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COLORECTAL CANCER MATTERS

THE SIDNEY KIMMEL COMPREHENSIVE CANCER CENTER AT JOHNS HOPKINS

Published by The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Office of Public Affairs Baltimore, Maryland 410-955-1287

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This publication is made possible through the generosity of Roger Leventer.

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Converging on Colorectal Cancer

Innovating Through Data and Technology

Imagine if doctors and researchers could predict how and where a cancer was going to grow and spread in the same way that meteorologists forecast the weather, streaming services predict what movie we will watch, and large online shopping sites predict what we are likely to buy.

Mathematician, chaos theory expert and former weather forecaster **Elana Fertig**, Ph.D., not only thinks about it, she is helping build the mathematical models that are making it a reality.

"Every problem — even cancer — can be informed by math," says Fertig.

She believes it will help researchers better understand the complexity of cancer, including colorectal cancer, and support the development of new therapies.

Fertig's background is in meteorology, not medicine. This made her the perfect choice to join the Convergence Institute as its Co-Director in 2021.

The Institute was created by Elizabeth Jaffee, M.D., the Albert "Cubby" Broccoli Professor of Oncology and Deputy Director of the Kimmel Cancer Center. She saw it as a way to bring together all of the available expertise throughout Johns Hopkins and beyond, apply it to cancer research and medicine, and pave the way for the next generation of researchers.

The Convergence Institute is an innovation hub that includes almost any expert one can imagine. In addition to mathematicians like Fertig, there are computer scientists, physicists, electrical engineers, astronomers, and more.

These disciplines bring a unique perspective to the fight against cancer, she says.

"As a mathematician, I think about a problem dif-

ferently than a clinician. You have to be willing to listen and learn from one another," explains Fertig.

This multispecialty collaboration, she stresses, is central to Convergence and the future of cancer research.

"We are working side by side with our clinical colleagues to gather as much data as possible on every patient so we can learn how tumors change."

"No one field serves the other. We are working as a unit to learn from each other to build something bigger and better together," says Fertig. "We are working side by side with our clinical colleagues to gather as much data as possible on every patient so we can learn how tumors change."

Convergence helps incorporate the depth of knowledge researchers have uncovered about cancer into new computational models.

The research is bolstered by revolutionary advances in technology.

"For the first time in the history of cancer medicine, we can take a patient's tumor and see what every cell is doing and also what each gene in each cell is doing," says Fertig.

The challenge before the Convergence Institute is how to distill the complexity of all of the information gathered — which may be different for each patient — to develop forecast models for tumors. These new tools are already being developed, she says, and they are helping experts predict how a tumor is going to behave in the short term and over time. This knowledge will also help doctors to better intercept cancer and intervene with therapies.

CoFests!

Among the Convergence Institute's latest endeavors is a training program aimed squarely at colorectal cancer. With generous support from the Marco Schnabl family, Colorectal Cancer Research Center of Excellence campaign team member, the Colorectal Cancer Convergence Program brings together researchers from diverse scientific backgrounds and specialties to analyze real-world colorectal cancer data and advance treatment.

Schnabl, who used data science to automate car sales, approached Nilo Azad, M.D., Director of the Colorectal Cancer Research Center of Excellence, about using data science to advance colorectal cancer research and treatment. Schnabl began supporting colorectal cancer research in 2019, establishing the Schnabl Family Fund in honor of his father, Fred, who lost his life to colorectal cancer. His most recent gift launched the Colorectal Cancer (CRC) Conver-

From left, top: brainstorming group, Allissa Dillman, bottom: Frederick Tan, CoFests! participants, with Marco Schnabl, center, who joined virtually.











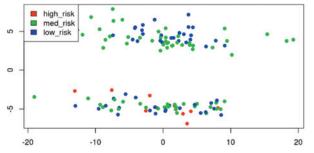
Marco Schnabl (on screen) addresses the CoFest! group.

gence Program. Schnabl's goal is to make sure every possible tool is being used to help the more than 150,000 people diagnosed with colorectal cancer each year in the U.S.

The CRC Convergence Program was launched in Fall 2023, and includes three initiatives: A genomics workshop, a hands-on course for researchers on gene, biostatistical, and computational methods needed to work with and manage big data sets; CoFests!; and the Convergence Institute Research Symposium, featuring the Schnabl Distinguished Lectureship

CoFests! (short for Collaboration Fests), brings together teams to tackle real-world colorectal cancer datasets and clinical problems and is directed by Allissa Dillman, Ph.D., founder of BioData Sage LLC. Each team includes a mathematician, bioinformatician, surgeon, medical oncologist, and basic biologist. The 2023 CoFests! teams analyzed a data set brought by basic cancer biologist Hari Easwaran, Ph.D., who also delivered the inaugural Schnabl Distinguished Lecture at the Convergence Research Symposium on May 29.

Team member **Frederick Tan**, Ph.D., bioinformatics research faculty at Carnegie Institution and assistant research professor at Johns Hopkins University, integrates computer science with biology to analyze large data sets like Easwaran's to advance clinical research.



In this image produced from the data analysis, the red dots mark the polyps that advanced to colorectal cancer

The CoFests! is the result of Fertig's idea — from the earliest stages of the Convergence Institute's founding — to build up team science across specialties.

Former faculty members **Sarah Wheelan**, M.D., Ph.D., and **Luigi Marchionni**, M.D., Ph.D., were integral to founding educational initiatives, including the Practical Genomics Workshop that teaches hands on analysis of gene sequencing data for biologists and clinical investigators who don't have any prior computational experience. This workshop is a feeder course for CoFests! participation and is now run by Tan.

The Data

Easwaran had data on 150 colon polyps — benign tumors that form in the colon and may, through biological changes, turn into cancer. The team's goal was to see if the data could be deciphered in a way that would distinguish polyps that are destined to turn cancerous from those likely to remain benign and harmless.



NILO AZAD

The group found epigenetic changes — chemical alterations to key genes, such as tumor suppressor genes or cancer-promoting oncogenes that can turn the genes off or on — in the data.

The results of the inaugural team's work eloquently illustrate why data science has become essential to cancer research. Working with Tan and using bioinformatic tools, they were able to uncover a unique cluster of 10 patients whose polyps advanced to colorectal cancers, or in some cases, who developed other abdominal cancers, Easwaran says.

"The patterns in data revealed polyps that were going to become cancer," he explains.

Their findings point to an opportunity to predict which patients will be diagnosed with colorectal cancer using these epigenetic chemical alterations as a biomarker. Easwaran plans to expand upon these illuminating first steps to build a deep learning

model to better forecast those most likely to develop colorectal cancer.

