivo with melanoma antigens and delivered to patients with stage IV melanoma as a cellular vaccine. These dendritic cells would then prompt the patient's immune system to target the melanoma antigens as invaders. The preliminary results were promising for safety and efficacy, especially in patients with limited disease.

By 2005, a larger clinical trial was underway to deliver antigen-primed immature dendritic cells as a cellular vaccine to patients with advanced melanoma. Other cellular vaccine therapy studies quickly followed, including a study combining dendritic cells with conventional chemotherapy for patients with stage IV melanoma and a study using dendritic cells loaded with HIV lipopeptides to treat HIV patients. Promising preliminary results for HIV have fueled interest in developing refined therapeutic approaches.

Also in 2005, the BSWRI cGMP cell manufacturing facility moved into its current home, an 1,800-square-foot FDA-regulated facility featuring 560 square feet of clean room space and additional support space for gowning, storage and freezers. The facility was designed to prevent cross-contamination and maximize cellular product consistency. The staff has over 25 collective years of cellular product manufacturing experience. According to Jennifer Finholt, MS, manager of the BSWRI cGMP cell manufacturing facility, "The current facility was built so we would have the capacity to scale up and meet the needs of multiple concurrent clinical trials. We have gone from open processes to closed processes, which has improved efficiency while minimizing the risk of contamination."

GMP manufacturing step using a cell washer and concentrator with personnel in full sterile gowning.

Starting in 2013, a clinical trial using dendritic cell vaccines for patients with triple-negative and ER+/HER2- breast cancer was established. This phase I/II trial, led by Joyce O'Shaughnessy, MD, assessed the safety and preliminary efficacy of a dendritic cell vaccine in combination with chemotherapy and surgery. Other recent trials include further development of dendritic cell vaccines for melanoma and a phase I trial evaluating dendritic cell vaccines in pancreatic cancer. In the last few years, over 200 patients have been treated with cellular vaccines generated by the BSWRI cGMP cell manufacturing facility.

Many phase I trials that rely on the resources provided by the BSWRI cGMP cell manufacturing facility are coordinated by the Swim Across America Innovative Clinical Trials Center (SAA-ICTC), a dedicated facility for early-stage clinical research at Baylor Scott & White Sammons Cancer Center. The SAA-ICTC provides an integrated hub for patients to receive evaluation, treatment, laboratory tests and follow-up at a single site.

According to Gerard Zurawski, PhD, scientific director of the BSWRI cGMP cell manufacturing facility, "This is an exciting time in cell therapy. As we have seen with chimeric antigen receptor (CAR)-T cell therapy, the patients can have a very high response rate. Many variations on cellular therapies are in the works."

An in-house cell therapy manufacturing facility allows investigators to easily translate their preclinical research into phase I human trials. Furthermore, the robust manufacturing processes can support more advanced trials. The immune monitoring infrastructure at BSWRI, including the Flow Cytometry Core, Genomics Core and Luminex/Biotechnology Core, can offer additional in-house support services that are necessary for immunotherapy development and scale-up. The facility also offers regulatory support for the FDA investigational new drug (IND) process.

The BSWRI cGMP cell manufacturing facility boasts three class 10,000 (ISO 7) clean rooms in a restricted access facility. The clean rooms contain incubators, class 100 biological safety cabinets, centrifuges and elutriators. Sterile tube welders, an automated cell separator and an automated membrane filtration system are available for all projects, as are a variety of freezers (controlled rate -30°C, -80°C and liquid nitrogen). An automated Rees system provides environmental and equipment control monitoring.

According to Jaime Walkowiak, JD, senior vice president of research and chief operating officer of BSWRI, "The BSWRI cGMP cellular manufacturing facility has played a critical role in the development of immunotherapies for over two decades. It is now poised to meet the challenges of the complex array of new cellular therapies entering the clinical trials pipeline."

The BSWRI cGMP cellular manufacturing facility is able to manufacture autologous and allogeneic cellular therapies and vaccines, including dendritic cells and natural killer cells. Transgenic cells, such as CAR-T cells, can be generated in collaboration with a vector production resource.

Current studies supported by the BSWRI cGMP cell manufacturing facility include a multicenter trial whereby ex vivo-activated natural killer cells are harnessed to target solid tumors. According to Jaime Walkowiak, "This cGMP cell manufacturing facility offers a depth of experience that is unlike other research institutions in North Texas. We are ready to support the growing need for cellular therapeutics throughout the region and nationwide."

