Precision Medicine for the Systemic Treatment of Cancer: New Developments at Baylor Dallas

The History of Systemic Treatment: Moving Toward Rational Design
The modern era of systemic treatment for cancer began during World War II with the accidental discovery that soldiers who were exposed to nitrogen mustard experienced profound lymphoid and myeloid suppression. This suggested that patients with lymphoma might respond favorably to treatment with a derivative of nitrogen mustard, a hypothesis that was validated by Alfred Gilman and associates at Yale. This represented the first indication that cancer could be successfully treated with a systemic pharmacologic agent. Shortly after World War II, Sidney Farber at Harvard Medical School discovered that folic acid, a vitamin necessary for DNA replication, stimulated the proliferation of acute lymphoblastic leukemia cells and that analogues antagonistic to folic acid would block this action. This discovery is widely credited as the first example of rational design of a chemotherapeutic agent for cancer. Nonetheless, it should be noted that, at the time Farber made this discovery, the significance of DNA had yet to be defined.

(Continued on page 3)
We Take It Personally—Precisely

In this issue of CancerUpdate, we talk about two of the growing trends in oncology. The first is high tech, the second is high touch. At least one of the terms used to describe them may be confusing. When we talk about personalized medicine from the technologic standpoint, we are talking about targeted therapy. We use this term to describe treatments that are determined by understanding the molecular nature of a defect in a tumor and then using an agent that exploits that defect. The lead article in this issue gives a brief history of systemic therapy and the evolution of this developing field. Also described are studies being conducted at Baylor Charles A. Sammons Cancer Center at Dallas directed against some of the most aggressive and fatal cancers, pancreatic carcinoma and malignant melanoma.

We also use the term “personalized” when we describe a patient-centric approach. We deal with the whole patient and his or her family, addressing their needs before, during, and after treatment. Nothing exemplifies this more than our patient navigation program. We have discussed aspects of this program in previous issues, and in this volume we focus on the intersection of navigation and clinical trials (page 11).

To differentiate between these two personalized approaches, we prefer to use the term precision medicine when we refer to targeted therapy. More treatment options using this approach are becoming available every day at our center. The addition of Yong-Jun Liu, MD, PhD to our team (page 6) will help us further expand these opportunities, especially in the area of immune-based therapies.

We do take it personally, and to that end Carlos Becerra, MD, Al Mollabashy, MD, several members of the cancer center team, and I joined hundreds of others in the Swim Across America event to raise funds for our Innovative Clinical Trials Center (page 7). I want to again thank the Olympians, volunteers, participants, and donors who helped make this a great success.
Our understanding of the biology of neoplasia grew rapidly during the last half of the 20th century; this increased knowledge was reflected in the design of new drugs with a variety of different mechanisms of action, including vinca alkaloids, camptothecins, platinum-based agents, nitrosoureas, anthracyclines, and taxanes. While the use of these drugs, alone or in combination, led to significantly improved outcomes for many types of cancer, there were drawbacks. The use of powerful cytotoxic poisons to kill cancer cells also resulted in profound adverse effects for many patients who received them. Not all patients responded to these treatments, and of those who did, many became resistant. In addition, standard treatment recommendations based on cancer type ignored the diversity of the disease as it manifested in individual patients, so that many patients with nonaggressive, slow-growing cancers were substantially overtreated.

An explosion of new technological developments from 1975 to 2000 transformed the playing field, enabling researchers to begin to unravel the mysteries of cancer at the molecular level. The late 1970s saw the development of methods to produce monoclonal antibodies and the development of rapid DNA sequencing technology. Polymerase chain reaction technology was introduced in the early 1980s, and the Human Genome Project was begun in 1990. In oncology research, this new technology allowed the introduction of the first rationally designed targeted therapies, with the approval of the monoclonal antibodies rituximab for B-cell lymphomas in 1997 and trastuzumab for the treatment of HER2-positive breast cancer in 1998, along with the tyrosine-kinase inhibitor imatinib for the treatment of chronic myelogenous leukemia in 2001.