"This is the future and what we hope to see in as little as 10 years," says Azad. "We talk about stool tests and other ways to detect colorectal cancer earlier, but we want to think bigger. What we really want is to find it before it becomes cancer. Someone can get a scope, get a dangerous polyp removed and never have cancer; never need surgery or chemotherapy. How can we take this and think beyond colonoscopy to get to other ways to screen patients?"

Schnabl says he is excited but not at all surprised to see how quickly this type of research is turning into advances for colorectal cancer.

The Next Generation

"We are training a whole new generation of doctors who are learning what is under the hood of computational methods and building the foundation of understanding how they can be used to fight cancer," says Fertig.

The CoFests! program is central to the educational mission of the Convergence Institute and its goal to train medical fellows and postdoctoral researchers in clinical research methods, quantitative sciences, and engineering technologies. The foundation in colorectal cancer will provide a platform on which to expand the CoFests! program and provide Convergence education across all cancer types and subtypes, says Fertig.

"We want to create a pipeline of medical experts who understand the importance of computational sciences."

"We want to create a pipeline of medical experts who understand the importance of computational sciences," says Fertig. "Data science is the future, and it is built into everything we do. We need to help clinicians get comfortable with it and train data scientists how to think of clinical problems."

The inaugural CoFests! was held in 2024, and another is planned for 2025 with an expansion to six teams and projects.

Fertig says this kind of training model is so new and unique that standard coursework or program grants are not available, emphasizing the importance of Schnabl's generosity, which made it possible.

"He saw the vision, and is moving the next generation of research forward," says Fertig. "The integration of information technologies into cancer research is not optional. In this information age, we have to learn how to do this, and in the world of cancer, the Kimmel Cancer Center is leading the way."



Our Story: Making Good from Tragedy

By Roger Leventer

"I found a tumor in Lynda's colon."

With those seven words, our lives, and the lives of our young boys (John and Bobby), changed forever. It was the beginning of our six-year journey of bravery, resilience and unthinkable strength. Lynda was never a cancer victim; she didn't even think of herself as a cancer patient most of the time. She was John and Bobby's mom. She faced her worst nightmare, and then got up and faced her worst nightmare again ... and again for six years. She never faltered even as the world around her was collapsing. I honestly do not know how she did it.

"You have an appointment on Wednesday with Dr. Laheru."

Life-changing words. Our world, spinning out of control as it was, met Dan Laheru's world. The world of medicine, research and compassion. Dan would be Lynda's doctor and our friend. For Lynda, it lasted six years, for me, a lifetime. Dan started our inconceivable journey with calm, hope, deep resources and a hug. Dan started planning Lynda's return to health the moment he met us.

It has been 16 years since we first met Dan. Dan's compassion and brilliance burn bright. He is ever present and always caring for his patients. As far as I can tell, Dan spends every waking moment caring for others and looking for ways to improve and often save lives. I do not know how he does it, but I am grateful that he does.

"Ella-Mae will be your oncology nurse."

Life-sustaining words. Ella-Mae journeyed with us for the entire six years. She always knew just what to do and how to do it. Nothing got by Ella-Mae. She cared for us and a roomful of others as though her life depended on it, when quite literally, Lynda's did.

"And Dr. Ahuja will remove your primary tumor." More life-changing words. **Nita Ahuja** operated on Lynda three times. Each surgery was long, difficult and complex. Nita cared for us, laughed with us,

hoped with us and even worried with us. No one looked after Lynda like Nita did. After a big surgery, we would see Nita four times in the same day and always at the beginning and end of the day. Nita always seemed to know when Lynda was in the hospital. Nita was always there to check on her. Nita took care of Lynda like she would her own family.

"I will make some good come out of this tragedy!"

Dan, Ella-Mae and Nita have dedicated their lives to fighting cancer every day. Lynda lost her life to cancer. My life was forever changed by cancer. I want to honor Lynda and match the commitment of her care team. I want to help end cancers so no one else must endure what Lynda and our family went through. I cannot go back to school, I cannot see patients, I cannot do research, but I can support the clinicians and researchers at the Colorectal Cancer Research Center of Excellence at the Johns Hopkins Kimmel Cancer Center with my time and money. As Lynda left me, I promised that I would make good come from the tragedy of Lynda's cancer. I am determined to do just that!



Swimming led Craig to the Kimmel Cancer Center's Colorectal Cancer Research Center of Excellence, and it remains an important part of his survivorship journey.

The Right Place at the Right Time

How innovative research, multispecialty care, and a promising new therapy saved a swimmer's life

Craig has a counter on his cellphone that chronicles his battle with colorectal cancer. It marks his survival - 680 days and counting, on this day, since his diagnosis on June 16, 2022.

The tech savvy information technology professional appreciates this gadget and the ease with which he can track his journey. It acknowledges his hard fought battle with stage 3 colorectal cancer and helps make him aware that every day is a victory.

He thinks of the shock he felt awakening from his screening colonoscopy to the news that a large mass had been found.

Craig was only 52 years old. This was a screening colonoscopy. It had been delayed two years due to the COVID pandemic, but still, he never imagined this outcome.

He had no symptoms, no indication that anything was wrong. A competitive open water swimmer, Craig had completed the 4.4 mile Chesapeake Bay swim just days earlier.

In an interesting twist of fate, it was swimming that led him to the Kimmel Cancer Center and helped provide the framework for his recovery.

A Connection

A fellow swimmer connected Craig with a former Kimmel Cancer Center researcher, who with colorectal cancer expert Dung Le, M.D., conducted a clinical trial that revealed an error in some colorectal cancers — called mismatch repair deficiency that led the cancers to respond to immunotherapy.

In the clinical trial, mismatch repair deficiency caused tumors to accumulate genetic mutations, and these mutations were red flags to the immune system, helping it recognize a cancer as a foreign invader. With the help of an immune checkpoint inhibitor, which is a type of immunotherapy, the immune cells attacked and destroyed cancer cells.

The findings were revolutionary, leading to approval by the Food and Drug Administration of this immunotherapy drug for any cancer with this genetic alteration. It was the first drug approval across all cancer types.

Unfortunately, Craig's cancer did not have the mutation. This treatment was not an option for him, but Le and her former colleague Luis Diaz, M.D., who is now the head of solid tumor oncology at the Memorial Sloan Kettering Cancer Center, referred him to a brilliant young colorectal cancer expert at Johns Hopkins: Eric Christenson, M.D.

A Plan

With stage 3 colorectal cancer, malignant cells have begun to break through the wall of the colon but have not yet spread to other organs. However, experts know that cells can move away undetected and seed new tumors in other parts of the body.

