



— MOFFITT —
MOMENTUM®

PORTRAITS OF HOPE, INNOVATION AND TRIUMPH

NAVIGATING EMOTIONS

A broader view of healing

A NEW RACE

Advocacy spurs speed to cure

FAITH, LOVE, TRUST

Fun "Aunt B" is back



Alan F. List, MD
President & CEO
Moffitt Cancer Center

MOFFITT MOMENTUM®
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Dear Friends,

As spring is a time of growth, renewal and hope, here at Moffitt Cancer Center we are encouraged by the inspirational stories of our patients, their caregivers and their health care team members, as well as those individuals in our community who support our mission.

Lesa France Kennedy and Bill Christy are chairing this year's Magnolia Ball, and we are pleased to feature them in the cover story of this issue of Momentum magazine. You will learn why Kennedy, named by Forbes as "The Most Powerful Woman in Sports," and Christy, a health care entrepreneur with 25 patents on various medical devices, share a personal commitment to see a cancer-free world.

In this issue, Aliya Hafeez, MD, reveals how as a Moffitt psychiatrist and cancer patient she is empowered through working and helping other patients while on her own challenging journey.

The effects of cancer can extend beyond the disease itself, sometimes triggering physical or emotional symptoms. When that happens, members of Moffitt's Supportive Care Department, led by Diane Portman, MD, can work with the patient's interdisciplinary care team to address these multiple challenges.

Hope and courage go hand in hand in Moffitt's Clinical Research Unit, where patients with cancer participate in clinical trials to test promising new treatments. Dan Beres was given less than four weeks to live after being diagnosed with a blood disease for which, at that time, no treatment existed. His dose of hope came in the form of a clinical trial, and today, three years later, he is disease free. Rich Jasinski describes how he relapsed from several treatments, including a stem cell transplant, after being diagnosed with Hodgkin lymphoma. That was 10 years ago, and Jasinski believes he is alive today because he enrolled in a clinical trial.

Brenda Nelson, known as "Aunt B," describes her bout with a rare cancerous tumor that was blocking the blood flow to her heart. She turned to Ricardo Gonzalez, MD, Moffitt's chief of surgery and chair of the Sarcoma Department, for help. He initiated extensive preparations for the complicated surgery, which involved partnering with expert transplant surgeons at Tampa General Hospital. Aunt B says her faith, family and the "surgical A team" brought her safely through the risky procedure.

We hope you will find these inspirational accounts of hope, new beginnings and courage as uplifting as we do.



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ON THE COVER: Lesa France Kennedy poses in Gallery500 in front of a painting by race artist Bill Patterson.

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SPEEDING TOWARD THE CURE

By Ann Miller Baker

Photography: Ray Reyes

Daytona's Lesa France Kennedy and Bill Christy bring urgency to advocacy for Moffitt

GROWING UP IN DAYTONA with the last name “France,” Lesa France Kennedy always had racing in her blood. Her grandfather, Bill France Sr., founded NASCAR and built Daytona’s World Center of Racing. Her father, Bill France Jr., created an audience for the sport on television and grew it internationally. Kennedy now manages Daytona International Speedway and 12 other premier motorsports entertainment venues nationwide as CEO of the International Speedway Corporation.

But currently, a different kind of speed is on the mind of this CEO whom Forbes once named “The Most Powerful Woman in Sports.” Kennedy and fiancé Bill Christy are focused on the race for a cure for cancer.

“We can’t move quickly enough in this space,” says Kennedy. “Cancer affects nearly 65,000* courageous patients at Moffitt alone and I can’t imagine how many others worldwide. There’s no better time than now and no better place than Moffitt Cancer Center to fast forward how we are battling this disease.”

To accelerate those efforts, Kennedy and Christy are chairing the 2019 Magnolia Ball, Moffitt’s signature fundraising event. “It will be an uplifting and touching evening,” says Kennedy, “but one that is also lots of fun.” Kool & The Gang will headline the April event in downtown Tampa, guaranteeing plenty of dancing. “And we have a few surprises in store,” adds Christy.



Photography: Ray Reyes

LESA FRANCE KENNEDY AND BILL CHRISTY
MOFFITT ADVOCATES

Kennedy first visited Moffitt Cancer Center in 2011 and recalls being “absolutely blown away by its staff and the groundbreaking work they’re doing. At Moffitt, the research and work in treating and curing cancer is moving so fast. Their logic challenges the current clinical mindset to someday treat cancer as a manageable chronic disease. That is an absolute game changer that allows patients to focus on a real quality of life, which, it goes without saying, is extremely important.”

For Christy, a health care entrepreneur who holds over 25 patents on various medical devices, the connection to Moffitt’s mission is personal. “When my father was diagnosed with cancer years ago, the best specialists were in New York or Los Angeles,” he recalls. “Such a huge part of a patient’s journey is having their family and home close by. Having this leading facility here in the Sunshine State is unbelievable.” In fact, he adds, the couple has referred several friends to Moffitt for care in just the past few months alone.

Since Kennedy became a member of Moffitt’s national Board of Advisors in 2012, the couple hasn’t missed a Magnolia Ball. Christy says they look forward to it every year. And while they’ve been known to bid on auction items, their support isn’t limited to one night a year.

In 2014, Kennedy hosted an awareness event at her home as part of Moffitt’s Leadership Series. “We had fellow Board of Advisors members in attendance, along with Dr. Alan List and Dr. Doug Letson who spoke of Moffitt’s clinical operation and his specialty in treating sarcoma. Dr. Keiran Smalley also attended and discussed personalized therapies for melanoma,” says Kennedy. “This was an eye-opening evening for many and one that led to further support and advocacy of this great organization.”

Located near the Daytona International Speedway, Gallery500 is a contemporary art gallery featuring works by local, regional and national artists including Beau Wild (behind Lesa and Bill) and Bill Patterson (shown bottom left).





Photography: Ray Reyes

“I think we all want to see a cancer-free world.”

There’s no shortage of demands on the couple’s time. The 2019 motorsports season is well underway, and new venues are opening within ONE DAYTONA, the retail/dining/entertainment center located across from Daytona International Speedway that is also owned by International Speedway Corporation. Close to the couple’s hearts is Gallery500, a collection of local and regional contemporary artwork, as well as works by race artists from across the country — some of them from Kennedy’s and Christy’s personal collection. Yet the pair say they are glad to make time for Moffitt and its mission to advance the prevention and cure of cancer.

“I think we all want to see a cancer-free world,” says Christy. “If cancer could be treated as a manageable disease where longevity and quality of life were all the patient needed to focus on, that would change life as we know it.”

“We believe so strongly in (cancer center founder) Lee Moffitt’s vision,” adds Kennedy, “and any small part we can play, we are very excited about. We’re stronger together, so let’s beat cancer together!”

**Editor’s Note: In fiscal year 2018 Moffitt saw 64,759 patients, of whom 23,199 were new patients. Additionally, the cancer center logged 406,117 outpatient visits during that time frame.*



Photography: Kevin Kirby

MIND AND BODY

AGAINST CANCER

Moffitt psychiatrist helps patients while on her own cancer journey

By Ann Miller Baker

ALIYA HAFEEZ, MD
CANCER WARRIOR + HEALER

When patients first see Moffitt psychiatrist Aliya Hafeez, MD, they inevitably bring a sense of anxiety along with their cancer diagnoses.