Left: GMP manufacturing step, looking at the cells under a microscope with personnel in full sterile gowning.
Right: Two quality control technicians working in a biosafety level II cabinet. Setting up a QC assay to test a cellular product manufactured in the GMP.

Pictured (Carlos Becerra, MD, and Ronan Kelly, MD, MBA). Many Phase I trials that rely on the resources provided by the BSWRI cGMP cell manufacturing facility are coordinated by the SAA-ICTC, a dedicated facility for early-stage clinical research at the Baylor Scott & White Sammons Cancer Center.

BAYLOR DALLAS: A DESTINATION CENTER FOR CELLULAR THERAPIES

Carlos Becerra, MD

Yair Levy, MD

Baylor Scott & White Sammons Cancer Center is at the forefront of cellular therapies for hematological malignancies. It was the first center in North Texas to offer Yescarta (axicabtagene ciloleucel), an FDA-approved CAR-T cell therapy. Yescarta was approved in 2017 as a second-line therapy for adult patients with diffuse large B-cell lymphoma and acute lymphoblastic leukemia. Kymriah (tisagenlecleucel), the only other FDA-approved CAR-T cell therapy for these hematologic malignancies, is also offered at Baylor Dallas. Kymriah is used to treat B-cell acute lymphoblastic leukemia. For CAR-T therapies, the patient's own T cells are removed, genetically engineered with modified T-cell receptors that target cancer cells, and then returned to the patient. According to M. Yair Levy, MD, medical director of hematology malignancy clinical research at Baylor Dallas, "In addition to being the first in North Texas to treat patients with CAR-T cells, we continue to lead the way with access to standard-of-care CAR-T therapies and a multitude of clinical trials for hematologic cancers and solid tumors. We have performed far more CAR-T treatments than our competitors combined."

The overwhelming success of CAR-T cells has generated enthusiasm for other cellular therapeutics in the development pipeline. A recent phase I trial represents a collaboration between the BSWRI cGMP cell manufacturing facility and the SAA-ICTC at Baylor Dallas. For this study, they are harnessing the power of natural killer (NK) cells, cytotoxic lymphocytes of the innate immune system, as cellular therapeutics to target solid tumors. According to Carlos Becerra, MD, medical director of the SAA-ICTC and an investigator on the study, "The whole idea is that NK cells normally recognize cancer and control it through immune surveillance. However, during cancer, this immune surveillance is disrupted." Their approach involves stimulating allogeneic NK cells from a family member ex vivo and delivering these cells to the patient to target solid tumors. This multicenter trial, in collaboration with FATE Therapeutics, is ongoing.

Another study underway includes a novel approach for delivering CAR-T cells. For this study, the researchers are using a universal, engineered cell therapy called antibody-coupled T cell receptor (ACTR) in combination with a tumor-specific antibody raised against human epidermal growth factor receptor 2 (HER2). This antibody directs the ACTR cell to the HER2-positive tumors. So, rather than creating a new CAR-T cell for each target, the same cellular therapy (ACTR) could be used in combination with multiple antibodies. Such an approach could permit each CAR-T cell product to have a broader ability to fight multiple cancers. Baylor Dallas is one of five sites in the US conducting this trial.

The unmatched clinical research infrastructure at Baylor Dallas contributes to the success of these trials. The SAA-ICTC has coordinated the clinical expertise and research infrastructure in one place; the BSWRI GMP cell manufacturing facility produces the therapies on-site; the soon to open facilities at the Gene and Jerry Jones American Cancer Society Hope Lodge will allow patients traveling from afar to stay free of charge for a prolonged period of time; and Pickens Cancer Hospital, which is the only dedicated cancer hospital in North Texas, provides an environment where the multistep clinical evaluations and procedures can all be done in a comforting, family-friendly environment.

Commenting on the promise for cellular therapies, Dr. Becerra mentioned, "It is an exciting time for immunotherapy. We now have multiple tools for provoking the immune system to control cancer. In the end, it is probably going to be a combination of things, the T cells, the NK cells, and macrophages and so on working in concert to be able to control the cancer." Baylor Dallas is well-positioned to continue to play a prominent national and international role in this exciting era, and we are proud to be able to offer our patients advanced novel therapeutics that are not available elsewhere.