Christenson's plan was to give chemotherapy and radiation therapy first to shrink the tumor, followed by surgery.

Craig already had one round of chemotherapy – powerful anti-cancer drugs that travel through the bloodstream to kill rapidly dividing cells, such as cancer cells. Sandwiched between four rounds of chemotherapy, Craig received 5x5, a new type of radiation therapy developed at the Kimmel Cancer Center by radiation oncologist and colorectal cancer expert Jeffrey Meyer, M.D., M.S.

With 5x5, patients receive an abbreviated course of radiation therapy, shortening treatment that typically lasts five weeks to just five days.

The 5x5 regimen is easier for patients and causes far less interruptions to their daily routines.

"Patients obtain better responses by giving radiation and chemotherapy up front before surgery," explains Meyer. The tumors become significantly smaller, making surgery easier and reducing the risk of complications, he says. In some cases, Meyer adds, tumors completely disappear, and surgery is not needed. Instead, patients are closely monitored for any signs of the tumor returning.

Craig wanted to be aggressive about going after the cancer. He says as he fought to beat it, swimming kept him grounded.

Swim Across America

After college, he trained and swam with Rob Butcher, who is now the president and CEO of Swim Across America, an organization that raises money for cancer research, prevention, and treatment through charity swims.

Swim Across America/Baltimore provided the funding that made the mismatch repair clinical trial possible. It also funded a Swim Across America laboratory at the Kimmel Cancer Center to help advance research. In addition, as a Swim Across America Scholar, Christenson — Craig's medical oncologist receives funding to support his research.

"Sometimes, being in the right place at right time is an amazing thing," says Craig. That's the theme of my story. I was fortunate to have this connection. All the money Swim Across America raises is helping me and so many others with cancer. It could poten-





CHRISTENSON







Swim Across America 2023 check presentation.



tially be saving my life, by supporting the development of new treatments and ways to prevent cancer from coming back and to detect it early, if it does come back."

Craig became a Swim Across America volunteer during his cancer treatment, and participants in the yearly event swam in his honor.

"I was handing out towels to people as they got out of the pool," says Craig. "They knew my story, and they thanked me. It is a special connection that has been so important to me. Swimming and these relationships helped me through my cancer treatment."

He got a Swim Across America bracelet when he volunteered. He hasn't taken it off since.

"It reminds me that we must never stop the fight," says Craig, who has been participating in swims to benefit Johns Hopkins cancer research since 1999.

The Right Place

Craig has a similar fondness and gratitude for Johns Hopkins.

"God puts you in places for a reason, and I knew I was lucky to be getting treated at Johns Hopkins," he says.

He was most impressed by the multispecialty care team at the Colorectal Cancer Research Center of Excellence and the way all of the experts worked together to help patients.

"I felt like they were looking out for me," says Craig In January 2023, he was ready for surgery. The chemotherapy and radiation therapy had done their job. The tumor was reduced by 95%.

"I remember my surgeon, Dr. Susan Gearhart, telling me, 'This is a teaching institution, and one great thing you get is a lot of doctors looking at things from different angles." That was wonderful to hear," says Craig.

The surgery to remove the cancer included an ileostomy, a procedure that creates an opening in the abdomen that allows waste to be passed out of the body.

He said the supportive care team was a lifeline to him during his recovery. Nurse practitioners **Katherine Braid**, C.R.N.P., and **Tam Warczynski**, M.S.N., prepared him for what to expect and were always available to answer questions and provide guidance in person and through MyChart messaging.

Swimming was essential to Craig's physical and mental health, and wound care coordinator **Cynthia Shephard**, M.S.N., worked with him, providing a tool to use on the ileostomy so he could continue to swim during his recovery.

In Craig's case, the ileostomy was temporary. It allowed his colon to heal from surgery. Gearhart returned everything to normal three months later in a procedure referred to as a reversal.

As his body recovered and returned to normal functioning, Craig sometimes had severe pain, and an underlying kidney condition prevented him from using medication to control it. However, physical therapist and clinical specialist **Laura Scheufele** was a pain management "magician," he says. She taught him specific techniques, and within 30 seconds, his pain was gone, Craig says.

Swimming On

Above all, Craig says, he credits his wife, Shannon, for helping him through the last two years.

"She was by my side through it all," Craig says. "I remind her every day how much she has helped me. I couldn't have done it without her. She is my rock."

They have matching tattoos of the iconic cancer ribbon, but the ribbon looks like it is made of water, marking the importance of swimming to his recovery.

Some of the next challenges he hopes to take on are more Swim Across America events, including the Tampa event that benefits Johns Hopkins All Children's Hospital, and the 28.5 mile Manhattan Island Marathon Swim.



GEARHART



BRAID



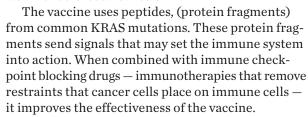
WARCZYNSKI

ADVANCES

KRAS Vaccines

ABOUT 40% TO 60% of colorectal cancers contain a mutation to a gene called KRAS. Historically, the mutation has been a negative marker, typically indicating a patient may not do as well and will not respond to certain therapies, says Valerie Lee, M.D., gastrointestinal cancer expert at the Kimmel Cancer Center at Sibley Memorial Hospital.

In addition to researching promising new drugs and drug combinations to target KRAS mutations in colorectal cancer, Lee says she is particularly interested in KRAS vaccines that have been used for pancreatic cancer. She wants to see if they may also work for colorectal cancer.



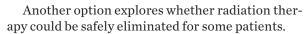
"The vaccine in combination with immune checkpoint inhibitors should be able to instruct the immune system to take out any cell that contains these KRAS mutations," explains Neeha Zaidi, M.D., assistant professor of oncology. She has already tested the vaccine in pancreatic cancer, and in collaboration with Nilo Azad, M.D., Director of the Colorectal Cancer Research Center of Excellence. and with support from Rhythm of Life, Cycling to End Cancer and the Roger Leventer Fund, is expanding studies of the vaccine to colorectal cancer.

"It's too early to tell if the KRAS vaccine will be effective against colorectal cancer, but it is promising, and something like this could help many patients," says Lee.

Rectal Cancer in Women

Women receiving radiation therapy for rectal cancers can experience serious side effects, including fertility issues, sexual dysfunction, and back fractures. The Multidisciplinary Rectal Cancer Clinic team is exploring ways to avoid these complications.

