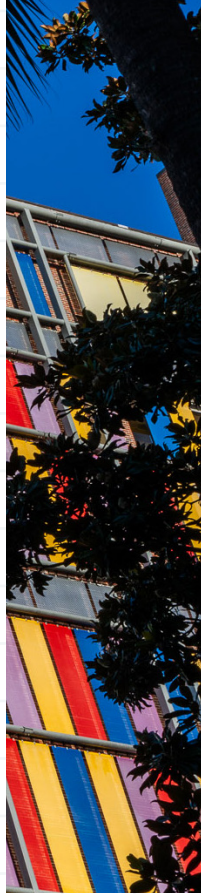




2025



**UF** | College of Medicine  
UNIVERSITY of FLORIDA

# Annual Report

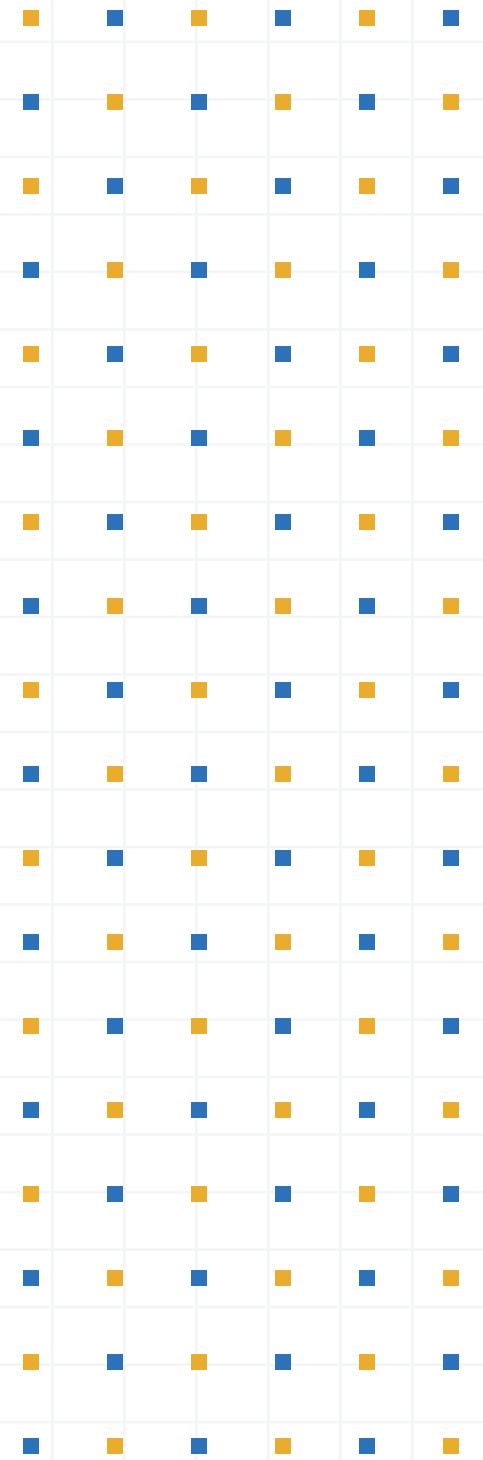
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Prepared for



**Stop Children's Cancer**





# Inside this Report

## Page two

From the interim chief

## Page eight

Clinical trials update and highlights

## Page ten

Patient story — Heart of a nurse, love of a mother

## Page thirteen

Breakthrough news — Cancer has a Gator problem

## Page four

Division of Pediatric Hematology and Oncology update

## Page nine

Stop Children's Cancer, Inc. return on investment summary & clinical trials update

## Page twelve

COG registry — Project:EveryChild

## Page sixteen

UF Health Cancer Center is now an Institute



# Interim Chief

**Joanne P. Lagmay, MD**  
Interim Chief, Division of Pediatric Hematology & Oncology

Joanne Lagmay, MD is the Interim-Chief of the Division of Pediatric Hematology and Oncology at the University of Florida College of Medicine and a nationally recognized leader in pediatric and adolescent/young adult (AYA) sarcoma care. She provides

comprehensive, multidisciplinary care for children and AYAs with complex bone and soft-tissue cancers, grounded in both clinical excellence and deep compassion for patients and families.

As Chief, Dr. Lagmay leads the division's vision to grow UF Health as a national destination program for pediatric and AYA cancer care, advancing innovative therapies while ensuring access to high-quality, family-centered care across Florida and beyond. Her leadership focuses on strengthening clinical programs, expanding early-phase and investigator-initiated clinical trials, and building sustainable infrastructure to

support discovery, workforce development, and long-term impact.

Dr. Lagmay's research integrates early-phase clinical trial design through the Children's Oncology Group, pediatric and AYA immunotherapy, and translational collaborations across UF Engineering, Veterinary Medicine, Chemistry, Materials Science & Engineering, and Radiation Oncology. Her work includes design of early phase clinical trials in osteosarcoma and pioneering efforts in liquid biopsy and circulating tumor cell technologies for pediatric bone sarcomas, accelerating the translation of scientific discovery to the bedside. She has deep and ongoing collaborations in the AYA cancer research and pediatric palliative care.