The promise of these targeted agents is to effectively treat specific tumors in specific patients, while avoiding the serious adverse effects associated with traditional chemotherapy. As we learn more about the intricate pathways associated with tumorigenesis, more potential targets for precision medicine are being revealed. At Baylor University Medical Center at Dallas, numerous researchers are investigating innovative targeted therapies for the treatment of a wide selection of cancers. For two diseases, pancreatic cancer and melanoma, traditional chemotherapy has resulted in only limited benefit, so the promise of targeted treatment is especially tantalizing.

**Pancreatic Cancer**

Ductal adenocarcinoma of the pancreas is the fourth most common cause of cancer-related death in the United States. For the more than 43,000 people diagnosed with pancreatic cancer each year, the average 5-year relative survival rate is only 6%. More than 50% of patients will have metastatic disease at the time of diagnosis, with an average life expectancy of 3 to 6 months. Even with the increased availability of potent chemotherapeutic agents, the survival rate has not improved substantially for almost 40 years. There is a critical need for more effective treatments for patients who develop this deadly disease.

Carlos Becerra, MD, medical oncologist with Texas Oncology and a physician on the medical staff at Baylor Dallas, is currently participating in the phase II portion of the IPI-926-03 trial (USON# 10004) at Baylor Research Institute (BRI). IPI-926 is an inhibitor of the hedgehog pathway. The trial is designed to test if IPI-926 in combination with gemcitabine may improve therapeutic outcomes in patients with pancreatic cancer. The phase II portion of the IPI-926-03 trial is a randomized, double-blind, placebo-controlled study with no cross-over option. Patients with previously untreated metastatic pancreatic cancer will be randomized to receive either IPI-926 plus gemcitabine or placebo plus gemcitabine. The primary outcome measures of this trial are overall survival and safety.

In addition to his participation in clinical trials, Dr. Becerra has been designated as the medical director of the new Innovative Clinical Trials Center at Baylor Sammons Cancer Center. This center, which will consolidate all phase I trials for Baylor researchers and their collaborators in one facility, will reflect Dr. Becerra’s core belief about clinical trials: “This is the only road to a cure for cancer.”

**Melanoma**

Although melanoma is not the most common type of skin cancer, it is the most deadly, accounting for 75% of skin cancer deaths. The outcome of melanoma depends on the stage at presentation. For patients who present with localized disease and primary tumors 1 mm or less in thickness, the 5-year survival rate is more than 90%, but this drops to around 65% if regional lymph nodes are involved, and less than 10% in patients with distant metastases. A variety of agents are used for the treatment of metastatic melanoma, including dacarbazine, high-dose interleukin-2, temozolomide, and paclitaxel, as well as various chemotherapy/biochemotherapy combination regimens. There has been no
consensus around any of these treatment options, reflecting their low level of activity in the metastatic setting. The targeted T cell antibody ipilimumab, which helps to sustain an active immune response from cytotoxic T cells, is the first agent ever shown to improve survival in patients with advanced melanoma. However, it carries the potential for significant immune-related complications.

Two precision medicine approaches for the treatment of advanced melanoma are being actively investigated at Baylor Dallas: the development of dendritic cell vaccines against melanoma, and the use of targeted therapy against melanoma-specific gene mutations.

As highlighted in the summer 2010 issue of Cancer Update, researchers at Baylor Institute for Immunology Research have been working for over 10 years on dendritic cell vaccines that target melanoma. Most studies have focused on the ex vivo generation and antigen loading of dendritic cells. A retrospective analysis of patients with advanced/metastatic melanoma treated with dendritic cell vaccines between 1999 and 2003 showed a 20% long-term survival, a promising result that needs to be confirmed in prospective randomized trials. The dendritic cell vaccines appear to be extremely safe, with mild, flu-like symptoms as the most common side effect.

According to Charles Lance Cowey, MD, a medical oncologist with Texas Oncology and a physician on the medical staff at Baylor Dallas, numerous clinical trials ongoing at BRI are investigating the efficacy of drugs that target specific genetic mutations in melanoma. Dr. Cowey and colleagues are participating in:

- The TEAM trial (Tasigna Efficacy in Advanced Melanoma), an international phase III trial comparing nilotinib with dacarbazine for the treatment of metastatic and/or inoperable melanoma harboring a c-Kit mutation (T01008).