In one approach, Rebecca Stone, M.D., M.S., Director of the Kelly Gynecologic Oncology Service, and a member of the multispecialty rectal cancer team, performs a uterine transposition before radiation therapy begins to reposition the uterus to the abdomen away from where the radiation will be given. Stone performs a similar procedure to protect ovaries and fallopian tubes, if needed.



"In patients with locally advanced stage 2 or 3 rectal cancer, we typically use a combination of radiation, chemotherapy, and surgery," says Lee, "but in some cases, we may be able to avoid one of the three. We thought radiation was one we could not do without, but a national clinical trial, called the PROSPECT trial, showed that in patients with higher rectal tumors, not close to the sphincter, radiation therapy could safely be eliminated."

In the study, patients received chemotherapy for a few months, followed by surgery. When the outcomes were compared to historical outcomes for patients who received chemotherapy and radiation therapy before surgery, the results were similar. Lee says this means radiation therapy could potentially be avoided in 80% of patients.

"It's another tool in the arsenal," says Lee.

When Cancer Spreads

A method to deliver anticancer drugs directly to tumors and liver transplant may be options for some patients with colorectal cancer that has spread to the liver.

Surgeon Kelly Lafaro, M.D., M.P.H., has developed a procedure for patients with colorectal cancer that has spread to the liver and is too large or too extensive to be surgically removed, or who had treatment to remove the tumors but are at risk of the cancer returning.

Lafaro uses a hepatic artery infusion pump (a chemotherapy pump) to deliver drugs directly into the liver. It allows her to get high doses of anticancer drugs through the hepatic artery and directly to tumors. When the drugs are given this way, Lafaro say, they only go to the liver metastases and do not travel through the body like traditional chemotherapy.

The pump can be used to reduce the size of tumors so they can be surgically removed and to prevent recurrence in patients who have had tumors removed.

New data from an international study finds that carefully chosen patients with colorectal cancer that has spread only to the liver could also be considered for a liver transplant.

Lafaro's surgical program for liver metastasis provides the foundation for this potential new option.

Watch a video about the hepatic artery infusion pump: https://bit.ly/3VD423j







Pushing the Limits

Chemotherapy has significantly improved colorectal cancer survival, says **Michael Pishvaian**, M.D., Ph.D., associate professor of oncology.

"Thirty years ago, patients diagnosed with advanced colorectal cancer survived just six months. Now, it's at least three years," says Pishvaian. "But that's not good enough. Unfortunately, 50,000 people still die each year. We have to keep pushing the limits."

To make these advances, Pishvaian is looking at novel approaches:

- •Biomarker-based therapies that identify the molecular alterations in a patient's tumor and uses them as targets for new drug therapies.
- Consideration of clinical trials and matching patients to studies that might benefit them.
- •Using combinations of immunotherapies with chemotherapy and/or targeted therapies to expand the promise of immune-based treatments to more colorectal cancer patients.

One drug combination currently being studied — botensilimab and balstilimab — resulted in significant responses in patients. Botensilimab targets CTLA-4, and balstilimab targets PD-1. Both CTLA-4 and PD-1 are immune checkpoints and allow cancer cells to avoid immune detection. The combination of Botensilimab and Balstilimab can help unharness the power of the immune system to attack cancer cells.

"Currently, immunotherapy works for about 5% of colorectal cancer patients," says Pishvaian. "We need new approaches like this that could help the other 95%. Trials like this one are beginning to break this ceiling."

The Colorectal Cancer Research Center of Excellence will participate in a phase 3 international clinical trial of the combination. It is expected to begin in late 2024 or early 2025.

"We are pushing the envelope with colorectal cancer," says Pishvaian. "Patients once considered incurable are now being cured. We are broadening the number of patients we are getting to chemotherapy, surgery and interventional radiology with the eye toward eradicating their cancer."

Defeating KRAS

Sandra Misale, Ph.D., is a new member of the Colorectal Cancer Research Center of Excellence whose research in KRAS mutations in colorectal cancer is promising to change the way the cancer is treated.

Misale was studying resistance to treatments that block another protein that promotes cancer cell growth, called EGFR, when she discovered that KRAS mutations were a key mechanism causing the resistance. KRAS mutations are common to many types of cancer, including colorectal cancer, and they are associated with more aggressive cancers and poorer survival.

Although using drugs to block KRAS, known as KRAS inhibitors, has proven effective against other cancers, including a type of lung cancer, it has not worked well in colorectal cancer, Misale says.

To understand why, she and her team compared the effects of KRAS inhibitors on lung cancer cells and colorectal cancer cells in the laboratory. They found that the way KRAS is activated in colorectal cancer explained the difference between the two tumor types, and this difference was the result of EGFR activity.

To get KRAS inhibitors to work better in colorectal cancer, she added another drug, already used to treat some types of colon cancer, to block EGFR. When she tested the two-drug combination in the laboratory, it worked so well in research models that it quickly advanced to clinical trials at the Kimmel Cancer Center and other cancer centers throughout the U.S. It worked as well in patients as it had in Misale's laboratory studies, and now the treatment is expected to become the standard of care for a subset of colorectal cancer patients with a specific KRAS mutation.

About 50% of colorectal cancers have KRAS mutations, but there are many different types of mutations, Misale explains. The combination KRAS-targeted treatment she developed works in about 3% to 8% of colorectal cancers. To expand the benefit to more patients, Misale and team are now researching new KRAS inhibitors, including a single drug that blocks all KRAS mutations.

"We are working in the lab to understand the molecular mechanisms of these new drugs and applying them to the biology of colorectal cancer and every KRAS mutation," she says. "We hope we can advance them quickly to clinical trials."

Again, Misale is looking at combination therapies. She is collaborating with Nilo Azad, M.D., Director of the Colorectal Cancer Research Center of Excellence, and cancer vaccine expert Neeha Zaidi, M.D. One approach, she says, combines a KRAS inhibitor to block KRAS from signaling cancer cells to grow, a KRAS vaccine that supercharges the immune system to go after any cell expressing a mutant KRAS gene, and another type of immunotherapy called immune checkpoint blockade that removes restraints cancer cells place on immune cells.

"As we continue to understand the molecular mechanisms of treatment resistance, we can develop the best approaches to overcome it," says Misale. "We think these therapies will work in synergy, providing a good and lasting antitumor response."



PISHVAIAN



/ISALE



LAFARO



AZAD



Lifesaving Combo

Trish was a healthy and active 60-year-old when a screening colonoscopy led to a diagnosis of stage 2 colorectal cancer in 2013.

Stage 2 cancers are those that have grown through the wall of the colon but have not spread to lymph nodes or other organs, and they present a bit of quagmire for doctors. Surgery followed by radiation therapy cures many patients, but others will need chemotherapy to stave off a recurrence. (See Guiding Chemotherapy, page 13.) The problem is there is no clear way to tell who is cured and whose cancer is destined to come back.