Central to Dr. Lagmay's leadership is a commitment to aligning innovation with compassion —ensuring that scientific progress directly improves the lives of children and families facing cancer. Her partnership with philanthropic supporters is foundational to this mission, enabling transformative growth in care, research, and hope for patients throughout the region.

# Words of Gratitude

On behalf of the University of Florida College of Medicine and the Division of Pediatric Hematology and Oncology, thank you for your continued generosity and steadfast commitment to children with cancer. We are profoundly grateful for your philanthropic support and for the trust you place in our shared mission. Your belief in our work allows us to stand with children and families during some of the most difficult moments of their lives — and to do so with compassion, excellence, and hope.

Your partnership plays a vital role in advancing the care, research, and support we provide to patients and families across Florida and beyond. Because of you, our dedicated and highly skilled team is able to deliver innovative, specialized pediatric cancer care and to continually raise the standard for what children and adolescents facing cancer can expect from their care team. National recognition of our program reflects this commitment and underscores the indispensable role of philanthropic partners such as Stop Children's Cancer in making this level of care possible

Importantly, your investment serves as a catalyst for progress. Your generosity enables us to pursue bold ideas, respond quickly to emerging opportunities, and build the people and infrastructure required to translate discovery into care. It also strengthens our ability to attract additional philanthropic partners, secure

competitive research funding, and develop sustainable programs that accelerate progress toward better outcomes for children and adolescents with cancer.

We are honored to share this 2025 Impact Update as a reflection of what your partnership makes possible. Thank you for standing with us, for believing in our shared mission, and for your unwavering dedication to improving the lives of children and families when it matters most. As we look ahead, your partnership remains foundational to our vision of a nationally leading, compassionate, and innovative pediatric and AYA cancer program — one that expands access, advances cures, and ensures exceptional care for every child, without exception.

With sincere appreciation,



Joanne P. Lagmay, MD  
Interim Chief, Division of Pediatric Hematology & Oncology  
STOP! Children's Cancer of Palm Beach County, Inc. Professor in  
Pediatric Oncology, Department of Pediatrics  
University of Florida College of Medicine

# Division Update



Turning discovery into hope  
What your generosity makes possible

## Program growth and national impact

### Growth, stability, and national standing

Because of Stop Children's Cancer's philanthropic partnership, UF Health's Division of Pediatric Hematology and Oncology continues to grow with intention, stability, and national impact. Your investment strengthens not only today's care, but the long-term foundation required to serve children with cancer across Florida and beyond.

### National recognition

UF Health Shands Children's Hospital's pediatric cancer specialty program is ranked No. 1 in Florida and No. 36 nationally, reflecting continued upward momentum and sustained progress among pediatric cancer programs across the country.

### Faculty, workforce, and program capacity

- Recruited two new full-time pediatric oncology faculty

- Added one pediatric psychologist and one clinical nutritionist, reinforcing whole-child, family-centered care
- Leadership transition planning underway:
  - Strategic recruitment of additional leukemia/lymphoma faculty to sustain one of our largest and most complex services
  - Dr. Joanne Lagmay appointed as incoming Division Chief
- Dr. Jordan Milner was recognized as the 2025 Physician of the Year by the UF Health Cancer Institute
- Advanced Practice Provider workforce stabilized, ensuring continuity of care

### Training the next generation

Under the leadership of Dr. Brian Stover, the fellowship program matched a full complement of trainees, creating a strong pipeline of pediatric hematologist-oncologists at a time of national workforce shortage. These fellows will carry forward the clinical excellence and research innovation made possible through philanthropy.

## Expanding access across Florida

- Pediatric oncology satellite clinic in Tallahassee opening soon
- Planning underway for expanded presence in Ocala

**Goal:** bring specialized pediatric cancer care closer to home, reducing travel burden and keeping families together during treatment

**Bottom line:** Your support builds durable capacity — people, programs, and access.

## Research that reaches children

### From discovery to first-in-human trials

Stop Children's Cancer funding plays a critical role in moving breakthroughs from the laboratory to the clinic — bridging the space where many promising ideas otherwise stall. This support allows researchers not only to discover new treatment strategies, but also to translate them into real-world options for children who urgently need them.

A key part of this process is first-in-human clinical trials. These trials involve treatments that have never before been used in people. For children enrolled, this means access to a truly novel therapy — one that has not been offered anywhere else in the world. Reaching this stage requires years of laboratory research, rigorous safety testing, and careful regulatory preparation, all of which depend on sustained funding.

However, recent funding cuts are creating significant delays. They are slowing the opening of new clinical trials and limiting how quickly new treatments can be offered to children with different types of cancer. At the same time, reduced resources in the laboratory are narrowing the pipeline of future therapies, meaning fewer discoveries are able to progress toward clinical testing.

Continued donor support is essential to keep this pipeline moving — ensuring that innovative ideas do not remain confined to the lab, but instead reach the children and families who are waiting for new hope.