Some are dealing with existing mental health issues and need help integrating their medications into this new cancer treatment protocol. All need help managing emotional distress while on their cancer journey.

But few know how well Hafeez can relate. Originally diagnosed with stage three breast cancer in 2009, her cancer returned in August 2018. Hafeez currently splits her week between chemo recovery and her work with her patients. And she says common central issues weave throughout most patients' experiences — including her own.

"The No. 1 thing is fear," says Hafeez. "As soon as you are diagnosed, your mind goes to the question, am I going to die? That's a legitimate fear. One thing I say to my patients all the time is that death was a certainty even before this diagnosis." Fear, she says, is just one of the emotions that normally comes with cancer, and it's OK for patients to feel all of those emotions, rather than to feel pressured to be positive all the time. Helping Moffitt patients to navigate those emotions is the work that Hafeez values so strongly.

EMPOWERED THROUGH HER WORK

Hafeez is not the first Moffitt team member to also become a Moffitt patient. The fact that she can be both simultaneously is, in some ways, a credit to the support she's received from her colleagues in Moffitt's Department of Supportive Care Medicine, where she is one of three psychiatrists helping patients deal with the emotional aspects of a cancer diagnosis.

"I feel empowered by working, and it was really important to me to be able to continue working at this point," says Hafeez. "I think part of it has to do with the fact that my cancer is metastatic, something I will have to live with. I was determined to learn how to live with it from the beginning."

"The No. 1 thing is fear."

She says it's important for all of us to recognize that life doesn't stop while you deal with difficulty. "Sure, you're going through something you don't want to, but you have to figure out how you're going to live to the best of your ability. It's not as if you can push a pause button and wait for the rest of your life to resume afterward. The days going by ARE your life."

Hafeez strives to make the most of those days through integrative therapies like acupuncture, nutrition and massage, services also offered through Moffitt and its Supportive Care Medicine Department (see article, page 13).

"One thing I've learned as a patient is that we need to be better at educating patients on the full range of options for their care. When you are diagnosed, there are protocols for treatment and those are vital. I believe supportive care should be an equally important part of our approach. We need to be better about letting patients know about options that can help with symptoms and the emotional component of a cancer diagnosis, things like acupuncture, reiki, yoga, healthy nutrition. Such measures can potentially help our clinical protocols work better or lessen their side effects." (see page 12)

"It's not as if you can push a pause button and wait for the rest of your life to resume afterward."

One more approach that sustains Hafeez is a sense of gratitude for what she views as a unique opportunity to learn and to help others. "Most people just look at cancer as this awful illness," she says. "But I see the opportunity in this, in terms of my psychological growth, my spiritual growth, in terms of my level of compassion and empathy and my ability to really contribute to my own healing and to help others."

"If you focus on gratitude, you don't focus as much on fear."

COLLEAGUES ON THE GRATITUDE LIST

When Hafeez thinks of her own gratitude list, she counts fellow psychiatrists Drs. Margarita Bobonis-Babilonia and Barbara Lubrano, who help to shoulder her patient load as well as their own. "They are so gracious and don't make me feel bad about the workload!" The same can be said of the Supportive Care psychologists who step up with patients when Hafeez can't be there, and the rest of the staff who are always sensitive to conserving Hafeez's energy for her patients.

"And Dr. Portman has been amazing," adds Hafeez. The department chair of Supportive/Palliative Care Medicine, Diane Portman, MD, says it's in keeping with her team's mission.

"Supportive Care is a team-based specialty that focuses on providing relief from the symptoms and stress of serious illness to patients and families," says Portman. "But the care also encompasses the well-being of our own team members. As such, a core team strength is our commitment to support each other during any challenges that affect our group or individual members. We are proud that Moffitt's commitment to

"I feel empowered by working, and it was really important to me to be able to continue working at this point."



Photography: Kevin Kirby

the well-being of its team members has allowed our colleagues the flexibility to adjust schedules and service structures to let our cherished teammates take care of themselves and still remain engaged in this work that they find so meaningful."

Portman typically shares small year-end gifts with her team. This year's gift was a pin shaped like a dolphin. It came with a story about how dolphins respond when a member of their pod is sick or injured. Pod members swim beneath the struggling dolphin, lifting them to the surface for needed breaths. For Hafeez, it's a poignant reminder.

"I feel like that's what my Moffitt colleagues have done for me," she says. "It's awesome, and it makes me appreciate them even more."

"We are proud that Moffitt's commitment to the well-being of its team members has allowed our colleagues the flexibility to adjust schedules and service structures to let our cherished teammates take care of themselves and still remain engaged in this work that they find so meaningful."



“If you focus on gratitude, you don’t focus as much on fear.”

Photography: Kevin Kirby

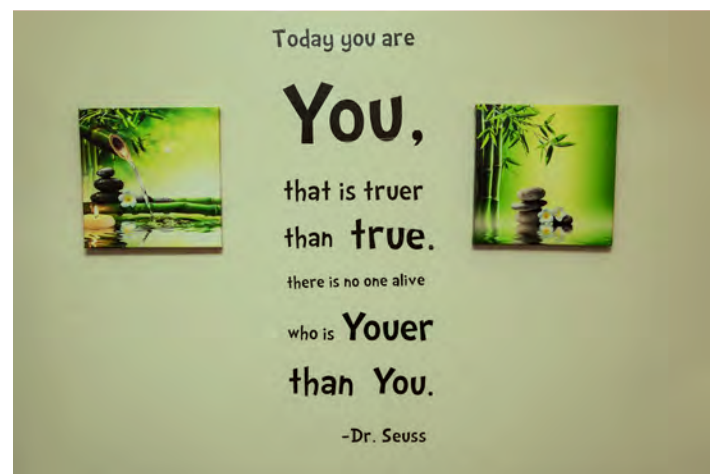
As a psychiatrist, Hafeez is particularly attuned to the emotional side of cancer’s effects. “Healing really begins in the mind, by giving patients another option of how to think about their cancer.” She says her work with fellow cancer patients usually follows six steps:

STEPS TO ENCOURAGE HEALING

- **CALMING EMOTIONS.** It’s important to acknowledge a patient’s fear and anxiety, says Hafeez. “But if they are paralyzed by it, I’m not going to be able to help them.” Medication can help, if the patient is willing.
- **CONNECT AND HEAR THE PATIENT’S STORY.** You’ve been diagnosed with cancer, what do you think happens now? “Our culture has given us a certain narrative about what the cancer journey looks like. But we know better – every patient’s story is different and unique,” says Hafeez. Even two patients who share the same diagnosis will have different experiences. It’s a point reinforced by the Dr. Seuss quote stenciled on her office wall: “There is no one alive who is Youer than You.”
- **CHALLENGE THE CENTRAL BELIEFS AND ASSUMPTIONS IN THE PATIENT’S STORY.** “A lot of patients come into this thinking they have no choice but to go through chemo, but hating chemo,” she explains. “If you go into chemo treatments thinking, ‘This is a poison and it’s going to make me sick,’ then it’s not going to help as much as it can. If you go in wanting chemo to heal you, you need to look at it as your friend. The power of belief is that strong. Beliefs guide not only emotions but the choices patients will make throughout their cancer journey.”
- **HELP PATIENTS TOLERATE UNCERTAINTY.** That’s really hard to do, Hafeez admits. Patients naturally gravitate to two disparate ends of the belief spectrum: “Either ‘God has my back and I’m going to survive,’ or ‘I’m going to die.’ It’s really hard to hold onto

the ground in between, which is that we really don’t know what’s going to happen. But psychologically, that’s the healthiest position because it’s the truth.”