- Two clinical trials (T01010 and T01014) investigating various aspects of the B-Raf inhibitor, PLX4032. Activating mutations of the BRAF gene have been observed in a variety of cancers, including 55–68% of malignant melanomas. In general, oncogenic mutations of BRAF correlate with a poor outcome.

- Two phase II clinical trials investigating the efficacy of E7080: (1) in combination with dacarbazine versus dacarbazine alone as first line therapy in patients with stage IV melanoma (USON 09191); and (2) as second-line treatment for patients with advanced melanoma who have been unsuccessfully treated with chemotherapy or a B-Raf inhibitor (USON 09194).

Dr. Cowey is hopeful about the prospect of improving outcomes in patients with advanced melanoma: “Until recently, melanoma has been a devastating disease with limited treatment options. With the approval of ipilimumab and the upcoming B-Raf inhibitor, PLX 4032, targeted treatments are beginning to change the landscape of therapeutics for this disease. The ongoing identification of important genetic features of various types of melanoma, such as B-Raf and c-Kit mutations, is opening doors for an influx of individualized treatments that have maximal efficacy and minimal toxicity.”

Cancer research studies on the Baylor Dallas campus are conducted through Baylor Research Institute, Texas Oncology, and US Oncology. Each reviews, approves, and conducts clinical trials independently.
News Briefs

**New App for Baylor Sammons Cancer Center.** The BCC Tour app offers viewing of the facility's artwork collection. Patients and families can also learn about Leadership in Energy and Environmental Design (LEED) building information, and keep connected with event and contact information. Users may view the facility art collection and educational information during their visit. They may also check out a complimentary iPod Touch® or iPad® at the Concierge Desk located on the first floor to tour the facility. The tour includes more than 35 points of interests, including Lovie’s Healing Garden, a monumental glass installation by artist Jim Bowman, local photography by Dallas artists, Dr. Marvin J. Stone’s microscope collection, the Horner Family Chapel, and much more. The BCC Tour is an innovative design by Healthcare Art Consulting LLC and is generously funded by Duke Realty.

**BIIR Selected as Member Site for National Network.** Karolina Palucka, MD, PhD, researcher at Baylor Institute for Immunology Research (BIIR), has announced that BIIR has been selected as a member site in the Cancer Immunotherapy Trials Network (CITN). The CITN was formed to bring together leading investigators in cancer immunotherapy to design and implement phase 1 and 2 immunotherapy trials to test novel agents and modalities. Trials will incorporate high-quality centralized immune-monitoring services, along with biomarker assessment and correlation studies using patient samples. As a member site, BIIR will undertake new trials through the Innovative Clinical Trials Center at Baylor Sammons Cancer Center. The CITN is sponsored by the National Cancer Institute and reflects its growing support for the field of cancer immunotherapy.

Upcoming Meetings of Interest to Oncologists

**Breast Cancer Symposium**  
September 8–11, 2011  
San Francisco Marriott Marquis  
San Francisco, California  
www.breastcasymposium.org/

**American Society for Radiation Oncology**  
October 2–6, 2011  
Miami Beach Convention Center  
Miami Beach, Florida  
www.astro.org/Meetings/

**Southwest Oncology Group Meeting**  
October 12–15, 2011  
Hyatt Regency Chicago  
Chicago, Illinois  
www.swog.org/visitors/gpmeeting.asp

**San Antonio Breast Cancer Symposium**  
December 6–10, 2011  
Henry B. Gonzalez Convention Center  
San Antonio, Texas  
www.sabcs.org/

**American Society of Hematology Annual Meeting and Exposition**  
December 10–13, 2011  
(Abstract submission Web site open until August 11)  
San Diego Convention Center  
San Diego, California  
www.hematology.org/Meetings/Annual-Meeting/

**North Texas Multidisciplinary Lung Cancer Symposium**  
October 1, 2011  
Baylor Sammons Cancer Center  
Dallas, Texas  
www.crmbaylor.org  
(See back cover for details)
International Star in Immunology Will Head BIIR