### 2025 philanthropic investment summary

- \$150,000 — Stop Children's Cancer/Bonnie R. Freeman Clinical Trials and Innovative Therapies Program Fund (see page seven)
- \$100,000 — Lyrics for Life/Stop Children's Cancer Jeffrey A. Block Research Fund (see page six)
- \$50,000 — Stop Children's Cancer/Kimberly H. Flaitz Research Grant (precision sarcoma vaccine research) (see page six)
- \$2.5M Endowment — Stop Children's Cancer/Bonnie R. Freeman Professor for Pediatric Oncology Research (see page five)
- Stop Children's Cancer Samuel and Ina Gross Memorial Lectureship Endowment — In 2025, we welcomed Dr. Jeffrey Toretzky as our guest lecturer. Dr. Toretzky is the leader of the molecular oncology program and the chief of pediatric hematology oncology division at Georgetown.

### 2025 breakthrough areas advanced

**mRNA cancer vaccines:** Dr. Elias Saylor is developing a new kind of cancer treatment called an mRNA cancer vaccine, which works by teaching the immune system how to recognize and attack cancer. In simple terms, the vaccine delivers a set of instructions — made of messenger RNA — that tells the body to briefly produce harmless markers that resemble a patient's cancer. These markers act like a "wanted poster," alerting the immune system that cancer cells are dangerous and should be eliminated. Unlike chemotherapy, which attacks both healthy and cancer cells, this approach aims to direct the body's own defenses precisely at the tumor. Dr. Saylor's research has shown that mRNA vaccines can act not only as a personalized guide — tailored to an individual patient's

tumor — but also as a powerful immune wake-up call, helping the immune system respond more strongly to cancer overall. Early studies, including first-in-human trials for aggressive brain tumors, suggest this strategy can trigger robust immune responses with the potential for longer-lasting control of cancer.

For donors, this work represents a paradigm shift: leveraging the same mRNA technology that transformed infectious disease care to create smarter, more targeted, and potentially life-saving cancer treatments for children and adults who urgently need new options.

**CART T-cell and immune therapies:** CART T-cell therapy is a cutting-edge treatment that turns a patient's own immune system into a precision cancer-fighting force. In the simplest terms, doctors take a sample of a patient's white blood cells — specifically the T cells, which are the body's natural defenders. In the lab, scientists re-train those T cells so they can better recognize cancer by equipping them with a special "sensor" on their surface called a Chimeric Antigen Receptor (CAR). This receptor acts like a GPS: it guides the T cells directly to the cancer cells. Once infused back into the patient, these engineered CAR T cells seek out and destroy cancer cells with remarkable precision, much like a trained search-and-rescue team finds its target. The power of CART T-cell therapy lies in its ability to offer long-lasting protection. After the modified T cells are infused, they can multiply and patrol the body for months or even years, continuing to guard against cancer's return. Early results in blood cancers have been dramatic, leading to durable remissions in patients who had few other options. Dr. Castillo's work is focused on expanding this promising approach to more types of cancer, especially those that have been stubbornly resistant to traditional treatments.

For donors, supporting this project means advancing a therapy that

doesn't just fight cancer — it empowers the patient's own immune system to win the battle, offering hope for deeper, more sustained cures.

**Stem cell transplant innovation and gene therapy:** Gene therapy for sickle cell disease is a groundbreaking approach that aims to fix the root cause of the disease, rather than just treating its symptoms. Sickle cell disease is caused by a single error in a person's DNA that leads red blood cells to become hard, sticky, and sickle-shaped, blocking blood flow and causing severe pain, infections, strokes, and organ damage. In gene therapy, doctors collect a patient's own blood-forming stem cells and, in a highly specialized laboratory, genetically correct those cells. This is done either by repairing the faulty gene or by switching on a healthy form of hemoglobin — the oxygen-carrying protein in red blood cells — that people naturally have before birth. Once corrected, these cells are returned to the patient, where they can take root in the bone marrow and begin producing healthy red blood cells. The promise of gene therapy is profound: it offers the possibility of a one-time, potentially curative treatment using the patient's own cells, eliminating the risk of rejection and freeing patients from a lifetime of pain crises, hospitalizations, and shortened life expectancy.

For donors, investing in gene therapy for sickle cell disease means supporting a future where children and adults are no longer defined by this inherited illness — but instead can live full, healthy lives with the disease truly left behind.

### **National and scholarly impact**

Research supported through philanthropy has resulted in landmark publications in *Cell*, *Nature*, *Nature Medicine*, and *Nature Biomedical Engineering*, positioning UF Health as a national leader in pediatric cancer immunotherapy.