Baylor University Medical Center's Baylor Scott & White Sammons Cancer Center and Pickens Cancer Hospital represent one of the largest cancer treatment centers in Texas.

DENDRITIC CELL VACCINES IN THE DEVELOPMENT PIPELINE

Gerard Zurawski, PhD

For over two decades, Baylor Dallas has been recognized as a research leader in dendritic cell immunotherapies. In addition to developing cellular therapies through the BSWRI cGMP cell manufacturing facility, research teams at Baylor Dallas are tackling the challenge of dendritic cell immunotherapy from multiple angles.

Gerard Zurawski, PhD, director of the Baylor Institute for Immunology Research and medical director of the BSWRI cGMP cell manufacturing facility, is developing an antibody-based approach to stimulate dendritic cells. His research takes advantage of the fact that immature dendritic cells, which are resident within the patient's tissues, can be provoked to take up, process and present antigens that are delivered as therapeutic agents. These stimulated dendritic cells can then provoke an immune response "on cue."

According to Dr. Zurawski, "The dendritic cell vaccines boost the patient's own cytotoxic T cell responses against cancer and infectious diseases. We have multiple therapies that are successful in preclinical tests and are ready for clinical trials."

One of their therapies targets human papillomavirus (HPV), a growing public health threat that causes approximately 34,000 new cases of cancer each year. For this work, they have used the knowledge that CD40 is a dendritic cell surface receptor that serves as a gateway for antigen uptake. By tethering an antibody against CD40 with a "payload" of HPV proteins E6 and E7, they can force the dendritic cells to process and present HPV-specific antigens. The dendritic cells then activate cytotoxic T cells and direct a targeted HPV-specific immune response.

Ronan Kelly, MD, MBA, medical director of the Baylor Scott & White Sammons Cancer Center, noted, "Baylor Dallas has been home to many immunotherapy trials over the last three decades and has become a destination location nationally and internationally for cutting edge immunotherapy trials. We will continue to push the envelope as we seek to offer our patients the chance of long-term control if not cure by engaging their own immune system to wage a war on their cancer cells at the microscopic level."

Fans of the Dallas Cowboys shared what "Cancer Hates Us" meant to them by personalizing the statement "Cancer hates me because."

TEAMING UP AGAINST CANCER

This year during the 2019/2020 National Football League season, Baylor Scott & White and The Dallas Cowboys organization teamed up in the fight against cancer. With the support of Dak Prescott, quarterback for the Cowboys, and the Cowboys organization, we spoke directly to fans to show our strength and encourage them to do the same.

Throughout the season, Baylor Scott & White engaged fans during the pre-game at AT&T Stadium. Our "Cancer Hates Us" events gave Cowboys fans the chance to create their own personal statement explaining why they're also on our team in the fight against cancer. This collaboration also gave fans the opportunity to learn more about our comprehensive cancer care services and our strength in immunotherapy treatment.

Baylor Scott & White, The Dallas Cowboys and Dak Prescott also created a series of videos, which were shared to millions of fans on social media, telling the story of why we're teaming up in this important fight: "Cancer Hates Teamwork," and we wouldn't have it any other way. Throughout the "Cancer Hates Us" collaboration with the Cowboys, Baylor Scott & White heard some powerful comments from like-minded fighting fans:

> Cancer hates me because it couldn't take me out.
>
> We all gotta continue the fight.
>
> I'm a three-time cancer survivor. I'm stronger because of it.
>
> I really appreciate you guys. I really loved my sister's doctor because he took the time out to explain all the fancy jargon to our family so we would understand.

GROUNDBREAKING HELD FOR GENE AND JERRY JONES FAMILY HOPE LODGE

On May 7, 2019, Baylor Scott & White and the American Cancer Society (ACS) held a groundbreaking ceremony and major gift announcement for a Hope Lodge facility in Dallas. Located on property donated by Baylor Scott & White, adjacent to the Baylor University Medical Center campus, the 40,000-square-foot facility will provide more than 16,000 nights of free lodging annually for cancer patients and their families once it opens its doors in 2021.

In recognition of their lead gift, the facility will be named the Gene and Jerry Jones Family Hope Lodge. It will offer cancer patients and their caregivers a comfortable home away from home when they have to travel to receive care from any of North Texas' premier medical centers.

