

Cancer 360+

FCS

FLORIDA CANCER
SPECIALISTS
& RESEARCH INSTITUTE

SPRING + SUMMER 2016

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World Class Medicine. Hometown Care.

Modern Cancer Treatment is not “One Size Fits All”

Ask your Senators and Members of Congress to stop the Medicare Experiment on Cancer Drugs

The Centers for Medicaid and Medicare (CMS) announced that it plans to “experiment” with alternative reimbursement plans for medications covered under Medicare Part B. If implemented, the CMS proposal could change the way cancer patients receive treatment and restrict patient access to the newest, most advanced treatments. This ill-conceived plan was designed without any input from the oncology community, and it is certainly not in the best interest of our patients. Its consequence could be a shift away from community-based cancer care, forcing patients to leave their doctor and undergo treatment in a more costly hospital setting.

Modern cancer treatment is not a one-size-fits-all approach. This extremely complex disease requires individualized treatment, based on each patient’s unique genetic profile. Our physicians at Florida Cancer Specialists have expressed their deep concerns that the CMS experiment could lead to restrictions on how physicians choose to treat patients, thereby interfering with the sacred doctor-patient relationship.

Medicare beneficiaries represent some of our oldest and sickest patients, people who sometimes require multiple prescription drugs and/or biologics before we find the most effective treatment for them. In fact, two people with exactly the same type of cancer will often respond differently to the same therapy, and appropriate treatment may require combining several types of therapies. These vulnerable patients should not have to face mandatory participation in an initiative that may force them to switch to a treatment that may be less appropriate and potentially less effective for them.

FCS has joined The Community Oncology Alliance, a coalition of over 300 cancer organizations and other healthcare and advocacy groups that are opposed to this “Medicare Experiment.” The COA is leading the effort to reach out to legislators, urging them to stop CMS from instituting this plan.

We are asking physicians to contact their Senators and Congressional Representatives and urge them to consider the health of their most fragile constituents and to do all they can to stop the Medicare Experiment on Cancer Drugs! To take action, go to CancerExperiment.org. There you will find an online form to fill out and email to your elected representatives. (The site includes a link for looking up your legislators.)

Help keep individualized cancer treatments available for everyone who struggles with this disease. Thank you for your support.



Brad Precht
Chief Executive Officer

FCS Cancer 360+

SPRING + SUMMER 2016

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Cancer 360 Plus is published by Florida Cancer Specialists & Research Institute to inform healthcare providers and patients of advances in multidisciplinary cancer treatment. Editorial features are developed in harmony with our goals to optimize health, quality of life and clinical outcomes for cancer patients and their families. Our writers cover a wide variety of topics related to modern advances in medical and radiation oncology, clinical research, coping with cancer treatment side effects, profiles of FCS physicians and researchers, news of our drug development unit and the nonprofit FCS Foundation.

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Publication developed by Consonant Custom Media, 1990 Main Street, Suite 750, Sarasota, FL 34236 (941) 309-5380



Bringing World-Class Cancer Care Close to Home

St. Petersburg attorney Rolfe Duggar and his wife, Jean, have been going to the Mayo Clinic for their annual check-ups for years. And for years, they had been given clean bills of health.

But in 2013, Duggar’s blood tests revealed the presence of multiple myeloma (a cancer formed by malignant plasma cells found in bone marrow), and the Clinic’s patient navigator sent him to Mayo’s Dr. Morie Gertz, one of the world’s experts in multiple myeloma and the man who had treated newscaster Tom Brokaw for the disease. Gertz said that while there was the presence of the disease in the blood, it “was smoldering” and had not yet become active.

In the summer of 2014, that changed. Duggar injured a rib reaching for something and returned to Mayo. After new tests, Gertz explained that the cancer had become active and that Duggar would need to find a community oncologist to coordinate care, because the distance and the expense of travel between St. Petersburg and Rochester made it impractical to be treated at Mayo.

Finding Care Close

Gertz recommended a number of local St. Petersburg oncologists, among them Dr. Michael Diaz of Florida Cancer Specialists. Small world. Duggar and Diaz had known one another for years, having served together on the local St. Petersburg American Cancer Society Board as well as the State Board.