## Research leadership highlights

### Dr. Elias Sayour

- Dr. Sayour is supported by the Stop Children's Cancer/Bonnie R. Freeman Professor for Pediatric Oncology Research
- UF Innovator of the Year (two consecutive years)
- Top 10 Clinical Achievement, Clinical Research Forum
  - The Clinical Research Forum (CRF) is a highly respected national organization made up of leaders in academic medicine, biomedical research, and translational science across the United States. Its members include physician-scientists, research deans, NIH leaders, and senior investigators from major academic medical centers whose work focuses on turning scientific discoveries into real treatments that improve patient care. In short, this is a community of people who shape what the future of medicine looks like. Each year, the Clinical Research Forum selects its Top 10 Clinical Research Achievement Awards, which recognize the most impactful clinical research advances in the nation — work that has already changed, or is clearly poised to change, how patients are diagnosed, treated, or cured. These are not early or speculative ideas; they are practice-changing breakthroughs with strong evidence and real-world implications. Past awardees include discoveries that led to new cancer therapies, gene therapies, vaccines, and life-saving diagnostic tools. Receiving a Top 10 award places a project among the most important clinical research achievements in the U.S. for that year. It signals that the work is innovative, rigorous, and nationally influential, and that it stands out even among elite academic institutions.
  - For donors, a CRF Top 10 designation is a powerful

external validation: it means the research you are supporting is not just promising — it is recognized by national experts as transformational science with real impact on patients' lives.

- 10 high-impact publications (2025–2026)
- International recognition for transformational work in mRNA cancer immunotherapy:
  - Redefined cancer vaccines by demonstrating nonspecific mRNA as a universal immune activator
  - Repurposed validated COVID-19 mRNA platforms for cancer treatment
  - Overcame immunotherapy resistance in aggressive brain tumors
- Why this matters:
  - Broad applicability across tumor types
  - Faster translation to patients
  - Paradigm-shifting credibility within the global scientific community

### Dr. John Ligon

- Next Gen Scholar, Blood and Marrow Transplant Clinical Trials Network
- 2025 Rising Star of the Year, UF Health Cancer Institute (UFHCI)
- Assistant Director for Translational Research, UFHCI
- Six publications and multiple national invited lectures

### Dr. Paul Castillo

- Supported by, Lyrics for Life/Stop Children's Cancer Jeffrey A. Block Research Fund, Dr. Castillo has:
  - 12 publications, including 7 high-impact journals
  - Secured funding for CD70 CART T-cell therapy targeting AML and other hematologic malignancies

## Clinical translation

- Supported by the Stop Children's Cancer/Kimberly H. Flaitz Research Grant, first-in-human RNA nanoparticle vaccine trials enrolling in osteosarcoma
  - The Kimberly Flaitz Research Grant is invested in advancing research on Ewing sarcoma, a rare and aggressive childhood cancer. This work focuses on identifying and targeting the specific genes that drive this disease, allowing scientists to understand why the cancer forms and how it grows. By zeroing in on the genetic "on-off switches" that fuel Ewing sarcoma, this research aims to develop smarter, more precise treatments — therapies designed to attack cancer cells while sparing healthy tissue. For donors, this investment supports science that moves beyond one-size-fits-all treatment toward targeted approaches with the potential for better outcomes and fewer side effects for children and young adults facing this devastating cancer.
- National leadership in immunotherapy trials for glioblastoma, DIPG, and relapsed osteosarcoma
- Phase III universal cancer vaccine trial launching imminently

## Why your philanthropy matters now

Philanthropy transforms ideas into treatments that reach children today. Because of you, **children with high-risk cancer can receive advanced therapies without leaving Florida**. This work requires courage — and partnership — to change what is possible.

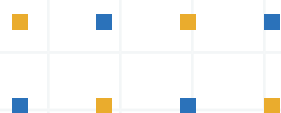
## 2025 clinical trials update

- 53 clinical trials were open during the year for patient enrollment.
  - 9 – investigator initiated treatment studies which are written by UF COM scientists.
  - 1 – UF PHO Biobank that collects samples for use in the research labs of Dr. Castillo, Dr. Ligon, Dr. Lagmay and Dr. Lamba.
  - 2 – late effect and supportive care studies to evaluate late effects of cancer therapy including earlier diagnosis and prevention.
  - 15 – Phase I or II studies for patients with relapsed or refractory disease – including all nine investigator initiated trials.
- 14 trials that we participated in were closed due to complete enrollment or slow enrollment.
- 3 trials are currently being developed with plans to open before the end of the third quarter of 2026.
- 95 patients screened for participation in one or more clinical trials. Patients may participate in a registry, biology study and/or treatment.
- 19 patients were enrolled in a treatment clinical trial.
- 70 patients were enrolled in a biology and/or registry study.