Image: The outdoor garden at Gene and Jerry Jones Family Hope Lodge will be a place for cancer patients and families to dine and relax.

Leaders at Baylor Scott & White and American Cancer Society celebrate the groundbreaking of the Hope Lodge with Gene and Jerry Jones. Pictured left to right: Rowland K. Robinson, Jim Hinton, Jerry Jones, Gene Jones, Jim Turner, Gary Reedy and Jeff Fehlis

"Through their decades of business and community investments, the Jones family has had a far-reaching impact in North Texas. Their support of Hope Lodge in Dallas will extend that reach and make a difference in the lives of those traveling to the region for their cancer care," said Rowland K. Robinson, president of Baylor Scott & White Dallas Foundation. "Together with ACS and with the support of all our generous donors, Hope Lodge will soon be a reality for North Texas, and we are so grateful."

The capital campaign for the facility has surpassed its original goal and has raised nearly $32 million to date. In addition to the Jones family, other major donors included the Don and Trudy Steen Charitable Foundation, Carmen and Jeff York, the Moody Foundation, the Horner family, the Mabee Foundation, and the Shapard family.

"This project, the first of its kind in North Texas, is a natural extension of our mission and deep commitment to patients," said Jim Hinton, CEO, Baylor Scott & White Health. "The Gene and Jerry Jones Family Hope Lodge will be a haven for healing on patients' journeys; its impact will be exponential, as it will not only help those fighting cancer but those fighting alongside them.

For the thousands of cancer patients and their families who travel to North Texas each year for their care, the trip often means days, weeks or even months away from home. The combined emotional and financial toll of medical bills, hotel rooms and dining out can be staggering.

The Gene and Jerry Jones Family Hope Lodge will include 50 private guest suites, each with two beds and a private bathroom. In addition, the facility will feature common living areas, a dining room, laundry facilities, library, meditation room and outdoor garden. The American Cancer Society's South Region headquarters also will be housed at this location in an adjacent facility.

"The American Cancer Society is committed to removing the emotional, physical and financial burdens that many cancer patients must face when they travel away from home for treatment," said Jeff Fehlis, executive vice president for the American Cancer Society's South Region. "Thanks to the generosity of partners and individuals who have stepped up to help with this project, we will soon be able to provide a home away from home for these patients, allowing them to focus on what's important–getting well."

BAYLOR DALLAS: AN UNMATCHED INFRASTRUCTURE FOR CANCER CARE IN NORTH TEXAS

Ronan Kelly, MD, MBA

Allison Steen, MSN, RN, OCN, NE-BC

The Baylor Scott & White commitment to unsurpassed quality in cancer care runs the full range from clinical research to manufacturing enhanced immune cells on-site to cancer outpatient support and lodging to inpatient hospital care. According to Ronan Kelly, MD, MBA, medical director of the Baylor Scott & White Sammons Cancer Center, “There is nowhere else in North Texas that has all of the components for cancer care on one campus. We have the only 24-hour urgent care that is exclusive for cancer patients, we have the only dedicated inpatient cancer hospital, and we have the first American Cancer Society Hope Lodge in North Texas. We also have the only cGMP manufacturing facility attached to a hospital system in North Texas. These firsts make us a destination center for cancer care.”

Excellence in coordinated cancer care is obvious across the patient journey. According to Allison Steen, MSN, RN, OCN, NE-BC, the director of nursing-oncology at Baylor Dallas, “We pride ourselves on a multidisciplinary approach to delivering top-quality care in a welcoming family-oriented environment.” Patients and their families can stay in one of the four inpatient units, totaling 100 beds, and receive multiple treatments, including transplant, in the same comforting environment. Accommodations for family members include large, private rooms with televisions and large bathrooms that allow access for a patient and caregiver. This patient-centered approach is backed up by a top-quality staff of dedicated oncology-trained nurses, specialized support staff and teams of expert physicians in a variety of specialties. Allison Steen also commented, “We are always looking for ways to improve the patient journey, and we take pride in empowering our nurses and all of our staff to take on quality improvement projects. We are not OK with the status quo.”

Opened in 2012, the Baylor Scott & White T. Boone Pickens Cancer Hospital, a 175,000-square-foot facility, was the first and remains the only dedicated cancer hospital in North Texas. It complements the 467,000-square-foot outpatient cancer facility, which opened in 2011.