“I called Dr. Diaz and asked if he would work with Dr. Gertz on my case,” Duggar says. “He told me that while the doctors at the Mayo Clinic see hundreds of cases of multiple myeloma a year, a local oncologist would rarely see one” – which is why, according to Duggar, the two men agreed they would be happy to collaborate on his care.

Diaz spent 10 years in an academic environment, having earned his medical degree at the University of Kentucky, completing his internship and residency at the University Medical College of Virginia and a fellowship in oncology



Bringing World-Class Cancer Care Close to Home
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and hematology at the University of South Florida/Moffitt Cancer Center in Tampa. He knows about the differences in treatment provided through community-based care, academic settings and hospitals.

Comparing Community Care to the Academic Center

“Academic centers have unique strengths, particularly in their ability to manage the rare and complex cancers that about 10 to 15 percent of patients suffer from,” Diaz says. “But about 85 to 90 percent of patients have cancers that are common enough that they don’t really need an academic center. Then there are the geographical limitations that can complicate care and make it impractical.

“There’s also the issue of higher costs to the patient, insurance co-pays, and Medicare,” he explains. “Even at local hospitals, costs are considerably more for patients. The administration of chemo in a hospital setting is about 34 percent more than it is at a community-based practice like FCS. The average out-of-pocket cost to a patient getting treatment in a hospital is about \$650 a year more than for a patient in a community clinic.”

Diaz points to a number of other benefits for patients receiving treatment at a community clinic.

“The sheer size of an academic environment can often be overwhelming and impersonal to a patient at a time they most need emotional support. Care at a hospital may put the patient closer to more physicians, but they’re often focused on their internal systems and not on the patient. The community setting is easier for most patients to navigate.” He asks, “Why add complexity to a process that’s already difficult?”

Diaz says that patients having more direct access to their physician in a community oncology clinic’s smaller setting allows for the development of a closer relationship between doctor and patient.

“Community clinics like FCS are run by doctors and staff, not administrators,” he explains, “so they’re not only less expensive, they’re much more patient-focused. That means the doctor is much more involved in every step of the health-care process, and treatment can more easily be tailored to the patient’s specific needs.

“A community oncology practice is most often owned by physicians who are part of the community, so they have a vested interest in optimizing care and satisfaction. In academic and hospital settings, the doctors are employed by the institution and must practice medicine according to protocols set forth by that institution.”

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Rx Delivery + Assistance

The Rx To Go pharmacy delivers specialty oral oncolytic medications to Florida Cancer Specialists patients throughout the state.

Today, thanks to research like that being done at the Florida Cancer Specialists Research and Drug Development Unit, nearly 35 percent of all cancer drugs are available in pill form, many of them for newer targeted therapies that are proving to be highly effective in treatment.

While these new drugs offer patients greater convenience, they do require timely delivery and careful monitoring to ensure patient compliance.

Meeting insurance requirements for these drugs and the high cost of their co-pays can prove to be difficult hurdles for patients who might benefit most from these drugs.