Trish opted for surgery and radiation therapy. Sadly, after four years, her cancer returned, and spread to her lungs and liver.

"It was very deflating," says Trish. The Colorado resident opted to travel to Chicago to receive chemotherapy combined with alternative therapies, such as nutritional supplements.

"Chemo was the worst thing. Nothing worked for my nausea," she recalls.

"I was weak, overwhelmed, and in a lot of pain."

After 12 months of treatment that included surgery, chemotherapy, and a highly focused type of radiation therapy, called stereotactic radiation surgery, which uses high dose, precision beams of radiation to cut through tumors, the cancer was gone.

The treatment and a resistant infection had taken its toll. Trish was weak but hopeful.

Unfortunately, the remission was short-lived, however. Just two months later, Trish's cancer was back.

"I was in trouble," she said. One doctor told her she had possibly two years to live and suggested she look into hospice. Trish struggled with the news. She was not ready to give up. Trish decided to call the therapist at the Chicago clinic who had helped her earlier in her battle against colorectal cancer.

"I was in tears," says Trish, "She was a lifeline. She told me, 'You are not a typical patient. Create your own trajectory."

A final piece of advice from the doctor proved to be lifesaving. He told Trish to call Johns Hopkins because he was aware of a clinical trial for colorectal cancer patients with a mutation to a gene called PIK3. The doctor knew from earlier gene testing he had done on Trish's tumor that it had a PIK3 alteration.

"I was weak, overwhelmed, and in a lot of pain," Trish recalls, but she followed the advice and called the Johns Hopkins Kimmel Cancer Center. She spoke to research nurse Maureen Berg, and the conversation ignited a spark of hope in Trish. There was a clinical trial that might help her.

"She was a blessing," says Trish of Berg.

Trish had an appointment just days later. Her tumor had a mutation of a gene called PIK3, and

Molecular Evidence

Cancers leave a molecular trail of evidence in the bloodstream that foretells how the cancer will behave. These molecular clues can be used to individualize cancer therapies toward those who need it and away from those who do not.

The use of chemotherapy in stage 2 colon cancer a colon cancer that has grown through the wall of the colon but does not extend to the lymph nodes or other organs — is controversial. There is no consensus among cancer experts on its benefit. However, a new study by Kimmel Cancer Center researchers is helping solve the controversy by assessing whether tumor DNA circulating in the blood stream could be used to provide a more precise prediction of recurrence risk after surgery.

The goal of chemotherapy in colon cancer is to eradicate micrometastases, cancer cells not vet visible through imaging that travel through the bloodstream and cause the cancer to come back or spread to other parts of the body.

The goal of chemotherapy in colon cancer is to eradicate micrometastases, cancer cells not yet visible through imaging that travel through the bloodstream and cause the cancer to come back or spread to other parts of the body.

"Stage 2 colon cancer presents a unique challenge," explains Bert Vogelstein, M.D., Clayton Professor of Oncology and co-director of the Kimmel Cancer Center's Ludwig Center. "In stage 1 colon cancer, patients do not receive chemotherapy because their prognosis for survival is over 90%. The risk of discomfort and toxicities from the therapy outweigh the benefits it can provide. On the other hand, every patient with stage 3 colon cancer currently receives chemotherapy because the risk of relapse is high."

Vogelstein and his group were the first to show that colon cancer is caused by a sequence of genetic mutations, and showed that DNA shed from tumors could be detected in blood, stool and other body fluids.

They sought to solve the puzzle of stage 2 colon cancer with science, using circulating tumor DNA to detect these invisible cells and identify which patients are most likely to have micrometastases and could most benefit from chemotherapy following surgery. Conversely, it helps identify those whose cancer is cured with surgery.

Patients who do not have circulating tumor DNA in their blood could avoid the toxicities of chemotherapy, and those who had remaining cancer could receive chemotherapy to attack the lingering malignant cells.

"Previous studies have theorized that circulating tumor DNA measurements might be useful in guiding patient management, and this new research provides real-world clinical evidence that supports these theories," says Vogelstein.

The findings are based on a 2022 multi-institutional, international study of more than 700 patients, led by researchers at the Kimmel Cancer Center in collaboration with WEHI in Melbourne, Australia, and published in the prestigious *New* England Journal of Medicine. Vogelstein and team found that testing for circulating tumor DNA after surgery and directing chemotherapy to patients positive for circulating tumor DNA reduced the use of chemotherapy overall without compromising recurrence-free survival.

This is believed to be the first clinical study showing that the measurement of circulating tumor DNA prior to therapy may benefit patients.

Vogelstein says a patient with stage 2 colon cancer who is negative for circulating tumor DNA actually has a lower chance of cancer recurrence than the average stage 1 patient, so the new findings have an opportunity to change clinical practice.

Colorectal cancer expert Eric Christenson, M.D., is collaborating with Vogelstein and team on ongoing studies to monitor patients for circulating tumor DNA in their blood following radiation therapy and chemotherapy.

"All drugs work better in patients with cancers that are detected relatively early, before they have given rise to large metastatic masses."

"Those patients who have circulating tumor DNA will proceed to surgery. Those who do not would have the option of foregoing surgery," says Christenson.

Vogelstein says the research also provides opportunities to test promising new drugs in patients with earlier stages of cancer.

"All drugs work better in patients with cancers that are detected relatively early, before they have given rise to large metastatic masses. However, new drugs are usually first tested in patients whose cancers are very advanced," says Vogelstein. "We hope that circulating tumor DNA analysis will enable testing of new drugs in patients with early-stage cancers and micrometastases, when the new drugs are most likely to save lives."





CHRISTENSON

Colorectal Cancer Research Center of Excellence Director Nilo Azad, M.D., was beginning a clinical trial of a drug called copanlisib, which targets and inhibits this cancer-promoting mutation, combined with an immunotherapy called nivolumab, which can stimulate an immune attack against cancer cells.

The PIK3-targeted drug had been used alone to treat colorectal cancer without much success. Similarly, nivolumab alone worked in less than 5% of patients. Building upon findings from a study of copanlisib in lymphoma patients, Azad and collaborator **Eric Christenson**, M.D., conducted a clinical trial that combined the two drugs to see if they worked better together.

In the clinical trial, which was supported by funds raised by Swim Across America, Cycling to End Cancer, and Rhythm of Life events, the drugs were given simultaneously over four weeks.

these patients whose cancers had continued to grow on other therapies saw their tumors shrink on the combined drug therapy, including one patient who did not have a PIK3 mutation.