## 2025 clinical trials highlights

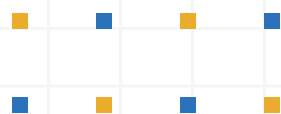
- 9 investigator initiated trials focused on treatment for leukemia, relapsed/refractory sarcoma, and relapsed/refractory brain tumors which enrolled 10 subjects.
- 60% of our trials are Phase I or Phase II trials
- Growing diversity of clinical trial sponsors
- Collaborating can result in support for UF investigators to develop multi-center trials that allow more patients access to early phase trials. These three trials are examples of our efforts:
  - Beat Childhood Cancer – Dr. Duane Mitchell is one of Study Chairs for BCC017 trial
  - Pediatric Neuro-Oncology Consortium – Dr. Ashley Ghaseddin and Dr. John Ligon are the National PIs for PNOC020 trial
  - National Pediatric Cancer Foundation – Dr. Ligon is the National PI for MCC23450 trial

# Return on investment Summary



Stop Children's Cancer's support  
has made it possible for the  
UF College of Medicine  
to attract further funding  
amounting to

**\$20,875,083**



<b>&lt;2016</b> <b>\$3,730,369</b>	<b>2016</b> Clinical Trials = 77 Accruals = 82 Publications = 6	<b>2017</b> Clinical Trials = 86 Accruals = 89 Publications = 7
<b>2018</b> Clinical Trials = 91 Accruals = 129 Publications = 12	<b>2019</b> Clinical Trials = 98 Accruals = 191 Publications = 18	<b>2020</b> Clinical Trials = 99 Accruals = 135 Publications = 18
<b>2021</b> Clinical Trials = 108 Accruals = 142 Publications = 22	<b>2022</b> Clinical Trials = 97 Accruals = 113 Publications = 26	<b>2023</b> Clinical Trials = 86 Accruals = 146 Publications = 16
<b>2024</b> Clinical Trials = 102 Accruals = 168 Publications = 21	<b>2025</b> Clinical Trials = 93 Accruals = 86 Publications = 27	

**Notes:**

- Dollar amounts reflect additional funding received due to Stop Children's Cancer direct funding.
- Prior to 2016 dollars reflect funding to Dr. Parker Gibbs, Dr. David Muir and Dr. Mingli Yang.
- Grants and clinical trials that were open prior to 2016, but active in that year are counted in the 2016 numbers.
- Funding is based on NCI guidelines of annual cancer-relevant direct costs and pulled from the annual funding data table.

- Clinical trials are all clinical research projects of which the faculty member is the PI.
- Accruals are from all clinical research projects the faculty member is the PI of, regardless of who puts the patient on the trial.
- Lower accrual numbers are reflective of not having a standard risk or high risk B-ALL leukemia trial open since August 2024. That disease makes up for a large proportion of new patients, and when the results of the study drug Blinatumomab came out, both trials were closed to accrual.

# Patient Story

## Heart of a nurse, love of a mother Taylor Smith, RN, brings compassion to both worlds

As both a UF Health Shands team member and the mother of a patient, Taylor Smith, RN, sees UF Health as more than a workplace — it's part of her family's story. Taylor has served in the UF Health Shands ER since 2018 and became an ER coordinator in 2021, a role she loves. Both of her children were born at UF Health Shands, strengthening her trust in the people and the place she calls home. Her dual perspective as a nurse and a mother became even more significant when her son's health took a sudden turn.

Taylor's son Ezra was 5 years old when everything changed. In February of 2025, he started complaining of leg pain. His pediatrician reassured Taylor that it was probably just growing pains. When he developed a fever, the explanation was the same — he was just fighting off viruses. As both a nurse and a mother, Taylor tried to accept those answers.

Not long after, Taylor left for Africa, where she spent nine days teaching with a nonprofit. When she returned home, she immediately sensed something was wrong. Ezra looked thinner, and the way he walked was different, unlike himself. The next morning,



she woke up to him calling for her. She found him in a sweat, with unbearable leg pain, and he was unable to walk.

Taylor took him straight to UF Health Shands Pediatric ER. There, doctors found he had blue cells in his marrow — an indicator of cancer. Ezra was admitted to UF Health Shands Children's Hospital Unit 44. She remembers how she got the news. Nancy Joseph, MBBS, FAAP, quietly wrote the results on a sticky note before embracing and supporting Taylor as she broke down. That small act of compassion stayed with her.

Ezra was soon moved to the children's hospital Pediatric Hematology/Oncology Unit 42, a place Taylor describes as "its own little family." The nurses know every patient's name, along with their preferences and routines. Taylor often said she was sure they could even remember Ezra's favorite color if asked.

Another team member who made a huge impact was child life specialist Madelyn Christian. From the start of the diagnosis,

Christian and Ezra have been inseparable, “besties,” Taylor said. Any time an appointment comes up, Ezra doesn’t complain or resist. He only wants to know one thing: “Is Ms. Maddie going to be there?” Taylor believes wholeheartedly that Ezra’s healing wouldn’t be the same without Christian and the Child Life Program.

Balancing life as both a mom and a nurse has been one of Taylor’s hardest challenges, but the surrounding teams at UF Health have helped her through every step. From the moment Ezra received his diagnosis to the nights when Taylor stayed at the hospital with him before heading straight into her shift the next morning, her team in the adult ER was always there. They were supportive, aware and incredibly considerate. Their understanding gave her room to breathe. Taylor also knew she could go in for her shifts, trusting the teams across the street would care for Ezra in the best way possible.