Yong-Jun Liu, MD, PhD, an internationally known expert in cancer immunology, joins Baylor Research Institute (BRI) as vice president and chief science officer and serves as the new director of Baylor Institute for Immunology Research (BIIR). Dr. Liu has been with the University of Texas M. D. Anderson Cancer Center since 2002, where he was professor and chair of the Department of Immunology, director of the Center for Cancer Immunology Research, and Vivian L. Smith Distinguished Chair in Immunology. Prior to that, he was senior staff scientist at biotech company, DNAX Research Institute of Molecular and Cellular Biology Inc.; maître de recherche at the Laboratory for Immunology Research at Schering-Plough in France; research fellow in the Department of Immunology at the University of Birmingham School of Medicine in England; and research associate in the Department of Cell Biology at Norman Bethune University School of Medicine in China. During his 25 years of research, Dr. Liu has published more than 200 scientific articles in prestigious journals and is among the most cited scientists in immunology. His work in basic immunology has led to major advances in the fields of innate immunity, dendritic cell biology, T cell biology, cytokine biology, and vaccines for cancers and viral infectious diseases. Among his many honors, Dr. Liu received the Dallas-Fort Worth Living Legend Faculty Achievement Award in Basic Research from M. D. Anderson in 2009, the Dana Foundation Award for Human Immunology Research in 2006, and the Sandler Award for Asthma Research in 2005. In addition, he was honored as the George and Barbara Bush Fellow for Innovative Cancer Research in 2004.

Dr. Liu sees his move to BIIR as an exciting and challenging opportunity to leverage the outstanding clinical platform available through Baylor Health Care System into the development of new diagnostic and therapeutic agents for human disease. His goal is to combine the expertise he has gained from his work in industry and at M. D. Anderson with the established excellence of BIIR, which he identified as one of the top human immunology research centers in the world. Dr. Liu has had close collaborations with researchers at BIIR over the years and is already working with them on a 5-year strategic plan. This plan calls for the reorganization of BIIR into centers of research excellence, encompassing tumor immunology, autoimmune disease, inflammatory disease, transplantation immunology, systems biology, and personalized medicine.

Dr. Liu stresses that the fundamental strategy for success at BIIR will be establishing a harmony among basic research, clinical development, and industrial involvement. He commented: “We want to build a culture based on research freedom, innovation, and collaboration. This will give us the ability to recruit top talent to BIIR and to mentor and train young basic and physician scientists.”

Dr. Liu will work closely with Alan Miller, MD, PhD, chief of oncology for Baylor Health Care System and medical director of Baylor Charles A. Sammons Cancer Center, in advancing programs in cancer immunology and cancer genomics. In addition to ongoing research in the area of melanoma vaccines, he plans to initiate new program projects with BIIR researchers in the areas of breast, pancreatic, and lung cancer. Dr. Miller commented: “The addition of Dr. Liu will allow us to accelerate the outstanding work done by our cancer immunology team and bring more options to our patients.”

Michael A. E. Ramsay, MD, president of BRI, called Dr. Liu a “phenomenal recruit for BIIR.” He anticipated that Dr. Liu will have a major influence not just on the development of innovative new therapies for cancer, but also in the transplant program, where new techniques will be developed to identify rejection early and treat it effectively. “Dr. Liu is a world-class basic immunologist,” said Dr. Ramsay. “He is very focused and has been incredibly successful in working with industry, in capturing federal grants, and in making major advances in his field. He is already serving as a magnet, and we expect his presence here to draw other key leaders in the field to BIIR.”

Baylor Health Care System welcomes Dr. Liu to the team; he will make his transition to Baylor over the next few months.
“Swim Across America” Program Will Support the New Innovative Clinical Trials Center at Baylor Sammons Cancer Center

“Swim Across America” (SAA), a national organization, holds dozens of community-oriented open-water swims from coast to coast, each used to raise funds for local beneficiaries supporting cancer research, prevention, and treatment. On June 11, 2011, SAA sponsored the inaugural open-water swim at Lake Ray Hubbard at the Harbor in Rockwall, Texas, to benefit the new Innovative Clinical Trials Center (ICTC) at Baylor Charles A. Sammons Cancer Center at Dallas. The event drew more than 300 participants from across the United States, Nicaragua, and Egypt and raised $350,000 that will be used to support clinical trials at the ICTC. Among those swimming at the event were Alan M. Miller, MD, PhD, chief of oncology for Baylor Health Care System and medical director of Baylor Sammons Cancer Center, and Carlos Becerra, MD, medical director of the ICTC and a Master swimmer.