"These patients had metastatic disease," says Christenson. "In all of these cases, their disease remains under good control, and in some cases, not even visible two years later. That's unprecedented."

Like these patients, Trish says she saw results almost immediately.

"From my first appointment at Johns Hopkins my pain went away, and I never had it again. I was dying, and this treatment saved my life."

"From my first appointment at Johns Hopkins my pain went away, and I never had it again," says Trish. "I was dying, and this treatment saved my life."

Trish, an ethnobotanist who studies how people of specific cultures and regions use indigenous plants, was now able to return to work.

"I was getting my energy back. I went back to the gym and was working in my garden. I was doing noticeably better," says Trish.

Today, at 72, Trish has completed the treatment and remains cancer-free. She is exercising, skiing and, last year, planted 15,000 trees in Ecuador and Peru.

She thought about retiring, but instead, she continues to travel around the world for her botany work.

"I am doing the jobs I dreamed of throughout my whole career," says Trish. "I'm having a good ride."

Christenson presented the findings in April at the annual meeting of the American Association for Cancer Research, one of a select few asked to give an oral presentation on breaking research.

Although the treatment was lifesaving for the four patients, most of the 39 patients in the study did not see long-term benefits. Christenson is continuing his research, exploring ways to make the treatment work for more patients.

"In patients who did not respond, tumor cells evolved to be nastier, with macrophages moving into the tumor and suppressing the immune system," Christenson explains. "We're exploring if we could safely add another drug to the combination to target these macrophages."

In addition, he is focused on identifying biomarkers that predict which patients are likely to respond well to the treatment and is also working with pharmaceutical collaborators to develop better PIK3 inhibitors.

Taking It to the Biobank

More than 100 colorectal cancer patients have generously provided samples of their tumors removed during biopsies and surgery for a Biobank started by Eric Christenson, M.D., a little over a year ago with funding from Swim Across America.

"Colorectal cancer can vary from patient to patient, and we hope to collect samples that represent all clinical scenarios," says Christenson.

In collaboration with pathologist Jackie Birkness -Gartman, M.D., Christenson is leaving no stone unturned. Among the things he and Birkness-Gartman will be exploring is the response of immune cells and potential targeted drug therapies that could make the immune system more active against a cancer. They are comparing tumors from patients whose cancers came back with those whose did not to look for differences that could point to new treatments.

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"If we can determine what makes a tumor more problematic, maybe we can figure out how to make it look and behave more like the ones that go away and stay away after treatment," says Christenson.

When Surgery Isn't an Option

Surgery is a good option for many patients with rectal cancer, colorectal cancer researcher Eric Christenson, M.D., says, but as patients age, the complications from surgery rise dramatically. In patients over 80, deaths from surgery can be as high as 18%. As a result, many older patients are not considered candidates for surgery. For them, hospice is often the only option offered.

Christenson is collaborating with colorectal cancer clinician-scientist Dung Le, M.D., and surgeon Alodia Gabre-Kidan, M.D., M.P.H., on a study aimed at patients age 70 or older that uses drugs that get the immune system to kill the cancer when surgery isn't an option.

The new clinical trial builds upon a research discovery Le and others made in 2017 that found that patients with a genetic alteration called microsatellite instability, or MSI, develop many gene mutations in their tumors. These mutations draw the attention of the immune system, and cancers that contain them often respond well to immunotherapy.

When Gabre-Kidan looked at samples of rectal tumors in the laboratory, she found that MSI alterations increase with age, and that many patients over age 70 were more likely to have them—and at higher numbers—than their younger counterparts. This made Christenson and Le wonder if immunotherapy could be used to eliminate cancer in patients who were not candidates for surgery.

The immune system includes several immune checkpoints in its natural repertoire. They are like on/off switches, engaging immune cells when they are needed to fight off a foreign invader, and shutting them down when the job is done. Cancer cells take advantage of this natural process, sending false signals that shut the immune response off before the cancer is eliminated. Immunotherapy drugs called immune checkpoint inhibitors block the cancer cells' communication with immune cells, re-igniting the immune response to cancer cells.

In this new study, which launched in Spring 2024, some patients receive a single immune checkpoint inhibitor, and others receive a combination that targets two immune checkpoints in an effort to eliminate their tumors without the need for surgery.







Multidisciplinary Rectal Cancer Clinic Launched

Patients receive a one-day comprehensive evaluation by top rectal cancer medical oncologists, radiation oncologists, and surgeons. Eric Christensen, M.D., Jeff Meyer, M.D., and Haniee Chung, M.D., are co-directors of the new multidisciplinary rectal cancer clinic.





When Vanessa was diagnosed with advanced colon cancer in 2014, just before her 60th birthday, the caring mother and grandmother learned the cancer had already spread to her stomach and liver.

Even after a five-hour surgery and nearly a year of grueling chemotherapy, the cancer continued to grow. Her doctor told her there was nothing left to try.

The news was devastating. Vanessa traveled around the country searching for treatment options.

"I was willing to try anything," she says.

She remembers the day her young grandson, Zion, asked her if she believed in miracles.

She did believe, and she began searching for information. Vanessa came upon the Kimmel Cancer Center's Bloomberg~Kimmel Institute for Cancer Immunotherapy website.

"I grew up on Caroline Street in the shadow of Johns Hopkins. As a little girl, my mother brought me to the Harriet Lane Clinic," she says, as she realized that the help she was searching for might be in her own backyard.

A new immunotherapy, based on more than 30 years of research, was being studied in a clinical trial at the Kimmel Cancer Center. Vanessa prayed it was the miracle she needed.

The new drug, called pembrolizumab, allowed immune cells to see and respond to cancer cells. The first studies did not look promising in colon cancer, but one patient whose cancer responded to the treatment left researchers curious.

Mismatch Repair

The answer, as it turns out, was based in Kimmel Cancer Center genetics research from 1993. Researchers uncovered a gene mutation that allowed DNA copying errors to accumulate, eventually leading to colon cancer in some people.

In 1993, immunotherapy was in its infancy, and researchers had no idea these copying errors could also attract the attention of the immune system.

The large number of mutations caused by this genetic error, known as mismatch repair deficiency/microsatellite instability flagged cancer cells as abnormal. However, when the immune system activated against them, the cancer cells were able to shut down the response through a natural on/off switch of the immune system, called an immune checkpoint.

Pembrolizumab is in a class of drugs known as immune checkpoint inhibitors. It could turn the immune switch back on and unleash the power of the immune system against the cancer.