- **ENCOURAGE A BROADER VIEW OF HEALING.** While the best modern medicine is essential, it’s also important for patients to appreciate the body’s incredible power to heal itself. Hafeez encourages patients to adhere to their physician’s treatment plan, but supplement it with measures that promote healing and emotional well-being. For her, this includes everything from diet, exercise, reiki therapy and acupuncture to considering the people who surround you (are they supportive or focused on their own fear?). She even uses visualization, imagining her cells as cartoon “minions” armored up to direct the chemo to its cancerous targets and not healthy tissues.
- **IF POSSIBLE, REFRAME YOUR APPROACH TO LIVING.** “I think cancer is an opportunity to make more conscious choices in life, for what you can create, do and accomplish. It can also bring an element of fearlessness, that life is short and we don’t have time to waste. None of us do.”



THE TEAM of SUPPORT

Moffitt’s Supportive Care Medicine Department Collaborates to Care for the Whole Patient

By Ann Miller Baker

Photography: Kevin Kirby

Supportive/palliative care is specialized medical care to relieve what's known as "total pain," whether physical, emotional, social or spiritual.



DIANE PORTMAN, MD
CHAIR, DEPARTMENT OF SUPPORTIVE CARE MEDICINE

Photography: Kevin Kirby

CANCER'S EFFECTS AREN'T LIMITED TO THE MALIGNANCY. Its diagnosis and treatment can trigger physical symptoms from sleep disturbance to nausea. It can leave patients depressed, anxious or distanced from friends who don't know how to react. And it sometimes raises existential questions and crises of faith. Helping to relieve these stressors is the role of Moffitt's Department of Supportive Care Medicine. Its chair, Diane Portman, MD, oversees more than 40 team members in both the inpatient and outpatient setting. They have varied areas of expertise and work together as a team to effectively address the multiple challenges faced by patients and caregivers. Their work, she says, can be affectionately referred to as a "team sport." But she's quick to add, "This department is but a part of the endeavor." Its members collaborate closely with physicians, nurses, social workers, chaplains and many others throughout Moffitt to evaluate patient referrals and deliver care.

Supportive/palliative care is specialized medical care to relieve what's known as "total pain," whether physical, emotional, social or spiritual. Left unattended, this multifaceted pain is a platform for utter misery. When these issues are addressed, patients can more easily face and manage their cancer journey.

ER visits and hospital stays can be avoided, and care can be aligned with patients' specific goals, values and priorities. It also benefits the institution by reducing the use of unnecessary resources. Supportive care can be provided together with curative and life-prolonging treatment. It's about more care — not less. And it's offered at any time, from diagnosis throughout the spectrum of care, wherever the cancer journey takes the patient.

In the past, Portman says, oncologists themselves provided for a patient's primary supportive care needs within their practice. Many still do today. But the field of oncology is becoming ever more complex. "Every day, there are multiple new drugs. There are multiple new developments in molecular or genetic understanding of the disease," she explains. "The amount of knowledge, skill and expertise required for oncologists to keep up with that can seem insurmountable at times." Add all the other dimensions of care that are required to keep patients feeling well through their journey, and Portman says it clearly can't be done by a single care team or one individual. "You really need multiple forms of support. Moffitt has recognized that having a supportive care department to collaborate with the disease-state departments on an equal footing is one of



Elaine Payne, massage therapist. Massage therapy is in high demand among Moffitt inpatients.

"There are so many other techniques that can help augment pain control that don't come in a syringe or a bottle."

the optimal ways to do this. It's a relatively unique approach compared to other cancer centers across the country."

The department is organized into three distinct sections: Behavioral Medicine, Integrative Medicine and Supportive/Palliative Care Medicine.

THE BEHAVIORAL MEDICINE section is home to Aliya Hafeez, MD (story, page 9), as well as two other psychiatrists and three PhD-trained psychologists. They offer medication management, therapy and counseling to help reduce and manage anxiety, depression, sleep problems and other stressors or coping challenges.

INTEGRATIVE MEDICINE is devoted to improving health and well-being through complementary therapies such as mindfulness and meditation techniques, acupuncture, yoga and massage therapy for stress reduction, relaxation, added comfort and relief. These modalities have been shown in multiple research studies to be beneficial when used in combination with traditional medical treatments. Practitioners are trained to work with the cancer patient population and collaborate with Moffitt medical providers.



Dr. Liem Quang Le, DAOM, administers acupuncture therapy to Robin Hesselink. Acupuncture is endorsed by the National Institutes of Health for pain management.

Photography: Kevin Kirby

“You really need multiple forms of support. Moffitt has recognized that having a supportive care department to collaborate with the disease-state departments on an equal footing is one of the optimal ways to do this. It’s a relatively unique approach compared to other cancer centers across the country.”

IN 2018, THE AMERICAN HOSPITAL ASSOCIATION AWARDED MOFFITT’S DEPARTMENT OF SUPPORTIVE CARE MEDICINE A NATIONAL CIRCLE OF LIFE AWARD CITATION OF HONOR FOR STRIDES AND INNOVATIONS IN SUPPORTIVE/PALLIATIVE CARE. ONLY SIX AWARDS ARE BESTOWED EACH YEAR.



Pain management is a good example of integrative care, especially in an opiate-challenged world. While the strong pain relievers have a valued place in helping cancer patients, Portman notes, “There are so many other techniques that can help augment pain control that don’t come in a syringe or a bottle.” Both acupuncture and massage therapy are endorsed by the National Institutes of Health for pain management. Both are offered through Integrative Medicine. And massage therapy, says Portman, is the section’s highest demand service among the inpatient population.

THE SUPPORTIVE/PALLIATIVE CARE MEDICINE section is led by Portman, who is credentialed in anesthesiology, pain management and palliative care medicine. With six physicians and five advanced practice nurses, this section provides pain and symptom management throughout the course of illness to improve comfort, quality of life and daily function. The section’s social worker and a designated chaplain offer emotional, spiritual and practical support for adjusting to life with a serious illness. Team members also help patients with transitions of care and advanced care planning. They are specially trained to clarify patient goals of care in order to help teams provide treatments that best align with what patients express is most important to them.

Patients aren’t the only ones served by this section’s experts. Moffitt team members benefit from training that raises the bar for palliative care practices by all. “We teach pain and

other symptom management,” Portman explains. “We offer communication skills training to master the ‘hard talks’ that all clinicians face with patients who are seriously ill. We provide specific training about end-of-life symptoms that all providers need to be familiar with and manage effectively.” Increasing the competence of all who do this work creates a greater comfort level among staff, makes the care more widely available and frees the Supportive/Palliative Care staff to deliver their specialized level of care when needed.