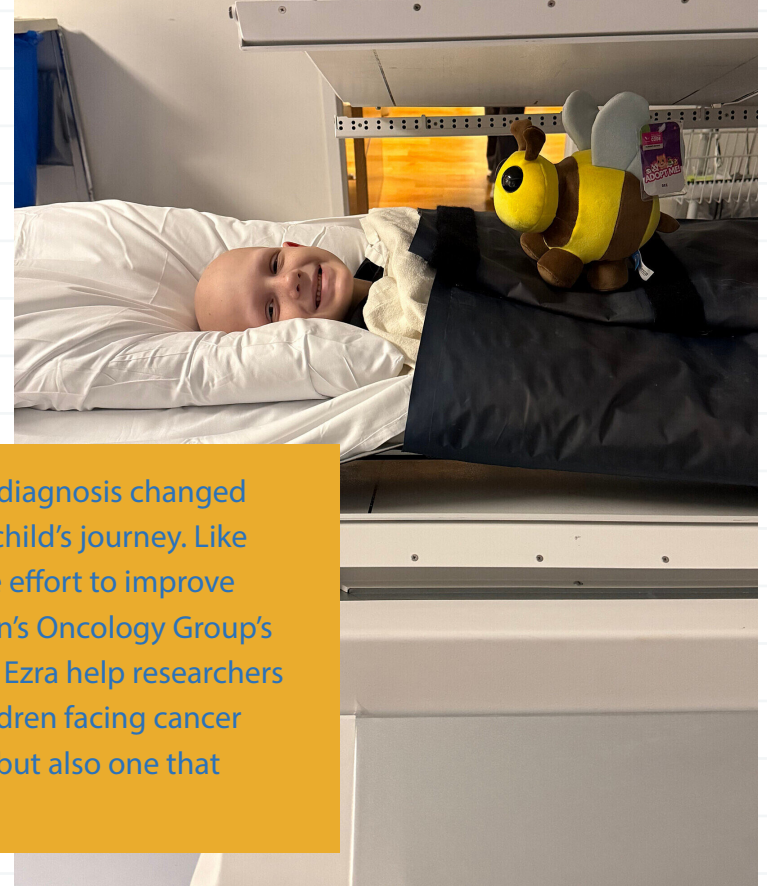
Through it all, Taylor’s gratitude is immense. She is deeply thankful for the pediatric ER, adult ER, the Pediatric Hematology/Oncology team on Unit 42, the child life specialists and everyone in between who has cared for their family with unwavering compassion and support. In every step of this journey, Taylor and Ezra have drawn strength from each other — and from the UF Health family that has held them up along the way.



**Ezra with Madelyn Christian, a child life specialist**

# Project: EveryChild

When Ezra arrived at UF Health Shands as a five-year-old who could no longer walk, his diagnosis changed everything for his family — but it also connected him to something far larger than one child's journey. Like thousands of children diagnosed with cancer each year, Ezra became part of a collective effort to improve how childhood cancer is understood, treated and ultimately cured. Through the Children's Oncology Group's Project:EveryChild registry, the experiences, data and biological samples of patients like Ezra help researchers uncover patterns, refine therapies and build the foundation for better outcomes for children facing cancer now and in the future. Ezra's story is not only one of compassionate care and resilience, but also one that contributes to advancing the science that will shape tomorrow's cures.



The Children's Oncology Group maintains a childhood cancer registry of infants, children, adolescents, and young adults with cancer called Project:EveryChild, which supports current and future therapeutic clinical trials and the discovery efforts that will lead to more effective therapies, prevention, earlier detection and reductions in early and late effects of treatment.

Participation in Project:EveryChild is available to all families of children diagnosed with cancer across the country at participating COG institutions, independent of the patient's enrollment on a therapeutic trial. The study collects demographic and epidemiologic information and takes extra tissue available from children who must undergo a diagnostic procedure and stores that tissue in COG's biorepository. Information on how effective the child's treatment is

will be maintained securely in COG's data center, allowing scientists to link laboratory findings to outcome data. Additionally, subjects may consent to banking of biomaterials for ongoing and future research and to be contacted for future biology, epidemiology and survivorship studies.

By sharing biospecimens and research data, the Children's Oncology Group's Project:EveryChild will help lead developments in the current and next generation of advances in cures for childhood cancer.

**Stop Children's Cancer's support of the UF Pediatric Oncology clinical trials program makes it possible to collect the data and samples for Project:EveryChild.**

# Cancer has a Gator problem

Stop Children's Cancer's endowed professorship provides resources for Dr. Sayour's lab.

A defining moment in cancer research.

UF researchers have made a significant breakthrough in the quest to find a universal “cancer vaccine.” This discovery supercharges the tumor-fighting effects of today’s treatments and aims to transform how we fight cancer tomorrow.

Patients with advanced lung or skin cancer who received a COVID-19 mRNA vaccine within 100 days of starting immunotherapy drugs lived significantly longer than those who did not get the vaccine, researchers have found.