As Kimmel Cancer Center cancer immunology researchers conferred with cancer genetics researchers, they figured out that the one colon cancer responder had mismatch repair deficiency/microsatellite instabil-

ity, and in 2013, the clinical trial of the drug was expanded to include any patient with colon cancer whose tumor had mismatch repair deficiency/microsatellite instability.

Vanessa's cancer tested positive for mismatch repair deficiency/microsatellite instability, and she was admitted to the clinical trial of the drug. It was the miracle little Zion had encouraged her to believe in.

This Was Different

Pembrolizumab was different than the treatments Vanessa had tried before that made her feel so ill but did nothing to stop her cancer. With this drug, her tumor was melting away, shrinking by 60%.

"During chemotherapy, I felt like I was dving. With immunotherapy, I felt like my body accepted it," she describes.

"My dream was to see my grandchildren grow up," says Vanessa. "Now I'm a great-grandmother. I truly feel like heaven opened up. Each day is a blessing."

Vanessa, who loves to help others, volunteers with the prison ministry in her church and does some catering, providing sandwiches for local police departments, where her stepdaughter is an officer.

She is certain the treatment saved her life. She shares her story to help others.

"I know other African Americans are afraid of clinical trials," says Vanessa. "If just one hears my story, and it changes that person's life, I've made a difference," she says.

The groundbreaking research built upon a 30-year-old discovery, and Vanessa's inspiring story has been the focus of media attention, including an article in Smithsonian magazine and in a local TV news segment showing Vanessa speaking at a Swim Across America Baltimore event. The organization was the lead donor for the pembrolizumab trial from which Vanessa benefited.

Zion, who just a few years earlier asked his grandmother to believe in miracles, sees her in these news stories and beams proudly, telling Vanessa, "You're a celebrity!"

Vanessa is grateful to her oncologist, Dung Le, and her nurse, Holly Kemberling.

They were so wonderful to my family and me," says Vanessa. "They explained everything. It was evident their hearts are in it."

Ultimately, the therapy bought her the one thing she most desired — more time with her family.

"I am so thankful. I've seen my grandchildren graduate and go off to college," says Vanessa, who enjoys gathering her family and cooking for them. "Being diagnosed with stage 4 cancer was the hardest journey. I was sad and hopeless. I thought I was going to die, but that didn't happen. I survived."

ON THE HORIZON



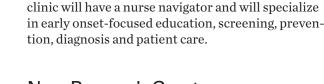
AZAD

Early Onset Clinic

Although colorectal cancer in adults under age 50 is rare, cancer experts report that it has been steadily increasing since the 1970s. Today, 18,000 young adults are diagnosed with colorectal cancer in the U.S. each year, according to the National Cancer Institute. This rise in incidence among a younger population is a major focus of research and changes in clinical recommendations among experts, including Nilo Azad, M.D., Director of the Colorectal Cancer Research Center of Excellence.

Azad, whose 2020 study found starting colorectal cancer screening at age 40 instead of age 50 was cost effective, has made early onset a priority. She is working with colorectal surgeon **Alodia Gabre-Kidan**, M.P.H., M.D., to develop a Colorectal Cancer Early Onset Clinic.

"Younger patients have unique needs," Azad says.
"They are in the primes of their lives. They are working, may have young kids at home, and for women, there are fertility concerns to think about." The new

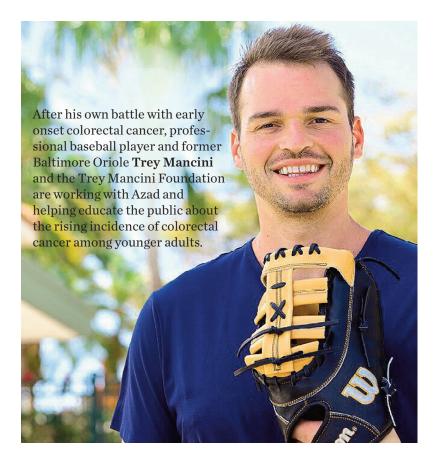




Azad recently announced the launch of a new competitive pilot grant program, using funds raised from 2023 events such as Rhythm of Life and Cycle to End Cancer. The grants are open to all Kimmel Cancer Center researchers, and two projects will be funded in the first round. Grants will focus on translational research that could be quickly turned into new therapies, says Azad, who adds that, if successful, she plans to continue and grow the grant program.

"We are looking for new research directions that test unconventional but important new ideas, the analysis of large datasets and collaborations with private partners," Azad says.

The grants are aimed at launching promising research that is not currently eligible to receive outside funding. She hopes the grants will help investigators leverage early findings to earn larger grants and advance new therapies for colorectal cancer.



Survivorship and Caregiving

Former and current caregivers and patients will support new patients and caregivers, answering questions and helping them prepare for treatment, in a new program currently in planning. In addition, colorectal cancer survivorship retreats, during which patients and caregivers meet and bond with others sharing similar circumstances, are being revisited. The weekend retreats were paused during the COVID-19 pandemic. Azad says funding is available to add a nurse navigator to facilitate survivorship programs.

Tam Warczynski, M.S.N., nurse practitioner and coordinator for the Multidisciplinary Rectal Cancer Clinic, leads a rectal cancer survivor support group that meets quarterly. Along with information provided by rectal cancer experts, the group offers informal mentorships between patients newly diagnosed with rectal cancer and survivors. For information on upcoming group meetings, send an email to twarczy1@jhmi.edu



Cancer-Causing Bacteria

What role do the colonies of micro-organisms that live in our gut play in the onset and growth of colorectal cancer? Infectious disease expert **Cynthia Sears**, M.D., unravels new clues about how, in some people, the balance of these microbes that aid in digestion and metabolism can turn against us.

Sears, a Bloomberg~Kimmel Professor of Cancer Immunotherapy and professor of medicine, studies biofilms, dense collections of bacteria on the colon surface, and other mechanisms promoted by this microbial community.

Cancer cells do not live and grow in isolation. Researchers know they are influenced by everything that exists around them, from normal cells to tiny microbial organisms, called the microbiome.

Sears has a lot of questions about the microbes that live in the gut, including how they may affect the immune system and the specific role they play in colorectal cancer development.

"It's time for a more comprehensive, prospective, thoughtful plan to understand their role. We need longitudinal, well-controlled human studies incorporating microbiome science," says Sears, who is also the microbiome program leader of the Bloomberg~Kimmel Institute for Cancer Immunotherapy.

Bacterial function is one area that could use more focus, she says.

Clostridioides difficile, or C. diff, a bacterial species well known for causing serious diarrheal infections, is a current focus of her group's research.