SAA swimmers are characterized by a desire to make a meaningful impact in the fight against cancer through their love of swimming. SAA began in 1987 with one event in Nantucket, Massachusetts, and has grown to include dozens of events from coast to coast. These events unite recreational swimmers, competitive swimmers, Masters swimmers, Olympians, kayakers, boaters, and hundreds of volunteers, all committed to finding a cure for cancer. Since its inception, SAA has raised over $35 million for cancer research, prevention, and treatment.

Baylor Sammons Cancer Center joins an elite slate of beneficiaries supported by SAA, including Memorial Sloan-Kettering Cancer Center, Dana Farber Cancer Institute, Cardinal Bernardin Cancer Center at Loyola University Medical Center, Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, and the University of California, San Francisco Children’s Hospital. According to Daniel Watters, chairman of the local SAA committee and a member of the 1988 Olympic swim team, SAA chose to support the ICTC at Baylor Sammons Cancer Center after an intensive search looking for the best of the best in terms of cancer research and treatment in North Texas. This year’s open-water swim represents the first year of an initial 4-year commitment. “Our goal is to raise in excess of $1 million during those 4 years,” said Mr. Watters. “We hope and anticipate that this commitment will be extended for many, many more years after that.”
The ICTC will consolidate all oncology phase I clinical trials from Baylor researchers and their academic and clinical research partners in one 6,376-square-foot center. These trials offer opportunities for patients to participate in the newest developing therapies in cancer, therapies that may be the last line of hope for many individuals. At the same time, phase I trials are an essential component in bringing new treatments from the bench to the bedside. The ICTC will be dedicated to providing access to treatments only available in a few centers around the world, including immunotherapeutic options such as cancer vaccines from the Baylor Institute for Immunology Research and pharmaceutical agents selected for specific molecular targets.

Swim Across America leaders present a $350,000 check from the inaugural event in Dallas on June 11, 2011. The money raised by more than 300 swimmers and 12 Olympians will benefit the Innovative Clinical Trials Center. L to R: Janel Jorgensen, President and CEO of Swim Across America, Jeanne Cunningham and Daniel Watters, both event directors for the swim, Ellen Dearman, development director for the Baylor Health Care System Foundation, Carlos Becerra, MD, medical director of the Innovative Clinical Trials Center at Baylor Charles A. Sammons Cancer Center, Alan M. Miller, MD, PhD, chief of oncology, Baylor Health Care System and medical director, Baylor Charles A. Sammons Cancer Center at Dallas, and Andrea Hayes Dickson, also an event director.

The ICTC will be located on the 7th floor of the new Baylor Sammons Cancer Center. According to Dr. Miller, most of the design work for the ICTC has been completed. Daniel Von Hoff, MD, an international leader in cancer drug development, is assisting in the development of the ICTC which is targeted for completion in January 2012.

(L to R) Peggy Walker, Quinn, and Alan M. Miller, MD, PhD, chief of oncology, Baylor Health Care System and medical director, Baylor Charles A. Sammons Cancer Center at Dallas, at the inaugural Swim Across America on June 11, 2011. Ms. Walker and Quinn visit the outpatient areas of Baylor Sammons Cancer Center twice a month. Quinn is one of 3 dogs that visit regularly with patients. They bring a smile to the faces of those they visit, giving them something to focus on while they wait for treatment.
Stone Lectureship Inaugurates New Tom Hunt Auditorium at Sammons

The third annual Marvin J. Stone Lectureship took place on March 29, 2011, the first lectureship held in the 10th floor Tom Hunt Auditorium of the new Baylor Charles A. Sammons Cancer Center at Dallas. The recipient of the lectureship was James Armitage, MD, professor of internal medicine in the division of hematology and oncology at the University of Nebraska Medical Center at Omaha.