Resources at the Baylor Scott & White T. Boone Pickens Cancer Hospital

The following resources are available on the first floor of the Pickens Cancer Hospital, allowing patients to receive unparalleled care in one centralized location:

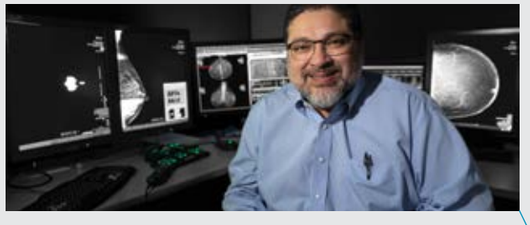
- **Apheresis.** The apheresis center is located on the first floor of Pickens Cancer Hospital. This outpatient area can accommodate up to eight simultaneous procedures, including cellular therapy collection, plasma exchange, red blood cell exchange and photophoresis.
- **Infusion.** The infusion department provides a variety of supportive therapies for both research and treatment, including chemotherapy and blood transfusion. Individual recliner chairs and televisions, as well as ample seating space, are available to maximize comfort.
- **Oncology Evaluation and Treatment Center.** This after-hours resource (Monday - Friday, 7:00 PM – 7:00 AM, and 24 hours on weekends) is available for oncology patients with urgent but non-life-threatening needs, including complications related to the cancer or treatments. The goal of this resource is to allow patients to bypass long wait times in typical emergency rooms and permit the patients to have their urgent needs met by oncology-trained personnel.

According to Shawnette Graham, MSN, RN, OCN, “Both the apheresis and infusion services can take orders from any licensed provider in Texas. In collaboration with the pharmacy team, these centers can obtain therapeutics and preauthorizations for treatments. This collaborative arrangement allows the Baylor Scott & White network to provide unparalleled oncology care to the North Texas region.”

The Patient Resource Center at the Sammons Cancer Center

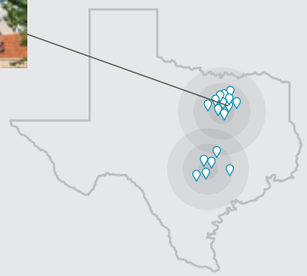
Since 1980, the Virginia R. Cvetko Patient Resource Center has served as a nexus for patient education and psychosocial support activities. The Patient Resource Center is home to 15 active support groups, as well as the Arts in Medicine program, the Behavioral Health Oncology consultancy and a genetic counseling program. According to Susan Sayles, MS, RN, OCN, manager of the Patient Resource Center, “We deal in a healing modality that has nothing to do with medicine but everything to do with healing the human spirit.”

This year, two new support groups were added: one for patients undergoing ostomy and another for those with inflammatory breast cancer. Because inflammatory breast cancer presents with atypical symptoms, diagnosis is often late, and the patients have support needs that differ from those of typical breast cancer patients. Susan Sayles noted that these changes are part of a larger vision to “identify and meet the current needs of our ever-changing patient population.”



The High-Risk Breast Screening Program combines current knowledge about your breast health—screening mammogram, breast self-exam and more—with an in-depth look at your personal health history and that of your family.

Texas Center for Proton Therapy



Baylor Scott & White has the largest network of hospital-based cancer programs in Texas with 16 cancer centers and the third largest network of cancer centers accredited by the Commission on Cancer in the US.

Baylor University Medical Center's Baylor Scott & White Sammons Cancer Center and Pickens Cancer Hospital represent one of the largest cancer treatment centers in Texas.

Our multidisciplinary teams across six Cancer Research and Treatment Centers thoroughly discuss treatment options and offer recommendations using clinical trials, medical therapies, minimally invasive treatment, surgery or advanced techniques.

Baylor Scott & White good manufacturing practice (GMP) lab for immune therapy is the most experienced GMP in North Texas manufacturing and delivering living drugs directly to the patients on our campus.

Patient-centered cancer services

Baylor University Medical Center's comprehensive cancer services treat the whole patient, making us a destination center for cancer care.