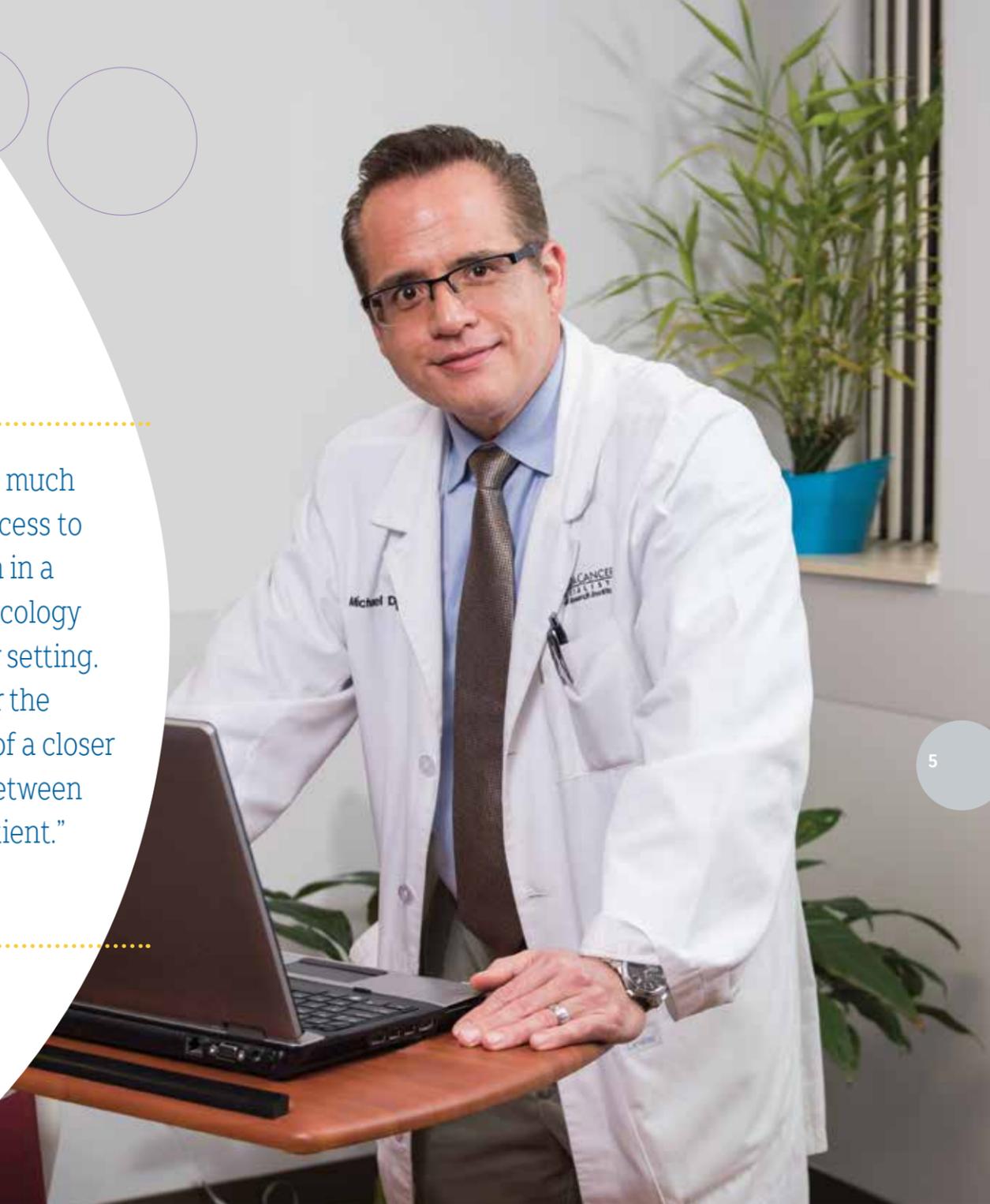
Getting Patients What They Need, When They Need It

The Rx To Go pharmacy specializes in overcoming all of these obstacles. FCS pharmacists have direct access to patient medical records, so they’re able to deliver the right medications directly to our patients or their doctors, wherever they are in the state. They also monitor usage, so if patients forget to re-order, a pharmacist will call to remind them.

Rx To Go has insurance specialists to help provide assistance in dealing with the paperwork that can sometimes make meeting insurance requirements seem overwhelming. Financial counselors are also available to help patients find ways to manage co-pays, sometimes through foundations and grants.

“Patients have much more direct access to their physician in a community oncology clinic’s smaller setting. That allows for the development of a closer relationship between doctor and patient.”

Michael Diaz, MD
St. Petersburg, FL



Michael Diaz, MD

Hometown:
Greenville, Kentucky

Undergraduate School:
University of Kentucky

Medical School:
University of Kentucky

Internship and Residency:
Virginia Commonwealth University
Medical College of Virginia

Fellowship:
University of South Florida
Moffitt Cancer Center

Board Certified:
Medical Oncology, Hematology
Internal Medicine

Board Appointments:
Florida Society of Clinical Oncology (FLASCO):
President
Board Member, Foundation
Legislative Committee, Co-Vice Chairman
Community Oncology Alliance (COA):
Board Secretary
Payment Reform Task Force

Q+A

Through the Lens: 5 Questions with Hematopathologist Dr. Ryan Olson

You can hear in his voice the enthusiasm Dr. Ryan Olson has for his work and the energy he brings to his role as medical director of the Florida Cancer Specialists & Research Institute pathology lab in Fort Myers.