The observation by researchers at the University of Florida and the University of Texas MD Anderson Cancer Center is a defining moment in a decade-plus of research testing mRNA-based therapeutics designed to “wake up” the immune system against cancer. Building on a previous UF study, the observation also marks a significant step toward a long-awaited universal cancer vaccine to boost the tumor-fighting effects of immunotherapy.

The findings from an analysis of more than 1,000 patients’ records at MD Anderson are preliminary, but if validated in a randomized clinical trial now in design, the study could have a widespread clinical impact.

“The implications are extraordinary — this could revolutionize the entire field of oncologic care,” said co-senior author Elias Sayour, MD, PhD, a UF Health pediatric oncologist and the **Stop Children's Cancer/Bonnie R. Freeman Professor for Pediatric Oncology Research**. “We could design an even better nonspecific vaccine to mobilize and reset the immune response, in a way that could essentially be a universal, off-the-shelf cancer vaccine for all cancer patients.”

Jeff Collier, PhD, a leading mRNA scientist and professor at Johns Hopkins University, said the findings point to yet another way Operation Warp Speed — part of the federal government’s early response to COVID-19 — continues to save Americans’ lives in “unique and unexpected ways.”

“The results from this study demonstrate how powerful mRNA medicines truly are and that they are revolutionizing our treatment of cancer,” Collier said.



A University of Florida and MD Anderson research team led by Elias Sayour, MD, PhD (left), and Christiano Marconi (middle) discovered that cancer patients who received a COVID-19 mRNA vaccine within 100 days of starting an immunotherapy treatment for advanced forms of lung cancer or melanoma lived significantly longer than those who didn't get the vaccine.

Published in *Nature*, the findings build upon Sayour's eight years of work combining lipid nanoparticles and mRNA. Short for messenger RNA, mRNA molecules are found in every cell and carry the genetic information needed to make proteins.

Notably, Sayour's lab reported a surprising finding in July: that to prompt a strong antitumor reaction, they needn't go after a specific target protein in a tumor; instead, they could simply rev up the immune system — as if fighting a virus.

Like a one-two punch, pairing Sayour's patented experimental "nonspecific" mRNA vaccine with common anticancer drugs called immune checkpoint inhibitors triggered a strong antitumor response in lab mice. The experimental vaccine was nonspecific to COVID spike protein or any other virus or cancer but rooted in similar technology to the COVID vaccines.

That discovery, years in the making, sparked a question from former lab member and first author Adam Grippin, MD, PhD, who trained

at UF's **Preston A. Wells Center for Brain Tumor Therapy** and now works at MD Anderson.

**Would the COVID-19 mRNA vaccine work like the nonspecific vaccine?**

To find out, the research team analyzed existing data from patients with Stage 3 and 4 non-small cell lung cancer and metastatic melanoma treated at MD Anderson from 2019 to 2023.

What they found was that receiving a COVID mRNA vaccine within 100 days of starting immunotherapy drugs was associated with living longer by a significant amount.

The most dramatic difference, Sayour said, was in patients not expected to have a strong immune response, based on their tumors' molecular makeup and other factors.

As with any observational study, the findings require confirmation from a prospective and randomized clinical trial.

Nonetheless, the discovery is pivotal.

"Although not yet proven to be causal, this is the type of treatment benefit that we strive for and hope to see with therapeutic

interventions — but rarely do,” said Duane Mitchell, MD, PhD, Grippin’s doctoral mentor and director of the **UF Clinical and Translational Science Institute**. “I think the urgency and importance of doing the confirmatory work can’t be overstated.”

In lung and skin cancers, doctors commonly engage the immune system with drugs designed to “release the brakes” and recognize and attack cancer cells more effectively. In advanced disease stages, however, most patients don’t respond well and often have exhausted other treatment options like radiation, surgery and chemotherapy.

The new study involved records of 180 advanced lung cancer patients who received a COVID vaccine within a 100-day period before or after starting immunotherapy drugs and 704 treated with the same drugs who did not receive the vaccine. Getting the vaccine was associated with a near doubling of median survival, from 20.6 months to 37.3 months.

Of the metastatic melanoma patients, 43 received a vaccine within 100 days of initiating immunotherapy, while 167 patients did not receive a vaccine. With the vaccine, median survival increased from 26.7 months to a range of 30 to 40 months; at the time the data were collected, some patients were still alive, meaning the vaccine effect could be even stronger.

Receiving non-mRNA pneumonia or flu vaccines resulted in no changes in longevity.

To back their findings, UF researchers then used mouse models to pair immunotherapy drugs with an mRNA vaccine targeted specifically at COVID spike protein. Those experiments showed they could turn unresponsive cancers into responsive ones, thwarting tumor growth.

“One of the mechanisms for how this works is when you give an mRNA vaccine, that acts as a flare that starts moving all of these immune cells from bad areas like the tumor to good areas like the lymph nodes,” Sayour said.

The next step is to launch a large clinical trial through the UF-led **OneFlorida+ Clinical Research Network**, a consortium of hospitals, health centers and clinics in Florida, Alabama, Georgia, Arkansas, California and Minnesota.