Together with physicians, a team of specially trained nurses staff the Supportive Care Medicine Outpatient Clinic, an especially busy service given Moffitt’s high volume of outpatient cancer care.

Patients access the department’s services by referral (outpatient) or consult (inpatient) from their primary oncology team. Supportive Care prompting measures are also being incorporated into Moffitt Clinical Pathways, decision support tools used to promote consistent, quality care. In all cases, the first step to obtaining services is an assessment of the patient’s condition and needs, to evaluate whether these needs can and should be handled by the department’s staff.

All these efforts have earned honors for the program. In 2014, The Joint Commission that accredits hospitals and health care organizations awarded Moffitt its first Certificate of Distinction in Advanced Palliative Care. The distinction

is based on adherence to 151 parameters of quality care as established by national guidelines and demonstration of performance with metrics that measure aspects of care. Since 2014, Moffitt Supportive Care has attained recertification every two years. Moffitt is one of only eight National Cancer Institute-designated cancer centers in America — and one of only two Florida hospitals of any sort — to achieve this certification. In 2018, the American Hospital Association awarded Moffitt’s Department of Supportive Care Medicine a national Circle of Life Award Citation of Honor for strides and innovations in Supportive/Palliative Care. Only six awards are bestowed each year.

The honors are welcomed and well-deserved, but Portman is quick to add they’re a reflection on collaborative leadership and teamwork within her department and beyond to all of the Moffitt team members who work together to support our patients. “We’re proud, but we have a long way to go,” she adds. “There’s so much out there on a national level that we can adopt and adapt to our Moffitt culture to make things even better for our patients.”

“We’re proud, but we have a long way to go.”

Photography: Kevin Kirby

Surgical “A” Team Saves “Aunt B”

Photography: Kevin Kirby

In a risky, all-day surgery, doctors removed a rare cancerous tumor blocking blood flow to a patient’s heart

By Sara Bondell

TO BRENDA NELSON’S FAMILY, SHE’S ALWAYS BEEN “FUN AUNT B.”

She is the middle of five children, a fighter from day one after she was born two months early.

She’s the first to volunteer to hit a theme park with her nieces and nephews. Not even a bout with colon cancer in 1999 could slow her down.

But in 2015, Nelson began having an aching, pulling pain under

her liver. Three years went by without a diagnosis, until last April when her belly pain got so bad it sent her to the emergency room. A CT scan found the sneaky culprit: a lesion doctors diagnosed as a rare type of cancer called leiomyosarcoma.

Nelson would once again have to fight.

RAREST OF THE RARE

A sarcoma is a type of cancer that starts in tissues like bone or muscle, and soft tissue sarcomas can develop in soft tissues like fat, muscles, nerves and blood vessels. About 13,000 new soft tissue sarcomas will be diagnosed in 2019 and only 5 to 10 percent of those will be leiomyosarcoma.

Nelson’s tumor was located inside the vena cava, making it even rarer. The inferior vena cava is the largest vein in the body, carrying deoxygenated blood from the lower half of the body back up to the heart. Nelson’s 6-centimeter tumor was shoved inside the only 2-centimeter-wide vein, eventually growing outside the wall of the vessel and into her liver. The tumor was preventing blood flow from the lower body to the

heart and would soon be blocking all blood flow out of the liver into the heart. With this main vein clogged, Nelson’s smaller veins had to do the heavy lifting, and more blood was flowing through them than they were built for. That caused restricted blood flow, explaining why Nelson’s feet were turning blue.

If the tumor wasn’t removed, Nelson’s liver could fail or the tumor would grow so large it could stop her heart. Surgery was her only option, but it would be risky.

MAKING PLANS

Nelson was only 58 years old — not even a grandmother yet — and she knew she had a lot of life left to live. After chemotherapy shrunk the tumor enough for it to be operable, Nelson decided to undergo the complicated surgery. “When the doctor explained to me how serious the surgery was, it was still better than the alternative,” said Nelson. “Without surgery, I had only about a year or less left to live.”

She decided to stay positive and put all her trust in her doctor, Ricardo Gonzalez, Moffitt Cancer Center’s chief of Surgery and chair of the Sarcoma Department.

Gonzalez began the massive preparations for a surgery of this magnitude. The procedure has been done only a fraction of times across the United States, and this would be the first time in the Tampa Bay area. “In this line of work, sometimes you have to think outside the box and oftentimes design a surgery around the problem, and that’s what we had to do here,” said Gonzalez.

Gonzalez called in the help of Tampa General Hospital transplant surgeons Angel Alsina and Julio Sokolich, thoracic

surgeon Robert Hooker, and a surgical critical care team led by trauma surgeon David Ciesla. Nelson would need extensive postoperative care in an intensive care unit, so the surgery needed to be performed at Tampa General.

Nelson would be placed on bypass during the surgery, while the surgical team separated her liver from part of its blood supply and cooled her liver. They would then remove the tumor and a portion of her liver before reconstructing her vena cava using a synthetic graft they would suture to her heart.

The medical team laid out the plan for surgery and created multiple backup plans if things didn’t go as expected. Gonzalez met with Nelson and her family several times before the surgery to make sure they understood the procedure and the risks. “Dr. Gonzalez promised me he wouldn’t leave me and he would get me through to the end,” Nelson said. “I had complete faith in him. My whole family wanted me to go up to New York for the surgery, but when they met Dr. Gonzalez, they saw what we saw and were at ease.”