Olson joined the lab in 2011, a year after its opening. He's overseen its growth from a staff of six to 24, a group that now performs about 5,000 biopsies a year. The Pathology Lab, combined with the FCS Central Lab, covers 10,000 square feet of space and serves more than 160 medical oncologists.

We caught up with the new father of twins and took a few minutes to learn more about him, the lab, and the work that he and his team do.

1 Pathologists are "the doctors' doctors." What drew you to pathology?

I was in med school and planning a career in ENT as a head and neck surgeon when I went to the pathology lab to look at the liver biopsy of a patient with auto-immune hepatitis I was writing about.

I ran into my old pathology teacher, David Jones, who asked if I'd ever considered pathology. I hadn't. It's not a core rotation, which means we study it from a book - we really don't experience it. He gave me quite a sales pitch. Within a week I switched from ENT to pathology for my residency.

The scientific investigations we get to do - defining diseases, studying them, doing research - are all part of the appeal. So are the autonomy and freedom from red tape with insurance companies.

The only drawback is that we don't work directly with patients, though we do impact them in a truly significant way.

2 What are the advantages - to referring physicians and patients - of a facility like this?

At FCS, everything is integrated, so communication between the oncologists and us is seamless. We know one another. They know they can reach me by text, email, cell phone, or at the office. If they have a question, if they want to discuss a case, add a test, or need a result quickly, we can accommodate them.

In hospitals, pathologists are more removed. Here, we're directly integrated into the patient's care system. That means their medical records are available to us, so we have unparalleled insight into what the doctor is

concerned about. We always know exactly what we're looking for, and if we don't, we can easily contact the doctor for information.

We also have the backing of the FCS. They support us in making sure we have the personnel and equipment we need to stay on the cutting edge and continually expand our capabilities.

We can usually get back to a doctor within 24 to 48 hours with the results of an innovative test, like flow cytometry that can diagnose and classify certain cancers. In an emergency, we can often get back within hours. With Acute Promyelocytic Leukemia, for example, where hours can mean survival, we can have that diagnosis within hours of receiving a sample. That's much more quickly than a hospital lab can.

3 What are some of the challenges of running such a fast-paced, high-volume lab like yours?

Our challenges are what make us better. For example, there's the volume of work. We do a lot of it, and we do a lot of highly specialized testing. After five years here, I've done as many bone marrow biopsies as my mentor in hematopathology did in 20 years. The entirety of what we do is blood, blood marrow and lymph nodes, as opposed to a generalist who only does a few of them a month. That gives us unequaled experience and expertise.

Then there are the challenges we don't have, because we get tremendous support from billing, compliance, marketing, and the rest of the FCS team. I have a luxury many pathologists working in hospitals don't have - the freedom to devote myself entirely to my work and my staff.

Our facilities and personnel are top-notch, which breeds a real desire for the best in the field to want to work with us. And they do. That's why, when the College of American Pathology inspected us, we received a perfect review.

4 Your lab has been described as state-of-the-art. Can you tell us about how it's equipped?

First, you need to know the work that we do. The pathology lab is made up of three departments: histology, where we examine cells on slides; immunohistochemistry (IHC), where we examine which proteins being produced by cells are healthy and which are cancerous; and FISH (fluorescent in situ hybridization), where testing detects and localizes the presence or absence of specific DNA sequences on chromosomes at the molecular level.

We have a robotic computer that actually takes a slide, puts it under its own microscope and analyzes up to 200 cells per slide. Then a licensed FISH technologist does an analysis. So both the computer and a human being check each cell. If there's a discrepancy in findings, the computer knows the location of every cell, so a correct determination can be made. For IHC, we work directly with Leica Bio

Systems, who provide us with cutting-edge anti-bodies that look for different proteins in the tissue.

In short, every biopsy is being evaluated by a highly trained and experienced pathologist who processes everything using state-of-the-art, cutting-edge techniques and technology.