“One of our key motivations at OneFlorida is to move discoveries from academic settings out into the real world and the places where patients get care,” said Betsy Shenkman, PhD, who leads the consortium.

If confirmed, the new findings unlock numerous possibilities, and the researchers said an even better nonspecific universal vaccine could be designed. For patients with advanced cancers, the increased survival from such a universal vaccine could provide a priceless benefit: more time.

“If this can double what we’re achieving currently, or even incrementally — 5%, 10% — that means a lot to those patients, especially if this can be leveraged across different cancers for different patients,” said Sayour, an investigator with UF’s **McKnight Brain Institute** and the **UF Health Cancer Institute**.

The study was funded by the National Cancer Institute and multiple foundations, including **Stop Children’s Cancer**.

Sayour, Grippin and Mitchell hold patents related to UF-developed mRNA vaccines that are licensed by iOncologi Inc., a biotech company born as a “spinout” from UF in which Mitchell holds interest.

# UF Health Cancer Center Is now an institute

The University of Florida has conferred the prestigious title of institute to the University of Florida Health Cancer Center, a reflection of its prominence in cancer research at UF and as one of the country's top institutions for cancer care and research.

Institute designation is reserved for units that provide a broad array of university services across multiple colleges and requires approval from its top research leadership and the state Board of Governors. The UF elevation recognizes that the UF Health Cancer Institute has engaged not only researchers in the health science colleges, but researchers across all 16 colleges at the state's flagship university, from Agricultural and Life Sciences to Engineering to Medicine to Veterinary Medicine.

The change reflects the institute's upward trajectory, coming two years after it became the only National Cancer Institute-designated cancer center at a public institution in the state.

"The UF Health Cancer Institute is responsible for driving cancer research throughout our university, impacting the lives of current and future generations," said David Norton, PhD, the university's vice president for research. "The efforts of this institute and its researchers will continue to elevate UF as a powerhouse in the field."

The change also reflects the institute's increasing impact on cancer

care in Florida, which has the nation's second-highest cancer burden. This year, UF Health Shands Hospital was ranked among the top 50 hospitals in the country for cancer care by U.S. News & World Report.

"Delivering exceptional clinical care means integrating innovation, education and discovery into our everyday work — a driving force and a commitment behind everything we do," said Stephen Motew, MD, MHA, FACS, UF Health president and system CEO. "Our patients have come to rely on us for this level of integrated care."

A multidisciplinary, cross-collaborative focus is the best way to unlock new, more effective approaches to cancer treatment, said Thomas George, MD, FACP, FASCO, the institute's interim director.

"Our approach has always been to engage the entire university to address the problem of cancer, and we have strengthened the academic coordination we provide for cancer researchers across UF," George said. "We plan to grow our impact by fostering collaborations to meet the challenges of cancer in the 21st century, while cultivating leaders in the field and training the next generation of investigators."

With an annual research budget of \$55 million, the UF Health Cancer Institute draws more than 350 members from all 16 UF colleges, including more than a dozen at The Herbert Wertheim UF Scripps

# With the power of this university behind us, we're more equipped than ever to accelerate cancer research and transform cancer care for the patients and families who need it most.

Institute for Biomedical Innovation & Technology. The institute drives cancer research by fostering team science through initiatives like pilot grants, symposia and a new grant program using highly specialized drug screening tools uniquely available at The Wertheim UF Scripps Institute.

Carlos Rinaldi-Ramos, PhD, a professor in the Herbert Wertheim College of Engineering, came to UF to expand his research in cancer nanomedicine. As an engineer, he found a supportive, thriving research environment at the UF Health Cancer Institute, where he met his research collaborator Duane Mitchell, MD, PhD, and received pilot funding.

"My current NIH-funded projects studying the use of magnetic particle imaging are a direct result of the highly collaborative cancer research environment at UF," Rinaldi-Ramos said. "I now help other engineering faculty to connect with cancer researchers. The new UF Health Cancer Institute recognizes how researchers from across all UF contribute to the mission of eradicating cancer."

Indeed, UF researchers work on all aspects of cancer. Communication researchers use AI to develop digital avatars to train physicians on patient communication. Data scientists harness large data sets to predict cancer patterns, molecular biologists unravel the genetic drivers of cancer and immuno-oncologists discover how the microbiome can help boost responses to cancer treatment.

Researchers prioritize prevalent and deadly cancers in the institute's 26-county service area like brain, breast, colorectal and lung. At UF Health, patients have access to more than 200 active cancer clinical trials. Many are for new treatments available only at UF for pediatric, brain and other cancers.

Now, the institute will further develop its research programs in cancer therapy, prevention and survivorship. Over the next decade, it will expand its focus on clinical research sciences as it works toward comprehensive designation from the National Cancer Institute.

by Leah Buletti | October 27, 2025



# Thank You

Your generosity has made a lasting impact on the trajectory of research and patient care. On behalf of our faculty and the countless patients who will benefit, we extend our sincere appreciation for your vital support.

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