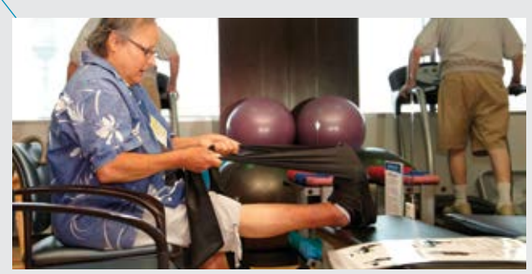
The Oncology Evaluation and Treatment Center is the only specialized urgent care/emergency after-hours facility specifically for cancer patients in Dallas-Fort Worth.

Patients can have a short-term stay at the Gene and Jerry Jones Family Hope Lodge before or after treatment. The lodge will open in 2021 on the campus of Baylor University Medical Center.

Baylor University Medical Center and Texas Oncology are the first programs in North Texas to offer adult commercial use of chimeric antigen receptor T-cell therapy, or CAR-T, to treat patients with large B-cell lymphoma and acute lymphoblastic leukemia.

Our multidisciplinary team includes certified genetic counselors who help patients review and understand family history that could contribute to their cancer risk. We also provide behavior psychology for patients and families, including children of cancer patients.

Baylor University Medical Center is known for its holistic approach to healing—offering psychological support, dedicated patient navigators, personalized rehabilitation programs to recover from cancer treatments, dietary counseling and healthy eating/food preparation classes, caregiver consultations, and arts and music therapy.



Through the FitSteps for Life® and ReVital programs, cancer patients at Baylor Dallas regain strength during and after cancer treatment.

PHILANTHROPY

Swim Across America: supporting groundbreaking phase I research

Over the last 32 years, Swim Across America has raised over $80 million in cancer research funds through a series of annual swimming events. On September 14, 2019, Swim Across America - Dallas held its ninth annual open water swim at Lake Ray Hubbard. This exhilarating event attracted over 350 swimmers, a record number. In addition to swimmers from Baylor Scott & White and other individuals, college teams from the University of North Texas, Texas Christian University and Southern Methodist University took to the water to support cancer research in Dallas. Swimmers could choose to swim a half mile, 1 mile or 2 miles and could raise money individually or as a group.

This year's open water swim raised more than $270,000, for a total of $2.75 million since 2011. According to Susan Sayles, MS, RN, OCN, manager of the Baylor Scott & White Sammons Cancer Center Patient Resource Center, patient advocate and cancer survivor, "Every bit of the money that is raised, aside from the cost of covering the event, comes back to Baylor Scott & White to support our phase I clinical trials." The SAA-ICTC, a dedicated phase I clinical research facility at Sammons Cancer Center, is one of nine named Swim Across America research laboratories. According to Carlos Becerra, MD, medical director of the SAA-ICTC, "The support from Swim Across America has allowed us to concentrate multidisciplinary expertise in one location, giving us the resources to develop complicated cancer therapies that are only possible at a few specialized centers in the country."

This year's open water swim raised more than $270,000, for a total of $2.75 million since 2011.

Celebrating Women Luncheon turns 20 with keynote speaker Kristin Chenoweth

The annual Baylor Scott & White Dallas Foundation's Celebrating Women Luncheon marked a milestone in 2019, celebrating its 20th anniversary year of raising money to support Baylor Scott & White's fight against breast cancer in North Texas. Tom Thumb and Albertsons served as presenting sponsor for the 15th consecutive year.

Highlighting the luncheon were remarks from featured speaker, Kristin Chenoweth, Emmy and Tony award-winning actress and singer. Chenoweth says one of the most important uses of her celebrity voice is to support causes that are close to her heart, including the fight against breast cancer. Not only has she lost a loved one to the disease, she's also been there as others close to her battled, including her mom, a two-time breast cancer survivor.

> I can tell you, from personal experience, show business is amazing, but it ain't everything. I believe this is what matters.
>
> **Kristin Chenoweth**
> Emmy and Tony award-winning actress and singer

Since the first Celebrating Women event in 1999, more than $35 million has been raised. The 20th annual luncheon was held on October 11 at the Hilton Anatole and focused on the impact made in the lives of women and families fighting breast cancer in our community.

"We launched Celebrating Women 20 years ago because we believed there was a better answer for women fighting breast cancer," said Baylor Scott & White Dallas Foundation president, Rowland K. Robinson. "Thanks to the generous support we have received from more than 12,000 donors over the last two decades, we have seen progress made in the way we are able to diagnose, treat and care for patients. However, we know the fight isn't over and remain committed to improving the lives of those battling this disease now and in the future."

June through November 2019

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