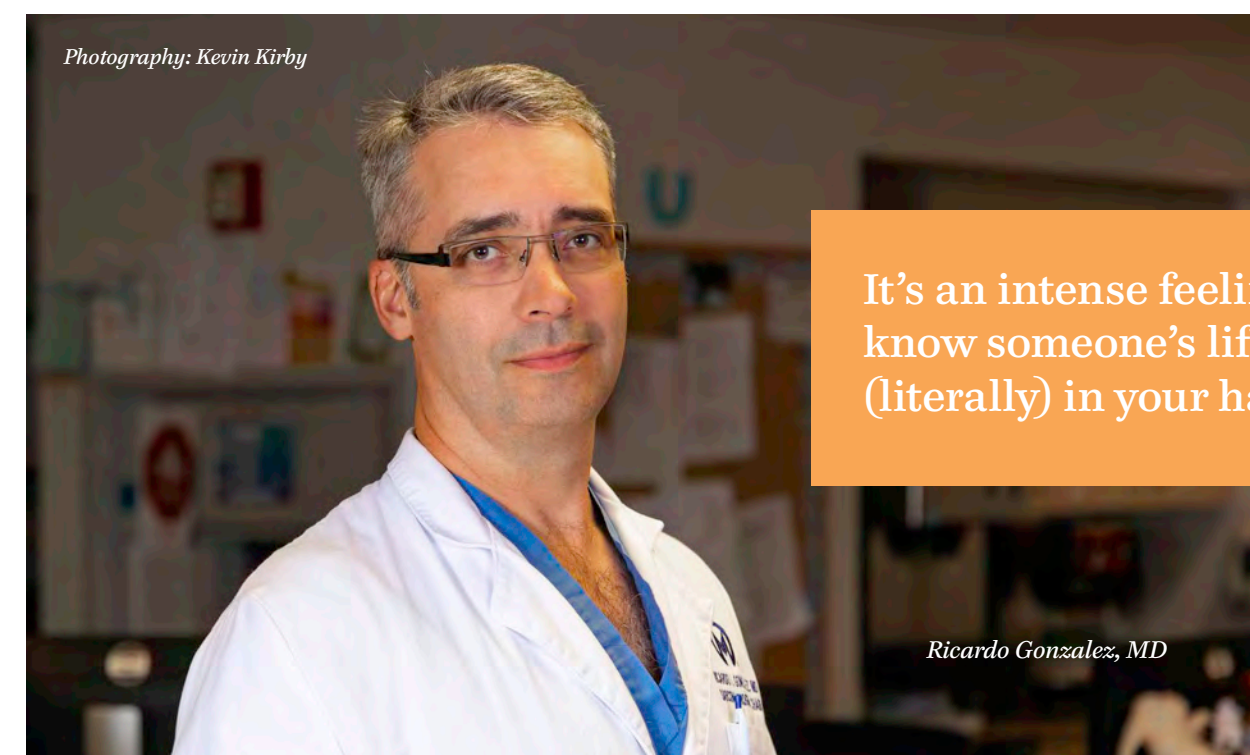
TWENTY HOURS IN THE OR

You can drive from Tampa to New York City in just shy of 17 hours. To complete an Ironman triathlon — a 2.4-mile swim, 112-mile bike ride and 26.2-mile run — it will take the average triathlete about 13 hours. You can binge watch all of the “Harry Potter” movies in 19 hours and 39 minutes.

Nelson was in the operating room for 20 hours over two days.

It’s an intense feeling to know someone’s life is (literally) in your hands, and Gonzalez says he took a few days to mentally prepare for the surgery that was scheduled for Oct. 8, 2018.

Photography: Kevin Kirby



It’s an intense feeling to know someone’s life is (literally) in your hands...

Ricardo Gonzalez, MD

“How many people it takes to get someone through this, through the entire cancer journey, is truly inspiring.”

He and the transplant team had designed the procedure, thought through different complications that could arise and devised alternative plans. Those plans came into play a few hours into the surgery, when the surgical team realized they couldn't save the veins they initially wanted to connect the reconstructed vena cava to. They would have to move forward with Plan B, which meant a more challenging approach to the reconstruction.

Another challenge the surgeons faced was blood loss. Because Nelson was on the operating table for so long, she lost a lot of blood and needed abdominal packing, a life-saving technique where doctors pack the abdomen with gauze to apply pressure to slow or stop bleeding. It was successful, but required a second surgery the following day to remove the gauze.



Brenda Nelson (“Aunt B”) and her husband, Mark

After the second surgery, Nelson spent almost the next two weeks in the intensive care unit — half of that on a ventilator. It was the first time she had been away from her husband since the high school sweethearts met as teens. But she wasn't alone; a team of critical care doctors and nurses watched Nelson around the clock.

“There was a lot going on during that time,” recalled Gonzalez. “You have to watch carefully because even the smallest things could mean something bad. Fortunately, she was very stable through most of it.”

That doesn't mean there weren't a few scares. At one point the ICU team had to shock Nelson's heart because it had started beating irregularly.

Nelson doesn't recall much during that time, except one foggy memory: “I remember my family speaking to me and telling me, ‘They got it all.’” Hearing those four words put Nelson at ease.

What put Gonzalez at ease was the amazing team of people working on Nelson's case. “How many people it takes to get someone through this, through the entire cancer journey, is truly inspiring,” he said. “And all they want is to get that person better.” Nelson's team was so large, Gonzalez can't even pinpoint the exact number of individuals who cared for her, but says they all deserve recognition.

Nelson's own team — her family and friends who called themselves the “B Team” — also rallied around her during her hospital stay. She received dozens of get-well cards and was the focus of multiple prayer groups. And as promised, Gonzalez was there for her the entire time, speaking to Nelson's husband on a daily basis.

“I told him, ‘I will tell you when I am worried,’” said Gonzalez. He never had to.

Almost a month later, Nelson was finally ready to go home.

RETURN OF AUNT B

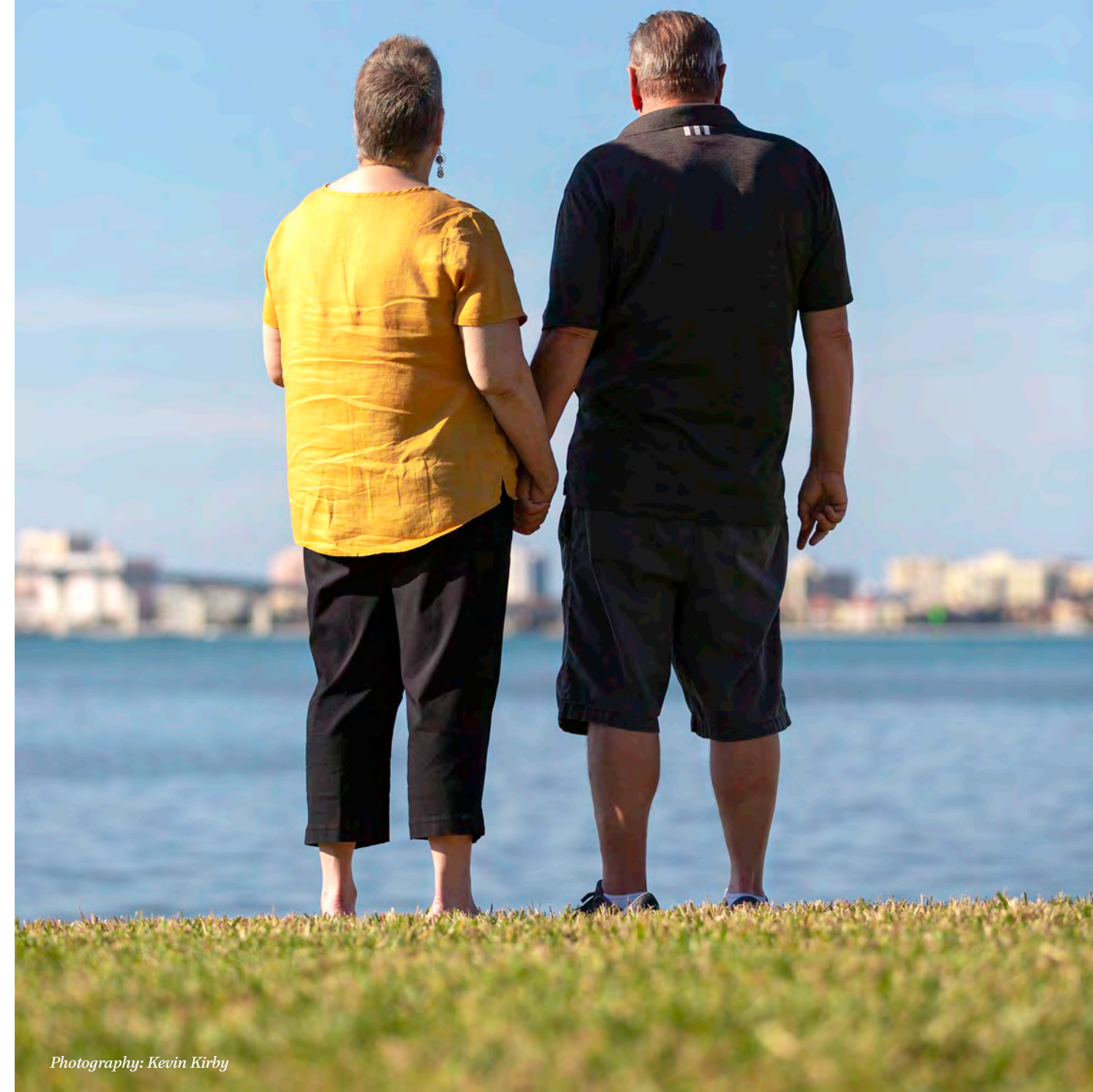
Nelson's husband expected months and months of recovery, but she was back walking and driving before the holidays. Looking at her postoperative scans, she still can't believe what the surgical team was able to accomplish. Her cancer and the pain the tumor brought with it are gone, and with proper blood flow restored, her feet no longer turn blue.