Dr. Armitage spoke to an audience of more than 150 attendees on “Developing Curative Therapy for Patients with Lymphoma: A Paradigm for Clinical Research.” He outlined the research paradigm for lymphoma as encompassing three components: (1) identifying a specific disease; (2) stratifying patients; and (3) identifying better treatments. Multiple approaches have been used to classify and stage lymphoma, since the assessment of therapeutic research requires the clinician to identify patients at comparable risk. Dr. Armitage anticipates that improvement in this area will be forthcoming with advances in functional imaging, which should assist in initial staging of patients as well as evaluation of treatment results. Treatment advances for lymphoma have included new approaches to chemotherapy and autologous and allogeneic hematopoietic stem cell transplantation, but the success of rituximab indicates that genetically targeted therapies may hold great promise for the future.

The Marvin J. Stone Lectureship was instituted in 2009 in honor of Marvin J. Stone, MD, MACP. Dr. Stone served as chief of oncology at Baylor Dallas and director of Baylor Sammons Cancer Center from 1976 to 2008. He currently heads the internal medicine clerkship for the third-year medical student hematology/oncology rotation and the medical oncology fellowship program at Baylor Dallas.
Site-Specific Tumor Conferences at Baylor Sammons Cancer Center

At Baylor Charles A. Sammons Cancer Center at Dallas, a key element at the heart of our approach to patient care and education is the site-specific tumor conference program. Rather than focusing solely on recommendations for patient care, the site-specific conferences also aim to educate the medical professionals attending the conference. Unlike tumor boards, continuing medical education credit is available for physicians who attend. Because several patients with the same diagnosis are presented at each conference, attendees are provided with an in-depth view from specialists, accompanied by lively discussion.

Most of the site-specific tumor conferences have been relocated to the 10th floor conference center in the new outpatient cancer center. The gynecology and skull base conferences remain in the Truett Hospital conference rooms. For more information about site-specific tumor conferences at Baylor Sammons Cancer Center, please call 214.820.4073.

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<th>Conference schedule:</th>
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<tr>
<td>Bone and Soft Tissue</td>
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<td>Breast</td>
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<td>Chest</td>
<td>1st, 2nd and 4th Wednesday</td>
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<td>Endocrine</td>
<td>3rd Tuesday</td>
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<td>Gastrointestinal</td>
<td>Alternating Thursdays</td>
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<td>Gynecology</td>
<td>Wednesdays</td>
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<td>Head and Neck</td>
<td>2nd and 4th Tuesday</td>
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<td>Head and Neck Journal Club</td>
<td>5th Tuesdays</td>
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<tr>
<td>Hematology/Oncology Journal Club*</td>
<td>Rotating Wednesdays</td>
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*Rotate during the month

For information about site-specific tumor conferences at Baylor Sammons Cancer Center, please call 214.820.4073.
Patient Navigation: The Bond Between Patient and Navigator Is Powerful Medicine

Baylor Charles A. Sammons Cancer Center at Dallas takes pride in being a center for the personalized treatment of patients with cancer. When we say personalized, we mean a broad picture that involves targeted therapy approaches for the disease but also encompasses the type of one-on-one assistance and support found in the patient navigation program.

The patient navigation program at Baylor Sammons Cancer Center provides personalized help with every aspect of cancer care, from diagnosis to treatment and recovery. Patient navigators begin by collecting necessary patient records and other information; they then work with the patient’s physician to determine what tests or appointments are needed and coordinate the scheduling process. In addition to these logistic needs, the navigators also offer support and education for patients during the whole process and are there for them even after treatment is completed.

For newly diagnosed patients, patient navigators provide an invaluable service, removing some of the intimidation from a frightening and complex process. According to Cynthia Robinson-Hawkins, MBA, RN, manager of Baylor’s patient navigation program, “We are like the concierge of the cancer center—ready to decipher all needs and concerns of patients and their families.”

But there are other patients, “experienced” patients, who also need help. They have been fighting their disease for a long time, going through multiple rounds of therapy, and finally reaching the point where standard treatments have little left to offer them. For these patients, the best option may be to enroll in a clinical trial for a new experimental therapy, but how do they find an appropriate trial, determine if they qualify for it, and gain access to the clinicians running the trial? Here again, the patient navigation program steps forward to assist.