Research that Sears has done with others, particularly **Julia Drewes**, Ph.D., has exposed a potential colorectal cancer-promoting role for this microbe, which is reported to cause approximately 500,000 infections a year in the U.S. — many of which prove incredibly difficult to clear.

Her interest in *C. diff* was sparked by studies done several years ago. Researchers in Sears' lab discovered that more than half of patients with colorectal cancer had bacterial biofilms — dense collections of bacteria on the colon surface — compared to 10% to 15% of healthy patients undergoing preventive colonoscopy. When the researchers infected mice with biofilm samples derived from people with colorectal cancer, one sample caught their attention because it markedly increased colorectal tumors in the mice.

As they looked to see if a single bacterial species or a community of bacteria was promoting tumors in the mice, they noted that toxigenic *C. diff* — the type of *C. diff* that causes diarrhea — was present in the samples that caused many tumors in mice but was not found in the samples that did not induce tumors in mice. When the researchers added this bacterium to the samples that did not induce tumors, colon tumors began forming in the mice. Further testing showed that the toxin B secreted by *C. diff* was alone enough to prompt tumor formation in the animal models. It brought about a range of changes within colon cells that made them turn cancerous.

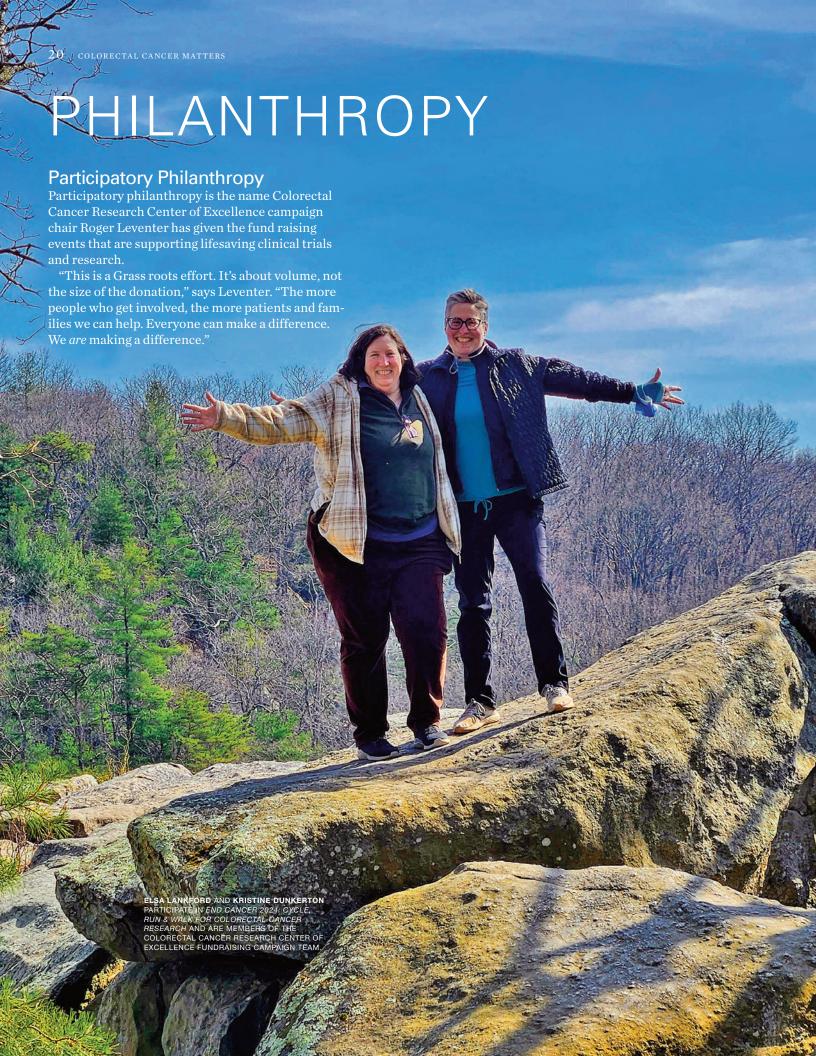
Sears, Drewes and team continue to study the bacterium and are exploring whether screening for *C. diff* infection that has not cleared the body or a previous infection could be used to predict an increased risk for colorectal cancer. Eliminating the infection in those affected, she says, could be explored as a strategy for colorectal cancer prevention.

She advocates better strategies and therapeutics to reduce the risk of *C. diff* infection and recurrence, as it could spare patients the immediate consequences of severe diarrhea and potentially limit colorectal cancer risk later on.

"Since we speculate that lengthy exposures to $\it C. diff$ may increase colorectal cancer risk, an important prevention effort could include heightened efforts to quickly and effectively eradicate this pathogen, which recurs — often repeatedly — in 15%–30% of infected patients after initial treatment, including in pediatric patients," says Sears.

Researchers in her lab checked samples used in their other studies and found *C. diff* infection was fairly pervasive and unexpectedly present in some samples.

"Now begins the very hard work to figure out the specific biology of its linkage to colorectal cancer," says Sears.



Spotlight on Two Events Making a Difference





End Cancer 2024: Cycle, Run & Walk

This event was organized by Eben Block and Roger Leventer, and they are joined this year by Brian Cornblatt. The event raised \$65,000 in 2022 and \$75,000 in 2023, and the goal for 2024 is \$100,000. This year, the event will have a name change. It will be called End Cancer 2024: Cycle, Run & Walk for Colorectal Cancer Research. The organizers hope they can expand participation by going beyond cycling to include walking and running.

Learn more on X: https://x.com/hopkinskimmel/status/1834290888349999150





Rhythm of Life

George Davis, his wife, Patricia, and the Trey Mancini Foundation host the Rhythm of Life event, a night of food, drink, and entertainment, at Gertrude's Chesapeake Kitchen restaurant in Baltimore. The 2024 event was held September 6 and again included acoustic performances by guitar maker and performer Paul Reed Smith and members of his band PRS Eightlock, including Kimmel Cancer Center Director William Nelson, M.D., Ph.D.





"Our goal is to raise funding for the Colorectal Cancer Center, while also creating more local awareness and celebrating survivorship," says George Davis.

The 2023 event sold out and raised \$95,000. They hope to surpass \$100,000 this year.



Help Us Make a Difference

Each contribution to the Johns Hopkins Kimmel Cancer Center makes a difference in the lives of cancer patients here at Johns Hopkins and around the world.

Our physician-scientists are leading the way on many of the scientific breakthroughs in cancer, and your donation will support patient care and innovative research that is translated to better, more effective treatments. We are also focusing on ways to prevent cancer and support survivors.

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