“My faith and love for my family and my trust in Dr. Gonzalez got me through,” said Nelson.

Nelson spent Christmas with her extended family and rang in the new year with a pledge to become the healthiest version of herself. She has plans to travel this year and return to the theme parks with her nieces and nephews.

“Fun Aunt B,” she says is here to stay.

“I remember my family speaking to me and telling me, ‘They got it all.’”



Photography: Kevin Kirby



CLINICAL RESEARCH UNIT: *A Source of Hope*

Dan Beres, Survivor, with Jacqueline Pray, RN

Photography: Kevin Kirby

WHAT IS HOPE?

Look online and you'll find Dictionary.com defines it as "the feeling that what is wanted can be had or that events will turn out for the best."

Look in Moffitt Cancer Center's Clinical Research Unit (CRU), and you'll find it in the work of a united team of nurses, patients, caregivers and loved ones doing whatever is necessary to transform hope into reality in the form of cures.

Dan Beres recalled being given three to four weeks to live after being diagnosed with a blood disease with a long name: blastic plasmacytoid dendritic cell neoplasm (BPDCN). The disease is tricky to diagnose, as it presents with features of both lymphoma and leukemia. There was no treatment at that time. Beres was told to go home and get his affairs in order.

A few days after his diagnosis, Beres was contacted by his medical team about a new trial of a drug called SL-401. For Beres, it was a dose of hope. He was able to transfer his treatment to Moffitt and enroll in the trial.

Three years later, Beres continues coming to Moffitt's Clinical Research Unit for treatment under the care of Lubomir Sokol, MD, PhD, a member of Moffitt's Malignant Hematology Department.

Sokol notes that BPDCN is an aggressive, complicated disease, adding that he has seen massive skin tumors on patients with BPDCN melt away while on this treatment through a clinical trial. Beres notes he did not present with skin lesions, making his diagnosis more challenging.

"Before SL-401, patients with BPDCN who did not have a stem cell transplant died," said Sokol. "SL-401 changed that." Results of the phase 1 trial were promising; the phase 2 trial showed an



Lubomir Sokol, MD, PhD

"Clinical trials are so important. For many patients, these studies can be their only hope."

overall response rate of 90 percent and a complete response rate of 72 percent. "Clinical trials are so important. For many patients, these studies can be their only hope."

CRU SUPPORTS CLINICAL RESEARCH

The Clinical Research Unit (CRU) at Moffitt supports clinical investigational research by monitoring patients undergoing clinical trials and administering investigational agents in an outpatient setting. The CRU has locations at both Moffitt's Magnolia and McKinley campuses.

Phase 1 and phase 2 trials requiring investigational treatments in all forms are administered in the CRU. The CRU is a self-contained treatment center in which most monitoring tests or procedures are performed on the unit. These include electrocardiograms, pharmacokinetic blood sampling and physical assessments.

The CRU sees 30 to 50 patients each day, and between 20 to 50 investigational treatments ranging from 30 minutes to 12 hours are conducted on the unit.

After three years of clinical trials, the drug Beres has been taking gained approval of the U.S. Food and Drug Administration in December 2018. Now marketed as ELZONRIS™, it is the first FDA-approved treatment for BPDCN. "Dan has been on this drug longer than any other patient," says Bucky Jones-Lombard, RN, who manages the CRU. "We call Dan 'The Mayor' because his treatment cycle is every 21 days, so he is here Monday to Friday every three weeks." Clearly a people person, The Mayor can be seen talking to fellow patients and their families and joking with the nurses. "After three years, I know most of the people here!"

Given how often he comes to the CRU, it's no wonder Beres moved from Vero Beach to Tampa. "I got tired of driving three hours each way," says Beres. The care has always been worth whatever travel was needed. "The nurses here are outstanding," he says.

An avid traveler, Beres makes the most of the off weeks when he doesn't receive treatment. He and his wife, Cindy, love to take cruises. "I've been to most of the Caribbean islands," he says, noting that Aruba and Cozumel were his favorites. When he's not cruising the islands or Moffitt's CRU, The Mayor plays golf, goes to the health club regularly and makes the most of every opportunity to enjoy life and socialize.

"You've just got to stay active," says Beres.

It seems the staff of the CRU has taken that advice to heart. "There now are more drug treatment options. Many of these trials are successful, as evidenced by Dan and others like him," says Jones-Lombard. "Our challenge now is that there are many patients who are with us [in the CRU] for a long time. We are running out of space!"

INCREASING VOLUME AND COMPLEXITY

In her 14 years as a clinical research nurse administering treatments in Moffitt's CRU, Jacqueline Pray, RN, said the growth in the number of patients has been the single biggest change. "The volume has increased exponentially, almost year over year."

The nature of her work has changed as well, and that's reflected in Pray's job title. "Over the years we have gone from being called infusion nurses to treatment nurses in the CRU because what we do is not limited to infusion. Treatment can include oral medications, vaccines, all sorts of different things."



Photography: Kevin Kirby

"We call Dan 'The Mayor' because... he is here Monday to Friday every three weeks."



L-R: Clinical research nurses Bucky Jones-Lombard, Jacqueline Pray, Elyce Turba

Photography: Kevin Kirby

Clinical research treatment nurses like Pray also are charged with managing increased complexity, starting with the patients themselves. “Today we are seeing much more complex patients, often after they have been through a number of treatments so they are depleted in a number of ways — a big difference from 2005 when I first joined,” said Pray.

Likewise, the studies also are more complex. “They used to be more straightforward. For example, we would have a pre-dose blood draw and then maybe two or three blood draws after the dosing,” said Pray. Today, it can involve a series of labs before dosing, electrocardiograms, use of multiple agents given by mouth or IV. And the whole scenario must be closely monitored with multiple blood draws through four, eight or even 12 hours of the day. Needless to say, Pray noted, “the labor intensity per patient has gone up.”

Through it all, Jones-Lombard said meticulous attention must be paid to every detail of the study requirements. “If trials are

not done properly, the findings would be off,” she notes, “and if the drug were to be approved, it could be dangerous.” Jones-Lombard said the most unique challenge facing the clinical research treatment nurses is the unknown surrounding the drugs they administer. “Some of this is ‘first in human’ research; no other human being has received this drug before. So, you might think you know what could happen, but you really don’t. It requires a certain amount of bravery.”