5 And how about your staff? What is it about them that distinguishes your lab?

Kim Fortunato, our histology manager, and Silvia Fernandez, our flow cytometry manager, deserve much of the credit. They have decades of experience coupled with great expertise. Frankly, they make my life easier, because I can trust and rely on them.

Because we're so specialized and have done so many cases in the last few years, we've gained experience and expertise that most pathologists might not get in a career. +



Offering Hope Now... and in the Future

Clinical Trials at the Florida Cancer Specialists and Research Institute Drug Development Unit Are Finding New Ways to Target Cancers.

Every cancer has its own specific genetic markers. That's led to a search for treatments that target specific cancers, a fact that over the past few years has dramatically changed the dynamics of the clinical trials that investigate new drugs. Today, trials are larger and more accessible through efforts like those at Florida Cancer Specialists, allowing more patients to be able to participate. That's leading to more effective therapies making their way to market faster. The result: Cancer survival rates continue to rise.

As Dr. Manish Patel, director of the Drug Development Unit (DDU) at Florida Cancer Specialists & Research Institute (FCS), explains, "Decades ago, early-phase clinical trials were for patients who had received many prior lines of chemotherapy. Now these trials are focused on targeted populations who have received minimal therapy - so a lot has changed over the past decade, even the past five years."

Dr. Judy Wang, the associate director of the DDU, concurs. "Developmental therapeutics in oncology have just exploded in the last decade. Now we're able to turn survival rates for select cancers that were previously measured in months into survival rates that are measured in years. For some of these patients, disease control can be maintained on a pill a day with an excellent quality of life."

Wang also serves as associate director of Drug Development for the world renowned Sarah Cannon Research Institute (SCRI). FCS is a strategic site for SCRI, which provides program development, contract and financial services, and clinical and regulatory services. The Institute's quality assurance department works with all strategic sites to assist with overall research quality assurance, and it provides good

clinical practice and standard operating procedures development.

In the five years since Patel joined FCS, he's grown the Sarasota DDU from himself and a staff of two to a highly sophisticated team of nearly 20, and there are now more than 40 active early-phase clinical trials, with over 170 participants. About a third of the trials are for hematology cancers, the other two-thirds for solid tumors. This focus on advancing therapies has led to the approval of several targeted and immunotherapies, and many more are expected soon.

"Being able to provide early access is very gratifying," Patel says. "It's an amazing feeling to see a patient respond, especially if they haven't responded to prior therapies."

Trials Close To Home

Historically, patients would only have access to Phase 1 clinical trials at large academic centers. But because of the size and scope of the FCS practice, that's no longer the case. Indeed, so broad is the scope of the drug development unit's program that between 10 and 15 percent of its participants are referrals from academic centers, and many of the trials the DDU has conducted have been cited in papers presented at national and international conferences.

While being an FCS patient gives a patient access, it isn't necessary for someone to take part in a trial. The patient's referring physician, an FCS physician and the DDU staff ultimately decide whether someone is eligible to participate.

"There's no difference between the trials we're conducting and what's done at academic centers,"

Patel explains. "What is different is that treatment happens where patients live. They don't have to travel and can continue treatment with their referring oncologist."

Avoiding the expense and inconvenience of
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"Being able to provide early access is very gratifying. It's an amazing feeling to see a patient respond, especially if they haven't responded to prior therapies."

Manish Patel, MD
Director, Drug Development Unit
Florida Cancer Specialists

Learn More

Learn more about clinical trials, why and how they're conducted, what's involved in participating, and more about insurance and Medicare costs, as well as the specific research being conducted by the FCS DDU. Contact your oncologist, talk to a member of our research team at (239) 274-9930, or visit us at FLCancer.com/ClinicalTrials

Search for Ongoing Trials

Referring physicians and patients can search for ongoing clinical trials by cancer type, clinic location and other filters by using the FCS Trial Navigator. Visit FLCancer.com/TrialNavigator

Late-phase research is available at more than 30 strategic FCS locations throughout the state.

70%
Of the new cancer drugs approved for use in the United States in 2015, 70 percent were studied in clinical trials conducted with FCS participation.*
*Prior to approval





1 Dr. Michael Diaz serves a second term as president of the Florida Society of Clinical Oncology. FLASCO, recognized as one of the top state societies and committed to promoting excellent patient care, leads efforts to respond to policies and legislation that effect quality cancer patient care. Diaz practices in two FCS offices in Pinellas County and serves on the FCS Executive Board. (Read more about Dr. Diaz on p. 5.)