One patient who came to the patient navigation program for help was Chad Summers, a businessman who lives in the metroplex area with his family and works in Dallas. When Chad developed shortness of breath, his doctor sent him for imaging studies. The spots that showed up on his lungs were biopsied, and the diagnosis was metastatic melanoma. Chad started treatment with chemotherapy, experiencing terrible side effects but gaining no lasting benefit from the treatment. He then switched to radiotherapy, which slowed down the disease for a while but did not stop it. Finally, he was referred to Baylor Sammons Cancer Center, and the first number he called was the patient navigation program. “They kept me informed and told me who to get in contact with,” said Chad. “They told me what to bring, helped to collect my tissue samples, got copies of everything, and made sure I had up-to-date medication lists.”

“We do all that we can to help the patient,” said Robinson-Hawkins. “We collect all the records that will be needed for a doctor to make a decision about whether the patient qualifies for a clinical trial.” They start with trials offered at Baylor Sammons Cancer Center, but if nothing appropriate is available, patients might be referred to trials at other institutions in Texas or across the country. “We try very hard to find something; we do what’s best for the patient.”

A trial was found for Chad at Baylor Sammons Cancer Center, and he is now being treated with a new type of medication that specifically targets melanoma. He reports that the side effects are mild compared to what he experienced with his previous therapy, and he is hopeful that his next assessment will show a good response from the drug. Although his day-to-day scheduling is now handled by the research nurse associated with the trial, when he is 3 months out, and again after a year, he will receive a follow-up phone call from patient navigation to see how he is doing and if he needs anything. In the meantime, he comments: “This is a great experience so far. I feel like I’m heading in the right direction on battling this.”

Research studies have shown that the one-on-one attention and assistance given to patients through patient navigation systems are associated with a decrease in the time between initial presentation and definitive treatment, increased treatment adherence, shorter duration of hospitalization, and fewer cancer-related problems. Based on patient feedback, Robinson-Hawkins believes that the patient navigation program at Baylor Sammons Cancer Center provides similar benefits, a belief that she expects to quantify in a nursing research study that is in the early planning stages.
Clinical Trials on the Baylor Dallas Campus: Phase I Studies in Oncology

Patients and their physicians can now access information about open clinical trials in oncology at Baylor Sammons Cancer Center by following these steps:

- Go to BaylorHealth.edu/Sammons.
- Click on “Cancer Clinical Trials” on the right hand menu.
- From the list of studies that appears, click on the study that is of interest to you to view details such as the inclusion/exclusion criteria.

For additional details or questions about the studies, please contact the Office of Clinical Oncology Research Coordination at 214.818.8472 or via email at cancer.trials@baylorhealth.edu.

The following phase I/II clinical trials at Baylor Dallas are currently open and recruiting patients:

**Solid Tumors**

**Study title:** A phase I/II multicenter, open-label study of BEZ235, administered orally on a continuous daily dosing schedule in adult patients with advanced solid malignancies, including patients with advanced breast cancer.

**Study ID number:** US Oncology ID: 10150

**Principal investigator:** Carlos Becerra, MD

**Sponsor:** Novartis

**Participating site:** Texas Oncology, Baylor Sammons Cancer Center

**Volunteers needed:**

phase I: study population enriched with female patients with histologically confirmed metastatic HER2+ breast cancer after failure of trastuzumab treatment. Tumors must have molecular alterations of PIK3CA and/or PTEN. Patients with non–small cell lung cancer will be prescreened for EGFR mutation.

**Study title:** A phase I/II study of the combination of RDEA119 and sorafenib in patients with advanced cancer.

**Study ID number:** US Oncology ID: 10022

**Principal investigator:** Carlos Becerra, MD

**Sponsor:** Ardea Biosciences, Inc.

**Participating site:** Texas Oncology, Baylor Sammons Cancer Center

**Volunteers needed:** Patients with an ECOG performance status of 0 or 1, with histologically or cytologically confirmed diagnosis of a solid tumor. In the dose-escalation phase, the tumor must be unresectable and locally advanced or metastatic, and either no proven effective therapy exists or the patient cannot tolerate such therapy. Only patients with hepatocellular carcinoma are being accrued into the study at Baylor Sammons Cancer Center.