For Pray and her colleagues, that bravery is rewarded by being on the cutting edge of the latest treatments. “We have been at the forefront of a lot of treatments that are now FDA standard treatment,” Pray said. It’s especially rewarding to see progress in patients who’ve been “regulars” in the CRU, some of them coming for years. “We get to know them intimately. We know their families, they know about our families,” said Pray. But such connection can also bring heartbreak. “When you become that close to people and things don’t go well for them, you can take it personally.”

“I have a great deal of respect for people who are willing to basically step off a ledge and take a chance.”

AMONG THE COURAGEOUS

Compared to the bravery necessary for nurses to administer new drugs, the courage of CRU patients receiving them is remarkable, said Pray.

“Most of our patients have been through other standard-of-care treatments. Often, they have exhausted their options and a clinical trial is their only other option,” said Pray. “They are not ready to throw in the towel just yet. They are motivated and hopeful. I have a great deal of respect for people who are willing to basically step off a ledge and take a chance.”

That’s what Beres did, though he said his decision to participate in the clinical trial was pretty clear. “It was this or death — not much of a choice!” He would recommend a similar choice for other cancer patients considering clinical trials. “If you have this disease, you gotta fight it somehow. Sometimes traditional things don’t work.”

Beres was quick to add, “This may not help me, but maybe the information you get from me taking this drug is going to help somebody else months or years down the line.” It’s a thought Pray said she has heard countless times from other patients.

“Some of these patients are doing this knowing they may not have a lot of time,” said Pray, “yet they are still willing to give us their time for the possibility that they may help somebody else in the future. It’s incredibly generous and courageous and inspiring.”

“Clinical studies — especially the phase 1 studies — are very important,” said Sokol. “There are so many more drugs available today compared to more than 10 years ago.” He cited the example of the drug Gleevec used to treat certain types of leukemia and other cancers. “We never knew it [Gleevec] would be such a success.” In the late 1990s when a study of Gleevec in patients with chronic myeloid leukemia was conducted, the patients who did not participate in the clinical trial could receive interferon, which improved survival, so not all patients ultimately had to die. If the patients responded to interferon, they could be switched to Gleevec after the drug was approved in 2001 and possibly become cured.



Richard Jasinski, survivor

Photo courtesy of Richard Jasinski

A 10-YEAR LIFESAVER

As battalion chief of the West Manatee Fire Rescue, Richard Jasinski has devoted his life to saving the lives of others.

Diagnosed with Hodgkin lymphoma, Jasinski endured several treatment regimens including a stem cell transplant, but ultimately relapsed. An experimental drug called conatumumab has kept him alive for the past 10 years.

“Had the doctor not recommended that trial, I don’t know where I would be today,” said Jasinski.

Jasinski began treatment with conatumumab in December 2008. As of February 2019, he has had 131 cycles of the drug with no relapse. “I’m blessed every day to be on it,” he said.

“In his case, we were performing personalized medicine by chance,” said Sokol. “Ten years later, we know so much more about targeted molecular therapy that we can attempt to find personalized therapy for individual patients. We need to outsmart the cancer through biologic or targeted therapy. And in some patients, like Rich Jasinski and Dan Beres, study treatment through a clinical trial can be a lifesaver.”

Jasinski remains hopeful. “A lot of people hear the word ‘cancer’ and think it is the end of the world, but it is not a death sentence by any means. There are so many treatments out there for a variety of things. Getting plugged in with the right doctor and the right facility is essential.”

CLINICAL RESEARCH NURSES TREAT THE WHOLE PERSON

Clinical research treatment nurses like Pray tend to the patients throughout their trials while in the CRU. But it takes a different kind of nurse to get them through the door. Clinical research nurses like Elyce Turba, RN, help to get the patient on the trial and to overcome obstacles along the way. “I like the excitement of [working in] hematology clinical trials,” said Turba. “Something new happens every day.”

Although Turba has been with Moffitt for 10 years, clinical research nursing just became a specialty in October 2016. Clearly proud of her profession, Turba says she wants people to know that clinical research nurses treat and care for the whole person. “We aim to be aware not only of the safety of the patients while they are on the clinical trial, but also their spiritual needs, their emotional needs, their social needs — those are the kinds of issues that we are trained to handle on a daily basis.”

Clinical research nursing comprises five separate, yet overlapping, domains:

- Human subject protection
- Care coordination and continuity
- Contribution to the science
- Clinical practice
- Study management

Within these five domains, clinical research nurses focus on maintaining equilibrium between the care of the patient and the integrity of the protocol.

CRU nurses like Pray focus on clinical care and coordination of care. “So we work hand in hand with the CRU team,” said

“We aim to be aware not only of the safety of the patients while they are on the clinical trial, but also their spiritual needs, their emotional needs, their social needs — those are the kinds of issues that we are trained to handle on a daily basis.”

Turba, “as well as in a collaborative nature with the other members of the research team.”

Turba has witnessed positive changes over her 10 years at the cancer center, including better processes like the FDA’s “fast track” efforts to speed some of the newer drugs to market. This is especially helpful when there are limited drugs available for a particular disease.

“It is very detailed; but now that the FDA has set up a process whereby they can expedite drugs that have shown promise and for diseases that have few available treatments, it is extremely encouraging,” said Turba. “Hematology includes a number of rare diseases. It takes a long time to find enough of these patients in order to do a trial with statistical significance at the end.”

Turba said the best part of her “dream job” is seeing FDA approval of a drug that was studied through clinical trials here at Moffitt in patients she has come to know and respect.

The biggest challenge she has seen is the cancer center’s rapid growth. “I want to treat and enroll as many patients as I can on clinical trials, and sometimes we are limited by space,” she said. “I happened to hear Mr. [H. Lee] Moffitt at a Speak Out for Moffitt meeting say that thousands of new patients a year come to Moffitt for treatment. But we basically have the same facilities. When I heard Mr. Moffitt say ‘we’re out of space,’ I thought, ‘Wow! Did he ever dream that this would happen when he came up with the concept of a cancer center in Tampa — that the growth would be so fast?’”

Clearly, hope is in high demand. And through its clinical research efforts, Moffitt will continue doing all it can to deliver.

Editor’s Note: In Fiscal Year 2018, Moffitt saw 23,199 new patients and had 406,117 outpatient visits.

INVESTIGATIONAL DRUG SERVICES PHARMACY



A team of pharmacists and technicians manages the drugs administered to patients participating in clinical trials at Moffitt. Back row, L-R: Jordan Fletcher, Aimee Horn, Anu Pradhan, Angela Jones, Karen Washington. Front row, L-R: Gregori Toselli, Anja Alpendre, Anay Moscu (IDS manager), Walt Harris, Jerry Yoder, Christina Wilburn.

TUCKED AWAY ON THE GROUND FLOOR of the Magnolia campus, the Investigational Drug Services (IDS) pharmacy manages the drugs needed for approximately 300 various early-phase clinical trials administered in Moffitt’s Clinical Research Unit (CRU). These are the life-saving, cutting-edge therapies that offer hope to patients without other treatment options.