2 Dr. Lucio Gordan accepted an invitation to serve on the editorial board of the Journal of Clinical Oncology - Clinical Cancer Informatics, a global online journal published by the American Society of Clinical Oncology that disseminates significant clinical oncology research. Gordan, a Gainseville Center physician, serves on the Executive Board of FCS and as Medical Co-Director of Health Information Technology.



3 Dr. Rasha Beg has joined FCS and will serve as a hospitalist for FCS patients who require hospitalization at Florida Hospital Deland, Central Florida Regional Sanford, and Florida Hospital Fish Memorial in Orange City. Beg will be working directly with FCS physicians and Electronic Medical Records system to continue patients' treatment plans while they are in the hospital.

FCS Foundation's Time to Remember Fundraiser

4 The 500 guests at the Motown-inspired Time to Remember FCS Foundation fundraiser had the opportunity to meet Martha Reeves, First Lady of Motown, and hear an outstanding performance of classic favorites by Martha and the Vandellas. Bidders at the live auction, inspired by a poignant video of how one cancer patient received vital help with living expenses, raised over \$1.2 million - funds that will help the most vulnerable FCS patients through treatment to recovery.



Leukemia & Lymphoma Society Chapters Honor FCS Physicians as Man/Woman of the Year

5 Dr. Meera Iyengar and Dr. Vipul Patel were named Woman/Man of the Year by the Central Florida chapter. Dr. Iyengar sees patients in Clermont and downtown Orlando, and Dr. Patel practices in Inverness and Ocala.

6 Dr. Julia Cogburn was named Woman of the Year by the Suncoast chapter. Dr. Cogburn, who practices in Tampa and Brandon, is shown with (L-R) the chapter's 2016 Boy of the Year, Carlos Hernandez, Man of the Year, Daniel Chinaese, and Girl of the Year, Marissa Peddie.

The FCS physicians conducted spirited campaigns to raise funds for blood cancer research, raising a combined \$308,000.



Helping for the "Here + Now"
While patients battle their cancer, the FCS Foundation helps them combat their bills.



The call came to Client Services Coordinator, Jessica McIntyre, at the Florida Cancer Specialists Foundation, the day before Christmas.

"After the usual season's greetings, I asked how everything was going," Jessica recalls. "There was a slight pause before the patient suddenly broke down. He told me that his family had lost their home, car, everything. They were now living in a rental car with their 16-year-old. He was begging for help."

"In between my own tears, I spent the morning on the phone getting them emergency shelter. Then I went to work on getting them a car, so getting to treatment need not be yet another worry."

Valerie Vance, the Foundation's Executive Director, picks up the story.

"While this kind of intervention isn't something we typically do, it is an example of the compassion and care patients find at the Foundation and how we continually support them," she says. "We don't want them to worry about money. We want them to concentrate on their treatment and on getting better. We believe that by helping, we facilitate the work of their referring and treating physicians. That's why other treatment centers, oncologists and physicians throughout the state refer patients to us."

Caring As Well As Curing

Established in 2011 as a 501(c)(3) organization by FCS doctors to help those battling cancers throughout the state - whether they are FCS patients or not - the Foundation's mission is to help with the financial strains the undergoing treatment may worsen.

"We establish an account of \$1,500 to help with rent, mortgage and car payments, as well as utilities, for patients who qualify. They decide what they want to use the money for, submit their bills to us, and we make the payments for them," Vance explains.

Initially, the practicing partners of FCS contributed \$500,000 to seed the Foundation in order to pay all its operating expenses, so that 100 percent of donations could be used to directly help patients. The doctors continue to make payroll deductions to maintain the Foundation's philanthropic mission, and many make additional contributions to supplement money raised by donor contributions. The Foundation also holds a number of truly spectacular fundraising events during the year, overseen by Development and Event Manager Terri Gagliardi (see Sidebar).