**Renal Cell Carcinoma**

**Study title:** Phase I/II study of BNC105P in combination with everolimus or following everolimus for progressive metastatic clear-cell renal cell carcinoma (RCC) following prior tyrosine kinase inhibitors.

**Study ID number:** Texas Oncology ID: TO920; BRI IRB: 010-043

**Principal investigator:** Thomas Hutson, DO, PharmD

**Sponsor:** Hoosier Oncology Group

**Participating site:** Texas Oncology, Baylor Sammons Cancer Center

**Volunteers needed:** Patients with metastatic or locally advanced unresectable RCC, with histological or cytological proof of a component (any percent) of clear-cell RCC and progressive disease after 1 or 2 prior VEGF-directed tyrosine kinase inhibitors.
## Additional Phase I/II Clinical Trials

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<tr>
<th>Principal Investigator</th>
<th>Study Number</th>
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<tr>
<td>Edward Agura, MD</td>
<td>BRI IRB: 010-139</td>
<td>An open-label, multicenter phase I trial of the safety and pharmacokinetics of escalating doses of MFGR1877S in patients with relapsed or refractory t(4;14)-positive multiple myeloma</td>
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<td>Karen Fink, MD</td>
<td>BRI IRB: 010-144</td>
<td>Phase I study to test the safety of TVAX immunotherapy as a treatment for recurrent grade IV glioma</td>
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<td>A phase Ib multiple ascending dose study to evaluate the safety of brivanib in combination with 5-fluorouracil/leucovorin (5FU/LV) and brivanib in combination with 5-fluorouracil/leucovorin/irinotecan (FOLFIRI) in subjects with advanced or metastatic gastrointestinal malignancies</td>
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<td>Carlos Becerra, MD</td>
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<td>Phase I study of an autologous recombinant idiotype vaccine manufactured by magnICON technology for the treatment of patients with follicular lymphoma in first relapse/progression</td>
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<td>Charles Cowey, MD</td>
<td>Texas Oncology ID: T01010</td>
<td>A phase I randomized, open-label, multicenter, two-period crossover study to investigate the effect of food on the pharmacokinetics of a single oral dose of RO5185426, followed by administration of 960 mg RO5185426 twice daily to BRAFV600E-positive metastatic melanoma patients</td>
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<td>Carlos Becerra, MD</td>
<td>US Oncology ID: 08008</td>
<td>A phase Ib multicenter dose-escalation study of LY573636-sodium in combination with 1) gemcitabine HCl, 2) docetaxel, 3) temozolomide, or 4) cisplatin in patients with advanced solid tumors</td>
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<tr>
<td>Carlos Becerra, MD</td>
<td>US Oncology ID: 09044</td>
<td>A phase I safety study of LY2787106 in patients with cancer and anemia</td>
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Cancer research studies on the Baylor Dallas campus are conducted through Baylor Research Institute, Texas Oncology, and US Oncology. Each reviews, approves, and conducts clinical trials independently.
Recent Publications from Baylor Sammons Cancer Center
January to May 2011


Scientific Publications

The newly established Baylor Charles A. Sammons Cancer Center at Dallas Office of Scientific Publications offers services focusing on the development of oncology-related research articles and grant applications. Services are available free of charge to all physicians on the medical staff at Baylor Health Care System facilities, medical oncology fellows, and nursing staff, and include editing cancer-related scientific manuscripts and investigator-initiated research grants; editing and assisting with the production of scientific posters and PowerPoint presentations; developing figures, tables, and graphic aids to enhance presentation of complex scientific concepts and data; and providing help in identifying funding opportunities. The office is under the direction of Margaret Hinshawel, PhD, and is located in Baylor Sammons Cancer Center, Suite 550. The phone number is 214.820.3549. 

Margaret Hinshawel, PhD

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NORTH TEXAS MULTIDISCIPLINARY LUNG CANCER SYMPOSIUM

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