“The Investigational Drug Services pharmacy manages investigator-initiated, National Cancer Institute and industry-sponsored trials,” said Anay Moscu, PharmD, who manages the IDS pharmacy. In addition to servicing the CRU, the IDS pharmacy manages dispensing of drugs for inpatients and the BMT treatment center.

The IDS team of seven pharmacists and four technicians develops all treatment order sets, which are approved by the principal investigator for each clinical research study. Considering there are more than 120,000 drugs or biologics-based registered studies worldwide, the work of this team to keep up with the drugs required for patients undergoing trials is quite an undertaking.

“Each study has specific clinical guidelines, compounding, documentation and administration instructions that are verified before each dispense,” said Moscu. Additionally, regulatory requirements involve approximately 450 monitor visits annually



Some of the services provided by IDS include:

- Phase 1-3 studies
- Immunotherapy
- Virus-based and vaccine-based therapies
- Combination tumor-infiltrating lymphocyte (TIL)-cell regimens

to inspect inventory, account for drugs and maintain the sites are ready for audit. Expansion plans underway include updating the IDS and relocating it closer to the CRU.

Clinical Research and Patient Safety

Before a trial can begin enrolling patients, it requires a significant infrastructure and a skilled, dedicated team to ensure all the regulations required to assure patient safety and scientific validity are met.

TRIALS CAN DIFFER IN SOURCES AND TYPE, and Moffitt Cancer Center investigator-initiated trials (IITs) are especially important. As a National Cancer Institute-designated cancer center, Moffitt is charged with conducting IITs, which are designed and managed by the cancer center's clinical faculty.

"Investigator-initiated trials are important largely because through them we are translating laboratory findings to our patients," said Daniel Sullivan, MD, associate center director of Clinical Science. "For example, if we discover a new drug or a new cell therapy, that's good. Or if we identify a molecular pathway that is important in cancer and if a pharmaceutical company has a drug that targets that pathway to interrupt the growth of cancer, that also could be important as an investigator-initiated trial."

In addition to IITs and trials designed by pharmaceutical companies, NCI's National Clinical Trials Network is a collection of organizations and clinicians that coordinates and supports cancer clinical trials at more than 3,000 sites, including Moffitt, across the United States and Canada.

Trials can focus on prevention, supportive care or clinical

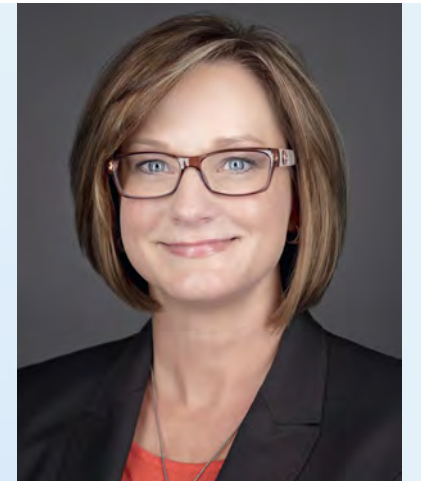
intervention. Usually referred to as clinical trials, clinical intervention trials at Moffitt are designed to test new treatments in people with cancer. These treatments investigate promising new drugs, drug combinations, new approaches to surgery or radiation therapy, and advances in new areas such as gene therapy.

"A clinical intervention trial could be investigating all kinds of things, including chemotherapy, drugs, small molecules or immunotherapies, even devices such as a prosthesis to prevent amputation in children with sarcoma," said Sullivan. The patients who participate in these clinical trials are protected by a rigorous informed consent process. They also are protected by regulations including those placed by the Institutional Review Board's (IRB) Scientific Review Committees and the U.S. Food and Drug Administration (FDA). As an NCI-designated comprehensive cancer center, Moffitt has a Protocol Review and Monitoring System (PRMS) that oversees various committees and boards and ensures all the federal regulations for human subjects' research are met.

"All NCI-designated cancer centers have a Protocol Review and Monitoring System. It might be called something else,

"When we can offer new therapies that allow people to live longer and give them quality of life — that is super rewarding."

Cheryl Byers



"A clinical intervention trial could be investigating all kinds of things, including chemotherapy, drugs, small molecules or immunotherapies, even devices such as a prosthesis device to prevent amputation in children with sarcoma."

but the function is the same," said Cheryl Byers, who directs Moffitt's PRMS, managing a team of people who administer the regulatory aspects of research.

"As an NCI-designated cancer center, we must have our trials reviewed by a Scientific Review Committee to evaluate the science and the statistical components," said Sullivan. This required oversight includes assurance that the research question is clear, the design is proper, the research team is qualified and the analysis is valid.

Another key safeguard, the FDA oversees clinical trials that are testing new medicines or medical devices. The federal agency reviews each trial proposal before any patient testing is performed.

"If one of our clinical faculty creates a trial involving a non-FDA-approved drug, referred to as an investigational new drug [IND], we must apply for and obtain an IND from the FDA, so that's another regulatory step," said Sullivan. "Clearly, you need all of those regulations, and as each trial is conducted, there are annual reviews by the Protocol Monitoring Committee here at the cancer center. There is constant monitoring and auditing of the trial to be sure protocol is adhered to. There

also are annual reports required by the IRB and the FDA. So there are a lot of regulatory requirements, beyond those up-front obligations, that go on throughout the life of the trial."

Another regulatory requirement is having trials pass through an IRB. These boards provide ethical and regulatory oversight of research that involves human participants. And as such, they must have high ethical and scientific standards, with patient protection at top of mind.

Moffitt uses the services of Advarra, an independent IRB, and several others. "A huge advantage of using the services of an independent IRB is the rapid turnaround time," said Byers. "Using an independent IRB improves efficiencies, which helps us activate trials quicker, so we can offer them to our patients as a treatment option."

This faster turnaround time can mean availability of a new drug through a clinical trial for patients who have relapsed and have no other treatment options. Additionally, being able to test a new drug more quickly through clinical trials helps assure quicker approval and availability of an efficient new standard of care. Advarra also has a biosafety committee, in addition to its IRB services.

Challenges of Moffitt's regulatory compliance initiatives include keeping up with the current regulatory requirements, as well as keeping up with changes in best practices, such as newer guidelines that come from federal agencies, notes Byers.

Byers is among the first to say the benefits of this work make the effort well worth it. She happily recalls the very first trials of CART cell therapy and how great it was to see them approved by the FDA. "It is exciting to see that something you were reviewing and on the front end of come to fruition," said Byers. "When we can offer new therapies that allow people to live longer and give them quality of life — that is super rewarding."



"Investigator-initiated trials are important largely because through them we are translating laboratory findings to our patients."

Daniel Sullivan, MD

ABOUT MOFFITT CANCER CENTER

Moffitt Cancer Center in Tampa, Florida, has made a lasting commitment to the prevention and cure of cancer, working tirelessly in the areas of patient care, research and education.

MISSION

To contribute to the prevention and cure of cancer

VISION

To transform cancer care through service, science and partnership

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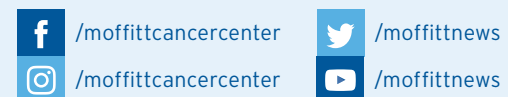
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