The result of the Foundation's efforts: In addition to a flourishing volunteer program, nearly 600 people received over \$600,000 in grants in 2015 - up nearly 20 percent from 2014 - to help defray their financial expenses as they wage their brave battles against cancer. +

Eligibility

To qualify for a grant, a patient must:

- Be 18 years of age or older
- Be a current resident of the state of Florida
- Have an annual combined household income at or below 200% of the national poverty level
- Be actively receiving cancer treatment in Florida

How to Apply

- Applications are available on the Foundation's website at Foundation.FLCancer.com
- FCS Financial Counselors can help patients apply
- Contact Client Services at 941-677-7181
- Email us at Foundation@FLCancer.com

Upcoming Events

Contact the Foundation for details and tickets. Visit Foundation.FLCancer.com.

- 10/8/16** 50 Shades of Awesome Pink Grand Hyatt, Tampa
- 10/30/16** Hope "Fore" Our Heroes Golf Tournament
Ritz-Carlton Grande Lakes Orlando Golf Club
- 11/17/16** Wine, Women & Shoes Westin, Lake Mary
- 1/28/17** Party Under the Stars 6-9 pm
Venue TBD, Sarasota



Bringing World-Class Cancer Care Close to Home

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Tailoring treatment might mean participation in a clinical trial. Dr. Diaz is quick to dispel the misconception that clinical trials are only available at large institutions.

"That's just not the case," he says. "Clinical trials are available to patients being treated at the FCS community clinics."

According to Diaz, there are also advantages for referring doctors, including better tailoring and coordinating of care in conjunction with the referring physician, because communication is more easily facilitated in a community setting.

Getting Better, Going Forward

Since the diagnosis, Duggar has continued to receive treatment from Dr. Diaz in St. Petersburg. He comes into the office twice a month for bloodwork and infusions and sees the doctor once a month. Over the course of the year, Duggar's M Spike blood test, a marker of the

disease's aggressiveness, has gone from a dangerous 3.5 to a near-remission level of .3.

"When I returned to the Mayo Clinic in late October of 2015, Dr. Gertz told me that he was very pleased with my progress, with the treatment I was getting from Dr. Diaz, and with their working relationship. Indeed, when Dr. Diaz had recommended lowering the dosage of my meds, Dr. Gertz agreed," Duggar says.

"Dr. Diaz is very personable and easy to talk to. When I have a question, I get a quick response. He takes the time to explain different concepts and exactly what's going on. It's just been a delight working with him.

"The convenience of having someone like Dr. Diaz nearby is terrific. But the big added benefit of being treated here is what it has meant emotionally. To be close to home, close to my wife, to my work, and to my support system of friends and family has made an incredible difference." +

Offering Hope Now... and in the Future

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traveling aren't the only advantages for patients participating in community-based Phase 1 trials, according to Patel. There is no extra cost to patients, because the pharmaceutical companies pay for the drugs.

But benefits can't be measured in dollars alone. It's about treating patients where they're most comfortable.

"What's done in the community is more efficient and more personal," Patel says. "There are relationship advantages between doctor and patient in a community environment, because patients can still see their own oncologist. Patients feel closer to their support systems in their own community. When they go to an academic center, they lose that characteristic of care." +



Age-Adjusted Cancer Incidence Rates By Cancer Site (2008-2012)

All Cancer Sites: USA **453.8** FL **434.9**

Prostate	131.7	Colon & Rectum	39.2
118.9		41.9	
Breast	115.2	Uterus	22.5
123.0		25.3	
Lung & Bronchus	64.6	Melanoma of the Skin	19.8
63.7		19.9	

Cases per 100,000 population per year
Source: National Cancer Institute/CDC, State Cancer Profiles

Florida Cancer Specialists & Research Institute (FCS), founded in 1984, is the largest independent medical oncology/hematology practice in the United States, with over 200 physicians, 150 nurse practitioners and physician assistants, and 90 locations. FCS delivers world-class cancer care in community-based settings, providing innovative clinical research and cutting-edge technologies that help advance targeted treatments and genetically-based immunotherapies.

FCS serves patients on the Gulf coast from Naples to Tallahassee, in central Florida communities, and on the east coast from Daytona to Palm Beach County.

For a listing of locations, helpful information about your first visit, and other patient resources, visit FLCancer.com.